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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

'08 CV 1512 LAB AJB

VIA-FAX

MEDTRONIC SOFAMOR DANEK USA, INC.; WARSAW ORTHOPEDIC, INC.; MEDTRONIC PUERTO RICO OPERATIONS CO.; and MEDTRONIC SOFAMOR DANEK DEGGENDORF, GmbH,

Plaintiffs,

v.

NUVASIVE, INC.

Defendant.

Case No.:

COMPLAINT FOR PATENT INFRINGEMENT

JURY TRIAL DEMANDED

Plaintiffs Medtronic Sofamor Danek USA, Inc. ("Medtronic USA"), Warsaw Orthopedic, Inc. ("Warsaw"), Medtronic Puerto Rico Operations Co. ("Medtronic Puerto Rico"), and Medtronic Sofamor Danek Deggendorf, GmbH ("Medtronic Deggendorf") bring this Complaint against defendant NuVasive, Inc. ("NuVasive"), alleging as follows:

PARTIES, JURISDICTION, AND VENUE

1. Plaintiff Medtronic USA is a Tennessee corporation, with its principal place of business in Memphis, Tennessee. Medtronic USA is a leading distributor of medical devices and instruments for use in the spine, including spinal implants.

2. Plaintiff Warsaw is an Indiana corporation, with its principal place of business in Winona Lake, Indiana.

3. Plaintiff Medtronic Puerto Rico is a Cayman Islands corporation, with its principal place of business in Villalba, Puerto Rico.

4. Plaintiff Medtronic Deggendorf is a German corporation, with its principal place of business in Deggendorf, Germany.

5. Defendant NuVasive is a Delaware corporation, with its principal place of business in San Diego, California. NuVasive manufactures and markets various medical devices and instruments for use in the spine, including spinal implants.

6. This action arises under the patent laws of the United States, Title 35 of the United States Code.

7. This Court has subject matter jurisdiction over the action pursuant to 28 U.S.C. §§ 1331 and 1338(a) in that this action arises under the Acts of Congress relating to patents.

8. Upon information and belief, NuVasive transacts business in this judicial district by manufacturing, selling, or offering to sell products that infringe, by contributing to the infringement of the patents at issue in this action, or by conducting other business within this judicial district.

9. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b), 1391(c) and/or 1400(b).

COUNT I

10. Paragraphs 1-9 are incorporated into this count by reference.

11. United States Patent No. 5,860,973 (the "'973 patent," a copy of which is attached hereto as Exhibit A), entitled "Translateral Spinal Implant," issued on January 19, 1999. Plaintiff Warsaw is the owner of the '973 patent by assignment, as recorded at the United States Patent and Trademark Office, Reel 018883, Frame 0400. Plaintiffs Medtronic USA, Medtronic Puerto Rico, and Medtronic Deggendorf are co-exclusive licensees of the '973 patent from Plaintiff Warsaw and, together with Plaintiff Warsaw, share the exclusive right to bring suit for infringement of the patent.

12. NuVasive is infringing and has infringed the '973 patent by making, selling, offering for sale, and using infringing products, including but not limited to its CoRoent XL product, within the United States.

13. NuVasive's infringement of the '973 patent has caused and will continue to cause Plaintiffs substantial damages, and has caused and will continue to cause Plaintiffs irreparable harm for which there is no adequate remedy at law.

COUNT II

14. Paragraphs 1-9 are incorporated into this count by reference.

15. United States Patent No. 5,772,661 (the "'661 patent," a copy of which is attached hereto as Exhibit B), entitled "Methods and Instrumentation for the Surgical Correction of Human Thoracic and Lumbar Spinal Disease from the Antero-Lateral Aspect of the Spine," issued on June 30, 1998. Plaintiff Warsaw is the owner of the '661 patent by assignment, as recorded at the United States Patent and Trademark Office, Reel 018323, Frame 0173. Plaintiffs Medtronic USA, Medtronic Puerto Rico, and Medtronic Deggendorf are co-exclusive licensees of the '661 patent from Plaintiff Warsaw and, together with Plaintiff Warsaw, share the exclusive right to bring suit for infringement of the patent.

16. On information and belief, NuVasive has contributed to acts of infringement of the '661 patent, such acts having been committed in the United States. Such acts of infringement have been committed by at least Doctors Burak M. Ozgur,

Henry E. Aryan, Luiz Pimenta, and William R. Taylor as evidenced by the technical report entitled "Extreme Lateral Interbody Fusion (XLIF): a novel surgical technique for anterior lumbar interbody fusion," published in The Spine Journal 6, in 2006, and attached as Exhibit C.

17. By selling, offering to sell, and promoting and teaching the use of at least its CoRoent XL product, NuVasive has contributed to the infringement and continues to contribute to the infringement of the '661 patent, under 35 U.S.C. § 271(c), by selling, offering to sell, and promoting and teaching components and/or materials that are especially made or especially adapted for use in direct infringement of at least one of the methods claimed in the '661 patent, and are not a staple article suitable for substantial non-infringing use.

18. NuVasive's contributory infringement of the '661 patent has caused and will continue to cause Plaintiffs substantial damages, and has caused and will continue to cause Plaintiffs irreparable harm for which there is no adequate remedy at law.

COUNT III

19. Paragraphs 1-9 are incorporated into this count by reference.

20. United States Patent No. 6,936,051 B2 (the "'051 patent," a copy of which is attached hereto as Exhibit D), entitled "Multilock Anterior Cervical Plating System," issued on August 30, 2005. Plaintiff Warsaw is the exclusive licensee of the '051 patent. Plaintiffs Medtronic USA, Medtronic Puerto Rico, and Medtronic Deggendorf are co-exclusive sub-licensees of the '051 patent from Plaintiff Warsaw and, together with Plaintiff Warsaw, share the right to bring suit for infringement of the patent.

21. NuVasive is infringing and has infringed the '051 patent by making, selling, offering for sale, and using infringing products, including but not limited to its Gradient product, within the United States.

22. NuVasive's infringement of the '051 patent has caused and will continue to cause Plaintiffs substantial damages, and has caused and will continue to cause Plaintiffs irreparable harm for which there is no adequate remedy at law.

COUNT IV

23. Paragraphs 1-9 are incorporated into this count by reference.

24. United States Patent No. 6,936,050 B2 (the "'050 patent," a copy of which is attached hereto as Exhibit E), entitled "Multilock Anterior Cervical Plating System," issued on August 30, 2005. Plaintiff Warsaw is the exclusive licensee of the '050 patent. Plaintiffs Medtronic USA, Medtronic Puerto Rico, and Medtronic Deggendorf are co-exclusive sub-licensees of the '050 patent from Plaintiff Warsaw and, together with Plaintiff Warsaw, share the right to bring suit for infringement of the patent.

25. NuVasive is infringing and has infringed the '050 patent by making, selling, offering for sale, and using infringing products, including but not limited to its Gradient product, within the United States.

26. NuVasive's infringement of the '050 patent has caused and will continue to cause Plaintiffs substantial damages, and has caused and will continue to cause Plaintiffs irreparable harm for which there is no adequate remedy at law.

COUNT V

27. Paragraphs 1-9 are incorporated into this count by reference.

28. United States Patent No. 6,916,320 B2 (the "'320 patent," a copy of which is attached hereto as Exhibit F), entitled "Anterior Cervical Plate System," issued on July 12, 2005. Plaintiff Warsaw is the owner of the '320 patent by assignment, as recorded at the United States Patent and Trademark Office, Reel 018207, Frame 0410. Plaintiffs Medtronic USA, Medtronic Puerto Rico, and Medtronic Deggendorf are co-exclusive licensees of the '320 patent from Plaintiff Warsaw and, together with Plaintiff Warsaw, share the exclusive right to bring suit for infringement of the patent.

29. NuVasive is infringing and has infringed the '320 patent by making, selling, offering for sale, and using infringing products, including but not limited to its Gradient product, within the United States.

30. NuVasive's infringement of the '320 patent has caused and will continue to cause Plaintiffs substantial damages, and has caused and will continue to cause Plaintiffs irreparable harm for which there is no adequate remedy at law.

COUNT VI

31. Paragraphs 1-9 are incorporated into this count by reference.

32. United States Patent No. 6,945,933 B2 (the "'933 patent," a copy of which is attached hereto as Exhibit G), entitled "Instruments and Methods for Minimally Invasive Tissue Retraction and Surgery," issued on September 20, 2005. Plaintiff Warsaw is the owner of the '933 patent by assignment, as recorded at the United States Patent and Trademark Office, Reel 018573, Frame 0086. Plaintiffs Medtronic USA, Medtronic Puerto Rico, and Medtronic Deggendorf are co-exclusive licensees of the '933 patent from Plaintiff Warsaw and, together with Plaintiff Warsaw, share the exclusive right to bring suit for infringement of the patent.

33. NuVasive is infringing and has infringed the '933 patent by making, selling, offering for sale, and using infringing products, including but not limited to its MaXcess product, within the United States.

34. NuVasive's infringement of the '933 patent has caused and will continue to cause Plaintiffs substantial damages, and has caused and will continue to cause Plaintiffs irreparable harm for which there is no adequate remedy at law.

COUNT VII

35. Paragraphs 1-9 are incorporated into this count by reference.

36. United States Patent No. 7,008,422 B2 (the "'422 patent," a copy of which is attached hereto as Exhibit H), entitled "Instruments and Methods for Stabilization of Bony Structures," issued on March 7, 2006. Plaintiff Warsaw is the owner of the '422

patent by assignment, as recorded at the United States Patent and Trademark Office, Reel 018323, Frame 0669. Plaintiffs Medtronic USA, Medtronic Puerto Rico, and Medtronic Deggendorf are co-exclusive licensees of the '422 patent and, together with Plaintiff Warsaw, share the exclusive right to bring suit for infringement of the patent.

37. On information and belief, NuVasive has contributed to acts of infringement of the '422 patent, such acts having been committed in the United States.

38. By selling, offering to sell, and promoting and teaching the use of at least its SpheRx Guide Assembly product, NuVasive has contributed to the infringement and continues to contribute to the infringement of the '422 patent, under 35 U.S.C. § 271(c), by selling, offering to sell, and promoting and teaching components and/or materials that are especially made or especially adapted for use in direct infringement of at least one of the methods claimed in the '422 patent, and are not a staple article suitable for substantial non-infringing use.

39. NuVasive's contributory infringement of the '422 patent has caused and will continue to cause Plaintiffs substantial damages, and has caused and will continue to cause Plaintiffs irreparable harm for which there is no adequate remedy at law.

COUNT VIII

40. Paragraphs 1-9 are incorporated into this count by reference.

41. United States Patent No. 6,530,929 B1 (the "'929 patent," a copy of which is attached hereto as Exhibit I), entitled "Instruments for Stabilization of Bony Structures," issued on March 11, 2003. Plaintiff Warsaw is the owner of the '929 patent by assignment, as recorded at the United States Patent and Trademark Office, Reel 018720, Frame 0500. Plaintiffs Medtronic USA, Medtronic Puerto Rico, and Medtronic Deggendorf are co-exclusive licensees of the '929 patent and, together with Plaintiff Warsaw, share the exclusive right to bring suit for infringement of the patent.

42. NuVasive is infringing and has infringed the '929 patent by making, selling, offering for sale, and using infringing products, including but not limited to its SpheRx DBR system, within the United States.

43. NuVasive's infringement of the '929 patent has caused and will continue to cause Plaintiffs substantial damages, and has caused and will continue to cause Plaintiffs irreparable harm for which there is no adequate remedy at law.

COUNT IX

44. Paragraphs 1-9 are incorporated into this count by reference.

45. United States Patent No. 6,235,028 B1 (the "'028 patent," a copy of which is attached hereto as Exhibit J), entitled "Surgical Guide Rod," issued on May 22, 2001. Plaintiff Warsaw is the owner of the '028 patent by assignment, as recorded at the United States Patent and Trademark Office, Reel 018688, Frame 0760. Plaintiffs Medtronic USA, Medtronic Puerto Rico, and Medtronic Deggendorf are co-exclusive licensees of the '028 patent and, together with Plaintiff Warsaw, share the exclusive right to bring suit for infringement of the patent.

46. NuVasive is infringing and has infringed the '028 patent by making, selling, offering for sale, and using infringing products, including but not limited to its SpheRx DBR Guide product, within the United States.

47. NuVasive's infringement of the '028 patent has caused and will continue to cause Plaintiffs substantial damages, and has caused and will continue to cause Plaintiffs irreparable harm for which there is no adequate remedy at law.

COUNT X

48. Paragraphs 1-9 are incorporated into this count by reference.

49. United States Patent No. 6,969,390 B2 (the "'390 patent," a copy of which is attached hereto as Exhibit K), entitled "Anterior Cervical Plating System and Bone Screw" issued on November 29, 2005. Plaintiff Warsaw is the owner of the '390 patent by assignment, as recorded at the United States Patent and Trademark Office, Reel

018720, Frame 0323. Plaintiffs Medtronic USA, Medtronic Puerto Rico, and Medtronic Deggendorf are co-exclusive licensees of the '390 patent and, together with Plaintiff Warsaw, share the exclusive right to bring suit for infringement of the patent.

50. NuVasive is infringing and has infringed the '390 patent by making, selling, offering for sale, and using infringing products, including but not limited to its Helix product, within the United States.

51. NuVasive's infringement of the '390 patent has caused and will continue to cause Plaintiffs substantial damages, and has caused and will continue to cause Plaintiffs irreparable harm for which there is no adequate remedy at law.

COUNT XI

52. Paragraphs 1-9 are incorporated into this count by reference.

53. United States Patent No. 6,428,542 B1 (the "'542 patent," a copy of which is attached hereto as Exhibit L), entitled "Single-Lock Anterior Cervical Plate," issued on August 6, 2002. Plaintiff Warsaw is the owner of the '542 patent by assignment, as recorded at the United States Patent and Trademark Office, Reel 018720, Frame 0323. Plaintiffs Medtronic USA, Medtronic Puerto Rico, and Medtronic Deggendorf are co-exclusive licensees of the '542 patent and, together with Plaintiff Warsaw, share the exclusive right to bring suit for infringement of the patent.

54. NuVasive is infringing and has infringed the '542 patent by making, selling, offering for sale, and using infringing products, including but not limited to its Helix product, within the United States.

55. NuVasive's infringement of the '542 patent has caused and will continue to cause Plaintiffs substantial damages, and has caused and will continue to cause Plaintiffs irreparable harm for which there is no adequate remedy at law.

COUNT XII

56. Paragraphs 1-9 are incorporated into this count by reference.

57. United States Patent No. 6,592,586 B1 (the "'586 patent," a copy of which is attached hereto as Exhibit M), entitled "Single-Lock Anterior Cervical Plating System," issued on July 15, 2003. Plaintiff Warsaw is the owner of the '586 patent by assignment, as recorded at the United States Patent and Trademark Office, Reel 018207, Frame 0410. Plaintiffs Medtronic USA, Medtronic Puerto Rico, and Medtronic Deggendorf are co-exclusive licensees of the '586 patent and, together with Plaintiff Warsaw, share the exclusive right to bring suit for infringement of the patent.

58. NuVasive is infringing and has infringed the '586 patent by making, selling, offering for sale, and using infringing products, including but not limited to its Helix product, within the United States.

59. NuVasive's infringement of the '586 patent has caused and will continue to cause Plaintiffs substantial damages, and has caused and will continue to cause Plaintiffs irreparable harm for which there is no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that the Court:

1. Adjudge that NuVasive has infringed and is infringing the '973 patent;

2. Adjudge that NuVasive has contributed and is contributing to the infringement of the '661 patent.

3. Adjudge that NuVasive has infringed and is infringing the '051 patent;

4. Adjudge that NuVasive has infringed and is infringing the '050 patent;

5. Adjudge that NuVasive has infringed and is infringing the '320 patent;

6. Adjudge that NuVasive has infringed and is infringing the '933 patent;

7. Adjudge that NuVasive has contributed and is contributing to the infringement of the '422 patent;

8. Adjudge that NuVasive has infringed and is infringing the '929 patent;

9. Adjudge that NuVasive has infringed and is infringing the '028 patent;

10. Adjudge that NuVasive has infringed and is infringing the '390 patent;

11. Adjudge that NuVasive has infringed and is infringing the '542 patent;

12. Adjudge that NuVasive has infringed and is infringing the '586 patent;

13. Preliminarily and permanently enjoin NuVasive and its affiliates, subsidiaries, officers, directors, employees, agents, representative, licensees, successors, and assigns, and all those acting for it and on its behalf, or acting in concert with it, from further infringement, including contributory infringement, of the '973, '661, '051, '050, '320, '933, '422, '929, '028, '390, '542, and '586 patents.

14. Award compensatory damages to Plaintiffs, together with interest;

15. Award Plaintiffs their costs and, where appropriate, reasonable attorneys fees under 35 U.S.C. § 285; and

16. Award Plaintiffs any other such relief as the Court deems just and proper.

Respectfully submitted,

Dated: August 18, 2008

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JURY TRIAL DEMAND

PLAINTIFFS DEMAND A TRIAL BY JURY ON ALL ISSUES SO TRIABLE.

Dated: August 18, 2008

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EXHIBIT A

US005860973A

United States Patent [19]

Michelson

[11] Patent Number: 5,860,973

[45] Date of Patent: Jan. 19, 1999

[54] **TRANSLATERAL SPINAL IMPLANT**

[76] Inventor: **Gary Karlin Michelson**, 438 Sherman Canal, Venice, Calif. 90291

[21] Appl. No.: **741,301**

[22] Filed: **Oct. 30, 1996**

Related U.S. Application Data

[63] Continuation of Ser. No. 479,596, Jun. 7, 1995, abandoned, which is a continuation-in-part of Ser. No. 394,836, Feb. 27, 1995.

[51] **Int. Cl.**[6] **A61B 17/56**

[52] **U.S. Cl.** **606/61**; 606/72

[58] **Field of Search** 606/61, 72–78, 606/86, 87, 88; 623/16, 17

[56] **References Cited**

U.S. PATENT DOCUMENTS

2,677,369	5/1954	Knowles .	
3,298,372	1/1967	Feinberg .	
3,867,728	2/1975	Stubstad et al. .	
3,875,595	4/1975	Froning .	
3,905,047	9/1975	Long .	
4,070,514	1/1978	Entherly et al. .	
4,259,072	3/1981	Hirabayashi et al. .	
4,309,777	1/1982	Patil .	
4,328,593	5/1982	Sutter	623/18
4,349,921	9/1982	Kuntz	623/17
4,501,269	2/1985	Bagby	623/18
4,535,485	8/1985	Ashman et al. .	
4,545,374	10/1985	Jacobson .	
4,553,273	11/1985	Wu .	
4,599,086	7/1986	Doty .	
4,636,217	1/1987	Ogilvie et al. .	
4,714,469	12/1987	Kenna .	
4,759,766	7/1988	Buettner-Janz et al. .	
4,759,769	7/1988	Hedman et al. .	
4,820,305	4/1989	Harms et al. .	
4,848,327	7/1989	Perdue .	
4,863,477	9/1989	Monson .	
4,865,603	9/1989	Noiles .	
4,877,020	10/1989	Vich .	
4,904,261	2/1990	Dove et al. .	
4,911,718	3/1990	Lee	623/17
4,936,848	6/1990	Bagby .	
4,955,908	9/1990	Frey et al. .	
4,961,740	10/1990	Ray et al. .	
5,015,247	5/1991	Michelson .	
5,015,255	5/1991	Kuslich .	
5,026,373	6/1991	Ray et al. .	
5,055,104	10/1991	Ray .	
5,059,193	10/1991	Kuslich .	
5,071,437	12/1991	Steffee .	
5,123,926	6/1992	Pisharodi .	
5,192,327	3/1993	Brantigan .	
5,258,031	11/1993	Salib et al. .	
5,263,953	11/1993	Bagby .	
5,306,309	4/1994	Wagner et al. .	
5,397,364	3/1995	Kozak et al. .	
5,425,772	6/1995	Brantigan .	
5,489,308	2/1996	Kuslich et al. .	

FOREIGN PATENT DOCUMENTS

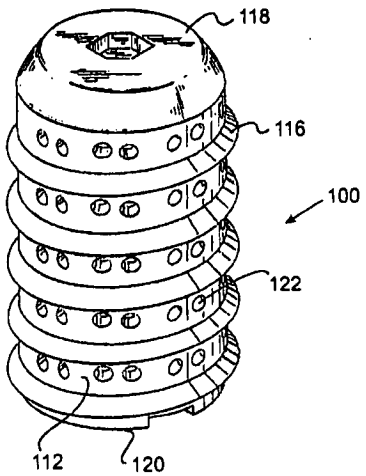
0 260 044	3/1988	European Pat. Off. .
0 179 695	4/1986	France .

Primary Examiner—Michael Buiz
Assistant Examiner—Kevin Truong
Attorney, Agent, or Firm—Lewis Anten, Esq.; Amedeo Ferraro, Esq.

[57] **ABSTRACT**

An oversized spinal implant for translateral insertion into the disc space between two vertebrae a length that is greater than one half of the transverse width of the vertebrae and is greater than the depth of the vertebrae. The translateral implant of the present invention has a height that is greater than the height of the disc space between two adjacent vertebrae so as to engage both of the vertebrae. The width of the implant need be only slightly less than the depth of the vertebrae themselves. The translateral spinal fusion implant of the present invention has more surface area of contact and thus permits greater stability so as to withstand torque, and in the case of a threaded implant, increases the depth which any threads are able to penetrate the vertebrae.

73 Claims, 8 Drawing Sheets



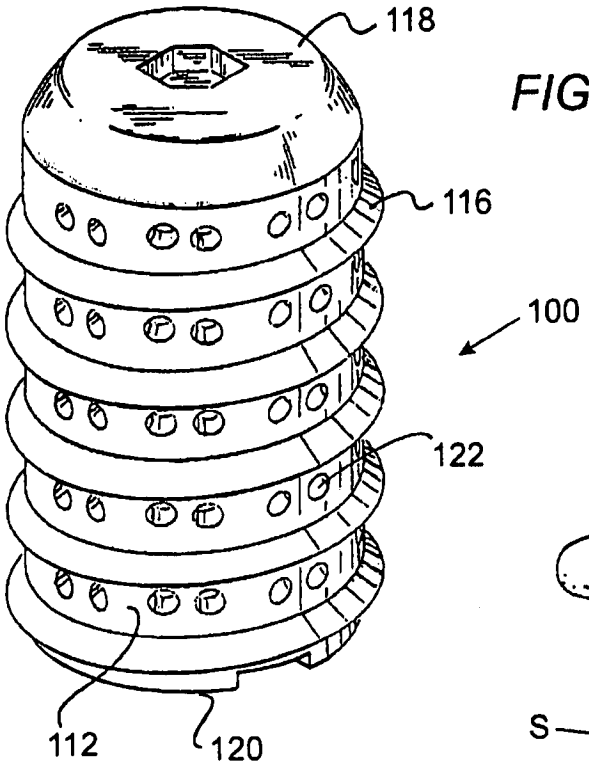
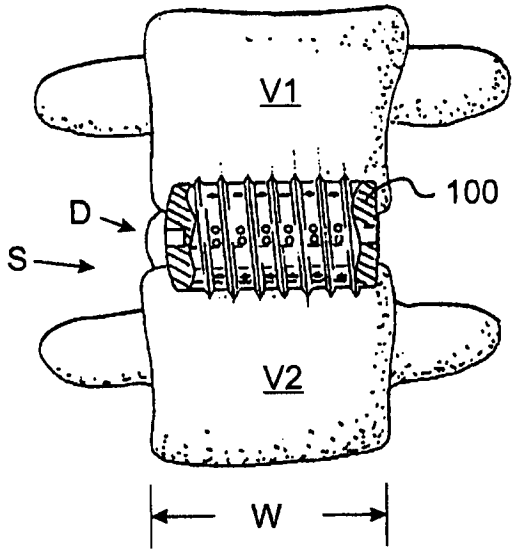


FIG. 1

FIG. 2



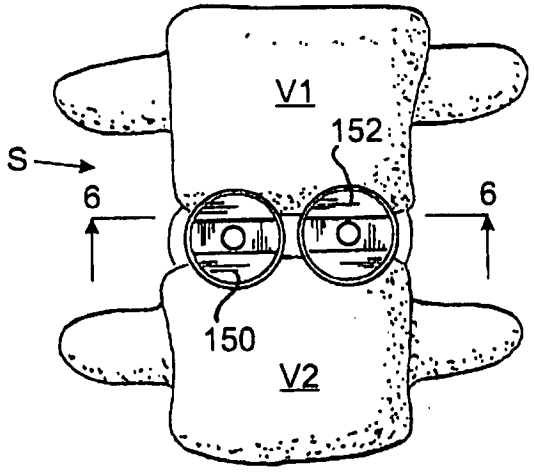
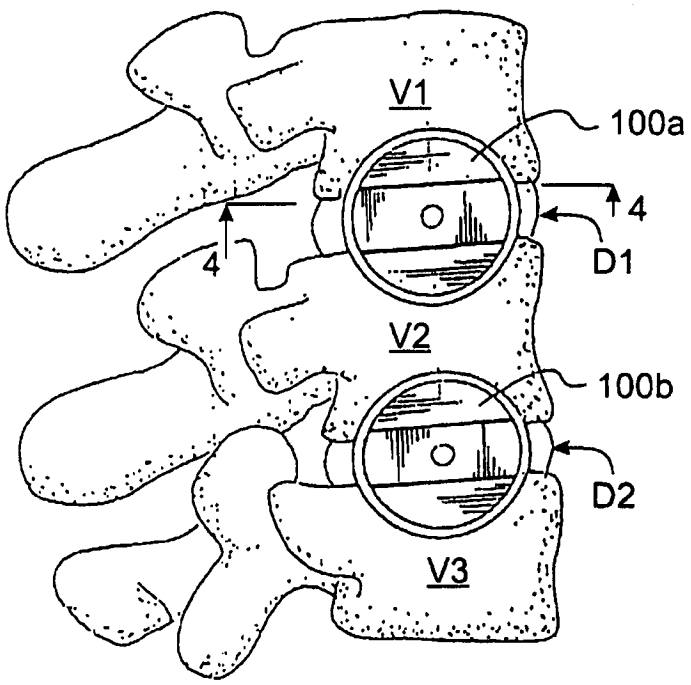


FIG. 5

FIG. 3



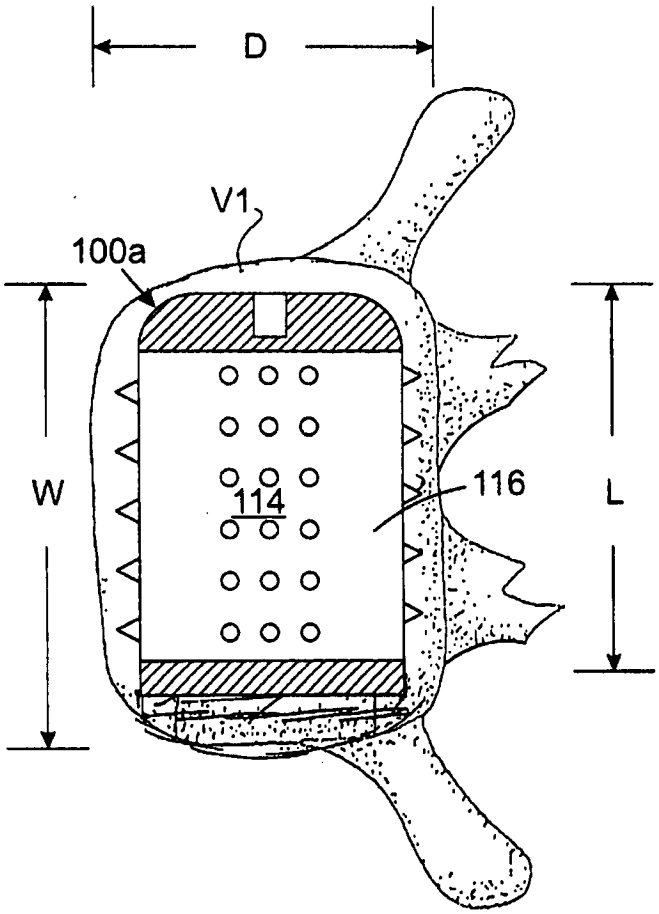


FIG. 4

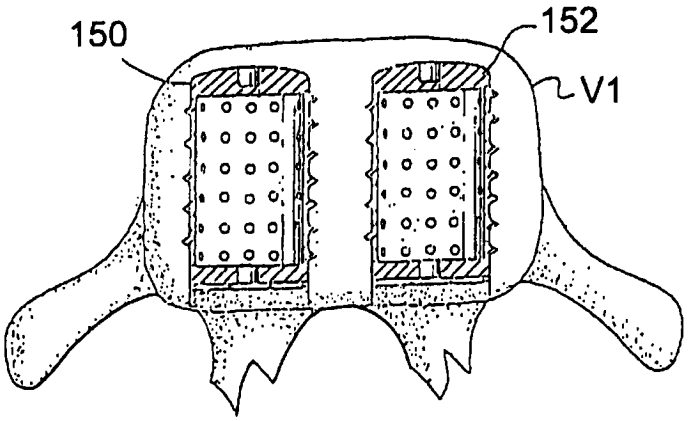


FIG. 6

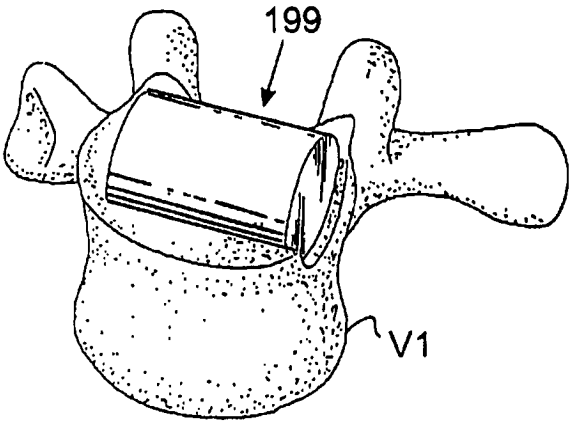


FIG. 7

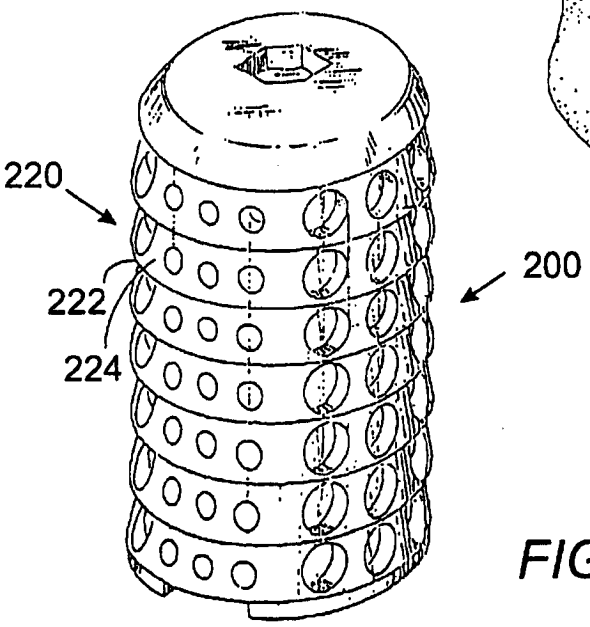


FIG. 8

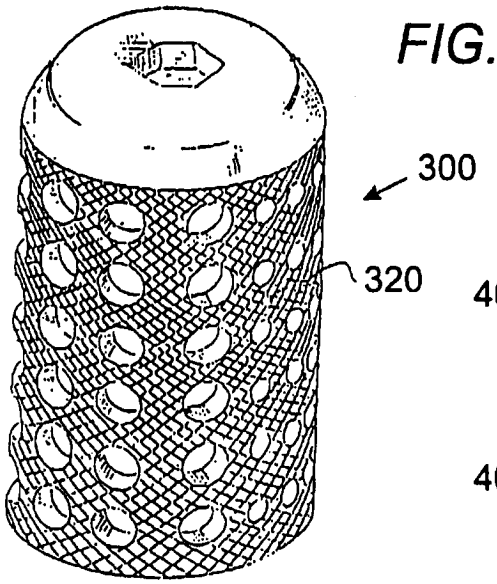


FIG. 9

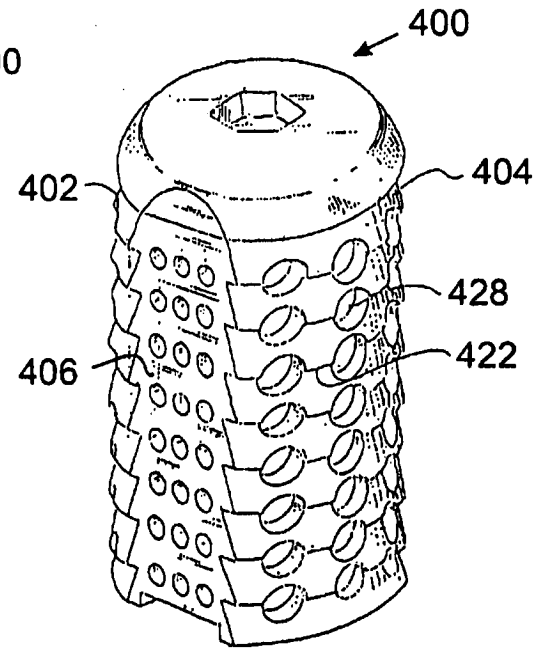


FIG. 10

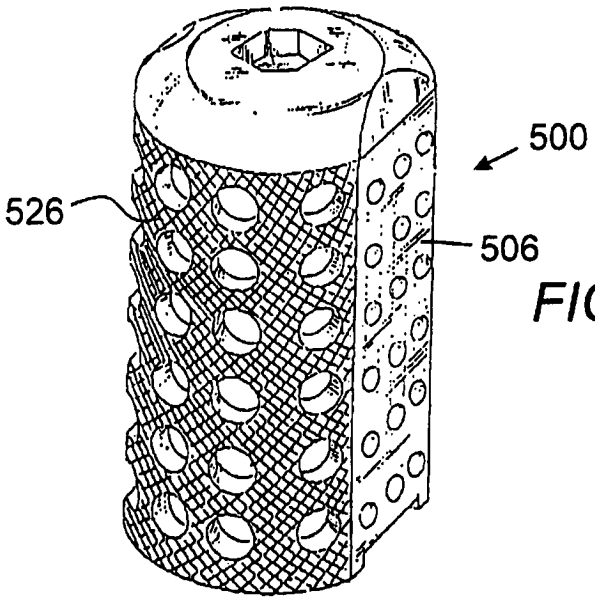


FIG. 11

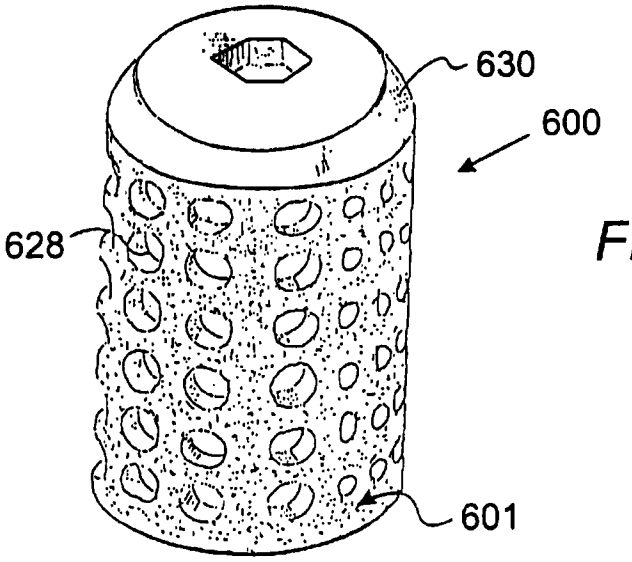


FIG. 12

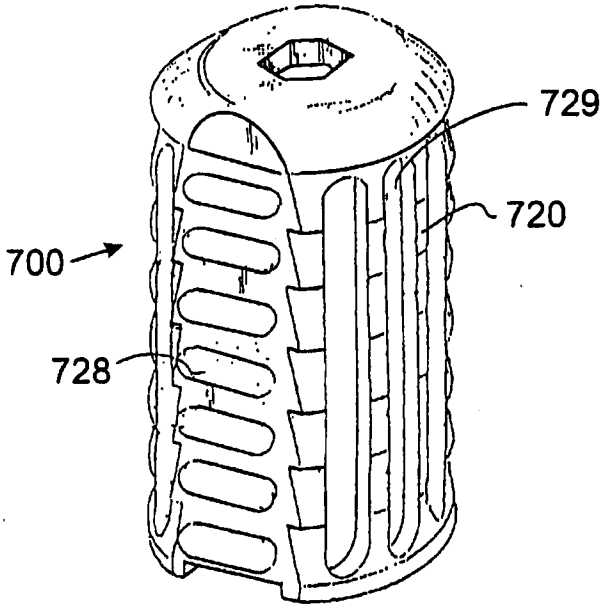
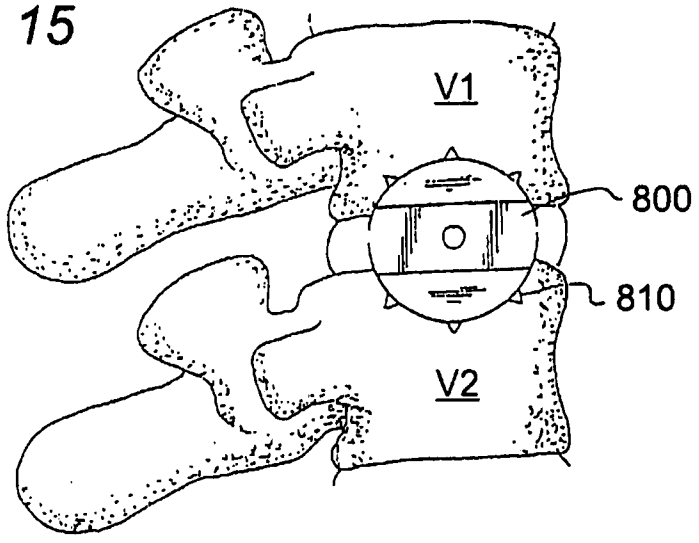


FIG. 13

FIG. 15



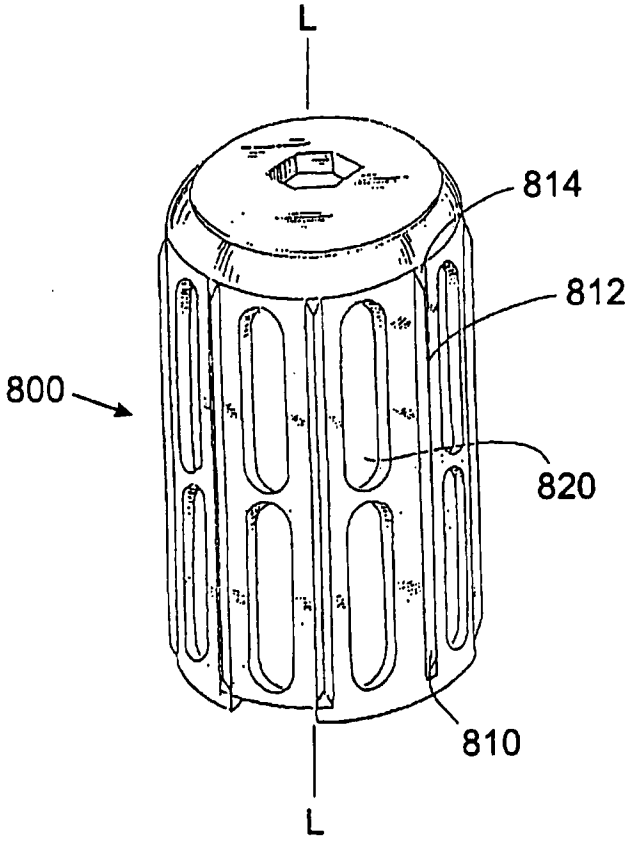


FIG. 15b

FIG. 18

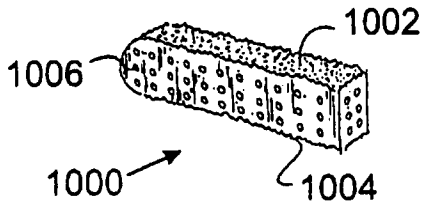
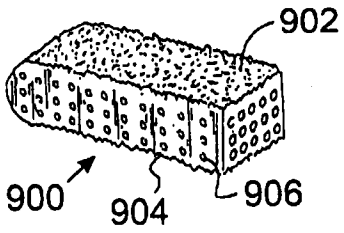


FIG. 16



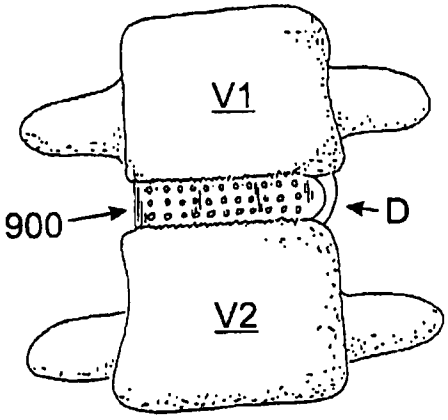


FIG. 17

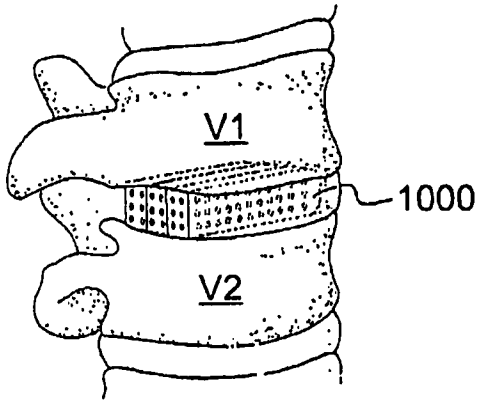


FIG. 19

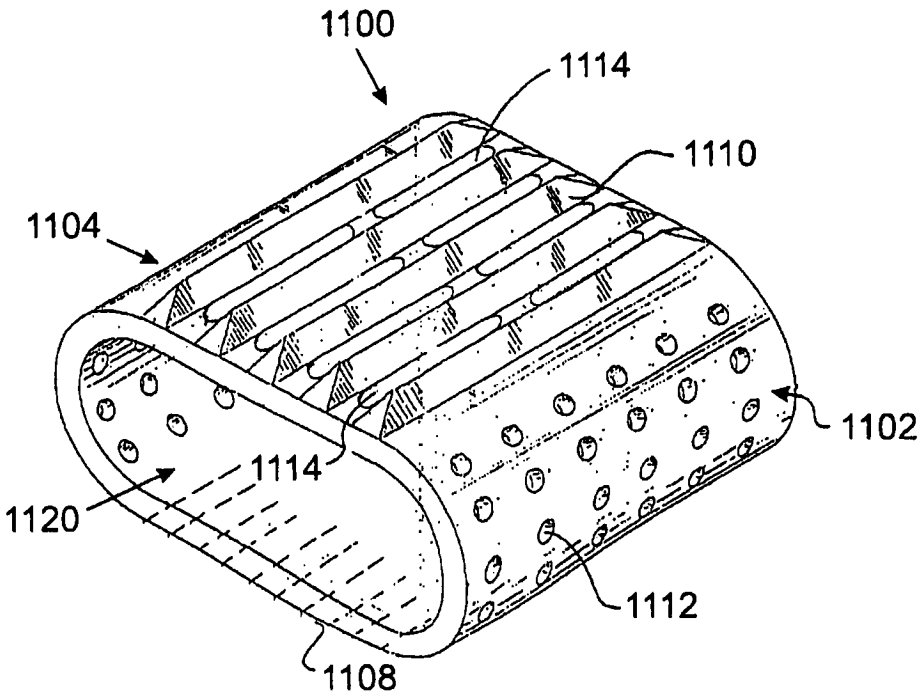


FIG. 20

TRANSLATERAL SPINAL IMPLANT

RELATED APPLICATIONS

This is a continuation of the application Ser. No 08/479,596 filed on Jun. 7, 1995, now abandoned, which is a continuation in part of application Ser. No. 08/394,836 entitled IMPROVED METHODS AND INSTRUMENTATION FOR THE SURGICAL CORRECTION OF HUMAN THORACIC AND LUMBAR SPINAL DISEASE FROM THE LATERAL ASPECT OF THE SPINE, filed on Feb. 27, 1995 now pending, incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates generally to spinal fusion implants, and more particularly to spinal fusion implants for insertion from the side of a patient (translateral) across the transverse width of the spine and between two adjacent vertebrae.

2. Description of the Related Art

In the past, spinal fusion implants have been inserted only from either an anterior or posterior direction, from the front or the back of the patient. Such implants are well known in the art and may have cylindrical, rectangular and other shapes. In the past, Cloward, Wilterberger, Crock, Viche, Bagby, Brantigan, and others have taught various methods involving the drilling of holes across the disc space between two adjacent vertebrae of the spine for the purpose of causing an interbody spinal fusion. Cloward taught placing a dowel of bone within that drilled hole for the purpose of bridging the defect and to be incorporated into the fusion. Viche taught the threading of that bone dowel. Bagby taught the placing of the bone graft into a metal bucket otherwise smooth on its surface, except for rows of radially placed holes communicative to the interior of the basket and to the bone graft. The Bagby device was disclosed as capable of being used in a horse. Brantigan taught the use of inert blocks preferably made of metal and having that metal at its external surface imitate the porosity of bone. Brantigan theorized that the bone dowel could be replaced entirely with a metal plug that, while not itself active in the fusion, would nevertheless serve to support the vertebrae from within the disc space while allowing fusion to occur around it.

U.S. Pat. No. 3,844,601 issued to Ma et al. on Nov. 19, 1974, teaches a method and instrumentation for preparing rectangular spaces across the disc space into the adjacent vertebrae and for preparing a rectangular graft of the bone itself that is inserted in the rectangular spaces.

U.S. Pat. No. 4,743,256 issued to Brantigan on May 10, 1988 teaches the use of an inert artificial spacer in the shape of a rectangle in place of using a rectangular bone graft as taught by Ma et al.

U.S. Pat. No. 4,878,915 issued to Brantigan on Nov. 7, 1989, teaches the use of fully cylindrical inert implants for use in interbody spinal fusion. Such implants do not participate in the bone fusion process but act as inert spacers and allow for the growth of bone to the outer surfaces of the implants.

U.S. Pat. No. 4,834,757 issued to Brantigan on May 30, 1989, teaches a rectangular shaped, hollow spinal fusion implant for use in lieu of a rectangular bone graft or Brantigan's earlier artificial inert spacer.

However, all of the prior implants have been inserted from either the front or the back of the patient. As a result, the spinal fusion implants of the past were necessarily limited in size to the dimensions of the vertebrae relative to the direction in which the implants were inserted. For example, the maximum possible length for an implant that is inserted from either the front or the back of the patient is limited to the depth of the vertebrae, the depth of a vertebrae being the dimension of the vertebrae measured from the anterior end to the posterior end of the vertebrae. It was not previously possible to insert an implant that had a length that was greater than the depth of the vertebrae from front to back as such an implant would protrude from either the anterior or posterior aspect of the spine resulting in great harm to the patient.

In U.S. Pat. No. 5,015,247 to Michelson, a cylindrical threaded implant is described for insertion across the disc space between two adjacent vertebrae. Such an implant was disclosed as being inserted either from the front of the patient or from the back and has a diameter larger than the disc space so that it engages both of the adjacent vertebrae.

The maximum diameter possible with a cylindrical implant that is inserted from the front or the back of the patient is limited by at least two factors. The first factor limiting the diameter of a cylindrical implant is realized when an attempt is made to use a single, centrally placed implant from either the front or the back of the patient. Such an implant must be large enough to occupy a sufficient portion of the transverse width of the disc space to promote firm stability. The use of an implant that is placed in the disc space to stabilize the two adjacent vertebrae requires that the vertebrae be stable when the implant is in place, otherwise there will not be any bone bridging between the implant and the vertebrae. If a single implant is used in the center of the disc space, inherent instability is created, as the vertebrae are generally free to rock back and forth over the implant which serves as a fulcrum. However, to achieve the required stability, it would be necessary to use the widest possible implant and the excursion of such a large single implant into the adjacent vertebrae would be so severe that the two vertebrae would be virtually cut in half.

The second factor which limits the diameter size of a cylindrical implant is in the situation where two cylindrical implants are implanted from either the front or the back of the patient and placed side-by-side across a disc space and into the two adjacent vertebrae in an attempt to gain stability while avoiding the problems of the single implant. Such implants require a diameter that is sufficiently large to penetrate into and significantly engage each of the adjacent vertebrae yet the diameter may not be so large that it is no longer possible to place two such implants side-by-side and to still have them contained within the transverse width of the spine.

The use of multiple implants requires that the implants be small enough so as to fit into the same limited spinal width. These implants being of smaller diameter as limited by the need to place more than one within the width of the spine then penetrate only minimally into the depth of the vertebral bone.

Also, the insertion of multiple implants requires multiple procedures, essentially a duplication of any procedure done on one side of the center line must also be performed on the other side of the center line.

Therefore, there exists a need for a spinal fusion implant that is inserted from the translateral approach to the spine that is capable of stabilizing the vertebrae adjacent to such an implant in order to permit bone bridging between the vertebrae and the implant to ultimately achieve fusion of the adjacent vertebrae.

SUMMARY OF THE INVENTION

The present invention discloses a spinal fusion implant that is inserted from the side of the patient, herein referred to as the translateral approach to the spine. The translateral spinal fusion implant of the present invention is inserted into the spine of a patient across the transverse width of the vertebrae to be fused. The transverse width of a vertebra is measured from one lateral aspect of the spine to the opposite lateral aspect. The depth of a vertebra is measured from the anterior aspect to the posterior aspect of the spine.

As the translateral spinal fusion implant of the present invention is inserted substantially along the transverse width of the vertebrae or at a slight angle to the vertebrae, it has a different structural configuration as compared to spinal implants for insertion from either the front or the back of the patient, as such implants are necessarily limited by the depth, measured from front to back of the vertebrae.

In one embodiment of the translateral spinal fusion implant of the present invention, the implant is dimensioned to fit within a bore created across the disc space and into the adjacent vertebrae. Such an implant may be substantially cylindrical and has an outer surface comprising bone engaging means for engaging the implant to the adjacent vertebrae. In this embodiment, for the lumbar spine, the translateral spinal fusion implant of the present invention has a length that is greater than one half of the transverse width of the vertebrae and is greater than the depth of the vertebrae. The translateral implant of the present invention has a height that is greater than the height of the disc space between two adjacent vertebrae so as to engage both of the vertebrae. The width of the implant need be only slightly less than the depth of the vertebrae themselves.

In another embodiment of the present invention, the translateral spinal fusion implant of the present invention is dimensioned to fit within the disc space created by the removal of disc material between two adjacent vertebrae. Such an implant is inserted from the translateral approach to the spine and has a length that is substantially greater than the depth of the vertebrae and a width that approximates the depth of the vertebrae. The height of such an implant is approximately the same height of the normal height of the disc space between two adjacent vertebrae and may be wedged so as to reproduce anatomic lordosis. The upper and lower surfaces of such an implant may be contoured so as t conform to the shape of the disc space and the adjacent vertebral endplate surfaces.

The dimensions of the translateral spinal fusion implant of the present invention permits a single implant to be inserted by a single procedure into the spine and to engage more of the adjacent vertebrae. As a result, the translateral spinal fusion implant of the present invention has more surface area of contact and thus permits greater stability so as to withstand torque, and in the case of a threaded implant, increases the depth which any threads are able to penetrate the vertebrae.

The translateral implants of the present invention are safer to use than implants inserted from the front or the back as the aorta and vena cava lie anterior to the spine and the dural sac and nerves posteriorly, all of which structures are simply avoided in the lateral approach.

The translateral spinal fusion implant of the present invention may be inserted into the disc space through a hollow tube which is engaged to the lateral aspect of the spine through a lateral, anterior, or anterolateral incision making the procedure safe and simple.

The translateral spinal fusion implant of the present invention may comprise at least in part fusion promoting and/or bioactive materials for active participation of the implant in the spinal fusion process.

OBJECTS OF THE PRESENT INVENTION

It is an object of the present invention to provide a spinal fusion implant that may be inserted from a translateral approach to the spine.

It is another object of the present invention to provide a spinal fusion implant that is safer to use than the implants of the past.

It is another object of the present invention to provide a spinal fusion implant that is easier to insert into the spine.

It is a further object of the present invention to provide a spinal fusion implant that provides greater stability of the vertebrae being fused.

It is yet another object of the present invention to provide a spinal fusion implant that is less likely to fail.

It is another object of the present invention to provide a spinal fusion implant that is more deeply embedded into the adjacent vertebrae.

These and other objects of the present invention will become apparent from a review of the accompanying drawings and the detailed description of the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective side view of the translateral spinal fusion implant of the present invention having an external thread for engaging the bone of two adjacent vertebrae.

FIG. **2** is an elevational view of the anterior aspect of a segment of the spinal column with the spinal fusion implant of FIG. **1** inserted from the lateral aspect along the transverse width of the vertebrae.

FIG. **3** is an elevational view of the lateral aspect of a segment of the lumbar spine with a first spinal fusion implant of the present invention inserted from the lateral aspect into a hole drilled across a first disc space and into two adjacent vertebrae, and a second spinal fusion implant of the present invention inserted from the lateral aspect into a second hole drilled across a second disc space and into two adjacent vertebrae.

FIG. **4** is top sectional view along lines **4—4** of FIG. **3** showing the area of contact of the spinal fusion implant of the present invention and the vertebra.

FIG. **5** is an anterior elevational view of a segment of the lumbar spine with two cylindrical implants inserted from the anterior of the spine into holes drilled across the same disc space and into two adjacent vertebrae.

FIG. **6** is sectional view along lines **6—6** of FIG. **5** showing the area of contact between the two implants of FIG. **5** and the vertebra.

FIG. **7** is a anterior perspective view of a single vertebra and an alternative embodiment of the spinal fusion implant of the present invention in the form of a dowel inserted translaterally into a hole drilled across a disc space and into the vertebra along the transverse width of the vertebra.

FIG. **8** is a perspective view of an alternative embodiment of the spinal fusion implant of the present invention having ratchetings for engaging the vertebrae.

FIG. **9** is a perspective view of an alternative embodiment of the spinal fusion implant of the present invention having a knurled surface for engaging the vertebrae.

FIG. **10** is a perspective view of an alternative embodiment of the spinal fusion implant of the present invention having ratchetings for engaging the vertebrae and a flattened side.

FIG. **11** is a perspective view of an alternative embodiment of the spinal fusion implant of the present invention having a knurled surface for engaging the vertebrae and a flattened side.

FIG. **12** is a perspective view of an alternative embodiment of the spinal fusion implant of the present invention having a blasted surface for engaging the vertebrae.

FIG. **13** is a perspective view of an alternative embodiment of the spinal fusion implant of the present invention having ratchetings for engaging the vertebrae with openings in the form of vertical and horizontal slots.

FIG. **14** is a perspective view of an alternative embodiment of the spinal fusion implant of the present invention having longitudinal splines for engaging the vertebrae and openings in the form of vertical slots.

FIG. **15** is elevational view of the lateral aspect of the spinal column having the spinal fusion implant of FIG. **14** inserted from the lateral aspect along the transverse width of the vertebrae into a hole created across the disc space and into two adjacent vertebrae.

FIG. **16** is a perspective side view of an alternative embodiment of the spinal fusion implant of the present invention.

FIG. **17** is a elevational anterior view of a segment of the spinal column having the spinal fusion implant of FIG. **16** inserted from the lateral aspect in the disc space between two adjacent vertebrae along the transverse width of the vertebrae.

FIG. **18** is a perspective side view of an alternative embodiment of the spinal fusion implant of the present invention.

FIG. **19** is a perspective lateral anterior view of a segment of the spinal column with a plurality of the spinal implants of FIG. **18** shown in hidden line inserted from the lateral aspect in a modular fashion in the disc space between two adjacent vertebrae along the transverse width of the vertebrae.

FIG. **20** is perspective view of an alternative embodiment of the spinal fusion implant of the present invention.

DETAILED DESCRIPTION OF THE DRAWINGS

Referring to FIGS. **1–5**, an embodiment of the translateral spinal fusion implant of the present invention, generally referred to by numeral **100**, is shown. The spinal fusion implant **100** has a substantially cylindrical configuration having an outer wall **112** surrounding an internal chamber **114** for holding fusion promoting material. The exterior of the spinal fusion implant **100** comprises an external thread **116** suitable for engaging the vertebrae of the spine to stabilize the spinal fusion implant **100** across the disc space and into adjacent vertebrae once surgically implanted. The spinal fusion implant **100** has a removable cap **118** at one end which provides access to the internal chamber **114** and has an insertion end **120** adapted to engage insertion instrumentation.

The cap **118** is removable to provide access to the internal chamber **114**, such that the internal chamber **114** can be filled and hold any natural or artificial osteoconductive, osteoinductive, osteogenic, or other fusion enhancing material. Some examples of such materials are bone harvested from the patient, or bone growth inducing material such as, but not limited to, hydroxyapatite, hydroxyapatite tricalcium phosphate; or bone morphogenic protein. The cap **118** and/or the spinal fusion implant **100** itself is made of material appropriate for human implantation such as titanium and/or may be made of, and/or filled and/or coated with a bone ingrowth inducing material such as, but not limited to, hydroxyapatite or hydroxyapatite tricalcium phosphate or any other osteoconductive, osteoinductive, osteogenic, or other fusion enhancing material.

The outer wall **112** comprises openings **122** which may be closed wells or openings communicating into the internal chamber **114** to permit bone ingrowth into the chamber **114**.

Referring specifically to FIG. **2**, an elevational view of the anterior aspect of a segment of the spinal column S with the spinal fusion implant **100** inserted from the lateral aspect of the spinal column S into a hole bored into the adjacent vertebrae V_1 and V_2 across the disc space D. The spinal fusion implant **100** is inserted along the transverse width W of the adjacent vertebrae V_1 and V_2 such that the spinal fusion implant **100** extends translaterally in the direction from one lateral aspect of the vertebrae to the opposite lateral aspect of the vertebrae.

Referring to FIG. **3**, an elevational view of the lateral aspect of a segment of the lumbar spine S is shown with a first implant **100*a***, identical to spinal fusion implant **100**, inserted from the lateral aspect into a hole bored across a first disc space D_1 and into two adjacent vertebrae V_1 and V_2, and a second implant **100*b***, identical to spinal fusion implant **100**, inserted from the lateral aspect into a second hole bored across a second disc space D_2 and into two adjacent vertebrae V_2 and V_3.

The translateral implants of the present invention are inserted by the translateral method disclosed in copending application Ser. No. 08/394,836 entitled IMPROVED METHODS AND INSTRUMENTATION FOR THE SURGICAL CORRECTION OF HUMAN THORACIC AND LUMBAR SPINAL DISEASE FROM THE LATERAL ASPECT OF THE SPINE, filed on Feb. 27, 1995, which is incorporated herein by reference. The tanslateral implants of the present invention may be made of an artificial material.

Referring to FIG. **4**, a top sectional view along lines **4—4** of FIG. **3** is shown illustrating the area of contact of the implant **100*a*** and the vertebra V_1. The vertebra V_1 has a depth D measured from the anterior to posterior aspect of the spine, and a transverse width W measured from one lateral aspect to the opposite lateral aspect of the vertebra V_1. The implant **100*a*** has a length L that is substantially greater than the depth D of the vertebra V_1such that the implant **100*a*** may extend substantially across the transverse width W of the vertebra V_1. In the preferred embodiment, the implant **100*a*** has a length L that is greater than one half the transverse width W of the vertebrae and has a diameter of a sufficiently large size that approximates the depth D of the vertebra V_1. As a result of the large length and diameter of the implant **100*a***, a large surface area of contact between the implant **100*a*** and the vertebrae V_1 is possible creating a highly stable construct. The implant **100*a*** has a much greater surface area of contact with the vertebra V_1 than was previously possible with implants that are inserted from the front or the back of the spine.

As described above in the Background of the Invention, a centrally placed single implant from either the front or the back of the patient must be large enough to occupy a sufficient portion of the transverse width W of the vertebrae to promote firm stability. However, the vertical height of such an implant and excursion into the adjacent vertebrae would be so severe that if any two consecutive disc spaces were to be operated upon, the vertebra in between the disc spaces would be cut in half. Therefore it has been the practice to use multiple implants, one on each side of the

center line (mid-saggital axis) of the vertebrae, thereby providing a greater degree of stability.

Referring to FIG. **5**, an anterior elevational view of a segment of the lumbar spine S is shown with two cylindrical implants **150** and **152** inserted from the anterior aspect of the spine S into holes drilled across the same disc space D and into two adjacent vertebrae V_1 and V_2.

Referring to FIG. **6**, sectional view along lines **6—6** of FIG. **5** illustrating the area of contact between the two implants **150** and **152** inserted from the anterior aspect of the spine and the vertebra V_1 is shown. As can be seen from FIG. **6**, the surface area of the two spinal implants **150** and **152** in contact with the vertebra V_1 is substantially less than that of a single translateral spinal fusion implant **100** that is inserted across the transverse width W of the vertebra V_1. As a result, a more stable construct is achieved with the translateral spinal fusion implant **100** of the present invention than was previously possible with implants that are inserted from either the front or the back of the patient promoting from stability of the fusion construction.

In the preferred embodiment, the spinal fusion implant **100** of the present invention has an overall length in the range of 35 mm to 50 mm, with 38–44 mm being preferred, and a maximum diameter in the range of 22 mm to 30 mm, with 24–26 mm being preferred when inserted in the lumbar spine. In the thoracic spine such implants would have a length in the range of 12–30 mm, and a maximum diameter in the range of 14–26 mm, with the preferred diameter being 20 mm.

Referring to FIG. **7**, an anterior perspective view of a single vertebra V_1 and an alternative embodiment of the translateral spinal fusion implant of the present invention, generally referred to by the numeral **199**, is shown. The spinal fusion implant **199** is a dowel inserted into a hole drilled across a disc space and into the vertebra V_1 along the transverse width of the vertebra V_1. The spinal fusion implant **199** has the same dimensions as the spinal fusion implant **100** described above. The spinal fusion implant **199** can be made of any material suitable for human implantation may comprise fusion promoting and/or bioactive material to actively participate in the spinal fusion process. The implant **199** can be made of a porous, and/or mesh-like, and/or cancellous material, or any other material suitable for the described purpose.

Referring to FIG. **8**, an alternative embodiment of the translateral spinal fusion implant of the present invention, is shown and generally referred to by the numeral **200**. The spinal fusion implant **200** has a substantially cylindrical configuration having a thin outer wall **212** surrounding an internal chamber **214**. The exterior of the spinal fusion implant **200** comprises surface roughenings that provide a surface suitable for engaging the bone of the vertebrae to stabilize the spinal fusion implant **200** across the disc space and into the adjacent vertebrae once surgically implanted. The surface roughenings comprise a plurality of ratchetings **220** along the circumference of the spinal fusion implant **200**. Each of the plurality of ratchetings **220** has a bone engaging edge **222** and an angled segment **224**.

The spinal fusion implant **200** is implanted into a cylindrical bore derived across the disc space and into two adjacent vertebrae. The spinal fusion implant **200** may be pushed into the cylindrical bore across the disc space by direct, linear advancement since it requires no thread to pull it forward through the spine. As no torque is required to advance the spinal fusion implant **200** there is no minimum requisite height of the surface roughenings.

The ratchetings **220** may face in one direction, the direction in which the spinal fusion implant **200** is inserted, and function to prevent the spinal fusion implant **200** from backing out of the disc space in a direction opposite to the direction of insertion once inserted between the two adjacent vertebrae. The ratchetings **220** urge the spinal fusion implant **200** forward against the unremoved bone of the vertebrae. Since implants generally want to back out along the same path in which they are inserted, the ratchetings **220** tend to urge the spinal fusion implant **200** forward against the solid unremoved bone at the end of the cylindrical bone, further resisting dislodgement and controlling motion resulting in an exceedingly stable implantation.

The spinal fusion implant **200** has an engagement means at one end for engaging a driver instrument for intimately engaging and binding the implant **200** and the driver instrument together. Once affixed to the implant driver instrument, the spinal fusion implant **200** may be then introduced through a hollow cylindrical tube and driven into the cylindrical hole that has been drilled across the disc space. The implant driver instrument may then be impacted by a mallet, or similar device, to linearly advance the spinal fusion implant **200** across the disc space. Once the spinal fusion implant **200** is inserted across the disc space, the ratchetings **220**, engage the bone of the vertebrae and the implant driver instrument is detached from the spinal fusion implant **200**.

Referring to FIG. **9**, an alternative embodiment of the spinal fusion implant of the present invention generally referred to by the numeral **300** is shown. The spinal fusion implant **300** has a substantially cylindrical configuration having surface roughenings for stabilizing the implant **300** within the intervertebral space D. The surface roughenings comprise a surface knurling **320** such as, but not limited to, the diamond-shaped bone engaging pattern shown in FIG. **9**. The spinal fusion implant **300** may have surface knurling **320** throughout the entire external surface of the spinal fusion implant **300**, throughout only a portion of the external surface, or any combination thereof, without departing from the scope of the present invention. In those circumstances where there is no undrilled bone in the disc space forward of the spinal fusion implant **300** to resist further forward advancement of the implant, surface knurling **320** is preferred as it produces an exceedingly high interference fit with the bone of the vertebrae and resists motion equally in all directions and without the tendency to urge itself forward.

Referring to FIG. **10**, an alternative embodiment of the spinal fusion implant of the present invention is shown and is generally referred to by the numeral **400**. The spinal fusion implant **400** has a similar configuration to that of the spinal fusion implant **200**, except that it comprises a partially cylindrical member having arcuate portions **402** and **404** which are arcs of the same circle with portions of its outer wall that are flattened so as to present a first flat side **406**. Alternatively, the implant **400** may have a second flat side that is diametrically opposite to the first flat side **406**. The spinal fusion implant **400** is substantially the same as the spinal fusion implant **200**, except that the openings **428** are positioned on the ratcheting **420** such that the openings **428** are positioned between the bone engaging edges **422** and are not bisected by the bone engaging edges **422**.

Referring to FIG. **11**, an alternative embodiment of the spinal fusion implant of the present invention is shown and generally referred to by the numeral **500**. The spinal fusion implant **500** is substantially identical to the spinal fusion implant **400** described above except that in place of ratchetings **420**, it has surface knurling **520**. The surface knurling

520 assists in the retaining of the spinal fusion implant 500 once it is inserted across the disc space between two adjacent vertebrae. It is recognized that the surface knurling 520 of the implant 500 may be combined with any of a number of other surface roughenings such as, but not limited to, ratchetings to assist in retaining the spinal fusion implant 500 across the disc space.

Referring to FIG. 12, an alternative embodiment of the spinal fusion implant of the present invention generally referred to by the numeral 600 is shown. The spinal fusion implant 600 has the same structure as the spinal fusion implant 300 described above but instead of knurling 320 has a different surface roughening. The spinal fusion implant 600 has a surface roughening comprising of a blasted external surface 601 which may be stippled to provide an engagement surface for the vertebrae when inserted across the disc space. The spinal fusion implant has a plurality of openings 628, a removable cap 630 for accessing an internal chamber.

Referring to FIG. 13, an alternative embodiment of the spinal fusion implant of the present invention generally referred to by the numeral 700 is shown. The spinal fusion implant 700 is similar to spinal fusion implant 400 described above except that it has openings in the form of horizontal slots 728 on the flat side 706 and vertical slots 729 on the cylindrical portion of the spinal fusion implant 700. The spinal fusion implant 700 has ratchetings 720 for engaging the bone of the vertebrae similar to the ratchetings 220 described above.

It is appreciated that the spinal fusion implants of the present invention may include any and all surface roughening configurations that either increase the surface area or interference fit of the implant and the vertebrae. It is appreciated that the ratchetings described above for the various embodiments of the spinal fusion implants of the present invention may also comprise a knurled or other surface roughenings in combination with the ratchetings to further enhance the retention of the spinal fusion implant across the disc space once inserted.

Referring to FIG. 14, an alternative embodiment of the spinal fusion implant of the present invention is shown and generally referred to by the numeral 800. The spinal fusion implant 800 is similar in configuration to the spinal fusion implant 100 discussed above. However, instead of an external thread, the spinal fusion implant 800 has a plurality of longitudinal splines 810 along its external surface. The splines 810 are parallel to the central longitudinal axis L of the implant 800 in the direction of insertion of the implant 800. The splines 810 have a sharp edge 812 and a sharpened leading end 814 to facilitate insertion of the spinal fusion implant 800 into the adjacent vertebrae. Located between the splines 812 are a plurality of slots 820 that allow bone growth into the implant and into the internal chamber of the implant 800 during spinal fusion.

Referring to FIG. 15, the spinal fusion implant 800 is shown inserted from the lateral aspect of the spine into a bore created across the disc space D and into the adjacent vertebrae V_1 and V_2 along the transverse width of the vertebrae V_1 and V_2. The spinal fusion implant 800 is pushed into place by linear advancement such that the splines 810 engage a portion of each of the adjacent vertebrae V_1 and V_2. The splines 810 function to engage the vertebrae V_1 and V_2 and stabilize the spinal fusion implant 800 once implanted. The splines 810 are oriented longitudinally with respect to the spinal fusion implant 800 to prevent any dislodgement of the spinal fusion implant 800 from between the vertebrae V_1 and V_2 as result of anterior to posterior motion of the spine. It is appreciated that the number of splines 810 and the configuration of the splines 810 can vary depending on the size of the spinal fusion implant 800 being implanted.

Referring to FIG. 16, an alternative embodiment of the spinal fusion implant of the present invention is shown and generally referred to by the numeral 900. The spinal fusion implant 900 differs from the implants described above in that it is inserted in the disc space D between the adjacent vertebrae of the spine and not into a cylindrical bore created across the disc space. Therefore, the spinal fusion implant 900 does not require the removal of any portion of bone from the adjacent vertebrae as the spinal fusion implant 900 fits within the natural disc space between the adjacent vertebrae. However, the removal of at least a portion of the disc material present between the adjacent vertebrae is required for proper insertion.

The spinal fusion implant 900 comprises a rectangular block 901 having a top surface 902 and a bottom surface 904 for engaging the adjacent vertebrae and may be flat or may conform at least in part. The top and bottom surfaces 902 and 904 may comprise any of the surface roughenings described herein for engaging the bone of the adjacent vertebrae to promote firm stability. The spinal fusion implant 900 may be solid or hollow at least in part and have a plurality of openings 906 to allow bone ingrowth. The openings 906 may be present on all surfaces of the implant 900 and may either pass through the entire implant 900, or may be closed bottom wells for holding fusion promoting materials.

Referring to FIG. 17, the spinal fusion implant 900 is shown implanted from the lateral aspect of the spine in the disc space D between two adjacent vertebrae V, V_1 and V_2 along the transverse width of the adjacent vertebrae V_1 and V_2. The spinal fusion implant 900 has a height that is substantially equal to the height of the disc space D, a length that is greater than one half the transverse width W of the vertebrae and a width that approximates the depth of the vertebrae.

In the preferred embodiment, the spinal fusion implant 900 has a height in the range of 8 mm to 16 mm, with the preferred height being 10–12 mm; a width in the range of 24 mm to 32 mm, with the preferred width being 26 mm; and a length in the range of 32 mm to 50 mm, with 42 mm being the preferred length.

Referring to FIG. 18, an alternative embodiment of the spinal fusion implant of the present invention is shown and generally referred to by the numeral 1000. The spinal fusion implant 1000 is similar to the spinal fusion implant 900, but has a narrower width such that more than one spinal fusion implant 1000 may be combined in a modular fashion for insertion within the disc space D between the adjacent vertebrae.

Referring to FIG. 19, a plurality of spinal fusion implants 1000 are shown combined in a modular fashion inserted in the disc space D from the lateral aspect of the spine and along the transverse width of the vertebrae V_1 and V_2.

Referring to FIG. 20, an alternative embodiment of the spinal fusion implant of the present invention is shown and generally referred to by the numeral 1100. The spinal fusion implant 1100 is inserted into the disc space between two adjacent vertebrae from the lateral aspect of the spine and along the transverse width of the vertebrae. The implant 1100 is dimensioned to replace the natural disc material present between two adjacent vertebrae. The implant 1100

has a generally rectangular body with curved sides **1102** and **1104**. The top and bottom surfaces **1106** and **1108** have a plurality of splines **1110** similar in structure and function as the splines **810** described above. As the implant **1100** is inserted in the disc space, the splines **1110** engage the bone of the adjacent vertebrae.

The implant **1100** is shown as being hollow with openings and slots **1114** in the outer surface of the implant **1100** permitting bone ingrowth into the interior of the implant **1100**. However, it is appreciated that the implant **1100** may be solid and may have channels or wells in place of opening **1112** to permit bone ingrowth and incorporation of the implant **1100** into the spinal fusion mass. The interior of the implant **1000** may be accessed through the aperture **1120** which may be closed with a snap fit cover.

While the present invention has been described in detail with regards to the preferred embodiment, it is appreciated that other variations of the present invention may be devised which do not depart from the inventive concept of the present invention.

What is claimed is:

1. A translateral spinal implant for insertion from the lateral aspect of the spine in the disc space between two adjacent vertebrae, said implant having a length that is greater than one half the transverse width of the vertebrae, said length being substantially greater than the depth of the vertebrae, and a height for contacting each of the two adjacent vertebrae.

2. The spinal implant of claim **1** in which said implant has a height that is greater than the disc space and is capable of engaging both of said vertebrae.

3. The spinal implant of claim **1** in which said implant has surface roughenings for engaging said two adjacent vertebrae and for maintaining said implant in place, said surface roughenings being present on at least a portion of the exterior of said implant.

4. The spinal implant of claim **3**, in which said surface roughenings include a plurality of ratchetings.

5. The spinal implant of claim **4**, in which said ratchetings face one direction.

6. The spinal implant of claim **3**, in which said surface roughenings include knurling.

7. The implant of claim **6** in which said implant has a cap on at least one end for removably closing said hollow portion of said Implant.

8. The spinal implant of claim **4** in which said surface roughenings include a plurality of longitudinal splines.

9. The spinal implant of claim **1** having a plurality of openings capable retaining fusion promoting material.

10. The spinal implant of claim **1** in which one end of said implant includes an engagement means for engaging instrumentation for the insertion of said implant.

11. The spinal implant of claim **1** in which said implant comprises a fusion promoting material.

12. The spinal implant of claim **1** in which said implant is at least in part bioabsorbable.

13. The spinal implant of claim **1** in which said implant has an internal chamber and an access opening for accessing said internal chamber.

14. The spinal implant of claim **13** in which said implant has means for closing said access opening.

15. The spinal implant of claim **13**, in which said internal chamber is capable of containing fusion promoting material.

16. The spinal implant of claim **13**, in which said implant comprises a wall surrounding at least in part said internal chamber.

17. The spinal implant of claim **16**, in which said wall has a plurality of openings passing therethrough in communication with said internal chamber.

18. The implant of claim **1** in which said implant includes driving engaging means for engaging a driving instrument for implanting said implant within the disc space between the two adjacent vertebrae.

19. The implant of claim **1** in which said implant is generally rectangular in shape.

20. The implant of claim **1** in which said implant is generally square in shape.

21. The implant of claim **1** which said implant comprises a plurality of modular members, each of said modular members having a length that is greater than one half the transverse width of the vertebrae, said length being substantially greater than the depth of the vertebrae, a height dimensioned to fit in the space created by the removed disc material from between two adjacent vertebrae, and a width less than the depth of the vertebrae.

22. The spinal implant of claim **21** in which said implant has a height that is greater than the disc space and is capable of engaging both of said vertebrae.

23. The spinal implant of claim **1** in which said implant comprises a bone ingrowth material.

24. The implant of claim **1** for use in the lumbar spine in which the length of said implant is in the range of approximately 35 mm to 50 mm.

25. The implant of claim **1** for use in the thoracic spine in which the length of said implant is in the range of approximately 12 mm to 30 mm.

26. The spinal implant of claim **1** in which said implant has a height that is greater than the disc space and is capable of penetrating into each of the two adjacent vertebrae.

27. The spinal implant of claim **26** in which said implant is at least in part cylindrical in shape.

28. The spinal implant of claim **27**, in which said implant has an external thread for engaging the vertebrae.

29. The spinal implant of claim **27**, in which said implant is hollow.

30. The implant of claim **27**, for use in the lumbar spine in which the diameter of said implant is in the range of approximately 22 mm to 30 mm.

31. The implant of claim **27**, for use in the thoracic spine in which the diameter of said implant is in the range of approximately 14 mm to 26 mm.

32. The implant of claim **27**, for use in the lumbar spine in which said implant has a length in the range of approximately 38 mm to 44 mm and diameter in the range of approximately 24 mm to 30 mm.

33. The implant of claim **27**, for use in the thoracic spine in which said implant has a length in the range of approximately 12 mm to 30 mm and diameter in the range of approximately 14 mm to 26 mm.

34. A translateral spinal implant for insertion from the lateral aspect of the spine in the disc space between two adjacent vertebrae, comprising:

a plurality of modular members, each of said modular members having a length that is greater than one half the transverse width of the vertebrae, said length being substantially greater than the depth of the vertebrae, a width less than the depth of the vertebrae, and a height for contacting each of the two adjacent vertebrae, each of said modular members comprising:

upper and lower walls, and side walls, said upper and lower walls forming a support structure including at least a portion of the interior surface of said upper and lower walls for bearing against the end plates of the adjacent vertebrae,

whereby said plurality of modular members are capable of being inserted in between said two adjacent vertebrae.

35. A translateral spinal implant for insertion from the lateral aspect of the spine in the disc space between two adjacent vertebrae, said implant having a length that is greater than one half the transverse width of the vertebrae, said length being substantially greater than the depth of the vertebrae, a height for contacting each of the two adjacent vertebrae, and a width that is at least as great as the height.

36. The spinal implant of claim 35 in which said implant has a height that is greater than the disc space and is capable of engaging both of said vertebrae.

37. The spinal implant of claim 36, in which said implant is at least in part cylindrical in shape.

38. The spinal implant of claim 37, in which said implant has an external thread for engaging the vertebrae.

39. The spinal implant of claim 37, in which said implant is hollow.

40. The spinal implant of claim 35, in which said implant has surface roughenings for engaging said two adjacent vertebrae and for maintaining said implant in place, said surface roughenings being present on at least a portion of the exterior of said implant.

41. The spinal implant of claim 40 in which said surface roughenings include a plurality of ratchetings.

42. The spinal fusion implant of claim 41, in which said ratchetings face one direction.

43. The spinal implant of claim 40, in which said surface roughenings include knurling.

44. The implant of claim 43, in which said implant has a cap on at least one end for removably closing said hollow portion of said Implant.

45. The spinal implant of claim 40, in which said surface roughenings include a plurality of longitudinal splines.

46. The spinal implant of claim 35, having a plurality of openings capable retaining fusion promoting material.

47. The spinal implant of claim 35, in which one end of said implant includes an engagement means for engaging instrumentation for the insertion of said implant.

48. The spinal implant of claim 35, in which said implant comprises a fusion promoting material.

49. The spinal implant of claim 35 in which said implant is at least in part bioabsorbable.

50. The spinal implant of claim 35 in which said implant has an internal chamber and an access opening for accessing said internal chamber.

51. The spinal implant of claim 50, in which said implant has means for closing said access opening.

52. The spinal implant of claim 50 in which said internal chamber is capable of containing fusion promoting material.

53. The spinal implant of claim 50, in which said implant comprises a wall surrounding at least in part said internal chamber.

54. The spinal implant of claim 53, in which said wall has a plurality of openings passing therethrough in communication with said internal chamber.

55. The implant of claim 35, which said implant comprises a plurality of modular members, each of said modular members having a length that is greater than one half the transverse width of the vertebrae, said length being substantially greater than the depth of the vertebrae, a height to the height of the space created by the removed disc material from between two adjacent vertebrae, and a width substantially less than the depth of the vertebrae.

56. The spinal implant of claim 55 in which said implant has a height that is greater than the disc space.

57. The implant of claim 35 in which said implant is generally rectangular in shape.

58. The implant of claim 35, in which said implant includes driving engaging means for engaging a driving instrument for implanting said implant within the disc space between the two adjacent vertebrae.

59. The spinal implant of claim 35, in which said implant comprises a bone ingrowth material.

60. The implant of claim 35, in which said implant is generally square in shape.

61. A translateral spinal fusion implant for insertion from the lateral aspect of the spine in the disc space between two adjacent vertebrae, said implant having a length that is greater than one half the transverse width of the vertebrae, said length being substantially greater than the depth of the vertebrae, and a height for contacting each of the two adjacent vertebrae; said implant having an outer surface with a plurality of openings passing through said implant, said plurality of openings capable of retaining fusion promoting substances and capable of permitting bone growth in continuity from one of said adjacent vertebrae to the other of said two adjacent vertebrae to permit fusion of said two adjacent vertebrae to occur at least in part through said implants capable of engaging both of said vertebrae.

62. The spinal implant of claim 1 in which said implant is made of an artificial material.

63. The spinal implant of claim 34 in which said implant is made of an artificial material.

64. The spinal implant of claim 35 in which said implant is made of an artificial material.

65. The spinal implant of claim 61 in which said implant is made of an artificial material.

66. The spinal implant of claim 1 in which said implant comprises bone morphogenetic protein.

67. The spinal implant of claim 34 in which said implant comprises bone morphogenetic protein.

68. The spinal implant of claim 35 in which said implant comprises bone morphogenetic protein.

69. The spinal implant of claim 61 in which said implant comprises bone morphogenetic protein.

70. The spinal implant of claim 1 in which said implant comprises a bioactive material.

71. The spinal implant of claim 34 in which said implant comprises a bioactive material.

72. The spinal implant of claim 35 in which said implant comprises a bioactive material.

73. The spinal implant of claim 61 in which said implant comprises a bioactive material.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

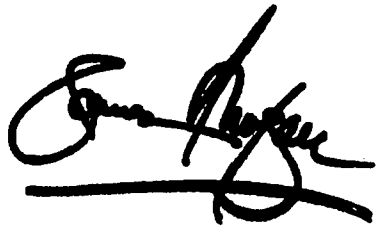
PATENT NO. : 5,860,973
DATED : January 19, 1999
INVENTOR(S) : Gary Karlin Michelson

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 12, claim 34,
Line 13, change "interior" to -- exterior --.

Signed and Sealed this

Sixteenth Day of April, 2002



Attest:

Attesting Officer

JAMES E. ROGAN
Director of the United States Patent and Trademark Office

EXHIBIT B

US005772661A

United States Patent [19]

Michelson

[11] Patent Number: 5,772,661

[45] Date of Patent: Jun. 30, 1998

[54] **METHODS AND INSTRUMENTATION FOR THE SURGICAL CORRECTION OF HUMAN THORACIC AND LUMBAR SPINAL DISEASE FROM THE ANTERO-LATERAL ASPECT OF THE SPINE**

[76] Inventor: **Gary Karlin Michelson,** 438 Sherman Canal, Venice, Calif. 90291

[21] Appl. No.: **394,836**

[22] Filed: **Feb. 27, 1995**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 74,781, Jun. 10, 1993, which is a continuation-in-part of Ser. No. 698,674, May 10, 1991, which is a division of Ser. No. 205,935, Jun. 13, 1988, Pat. No. 5,015,247, and a continuation-in-part of Ser. No. 219,626, Mar. 28, 1994.

[51] **Int. Cl.**[6] **A61B 17/56**

[52] **U.S. Cl.** **606/61**; 623/17

[58] **Field of Search** 606/60, 61, 72–79; 623/16, 17

[56] **References Cited**

U.S. PATENT DOCUMENTS

Re. 31,865	4/1985	Roux .
Re. 34,871	3/1995	McGuire et al. .
D. 245,259	8/1977	Shen .
D. 257,511	11/1980	Zahn .
350,420	10/1886	Dillon .
1,137,585	4/1915	Craig .
2,065,659	12/1936	Cullen .
2,181,746	11/1939	Siebrandt .
2,243,718	5/1941	Moreira .
2,372,622	3/1945	Fassio .
2,514,665	7/1950	Myller .
2,537,070	1/1951	Longfellow .
2,543,780	3/1951	Hipps et al. .
2,677,369	5/1954	Knowles .
2,774,350	12/1956	Cleveland .
2,789,558	4/1957	Rush .
2,832,343	4/1958	Mose .
2,842,131	7/1958	Smith .
3,128,768	4/1964	Giestauts .
3,298,372	1/1967	Feinberg .
3,426,364	2/1969	Lumb .
3,486,505	12/1969	Morrison .

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

0 260 044	3/1988	European Pat. Off. .
0 307 241	3/1989	European Pat. Off. .
0 599 419 A2	6/1994	European Pat. Off. .
0 179 695	4/1986	France .
2 581 336	11/1986	France .
1961531	7/1970	Germany .
3101333 A1	12/1981	Germany .
3132520 A1	6/1982	Germany .
3505567 A1	6/1986	Germany .
106 101	7/1939	Sweden .

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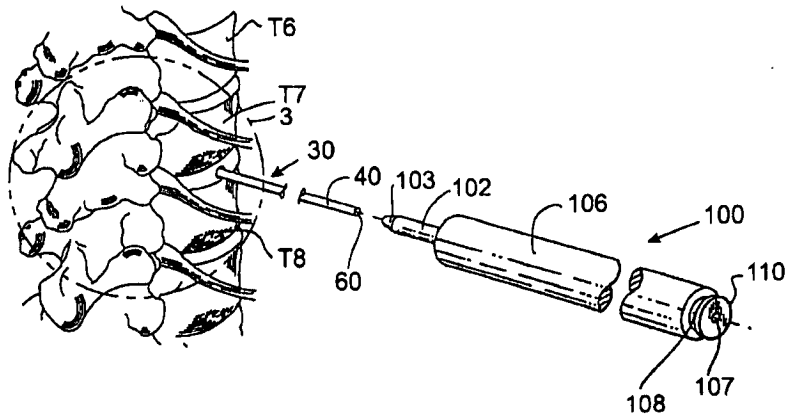
[57] **ABSTRACT**

An improved method and instrumentation for performing spinal surgery, including discectomy, interbody fusion and rigid internal fixation of the spine, from the lateral aspect of the spine is disclosed. The surgical procedure can be performed through a very small incision. The instrumentation of the present invention, all of which is inserted from a lateral position into the spine in the preferred embodiment, comprises a guide pin, a distractor, an extended outer sleeve, an inner sleeve an adjustable drill and an implant driver. The distractor of the present invention is driven into the disc for spacing apart and realigning the adjacent vertebrae. It further functions as an alignment rod for inserting the extended outer sleeve which is a hollow tubular member capable of maintaining said spacing and alignment of two adjacent vertebrae and defines a protected space through which subsequent instruments which may include, but are not limited to, a drill and a diameter reducing inner sleeve may be passed, as well as a spinal implant. The remainder of the surgical procedure consisting of the removal of spinal material across the disc, fusion, and rigid internal stabilization via the implant may all be performed via the closed space within the extended outer sleeve.

87 Claims, 14 Drawing Sheets



U.S. PATENT DOCUMENTS

3,604,487	9/1971	Gilbert .	
3,605,123	9/1971	Hahn .	
3,709,219	1/1973	Halloran .	
3,720,959	3/1973	Hahn .	
3,750,652	8/1973	Sherwin .	
3,848,601	11/1974	Ma	606/61
3,855,638	12/1974	Pilliar .	
3,867,728	2/1975	Stubstad et al. .	
3,875,595	4/1975	Froning	623/17
3,892,232	7/1975	Neufeld .	
3,905,047	9/1975	Long .	
3,915,151	10/1975	Kraus .	
3,948,262	4/1976	Zaffaroni .	
3,952,334	4/1976	Bokros et al. .	
3,987,499	10/1976	Scharbach et al. .	
4,016,651	4/1977	Kawahara et al. .	
4,051,905	10/1977	Kleine .	
4,059,115	11/1977	Jumashev et al. .	
4,070,514	1/1978	Entherly et al. .	
4,086,701	5/1978	Kawahara et al. .	
4,124,026	11/1978	Berner et al. .	
4,142,517	3/1979	Stravropoulos et al. .	
4,168,326	9/1979	Broemer et al. .	
4,175,555	11/1979	Herbert .	
4,177,524	12/1979	Grell et al. .	
4,181,457	1/1980	Holmes .	
4,206,516	6/1980	Pilliar .	
4,222,128	9/1980	Tomonaga et al. .	
4,237,948	12/1980	Jones et al. .	
4,259,072	3/1981	Hirabayashi et al. .	
4,262,369	4/1981	Roux .	
4,271,832	6/1981	Evans et al. .	
4,289,123	9/1981	Dunn .	
4,293,962	10/1981	Fuson .	
4,309,777	1/1982	Patil .	
4,328,593	5/1982	Sutter et al. .	
4,333,469	6/1982	Jeffcoat et al. .	
4,341,206	7/1982	Perrett et al. .	
4,349,921	9/1982	Kuntz .	
4,356,572	11/1982	Guillemin et al. .	
4,401,112	8/1983	Rezaian .	
4,405,319	9/1983	Cosentino .	
4,423,721	1/1984	Otte et al. .	
4,439,152	3/1984	Small .	
4,450,834	5/1984	Fischer .	
4,484,570	11/1984	Sutter et al. .	
4,492,226	1/1985	Belykh et al. .	
4,501,269	2/1985	Bagby .	
4,507,115	3/1985	Kambara et al. .	
4,530,360	7/1985	Duarte .	
4,535,374	8/1985	Jacobson	606/61
4,535,485	8/1985	Ashman et al. .	
4,542,539	9/1985	Rowe, Jr. et al. .	
4,545,374	10/1985	Jacobson .	
4,547,390	10/1985	Ashman et al. .	
4,552,200	11/1985	Sinha et al. .	
4,553,273	11/1985	Wu .	
4,554,914	11/1985	Kapp et al. .	
4,570,623	2/1986	Ellison et al. .	
4,570,624	2/1986	Wu .	
4,599,086	7/1986	Doty .	
4,600,000	7/1986	Edwards .	
4,604,995	8/1986	Stephens .	
4,608,052	8/1986	Van Kampen et al. .	
4,611,581	9/1986	Steffee .	
4,628,921	12/1986	Rousso .	
4,634,720	1/1987	Dorman et al. .	
4,636,217	1/1987	Ogilvie et al. .	
4,636,526	1/1987	Dorman et al. .	
4,645,503	2/1987	Lin et al. .	
4,653,486	3/1987	Coker .	
4,655,777	4/1987	Dunn .	
4,661,536	4/1987	Dorman et al. .	
4,665,920	5/1987	Campbell .	
4,677,883	7/1987	Lee .	
4,677,972	7/1987	Tornier .	
4,693,721	9/1987	Ducheyne .	
4,696,290	9/1987	Steffes .	
4,698,375	10/1987	Dorman et al. .	
4,710,075	12/1987	Davison .	
4,713,004	12/1987	Linkow et al. .	
4,714,469	12/1987	Kenna .	
4,721,103	1/1988	Freedland .	
4,736,738	4/1988	Lipovsek et al. .	
4,743,256	5/1988	Brantigan .	
4,743,260	5/1988	Burton .	
4,759,766	7/1988	Buettner-Janz et al. .	
4,759,769	7/1988	Hedman et al. .	
4,790,303	12/1988	Steffee .	
4,820,305	4/1989	Harms et al. .	
4,830,000	5/1989	Shutt .	
4,834,757	5/1989	Brantigan .	
4,848,327	7/1989	Perdue .	
4,851,008	7/1989	Johnson .	
4,863,477	9/1989	Monson .	
4,865,603	9/1989	Noiles .	
4,877,020	10/1989	Vich .	
4,878,915	11/1989	Brantigan	623/17
4,903,882	2/1990	Long .	
4,904,260	2/1990	Ray et al. .	
4,904,261	2/1990	Dove et al. .	
4,911,718	3/1990	Lee et al. .	
4,913,144	4/1990	Del Medico .	
4,936,848	6/1990	Babgy .	
4,943,291	7/1990	Tanguy .	
4,955,885	9/1990	Meyers .	
4,955,908	9/1990	Frey et al. .	
4,957,495	9/1990	Kluger .	
4,960,420	10/1990	Goble et al. .	
4,961,740	10/1990	Ray et al. .	
4,968,316	11/1990	Hergenroeder .	
4,969,888	11/1990	Scholten et al. .	
4,987,904	1/1991	Wilson .	
5,015,247	5/1991	Michelson .	
5,015,255	5/1991	Kuslich .	
5,026,373	6/1991	Ray	606/61
5,055,104	10/1991	Ray .	
5,059,193	10/1991	Kuslich .	
5,071,437	12/1991	Steffee .	
5,084,050	1/1992	Draenert .	
5,102,414	4/1992	Kirsch .	
5,116,304	5/1992	Cadwell .	
5,122,130	6/1992	Keller .	
5,123,926	6/1992	Pisharodi .	
5,192,327	3/1993	Brantigan .	
5,258,031	11/1993	Salib et al. .	
5,263,953	11/1993	Bagby .	
5,306,309	4/1994	Wagner et al. .	
5,364,399	11/1994	Lowery et al. .	
5,370,662	12/1994	Stone et al. .	
5,393,036	2/1995	Sheridan .	
5,396,880	3/1995	Kagan	604/280
5,397,364	3/1995	Kozak et al. .	
5,425,772	6/1995	Brantigan .	
5,435,723	7/1995	O'Brien .	
5,489,307	2/1996	Kuslich et al. .	
5,489,308	2/1996	Kuslich et al. .	
5,571,109	11/1996	Bertagnoli .	

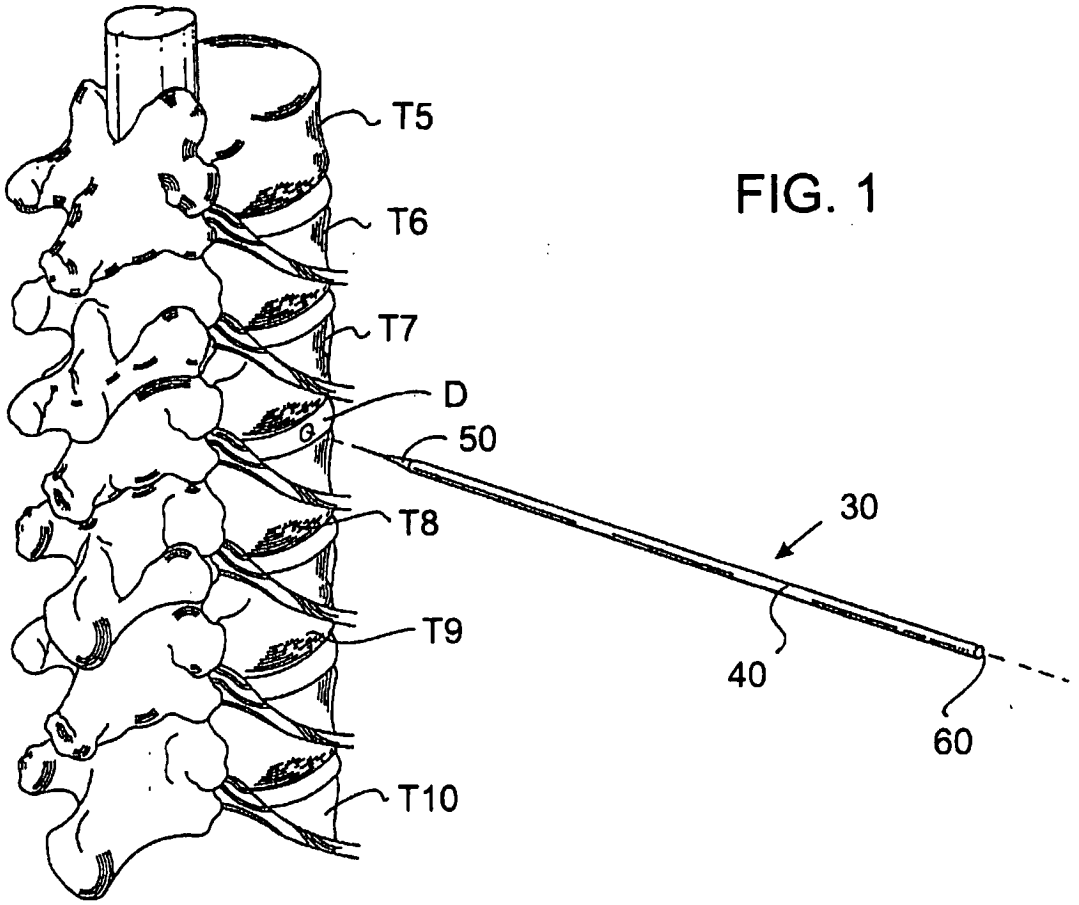
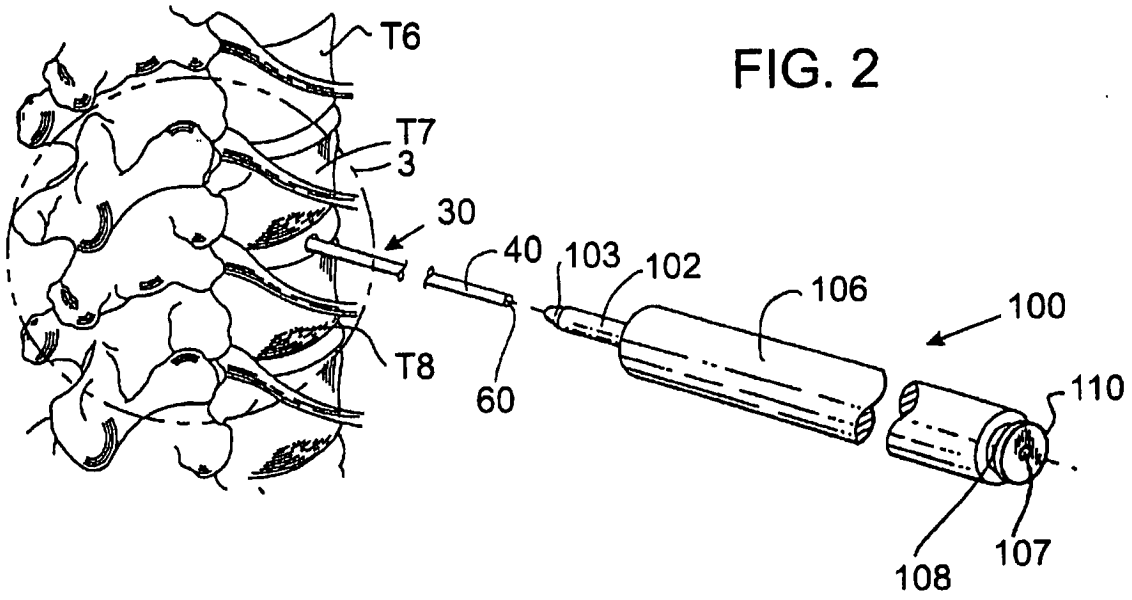

T5
T6
T7
D
50
30
T8
T9
40
60
T10

FIG. 1


T6
T7
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30
40
103
102
106
100
T8
60
110
108
107

FIG. 2

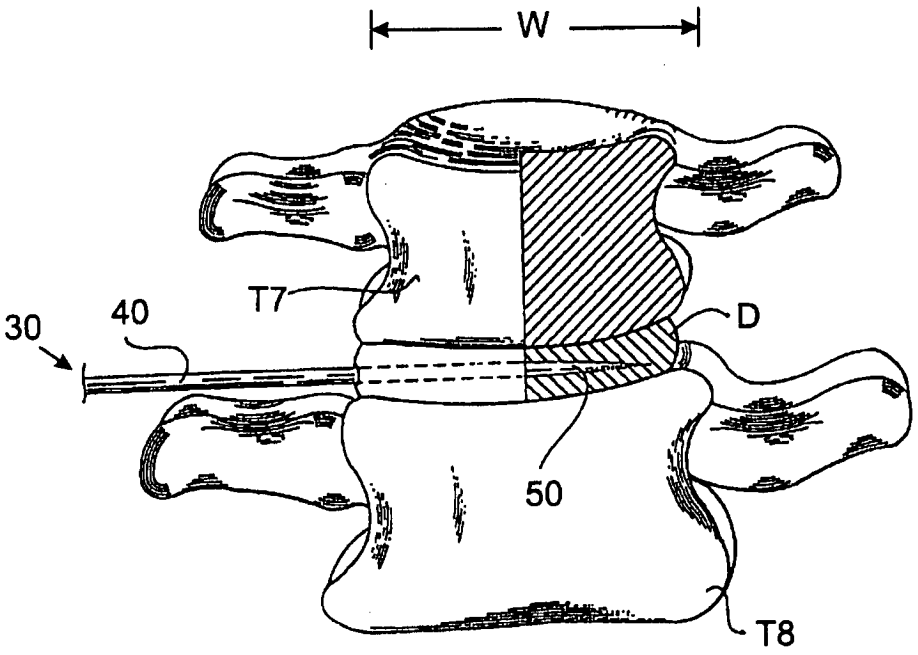


FIG. 3

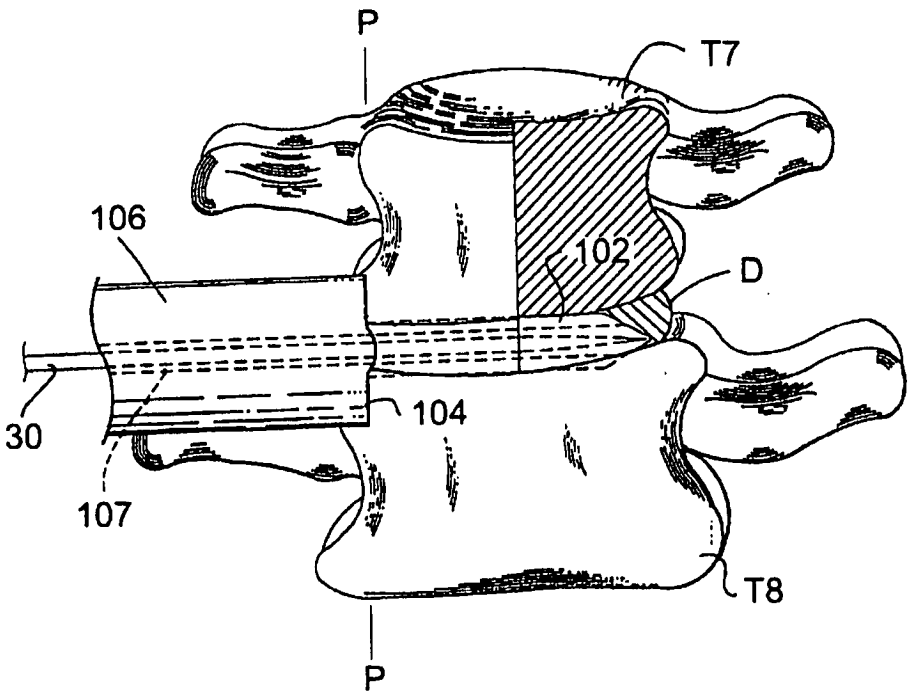


FIG. 4

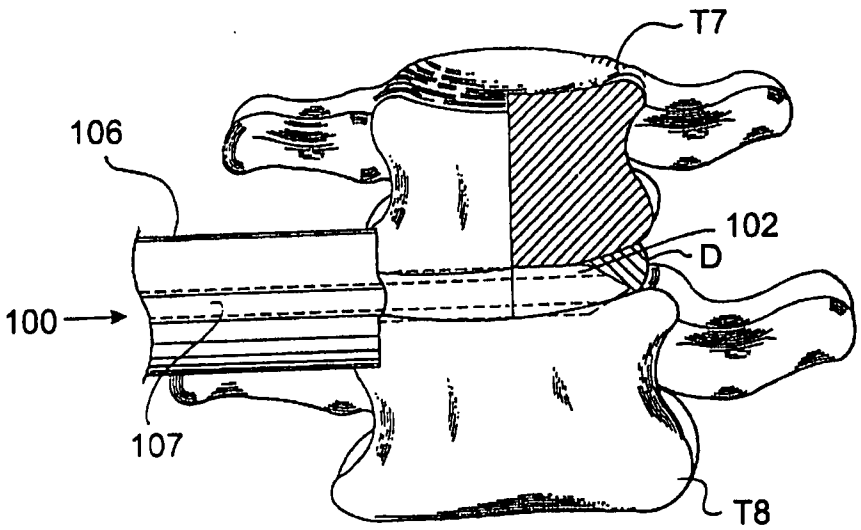


FIG. 5

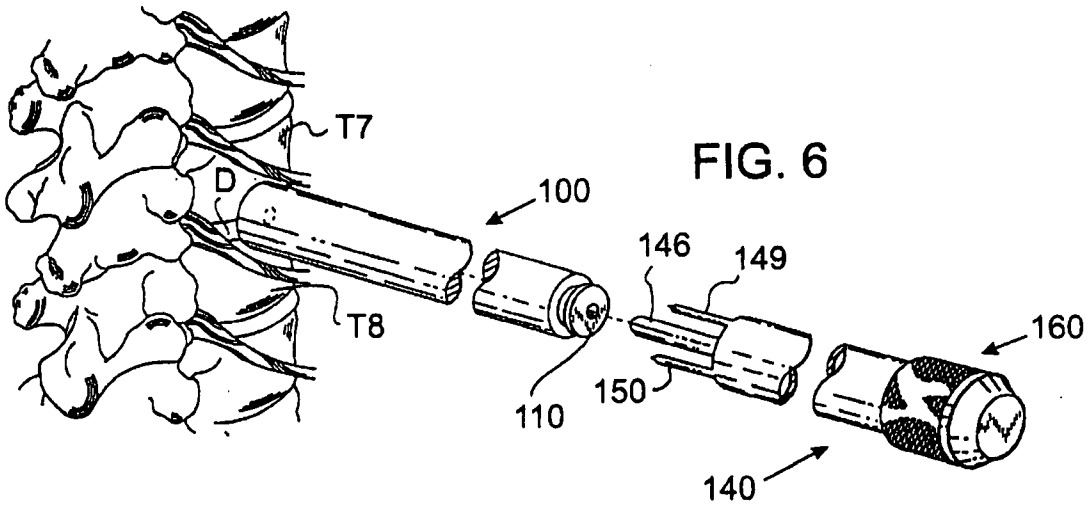


FIG. 6

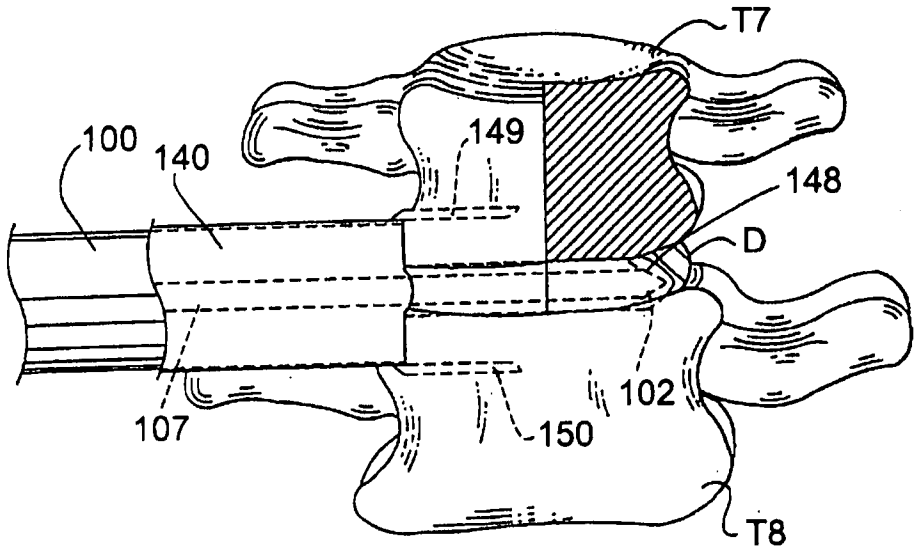


FIG. 7

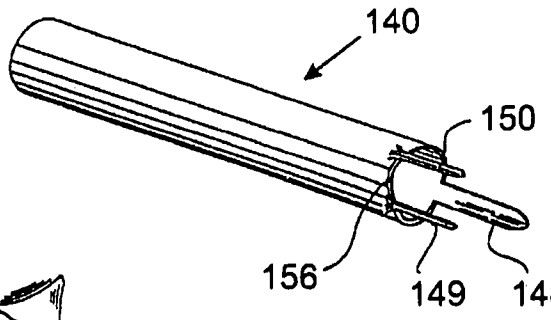


FIG. 7A

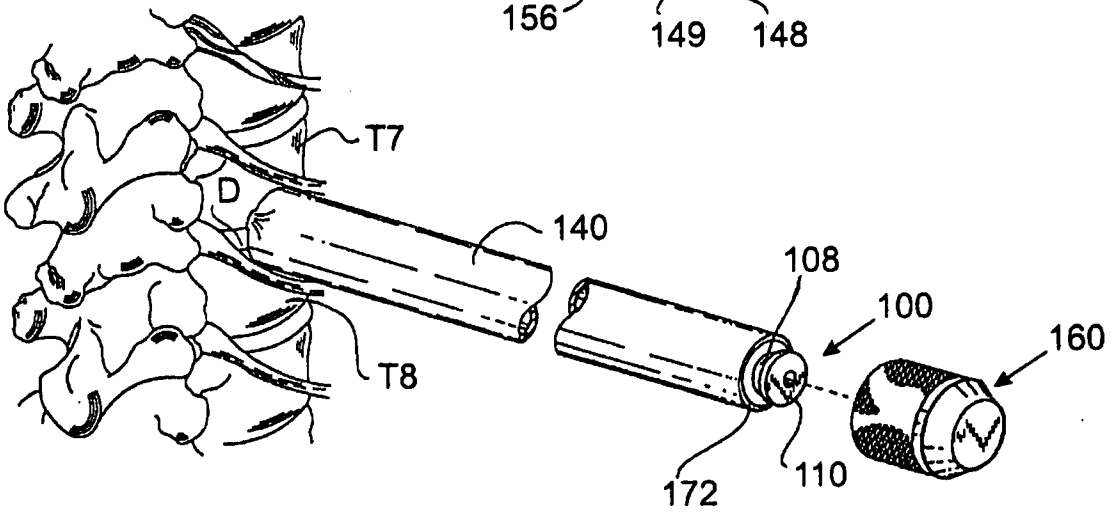


FIG. 8

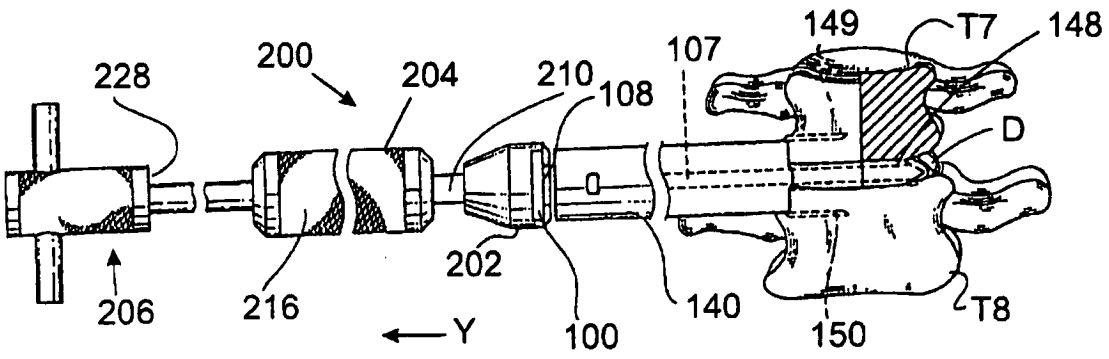

228
200
204
210
108
107
149
T7
148
D
206
216
202
Y
100
140
150
T8

FIG. 9

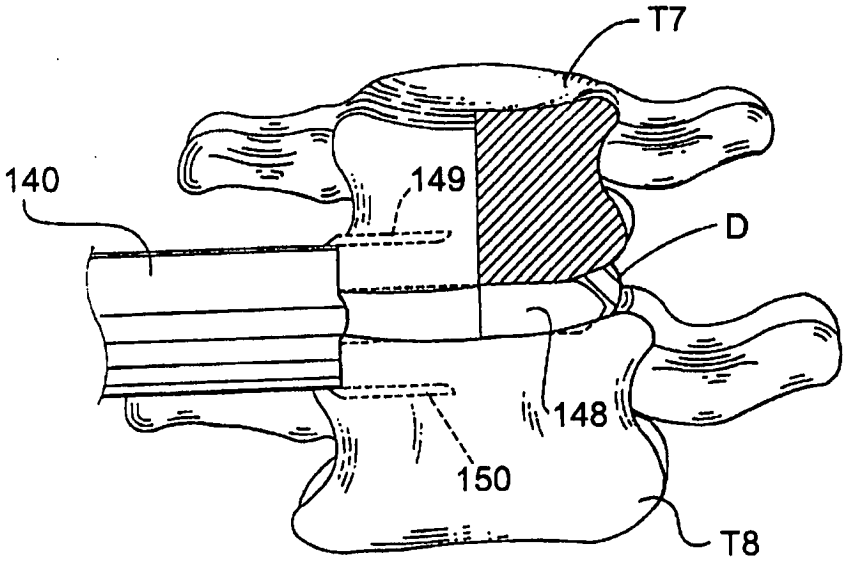

T7
140
149
D
148
150
T8

FIG. 10

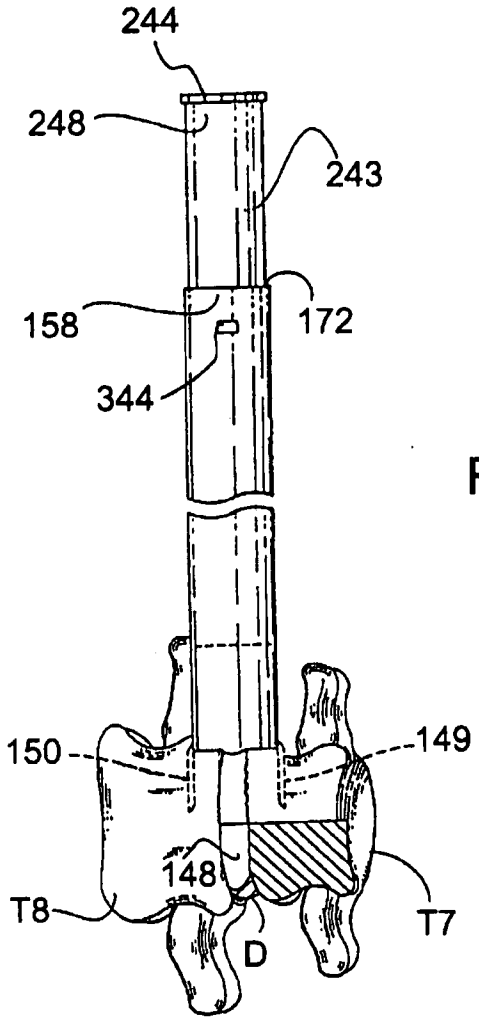
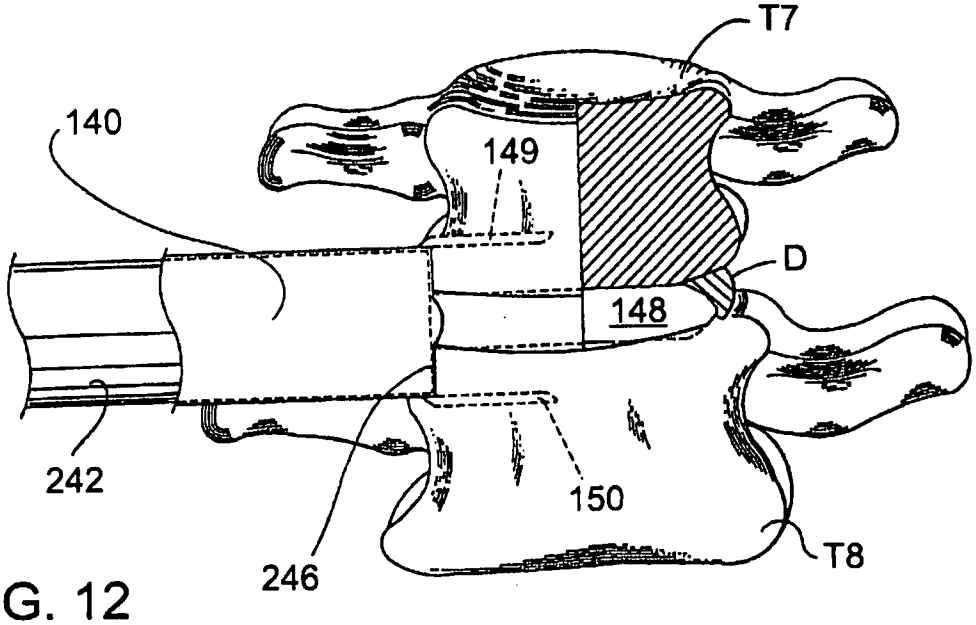

244
248
243
158
172
344
150
149
148
T8
T7
D

FIG. 11


T7
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D
148
242
150
T8
246

FIG. 12

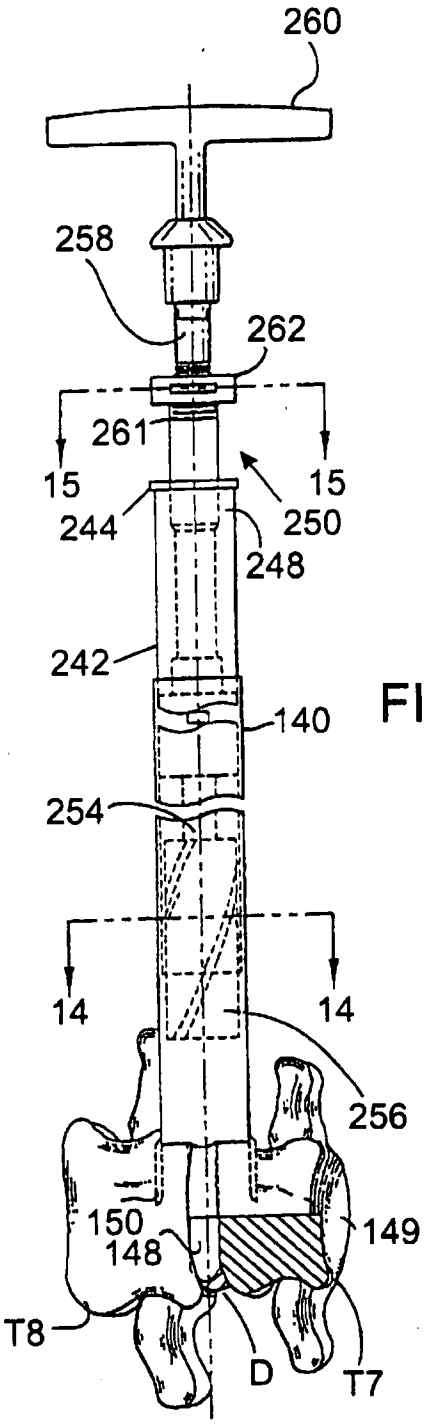


FIG. 13

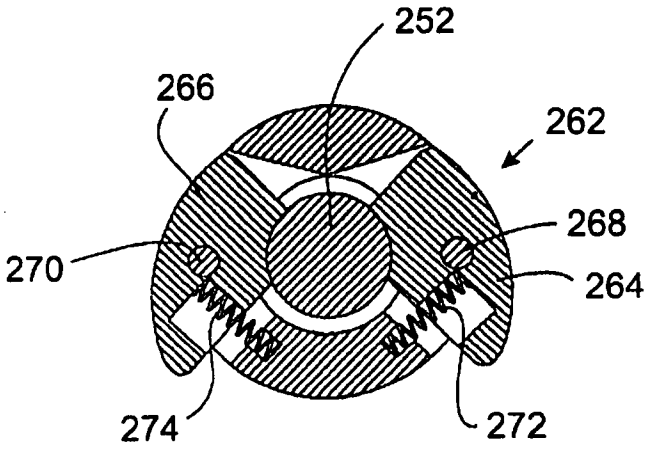


FIG. 15

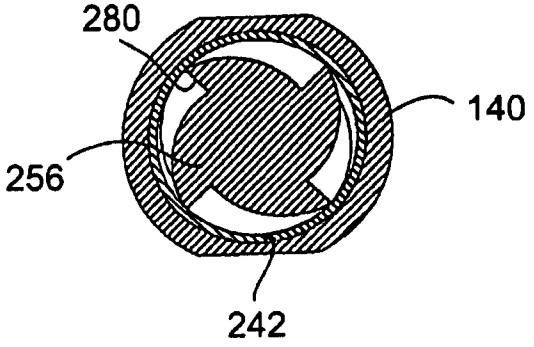
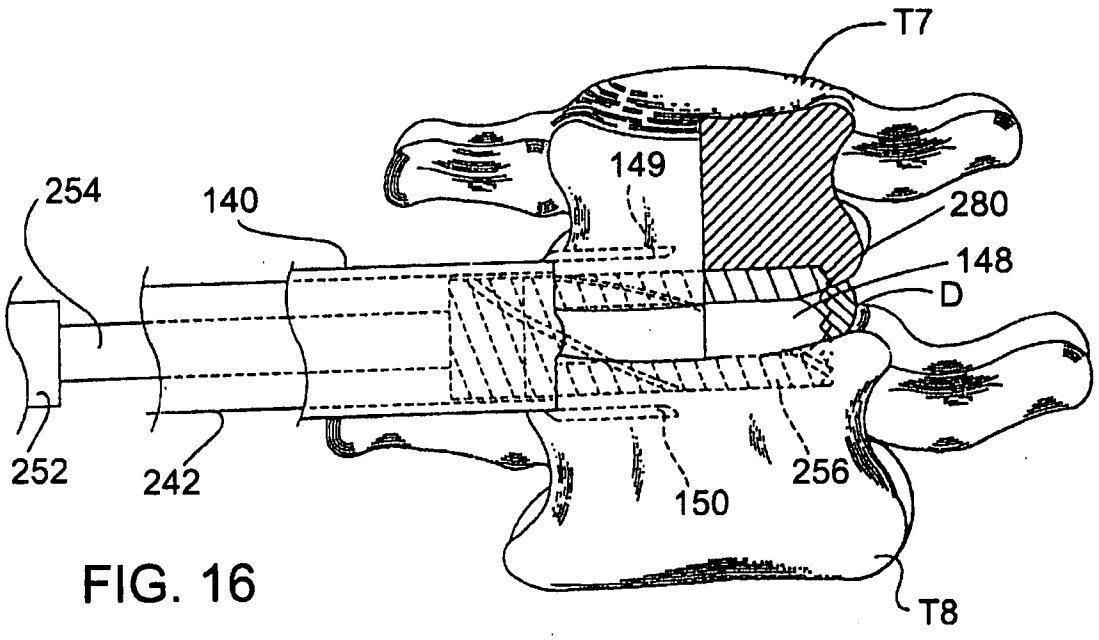


FIG. 14


T7
149
254
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280
148
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252
242
150
256
T8

FIG. 16

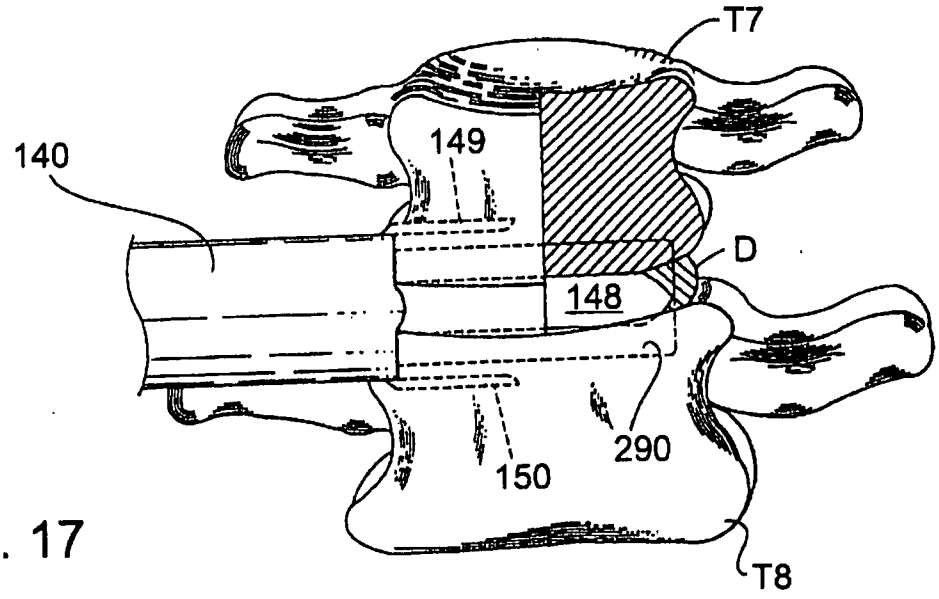
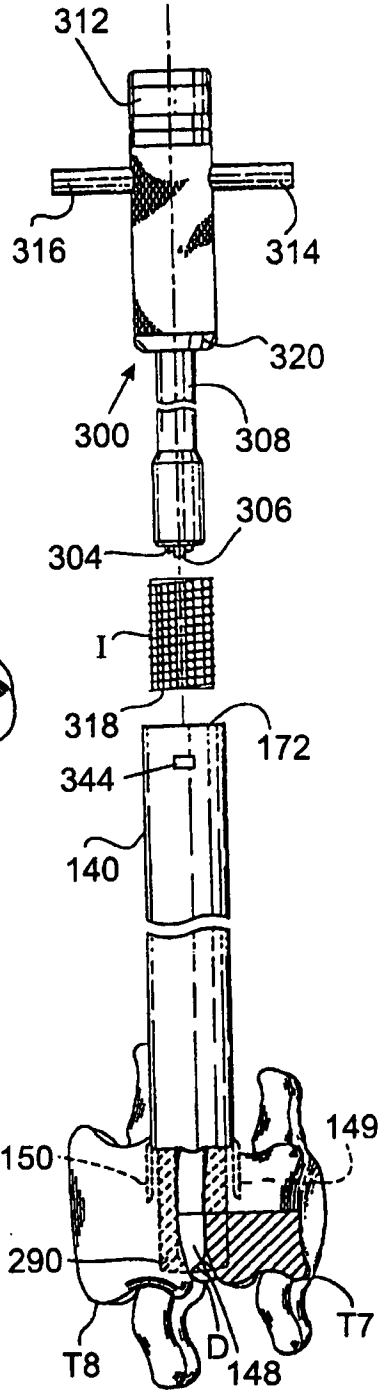

T7
140
149
D
148
290
150
T8

FIG. 17

FIG. 18


312
316
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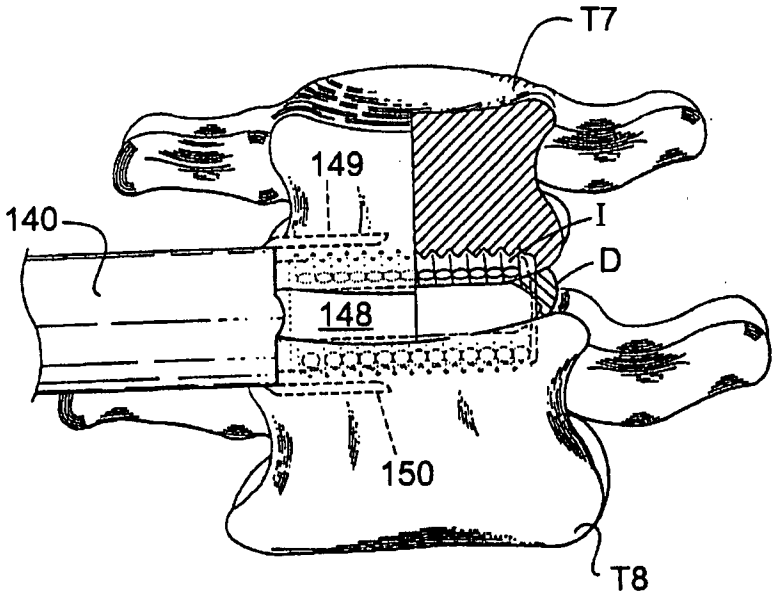
308
306
304
I
318
172
344
140
149
150
290
T7
T8
D
148


T7
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T8

FIG. 19

FIG. 21

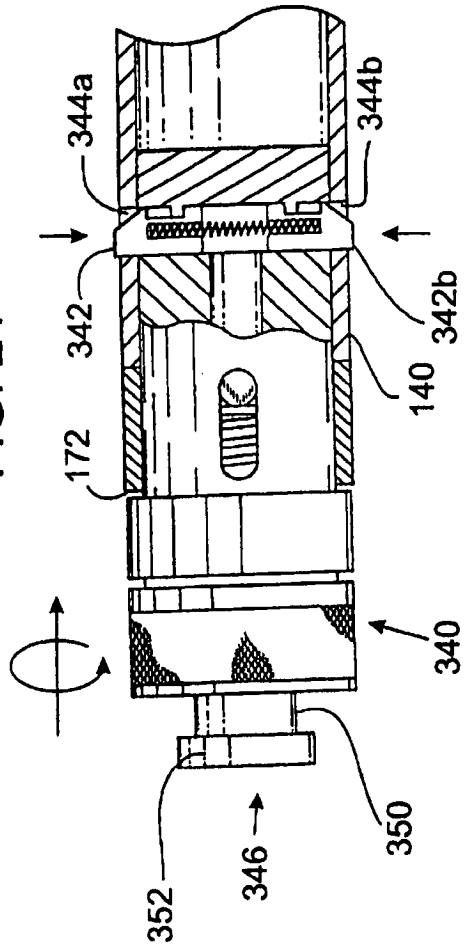
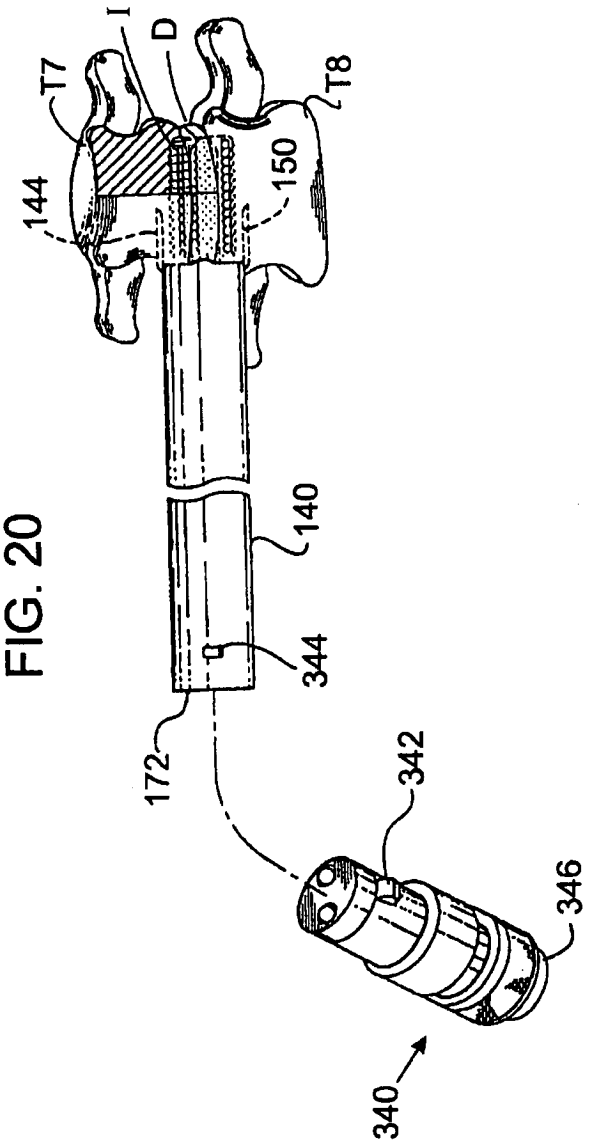

344a
344b
342
342b
140
172
340
350
346
352

FIG. 20


I
D
T7
T8
144
150
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344
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342
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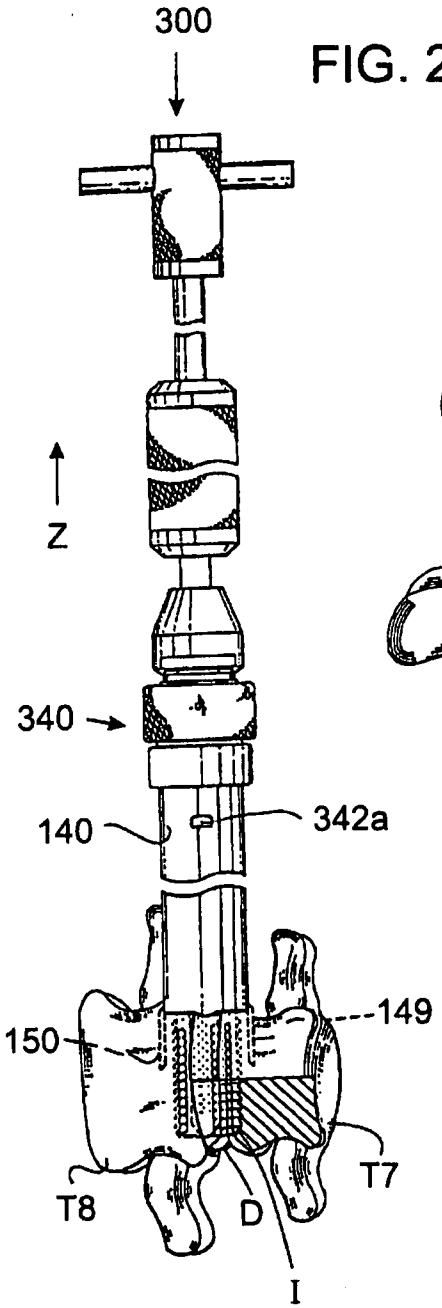
340

FIG. 22



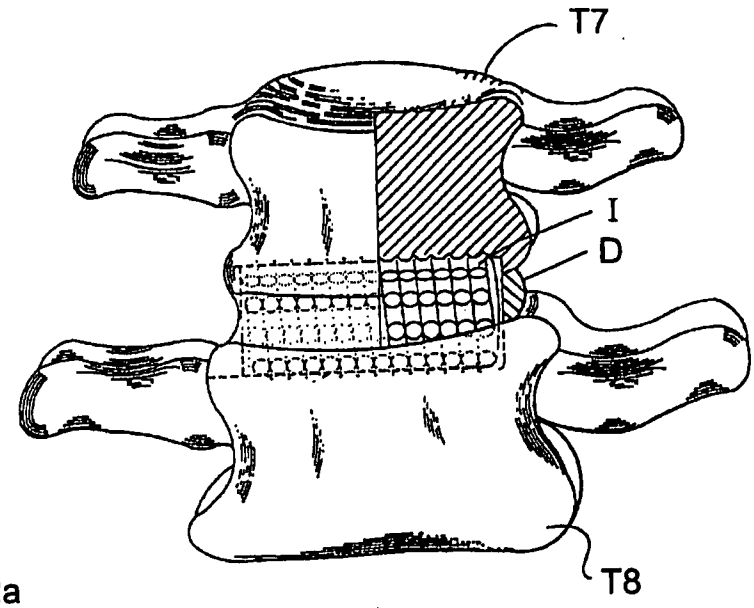


FIG. 23

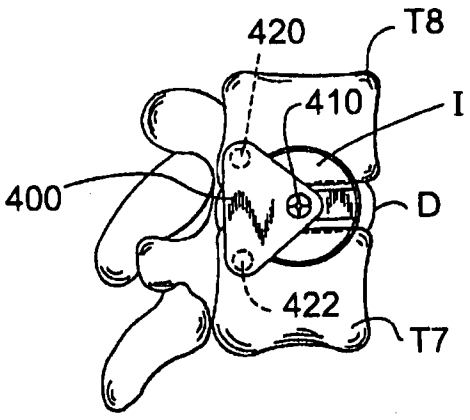


FIG. 24

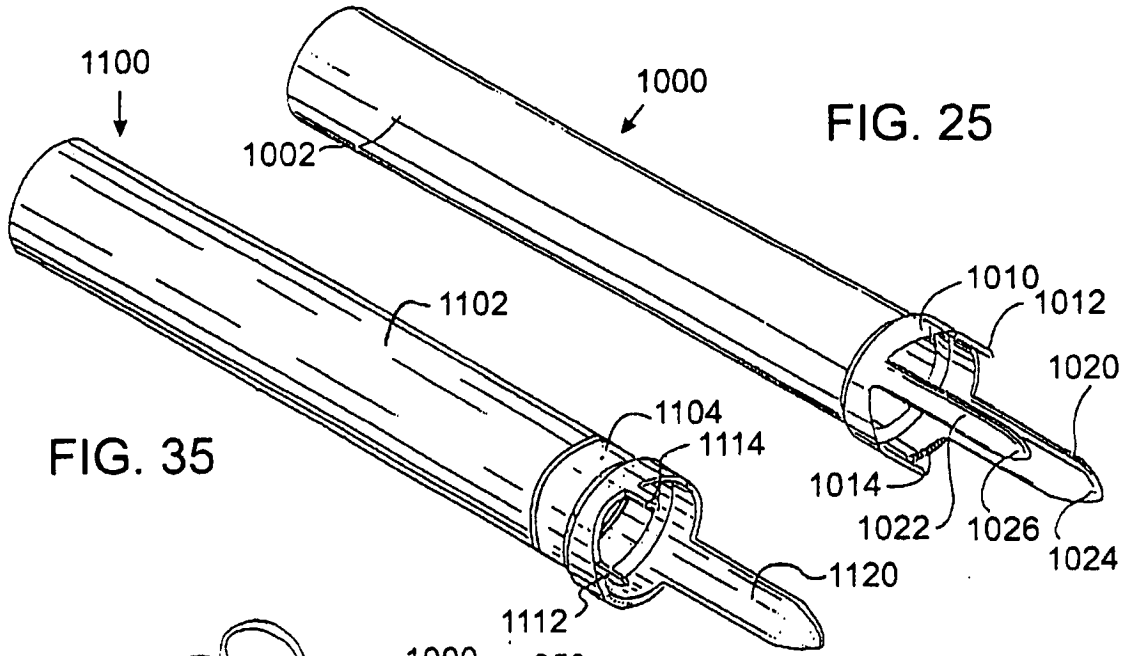


FIG. 35

FIG. 25

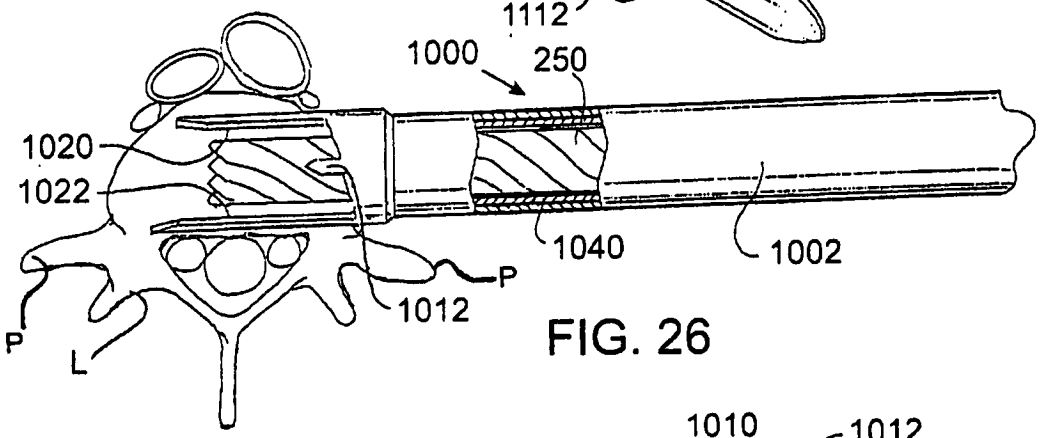


FIG. 26

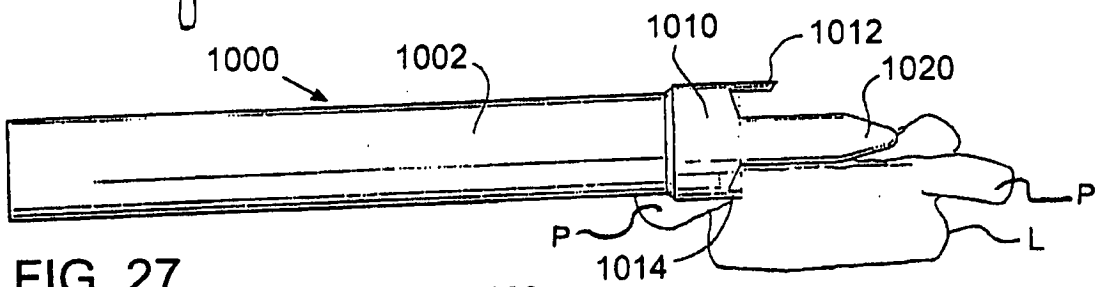


FIG. 27

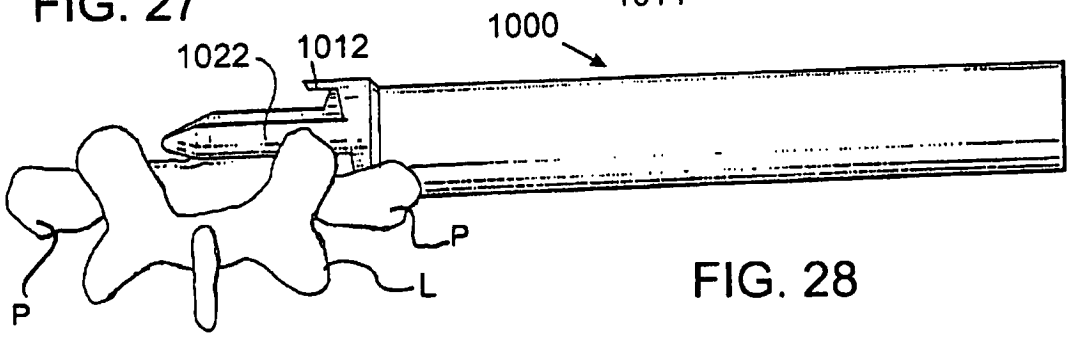
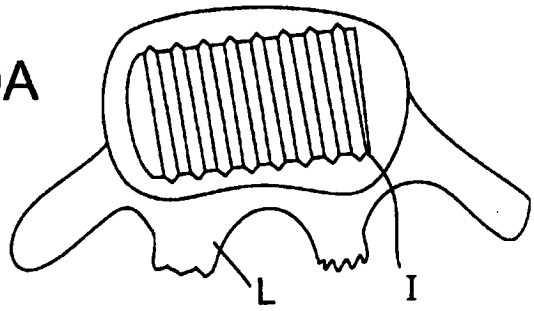


FIG. 28

FIG. 30A



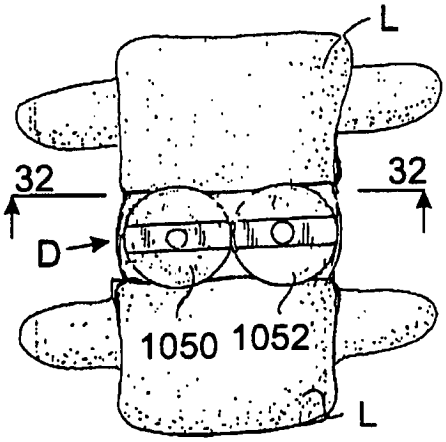


FIG. 31

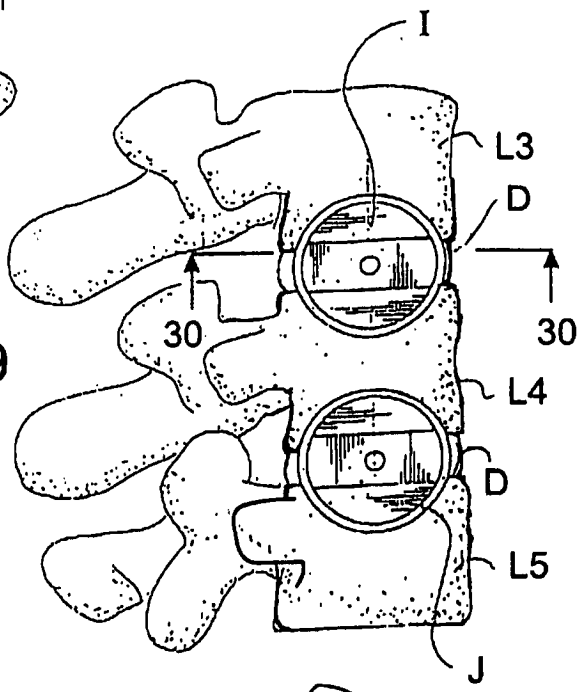


FIG. 29

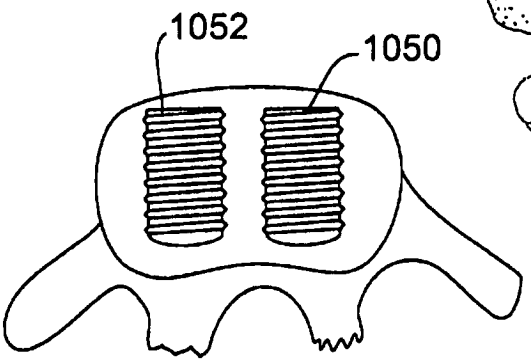


FIG. 32

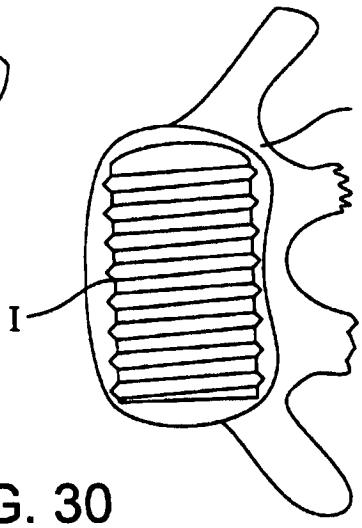


FIG. 30

FIG. 33

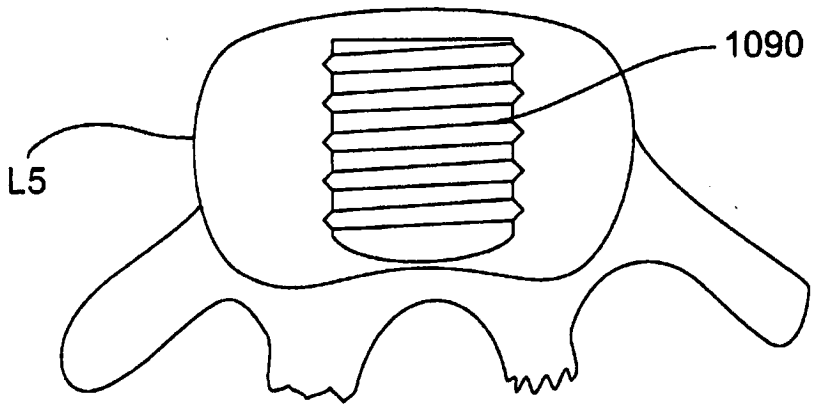
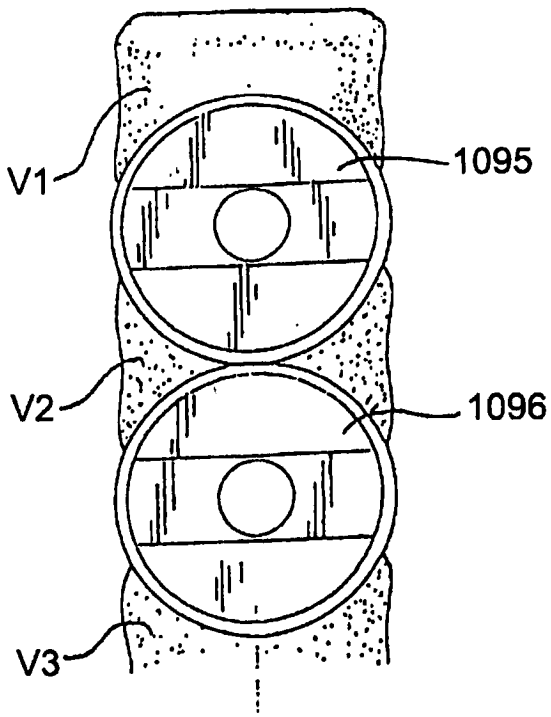


FIG. 34



METHODS AND INSTRUMENTATION FOR THE SURGICAL CORRECTION OF HUMAN THORACIC AND LUMBAR SPINAL DISEASE FROM THE ANTERO-LATERAL ASPECT OF THE SPINE

RELATED APPLICATIONS

This application is a continuation in part of copending U.S. application Ser. No. 08/074,781 filed on Jun. 10, 1993, which is a continuation in part of U.S. application Ser. No. 07/698,674 filed on May 10, 1991 which is a divisional of application Ser. No. 07/205,935 filed on Jun. 13, 1988, now U.S. Pat. No. 5,015,247 all of which are incorporated herein by reference. This application is also a continuation in part of copending U.S. application Ser. No. 08/219,626 filed on Mar. 28, 1994 which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to instrumentation and methods of performing surgical procedures on the human thoracic and lumbar spine along the lateral aspect of the spine and from a true lateral or anterolateral approach, and specifically to the surgical correction of thoracic and lumbar disc disease and spinal deformities where concomitant fusion is desired.

2. Description of the Related Art

As regards the thoracic spine, it may be afflicted with a variety of ailments, some so severe as to require surgical intervention. A disc herniation may compress the spinal cord and/or nerve roots and cause pain, loss of function, and even complete paralysis of the legs with loss of bowel and bladder control. The correct treatment for such conditions is the removal of the offending discal tissue. However, this has proven both difficult and quite dangerous. When the discs of the thoracic spine are approached posteriorly (from behind) the spinal cord is in the way. To approach the same herniation anteriorly (from the front) requires the very formidable procedure of thoracotomy (cutting open the chest) and moving the heart and lungs out of the way.

Quite recently surgeons have begun performing these procedures from a lateral approach to the spine (from the side) using fiber optic viewing instruments called thoracscopes and numerous small surgical openings through the chest wall (portals) through which various surgical instruments, such as burrs, rongeurs and curettes, may be placed to remove these disc herniations while avoiding formal thoracotomy. Because the discs are very narrow in the thoracic spine and the surgeon is approaching the spine laterally, there is very little space in which to work as the disc is entered in order to get to the back of the disc space. Therefore, the amount of disc removal may be limited. In the alternative, the surgeon might remove the pedicle to gain access to the spinal canal risking further weakening of the already diseased area.

Sometimes, for a variety of reasons including the removal of disc material, the thoracic spine may become unstable (too much motion) at any given level. Historically, this has been treated by fusion, the joining together permanently of the unstable vertebrae via a bridge of bone so as to eliminate all motion at that location. Fusions about the thoracic spine have been performed either anteriorly or posteriorly, either procedure being a rather large surgical undertaking.

Stability of the spine is required for fusion to occur. For this reason, and for the purpose of correcting spinal

deformity, it is often necessary to use hardware to rigidly internally fixate (stabilize) the spine. To date, the only benefit the use of the thorascope has provided in this regard is to allow the previous thoracotomy incision to be somewhat smaller.

So to date the following problems remain even utilizing the most recent technology as regards the surgical treatment of thoracic disc disease:

Firstly, the working space within the disc itself to access the herniation which is more posterior is quite limited.

Secondly, multiple or long incisions through the chest are still required.

Thirdly, when fusion is required a major surgical undertaking with its considerable risks is required.

Fourthly, the installation of hardware affixed to the spine still requires a thoracotomy, albeit a smaller one if visualization is assisted via the thorascope.

Fifthly, when, as is often the case, the patient requires all three, that is, discectomy (excision, in part or whole, of an intervertebral disc), fusion, and the application of hardware to the spine, those procedures are performed as serially (one after the other) combined surgical procedures with added surgical times, complications, morbidities, and mortalities.

As regards to the human lumbar spine, the treatment of discal disease with neural compression has generally been from a posterior (from behind) approach. This is sensible as the lumbar discs are generally quite large and it is only those protrusions occurring posteriorly which compress the neural elements which are themselves posterior to the discs. These posterior approaches have included both true posterior approaches and posterolateral approaches to the discs. Further, such approaches have been made via open incisions or through percutaneous stab wounds. In the latter case, instruments are inserted through the stab wounds and monitored by the use of radiographic imaging or the use of an endoscopic viewing device. While it is possible to also decompress a posterior disc herniation in the lumbar spine from an anterior approach (from the front) doing so requires the removal of a very substantial portion or all of the disc material in the front and mid portions of the disc thus leaving that disc incompetent and that spinal segment generally unstable. Therefore, such an anterior approach to the lumbar spine has been reserved for those instances where a fusion is to be performed in conjunction with, and following such a disc removal.

As regards to fusion, the application of bone or bone like substances between bones to induce bony bridging, such procedures have been performed outside the vertebral bodies and/or between the vertebral bodies. The latter being known as an interbody fusion. Such interbody fusions have been performed from posterior, posterolateral and anterior. The adjective applying specifically to the direction from which the bone grafts enter the intervertebral space. Interbody fusion from the posterior approach while still in use has been associated with significant complications generally related to the fact that the delicate dural sac and the spine nerves cover the back of the disc space and are thus clearly in harms way with such an approach. The posterolateral approach has generally been utilized as a compliment to percutaneous discectomy and has consisted of pushing tiny fragments of morsalized bone down through a tube and into the disc space.

Anterior interbody spinal fusion is performed from a straight anterior position as regards the path of entry of the fusion material into the intervertebral space. Such an anterior position is achieved in one of two ways. First, by a

straight anterior approach which requires that the peritoneal cavity, which contains the intestines and other organs, be punctured twice, once through the front and once through the back on the way to the front of the spine; or secondly, by starting on the front of the abdomen off to one side and dissecting behind the peritoneal cavity on the way to the front of the spine. Regardless of which approach to the front of the spine is used, and apart from the obvious dangers related to the dense anatomy and vital structures in that area, there are at least two major problems specific to the anterior interbody fusion angle of implant insertion itself. First, generally at the L_4L_5 disc, the great iliac vessels bifurcate from the inferior vena cava lie in close apposition to, and, covering that disc space making fusion from the front both difficult and dangerous. Secondly, anterior fusions have generally been done by filling the disc space with bone or by drilling across the disc space and then filling those holes with cylindrical implants. As presently practiced, the preferred method of filling the disc space consists of placing a ring of allograft (bone not from the patient) femur into that disc space. An attempt to get good fill of the disc space places the sympathetic nerves along the sides of the disc at great risk. Alternatively, when the dowel technique is used, because of the short path from the front of the vertebrae to the back and because of the height of the disc as compared to the width of the spine, only a portion of the cylindrical implant or implants actually engages the vertebrae, thus, compromising the support provided to the vertebrae and the area of contact provided for the fusion to occur.

There is therefore, in regard to the lumbar spine, a need for a new method and means for achieving interbody fusion which method avoids the problems associated with all prior methods, and which have included, but are not limited to, nerve damage when performed posteriorly, or the need to mobilize the great vessels when performed anteriorly. Further, the size of the implants are limited by the dural sac posteriorly, and the width of the spine and the delicate vital structures therewith associated anteriorly. An improved method and means for interbody fusion should provide for optimal fill of the interspace without endangering the associated structures and allow for the optimal area of contact between the implant or implants and the vertebrae to be fused.

SUMMARY OF THE INVENTION

The present invention is directed to methods and instrumentation for performing surgery on the spine along its lateral aspect (side) and generally by a lateral or an anterolateral surgical approach, from a position anterior to the transverse processes of adjacent vertebrae of the spine, such that the instruments enter the body from an approach that is other than posterior and make contact with the spine along its lateral aspect. The present invention provides for the entire surgical procedure to be performed through a relatively small incision and may be performed in either the thoracic or lumbar spine.

In the preferred embodiment, the instrumentation of the present invention comprises a guide pin, a distractor, an extended outer sleeve, an inner sleeve and drill adjustable for depth and with a depth limiting means. The distractor of the present invention is used for initially distracting (spacing apart) and realigning adjacent vertebrae of the spine and also functions as an alignment rod for inserting the extended outer sleeve. The distractor is placed at the affected disc space between adjacent vertebrae through a small incision in the body. For example, for surgery in the thoracic spine, a small incision in the chest cavity of the patient is made from a lateral approach to the thoracic spine. For surgery in the lumbar spine a small incision may be made in the abdominal wall of the patient. The insertion of the distractor may be guided by a guide pin previously inserted in the disc space and visually monitored for proper orientation and placement by the surgeon either indirectly through an image intensifier, or directly through a thorascope or by direct vision.

The extended outer sleeve in the preferred embodiment is a hollow tubular member having an extension member that is inserted in the disc space and is capable of distracting and aligning the two adjacent vertebrae from the lateral aspect of the spine. In the preferred embodiment, the extended outer sleeve has a pair of prongs for fixedly engaging the two adjacent vertebrae and further stabilizing the adjacent vertebrae. With the distractor in place in the affected disc space, the extended outer sleeve is placed over the distractor, and the distractor guides and aligns the insertion of the extended outer sleeve. As the extended outer sleeve is seated, the extension member becomes inserted in the disc space and the prongs engage the outside wall of the adjacent vertebrae. The distractor is then removed and the extended outer sleeve maintains the proper distraction and alignment of the adjacent vertebrae. The remainder of the surgical procedure consisting of disc removal, fusion, and rigid internal stabilization may all be performed via the closed space within the extended outer sleeve. Alternatively, a convertible extended outer sleeve comprising a hollow tubular member that can be dissociated from its insertion end which remains engaged to the vertebrae to maintain distraction and alignment, may be used where it is desired to have direct visualization and access to the surgical site for at least a portion of the surgical procedure.

The drilling out and the subsequent removal of a rather significant mass of the disc itself may be curative in relieving a posterior disc herniation as the mass of tissue pushing from within the disc outward and posteriorly is thus removed. Further, the distractor in driving the vertebrae apart exerts significant tension on the walls of the disc which are pulled straight also tending to correct any disc herniation. Finally, since the hole drilled across the disc space is quite close to the posterior borders of the vertebrae, it makes the removal of any persisting posterior disc herniation quite simple. With the drill removed and the extended outer sleeve cleaned out by irrigation and suction, one can then place the endoscope directly down the outer sleeve and into the large space created by the removal of the disc, and in the preferred method, the adjacent vertebral bone, and then remove any remaining fragments of disc using conventional hand held instruments such as rongeurs and curettes under endoscopic visualization.

When it is desirable to remove posterior disc material, then a specialized modification of the extended outer sleeve having at its distal end a spine engaging portion comprising one anterior extension and posteriorly two prongs one each above and below the disc space may be used. Further, such an extended outer sleeve may be configured such that the great length of the hollow tubular portion of the extended outer sleeve is detachable, as by unscrewing, from the distal working end such that when uncoupled the distal end may remain in place maintaining distraction even after the hole is drilled and thus allowing the surgeon to work through that remaining portion of the extended outer sleeve and the space provided by the drilling to remove the posterior disc material under direct vision. For those instances where the surgeon has elected to access the spine through a more standard incision and is viewing the spine directly, the surgeon is then able to continue to operate through the distal spine engaging

portion of the extended outer sleeve and still maintain the distraction and alignment of the vertebrae.

A spinal implant may then be inserted through the extended outer sleeve and into the hole in the adjacent vertebrae. The extended outer sleeve is removed once the spinal implant has been inserted. If the spinal implant being inserted has surface projections such as a thread, then an inner sleeve is inserted in the extended outer sleeve prior to drilling to accommodate the height of the projections or as in the case of a thread, the difference between the major and minor diameters of the implant.

To further stabilize the spinal implant, a staple alignment rod may be mechanically coupled to the spinal implant prior to the removal of the extended outer sleeve. The extended outer sleeve is then removed and a staple having spine engaging prongs is inserted via the alignment rod and is coupled to the spinal implant. The alignment rod is removed and replaced with a locking screw to secure the staple to the spinal implant.

While the preferred method utilizing a cylindrical implant and involving the removal of some bone from each of the adjacent vertebrae in preparation for fusion has been described, it is understood that the distractor and sleeve could as well be rectangular and the drill supplemented with or replaced by a box chisel, or other chisel so as to produce a rectangular fusion site or similarly any of a variety of shapes. Further, it is understood that the outer sleeve could be dimensioned so as to confine the removal of the disc material, regardless of the means, to the area between the adjacent vertebrae rather than providing for the removal of the bone as well.

OBJECTS OF THE PRESENT INVENTION

It is an object of the present invention to provide instrumentation for performing surgery on the thoracic spine through the chest cavity from a lateral approach to the spine.

It is another object of the present invention to provide a method of performing surgery on the thoracic spine through the chest cavity from a lateral approach to the spine that is safer, more effective and faster than previously possible.

It is a further object of the present invention to provide instrumentation and method of inserting a spinal implant in a hole drilled across the disc space and into two adjacent vertebrae of the thoracic spine through the chest cavity from a lateral approach to the spine.

It is another object of the present invention to provide for a method and instrumentation for performing a thoracic discectomy, an interbody fusion, and rigid internal fixation of the spine through the chest cavity from a lateral approach and all as a single integrated procedure.

It is yet another object of the present invention to provide for a method and instrumentation for performing a lumbar fusion from the lateral aspect of the spine.

It is further another object of the present invention to provide for a method and instrumentation for performing a lumbar fusion and spinal canal decompression from the lateral aspect of the spine.

It is further still another object of the present invention to provide for a method and instrumentation for performing a lumbar fusion, decompressive discectomy, and a rigid internal fixation of the spine and all as a single integrated surgical procedure.

It is further yet another object of the present invention to provide for a method and instrumentation to achieve discectomy, fusion and interbody stabilization of the lumbar without the need to mobilize the great vessels from the front of the vertebral bodies.

These and other objects of the present invention will become apparent from a review of the accompanying drawings and the detailed description of the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a rear perspective view of a segment of the thoracic spine with the guide pin of the present invention about to be inserted from a lateral approach to the thoracic spine into the disc space between two adjacent vertebrae.

FIG. **2** is a rear perspective view of a segment of the thoracic spine with the guide pin inserted in the disc space between two adjacent vertebrae and the distractor of the present invention about to be placed over the guide pin.

FIG. **3** is an enlarged front elevational view of a segment of the thoracic spine along line **3** of FIG. **2** having a portion of the top vertebrae removed and a portion of the disc removed with the guide pin, shown partially in hidden line, inserted from a lateral approach to the thoracic spine into the disc space.

FIG. **4** is an enlarged front elevational view of the segment of the thoracic spine of FIG. **3** with the guide pin and distractor, shown partially in hidden line, inserted from a lateral approach to the thoracic spine in the disc space.

FIG. **5** is an enlarged front elevational view of the segment of the thoracic spine of FIG. **3** with the distractor, shown partially in hidden line, inserted from a lateral approach to the thoracic spine and seated in the disc space and the guide pin removed.

FIG. **6** is a rear perspective view of a segment of the thoracic spine having a distractor inserted from a lateral approach to the thoracic spine and seated in the disc space and the extended outer sleeve of the present invention coupled to a driver cap and about to be placed over the distractor.

FIG. **7** is an enlarged front elevational view of the segment of the thoracic spine of FIG. **3** with the distractor and the extended outer sleeve inserted from a lateral approach to the thoracic spine and seated in the disc space.

FIG. **7A** is side perspective view of the extended outer sleeve of the present invention.

FIG. **8** is a rear perspective view of a portion of the thoracic spine with the extended outer sleeve fully seated over the distractor inserted from a lateral approach to the thoracic spine and seated in the disc space and with the driver cap removed.

FIG. **9** is a front elevational view of a segment of the thoracic spine of FIG. **3** with the extended outer sleeve inserted from a lateral approach to the thoracic spine and seated in the disc space and engaging the adjacent vertebrae showing the distractor being removed by a distractor puller.

FIG. **10** is an enlarged front elevational view of the segment of the thoracic spine of FIG. **3** with the extended outer sleeve inserted from a lateral approach to the thoracic spine and seated in the disc space and engaging the two adjacent vertebrae.

FIG. **11** is a front elevational view of a segment of the thoracic spine of FIG. **3** with the inner sleeve of the present invention being inserted into the extended outer sleeve.

FIG. **12** is an enlarged front elevational view of the segment of the thoracic spine of FIG. **3** with the inner sleeve, shown in partial hidden line, inserted into the extended outer sleeve that is inserted from a lateral approach to the thoracic spine in the disc space and engages two adjacent vertebrae.

FIG. **13** is a side elevational view of a segment of the thoracic spine of FIG. **3** showing the extended outer sleeve inserted from a lateral approach to the thoracic spine in the disc space and engaging the two adjacent vertebrae with the inner sleeve and drill shown in an exploded view and partially in hidden line.

FIG. **14** is a cross sectional view along lines **14—14** of FIG. **13** of the drill, inner sleeve and extended outer sleeve.

FIG. **15** is a cross sectional view along lines **15—15** of FIG. **13** of the collar for limiting the drilling depth of the drill.

FIG. **16** is an enlarged front elevational view of the segment of the thoracic spine of FIG. **3** showing the extended outer sleeve inserted from a lateral approach to the thoracic spine and seated in the disc space and engaging the two adjacent vertebrae, the inner sleeve inserted in the extended outer sleeve, and the drill passing through the inner sleeve to create a hole across the disc space and into the adjacent vertebrae.

FIG. **17** is an enlarged front elevational view of the segment of the thoracic spine of FIG. **3** with the extended outer sleeve inserted from a lateral approach to the thoracic spine and seated in the disc space and engaging the two adjacent vertebrae illustrating a hole drilled across the disc space and into the adjacent vertebrae.

FIG. **18** is a front elevational view of the segment of the thoracic spine of FIG. **3** showing the extended outer sleeve inserted from a lateral approach to the thoracic spine and seated in the disc space and engaging the two adjacent vertebrae, an implant driver, and a spinal implant about to be inserted through the extended outer sleeve and into the hole drilled across the disc space and into the adjacent vertebrae.

FIG. **19** is a front elevational view of the segment of the thoracic spine of FIG. **3** showing the extended outer sleeve inserted from a lateral approach to the thoracic spine and seated in the disc space and engaging the two adjacent vertebrae and a spinal implant implanted in the hole drilled across the disc space and into two adjacent vertebrae.

FIG. **20** is a front elevational view of the segment of the thoracic spine of FIG. **3** showing the extended outer sleeve inserted from a lateral approach to the thoracic spine and seated in the disc space and engaging the two adjacent vertebrae and an extractor cap for removing the extended outer sleeve about to be coupled to the extended outer sleeve.

FIG. **21** is an enlarged partial sectional view of the extractor cap engaging the extended outer sleeve.

FIG. **22** is a front elevational view of the segment of the thoracic spine of FIG. **20** with the distractor puller coupled to the extractor cap shown removing the outer sleeve from the disc space and the adjacent vertebrae in the direction of the arrow.

FIG. **23** is an enlarged front elevational view of a segment of the thoracic spine having a portion of the top vertebrae removed and a portion of the disc space removed and a spinal implant implanted from a lateral approach to the thoracic spine in the hole drilled across the disc space and into the two adjacent vertebrae.

FIG. **24** is a front elevational view of a segment of the thoracic spine having a spinal implant implanted from a lateral approach to the thoracic spine into a hole drilled across the disc space and into the adjacent vertebrae with a spinal fixation device coupled to the spinal fusion implant and engaging the adjacent vertebrae to lock the spinal implant in place.

FIG. **25** is a side perspective view of an alternative embodiment of the extended outer sleeve of the present invention having a pair of extension members and a pair of prongs.

FIG. **26** is a top plan view of the extended outer sleeve of FIG. **25** shown in partial cutaway with an inner sleeve and a drill inserted within its interior and placed adjacent to a vertebra of the spine with the major vessels and the dural sac and spinal nerves proximate to the vertebra shown in cross section.

FIG. **27** is an anterior elevational view of a vertebra of the spine with the extended outer sleeve of FIG. **25** shown inserted from the lateral approach and seated in the disc space and engaging the vertebra.

FIG. **28** is a posterior elevational view of a vertebra of the spine with the extended outer sleeve of FIG. **25** shown inserted from the lateral approach of the spine and seated in the disc space and engaging the vertebra.

FIG. **29** is a side elevational view of a segment of the lumbar spine with a first spinal implant inserted from the lateral aspect into a hole drilled across a first disc space and into two adjacent vertebrae, and a second spinal implant inserted from the lateral aspect into a second hole drilled across a second disc space and into two adjacent vertebrae.

FIG. **30** is top sectional view along lines **30—30** of FIG. **29** showing the area of contact of the first spinal implant and the vertebra.

FIG. **30A** is a top sectional view similar to FIG. **30** showing the area of contact of a spinal implant inserted from slightly anterior (anterolateral) along the lateral aspect of the spine and oriented at least partially from side to side with respect to the vertebra.

FIG. **31** is an anterior elevational view of a segment of the lumbar spine with spinal cylindrical implants inserted from the anterior of the spine into holes drilled across the same disc space and into two adjacent vertebrae.

FIG. **32** is a top sectional view along lines **31—31** of FIG. **31** showing the area of contact of the two spinal implants and the vertebra which is the same size as the vertebra of FIG. **30**.

FIG. **33** is a top sectional view of a single implant having a diameter equal to the diameter of the implant of FIG. **30** showing the area of contact with the vertebra which is the same size as the vertebra of FIG. **30**.

FIG. **34** is a side elevational view of a segment of the spinal column with two spinal implants inserted from front to back at adjacent disc levels between three vertebrae.

FIG. **35** is a perspective side view of an alternative embodiment of the extended outer sleeve of the present invention having a removable distal end with a single extension member and a pair of prongs.

DETAILED DESCRIPTION OF THE DRAWINGS

Referring to FIG. **1**, a rear perspective view of a segment of the thoracic spine S is shown with a guide pin **30** about to be inserted from a lateral approach anterior to the transverse processes of the adjacent vertebrae, (through the lateral chest wall) to the thoracic spine S into the disc space D between two adjacent vertebrae, for example vertebrae T_7 and T_8. The guide pin **30** may first be used as radiological marker to confirm the correct disk level and instrument position, and then functions to align and guide the insertion of the instrumentation described below into the disc space D. The guide pin **30** is inserted through a small incision on the side of a patient's chest cavity perpendicular to the lateral

aspect of the vertebrae T_7 and T_8 of the thoracic spine S. The guide pin **30** is made of a material appropriate for surgical use and comprises a shaft portion **40**, a tip **50** which may be pointed to facilitate insertion into the disc space D, and a distal end **60**. In the preferred embodiment, the guide pin has a diameter in the range of 1.5 mm to 5.0 mm, with 2.5 mm being the preferred diameter, and a length in the range of 200 mm to 800 mm, with 350 mm being the preferred length.

Referring to FIGS. **2** and **3**, the guide pin **30** is shown inserted from a lateral approach to the thoracic spine S and into the disc space D between adjacent vertebrae T_7 and T_8, with a substantial part of the shaft portion **40** of the guide pin **30** remaining external to the disc space D and functions as a guide post. The tip **50** of the guide pin **30** may penetrate the disc space D for a substantial part of the transverse width W of the vertebrae T_7 and T_8 such that at least a part of the shaft portion **40** is within the disc space D. The guide pin **30** is firmly embedded in the discal material present within the disc space D, but does not protrude through the opposite side of the disc space D to prevent any unwanted damage to that area. The guide pin **30** is placed in the disc space D so that it is parallel to the end plates of the vertebrae T_7 and T_8, and centered within the disc space D to bisect the disc space D along the transverse width W of the vertebrae T_7 and T_8. In this manner, a substantial portion of the vertebrae T_7 and T_8 is present near the circumference of the guide pin **30** such that instruments having a diameter greater than the guide pin **30** may be inserted into the vertebrae T_7 and T_8 coaxial to the guide pin **30** without protruding from the vertebrae T_7 and T_8. Such instruments are guided and aligned during insertion by the guide pin **30** so that they are correctly oriented with respect to the vertebrae T_8 and T_8. The surgeon may monitor the correct orientation of the guide pin **30** within the disc space D indirectly with an image intensifier, or directly with a thorascope if one is being used.

Once inserted in the disc space D, the guide pin **30** functions as a guide post for a distractor **100** which is placed over the guide pin **30** and inserted in the disc space D to distract the disc space D and align the adjacent vertebrae T_7 and T_8 by urging them apart. Circumstances permitting, the surgeon may elect to bypass the use of the guide pin **30** and insert the distractor **100** directly. The distractor **100** has a cylindrical barrel **106** that terminates at one end in a reduced diameter disc penetrating portion **102** that is essentially cylindrical, with a further reduced diameter, bullet-shaped front end **103** to facilitate insertion into the disc space D. The distractor **100** has a shoulder portion **104** where the penetrating portion **102** extends from barrel **106** and has a hollow longitudinal passageway **107** extending the entire length of the distractor **100** for receiving the guide pin **30**. The passageway **107** of the distractor **100** is open at both ends of the distractor **100** and has a diameter that is slightly greater than the diameter of the shaft portion **40** of guide pin **30**. The shaft portion **40** of the guide pin **30** may pass through the passageway **107** as the distractor **100** is placed coaxially over the guide pin **30**. In this manner, the distractor **100** can be guided and aligned by the guide pin **30** so that it is inserted into the disc space D coaxial to the guide pin **30** and is properly aligned with respect to the vertebrae T_7 and T_8. Once the distractor **100** is properly placed within the disc space D, the guide pin **30** may be removed from the disc space D through the passageway **107** of the distractor **100**.

The appropriate placement of distractor **100** in the disc space D may be determined visually by the surgeon by the use of a thorascope and or by the use of radiographic, fluoroscopic, or similar procedures, such as utilizing an image intensifier, all of which allow the surgeon to determine the correct orientation and placement of the guide pin **30** and distractor **100** within the disc space D. The correct orientation and placement of the distractor **100** is important to the success of the method of the present invention, as the purpose of the distractor **100** is to space part and align the vertebrae T_7 and T_8 and to guide the insertion into the disc space D of the extended outer sleeve **140** described in detail below. As the diameter of the distractor **100** is almost the same as the inner diameter of the extended outer sleeve **140** and is the same as the spinal implant I, also described in detail below, the surgeon can use x-rays to determine whether the distractor **100** is properly oriented with respect to the adjacent vertebrae T_7 and T_8, such that any subsequent drilling through the extended outer sleeve **140** and insertion of spinal implant I will be correctly oriented with respect to the vertebrae T_7 and T_8. Such a precaution will permit the surgeon to correct any misplacement of the distractor **100** before any irreversible drilling or implant insertion has occurred.

The penetrating portion **102** of the distractor **100** may be of various diameters and lengths, the preferred length being less than the known transverse width W (side to side) of the vertebrae T_7 and T_8. This combined with the circumferential shoulder portion **104** of the distractor **100**, which is too large to fit within the disc space D, protects against the danger of overpenetration. The barrel **106** of the distractor **100** may have at its distal end a recessed portion **108** below the crown **110** which allows for the distractor **100** to be engaged by an extractor unit shown in FIG. **9**.

In the preferred embodiment of the distractor **100**, the barrel **106** has a diameter in the range of 10 mm to 30 mm, with 20 mm being the preferred diameter, and the penetrating portion **102** has a diameter in the range of 3 mm to 10 mm, with 6 mm being the preferred diameter.

Referring to FIGS. **4** and **5**, once the distractor **100** is inserted into the disc space D, the penetrating portion **102** of the distractor **100** distracts the vertebrae T_7 and T_8 apart, such that the vertebrae T_7 and T_8 to either side of the penetrating portion **102** are forced into full congruence and thus become parallel, not only to the penetrating portion **102**, but to each other. Because of the forced opposition of the vertebrae T_7 and T_8 to the penetrating portion **102** the distractor **100** will then come to lie absolutely perpendicular to the plane P of the lateral aspect of the thoracic spine S and absolutely parallel to the vertebral endplates, allowing optimal alignment for the procedure to be performed.

Referring to FIGS. **6**, **7** and **7A**, the distractor **100** now serves as both a centering post and an alignment rod for the extended outer sleeve **140** which is fitted over the distractor **100** and inserted into the disc space D. As shown in FIG. **7A**, the extended outer sleeve **140** is a hollow tubular member made of material appropriate for surgical use and preferably metal, and has an inner diameter sufficiently sized to receive the distractor **100**. The inner diameter of the extended outer sleeve **140** closely matches the outer diameter of the distractor **100**, so that a close fit is achieved and the extended outer sleeve **140** is precisely guided by the distractor **100**. The extended outer sleeve **140** has at its distal end **146** an extension member **148** and two prongs **149** and **150** sufficiently spaced apart to penetrate and hold fixed the two adjacent vertebrae T_7 and T_8. The extension member **148** is essentially a continuation of the extended outer sleeve **140** and the prongs **149** and **150** are offset from the extended outer sleeve **140** or can also be a continuation of the extended outer sleeve **140** like extension member **148**. The prongs **149** and **150** may have sharp insertion edges **152** and **154** to facilitate insertion into the vertebrae T_7 and T_8.

Where the surgery is for a disc herniation, the extension member **148** of the extended outer sleeve **140** located anteriorly is used without a second extension member posteriorly, as the use of the two prongs **149** and **150** in conjunction with the anterior extension member **148** makes it possible to operate through the extended outer sleeve **140** posteriorly, without obstruction and with good visibility when an endoscope is used such that any remaining disc herniation may be removed. The extension member **148** of the extended outer sleeve **140** provides a protective barrier to the structures lying beyond it.

However, if the surgery is not for a disc herniation, but for example, for stabilization of the spine, then the extended outer sleeve may have both an anterior extension member **148** and a corresponding posterior extension member with or without prongs, such as the extended outer sleeve **1100** shown in FIG. **35** and described in greater detail below.

In the preferred embodiment, the extension member **148** of the extended outer sleeve **140** functions to maintain the distraction and alignment of the vertebrae T_7 and T_8, as the extension member **148** is being inserted from the lateral aspect of the thoracic spine S. Without the extension member **148**, in order to maintain the proper distraction of the adjacent vertebrae T_7 and T_8, it would be necessary to place a surgical instrument, such as a second distractor (not shown) on the opposite side of the vertebrae T_7 and T_8. This would require a second incision in the opposite side of the patient's chest cavity for insertion of the required surgical instruments. Further, as it is desired to insert an implant of the maximum possible length across the transverse width W of the vertebrae T_7 and T_8, the presence of any instrumentation at the opposite end of the vertebrae T_7 and T_8, would interfere with the insertion of such an implant. For example, the second distractor on the opposite side of the vertebrae T_7 and T_8 would be in the way of a drill used to create a hole across the transverse width W of the vertebrae T_7 and T_8, since the drilled opening would overlap the second distractor. Therefore, the extension member **148** solves the problem of maintaining an even distraction of the two adjacent vertebrae T_7 and T_8 across their transverse width W from only one side of the thoracic spine S, allowing for the unimpeded insertion of instruments and/or implants. While in the preferred embodiment, the extended outer sleeve **140** has an extension member **148**, it is also possible to have an extended outer sleeve without any extension members and instead, having prongs of sufficient length that engage the bone of the adjacent vertebrae to maintain the distraction and alignment of the adjacent vertebrae created by the distractor **100**. However, the use of such an extended outer sleeve capable of holding, but not of obtaining, the desired intervertebral distraction and alignment would require the use of a distractor prior to its insertion as earlier described herein.

In the preferred embodiment of the extended outer sleeve **140**, a single extension member **148** is present and oriented anteriorly to protect the major vessels located to the anterior aspect of the thoracic spine S. The extended outer sleeve **140** has no extension member near the posterior aspect the spine as it is often necessary to access the spinal canal in order to remove any diseased discal material. In the special circumstances where only vertebral fusion is desired, the extended outer sleeve **140** may have a second extension member (not shown) identical to the extension member **148** positioned diametrically opposite the extension member **148** in order to protect the spinal canal, and in such instance may or may not have the bone penetrating prongs **149** and **150**.

The extension member **148** of the extended outer sleeve **140** has a height that is generally approximately equal to the diameter of the penetrating portion **102** of the distractor **100**, such that the extension member **148** is capable of maintaining the spacing created by the insertion of the distractor **100** between the adjacent vertebrae T_7 and T_8 which is generally the restoration to normal of the disc space D. The extension member **148** is tapered at its leading edge **151** to facilitate insertion into the disc space D and is positioned approximately 120 degrees from each of the two prongs **149** and **150**. The extension member **148** of the extended outer sleeve **140** works in conjunction with the prongs **149** and **150** which engage the vertebrae T_7 and T_8, respectively, to maintain the distraction and alignment of the vertebrae T_7 and T_8. Further, the prongs **149** and **150** not only hold the vertebrae T_7 and T_8 apart, but during drilling also help to hold them together so as to resist them moving apart.

In the preferred embodiment, the extension member **148** of the extended outer sleeve **140** has a length that is less than the transverse width W of the vertebrae T_7 and T_8. The extension member **148** needs to be relatively long because it must maintain distraction of the adjacent vertebrae T_7 and T_8 when placed across the transverse width W of the vertebrae T_7 and T_8. Therefore, if the extension member **148** is shorter than one half the transverse width W of the vertebrae T_7 and T_8, it may not be capable of distracting and aligning the vertebrae T_7 and T_8, and a second distractor would be required as described above, to achieve the correct distraction and alignment of the vertebrae T_7 and T_8.

In the preferred embodiment, the extended outer sleeve **140** has an outer diameter in the range of 12 mm to 34 mm, with 24 mm being the preferred outer diameter, and an inner diameter in the range of 10 mm to 28 mm, with 20 mm being the preferred inner diameter of the extended sleeve **140**.

In the preferred embodiment, the extension member **148** of the extended outer sleeve **140** has a length in the range of 14 mm to 30 mm, with 24 mm being the preferred length, and a height in the range of 3 mm to 10 mm, with 6 mm being the preferred height. In the preferred embodiment, the prongs **149** and **150** of the extension member **140** have a length in the range of 6 mm to 20 mm, with 14 mm being the preferred length and a diameter in the range of 2 mm to 3 mm, with 2 mm being the preferred diameter of the prongs **149** and **150**.

Referring specifically to FIG. **6**, coupled to the proximal end **157** of the extended outer sleeve **140** is a driver cap **160** in the form of an impaction cap which has at its far end a flat, closed-back surface **162** and at its other end a broad, circular opening. The driver cap **160** is used for driving the extended outer sleeve **140** toward the vertebrae T_7 and T_8 and fits over both the extended outer sleeve **140** and the distractor **100**. An impaction force, such as a mallet blow, is applied to surface **162** of the driver cap **160** to advance the extended outer sleeve **140**. That force is transmitted to the extended outer sleeve **140** via its proximal end **157**, seating the prongs **149** and **150** of the extended outer sleeve **140** into the vertebrae T_7 and T_8 and inserting the extension member **148** into the disc space D. As the extended outer sleeve **140** is advanced forward, the crown **110** of the distractor **100** is allowed to protrude within the driver cap **160** unobstructed until it contacts the interior of the driver cap **160**, such that further taps of the mallet will not further advance the extended outer sleeve **140**. Any further motion is resisted by the flat shoulder portion **104** of the distractor **100** abutting the hard lateral outer surfaces of the adjacent vertebrae T_7 and T_8. The flat, planar area **156** of the distal end **146** of extended outer sleeve **140** serves to resist the further insertion of the extension member **148** into the disc space D and to resist further insertion of the prongs **149** and **150** into the

vertebrae T_7 and T_8. In this way, the extended outer sleeve **140** is safely and assuredly inserted to its optimal depth, and no further, and rigidly secures the two adjacent vertebrae T_7 and T_8 as shown in FIG. **7**.

Referring to FIGS. **8** and **9**, the driver cap **160** is then removed and the crown **110** and the recessed portion **108** of the distractor **100** protrude from the proximal end **157** of the extended outer sleeve **140**. The distractor **100** may now be removed from within the extended outer sleeve **140** since the extended outer sleeve **140** functions to maintain the distraction and alignment of the vertebrae T_7 and T_8. The extended outer sleeve **140** is held secure by the extension member **148** inserted within the disc space D and by the prongs **149** and **150** engaging the vertebrae T_7 and T_8.

A distractor puller **200** is utilized to remove the distractor **100** in the direction of arrow Y from within the disc space D leaving the extended outer sleeve **140** in place. The distractor puller **200** has front portion **202**, a mid portion **204**, and a back handle portion **206**. The front portion **202** of the distractor puller **200**, is connected to one end of shaft **210** which at its far end is connected to the back handle portion **206**. The distractor puller **200** is described in detail in copending application Ser. No. 08/074,781, entitled APPARATUS AND METHOD FOR INSERTING SPINAL IMPLANT, and is incorporated herein by reference. The socket-like front portion **202** of the distractor puller **200** engages the circumferential recessed portion **108** of the distractor **100**.

A cylindrical and freely movable weight **216** is fitted around shaft **210** between the front portion **202** and the rear handle portion **206** of the distractor puller **200** so as to form a slap hammer . The weight **216** of the distractor puller **200** is gently and repeatedly slid along the shaft **210** and driven rearwardly against flat surface **228** of the rear handle portion **206** to transmit a rearward vector force to front portion **202** and to the distractor **100** to which it is engaged. In this manner, the distractor **100** is removed from within the disc space D and out of the extended outer sleeve **140** without disturbing it.

Referring to FIG. **10**, once the distractor **100** has been completely removed from within the extended outer sleeve **140** and from within the disc space D, the extension member **148** remains within the disc space D and the prongs **149** and **150** rigidly maintain the appropriate distraction and the relative position of the adjacent vertebrae T_7 and T_8. The remainder of the procedure occurs entirely through the extended outer sleeve **140** and the space therein is sealed off from any of the organs of the chest.

Referring to FIGS. **11** and **12**, since the extended outer sleeve **140** is of a fixed length and rigid, the flat rearward surface **172** of the distal end **146** may be used as a stop to the advancement of any instruments placed through the extended outer sleeve **140**, thus protecting against accidental overpenetration. Further, the extended outer sleeve **140** assures that the further procedure to be performed will occur coaxial to the disc space D and further, be symmetrical in regard to each of the adjacent vertebrae T_7 and T_8.

Where it is desirable to drill a hole smaller in diameter than the spinal implant to be inserted, such as in the case where the spinal implant is threaded, an inner sleeve **242** which functions as a drill guide and spacer having a thickness which corresponds to the difference between the major and minor diameters of the spinal implant, is inserted in the proximal end **158** of the extended outer sleeve **140**. The inner sleeve **242** is a hollow tubular member comprising a barrel portion **243** and a cuff portion **244** having a greater outer diameter than the barrel portion **243**. The cuff portion **244** of the inner sleeve **242** seats against the flat rearward surface **172** of the extended outer sleeve **140** to prevent further insertion of the inner sleeve **242**. The distal end **246** of the inner sleeve **242** extends towards but does not impact the lateral aspect of the adjacent vertebrae T_7 and T_8 in the interior of the extended outer sleeve **140** when fully seated. The barrel portion **243** of the inner sleeve **242** has an outer diameter that fits within the inner diameter of the extended outer sleeve **140**. In the preferred embodiment, the barrel portion **243** of the inner sleeve **242** has an outside diameter in the range of 10 mm to 28 mm, with 20 mm being the preferred outer diameter, and a wall thickness in the range of 0.5 mm to 3 mm, with approximately 0.75 to 1.5 mm being the preferred thickness.

Referring to FIGS. **13–15**, once the inner sleeve **242** is seated within the extended outer sleeve **140**, a drill **250** connected to a handle **260** or to a drill motor (not shown), is introduced through the aperture in the proximal end **248** of the inner sleeve **242** and utilized to create a hole across the disc space D and into the adjacent vertebrae T_7 and T_8. The drill **250** reams out arcs of bone which it engages from the adjacent vertebrae T_7 and T_8, as well as any discal material within its path down to its predetermined and limited depth. It is appreciated that if an inner sleeve **242** is not used, the drill **250** may be placed directly into the extended outer sleeve **140** to create a hole across the disc space D and into the adjacent vertebrae T_7 and T_8.

The drill shaft of drill **250** comprises an upper portion **252**, a central recessed portion **254** of a smaller diameter and a lower cutting portion **256**. The drill **250** has a narrow engagement portion **258**, which allows it to be affixed to a driving mechanism which may be either a manual unit such as, handle **260**, or a power unit such as an electric drill motor. The upper portion **252** has a plurality of grooves **261** for engaging a circumferential collar **262** of an increased diameter which serves to limit the depth of penetration of the drill **250** and may be fixed, or lockably adjustable.

Referring to FIG. **15**, a cross sectional view of the circumferential collar **262** is shown engaging the upper portion **252** of the shaft of drill **250**. The collar **262** comprises diametrically opposite first and second flanges **264** and **266**. The first and second flanges **264** and **266** are pivotably attached to the collar **262** by first and second pins **268** and **270** and spring biased by first and second spring **272** and **274**. The first and second flanges **264** and **266** of the collar **262** are contoured to correspond to the curvature of the upper portion **252** of the drill **250**. The first and second flanges **264** and **266** engage one of the grooves **261** when in the full biased position as shown in FIG. **15**. To disengage the grooves **261**, the first and second **264** and **266** are compressed together by the surgeon such that the first and second springs **272** and **274** are compressed and the first and second flanges **264** and **266** pivot away from the upper portion **252** of the shaft, such that the collar **262** can slide along the upper portion **252** of the drill **250**. The first and second flanges **264** and **266** of the collar **262** are oriented opposite each other and need to be compressed together in order to disengage the grooves **261**. The compression of one of the flanges **264** and **266** alone will not disengage the collar **262** from the grooves **261**. In this manner, collar **262** can not become accidentally disengaged during the rotation of the drill **250**.

While it is believed that this mechanism is entirely novel, it is appreciated that various mechanisms to lockably adjust drills are well-known to those skilled in the art. Such mechanisms include, but are not limited to, the use of

collets, threaded shafts with lock nuts, and flanges engaging grooves forced therein by either a cap pulled over the flanges or screwed down upon them.

Referring to FIGS. **13** and **14**, in the preferred embodiment, the forward cutting edge **280** of drill **250** is a four cutting edge end mill modification of a large fluted drill design. The cutting portion **256** of the drill **250** resembles an end cutting mill which may contain any workable number of cutting surfaces, but preferably four or more, that are relatively shallow such that the advancement of the drill **250** occurs more slowly. The cutting portion **256** of the drill **250** may be of a different diameter depending on the type of spinal implant that is being inserted. If the spinal implant being inserted is threaded, the outside diameter of the cutting portion **256** of the drill **250** would generally correspond to the minor diameter of the threaded implant. The inner sleeve **242** has an inner diameter slightly greater than the minor diameter of a threaded implant and its outer diameter is slightly smaller than the inside diameter of the extended outer sleeve **140** which has the same outer diameter as the major diameter (with threads) of the threaded implant. If the implant is not threaded, the outside diameter of the drill **250** corresponds to the inside diameter of the extended outer sleeve **140** such that a hole the maximum diameter of the extended outer sleeve may be drilled.

The inner sleeve **242** serves many functions. First, it provides an intimate drill guide for drill **250** in the event a smaller diameter hole is to be drilled than that of the inside diameter of the extended outer sleeve **140**. Second, since the inner sleeve **242** guides the drill **250**, it allows for the extended outer sleeve **140** to have an internal diameter large enough to admit a threaded implant, which is larger in diameter than the outer diameter of the drill **240**.

If a larger extended outer sleeve **140** were utilized absent the inner sleeve **242**, then the drill **250** would be free to wander within the confines of that greater space and would not reliably make parallel cuts removing equal portions of bone from the adjacent vertebrae T_7 and T_8. Further, the bone removal not only needs to be equal, but must be correctly oriented in three dimensions. That is, the path of the drill **250** must be equally centered within the disc space, parallel the endplates, and perpendicular to the long axis of the spine dissecting the disc space D.

A further purpose of the inner sleeve **242** is that it may be removed simultaneously with the drill **250**, thereby trapping the debris, both cartilaginous and bony, generated during the drilling procedure. The debris is guided rearward by the large flutes **251** of the lower cutting portion **256** and is collected around the central recessed portion **254** and then contained and between the recessed portion **254** and the inner wall of the inner sleeve **242**. Thus, by removing the drill **250** in conjunction with the inner sleeve **242**, much of the debris generated by the drilling procedure is safely removed from the drilling site.

Referring to FIG. **17**, once the drill **250** and the inner sleeve **242** are removed from the extended outer sleeve **140** a cylindrical hole **290** remains across the disc space D and into the two adjacent vertebrae T_7 and T_8. The cylindrical hole **290** is oriented across the transverse width W of the vertebrae T_7 and T_8 in which an implant of appropriate diameter is to be implanted. The proper distraction and orientation of the two adjacent vertebrae T_7 and T_8 is maintained by the extension member **148** and the prongs **149** and **150** of the extended outer sleeve **140**.

The cylindrical hole **290** may then be irrigated and vacuumed through the extended outer sleeve **140** to remove any remaining debris from the drilling. If necessary, a thrombin soaked sponge may be inserted through the extended outer sleeve **140** and into the cylindrical hole **290** to coagulate any bleeding. The thrombin soaked sponge is then removed and the surgeon utilizing an endoscope then visually inspects the cylindrical hole **290** for any remaining discal material, and removes any such material requiring such removal with a surgical instrument such as a curette or rongeur.

Referring to FIG. **18**, with the extended outer sleeve **140** still in place, the surgical site is now fully prepared to receive a spinal implant I for fusion of the vertebrae T_7 and T_8. The spinal implant I may be coated with, and/or made of, and/or loaded with substances consistent with bony fusion which may promote bone growth and/or fusion prior to being implanted. Once the spinal implant I has been prepared for implantation, a driver instrument, such as driver **300** may be used to either insert or to remove spinal implant I. Driver **300** has at its distal end **302**, a rectangular protrusion **304**, which intimately engages the complimentary rectangular slot in the rear of implant I. Extending from the rectangular protrusion **304** is threaded portion **306**, which extends as a rod through hollow shaft **308** and hollow barrel portion **310** to knob **312** where it can be rotationally controlled. Threaded portion **306** screws into a threaded aperture in the spinal implant I and binding them together such that driver **300** can be rotated via paired and diametrically opposed extending arms **314** and **316** and in either direction while maintaining contact with the spinal implant I. Affixed to the driver **300**, the spinal implant I is then introduced through the extended outer sleeve **140** and if the spinal implant I is threaded, screwed into the cylindrical hole **290** between the two vertebrae T_7 and T_8 until such time as the leading edge of the implant cap **318** reaches the depth of the cylindrical hole **290** at which time its forward motion is impeded by the bone lying before it which had not been drilled out. This allows for a progressive feel to the surgeon as the spinal implant I is inserted into place. It is appreciated that if the spinal implant I is not threaded, instead of being screwed into hole **290**, it may be linearly advanced into hole **290** by pushing the driver **300** toward the hole **290**.

The terminal resistance to further seating provides significant tactile feedback to the surgeon. Visual monitoring of the depth of insertion of the spinal implant I is provided to the surgeon by observing the progressive approximation of the forward surface **320**, of barrel portion **310**, as it approaches the rearward facing surface **172** of extended outer sleeve **140** and/or by the use of an image intensifier. As a final safety mechanism, when the full depth of insertion has been achieved, forward surface **320** of instrument **350** will abut surface **172** of the extended outer sleeve **140**, prohibiting any further installation of the implant. Once the spinal implant I has been fully installed, the driver **300** is dissociated from the implant by turning knob **312** in a counterclockwise direction. The driver **300** is then withdrawn from the extended outer sleeve **140**.

Referring to FIG. **19**, the spinal implant I is shown fully installed to the determined depth in the cylindrical hole **290** drilled across the disc space D and into the adjacent vertebrae T_7 and T_8. The spinal implant I shown comprises a hollow tubular member which in the preferred embodiment is made of an ASTM surgically implantable material, preferably titanium. However, it is appreciated that other implants, cylindrical or partially cylindrical, or of a variety of shapes, and with or without threads or surface roughenings may be used with the instrumentation and method of the present invention.

Referring to FIG. **20** and **21**, an extractor cap **340** for removing the extended outer sleeve **140** is shown about to be coupled to the extended outer sleeve **140**. The extractor cap **340** engages the proximal end **157** of the extended outer sleeve **140** by spring tabs **342***a* and **342***b* on either side of extractor cap **340** which snapfit into openings **344***a* and **344***b* on either side of the extended outer sleeve **140** to lock in place. The extractor cap **340** has a top **346** that is similar in structure to the proximal end of the distractor **100**, having a recess portion **350** and a crown portion **352**.

Referring to FIG. **22**, once the extractor cap **340** is coupled to the extended outer sleeve **140**, the distractor puller **200** is coupled to the top **346** of extractor cap **340** to remove the extended outer sleeve **140** from the disc space D and from the adjacent vertebrae T_7 and T_8 in the direction of the arrow Z.

Referring to FIG. **23**, once the extended outer sleeve **140** has been removed, the spinal implant I remains implanted within the cylindrical hole **290** drilled across the disc space D and the implant engages the two adjacent vertebrae T_7 and T_8.

Referring to FIG. **24**, the spinal implant I may be further stabilized with use of a spinal fixation device **400** such as the staple disclosed in copending application Ser. No. 08/219,626 entitled APPARATUS, INSTRUMENTATION AND METHOD FOR SPINAL FIXATION, which is incorporated herein by reference. The spinal fixation device **400** is coupled to the spinal implant I with a locking screw **410** and engages the vertebrae T_7 and T_8 via prongs **420** and **422**. The spinal fixation device **400** functions to stabilize the spinal implant I and prevent any unwanted excursion of the spinal implant I during the spinal fusion process. It is appreciated that prior to removal of the extended outer sleeve **140**, a centering post (not shown) may be inserted through the extended outer sleeve **140** and attached to the threaded opening in the back of the spinal implant I. The extended outer sleeve **140** is then removed and the centering post functions as guide to align the spinal fixation device **400** as it is being driven into the vertebrae T_7 and T_8 as described in detail in the copending application referenced immediately above.

In the above description in regard to the thoracic spine, the surgical procedure has been described as being performed through a hollow tube (extended outer sleeve **140**) and with the aid of a thorascope. It is appreciated that there may be circumstances where the surgeon will elect to perform the surgical procedure through an incision, such as a thoracotomy, where direct visualization of the surgical site is possible obviating the need for the thorascope but without diminishing the teaching of the method of the present invention. In such cases, a modification of the extended outer sleeve **140**, such as the extended outer sleeve **1100** shown in FIG. **35** and described in detail below, having a detachable distal end may be beneficially utilized by the surgeon. In this manner, the surgeon has direct visualization of the surgical site while the proper distraction and alignment of the adjacent vertebrae is maintained throughout the procedure by the distal end of the extended outer sleeve.

While the present invention has been described in association with the insertion of a threaded spinal implant, it is recognized that other forms of implants may be used with the present method. For example, dowels, made from bone, coral or artificial materials, knurled or irregularly shaped cylinders or spheres, partial cylinders or any other shaped implants that can be introduced through the extended outer sleeve **140**, which itself need not be cylindrical may be used.

When such implants are used, it is appreciated that the steps of the method of the present invention described above may be reduced. For example, once the extended outer sleeve **140** has been seated such that the extension portion **148** is inserted in the disc space D and the prongs **149** and **150** engage the adjacent vertebrae, the step of inserting the inner sleeve **242** may be omitted and a drill having a diameter approximating that of the inner diameter of the extended outer sleeve **140** may be used to drill a hole the size of the inner diameter of the extended outer sleeve **140** across the disc space D and into the adjacent vertebrae. Once the drill has been removed, any remaining discal material or debris may be removed by irrigating and vacuuming the hole, and an implant such as a bone dowel or an implant without threads, may be linearly advanced through the extended outer sleeve **140** and implanted into the hole. The extended outer sleeve **140** is then removed in the same manner described above. Where the implant shape is generally not circular, an appropriately shaped chisel may be used by itself or in conjunction with a drill to prepare an opening for the fusion implant that is other than round.

It is further appreciated that it is also within the scope of the present invention to provide a method and instrumentation for the insertion of a spinal implant into the disc space between two adjacent vertebrae, without the drilling away of significant bone from the vertebrae. Such implants may have a height corresponding to the height of a disc space D and may be pushed into the disc space D when distracted once the disc space D has been cleaned out. This type of implant would preferably have in part a rectangular cross section and an extended outer sleeve used for the insertion of such implants would have a corresponding cross section and shape. Further, it is appreciated that the extended outer sleeve and inner sleeve of the present invention may have any shape or size corresponding to the shape and size of the implant to be inserted without departing from the scope of the present invention.

While the above description has been directed to the thoracic spine, the method and instrumentation of the present invention may also be utilized in the lumbar spine. In the preferred method, the surgeon makes a small incision in the abdominal wall and gently dissects his way retroperitoneal to reach the lateral aspect of the spine. As with the thorascopic method described above, the surgeon may use an endoscope within and/or outside of the extended outer sleeve to facilitate the surgery, and thereby require an incision barely larger than the diameter of the extended outer sleeve which itself is not much larger than the implant.

Referring to FIG. **25**, an extended outer sleeve **1000** for use with the lateral method in the lumbar spine is shown. The extended outer sleeve **1000** is similar to the extended outer sleeve **140** described above and comprises a hollow tubular member **1002** having a distal end **1010** which is contoured to hug the vertebrae, for example L_4 and L_5. The extended outer sleeve **1000** has anterior and posterior extension members **1020** and **1022**, each having different heights, that are opposed 180 degrees from each other. Also extending from the distal end **1010** may be prongs **1012** and **1014**, similar to prongs **149** and **150** described above, for engaging the bone of the adjacent vertebrae L_4 and L_5. The extension members **1020** and **1022** are tapered at their leading edges **1024** and **1026** respectively, to facilitate insertion.

As shown in FIGS. **26–28**, the extended outer sleeve **1000** is designed to be used in approaching the lumbar spine laterally from either side of the spinal column. The extended outer sleeve **1000** is shown inserted from a position anterior to the transverse processes P of the vertebrae L. The

extended outer sleeve **1000** by means of its extended portions **1020** and **1022** is capable of correcting those spinal deformities, such as scoliosis or any abnormality of kyphosis or lordosis, occurring specifically from a deformity of the disc. For example, in order to restore lordosis in the lumbar spine, the anterior extension member **1020** is placed anteriorly between the adjacent vertebrae L_4 and L_5 and the posterior extension member **1022**, having a lesser height than the extension member **1020**, is placed posteriorly. The greater height of the extension member **1020** relative to the extension member **1022** maintains the anterior portions of the vertebrae L_4 and L_5 spaced apart at a greater distance than the posterior portions of the vertebrae L_4 and L_5 producing an angular relationship between the bodies as would exist with naturally occurring physiologic lordosis. Once restored, lordosis is maintained throughout the surgical procedure.

Scoliosis refers to an abnormal curving of the spine when viewed from straight ahead or behind. Since the extension members **1020** and **1022** may be of a specific and constant height throughout their entire lengths, both sides of the disc space D are lifted to exactly the same height, thus eliminating any side to side angular deformity occurring through that disc space.

Referring specifically to FIG. **26**, it can be appreciated that the posterior extension member **1022** effectively prevents any injury to the dural sac and neural elements, while the anterior extension member **1020** in a similar fashion, protects the great blood vessels including the aorta, vena cava and the iliac arteries and veins. As the extended outer sleeve **1000** of the present invention is quite stable once inserted, the preferred embodiment is shown as having only two prongs **1012** and **1014**, one each to engage each of the adjacent vertebrae L_4 and L_5. It is, however, understood that the extended outer sleeve **1000** may have more or less prongs or none at all. The distal end **1010** of the tubular member **1002** is contoured adjacent the origin of the anterior and posterior extended members **1020** and **1022** so as to assure an intimate fit between the tubular member **1002** and the vertebrae L_4 and L_5 adjacent the disc space D to which it is opposed, and for the purpose of confining the surgery to within the extended outer sleeve **1000** and excluding the adjacent soft tissues from potential injury. In the preferred embodiment, the distal end of the tubular member **1002** and the anterior and posterior extended members **1020** and **1022** themselves have been reinforced, that is are thicker than the adjacent tubular member **1002** itself so as to provide for increased support within the lumbar spine.

Referring still to FIG. **26**, the extended outer sleeve **1000** engages the spine laterally, although the surgical approach in reaching the spine may be from an anterior, lateral, or anterior-lateral incision on the outside of the body, from a position anterior to the transverse processes P, and is hereinafter referred to as the "Lateral Method". The "Lateral Method" involves the insertion of a distractor, such as, but not limited to the distractor **100** described above into the lateral aspect of the spine, and generally from a side to side direction although said direction could be slightly from anterolateral to slightly posterolateral (diagonalized from the transverse axis) without departing from the teaching of the method of the present invention to distract the adjacent vertebrae, in this example, L_4 and L_5. Once the distractor **100** is in place, if fusion alone is to be performed, then the extended outer sleeve **1000** having both anterior and posterior extension members **1020** and **1022** is utilized. The extended outer sleeve **1000** is placed over the distractor **100** such that the posterior extension member **1022** is positioned at the posterior aspect of the spine and the anterior extension member **1020** is positioned at the anterior aspect of the spine. Once the extended outer sleeve **1000** is in place, the distractor **100** is removed. Alternatively, it is appreciated that the "Lateral Method" may be performed without the use of a distractor. Instead, the extended outer sleeve **1000** may be inserted from the lateral aspect of the spine directly since the extension members **1020** and **1022** function to distract the adjacent vertebrae L_4 and L_5 to restore and maintain the normal angular relationship of those vertebrae L_4 and L_5.

If the implant to be inserted has surface irregularities such that there is a major diameter (including the surface irregularities) and a minor diameter (excluding the surface irregularities), then an inner sleeve **1040** similar to the inner sleeve **242** described above, may be inserted into the extended outer sleeve **1000**. The inner sleeve **1040** functions as a drill guide and spacer having a thickness which corresponds to the difference between the major and minor diameters of such implant as described in detail above in reference to an inner sleeve **1040**. A drill **250**, described above, is inserted into the inner sleeve **1040** and is used to drill the vertebrae with the inner sleeve **1040** providing a more intimate fit to the drill **250**, than the larger bore of the extended outer sleeve **1000** could have alone and thus more precisely controlling the path of the drill **250**. The inner sleeve **1040** and the drill **250** may be removed from the extended outer sleeve **1000** together thus trapping and removing much of the debris produced by the actual drilling. It is appreciated that in the alternative, a drill (not shown) may be used such that the distal bone engaging portion has an outside diameter generally corresponding to the minor diameter of the implant and more proximally, a shaft portion with a larger diameter generally corresponding to the major diameter of the implant. An implant I may then be inserted according to the method described above. If the implant to be inserted does not have a major and minor diameter, then no inner sleeve is required, and the drill **250** having a diameter corresponding with the diameter of such an implant may be inserted directly into extended outer sleeve to drill the vertebrae L_4 and L_5.

While not considered the preferred method under most circumstances it is nevertheless anticipated that one could drill the described hole across the disc space and into each of the adjacent vertebrae from the lateral aspect of the spine and in at least a partially side to side direction through the extended outer sleeve and then remove the extended outer sleeve and insert at least one spinal implant also from the lateral aspect of the spine and in an at least a partially side to side direction and with or without the use of some form of spinal distractor. In which circumstance the use of an inner sleeve is of less importance than that the size of the opening created is sufficient such that it is possible to insert the implant. To that end and independent of whether the extended outer sleeve is left in place for implant insertion, and whether an inner sleeve is used during drilling it is anticipated and should be appreciated that the extended outer sleeve and opening may be of a variety of shapes and that the creation of spaces of varied shapes across a disc and within the spine may be achieved by use of an instrument appropriate for the surgical removal of spinal material, such as a chisel or a router, and with or without the use of a drill, and/or an inner sleeve, and/or an extended outer sleeve; and with the essential element being that the space within the spine is being created across a disc intermediate two adjacent vertebrae from the lateral aspect of said disc and at least in part in a from side to side direction and that an implant is then inserted also from the lateral aspect of said disc which

implant occupies at least in part said space, engages at least in part each of the vertebrae adjacent said disc space and comes to lie in an at least partially side to side direction across said disc space.

Referring to FIGS. **29** and **30**, the implants I and J are shown inserted across the disc spaces D between vertebrae L_3, L_4 and L_5, respectively. FIG. **30** is a top sectional view along lines **30—30** of FIG. **29** showing the area of contact of the implant I and the vertebrae L_4. It can be seen from FIG. **30** that the implant I has a true lateral orientation with respect to the vertebra L_4, such that there is a great area of contact between the implant I and the vertebra L_4.

Referring to FIG. **30A**, a top sectional view of a vertebra similar to FIG. **30** is shown illustrating the area of contact of the implant I and the vertebrae L_4 when the implant I is inserted with the "Lateral Method" of the present invention from a slightly anterior position (anterolateral) along the Lateral aspect of the spine and in an at least partially side to side direction.

Referring to FIGS. **31** and **32**, illustrating the prior art method, two implants **1050** and **1052** are inserted from the anterior or posterior aspect of the spine so that they are oriented in an anterior to posterior direction across the disc space D and vertebrae L_4 and L_5. It can be seen that implants **1050** and **1052** must have a much smaller diameter than implant I to fit within the width of the spine and therefore have very small areas of engagement to the vertebrae themselves as most of the diameter of the implants is used in just spanning across the height of the disc before contacting said vertebrae. FIG. **32** is a top sectional view along lines **32—32** of FIG. **31** showing the area of contact of the two spinal implants **1050** and **1052** and the vertebra L_5.

Referring to FIG. **33**, a top sectional view showing the area of contact of a cylindrical spinal implant **1090** having the same diameter as implant I shown in FIG. **30**, inserted from the anterior to posterior direction across the vertebra L_5 is shown and seen to have by necessity a much shorter length.

Referring to FIGS. **30** and **32–33**, it can then be appreciated that an implant I inserted from the lateral aspect of the spine may have a diameter almost as great as the depth of the spine from front to back at that location unlike two implants such as implants **1050** and **1052** inserted side by side from front to back or the reverse where each implant can have a diameter no greater than one half the width of the spine at that level. It can further be appreciated that while the height of the disc space itself hardly affects the area of contact of the single large implant I with the adjacent vertebrae, it substantially effects the area of contact of the two implants **1050** and **1052** inserted in the front to back directions side by side. Further, as the lumbar vertebrae and discs are much wider from side to side then they are deep from front to back, it can be appreciated that when single implants of the same diameter are inserted across a given lumbar disc, the laterally inserted implant I may be of a much greater length and thus have more area of contact, for stability and fusion than implant **1090** inserted from anterior to posterior.

Referring to FIG. **34**, a segment of the spinal column having single implants **1095** and **1096** inserted from front to back at adjacent disc levels between three vertebrae V_{1-3} is shown. As it can be seen in FIG. **34**, it is generally not possible to increase the diameter of singular implants inserted from front to back without risking severe structural and vascular damage to that area of the spine. Implants **1095** and **1096** each have a diameter that is substantially greater than the diameter of implant **1090**, such that implants **1095** and **1096** could in theory have a greater area of contact with the adjacent vertebrae than implant **1090**. However, in application, as a result of the larger diameter of the implants **1095** and **1096**, a large portion of bone from the adjacent vertebrae would have to be removed to accommodate the large diameter of each of the implants **1095** and **1096** which would significantly weaken the structural integrity of those vertebrae. This is especially a problem when as shown in FIG. **34**, implants **1095** and **1096** are inserted at adjacent disc levels such that the intermediate vertebrae V_2 would be cut in half to form a "butterfly" pattern resulting in the complete loss of the structural integrity of vertebrae V_2.

Thus, the implant I of the present invention inserted laterally provides for greater surface area of contact, the largest volume of fusion promoting material, and the greatest mechanical engagement and thus stability, and is therefore an improvement upon other methods of implant insertion in facilitating a successful fusion.

Referring to FIG. **35**, an alternative embodiment of the extended outer sleeve is shown and generally referred to by the numeral **1100**. As only a single relatively small incision (approximately three inches or less) is required through the abdominal wall of the patient to perform the procedure for the fusion of two vertebrae adjacent a disc space in the lumbar spine, it is anticipated that the surgeon may prefer to perform the method of the present invention under direct vision, without the need for an endoscope. In such a circumstance, a convertible extended outer sleeve **1100** may be used. The convertible extended outer sleeve **1100** may be similar in structure to the extended outer sleeve **1000**, except that it comprises a hollow tubular member **1102** that is disengageable from the distal end portion **1104** of the convertible extended outer sleeve **1100**. As shown in FIG. **35** the extended outer sleeve **1100** has a detachable hollow tubular member **1102**. The vertebrae engaging distal end portion **1104** may be as shown in FIG. **35** or may be similar to the distal end shown previously in FIG. **7A**, such that the convertible extended outer sleeve **1100** may be useable throughout the spine.

The convertible extended outer sleeve **1100** is inserted in the disc space D and the adjacent vertebrae L_4 and L_5 as described above for the extended outer sleeve **1000**. Once the extension member **1120** is seated in the disc space D and the prongs **1112** and **1114** are engaged to the vertebrae L_4 and L_5, the hollow tubular member **1102** may be dissociated from the distal end portion **1104** which remains engaged to the vertebrae L_4 and L_5. In this manner, if an incision is made to access the spine directly, the surgeon may access the disc space D through the distal end portion **1104** which is closer to the spine, without having to pass through the entire length of the convertible extended outer sleeve **1100**. With the distal end portion **1104** in place, the vertebrae remain distracted and aligned, and since the hollow tubular member **1102** has been removed, it is then possible for the surgeon to work in and around the spine under direct vision. The shortened distal end portion **1104** of the convertible extended outer sleeve **1100** left protruding from the adjacent vertebrae may be selected to be of a length such that it still serves to offer some protection to the large blood vessels which are safely positioned outside of the remaining working channel. Alternatively it can be of any length so as to fulfill the surgeon's purposes. The hollow tubular member **1102** may be re-engaged to the distal end portion **1104** for inserting an implant I in the manner described above.

In the specific embodiment of the convertible extended outer sleeve **1100**, the distal end portion **1104** has a single extension member **1120** and two prongs **1112** and **1114**

positioned approximately 120 degrees from the extension member **1120** for engaging the two adjacent vertebrae L_4 and L_5, for the purpose of allowing the surgeon direct access to the spinal canal. Thus, if a discectomy is to be performed, an extended outer sleeve having a single anterior intradiscal extended member **1120**, but without a posterior extended member, and with two vertebrae engaging prongs **1112** and **1114** may be used.

It is appreciated that for surgery on the thoracic spine, while the method described above wherein the entire procedure is performed through the extended outer sleeve **140** is preferred, it is also possible to utilize the convertible extended outer sleeve **1100** when a full thoracotomy is made to access the thoracic spine without having to work through the entire length of the extended outer sleeve. In this manner the surgeon may directly visualize and access the surgical site.

Further, combining the features of the absence of any posterior intradiscal extended member with the convertible extended outer sleeve **1100** permits easy and direct access to the spinal canal for removal of any diseased discal material.

While the present invention has been described in detail with regards to the preferred embodiments, it is appreciated that other variations of the present invention may be devised which do not depart from the inventive concept of the present invention.

What is claimed is:

1. A method for inserting an interbody intraspinal implant into a disc space between adjacent vertebrae located within a human thoracic and lumbar spine having an anterior aspect and a posterior aspect being divided by a plane through transverse processes of the adjacent vertebrae, and having a lateral aspect, the method comprising the steps of:

penetrating from a position anterior to the transverse processes the lateral aspect of a spinal disc intermediate the adjacent vertebrae;

removing from between the adjacent vertebrae at least a portion of the spinal disc to form a laterally facing opening; and

inserting from a position anterior to the transverse processes of the adjacent vertebrae said implant into the laterally facing opening.

2. The method of claim **1** further comprising the step of positioning an extended outer sleeve in contact with the lateral aspect of the spine.

3. The method of claim **2** further comprising the step of engaging said extended outer sleeve to the spine.

4. The method of claim **3** in which the engaging step includes the sub-step of penetratingly engaging said extended outer sleeve into the spine.

5. The method of claim **3** in which the engaging into the step includes the sub-step of engaging disc space said extended outer sleeve having at least one distal extension.

6. The method of claim **3** further comprising the step of driving said extended outer sleeve having at least one extended member into the spinal disc from the lateral aspect of the spine in at least a partially side to side direction across the spinal disc.

7. The method of claim **6** in which the driving step includes the sub-step of guarding the spinal cord with said extended member.

8. The method of claim **6** in which the driving step includes the sub-step of guarding the neural and vascular structures along the posterior and anterior aspects of the spine with said extended member.

9. The method of claim **3** further comprising the step of distracting the adjacent vertebrae with said extended outer sleeve.

10. The method of claim **3** in which said extended outer sleeve includes means for corrective realignment of the vertebrae adjacent the disc space.

11. The method of claim **3** further comprising the step of disassociating said extended outer sleeve having a proximal portion oriented furthest from the spine from a distal portion of said extended outer sleeve being adjacent and oriented lateral to the spine such that said proximal portion is removed and said distal portion is left in place for at least a portion of said method.

12. The method of claim **3** in which a portion of said extended outer sleeve protrudes outside the body of a patient for at least a portion of said method.

13. The method of claim **3** in which the step of engaging includes the sub-stem of engaging said extended outer sleeve being at least in part tubular.

14. The method of claim **3** in which the removing step includes the sub-step of forming said opening through said extended outer sleeve and across the disc space and into the two adjacent vertebrae.

15. The method of claim **3** further comprising the step of inserting hand-held instruments through said extended outer sleeve to remove a portion of the spinal disc.

16. The method of claim **15** further comprising the step of passing an endoscopic viewing device through said extended outer sleeve to observe the removal of a portion of the spinal disc.

17. The method of claim **3** in which the inserting step includes the sub-step of inserting said implant through said extended outer sleeve.

18. The method of claim **3** wherein the step of removing includes the sub-steps of inserting a drill through at least a portion of said extended outer sleeve, drilling at least a portion of the spinal disc and at least a portion of bone from each of the adjacent vertebrae, and removing said drill.

19. The method of claim **18** further comprising the step of removing any debris left in a space formed by the step of drilling following the step of removing said drill.

20. The method of claim **18** in which the step of inserting a drill includes the sub-step of passing said drill through a hollow inner sleeve fitting at least in part around said drill, said inner sleeve having at least a portion thereof fitting within said extended outer sleeve.

21. The method of claim **3** further comprising the step of inserting an inner sleeve member into said extended outer sleeve prior to the removing step.

22. The method of claim **21** further comprising the step of removing said hollow inner sleeve member from said extended outer sleeve prior to the step of inserting said implant.

23. The method of claim **21** in which the step of removing includes the sub-steps of passing a drill through said inner sleeve member and penetrating said drill across at least a part of the spinal disc in at least a partial side to side direction across the adjacent vertebrae.

24. The method of claim **21** further comprising the step of inserting into the lateral aspect of a spinal disc a distractor having a penetrating portion prior to the step of inserting said extended outer sleeve.

25. The method of claim **2** further comprising the steps of making at least one incision along the lateral chest wall of a patient and driving said extended outer sleeve through said incision to the lateral aspect of the thoracic portion of the spine.

26. The method of claim **35** further comprising the step of tapping the opening to provide threads on at least a portion of the adjacent vertebrae prior to the step of inserting said implants.

27. The method of claim 2 further comprising the step of tapping the opening by passing a tap through at least a portion of said extended outer sleeve.

28. The method of claim 1 further comprising the steps of driving toward the lateral aspect of the spine an extended outer sleeve having means for distracting the disc space between the two adjacent vertebrae and inserting the distraction means into the disc space.

29. The method of claim 2 further comprising the steps of inserting a guide pin into the disc space between the adjacent vertebrae prior to the step of positioning said extended outer sleeve; placing over said guide pin an alignment rod having a penetrating portion and a passageway for receiving said guide pin; and inserting said penetrating portion into the disc space.

30. The method of claim 1 in which the inserting step includes the sub-step of inserting said implant oriented at least partially in a side to side direction across the disc space and occupies at least in part a portion of a space created by the removal of said portion of said spinal disc.

31. The method of claim 1 in which the step of inserting includes the sub-step of engaging said implant into at least a portion of each of the adjacent vertebrae.

32. The method of claim 1 in which said implant is inserted in at least a partial side to side direction across the disc space and into contact with the adjacent vertebrae.

33. The method of claim 1 in which the removing step includes the sub-step of drilling the opening.

34. The method of claim 33 in which the removing step includes the sub-step of limiting the penetration of said drill.

35. The method of claim 1 in which the removing step includes the sub-step of removing at least a portion of bone from at least one of the adjacent vertebrae.

36. The method of claim 35 in which said sub-step of removing a portion of bone includes the sub-step of using one of a drill, a router, and a mill.

37. The method of claim 1 in which said removing step includes the sub-step of chiseling to form the opening.

38. The method of claim 1 further comprising the step of inserting from a position anterior to the transverse processes an alignment rod into the lateral aspect of the spine.

39. The method of claim 38 in which said alignment rod extends from the spinal disc and protrudes outside of the patient's body.

40. The method of claim 38 further comprising the step of placing an extended outer sleeve over said alignment rod.

41. The method of claim 38 in which the step of inserting said alignment rod includes the sub-step of inserting said alignment rod being at least in part hollow.

42. The method of claim 41 further comprising the steps of inserting into the lateral aspect of the spinal disc a guide pin having at least a portion extending laterally from the spinal disc, and placing said alignment rod over said guide pin.

43. The method of claim 38 in which the step of inserting said alignment rod includes the sub-step of inserting into the disc space an intervertebral distractor that spaces apart the adjacent vertebrae.

44. The method of claim 38 in which the step of inserting said alignment rod includes the sub-step of inserting said alignment rod having a distal end portion for insertion into the spinal disc and distracting the two adjacent vertebrae.

45. The method of claim 1 further comprising the step of distracting the adjacent vertebrae prior to the stem of removing.

46. The method of claim 1 further comprising the step of inserting a distractor into the disc space between the adjacent vertebrae to provide for appropriate spacing of the disc space between the vertebrae.

47. The method of claim 46 in which the step of inserting said distractor includes the sub-step of inserting said distractor having a first extended member for insertion in the disc space.

48. The method of claim 47 in which the step of inserting said distractor includes the sub-step of inserting said distractor having a second extended member for insertion in the disc space.

49. The method of claim 1 further comprising the step of inserting a guide pin from a position anterior to the transverse processes of the adjacent vertebrae into the lateral aspect of the spinal disc.

50. The method of claim 47 further comprising the steps of placing over said guide pin a hollow distractor having a penetrating portion and a passageway for receiving said guide pin and inserting said penetrating portion into the disc space between the two adjacent vertebrae.

51. The method of claim 1 further comprising the step of making at least one incision into the lateral aspect of the body of a patient for the purpose of accessing the lateral aspect of the spine.

52. The method of claim 1 further comprising the step of accessing the lateral aspect of at least one spinal disc in the lumbar spine and at least a portion of the two vertebrae adjacent the disc by a retroperitoneal surgical dissection.

53. The method of claim 1 further comprising the step of tapping the opening to provide threads on at least a portion of the adjacent vertebrae prior to the step of inserting said implants.

54. The method of claim 1 further comprising the step of utilizing an endoscope during at least a portion of the method.

55. The method of claim of 1 further comprising the step of utilizing a radiographic imaging device during at least a portion of the method.

56. The method of claim 1 further comprising the steps of coupling a spinal fixation device to said implant and engaging said spinal fixation device to the adjacent vertebrae.

57. The method of claim 1 in which the step of inserting said implant includes the sub-step of inserting said implant having a width that occupies more than one half of the depth of the spinal disc, said depth measured from the anterior aspect to the posterior aspect of the spinal disc.

58. The method of claim 1 in which the step of inserting includes the sub-step of inserting at least two implants.

59. The method of claim 58 in which the sub-step of inserting said at least two implants includes inserting implants having a combined width that is greater than one half the depth of the spinal disc, said depth being measured from the anterior aspect to the posterior aspect of the spinal disc.

60. The method of claim 1 in which the inserting step includes the sub-step of inserting said implant having a width of at least 20 millimeters.

61. The method of claim 46 in which the step of inserting a distractor includes the sub-step of inducing angulation to the adjacent vertebrae.

62. The method of claim 61 in which the inducing angulation sub-step includes the sub-step of restoring lordosis to the adjacent vertebrae.

63. The method of claim 61 in which the inducing angulation sub-step includes the sub-step of restoring kyphosis to the adjacent vertebrae.

64. The method of claim 61 in which the inducing angulation sub-step includes the sub-step of correcting scoliosis of the adjacent vertebrae.

65. The method of claim 1 in which the removing step includes the sub-step of removing bone from the vertebrae along a substantial portion of the transverse width of the vertebrae.

66. The method of claim 1 in which the step of inserting includes the sub-step of inserting said implant having a length greater than one half of the depth of the spinal disc.

67. The method of claim 1 further comprising the step of attaching a driving member to said implant prior to the step of inserting.

68. A method for inserting an interbody intraspinal implant into a disc space between adjacent vertebrae located within a human thoracic and lumbar spine having an anterior aspect and a posterior aspect being divided by a plane through transverse processes of the adjacent vertebrae, and having a lateral aspect, the method comprising the steps of:

engaging from a position anterior to the transverse processes of the adjacent vertebrae into the lateral aspect of the spine a tubular member;

removing from a position anterior to the transverse processes of the adjacent vertebrae at least a portion of the spinal disc through said tubular member to form a laterally facing opening; and

inserting from a position anterior to the transverse processes of the adjacent vertebrae at least one implant into the laterally facing opening.

69. The method of claim 68 in which the removing step includes the sub-step of removing at least a portion of bone from at least one of the adjacent vertebrae.

70. The method of claim 69 in which the insertion step includes the sub-step of penetrating said implant into the bone of each of the adjacent vertebrae.

71. The method of claim 68 in which the inserting step further comprises the sub-step of inserting said implant through said tubular member.

72. A method for inserting an interbody intraspinal implant into a disc space between adjacent vertebrae located within a human thoracic and lumbar spine having an anterior aspect and a posterior aspect being divided by a plane through transverse processes of the adjacent vertebrae, and having a lateral aspect, the method comprising the steps of:

driving from a position anterior to the transverse processes of the adjacent vertebrae toward the lateral aspect of a spinal disc intermediate the adjacent vertebrae an extended outer sleeve having means for penetrably engaging the spine along its lateral aspect;

removing from a position anterior to the transverse processes of the adjacent vertebrae through said extended outer sleeve at least a portion of the spinal disc to create a space; and

inserting from a position anterior to the transverse processes into the lateral aspect of the spine at least one implant, said implant occupying at least in part the space created by the removing step.

73. The method of claim 72 in which the removing step includes the sub-step of removing at least a portion of bone from at least one of the adjacent vertebrae.

74. The method of claim 73 in which the insertion step includes the sub-step of penetrating said implant into the bone of each of the adjacent vertebrae.

75. The method of claim 72 in which the inserting step further comprises the sub-step of inserting said implant through said extended outer sleeve.

76. The method of claim 76 in which the driving step includes the sub-step of penetrating the disc space with said engaging means, and wherein said engaging means includes a disc penetrating extension.

77. The method of claim 76 in which the sub-step of penetrating includes the sub-step of urging apart the adjacent vertebrae with said disc penetrating extension.

78. A method for inserting an interbody spinal implant into a disc space between two adjacent vertebrae located within a human thoracic and lumbar spine having an anterior aspect and a posterior aspect being divided by a plane through transverse processes of the adjacent vertebrae, and having a lateral aspect, the method comprising the steps of:

inserting from a position anterior to the transverse processes of the adjacent vertebrae a distractor into the lateral aspect of the disc space to provide for appropriate spacing apart of the adjacent vertebrae;

inserting from a position anterior to the transverse processes of the adjacent vertebrae an extended outer sleeve into contact with the lateral aspect of the spine;

driving said extended outer sleeve into engagement with the spine;

removing said distractor;

removing from a position anterior to the transverse processes of the adjacent vertebrae at least a portion of a spinal disc intermediate the adjacent vertebrae to form a lateral facing opening;

inserting from a position anterior to the transverse processes of the adjacent vertebrae an implant into the disc space intermediate the adjacent vertebrae through the laterally facing opening; and

removing the extended outer sleeve.

79. The method of claim 78 further comprising the step of inserting an alignment rod having a said penetrating portion into the disc space prior to the step of inserting a distractor.

80. The method of claim 78 in which the step of inserting a distractor includes the sub-step of inserting a said distractor having first and second extended members for distracting the disc space between two adjacent vertebrae.

81. The method of claim 78 further comprising the step of inserting an inner sleeve into the extended outer sleeve.

82. The method of claim 78 including the step of inserting a drill into the inner sleeve.

83. The method of claim 78 in which the step of removing at least a portion of the spinal disc includes the sub-step of forming a hole across the disc space and into the two adjacent vertebrae.

84. The method of claim 78 in which said distractor includes an alignment rod.

85. The method of claim 78 in which the step of removing at least a portion of the spinal disc includes the sub-step of removing at least a portion of bone from at least one of the adjacent vertebrae.

86. The method of claim 78 in which the inserting step further comprises the sub-step of inserting said implant through said extended outer sleeve.

87. The method of claim 85 in which the insertion step includes the sub-step of penetrating said implant into the bone of each of the adjacent vertebrae.

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EXHIBIT C

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Technical Report

Extreme Lateral Interbody Fusion (XLIF): a novel surgical technique for anterior lumbar interbody fusion

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Abstract

BACKGROUND: Minimally disruptive approaches to the anterior lumbar spine continue to evolve in a quest to reduce approach-related morbidity. A lateral retroperitoneal, trans-psoas approach to the anterior disc space allows for complete discectomy, distraction, and interbody fusion without the need for an approach surgeon.

PURPOSE: To demonstrate the feasibility of a minimally disruptive lateral retroperitoneal approach and the advantages to patient recovery.

METHODS/RESULTS: The extreme lateral approach (Extreme Lateral Interbody Fusion [XLIF]) is described in a step-wise manner. There have been no complications thus far in the author's first 13 patients.

CONCLUSIONS: The XLIF approach allows for anterior access to the disc space without an approach surgeon or the complications of an anterior intra-abdominal procedure. Longer-term follow-up and data analysis are under way, but initial findings are encouraging.

Keywords: XLIF; Lateral; Retroperitoneal; Trans-psoas; Minimally Invasive; Split-blade retractor; EMG; Minimally disruptive

Introduction

Since 1991, when Obenchain described the first laparoscopic lumbar discectomy [1], the field of minimally invasive spine surgery has continued to evolve. Surgeon and patient alike have been attracted by the advantages of minimally invasive surgery, including less tissue trauma during the surgical approach, less postoperative pain, shorter hospital stays, and faster return to activities of daily living. These reported advantages led to the laparoscopic anterior lumbar approach and mini-open anterior lumbar interbody fusion (ALIF) becoming commonly performed procedures [2–7].

However, greater acceptance of these minimally invasive procedures has been hampered by known complications and challenges associated with endoscopic spine surgery. Reported problems include anesthetic complications [8], visceral damage [9], large vessel bleeding [10,11], and sexual dysfunction [12,13]. Surgeons attempting to use this surgical technique are challenged by the required technical skills, steep learning curve, and continued requirement for access surgeon.

The current report describes a novel, minimally disruptive spine procedure called the Extreme Lateral Interbody Fusion or XLIF (NuVasive, Inc., San Diego, CA). This technique is novel in that it can be used to gain access to the lumbar spine via a lateral approach that passes through the retroperitoneal fat and psoas major muscle. Hence, the potential complications with an anterior transperitoneal approach to the lumbar spine can be avoided, major vessels are not encountered, an anterior access is not required, and the procedure can be done through two, 3–4-cm incisions. Here we report the techniques of this approach to the lower lumbar spine.

FDA device/drug status: not applicable.

Nothing of value received from a commercial entity related to this manuscript.

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Materials and methods

Patient selection and surgical indications

Patients who presented with axial low back pain without severe central canal stenosis were considered candidates for this surgery if they failed at least 6 months of conservative, traditional nonoperative management. Contraindications included significant central canal stenosis, significant rotatory scoliosis, and moderate to severe spondylolisthesis. In some patients, discography was used as a tool to assist in level selection. The group of patients is essentially the same as those with degenerative disc disease and considered candidates for fusion (ALIF) or more potentially lumbar disc arthroplasty. Figure 1 demonstrates images from a representative patient with degenerative disc disease at L2–L3.

Surgical technique

Patient preparation

With general endotracheal anesthesia achieved and intravenous lines started, the patient is placed in a true 90° right lateral decubitus position with the left side elevated and taped in this position. A cross-table anterior-posterior (AP) image helps to confirm the true 90° position. The table and/or patient should be flexed in such a way as to increase the distance between the iliac crest and the rib cage, especially useful at upper lumbar levels and at L4–L5. At times it is helpful to place a bump/roll under the contralateral flank (Fig. 2).

After aseptic treatment of the skin, a k-wire and lateral fluoroscopic image are used to identify the lumbar disc's mid-position (Fig. 2). A mark is made on the patient's lateral side, overlying the center of the affected disc space.

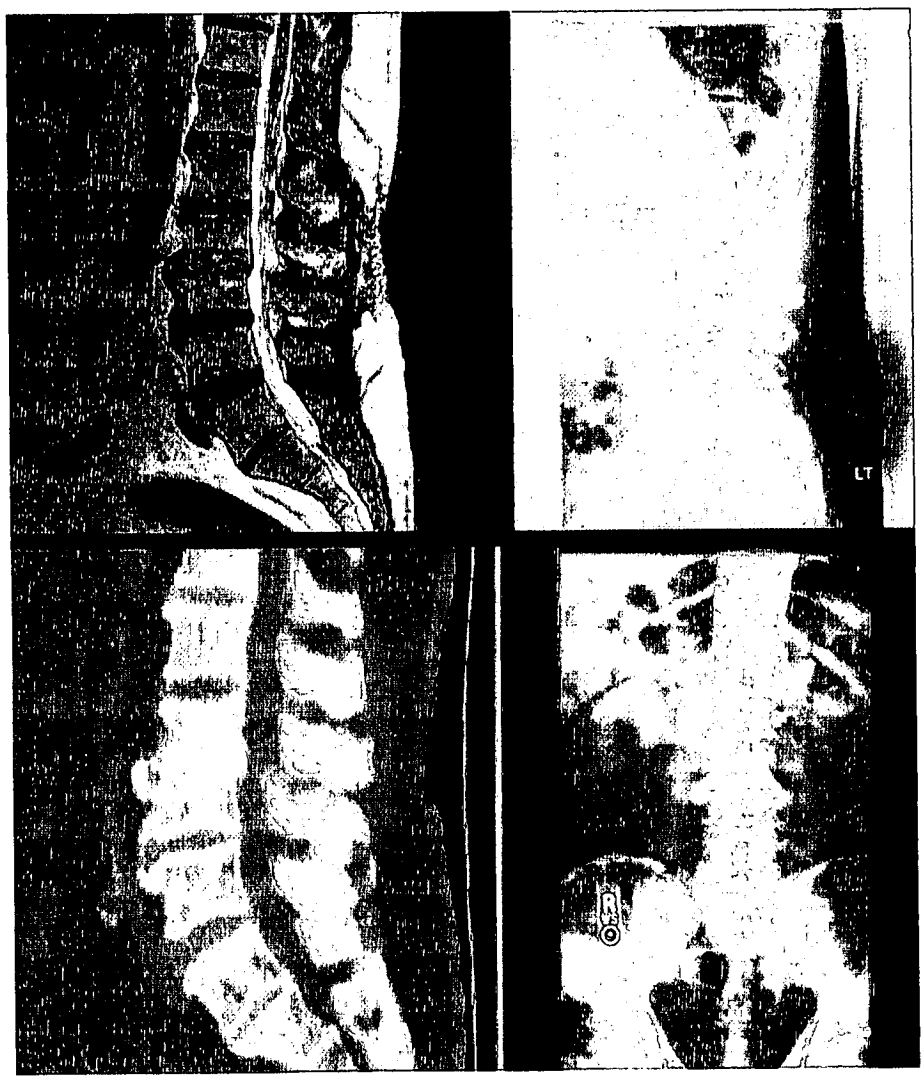

Fig. 1. Preoperative images demonstrating degenerative disc disease at L2–L3.

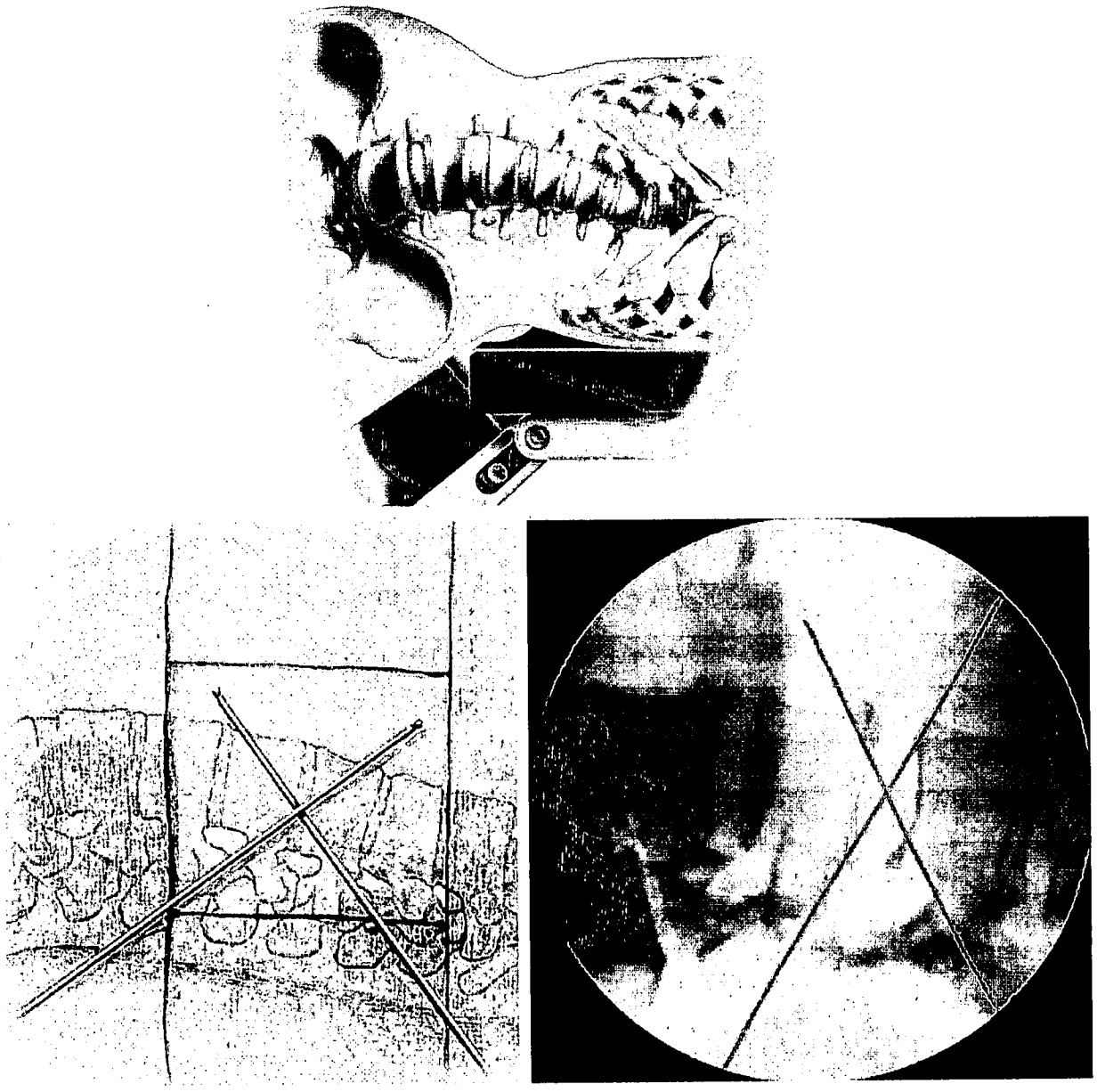

Fig. 2. Images demonstrating patient positioning and k-wire planning.

Through this mark, a small incision will be created for insertion of atraumatic tissue dilators and an expandable retractor, which will be the working portal (Fig. 3).

Retroperitoneal access

A second mark is made posterior to this first mark at the border between the erector spinae muscles and the abdominal obliques. At this second mark, a longitudinal incision of about 2 cm is made to accommodate the surgeon's index finger which is inserted anteriorly through the muscle layers (Fig. 4A) to identify the retroperitoneal space. Blunt dissection scissors are used to carefully spread the muscle fibers until the retroperitoneal space is reached. Care should be taken to avoid perforation of the peritoneum. After passing through the fascia and accessing the retroperitoneal space (Fig. 4B), the index finger is used to sweep the peritoneum anteriorly and then to palpate down to the psoas muscle. Once the psoas muscle is identified, the index finger is swept up to the direct lateral target mark. An incision is made at this direct lateral location and an initial dilator (MaXcess System, NuVasive, Inc.) is introduced. The index finger, which is already in the retroperitoneal space, is used to escort the dilator safely from the direct lateral incision to the psoas muscle, protecting the intra-abdominal contents

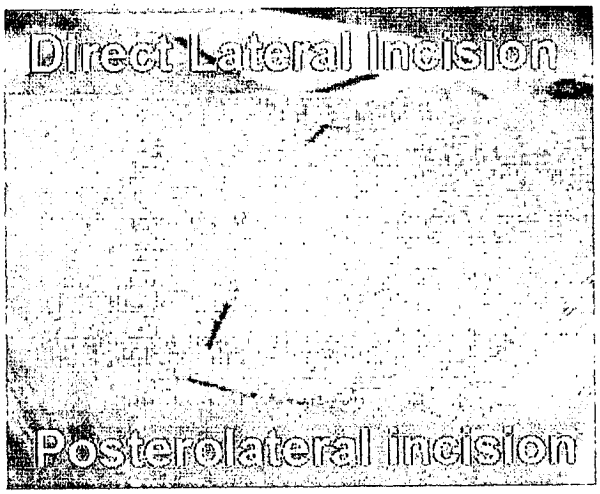

Fig. 3. Image demonstrating incision planning.

(Fig. 4C). The dilator is then placed over the surface of the psoas muscle, exactly over the disc space to be operated, as confirmed by AP and lateral fluoroscopy.

Trans-psoas access

The fibers of the psoas muscle are then gently separated with the initial dilator using blunt dissection and the NeuroVision JJB electromyographic (EMG) monitoring system (NuVasive, Inc.) to assess close proximity of the lumbar nerve roots to the advancing dilator. Care should be taken to minimize trauma to the psoas muscle. The psoas should be parted between the middle and anterior third of the muscle, ensuring that the nerves of the lumbar plexus are located posteriorly and outside the operative corridor. Additionally, direct lateral trajectory through the psoas ensures that the great vessels remain anterior to the operative corridor. The nerves are not visualized, and the size of the psoas muscle does not seem to be a factor in this technique.

The MaXcess dilators are insulated to minimize current shunting while an isolated electrode at the distal tip acts as the stimulation source, connected via a Dynamic Stimulation Clip attached to the proximal end of the dilator. In the posterior one-third of the psoas muscle lie the descending nerves of the lumbar plexus [14–16]. The NeuroVision System assists with safe passage by these nerves or confirmation of their posterior location via evoked-EMG monitoring. In Detection mode, the NeuroVision System will continuously search for the stimulus threshold that elicits an EMG response on the myotomes monitored and audibly and visually report the thresholds. As the dilator is advanced through the psoas muscle, the stimulus necessary to elicit an EMG response will vary with distance from the nerve; ie, the closer the stimulus source is to the nerve, the less stimulus intensity will be required to elicit a response, and the lower the resulting threshold will be, providing an indication of relative proximity of the dilator to the nerves [17,18]. Experience has suggested that threshold values greater than 10 mA indicate a distance that allows for both continued nerve safety and ample working space.

Disc exposure

The dissection continues, delicately spreading the mid portion of the psoas muscle fibers laterally, while avoiding the genitofemoral nerve, until the surface of the disc is reached (Fig. 4D). Final position should be reconfirmed by fluoroscopy. Subsequent dilators are introduced, gradually spreading the psoas muscle until the MaXcess retractor is inserted over the final dilator (pointing handles of the retractor directly posteriorly) (Fig. 5). Cross-table AP fluoroscopy is used to confirm the position of the retractor blades on the lateral border of the spine. A rigid articulating arm is attached to both the retractor and the surgical table to provide hands-free retraction. The retractor blades are expanded in a cranio-caudal direction to the desired aperture by squeezing the retractor handles. Anterior-posterior exposure is achieved by turning the knobs on the sides of the retractor. Because the articulating arm is attached to the independent posterior blade, expansion by turning the knobs is preferentially anterior so as to minimize blade pressure on the posterior portion of the psoas muscle and the nerves within it. The size of the exposure is customizable as needed and changeable intraoperatively.

A bifurcated light cable is provided with the MaXcess System to provide direct light and visualization into the wound. The single end of the bifurcated cable should be passed off and attached to a xenon arthroscopy light source; the two remaining ends placed down into the retractor blades and bent out of the way of the exposure. The operative corridor is thus established and should be thoroughly explored. Direct visualization and the NeuroVision EMG pedicle probe can be used to affirm a neurologically clear operative corridor. Bipolar electrocautery can be used to prepare disc visualization.

Discectomy and interbody implant placement

Under direct vision (Fig. 6), a thorough discectomy is performed using standard instruments such as an up-biting curette, pituitary rongeur, and various scrapers and broaches (Figs. 7 and 8). The posterior annulus is left intact, with the annulotomy window centered in the anterior half of the disc space and wide enough to accommodate a large implant. Disc removal and release of the contralateral annulus using a Cobb dissector provides the opportunity to place a long implant that will rest on both lateral margins of the epiphyseal ring, maximizing end plate support. Interbody distraction and implant placement in this anterior and bilateral epiphyseal position provides strong support for disc height restoration, and sagittal and coronal plane imbalance correction.

Closure

The exposure is copiously irrigated, and the retractor is removed slowly, so as to observe the psoas muscle

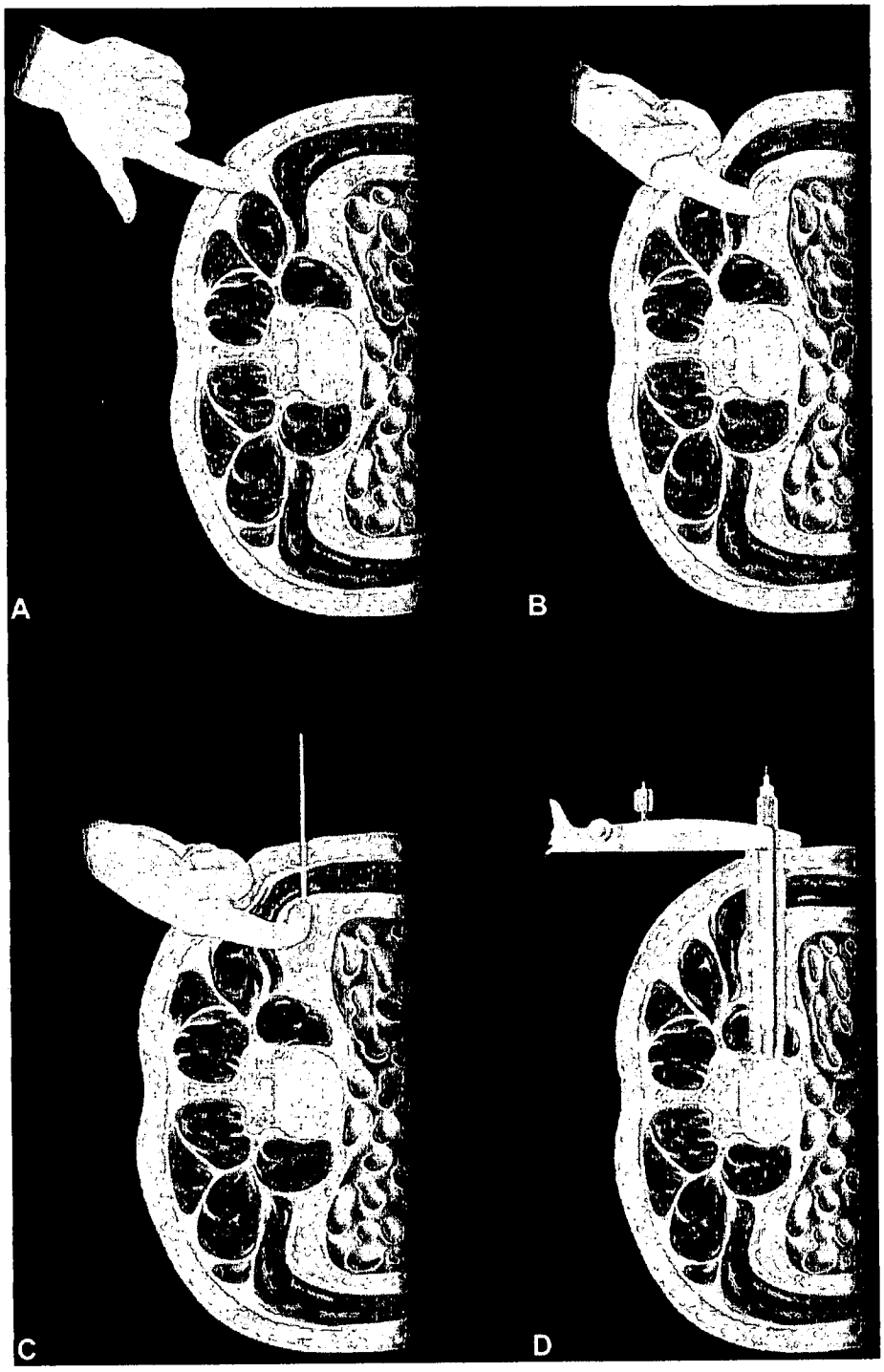

Fig. 4. Extreme Lateral Interbody Fusion procedure demonstrated sequentially. Schematic drawing showing (A) the surgeon's index finger inserted into the paraspinal incision site, (B) identifying the retroperitoneal space, and (C) guiding the initial dilator into position. Completion of the dilator positioning is achieved when (D) the retractor is inserted into the retroperitoneal space, penetrating the psoas major, and positioned directly on the lateral intervertebral disc space. (Schematics reprinted with permission from NuVasive, Inc., San Diego, CA).

rebounding and to confirm hemostasis. For both incision sites, the fascial layer is closed with 0 Vicryl and the subcutaneous layer is closed with 2.0 Vicryl sutures (Fig. 9). A 4.0 monocryl is used for subcuticular closure followed by skin glue for the final layer of closure. No drains have thus far been required. The patient is then placed prone for placement of percutaneous pedicle screws or done later at a second stage.

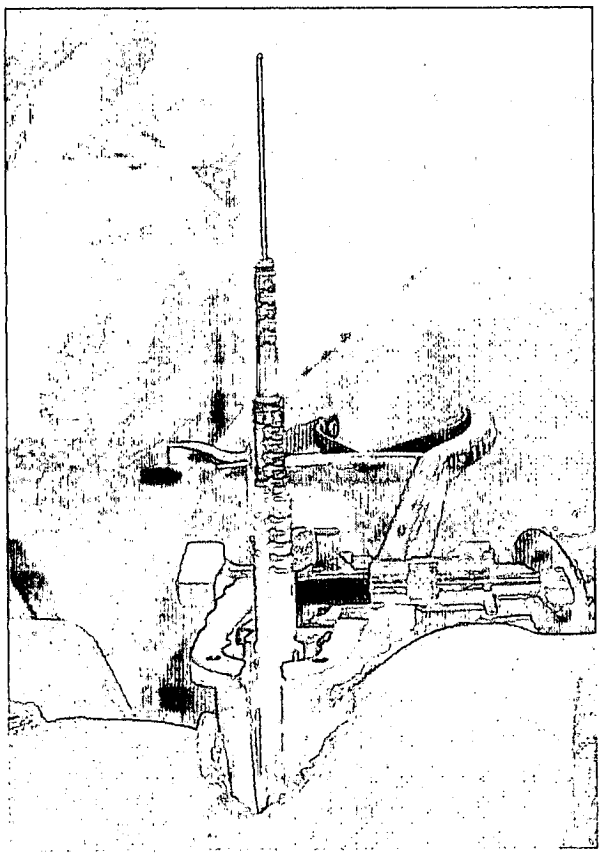

Fig. 5. Operative photograph of laterally inserted dilators. With patient in lateral decubitus position, sequentially larger dilators are shown inserted into the patient's side, penetrating the psoas major, and resting on the desired disc space.

Results

During preoperative consultation, all patients were informed of all surgical options including ALIF, posterior lumbar interbody fusion, transforaminal lumbar interbody fusion (TLIF), and XLIF. A complete discussion and description of the XLIF technique was described to all patients interested in the technique. Informed consent was attained for every patient.

Fig. 6. View of the lateral lumbar spine. The retractor has been inserted through the retroperitoneal space and psoas muscle, exposing the disc space. A bifurcated light cable clearly illuminates the lumbar spine.

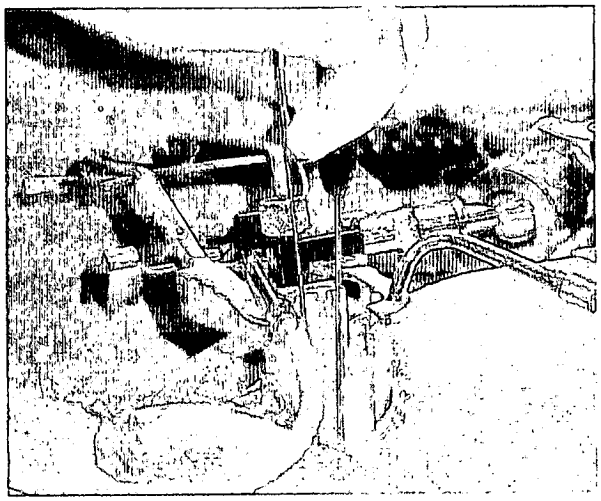

Fig. 7. Operative photo of discectomy being conducted under direct vision, facilitated by elongated instruments, a secured retractor, and fiber-optic lighting.

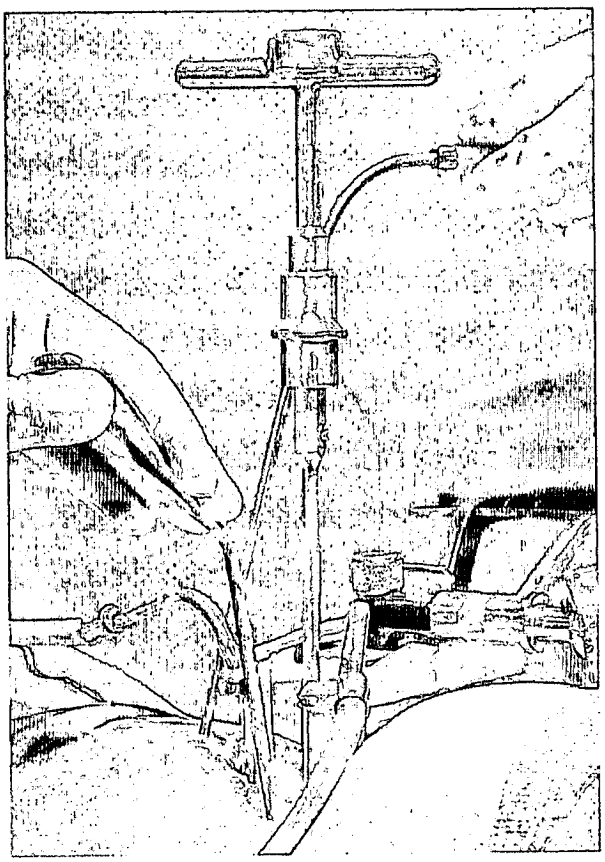

Fig. 8. Operative photo of a distractor inserted into the lumbar disc space, before insertion of a bone graft.

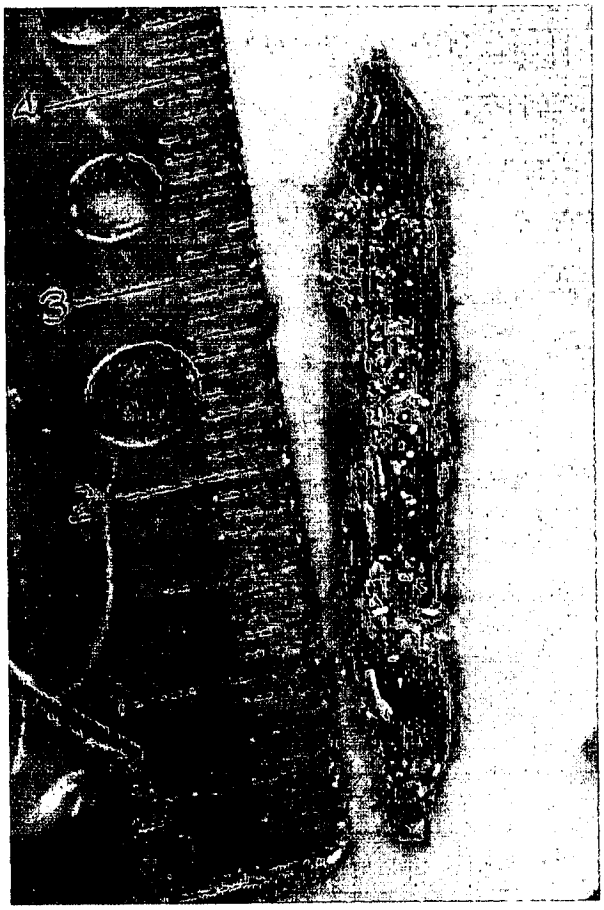

Fig. 9. Operative photo of lateral incision site after interbody graft placement, measuring approximately 4 cm. The length of this closure site was extended from the original 2.5 cm incision.

All XLIF procedures were supplemented with percutaneous pedicle screw fixation (either immediate or staged), and all procedures concluded without complication. Figure 10 represents images from a patient having had an L3–L4 XLIF followed by percutaneous pedicle screw instrumentation. Nerve avoidance equipment alerted us to a nearby spinal nerve during the trans-psoas approach in one patient, prompting redirection of the approach more anteriorly, away from the nerve, with no consequence. Thus far, there have been no complications in this institution's first 13 patients. No postoperative intensive care unit stay or blood transfusions were required. The majority of patients needed only Vicodin and nonsteroidal anti-inflammatory drugs for analgesia and ambulated on postoperative day 1. Visual analog scale and Oswestry disability indexes were collected by our clinic nurse by means of a patient questionnaire that was filled out at every clinic visit. These follow-up results are forthcoming.

Discussion

New techniques and technologies continue to push the limits of minimally invasive spine surgery [19]. Laparoscopic ALIF has been reported to be a safe surgical technique [2] and is commonly performed [2–7]. The primary advantages over the open surgical approach are less tissue trauma, reduced postoperative pain, shorter hospital stays, and earlier return to work. Nonetheless, the advantages of laparoscopy over open techniques have recently been questioned [20].

Laparoscopic techniques are not without their complications. During the initial percutaneous approach, the bowel may be injured [9]. CO_2 insufflation may lead to physiological complications [8] such as low cardiac output, elevated mean arterial pressure, and elevated vascular and systemic resistance. Other reported complications have included injury to great vessels [10,11], retrograde ejaculation [12,13], and arterial thromboembolism [21].

Moreover, significant technical challenges limit the value of laparoscopic anterior approaches. Mastering the operative use of laparoscopic instruments is a significant challenge, especially if not routinely employed. Depth perception is compromised with the use of two-dimensional video imaging. Access to the anterior lumbar spine at L4–L5 is particularly challenging with laparoscopy, given that it requires ligation of the iliolumbar vein and mobilization of the great vessels. Lastly, access to the anterior lumbar spine is still dependent on the general surgeon.

Reports have shown that the laparoscopic anterior lumbar approach offers no significant advantage over the mini-open approach [6,22]. Recently, Kaiser et al. reported on 98 patients who underwent ALIF procedures, 47 via laparoscopic approach and 51 via mini-open technique [22]. A significantly longer preparation time was observed when using a laparoscopic approach versus a mini-open approach. The average procedural time for the laparoscopic approach was 185 minutes. Although some of our earlier cases took longer than this time, it is notable that there is a learning curve associated with using a new technique and trusting the nerve monitoring equipment in avoiding nerve injury. Currently we are averaging 45 minutes per XLIF level.

The XLIF technique is a modification of the retroperitoneal approach to the lumbar spine. The technique was first presented in 2001 by Pimenta, who has performed more than 100 lateral trans-psoas surgeries since 1998 [23]. The equipment used in this procedure is uncomplicated, conventional, and does not require additional capital expenditure. An operative microscope may be used, but certainly is not required. In fact, thus far all of our cases have been performed simply using operative loupes. Furthermore, the attachable illumination provided by the MaXcess System enables unparalleled visibility without the discomfort of wearing a headlight.

When compared with anterior laparoscopic approaches to the lumbar spine, the lateral approach has several advantages. First, a general surgeon is not needed for access. A far lateral approach eliminates the need to violate or retract the peritoneum, or to retract the great vessels. Second,

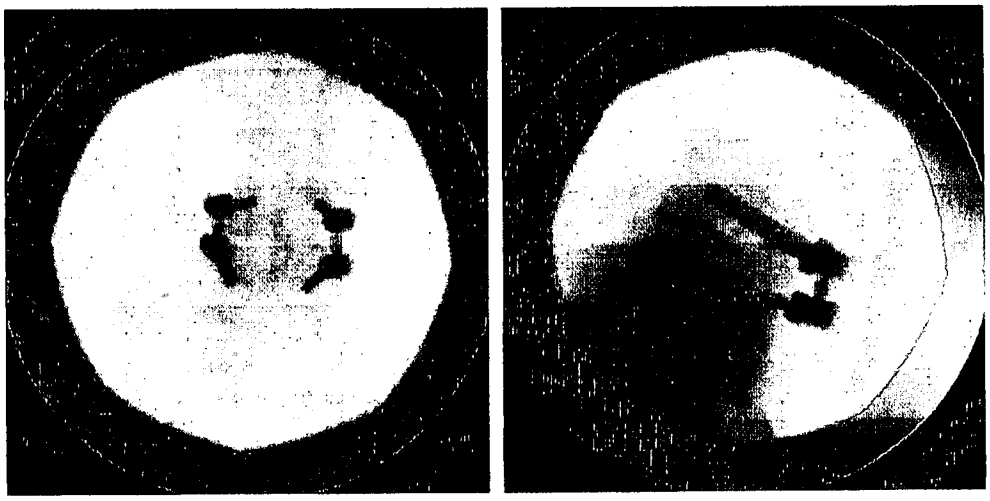

Fig. 10. Postoperative images demonstrating Extreme Lateral Interbody Fusion and percutaneously placed pedicle screws and instrumentation at L3–L4.

compared with laparoscopic techniques, no steep learning curve exists for this minimally disruptive technique. All tissue dissection occurs under direct vision, without impairment of depth perception. Third, a far lateral approach avoids many of the known complications of laparoscopic anterior approaches, such as damage to the great vessels during mobilization [10,11], and retrograde ejaculation [12,13] most likely from disturbance of the superior hypogastric nerve plexus. Fourth, the most significant advantage we report between the laparoscopic ALIF and our XLIF is in operative time. When compared with mini-open laparotomy, a laparoscopic ALIF has been noted to have longer operative time [24].

Limitations do exist with this far lateral approach. First, the inferior edge of the 12th rib and the superior edge of the iliac crest limit the potential exposure sites to L1–L2, L2–L3, L3–L4, and L4–L5. Also, dissecting the psoas major, though technically straightforward, must be done carefully so as not to injure the nerves of the lumbar plexus or cause significant trauma to the psoas major. Prior reports of lateral retroperitoneal approaches included mobilization of the psoas muscle from the lumbar spine, but a high incidence of transient numbness along the genitofemoral nerve has been reported after retraction of the psoas muscle [25,26]. Because the XLIF approach requires neither retraction of the psoas major, nor significant dilation of the dissection site in the psoas major (as the exposure is expanded preferentially anteriorly by locking the posterior retractor blade to the surgical table), transient sensory deficits along the genitofemoral nerve are unlikely. Use of the NeuroVision EMG monitoring system is critical to the safe passage by the nerves within the psoas muscle itself. To date, this initial cohort has not shown any evidence of trauma to the psoas muscle or nerves.

As with most minimally disruptive spinal techniques, intraoperative fluoroscopy use is critical. The actual timing of fluoroscopy use is important; however, it is significantly affected by the experience of the technician as well as the surgeon. We found that our fluoroscopy time was decreased; however, quantitative analysis has not been performed thus far. We hope that we can provide this information in future follow-up studies.

The surgical results of this procedure have shown that it is a safe and reproducible technique. It has demonstrated the benefits of a minimally invasive procedure, with quick recovery and improvements in pain and function scales. It has also demonstrated that the underlying objectives of surgery need not be compromised for the sake of less morbidity. Disc heights were restored and stability maintained by preserving ligamentous structures and inserting a large interbody implant. This can indirectly improve the foraminal volume and result in reduction of radiculopathy. Sagittal balance was maintained or improved by placement of the implant in an anterior position. Coronal imbalances were corrected by ensuring full bilateral end plate coverage by the implant. Although it is still early to fully assess fusion rates, the longer follow-up patients in this study have shown solid fusion progression, apparently uncompromised by the technique.

Conclusion

Given the known complications and challenges of endoscopic spine surgery, the XLIF may be a valuable alternative to laparoscopic anterior approaches for an interbody spine fusion. Subsequent articles shall report our longer-term follow-up data and efficacy. As comfort with this technique expands, so too do the indications for it. It has more recently also been used to treat low-grade spondylolisthesis and adult degenerative lumbar scoliosis with great success [27]. Longer follow-up is certainly required, but early results are encouraging. Time and increased numbers will also help us in determining fusion rates for future studies. Furthermore, we are in the process of trying to come up

with a control group as well as a more traditional surgical group for comparison.

References

[1] Obenchain TE. Laparoscopic lumbar discectomy: case report. J Laparoendosc Surg 1991;1:145–9.

[2] Regan JJ, Aronoff RJ, Ohnmeiss DD, Sengupta DK. Laparoscopic approach to L4–L5 for interbody fusion using BAK cages. Spine 1999;4:2171–4.

[3] Lieberman IH, Willsher PC, Litwin DE, Salo PT, Kraetschmer BG. Transperitoneal laparoscopic exposure for lumbar interbody fusion. Spine 2000;25:509–14.

[4] Olsen D, McCord D, Law M. Laparoscopic discectomy with anterior interbody fusion of L5–S1. Surg Endosc 1996;10:1158–63.

[5] Regan JJ, Yuan H, McAfee PC. Laparoscopic fusion of the lumbar spine. Spine 1999;24:402–11.

[6] Zdeblick TA, David SM. A prospective comparison of surgical approach for anterior L4–L5 fusion. Spine 2000;25:2682–7.

[7] Zucherman JF, Zdeblick TA, Bailey SA, Mahvi D, Hsu KY, Kahrs D. Instrumented laparoscopic spinal fusion. Spine 1995;20:2029–35.

[8] Hannon JK, Faircloth WB, Lane DR, et al. Comparison of insufflation vs. retractional technique for laparoscopic-assisted intervertebral fusion of the lumbar spine. Surg Endosc 2000;14:300–4.

[9] Jacobs M, Verdeja JC, Goldstein HS. Minimally invasive colon resection (laparoscopic colectomy). Surg Laparosc Endosc 1991;1:144–50.

[10] Baker JK, Reardon PR, Reardon MJ, Heggeness MH. Vascular injury in anterior lumbar spine surgery. Spine 1993;18:2227–30.

[11] Regan JJ, McAfee PC, Guyer RD, Aronoff RJ. Laparoscopic fusion of the lumbar spine in a multicenter series of the first 34 consecutive patients. Surg Laparosc Endosc 1996;6:459–68.

[12] Christensen FB, Bunger CE. Retrograde ejaculation after retroperitoneal lower lumbar interbody fusion. Int Orthop 1997;21:176–80.

[13] Flynn JC, Price CT. Sexual complications of anterior fusion of the lumbar spine. Spine 1984;9:489–92.

[14] Ebraheim NA, Xu R, Huntoon M, Yeasting RA. Location of extraforaminal lumbar nerve roots: an anatomic study. Clin Orthop 1997;340:230–5.

[15] Gu Y, Ebraheim NA, Xu R, Rezcallah AT, Yeasting RA. Anatomic considerations of the posterolateral lumbar disk region. Orthopedics 2001;24:56–8.

[16] Moro T, Kikuchi S, Konno S, Yaginuma H. An anatomic study of the lumbar plexus with respect to retroperitoneal endoscopic surgery. Spine 2003;28:423–8.

[17] McLaughlin J, Marks R, Goldberg M, Niznik G. Transcutaneous discectomy and cannula stimulation for detecting proximity to lumbar nerve roots. Paper presented at: American Society of Neurological Monitoring (ANSM) meeting; May 2003; Las Vegas, NV.

[18] Peloza J. Validation of neurophysiologic monitoring of posterolateral approach to the spine via discogram procedure. Proceedings of the 9th International Meeting on Advanced Spine Techniques (IMAST); May 2002; Montreux, Switzerland.

[19] Fessler RG. Minimally invasive surgery of the spine. Neurosurgery 2002;51(5 suppl):Siii–iv.

[20] Rodriguez HE, Connolly MM, Dracopoulos H, Geisler FH, Podbielski FJ. Anterior access to the lumbar spine: laparoscopic versus open. Am Surg 2002;68:978–82; discussion 982–3.

[21] Hackenberg L, Liljenqvist U, Halm H, Winkelmann W. Occlusion of the left common iliac artery and consecutive thromboembolism of the left popliteal artery following anterior lumbar interbody fusion. J Spinal Disord 2001;14:365–8.

[22] Kaiser MG, Haid RW Jr, Subach BR, Miller JS, Smith CD, Rodts GE Jr. Comparison of the mini-open versus laparoscopic approach for anterior lumbar interbody fusion: a retrospective review. Neurosurgery 2002;51:97–103; discussion 103–5.

[23] Pimenta L. Lateral endoscopic transpsoas retroperitoneal approach for lumbar spine surgery. Paper presented at: VIII Brazilian Spine Society Meeting; May 2001; Belo Horizonte, Minas Gerais, Brazil.

[24] Liu JC, Ondra SL, Angelos P, Ganju A, Landers ML. Is laparoscopic anterior lumbar interbody fusion a useful minimally invasive procedure? Neurosurgery 2002;51(5 Suppl.):155–8.

[25] Bergey D, Villavicanero AT, Goldstein T, Regan JJ. Endoscopic lateral trans-psoas approach to the lumbar spine. Spine 2004;29:1681–8.

[26] Nakamura H, Ishikawa T, Konishi S, Seki M, Yamano Y. Psoas strapping technique: a new technique for laparoscopic anterior lumbar interbody fusion. J Am Coll Surg 2000;191:686–8.

[27] Pimenta L, Vigna F, Bellera F, Schaffa T, Malcolm J, McAfee P. A new minimally invasive surgical technique for adult lumbar degenerative scoliosis. Proceedings of the 11th International Meeting on Advanced Spine Techniques (IMAST), Southampton, Bermuda, July 2004.

EXHIBIT D

US006936051B2

(12) **United States Patent**
Michelson

(10) **Patent No.: US 6,936,051 B2**
(45) **Date of Patent: Aug. 30, 2005**

(54) **MULTILOCK ANTERIOR CERVICAL PLATING SYSTEM**

(76) Inventor: **Gary K. Michelson**, 438 Sherman Canal, Venice, CA (US) 90291

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 259 days.

(21) Appl. No.: **10/410,902**

(22) Filed: **Apr. 10, 2003**

(65) **Prior Publication Data**

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Related U.S. Application Data

(62) Division of application No. 10/386,275, filed on Mar. 11, 2003, which is a division of application No. 09/618,036, filed on Jul. 17, 2000, now Pat. No. 6,620,163, which is a division of application No. 09/022,293, filed on Feb. 11, 1998, now Pat. No. 6,193,721.

(60) Provisional application No. 60/037,139, filed on Feb. 11, 1997.

(51) **Int. Cl.**[7] **A61B 17/70**

(52) **U.S. Cl.** **606/61**; 606/69; 606/70; 606/71; 606/76; 606/77

(58) **Field of Search** 606/61, 69, 70, 606/71, 76, 77

(56) **References Cited**

U.S. PATENT DOCUMENTS

74,489	A	2/1868	Bidwell
824,867	A	7/1906	Houghton
1,105,105	A	7/1914	Sherman
2,423,511	A	7/1947	Luben et al.
2,757,457	A	8/1956	Ziegelski, Sr.
3,244,170	A	4/1966	McElvenny
3,386,437	A	6/1968	Treace
3,604,414	A	9/1971	Borges
3,709,219	A	1/1973	Halloran
3,750,652	A	8/1973	Sherwin
3,840,014	A	10/1974	Ling et al.

(Continued)

FOREIGN PATENT DOCUMENTS

DE	4409833	10/1995
DE	4414781	11/1995
EP	0 554 915	8/1993
EP	1106144	6/2001
FR	2 740 321	4/1997
WO	WO 90/02526	3/1990
WO	WO 94/17744	8/1994
WO	WO 94/26193	11/1994
WO	WO 95/11632	5/1995
WO	WO 95/31941	11/1995
WO	WO 95/35067	12/1995
WO	WO 96/08206	3/1996
WO	WO 96/39975	12/1996

OTHER PUBLICATIONS

European Search Report dated Jan. 20, 2004 of corresponding European Patent Application No. 03028649.

Advertisement for Codman Anterior Cervical Plate System by Codman; Johnson & Johnson; Professional, Inc.; undated.

AESCULAP Scientific Information Booklet; *Anterior Cervical Fusion and Interbody Stabilization with the Trapezial Osteosynthetic Plate Technique* by Wolfhard Casper; Feb. 1986.

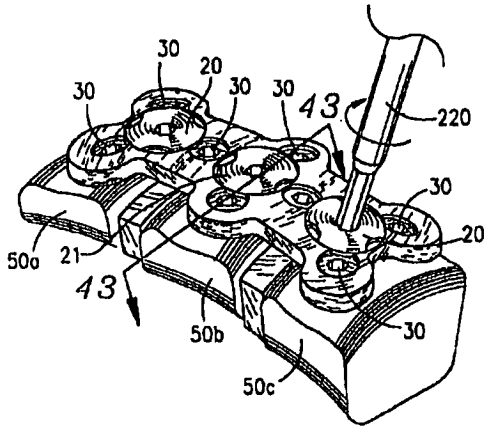
(Continued)

Primary Examiner—David O. Reip
(74) *Attorney, Agent, or Firm*—Martin & Ferraro, LLP

(57) **ABSTRACT**

Anatomically contoured anterior cervical plates with bone ingrowth surfaces, providing for intersegmental compressive preloading, and a rigid and locked interface to all of the bone screws, with those engaging the vertebrae deployed in highly convergent pairs. The bone screws have a tapered self-tapping leading end, an increasing root diameter with a generally constant outer diameter with a thread that is narrow and sharp throughout and an enlarged head portion capable of an interference fit to the receiving holes of the plate. Instrumentation consists of plate holders, a compression apparatus and a pilot hole forming device that interlocks with the plate. Methods for spinal compression and bone hole preparation are provided.

39 Claims, 20 Drawing Sheets



U.S. PATENT DOCUMENTS

3,960,147	A	6/1976	Murray
4,069,586	A	1/1978	Skelton
4,102,339	A	7/1978	Weber et al.
4,338,926	A	7/1982	Kummer et al.
RE31,628	E	7/1984	Allgower et al.
4,488,543	A	12/1984	Tornier
4,493,317	A	1/1985	Klaue
4,503,848	A	3/1985	Caspar et al.
4,542,539	A	9/1985	Rowe, Jr. et al.
4,651,724	A	3/1987	Berentey et al.
4,733,657	A	3/1988	Kluger
4,794,918	A	1/1989	Wolter
4,896,661	A	1/1990	Bogert et al.
4,898,161	A	2/1990	Grundei
4,957,495	A	9/1990	Kluger
4,959,065	A	9/1990	Arnett et al.
5,000,166	A	3/1991	Karpf
5,019,079	A	5/1991	Ross
5,041,113	A	8/1991	Biedermann et al.
5,052,373	A	10/1991	Michelson
5,053,036	A	10/1991	Perren et al.
5,059,194	A	10/1991	Michelson
5,127,912	A	7/1992	Ray et al.
5,147,361	A	9/1992	Ojima et al.
5,167,662	A	12/1992	Hayes et al.
5,180,381	A	1/1993	Aust et al.
5,190,544	A	3/1993	Chapman et al.
5,209,751	A	5/1993	Farris et al.
5,217,497	A	6/1993	Mehdian
5,234,430	A	8/1993	Huebner
5,300,073	A	4/1994	Ray et al.
5,338,197	A	8/1994	Kwan
5,364,399	A	11/1994	Lowery et al.
5,380,328	A	1/1995	Morgan
5,397,363	A	3/1995	Gelbard
5,423,826	A	6/1995	Coates et al.
5,456,685	A	10/1995	Huebner
5,478,340	A	12/1995	Kluger
5,478,348	A	12/1995	Bajada
5,492,442	A	2/1996	Lasner
5,520,690	A	5/1996	Errico et al.
5,527,314	A	6/1996	Brumfield et al.
5,531,554	A	7/1996	Jeanson et al.
5,531,746	A	7/1996	Errico et al.
5,545,163	A	8/1996	Miller et al.
5,545,165	A	8/1996	Biedermann et al.
5,549,612	A	8/1996	Yapp et al.
5,558,674	A	9/1996	Heggeness et al.
5,562,663	A	10/1996	Wisnewski et al.
5,562,672	A	10/1996	Huebner et al.
5,578,034	A	11/1996	Estes
5,601,553	A	2/1997	Trebing et al.
5,607,426	A	3/1997	Ralph et al.
5,616,142	A	4/1997	Yuan et al.
5,643,265	A	7/1997	Errico et al.
5,662,652	A	9/1997	Schafer et al.
5,672,175	A	9/1997	Martin
5,676,666	A	10/1997	Oxland et al.
5,676,703	A	10/1997	Gelbard
5,735,853	A	4/1998	Olerud
5,735,899	A	4/1998	Schwartz et al.
5,755,796	A	5/1998	Ibo et al.
5,766,254	A	6/1998	Gelbard
D402,032	S	12/1998	Stone
5,849,012	A	12/1998	Abboudi
D406,646	S	3/1999	Stone
5,876,402	A	3/1999	Errico
5,876,446	A	3/1999	Agrawal et al.
5,954,722	A	9/1999	Bono
6,022,350	A	2/2000	Ganem
6,030,389	A	2/2000	Wagner et al.
6,152,927	A	11/2000	Farris et al.
6,342,055	B1	1/2002	Eisermann et al.

OTHER PUBLICATIONS

Article from Plastic and Reconstructive Surgery; *Comparison of Compression and Torque Measurements of Self-Tapping and Pretapped Screws* by John T. Phillips, M.D., F.R.C.S. (C), and Berton A. Rahn, M.D., D.D.S.; Mar. 1989.

Article from The Journal of Prosthetic Dentistry; *Bone–implant interface structures after nontappping and tapping insertion of screw–type titanium alloy endosseous implants* by Keiichi Satomi, D.D.S.; Yasumasa Akagawa, D.D.S.; Ph.D.; and Hiroshima Tsuru, D.D.S., Ph.D.; Mar. 1988; vol. 59, No. 3.

Article from The Surgeon; *The Anterior Plating of the Cerivcal Spine with the Titanium Hollow Screw System* by E. Morshcer, F. Sutter, H. Jenny and S. Olerud; (1986).

Brochure by SYNTHES Spine for *Cervical Spine Locking Plate*; 1991.

Orion Brochure; *Anterior Cervical Plate System, Surgical Technique*, as described by Gary L. Lowery, M.D., Ph.D.; 1996.

Codman Brochure; *Anterior Cervical Plate Sytstem*; Sep. 1995.

Acromed; *AcroPlate Anterior Cervical System: Ordering Information for Implants and Instruments*; 1994.

Acromed; *Kaneda Anterior Spinal Instrumentation System, Technique Manual.*

Acromed; *University Plate Titanium Anterior System: Ordering Information for Implants and Instruments*; 1994.

Caspar et al.; *Experimental and Clinical Studies, Anterior Cervical Fusion and Caspar Plate Stabilization for Cervical Trauma*; Neurosurgery; vol. 25; No. 4; 1989; pp. 491–502.

Caspar, Wolfhard; *Anterior Cervical Fusion and Interbody Stabilization with the Trapezial Osteosynthetic Plate Technique*; AESCULAP Scientific Information Booklet.

Cloward Instrument Corporation; *Brochure, New Cloward Cervical Dislocation Reducer*; Catalog No. C17–1000.

Cloward Instrument Corporation; *Brochure, New Cloward Lumbar Vertebra Spreader*; Catalog No. C61–1025/ C61–1026.

Cloward Instrument Corporation; *Catalog, Cloward Instruments*; 1993; 1–38.

Foley et al.; *Aline Anterior Cervical Plating System: Surgical Technique*; Surgical Dynamics; 1998; pp. 1–16

Stryker Implants; *alpha plate*; 1997.

Synthes Spine; *New Additions, Cervical Spine Locking Plate System*; 1995; pp. 1–17.

Synthes Spine; *Product Profile*; 1993; pp. 1–8.

Synthes Spine; *The Titanium, Anterior Thoracolumbar Locking Plate System, Technique Guide*; 1994; pp. 1–13.

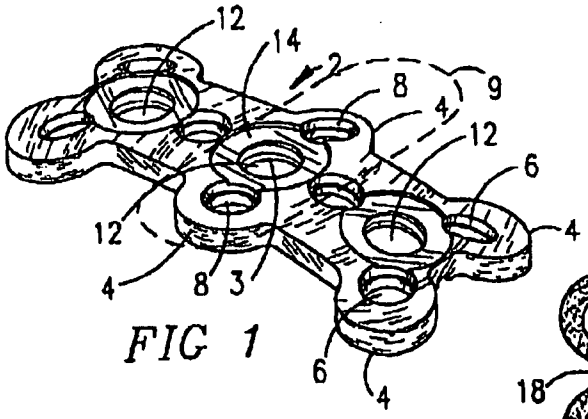


FIG 1

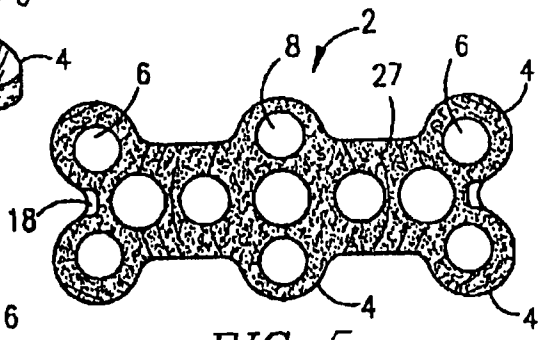


FIG 5

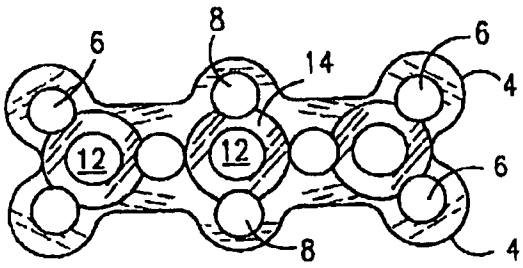


FIG 2

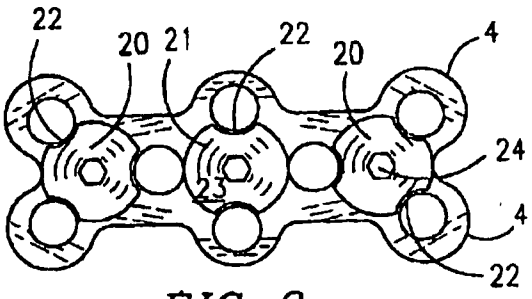


FIG 6

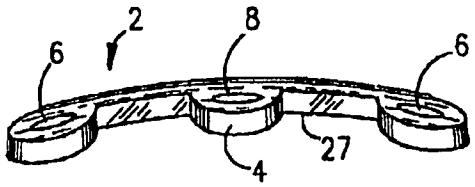


FIG 3

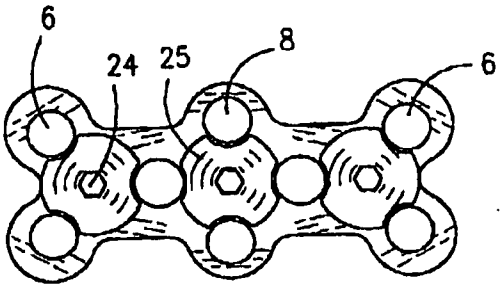


FIG 7

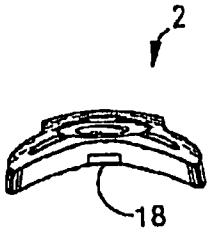


FIG 4

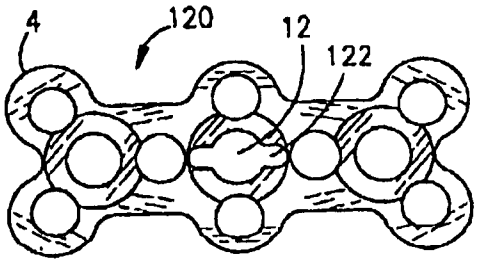


FIG 8

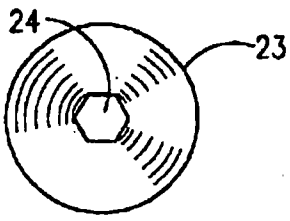


FIG 9

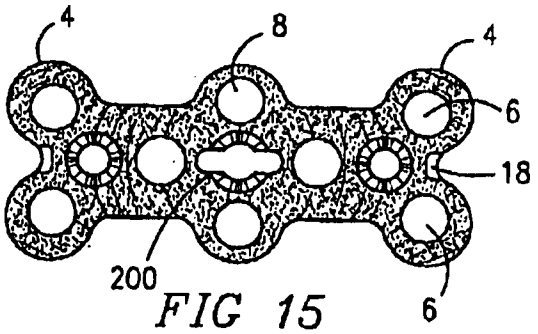


FIG 15

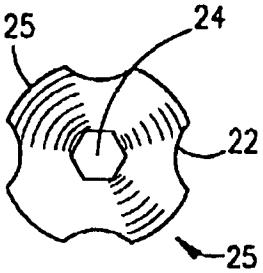


FIG 10

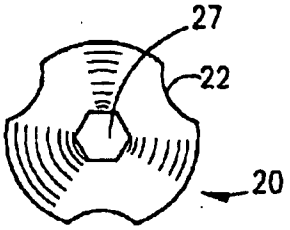


FIG 11

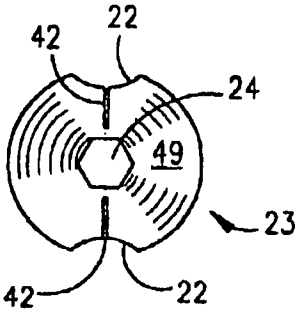


FIG 16

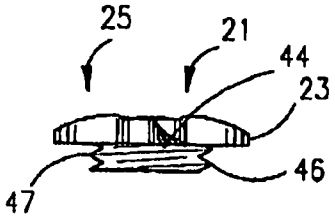


FIG 12

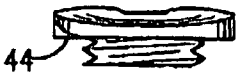


FIG 13

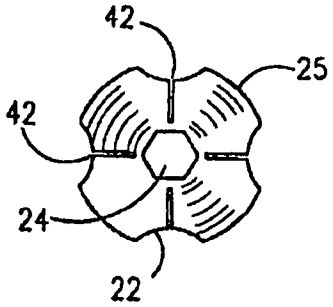


FIG 17

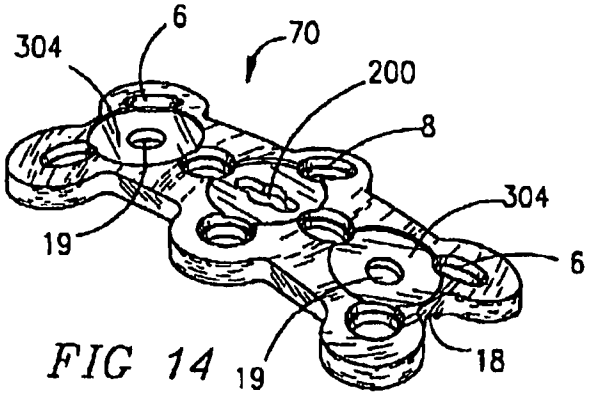


FIG 14

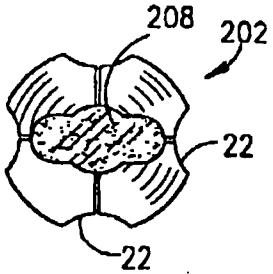


FIG 18

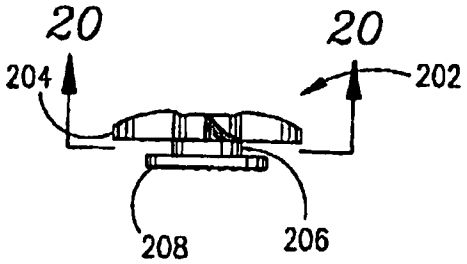


FIG 19

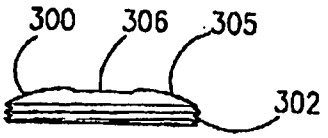


FIG 23

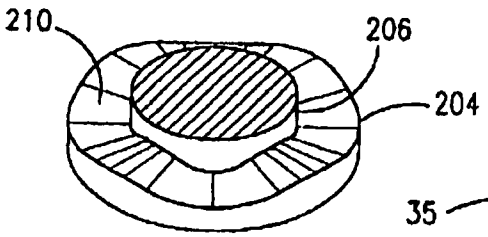


FIG 20

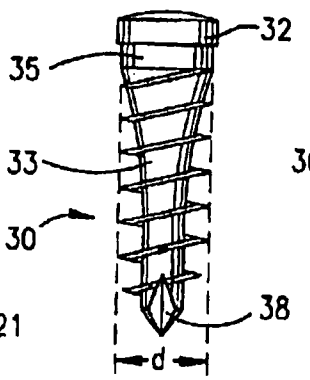


FIG 24A

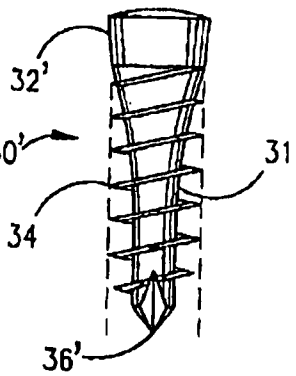


FIG 25

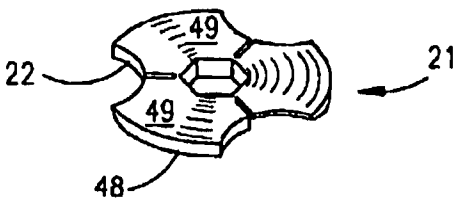


FIG 21

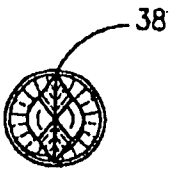


FIG 26

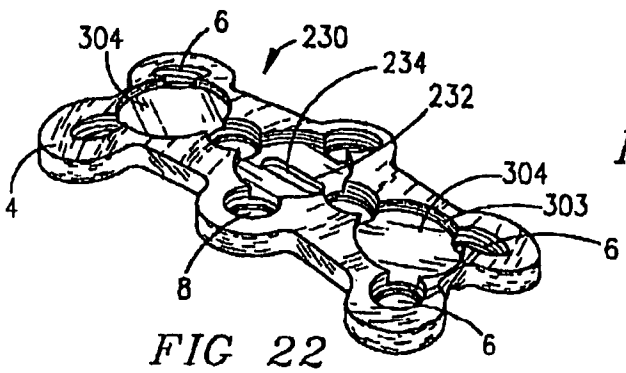


FIG 22

FIG 27

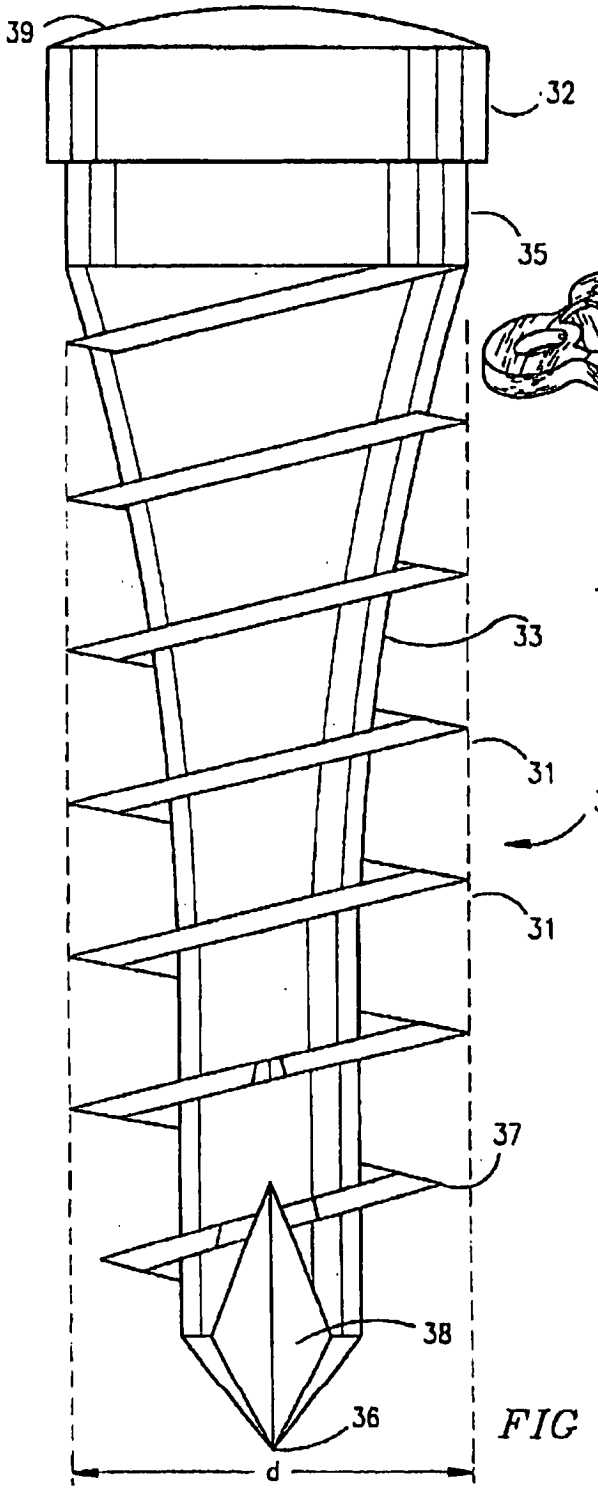


FIG 24B

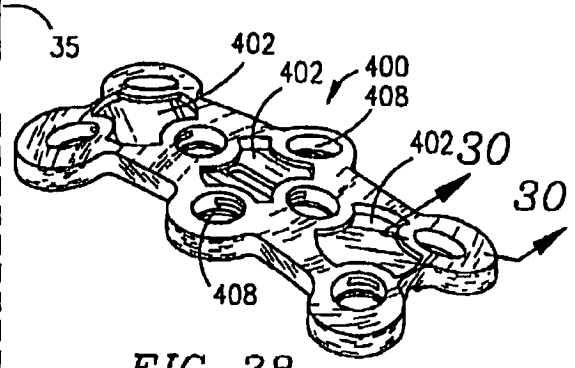


FIG 28

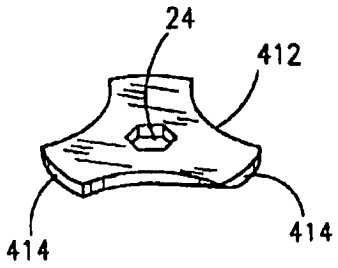


FIG 29

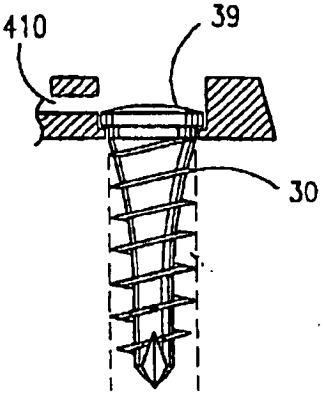


FIG 30

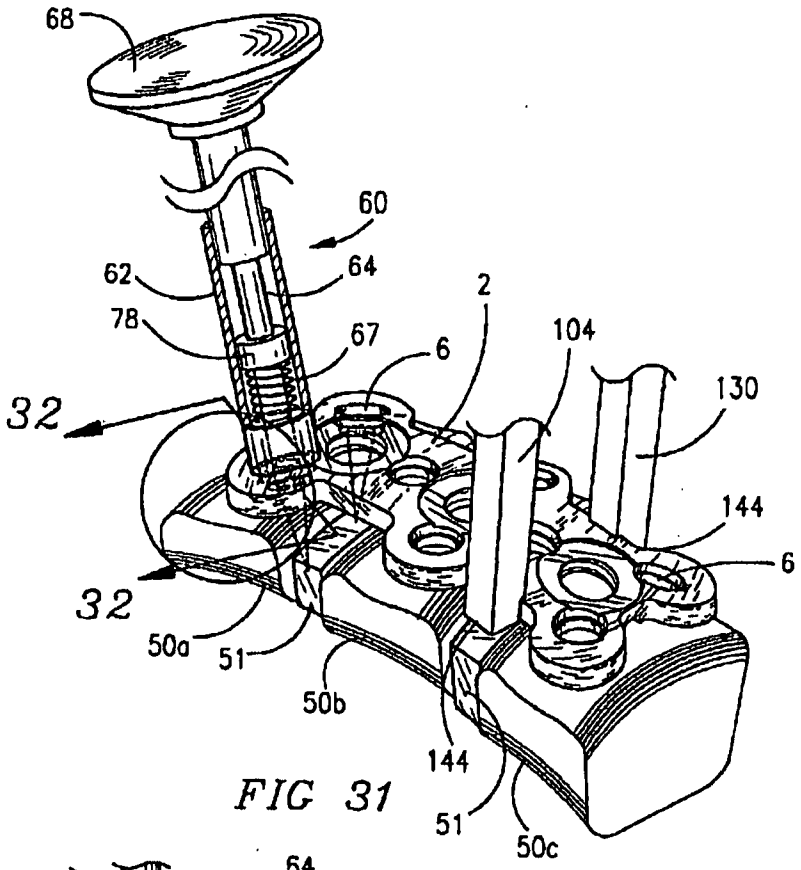


FIG 31

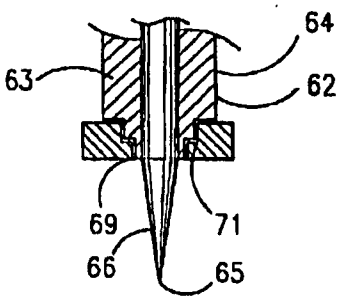


FIG 32

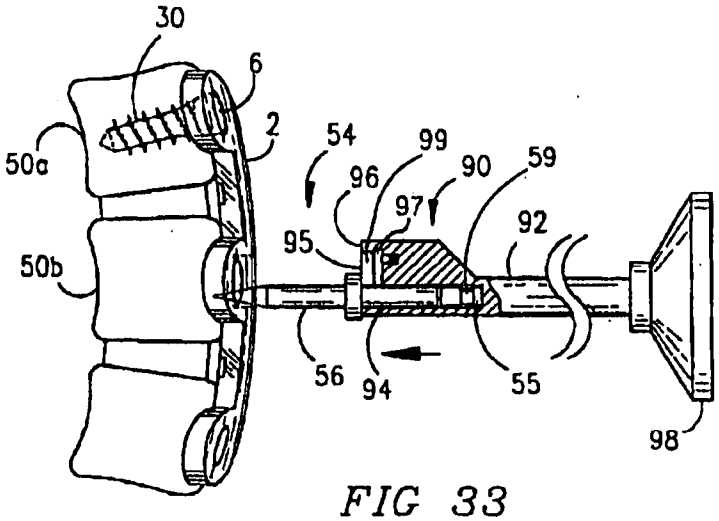


FIG 33

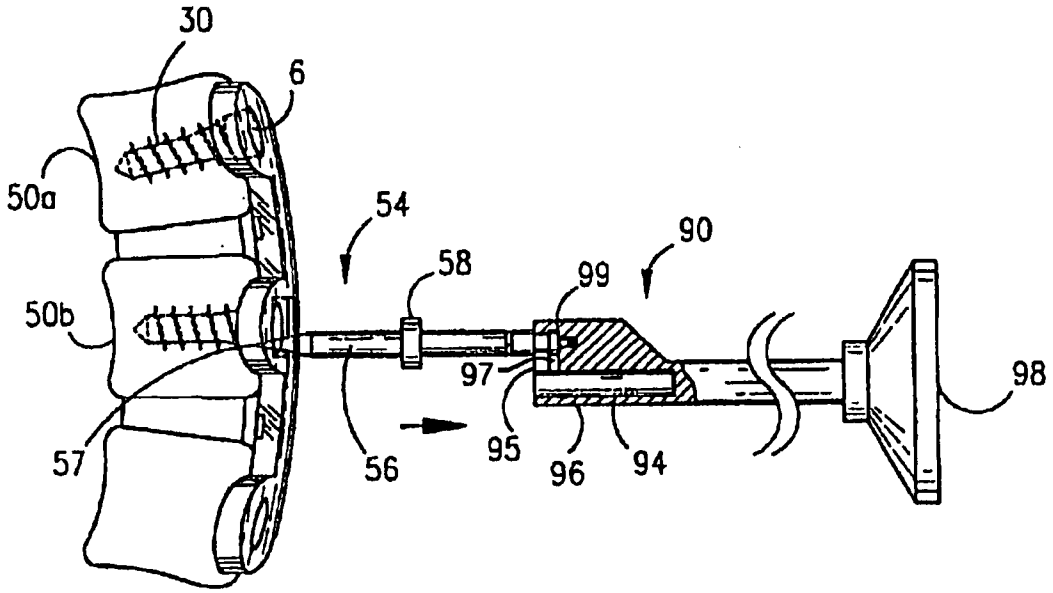


FIG 34

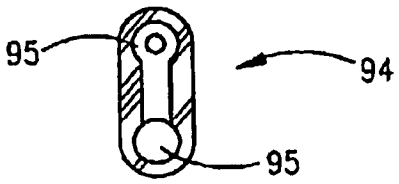


FIG 35

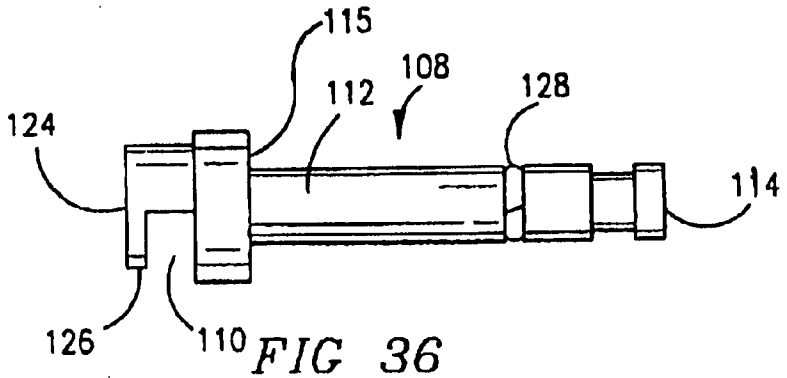


FIG 36

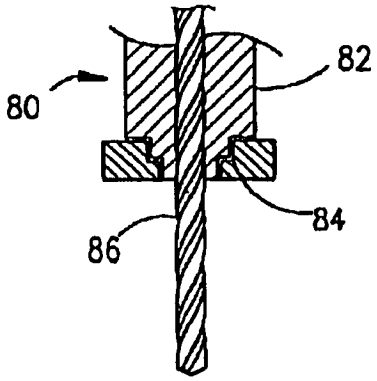
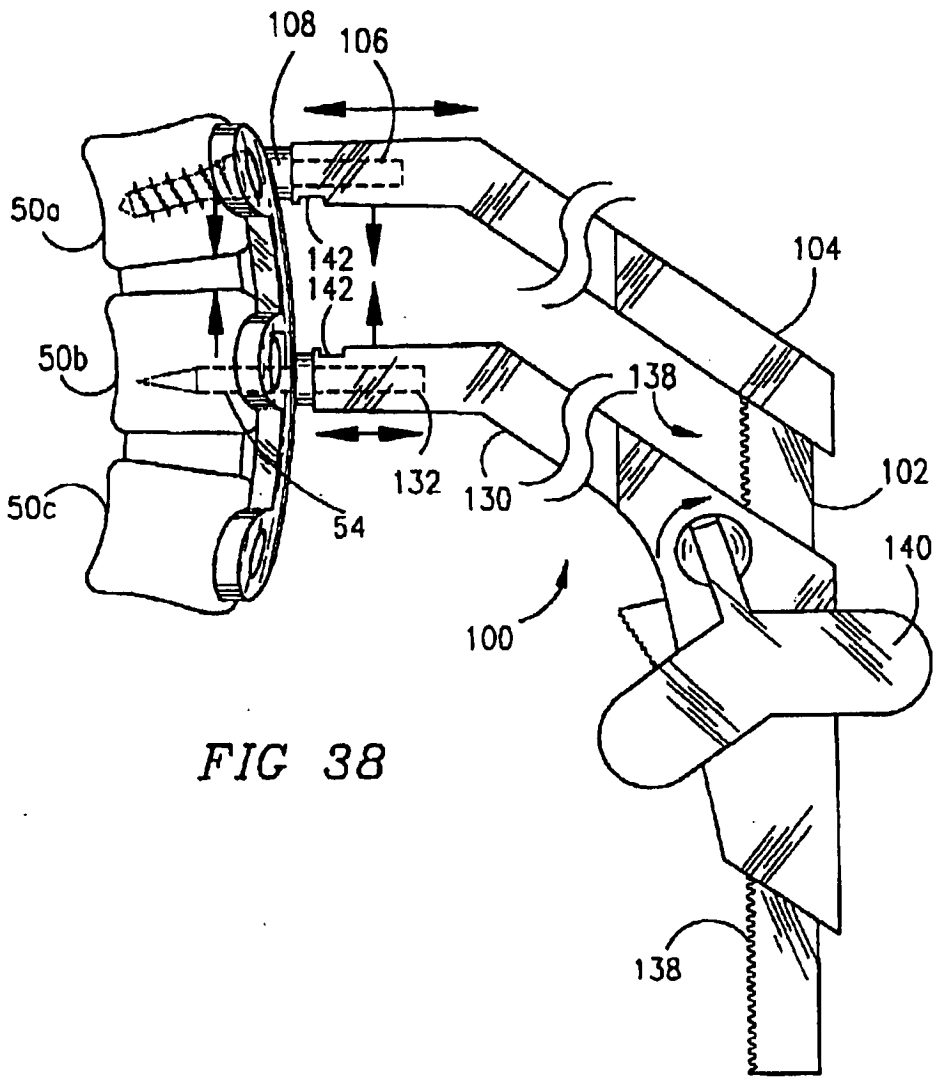

80
82
84
86

FIG 37


108
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50b
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132
130
102
50c
54
140
100
138

FIG 38

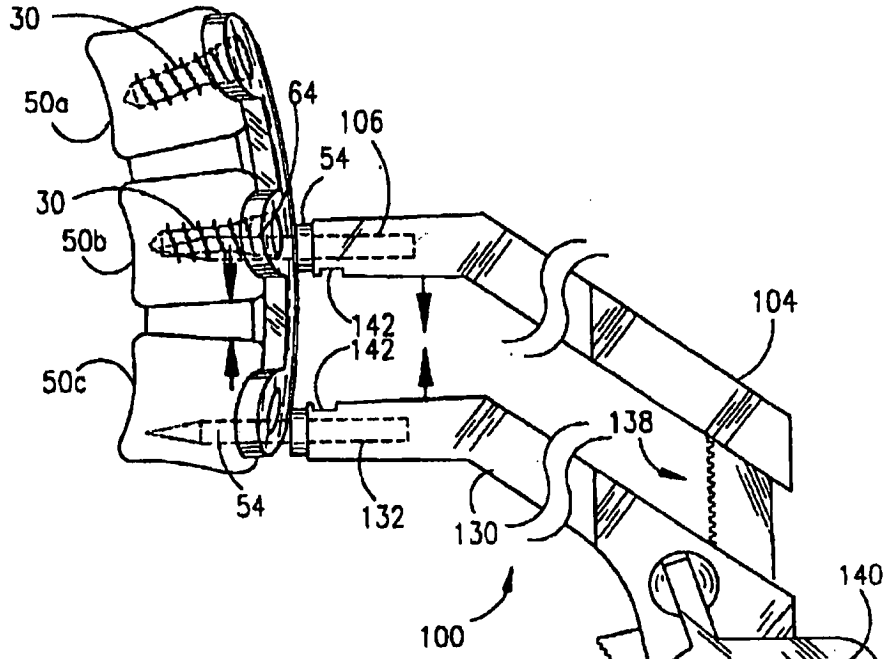


FIG 39

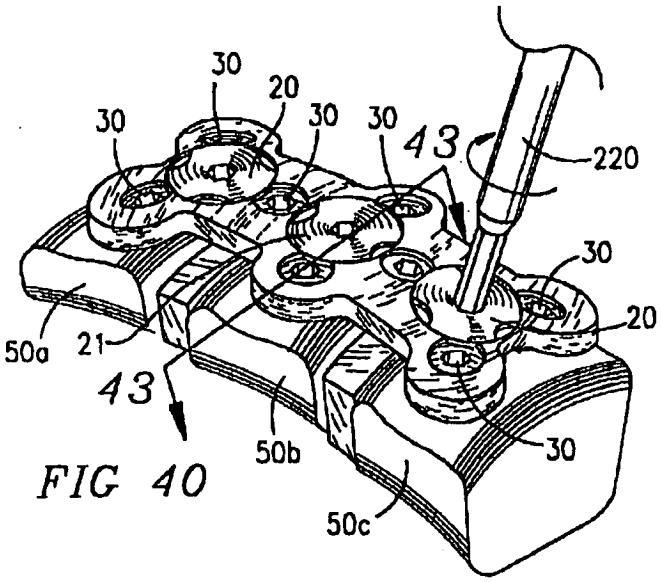


FIG 40

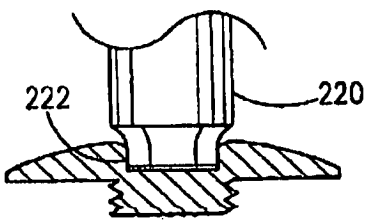


FIG 41

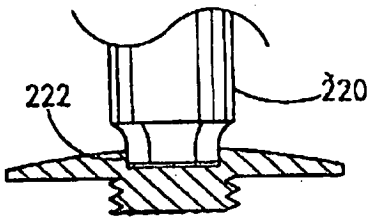


FIG 42

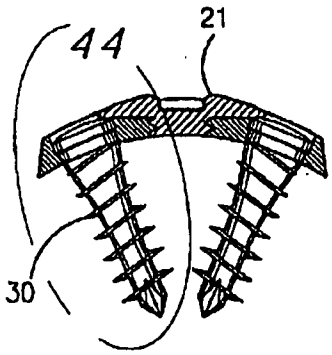


FIG 43

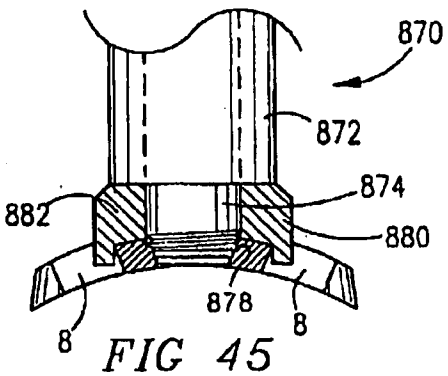


FIG 45

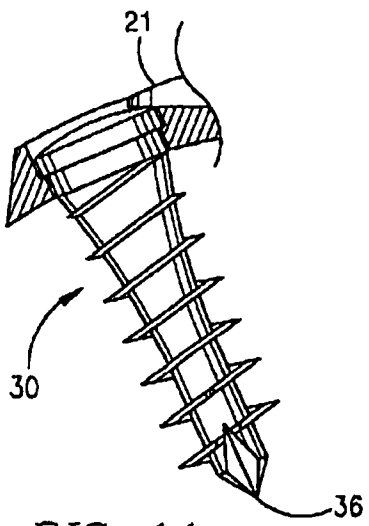


FIG 44

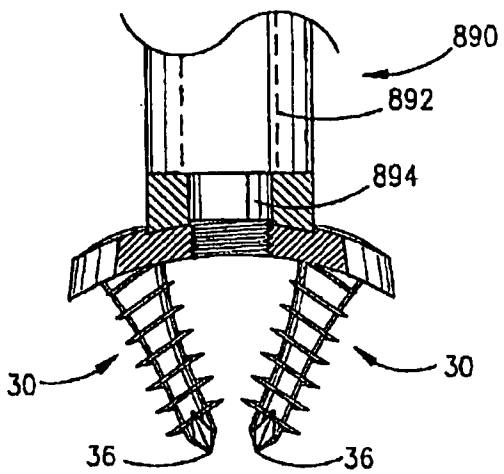


FIG 46

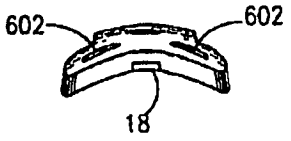


FIG 50

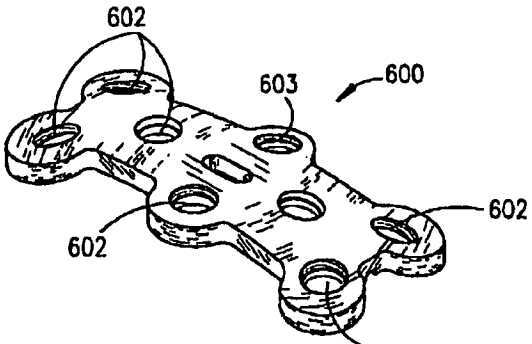


FIG 47

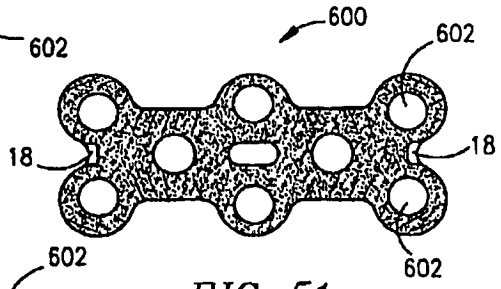


FIG 51

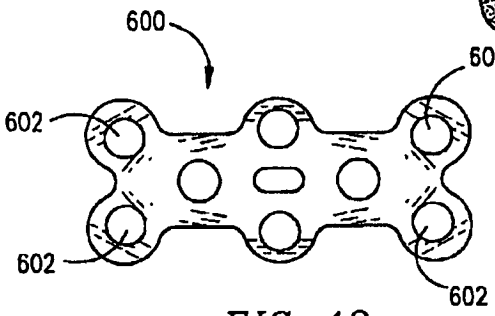


FIG 48

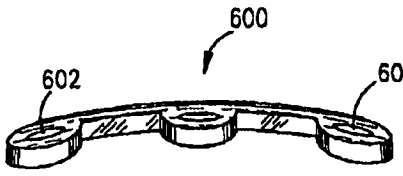


FIG 49

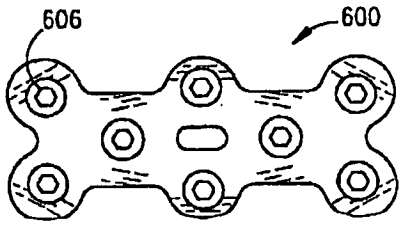


FIG 52

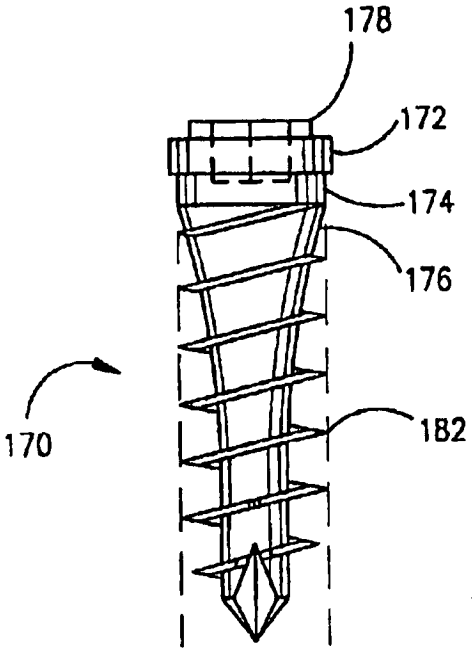


FIG 53

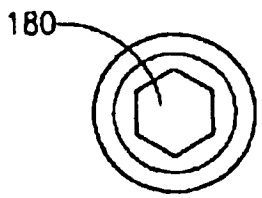


FIG 54

FIG 55

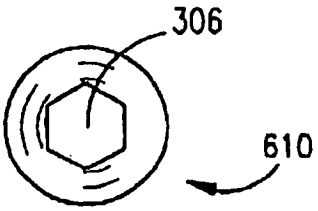


FIG 56

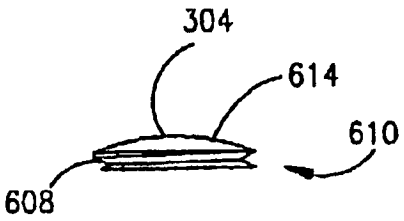


FIG 57

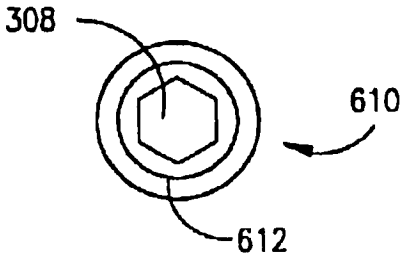


FIG 58

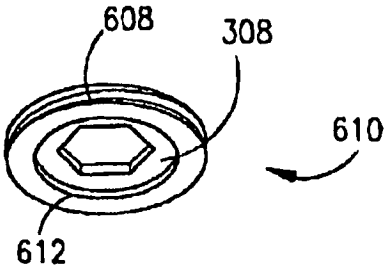


FIG 59

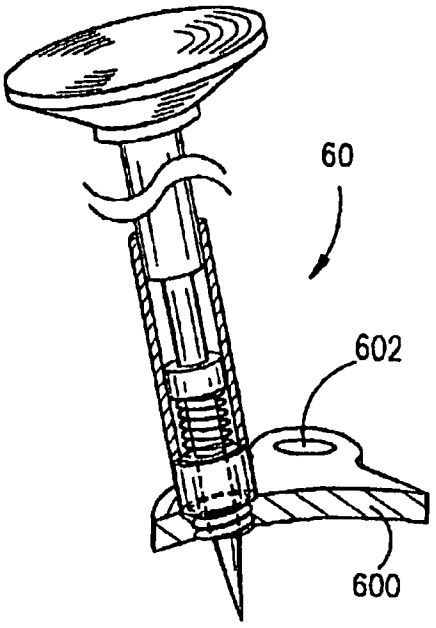


FIG 61

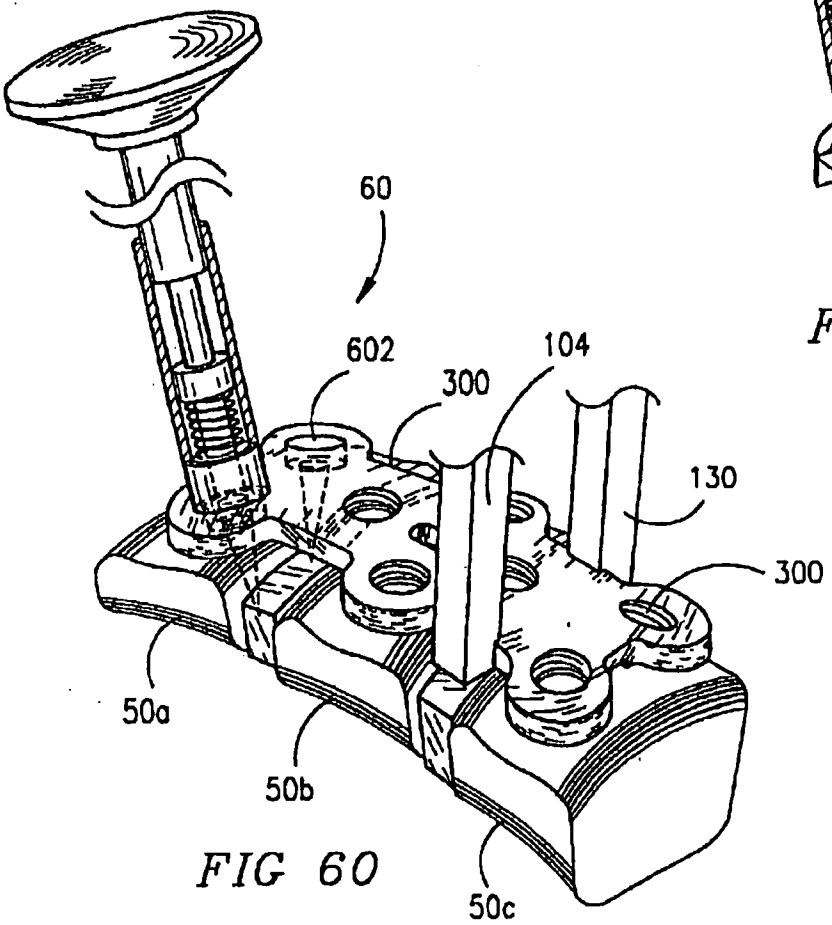


FIG 60

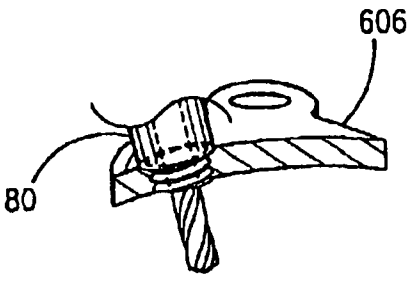


FIG 62

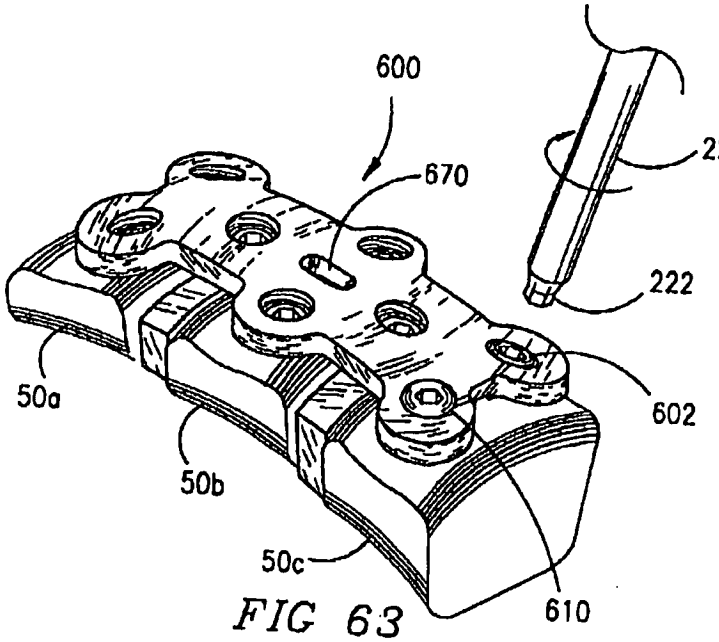


FIG 63

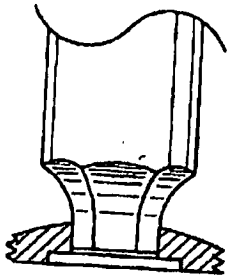


FIG 64

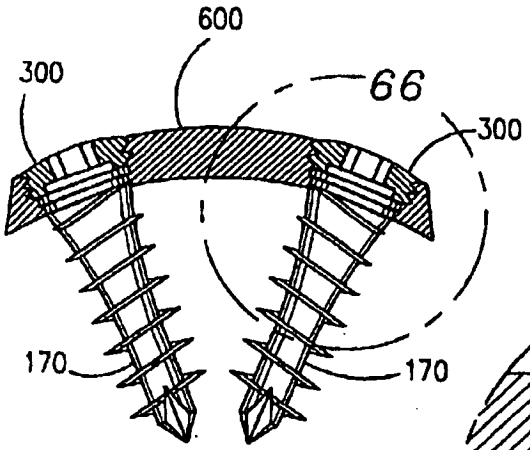


FIG 65

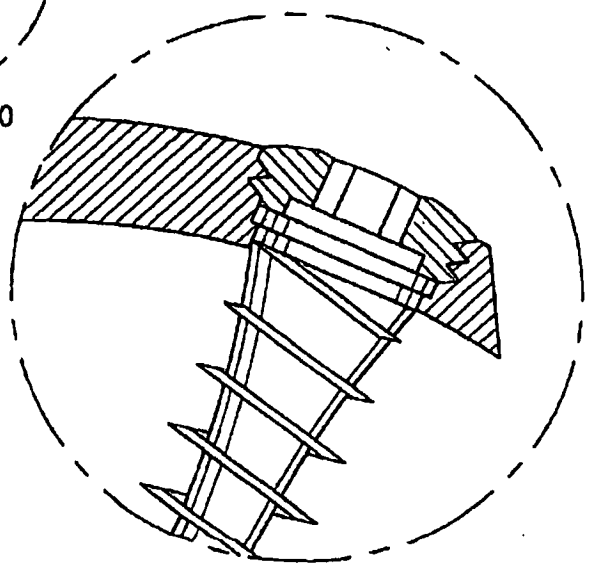


FIG 66

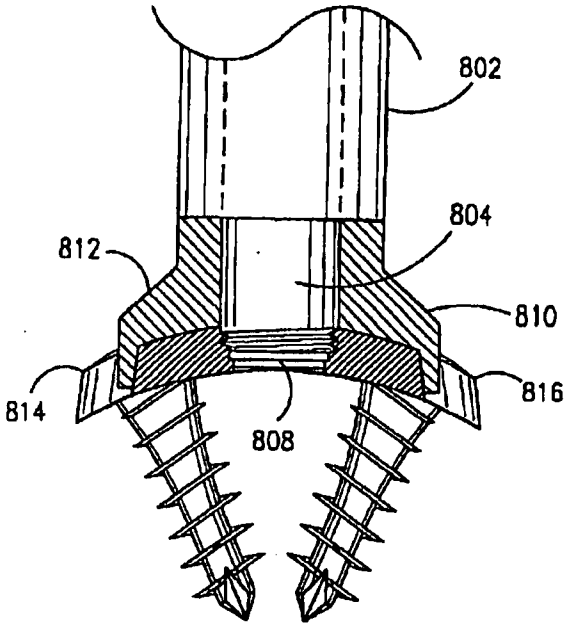


FIG 68

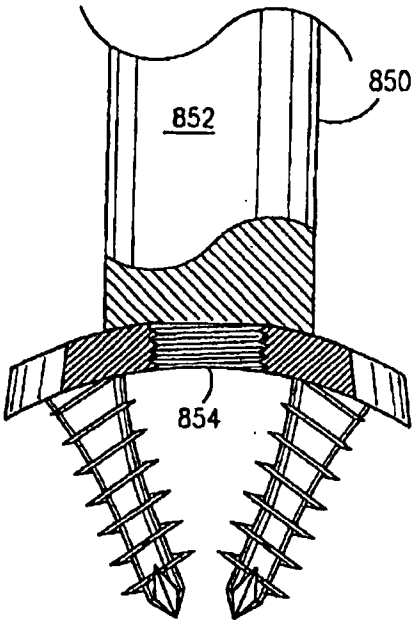


FIG 69A

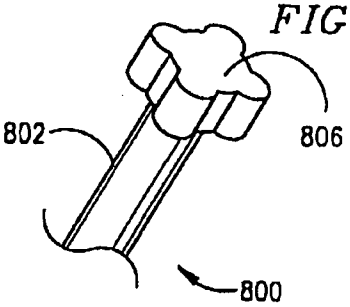
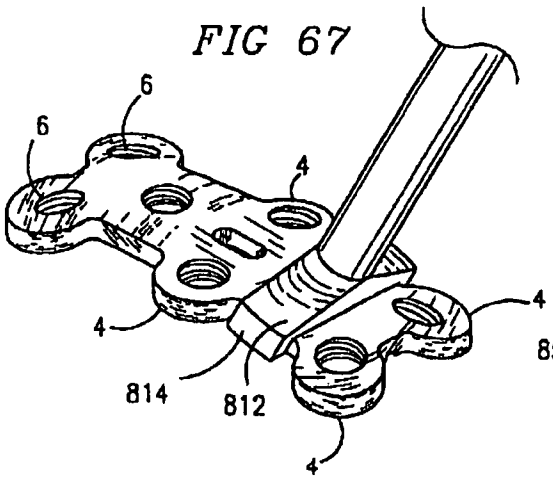


FIG 67



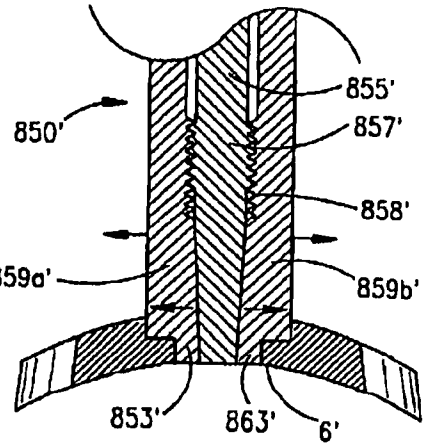


FIG 69B

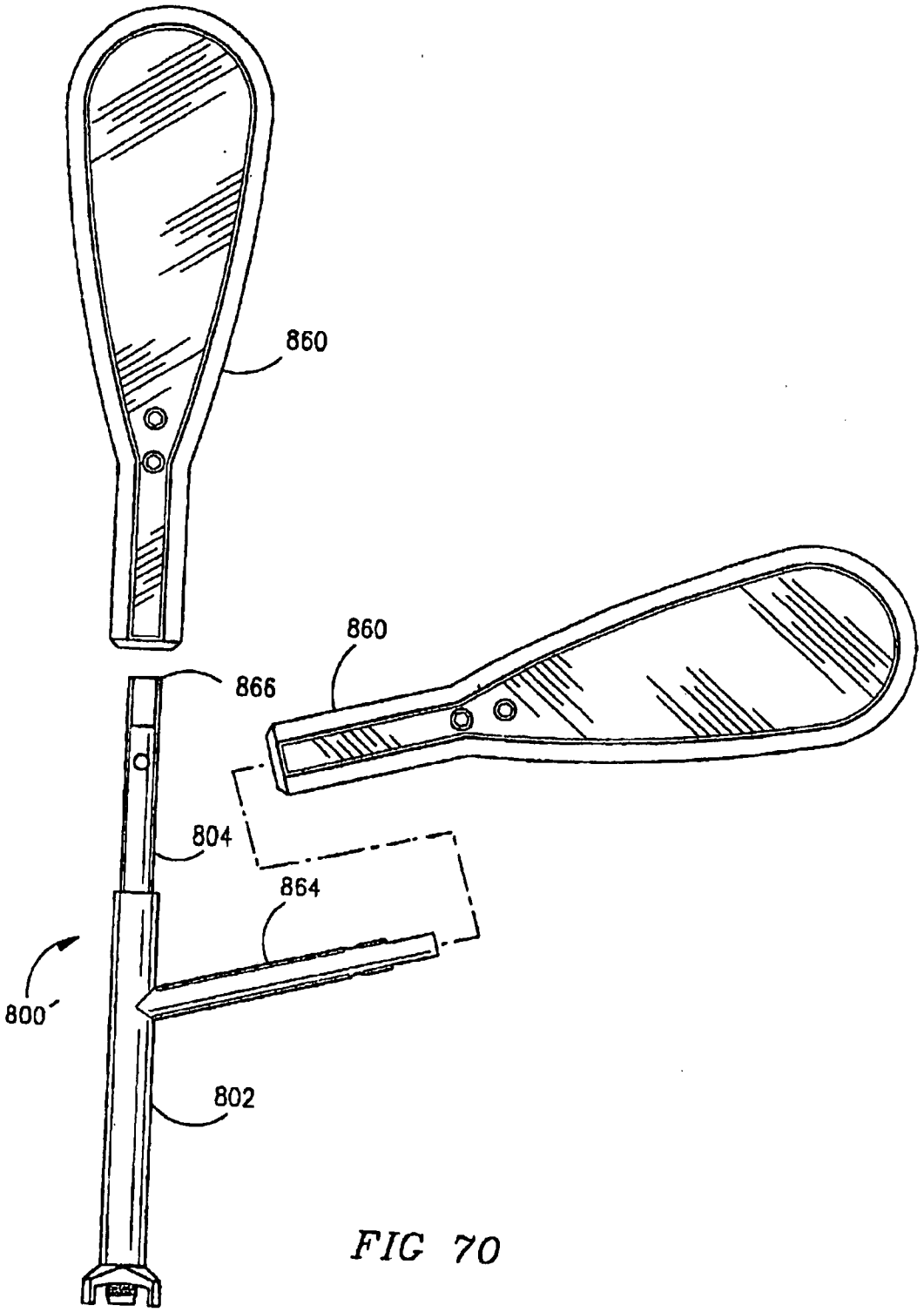


FIG 70

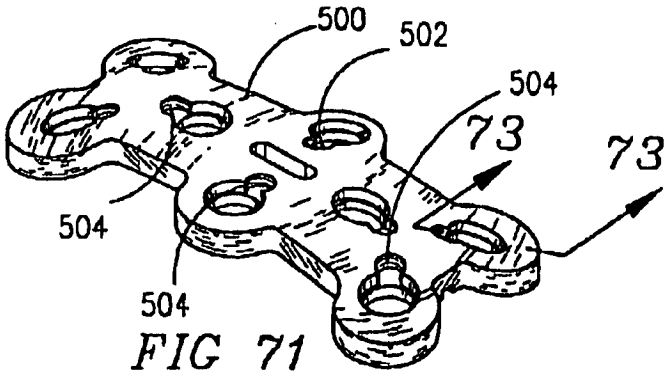


FIG 71

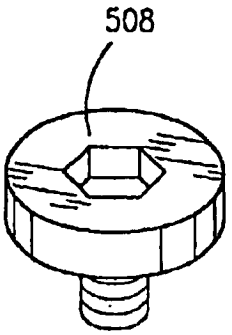


FIG 74

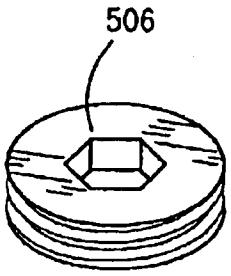


FIG 72

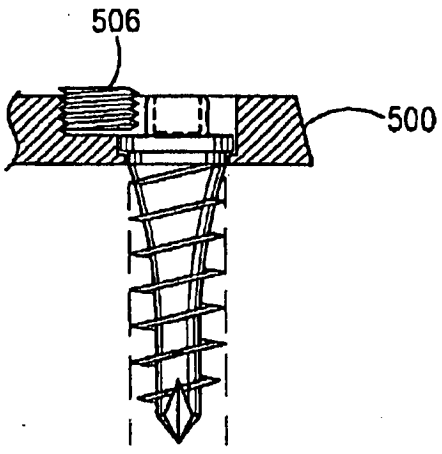


FIG 73

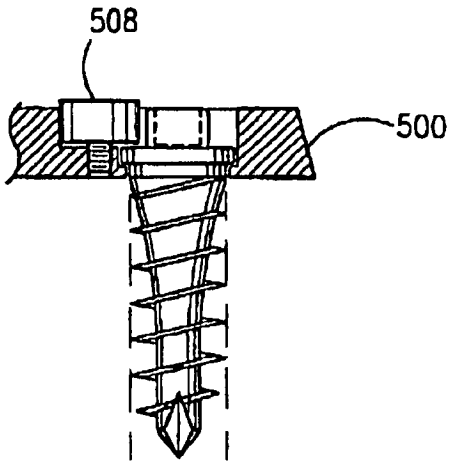


FIG 75

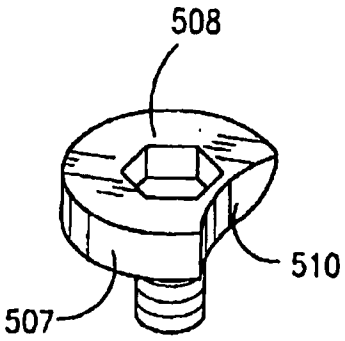


FIG 76

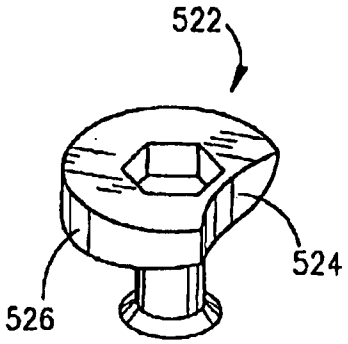


FIG 78

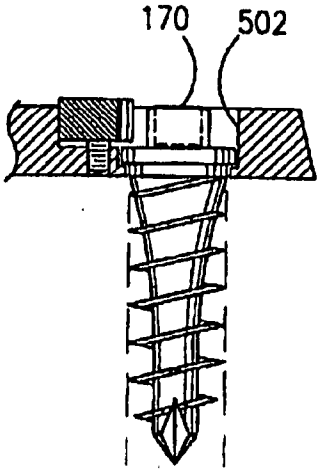


FIG 77

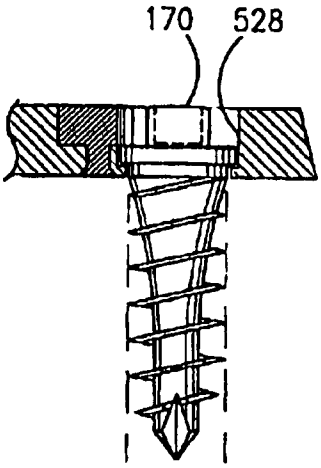
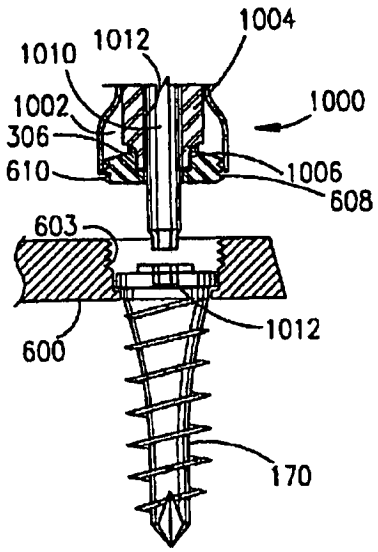


FIG 79


1004
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1000
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610
1006
608
603
1012
600
170

FIG 80

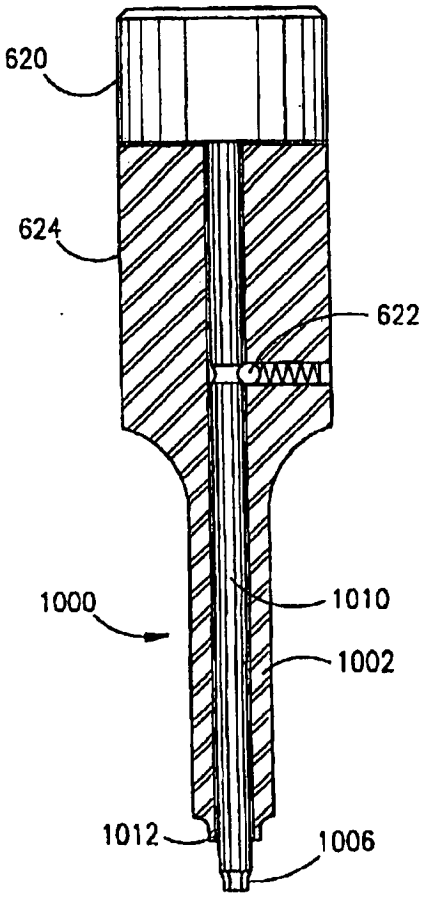
620
624
622
1000
1010
1002
1012
1006

FIG 81

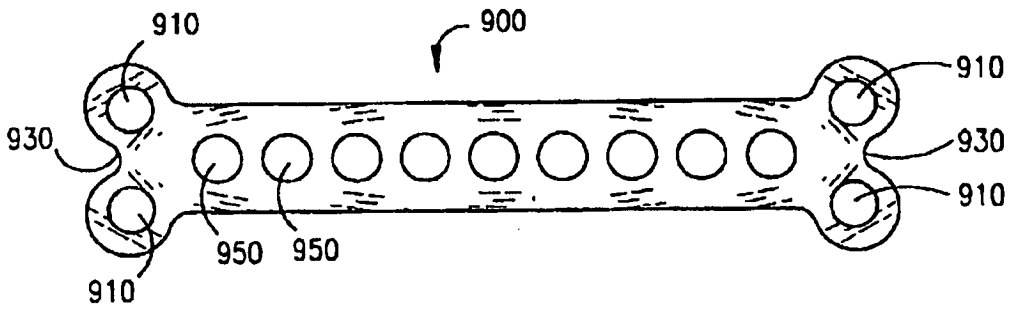

FIG 82

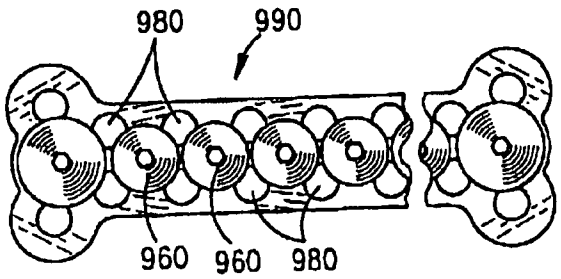

FIG 83

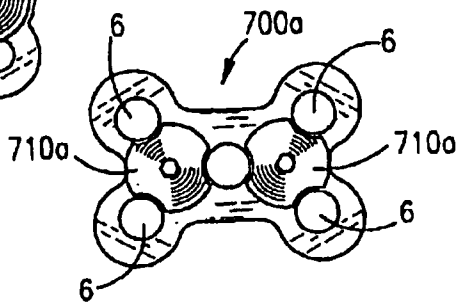

FIG 84A

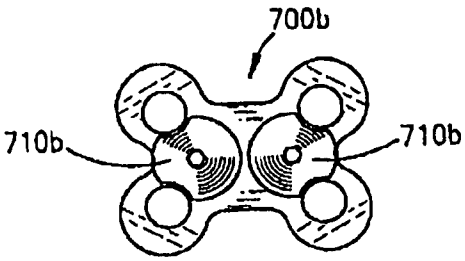

FIG 84B

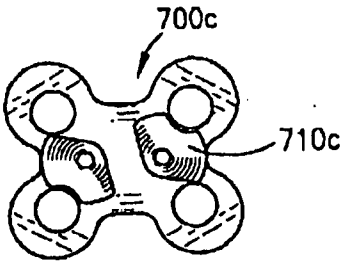

FIG 84C

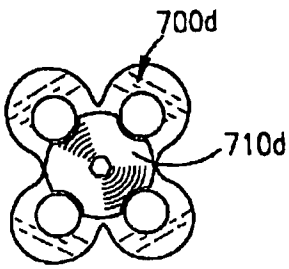

FIG 84D

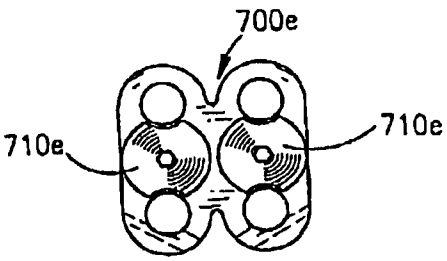

FIG 84E

MULTILOCK ANTERIOR CERVICAL PLATING SYSTEM

RELATED APPLICATIONS

This application is a divisional of application Ser. No. 10/386,275, filed Mar. 11, 2003; which is a divisional of application Ser. No. 09/618,036, filed Jul. 17, 2000, now U.S. Pat. No. 6,620,163; which is a divisional of application Ser. No. 09/022,293, filed Feb. 11, 1998, now U.S. Pat. No. 6,193,721; which claims the benefit of U.S. provisional application Ser. No. 60/037,139, filed Feb. 11, 1997; all of which are incorporated herein by reference. Application Ser. No. 09/022,344, filed Feb. 11, 1998, and titled SKELETAL PLATING SYSTEM, now U.S. Pat. No. 6,139,550, is incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to implants, method, and instrumentation for fusion of the human cervical spine from the anterior aspect, and in particular to plate systems for aligning and maintaining adjacent cervical vertebrae in a selected spatial relationship during spinal fusion of those vertebrae.

2. Description of the Related Art

It is current practice in the art to use cervical plating systems for this purpose. Such systems are composed essentially of plates and screws for aligning and holding vertebrae in a desired position relative to one another. The earliest such devices consisted of stainless steel plates and screws and required that the screws passed entirely through the vertebrae and into the spinal canal in order to engage the strong bone tissue (the posterior cortex) of the vertebral bodies. This required the ability to observe or visualize this area radiographically, which is not always possible, especially in the lower cervical spine where the vertebrae may be hidden radiographically by the shoulders.

In order to form holes in the vertebral bodies for insertion of each screw, a drilling operation was performed, followed by a tapping operation. Each of these operations involved the passage of an instrument entirely through the associated vertebral body and into the spinal column. Thus, these instruments come into close proximity to the spinal cord and the dural sac which are in close proximity to the back surfaces of the vertebral bodies. Any procedure which introduces an object into the spinal canal presents serious risks which are of concern to the surgeon.

The conventional technique of forming a bone screw receiving hole in vertebral bodies by drilling has a number of significant disadvantages. For example, drilling removes bone material, leaving a void and resulting in a loss of bone material. Drilling also causes microfracturing of the bone at the drill bit-bone interface and the resulting fracture lines tend to propagate in directions perpendicular to the wall of the hole. More specifically, the bone material is essentially a type of ceramic which exhibits a brittle pattern of fracture formation and propagation in response to drilling. Furthermore, drilling generates heat which can result in thermal necrosis of the bone material precisely at the interface between the bone and a subsequently installed screw, where necrosis is most harmful. Any bone which does experience necrosis will subsequently be resorbed by the body as part of the bone repair process and this can lead to the loosening of the screw.

Another problem with drilling is that the path of the drill bit is difficult to control and since the drill bit operates by rotation, it can wind up soft tissue about the associated plate. In addition, unless great care is taken, the drill bit may be driven significantly past the posterior cortex and cause irreparable harm within the spinal canal. Finally, a drill bit may bind and fracture within the vertebral body and can then cause serious injury as the still rotating portion of the drill bit passes into the wound, while the portion of the bit which has broken off may either protrude dangerously from the vertebral body or may be broken off flush with the upper surface of the body so as to be irretrievably embedded therein. In any event, the steps that must be taken to retrieve the broken-off portion of a drill bit will inevitably prolong and complicate the surgical procedure.

In known plating systems, there have been problems with loosening and failure of the hardware; breakage of the screws and plates, and backing out of screws into the patient's throat area. These occurrences generally require further surgical procedures to replace the broken parts or the plates and screws entirely, and to repair any damage that may have been caused.

Other problems which have been encountered with known systems result from the failure of the screws to achieve a sufficient purchase in the bone and the stripping of the screws. Also, the use of the known plating systems may result in a loss of lordosis, which is the normal curve of the cervical spine when viewed from the side.

Known plating systems additionally experience problems in connection with those procedures where bone grafts are placed between vertebral bodies to achieve an interbody fusion which heals by a process called "creeping substitution". In this process, bone at the interface between the graft and a vertebra is removed by a biological process which involves the production of powerful acids and enzymes, as a prelude to invasion of the interface by living tissue and the deposition, or growth, of new bone. While the plates allow for proper alignment of the vertebrae and their rigid fixation, they can therefore, at the same time unfortunately, hold the vertebrae apart while the resorption phase of the creeping substitution process forms gaps in the bone at the fusion site with the result that the desired fusion does not occur. Such failure is known as pseudoarthrosis. When such a failure occurs, the hardware itself will usually break or become loosened from the spine, thus requiring a further surgical procedure to remove the broken components and another surgical procedure to again attempt fusion.

In response to the problems described above, a second generation of plating systems has been developed and/or proposed. These include a system disclosed in U.S. Pat. No. 5,364,399 to Lowery and U.S. Pat. No. 5,423,826 to Morscher, as well as cervical spine locking plating systems offered by SYNTHES Spine, the DANEK ORION plate, the CODMAN SHURTLEFF plate, and the SMITH NEPHEW RICHARDS plate, among others. The systems' forming members of this second generation have a number of common properties. They are all made of either a titanium alloy or pure titanium rather than stainless steel, to minimize adverse tissue reactions and are MRI compatible, which stainless steel is not. The screws and the plates have been given increased thickness in order to achieve increased strength. The screws have larger diameters to improve their purchase without requiring that they engage the posterior cortex of the vertebral bodies. Some mild longitudinal contouring of the plates is employed to allow for some lordosis, and/or limited transverse contouring to better follow the generally curved aspect of the front of the vertebral bodies. Mechanisms are employed for securing the vertebral bone screws to their associated plates in a manner to prevent

the screws from backing out. While this second generation of plating systems represents a significant improvement over earlier systems, certain existing problems persist, while new problems have been created.

For example, since the screws no longer extend into the posterior cortex, it is common for the threads in the tapped screw hole to become stripped and for the screws to fail to gain a suitable purchase. In addition, screw breakage continues to be experienced and occurs most commonly at the junction of the screw to the posterior aspect of the plate. The screws employed in both the SYNTHES system and the SMITH NEPHEW RICHARDS system are particularly vulnerable to this problem because those screws are hollow at the level where they attach to the plate to permit the internal reception of locking screws.

In an attempt to prevent screw to plate junction breakage of the screw, more recent designs of screws have an increasing root diameter from tip to head, which thus far has resulted in a near useless stubby and blunt thread near the screw head with little holding power and little tactile feedback to the surgeon to signal the completion of tightening prior to stripping of the screw within the bone. Based on empiric studies testing these prior art screws, the use of a pretapped hole, rather than a self-tapping screw, was found to be preferred for pullout strength and thus these screws have not been self-tapping and thus the screw holes must be pre-tapped. Since the thread cutting portion of a tap is necessarily sharp and rotated to work, there is a serious risk of damage to the surrounding soft tissues when it is used. This is compounded by the fact that the plates employed in these systems do not provide sufficient long axis contouring to make full allowance for lordosis and do not have sufficient transverse contouring to prevent rocking of the plate about its longitudinal axis and to conform to the anterior shape of the vertebral bodies, so that these plates do not prevent soft tissue from creeping in from the sides and beneath the screw holes thus exposing these tissues to damage by the drill and the tap. While it is possible, at the time of surgery, to make some change in the contouring of these plates, this is generally limited to contouring of the longitudinal axis and quite often causes distortion of the plate's bone screw holes and screw hole to plate junctions in a manner which has an adverse effect on the screw-plate interlock. Lack of proper contouring prevents these plates from having an optimally low profile relative to the spine.

In some of the second generation cervical plating systems, screw backout continues to occur, because these plates could not be designed to allow for the locking of all of the screws. Specifically, while the designers of these plates recognized the importance of securing the bone screws to the plates, they were unable to lock all of the screws and had to settle for leaving some of the screws unlocked.

Furthermore, several of these second generation systems utilize tiny and delicate "watchmaker" parts to achieve interlocking. These parts are characterized by the need to engage them with particularly delicate small ended screw drivers. These interlocking components are easily rendered ineffective by any effort to alter the contours of a plate during surgery.

Despite the improvement of these second generation plating systems over the first problems, the problems still persist, the most important of which is pseudoarthroses, and particularly "distraction pseudoarthroses". Although these second generation plates have clearly led to an increase in fusion rate, when a failure to produce fusion occurs, it is generally accompanied by bone resorption along a line at the graft-to-vertebra junction, which can be seen on a radiograph.

In the case of the weak first generation plates and screws, the plates might hold the vertebrae apart, preventing fusion, but only until the hardware would break, relieving the distraction, and then allowing the fusion to occur. The second generation systems of plates are too strong to allow this to occur, thus requiring further surgical procedures for the correction of the pseudoarthroses.

Compression plates are well known and are widely used in orthopedic surgery for the stabilization of tubular bones, and sometimes also flat bones. Such plates may rely on some external compression means or may be self-compressing, relying on the ability of the screw head to slide within a ramped slot such that the tightening of the bone screws through the plate imparts a linear motion perpendicular to the screw axes. U.S. Pat. No. 5,180,381 discloses an attempt to employ such a mechanism in connection with anterior spinal fixation.

However, it has been found that all of the proposed self-compressing plating systems have in common the need for a screw to engage both a proximal and a distal cortex, (bone casing of very dense bone material), so as to anchor the screw tip in a manner to allow the plate to move relative to the screw when tightened rather than allowing the plate to drag the screw off axis. However, as already discussed earlier herein, when a screw is to engage the posterior cortex of the vertebral body, it is necessary for the drill and the tap which form the screw hole, as well as the screw tip itself, to all enter the spinal canal, thereby exposing the spinal cord to damage.

While the system disclosed in U.S. Pat. No. 5,180,381 avoids such danger by engaging the vertebral body end plate instead of the posterior vertebral body cortex, the path of the screw is of necessity quite short, so that there is very little opportunity for the screw threads to achieve additional purchase within the vertebral body. It would therefore appear that to the extent that the device disclosed in U.S. Pat. No. 5,180,380 is able to achieve its stated objectives, it would pull the front of the spine together more than the back and would not appear to compress the back of the vertebral bodies at all, thus producing an undesirable iatrogenic loss of the normal cervical lordosis. Such a situation is disruptive to the normal biomechanics of the cervical spine and potentially quite harmful.

The creation of compression between adjacent vertebrae would offer a number of advantages, including reduced distraction pseudoarthrosis, increased surface area of contact between the graft and vertebrae as slightly incongruent surfaces are forced together, increased osteogenic stimulation, since compressive loads stimulate bone formation, and increased fusion graft and spinal segment stability.

Among the new problems created by these second generation systems is a tendency for the small "watchmaker" parts used to lock the bone screws to the plate to fall off of the driver used for attaching those parts, or out of the associated plates and to become lost in the wound. In addition, these small parts are quite fragile and require specialized additional instruments for their insertion and/or manipulation. Furthermore, incorrect bone screw placement relative to the axis of a plate hole may render the screw locking mechanism unworkable or may cause sharp and jagged shavings of titanium to be formed as a locking screw is driven into contact with an improperly seated bone screw. The means for establishing bone screw to plate hole alignment and preparation are less than reliable. Furthermore, most of these second generation systems lack a reliable and effective means for positioning and holding the plate during attachment.

Specific features of various prior art systems will be summarized below.

The system disclosed in U.S. Pat. Nos. 5,364,399 and 5,423,826, cited earlier herein, includes a thin stainless steel plate which allows for side-by-side or offset bicortical screw placement, the plate having a combination of screw holes and slots.

The "Acromed" system includes a titanium plate and screws which require bicortical screw placement. This system does not include any locking means for the bone screws.

The system disclosed in U.S. Pat. No. 5,180,381 includes an "H" shaped plate having a combination of ramped slots and a hole which requires bicortical screw placement at a 45N angle to the plane of the plate. This patent discloses that this angular positioning is for the purpose of producing compression.

The SYNTHES Morscher plate system employs hollow, slotted screw heads. The screws are placed unicortically so that the heads, when properly aligned, come to rest in the upper portion of the plate holes. The upper portion of each screw is internally threaded to receive a tiny screw which is screwed into the bone screw head in order to increase the interference fit between the bone screw head and the wall of the associated plate hole.

In the system disclosed in U.S. Pat. Nos. 5,364,399 and 5,423,826, use is made of pairs of unicortical bone screws that may be locked in place at both ends of the associated plate by locking screws which have a small diameter shank and a large head. At each end of a plate two bone screws may be locked in place by a single locking screw which is situated between the bone screws. Generally, the plate is provided, between its two ends, with a diagonal slot or slots for receiving one or more additional screws, each additional screw being securable in a bone graft or a respective vertebra which is spanned by the plate. There is no locking screw associated with these intermediate bone screws to lock the bone screws to the plate.

The Codman Shurtleff plating system utilizes the side of a preinstalled rivet having a head rotatable to press against the side of the head of a bone screw so as to secure that one screw to the plate. The plates of this system also are provided with holes for receiving intermediate screws, but these screws are not associated with any locking means.

While the designers of the last-mentioned systems recognized the importance of locking the bone screws in position on their associated plates, they did not provide for any locking of the intermediate bone screws in their associated holes.

In an earlier version of the Codman Shurtleff system, the locking mechanism was a lever pivotable about a shaft passing entirely through the plate and then flared so as to retain the shaft within the plate. The lever was rotated after the bone screw had been inserted to engage the head of the bone screw and thus secure the bone screw to the plate.

Based on a consideration of the features of all of the known cervical plating systems, it appears that there remains a need for an improved system having the following combination of features:

1) The plate should be sufficiently strong to perform its intended function without mechanical failure;
2) The plate should be preformed in three dimensions so as to anatomically conform in both the longitudinal and transverse planes to the anterior cervical spine;
3) The plate should be constructed so that all of the bone screws are generally perpendicular to the plate when viewed from the side, but pairs of screws are highly convergent corresponding to any vertebral level when viewed from the bottom, or on end;
4) Each pair of screws engages in a respective vertebra and the high convergence of screws in a pair allows the length of the screws which engage the bone to be longer and still remain within that vertebra and provide a safer and stronger engagement with the vertebrae;
5) The system should include bone screws which are capable of achieving enhanced purchase within the bone of the vertebral body and without the need to penetrate the posterior vertebral cortex and enter the spinal canal;
6) Use should be made of a screw which is self-tapping, thereby eliminating the need for separate tapping steps;
7) A reliable means should be provided for engaging and manipulating the plate during installation;
8) The plate should be engageable with an instrument means which can reliably produce bone screw holes which are coaxial with the screw holes in the plate;
9) It should be possible to prepare the vertebral bone to receive the bone screws so as to produce a stronger connection and a reduced danger of thread stripping by means of a pilot hole punch creating a pilot hole for the bone screws;
10) Alternatively to the use of a pilot hole punch, a relatively (compared to the overall root diameter of the screw) small diameter drill may be used to create the pilot hole.
11) Means should be provided for locking each and every bone screw in position relative to the plate, and the locking means should be of sufficient size and strength to reliably perform its intended functions;
12) Bone screw locking means should preferably be retainable by the plate prior to bone screw insertion, or should be reliably attachable to a driver to prevent any small parts from becoming loose in the wound; and
13) The system should be capable of effecting compression of the vertebral segments to be fused while maintaining and/or restoring lordosis.

OBJECTS OF THE INVENTION

It is an object of the present invention to provide an improved anterior cervical plating system, installation instrumentation, and installation method which has the above described features and which avoids many of the shortcomings of previously known systems.

One object of the present invention is to provide a locking mechanism where a plurality of bone screws used for attaching the plate to the vertebrae can be easily and reliably locked in place at the same time by a single operation.

Another object of the present invention is to provide a vertebral plate in which the locking mechanisms for locking the bone screws may be pre-installed by the manufacturer prior to the insertion of the bone screws by the physician so that the physician does not have to attach the locking mechanism to the plate as a separate procedure during the operation.

Another object of the invention is to provide an anterior cervical plating system which allows for the intersegmental compression of the spinal segment (compression of the adjacent vertebrae and the fusion graft in the disc space between the adjacent vertebrae) in lordosis, and similarly, where desired, multisegmental compression.

A further object of the invention is to provide bone screws which provide for tactile feedback to the surgeon to assure sufficient tightening of the screws while avoiding stripping and are less prone to failure by breakage or by loosening.

Another object of the invention is to provide bone screws which achieve optimal purchase within the bone, without the need to penetrate the posterior cortex of the vertebrae.

A further object of the invention is to provide plates which are textured or otherwise treated to promote bone growth from vertebrae to vertebra beneath the plate.

Another object of the invention is to provide a plate which is constructed to reliably engage an instrument for forming all bone screw holes coaxial with the holes formed in the plate, the instrument having integral depth limiting means which completely eliminates the danger of perforation of the posterior vertebral wall or entry into the spinal canal.

Yet another object of the invention is to provide a system in which the bone screws and locking mechanisms, when fully installed, have a low profile.

It is another object of the present invention to provide for an anterior cervical plating system which is at least in part bioresorbable.

It is another object of the present invention to provide for an anterior cervical plating system comprising at least in part of bone ingrowth materials and surfaces.

It is another object of the present invention to provide for an anterior cervical plating system comprising at least in part of bone growth promoting substances.

It is another object of the present invention to provide instruments for reliably and easily performing the installation of the plates of the present invention.

It is still another object of the present invention to provide an improved method of installing the plates of the present invention.

The above and other objects and features of the invention will become more readily apparent from the following description of preferred embodiments of the invention, provided with reference to the accompanying drawings, which illustrate embodiments of the invention solely by way of non-limiting example.

SUMMARY OF THE INVENTION

The plating system of the first preferred embodiment of the present invention comprises a plate having a length sufficient to span a disc space and to overlap, at least in part, at least two adjacent cervical vertebrae, a substantial portion of the lower surface of the plate preferably being biconcave, that is concave curved along a substantial portion of the longitudinal axis of the plate and concave curved along a substantial portion of the transverse axis of the plate. The lower surface of the plate may also textured and/or treated to induce bone growth along the lower surface of the plate which contacts the cervical vertebrae. The plate is provided with a plurality of bone screw receiving holes which extend through the plate, from the upper surface to the lower surface of the plate, and at least one locking element is associated with the bone screw receiving hole. The plate and its component parts, may be made of any implant quality material suitable for use in the human body, and the plate and associated component may be made of a bioresorbable material.

Bone screws are each insertable into a respective bone screw receiving hole for attaching the plate to a vertebra. A locking element, is engageable to a locking element receiving recess and has a head formed to lock the bone screws to the plate. In the preferred embodiment, a single locking element locks a number of different bone screws in place. The locking elements are pre-installed prior to use by the surgeon in a manner so as to not impede installation of the bone screws.

As a result, the problems previously associated with the locking screws of the type applied after the insertion of the bone screws, including the problems of instrumentation to position and deliver to the plate the locking means, backing out, breakage, stripping and misthreading associated with the prior art more delicate locking screws resembling "watchmaker's parts", are eliminated.

In an alternative embodiment of the present invention, a locking element fits within a respective bone screw receiving hole to lock a respective one of the bone screws in place. According to this second embodiment of the invention, each of the bone screws is locked to the plate by means of an individual locking element which bears against at least a portion of the bone screw. Since no other holes need be formed in the plate to attach the locks to the plate, the plate remains quite strong.

The locking elements can be in many forms to achieve their intended purpose, such as, but not limited to, screws, threaded caps, rivets, set screws, projecting elements, and the like.

Also, a novel bone screw is disclosed so as to prevent pulling out of the bone screw during use. This is achieved by a design which includes a screw in which the outer diameter or crest diameter of the thread is maintained substantially constant along the entire length of the shaft of the bone screw, from below the head to above the tip, where threads of a lesser outer diameter facilitate insertion. The screw tip is fluted at its distal end to be self-tapping. The thread also has an extremely thin and sharp profile to cut into and preserve the integrity of the vertebral bone stock.

The plating system does not require that the head of the bone screw be hollow, or that additional holes be placed through the plate in addition to those provided for the passage of the bone screws. It will be appreciated that bone screws are weakened when their heads are hollow and that plates are weakened when they are provided with additional holes.

Additionally, the plate of the disclosed systems permit the proper aligning of the holes in the plate for the bone screws and for the plate to be easily applied to the vertebrae in compression. The plates include appropriate slots and engagement means for engaging compression instrumentation, described in detail below, for applying a compression force between adjacent vertebrae to which the plate is attached, in a reliable and easy manner.

An improved locking screw driver is provided. The driver provides for a wedged interference fit with a recess in the head of the bone screws and the head of the locking elements. The same driver is usable for both bone screws and locking elements. The driver ensures that the locking element cannot fall off the driver and become lost in the wound. The driver has a tapered end to facilitate insertion into the complimentary recess in the head of the screws and is used to engage and pick up the locking elements. Alternatively, the receiving socket can be tapered to the same purpose.

Alternatively, a combination bone screw and locking screw driver is disclosed in which the bone screw driver passes through a longitudinal opening in the locking screw driver so that both the bone screw and the locking screw can be loaded prior to insertion of the bone screw and both can be tightened with one instrument, without removing it from position.

Also, instruments are provided for forming pilot holes to assist in the ease and accuracy of the installment of the bone screws, and for creating a creating a compression force between adjacent vertebrae during installation of the plate and for holding the plate during installation.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a top perspective view of a first embodiment of a cervical spine multiple locking plate.

FIG. **2** is a top plan view of the cervical spine multiple locking plate shown in FIG. **1**.

FIG. **3** is a side elevational view of the cervical spine multiple locking plate shown in FIG. **1**.

FIG. **4** is an end view of the cervical spine multiple locking plate shown in FIG. **1**.

FIG. **5** is a bottom plan view of the cervical spine multiple locking plate shown in FIG. **1**.

FIG. **6** is a top plan view of the cervical spine multiple locking plate shown in FIGS. **1–5**, with locking elements installed in an open configuration.

FIG. **7** is a top plan view of a modification of the plate of FIGS. **1–6** with a four bone screw locking element in place.

FIG. **8** is a top plan view of a further embodiment of a cervical locking plate of FIG. **1** with an elongated central slot for increased compression capability.

FIG. **9** is a top plan view of a locking element for use with the plates of FIGS. **1–6**.

FIG. **10** is a top plan view of a locking element for use with the central opening of the plate of FIGS. **7** and **22**.

FIG. **11** is a top plan view of a locking cap for use in the end openings shown in FIGS. **1**, **6**, and **7**.

FIG. **12** is a side elevational view of the locking element of FIG. **16**.

FIG. **13** is a side elevational view of another embodiment of the locking element of FIG. **16**.

FIG. **14** is a top perspective view of an alternative embodiment of cervical spine multiple locking plate for use with locking rivets.

FIG. **15** is a bottom plan view of the cervical spine multiple locking plate of FIG. **14**.

FIG. **16** is a top plan view of a two bone screw locking element.

FIG. **17** is a top plan view of an alternative embodiment of a four bone screw locking element having head slits for increased flexibility of the locking tabs.

FIG. **18** is a bottom plan view of a rivet type locking element for use with the central opening of the plate of FIG. **14**.

FIG. **19** is a side elevational view of a rivet locking element.

FIG. **20** is a top perspective view of the bottom portion of the head of rivet of FIG. **19** viewed along lines **20—20**.

FIG. **21** is a top perspective view of the head portion of a three bone screw locking element.

FIG. **22** is a top perspective view of a third embodiment of a cervical spine multiple locking plate utilizing locking elements in the form of threaded caps.

FIG. **23** is a side elevational view of a locking element for use with the plate of FIG. **22**.

FIG. **24A** is a side elevational view of a bone screw in accordance with the present invention.

FIG. **24B** is an enlarged side elevational view of the bone screw of FIG. **24A**.

FIG. **25** is a side elevational view of an alternative embodiment of a bone screw in accordance with the present invention.

FIG. **26** is a bottom end view of the bone screw shown in FIG. **24A**.

FIG. **27** is a top end view of the bone screw shown in FIG. **24A**.

FIG. **28** is a top perspective view of a fourth embodiment of a cervical spine multiple locking plate.

FIG. **29** is a top perspective view of a locking element for use with the plate of FIG. **28**.

FIG. **30** is a partial side sectional view of the plate of FIG. **28** along lines **30—30** with a bone screw in place.

FIG. **31** is a top perspective view of the plate of FIG. **1** positioned against the anterior aspect of three successive vertebral bodies in the cervical spine, a plate holder, and an instrument for forming bone screw receiving holes in to the vertebral bodies.

FIG. **32** is a cross-sectional view of a portion of the bone forming device shown in FIG. **31** viewed along lines **32—32**.

FIG. **33** is a side elevational view in partial cross section illustrating a compression post tool and a compression post engaged to it for insertion into a vertebral body.

FIG. **34** is a side elevational view in partial cross section of the compression post tool engaged for removal of the compression post from the vertebral body.

FIG. **35** is a bottom end view of the compression post tool of FIG. **34**.

FIG. **36** is a side elevational view of a plate engaging hook for use with the compression apparatus shown in FIG. **38**.

FIG. **37** is a cross-sectional view through the plate of an alternative embodiment of a hole forming instrument in the form of a drill guide and drill for use during the plate installation procedure.

FIG. **38** is a side elevational view showing intersegmental compression of the spine and compression apparatus.

FIG. **39** is a view similar to that of FIG. **38** showing the compression apparatus in a further stage of the plate installation procedure.

FIG. **40** is a top perspective view showing the locking of the bone screws to the plate.

FIG. **41** is a partial side sectional view of a locking element attached to a driver instrument.

FIG. **42** is a partial side sectional view of another embodiment of the locking element attached to a driver instrument.

FIG. **43** is a partial cross-sectional view showing a cervical plate, locking element, and bone screws along lines **43—43** of FIG. **40**.

FIG. **44** is an enlarged portion of detail along line **44** of FIG. **43**.

FIG. **45** is a side view in partial cross section of a plate holder attached to a plate.

FIG. **46** is a side view in partial cross section of another embodiment of a plate holder attached to a plate.

FIG. **47** is a top perspective view of a first embodiment of a single locking plate.

FIG. **48** is a top plan view of the plate shown in FIG. **47**.

FIG. **49** is a side elevational view of the plate shown in FIG. **47**.

FIG. **50** is an end view of the plate shown in FIG. **47**.

FIG. **51** is a bottom plan view of the plate shown in FIG. **47**.

FIG. **52** is a top plan view of the plate shown in FIG. **47**, with locking elements in place.

FIG. **53** is a side elevational view of a bone screw used with the plate shown in FIG. **47**.

FIG. **54** is a top end view of the bone screw shown in FIG. **53**.

FIG. **55** is a bottom end view of the bone screw of FIG. **53**.

FIG. **56** is a top plan view of a locking cap for use with the single locking plate of FIG. **47**.

FIG. **57** is a side elevational view of the locking cap shown in FIG. **56**.

FIG. **58** is a bottom plan view of the locking cap shown in FIGS. **56** and **57**.

FIG. **59** is a bottom perspective view of the locking cap of FIGS. **56–58**.

FIG. **60** is a top perspective view of the single locking plate of FIG. **47** shown being held by a plate holder against three vertebral bodies, with the hole forming instrument for punching a pilot hole into the vertebral bodies for receiving a bone screw.

FIG. **61** is a side elevational view in partial cutaway of the hole forming instrument threaded to a bone screw receiving hole.

FIG. **62** is a perspective side sectional view of the drill and drill guide threadably engaged to the plate for drilling a hole for insertion of a bone screw.

FIG. **63** is a top perspective view of a single locking plate installed along a segment of the spine with two locking caps installed in two bone screw receiving holes.

FIG. **64** is a side elevational view in partial cross section of a locking cap engaged to a driver for installing the locking cap.

FIG. **65** is a partial cross sectional view of the plate, bone screws and locking caps along line **65—65** of FIG. **63**.

FIG. **66** is an enlarged fragmentary view of area **66** of FIG. **65**.

FIG. **67** is a perspective view of a cervical locking plate being held by an alternative plate holder instrument.

FIG. **68** is an end sectional view showing the plate holder of FIG. **67** engaging a plate.

FIG. **69A** is an end sectional view of an alternative embodiment of the plate holder.

FIG. **69B** is an end sectional view of another alternative embodiment of the plate holder.

FIG. **70** is a plate holder instrument with an offset and removable handle.

FIG. **71** is a top perspective view of a second embodiment of a cervical single locking plate having individual locking elements to lock each bone screw.

FIG. **72** is a top perspective view of a threaded locking element for use with the cervical single locking plate of FIG. **71** FIG. **73** is a partial side sectional view of the plate of FIG. **71** viewed along lines **73—73** with the locking element of FIG. **72** in place to hold a bone screw, but not fully tightened.

FIG. **74** is a top perspective view of an alternative locking element for use with a first modification of the cervical single locking plate of FIG. **71**.

FIG. **75** is a side sectional view of the first modification of the plate of FIG. **71** with the locking element of FIG. **74**.

FIG. **76** is a perspective view of an alternative locking element for use with the first modification of the plate of FIG. **71**.

FIG. **77** is a partial side sectional view of the first modification of the plate of FIG. **71** with the locking element of FIG. **76** in place.

FIG. **78** is a top perspective view of another alternative locking element in the form of a rivet for use with a second modification of the locking plate of FIG. **71**.

FIG. **79** is a partial side sectional detail view of the plate of FIG. **71** modified to use a locking element of FIG. **78** shown in place.

FIG. **80** is a partial cross sectional view of a plate and bone screw with the end of a tool shown for use in inserting both the bone screws and locking caps.

FIG. **81** is a side elevational view of another embodiment of the tool of FIG. **80**.

FIG. **82** is a further embodiment of a cervical spine single locking plate for use in stabilizing multiple segments of the spine.

FIG. **83** is a further embodiment of a cervical spine multiple locking plate for use in stabilizing multiple segments of the spine.

FIGS. **84A–84E** are various embodiments of cervical spine multiple locking plates for use in stabilizing a single segment of the spine.

DETAILED DESCRIPTION OF THE DRAWINGS

The present invention will be described first in association with the preferred embodiment of the plate system in which a plurality of bone screws are locked in place with one locking element. This is referred to as the multiple locking plate system. The multiple locking plates will be described, then the locking elements for locking the bone screws to the plate, then the bone screws associated with the multiple locking plates, and finally the instrumentation and method of installation of the multiple locking plates. Thereafter the plate systems in which a single locking element locks a single bone screw will be described. This is referred to as the single locking plate system. The locking elements, bone screws, instrumentation, and method of installation associated with the single locking plate will then be discussed.

1. Multiple Locking Plate System

The preferred embodiment of the multiple locking anterior cervical locking plate **2** according to the present invention (here shown by way of example for use in a two level fusion (three adjacent vertebrae)) is shown in FIGS. **1–5**. Plate **2** has a generally elongated form whose outline generally departs from rectangular due to the presence of lobes or lateral projections **4** at the corners and at the center of the sides of plate **2**. Each lobe **4** has a rounded outline and contains a respective circular bone screw receiving hole **6**. Two additional intermediate circular bone screw receiving holes **8** are located inwardly of the sides of plate **2** and are centered on the longitudinal center line of plate **2**. Lobes **4** give plate **2** additional strength in the region surrounding each bone screw receiving hole **6**. It is recognized that other shapes for the plate **2** may be employed.

The intermediate paired bone screw receiving holes **8** are for use with a two level (three vertebrae) fusion. The intermediate bone screw receiving holes **8** may be eliminated for a single level (two vertebrae) fusion, or additional intermediate bone screw receiving holes **8** may be added if additional levels are to be fused.

Plate **2** is further provided with three locking element holes **12**, each of which in the preferred embodiment is internally threaded **3**, and each of which is surrounded by a shallow countersunk region **14**. As will be described in greater detail below, in the preferred embodiment, bone

screws are inserted in the bone screw receiving holes and a single pre-installed locking element associated with each of the locking element holes **12** locks a number of bone screws **30** in position at one time.

The number of paired bone screw holes generally correspond to the number of vertebrae to be fused. A plate for a one level fusion could have but a single locking element hole **12**, while plates for fusing more than two levels (three vertebrae) could have additional middle locking element holes **12** corresponding to additional paired bone screw holes. In the embodiment illustrated in FIGS. **1–6**, each end locking element **20** will lock three bone screws **30** in place, while the locking screw **21** in the central locking hole **12** locks two bone screws **30** in place. As shown in FIG. **7**, central locking element **25** can also be configured so that four bone screws **30** are locked at one time.

As shown particularly in FIGS. **3**, **4** and **5**, plate **2** is shaped so that its bottom surface **27** (the surface which will be in contact with the vertebral bodies) has a bi-concave curvature, being concave both in the longitudinal plane (corresponding to its length) and in the plane transverse thereto, corresponding to its width. The concave curvature in the longitudinal plane conforms to the proper shape of the anterior aspect of the spine with the vertebrae aligned in appropriate lordosis. That longitudinal curve is an arc along the circumference of a circle (referred to herein as the "radius of curvature") 15.0 cm to 30.0 cm in radius and more preferably 20.0–25.0 cm in radius. Viewed on end in FIG. **4**, the plate **2** has a radius of curvature of a circle 15–25 mm in radius, but preferably 19–21 mm in radius. While the plate **2** may have a thickness between 2 to 3 mm, a thickness of between 2.25 and 2.5 mm is preferred.

Having the bottom surface **27** of plate **2** contoured so that it is able to lie flush against the associated vertebral bodies is in contrast to conventional plates which have larger radii of curvature that contact the vertebral bodies only along the longitudinal centerline of the plate, thereby permitting side-to-side rocking of the plate relative to the vertebral bodies. The contour of the plate of the present invention provides effective resistance to rocking of the plate **2** relative to the vertebral bodies about the longitudinal center line of the plate, thereby reducing stress on the plate **2** and bone screws **30**, and preventing the soft tissues from becoming engaged beneath the plate.

Other advantages produced by the above curvature are that the plate **2** will conform more closely to the facing bone surface; the plate **2** will project from the spine by a smaller distance; soft tissue will be prevented from sliding underneath the edges of the plate **2**, where it could be subject to damage; and the angle of the bone screws **30**, perpendicular to the plate when viewed from the side, when installed will be at a substantial converging angle, trapping the vertebral bone between the bone screws **30**, and thus more strongly anchoring the plate to the spine.

As shown in FIG. **5**, the bottom surface **27** of plate **2**, preferably has a porous, roughened, and/or textured surface layer and may be coated with, impregnated with, or comprise of fusion promoting substances (such as bone morphogenetic proteins) so as to encourage the growth of bone along the underside of the plate **2** from vertebrae to vertebrae. The textured bottom surface **27** also provides a medium for retaining fusion promoting substances with which the bottom surface **27** layer can be impregnated prior to installation. The bottom surface **27** of plate **2** may be given the desired porous textured form by rough blasting or any other conventional technology, such as etching, plasma spraying, sintering, and casting for example. If porous, the bottom surface **27** is formed to have a porosity or pore size in the order of 50–500 microns, and preferably 100–300 microns. Fusion promoting substances with which the porous, textured bottom surface **27** can be impregnated include, but are not limited to, bone morphogenetic proteins, hydroxyapatite, or hydroxyapatite tricalcium phosphate. The plate **2** may comprise of at least in part a resorbable material which can further be impregnated with the bone growth material so that as the plate **2** is resorbed by the body of the patient, the bone growth material is released, thus acting as a time release mechanism. Having the plate **2** being made from a material that is resorbable and having bone growth promoting material present permits the vertebrae to be fused in a more natural manner as the plate becomes progressively less load bearing thereby avoiding late stress shielding of the spine.

As further shown in FIGS. **4** and **5**, at least one end of plate **2** has a recess **18** that can cooperate with a compression apparatus, described in detail later in reference to FIGS. **36** and **38**.

FIG. **6** is a top plan view of the plate **2** of FIG. **1** with locking elements **20**, **21** inserted into the locking element receiving holes. In the preferred embodiment, the locking elements **20**, **21** are in the form of screws that cooperate with the threaded interior **3** of the locking holes **12**. Each of these locking elements **20**, **21** is shown in its initial open orientation, where the orientation of the cutouts **22** in the head **23** of each locking element **20**, **21** is oriented so as to permit introduction of bone screws **30** into adjacent bone screw receiving holes **6**,**8** without interference by the head **23** of the locking element **20**, **21**. It is appreciated that other configurations of the head **23** are possible so as to permit introduction of bone screw into adjacent bone screw receiving holes without interference by the head **23**.

FIG. **8** is a top view of another embodiment of plate **2** of FIGS. **1–5**, and is generally referred to as plate **120**. Plate **120** is provided with a longitudinally extending elongated slot **122** along its longitudinal axis which is superimposed on the middle locking hole **12**. Elongated slot **122** allows additional relative movement between plate **120** and a compression post **54** associated with a compression tool during the compression procedure, as discussed below.

Referring to FIGS. **14** and **15**, an alternative embodiment of a multiple locking plate referred to by the number **70** is shown. In plate **70**, rather than the threaded locking hole **12**, a central opening **200** for receiving a removable rivet **202**, of the type shown in FIGS. **17–20**, is provided. FIG. **15** is a bottom plan view of the plate **70** shown in FIG. **14**. The contour of the plate **70** is the same as that of the plate **2** shown in FIGS. **1–5**. The rivet **202** is removable and fits within the unthreaded opening **200**, comparable to the locking hole **12** and slot **122** described above. Other embodiments may employ a rivet that is not removable, but is manufactured as part of the plate **70** as would be used in the end locking holes **19** of FIGS. **14** and **15**.

Referring to FIG. **22**, another alternative embodiment of a multiple locking plate is shown and is generally referred to by the number **230**. The plate **230** uses threaded caps, such as cap **300** shown in FIGS. **9** and **23**, for a locking element or preferably one with cut outs as described having an appearance in a top view such as the locking element in FIGS. **10–11**, for example. The central locking hole **232** has an elongated slot **234** for providing an increased compression capability, as will be discussed further herein.

Referring to FIGS. **10–13**, a first embodiment of a locking element **20**, **21**, **25** in the form of locking screws according to the present invention for use with plate **2** is shown. FIG.

10 is a top plan view which illustrates the head 23 of the central locking element 25 shown in FIG. 7. The shaft 46 of locking element 25 is threaded 47 to mate with the threading 3 within the associated locking hole 12 of plate 2. As shown in FIG. 21, each segment 49 on each side of cutouts 22 of the locking element 21 has a bearing surface 48 formed at the lower surface of locking element head 23. As shown in FIG. 16, the locking element head 23 can be provided with two slots 42 for providing flexibility to the locking element head 23 to assist in the locking element's ability to ride over the top of the bone screw head 32 during the bearing action when the locking element is rotated. Alternatively, it is appreciated that the bearing surface can be cammed, ramped or wedged. The cammed, ramped or wedged features can also be used with the other locking elements described herein.

Referring to FIGS. 6 and 10–13, it will be appreciated that when the locking elements 20, 21 are rotated in the clockwise direction with respect to the view of FIG. 6, a respective bearing surface 48 (as best seen in FIG. 21) will ride upon the curved top surface 39 of a respective bone screw head 32 in order to positively lock the associated bone screws 30 and the locking elements 20, 21 in place.

Alternatively, as shown in FIGS. 12 and 13 in place of a bearing surface 48, a ramp or wedge shaped surface 44 may be used to increase the force applied to the bone screw head 32. When locked, the leading end of the ramped portion of the locking element would be lower than the prominence of the bone screw head 32 so that more force is needed to lift the locking element and untighten it than is needed for the locking element to remain tight and locked. However, the locking element heads 23 need not have slots, be cammed, or have a ramped surface to achieve the locking of the bone screw 30 in place. Pressure, friction, interference fits, or other engagement means capable of preventing the locking element from moving from its locked position may be employed.

The rivet 202, shown in FIGS. 17–20 is intended for use in association with plate 70 shown in FIGS. 14–15, is shown in detail in cross section in FIGS. 19 and 20. The rivet 202 has a head 204, a shaft 206, and an elongated bottom segment 208 for fitting within the corresponding opening 200 in the plate 70. The lower surface 210 of the head 204 of the rivet 202 has an irregular surface which may be cammed, such as on the bottom of locking element 20, 21, for engaging the top surface 39 of the bone screw head 32. For use in the end locking holes 19, the upper surface of the elongated bottom segment 208 can have an irregular surface for cooperating with the irregular surface of the bottom of the plate 70 to hold the rivet 202 in the locked position against the bone screw head 32, as shown in FIG. 15. While the rivet of FIG. 18 is a separate, removable component from the plate, the rivets, and particularly those for use with the end locking holes, can be formed as part of the plate during the manufacturing process of the plate and rivet can be non-removable.

Each of the above embodiments provides tight attachment of the locking element relative the bone screw 30 and relevant plate.

In the alternative embodiment of multiple locking plate 23 shown in FIG. 22, the locking element can be in the form of threaded locking cap 300 shown in FIG. 23. The threaded locking cap 300 has a thread 302 on its outer circumference corresponding to the thread 303 on the inner circumference of the locking element depressions 304 in the top of the plate 230 shown in FIG. 22. The locking cap 300 is relatively thin, particularly compared to its width. The top 305 of locking cap 300 is provided with a noncircular through hole 306 for receiving a similarly configured driving tool.

Referring to FIGS. 28, 29, and 30 another embodiment of the multiple locking plate generally referred to by the number 400 and a locking element in the form of a thin locking member 412 are shown. Plate 400 has an opening in its top surface for insertion of the thin locking member 412, a recess 402 associated with each of the bone screw receiving holes 408 and a slot 410 in the side wall of the bone screw receiving holes 408 to permit the thin locking member 412, having a series of thin projections or blades 414, thinner than the slot 410, that give this locking member 412 an appearance similar to that of a propeller. The thin locking member 412 is able to be rotated within the plate so as to not cover the bone screw holes, thus allowing the thin locking member 412 to be pre-installed prior to the installation of the bone screws by the surgeon. Limited rotation of the thin locking member 412 allows the blades 414 to protrude through the slot 410 and to cover a portion of the top of the associated bone screws 30. The blades 414 of the thin locking member 412 are flexible and, when rotated, slide over the top surface 39 of the bone screw head 32 to lock the bone screw 30 in place. As with the other embodiments discussed, each of the embodiments of the locking element is capable of locking more than one bone screw 30. It is appreciated that the various multiple locking plates and locking element combinations are capable of locking as many as four bone screws at once, but are equally effective for locking a lesser number or none at all, that is securing itself to the plate.

It will be noted that one characteristic of each of the above described locking element embodiments is to have a driver engagement means, in these cases for example, a recess 24 as large as the recess 34 in the bone screws 30 so that the same tool can be used to turn both the bone screws 30 and the locking elements. Also, the locking elements are sufficiently strong and have sufficient mass so as to be able to withstand being locked without breakage.

All of the shown examples of the multiple locking elements that have a number of cutout portions have an arc with a radius greater than that of the bone screw head. In addition, the head 23 of each locking element 20, 21 is provided at its center with a noncircular recess 24, such as shown in FIG. 9 which is engageable by an appropriate manipulation tool, such as shown in FIGS. 40–42. In the embodiment of head 23 shown in FIG. 9, the associated tool would have a hex head, but as discussed with regard to FIGS. 80 and 81, other shapes of recesses in the head 23 may be used. The thread of each locking hole 12 and of each locking element 20, 21 has a close tolerance so that they will reliably retain their orientations so as to permit introduction of bone screws 30 into bone screw receiving holes 6, 8 without interference.

It is appreciated that while various forms of locking elements have been disclosed, in light of the teaching, other equivalent means can be used for the purpose of locking the bone screws 30 in place. In FIG. 83, an alternative multiple locking plate 990 is shown having additional intermediate bone screw receiving holes 980 and associated locking elements 960 for locking bone screws 30 in place. Plate 990 allows for a more close spacing and more pairs of bone screw holes than the number of vertebrae to be engaged.

In FIGS. 84A–84E various plates 700*a–g* used for a single level fusion are shown. Each of these plates 700*a–g* is designed to span one spinal segment consisting of one disc space and two adjacent vertebrae (containing the bone graft), and have bone screws inserted into the end of the vertebrae through the bone screw receiving holes 6 associated with the

two adjacent vertebrae and then locked in place. As shown in FIGS. **84A–84E**, one locking element **710**, or two locking elements can be used to lock four bone screws in place. In FIGS. **84A–84E**, each of the plates **700*a–e*** is shown with the locking elements in their open orientation, before being rotated to lock the bone screws.

Each of the above described plates can have the same generally biconcave contour as already described for conforming to the anterior aspect of the spine.

FIGS. **24A** and **24B** provide a side view of one embodiment of a bone screw **30** according to the present invention. FIG. **27** is a top view of the bone screw **30**. At the center of bone screw head **32** is a profiled recess **34** which may have the same form as the recess **24** of each locking element **20, 21** in which case it may be turned with the same tool as that employed for turning locking elements **20, 21**. It is appreciated that the driver engaging portion of the bone screw **30** could be slotted, and be either male or female (as is shown).

In the embodiment of bone screw **30** shown in FIGS. **24A** and **24B**, the bone screw head **32** is stepped, with the first lower head portion **35** being contiguous with the screw shank **33** and has a smaller diameter than the upper portion of the bone screw head **32**. When this embodiment of bone screw **30** is employed, each bone screw receiving hole **6, 8** of the plate **2** has a countersunk region **14** matching the diameter of the upper portion of the bone screw head **32** and dimensioned for an interference fit. The lower portion **35** of the bone screw head **32** is dimensioned to achieve an interference fit with its associated portion of bone screw receiving holes **6, 8**. The larger diameter upper portion of bone screw head **32** assures that the bone screw **30** cannot be advanced completely through bone screw receiving holes **6, 8** of plate **2**. The bone screw **30** passes completely through the upper surface of the plate **2** without engaging the upper surface in any way.

As shown in FIG. **44**, the head **32** of screw **30** passes unobstructed through the upper surface of the plate until the lower surface of enlarged screw head **32** engages the upper face of the narrowed bone screw receiving portion at the midsubstance or below the midsubstance of the plate. This is considered optimal for allowing for the greatest screw to plate stability, even absent the lock, against all forces except those reverse the path of insertion, while still providing for the greatest plate strength beneath the bone screw head **23**. That is, since the plate is of only generally 2–3 mm in thickness, a sheer vertical circumferential wall is best able to constrain the motion of a screw if the head is similarly configured and there is little tolerance between them. Placing the support of the head near the mid thickness of the plate is preferred as it allows the head to remain large to accommodate the recess for the driver without being weakened, while placing the support of the head away from the upper surface of the plate allows the screw head to be deep into the plate. Placing the support of the head at approximately the mid thickness of the plate assures plenty of plate material beneath the head to support while providing adequate head length above and below the contact point to prevent the contact point from acting as a fulcrum by providing adequate lever arms to prevent unwanted motion.

In the alternative embodiment of bone screw **30'**, as shown in FIG. **25**, bone screw head **32'** is tapered in the direction from the top of the bone screw head **32'** toward screw tip **36'**. Again, the bone screw head **32'** is dimensioned to achieve an interference fit in the associated bone screw receiving hole **6,8** when the bone screw **30'** has been fully installed. When this embodiment of bone screw **30'** is employed, bone screw receiving holes **6, 8** need not be provided with a countersunk region **4**.

In each of the above embodiments of the bone screws, the bone screws **30** and **30'** present a unique combination of a tapered screw shaft **33** and a helical thread **31**. The diameter of screw shaft **33** generally increases from a distal portion of the shaft near the screw tip **36** toward the proximal portion of the shaft near screw head **32**. In the preferred embodiment, the rate of increase in diameter is also greater near the bone screw head **32**. Such a shape avoids stress risers and provides increased strength at the screw-plate junction, where it is needed the most. The tapering of screw shaft **33** may have a concave form, as shown in FIG. **24A**, or may be linear. The distal portion of the screw shaft **33** may assume a constant diameter.

Referring again to FIGS. **24A** and **24B**, the thread **31** of the bone screw **30** has a substantially constant outer, or crest, diameter "d" from the proximal portion of the shaft below the bone screw head **32** to the distal portion of the shaft near the bone screw tip **36**. In the screw tip **36**, the crest diameter of thread **31** may be reduced for preferably one to two turns to facilitate the insertion and penetration of the bone screw **30** into the bone.

In the preferred embodiment, the thread **31** of each bone screw **30** has an outer diameter slightly smaller than the diameter of the lowest portion **35** of the bone screw head **32**, which is adjacent the trailing, or upper, end of the associated thread **31**. In addition, the thread **31** is relatively thin, in the direction of the longitudinal axis of the screw, and tapers outwardly, and has a cross section of a triangle.

An example of the dimensions of a bone screw for use in human anterior cervical spinal surgery for insertion into the vertebrae is as follows: the threaded portion of said screw has a length from about 10 mm to about 22 mm (12–18 mm preferred) and a head length from about 1 mm to about 3 mm (2–2.5 mm preferred). The threaded portion should have a maximum outside diameter from about 3.6 mm to about 5.2 mm (3.8–4.5 mm preferred) and the head has a diameter from about 3.8 mm to about 6 mm (4–5.5 mm preferred). The thread pitch is from about 1.25 mm to about 2.5 mm (1.5–2.0 mm preferred) and has a sharp and thin threaded profile. The apex of the two faces of the thread have an angle of less than about 21 degrees (15 degrees preferred) and the base of the thread is less than about 0.60 mm thick (0.25 mm–0.35 mm preferred). The screw has a root diameter that increases from proximately above the tip of the shank, along the longitudinal axis to proximately below the head portion of the screw. Preferably, the tip of the screw tip is fluted by at least one cut out section so as to make the screw self-tapping.

Even though the thread **31** of the bone screw **30** has a thin profile, the thread will nevertheless be stronger than the bone into which it is introduced so that this thread will efficiently cut a thin helical groove in the bone tissue. The volume of bone that will be displaced by the thickness of the thread is minimized by the thin form of the thread, yet the substantial crest diameter of the screw thread maximizes the surface area of the threads in contact with the bone. While enlarging the screw shaft **33** diameter near the bone screw head **32** increases its strength where needed, reducing the screw shaft **33** diameter away from the bone screw head **32** where such strength is not required allows for the maximum area of engagement for the thread **31** to the bone.

In the preferred embodiment, as shown in FIGS. **24A** and **26**, bone screw tip **36** is provided with cutting flutes **38**, to make the bone screw **30** self-tapping. Unlike the prior art bone screws, used for anterior cervical spinal surgery which are not self-tapping, the thread form of the present invention screw is itself more like a tap than a conventional screw in

that the threads are very sharp and fluted. Additional embodiments of the bone screws **30** is shown in FIGS. **53–55**.

By way of example, plates for fusing three adjacent vertebrae (2 interspaces, or two spinal segments) are shown. Each set of the bone screw receiving holes associated with a vertebrae is considered to be a segment of the plate so that for example, in FIG. **1** three segments are shown—an upper, a central, and a lower segment. While the present discussion is in association with plates for use in fusing three vertebrae across two interspaces, it should be understood that longer and shorter plates having the appropriate number and location of bone screw receiving holes corresponding to the number of vertebrae to be fused are contemplated, and would take the form of the plates shown with fewer or more intermediate segments, such as the segment along line **9** of FIG. **1**, or the intermediate segments of the plates shown in FIGS. **82–84**F.

Referring to FIGS. **31–42**, an outline of the steps of the method for installing the plates of the present invention is set forth below. A detailed description of the instrumentation and method for installing the plates of the present invention follows the outline.

Step 1

Having completed the interbody fusions, the surgeon removes any bone spurs or localized irregularities along the front of the spine of the area to be fused.

Step 2

The correct length plate is selected by the surgeon by measuring the distance on the spine by a caliper, ruler, template, and the like. That plate having a length sufficient to span the distance of the spine to be fused and to partially overlap a portion of each of the end vertebrae to be fused.

Step 3

Utilizing a plate holder, the plate is placed into the wound and positioned to confirm positioning, length, and screw hole alignment relative to the segments of the spine to be fused.

Step 4

As shown in FIG. **31**, with the plate thus positioned and securely held, the plate may be attached to any of the vertebrae to be fused (by example only, here shown as the top vertebra).

Sub-Step 4A

The pilot (guide) hole punch **60** is attached to the plate **2** as per FIG. **32**, or alternatively, while not preferred the drill guide may be used as per FIG. **37**. In either event, the pilot hole forming means rigidly aligns with and is captured by the plate bone screw receiving hole wall.

Sub-Step 4B

The pilot hole is then formed by impacting the pilot hole punch of FIG. **32** or drilling with the drill of FIG. **37**. In the alternative while not preferred, the formation of the pilot hole can be done away with altogether and the correct screw selected so as to have a length less than the distance along its path to the posterior vertebral cortex can be directly inserted.

The determination of the appropriate screw length is made by measuring or templating from radiographs, MRI's, or CT scans, or determined directly by measuring the depth of the disc space.

Step 5

The correct screw is then attached to the screw driver which regardless of the specific form of the screw driver engagement means, is designed to have an interference fit so as to remain firmly bound to the driver during transport to the insertion site. FIGS. **41, 42, 63, 64, 80** and **81** show various ways of achieving such a fit of the driver and screw. In addition to a wedging at the screw and driver interface, clips, and springs and other means are well known for temporarily and reversibly securing the screw to the driver, such as is shown in FIG. **80** where a slotted inwardly springing sleeve holds a threaded cap peripherally until, as it is screwed into the plate, it is automatically pushed back releasing the threaded cap.

Once a first bone screw has been fully inserted into a vertebra through the plate, it is preferable to insert the other of the transverse pair in the manner already described as per FIG. **33**.

In a similar manner, it is possible to insert the remaining bone screws as per the surgeon's preference into each of the vertebrae to be included into the fusion, just the end vertebrae of the fusion construct, or additionally place screws into the fusion grafts.

However, as shown in FIGS. **33, 34, 38** and **39**, it is possible with the present invention at the surgeon's option to place any portion or all of the fusion construct under compression and to do so intersegmentally or across the entire length of the fusion construct even when multi-segmented.

It is appreciated that the same procedure could be generally used for any of the plate systems of the present invention.

As shown in FIG. **31**, the vertebrae **50***a–c* are separated from one another by fusion graft blocks **51** which were previously installed in the spinal disc space between adjacent vertebrae **50** forming a fusion bone graft construct. Plate **2** is shown in FIG. **31** with the locking elements **20, 21** removed in order to simplify the illustration. It will be understood, however, that in the preferred embodiment the locking elements **20, 21** can be, and preferably are, pre-installed in the positions shown in FIG. **6** prior to positioning plate **2** upon vertebral bodies of the vertebrae **50**, thereby saving the surgeon time and trouble.

Plate **2** may be held in position by any known plate holding means, but preferably by the holding tools shown in FIGS. **45, 46** or **70** by the notches **142** in the sides of the compression arms **104, 130** of a vertebral compressor tool **100** shown in FIG. **39**, or as a further alternative, by the unitary plate holder similar to the FIG. **70** design.

As shown in FIG. **45**, plate holder **870** has a hollow tubular housing **872**, with a central rod **874** having a thread **878** at one end for engaging one of the threaded locking holes **12** in the plate **2**. The bottom end of the housing **872** has projections **880, 882** that extend outwardly and then downwardly to fit into the bone screw receiving holes **8** of the plate **2** preventing the housing **872** from rotating. The central rod **874** is located in the housing **872** such that it can be rotated by rotating a handle (not shown) which is fixed to the central rod **874** at its upper end.

In FIG. **46** an alternative embodiment of the plate holder **890** is shown. A single solid member **890** has a threaded projection **894** at its bottom end for attachment to the central threaded locking hole **12** in the plate. The bottom surface of the holder **890** of this embodiment is contoured so as to match the contours of the top surface of the plate adjacent to the locking hole **12**, shown as a depression **14** (FIG. **1**).

Referring to FIGS. **67–68**, an embodiment of a plate holder for holding any of the plates while being positioned on the vertebrae is shown and generally referred to by the number **800**. The plate holder **800** has a hollow tubular housing **802**, with a central rod **804** having a handle **806** at one end and a thread **808** at its other end for engaging one

of the threaded locking holes **12** in the plate **600**. The bottom end of the housing **802** has projections **810, 812** that extend outwardly and then downwardly **814, 816** to fit along the side edge of the plate **2** between the end and intermediate lobes **4**, preventing the housing **802** from rotating. The central rod **804** is located in the housing **802** such that it can be rotated by rotating the handle **806** which is fixed to the central rod **804** at its upper end. This central rod **804** can also be attached to the housing **802** so that it can move up and down to some extent, by any number of conventional ways, such as by having the central rod **804** have an annular depression with a length of approximately 3–5 mm, and a set screw projecting inward from the housing to engage the central rod **804**. Once the plate **600** is in the proper place and the plate is attached to one of the vertebrae by bone screws **30**, the central rod **804** is disconnected from the opening in the plate **600** and the holder **800** is removed.

FIG. **69**A is an alternative embodiment of the plate holder **850**. A single solid member **852** has a threaded projection **854** at its bottom end for attachment to the central threaded locking hole **12** in the plate. The solid member **852** could also be threaded into a bone screw receiving hole **6**. The bottom surface of the holder **850** of this embodiment is contoured so as to match the contours of the top surface of the plate adjacent to the locking hole **12**, shown as a depression **14** (FIG. **1**).

FIG. **69**B is another embodiment of the plate holder **850'**. A housing **851'** having an end **853'** configured to engage a bone screw receiving hole **6** contains a rod **855'** having an uneven diameter and having a threaded portion **857'**. As rod **855'** is rotated by a handle similar to handle **806** shown in FIG. **68**, rod **855'** screws downward into the housing **851'** into matching threads **858'**. As the end of rod **855'** is driven down, it spreads portions **859***a'* and **859***b'* (**859***c'* and **859***d'* not shown) wedging plate holder **850'** into a bone screw receiving hole of the plate. Plate holder **850'** is best used with non-threaded bone screw receiving holes, but works for all types of bone screw receiving holes.

Referring to FIG. **70**, an alternative embodiment of the plate holder referred to by the number **800'** is shown in which there is a removable handle **860** that is used for first attaching the plate holder **800'** to the plate, by rotating the shaft **804**, and then for holding the plate holder **800'** off to the side by extension **864**, during the attachment procedure reducing the interference of the plate holder **800'** with the surgical procedure.

Referring to FIG. **38**, a compression tool **100** is shown with a toothed gear bar **102** having a first compression arm **104** secured to its free end. Compression arm **104** has at its distal end a bore **106** for removably holding either a plate engaging element **108**, shown in FIG. **36**, having a hook **110** at one end for engaging a depression or notch **18** in the end of plate **2**, or for removably holding a compression post **54** shown in FIGS. **33–34**. As shown in FIG. **36**, plate engaging element **108** includes a shaft **112** that will be inserted into the corresponding bore **106** of compression arm **104**, and a flange **115** for resting against the bottom face of bore **106** to accurately limit the depth of insertion of plate engaging element **108** into the bore **106**. A ring spring **128**, preferably of metal, is located in an annular depression of the shaft **112**, for holding the plate engaging element **108** in the bore **106**.

Referring to FIGS. **38–39**, compression tool **100** includes a second moveable compression arm **130** movable along toothed bar **102** parallel to first compression arm **104**. The distal end of the second compression arm **130** also has a bore **132**, the same as bore **106**, that can receive a removable compression post **54**. Bores **106** and **132** are the same so that either compression arm **104, 130** can be used to hold the removable compression post **54**, permitting the compression tool **100** to be used in any orientation. By permitting the plate engaging element **108** and the compression post **54** to both rotate and slide in the bores **106, 132** of the two compression arms **104, 130**, with the plate engaging hook **110** able to work even at an angle to the plate allows for the apparatus to be readily attachable to the spine through the compression post **54** and plate.

Compression arm **130** has a driving assembly consisting of a toothed wheel (not visible) which is engaged with the tooth gear **138** of bar toothed gear **102** and is connected to compression arm **130** such that compression arm **130** is movable along the length of toothed gear bar **102** by means of the rotation of handle **140**, which is connected to the toothed wheel. When the handle **140** is turned in the direction of the arrow shown in FIG. **38**, compression arm **130** is moved toward compression arm **104**. The driving assembly has a self lock release mechanism whereby the movement of the two compression arms **104, 130** away from one another is prevented, without the activation of the release. On the inward distal end of each compression arm, on facing sides, is a notch **142** or recess for holding the plate **2** along its sides between the central lobes **4** and end lobes **4**, as shown in FIG. **38**.

While the toothed gear bar **102** and compression arms **104, 130** have been described as being straight, it is possible that the toothed gear bar **102** and compression arms **104, 130** may be arcuately or otherwise shaped, so as to induce lordosis in the vertebrae, if so desired.

As shown in FIG. **31**, in the event that the compression tool **100** is used to hold the plate **2**, the ends **144** of the compression arms **104, 130** will be located in line with the fusion graft construct **51** which was placed in the disc space when plate **2** is properly positioned. A gap will exist between plate **2** and each fusion graft construct **51**, providing a space to accommodate the free ends of arms **104, 130** should they extend beyond the bottom surface of the plate **2**. As will be described below, the same compression tool **100** can also be used for compressing a plurality of cervical vertebral bodies with bone grafts interposed during the attachment of plate **2** to the vertebrae **50**.

Referring to FIG. **31**, plate **2** is held by a suitable holder, in this case shown as the compression arms **104** and **130**. Once the appropriate length plate **2** has been properly positioned so that the bone screw receiving holes **6** are aligned with each of the respective vertebrae **50***a–c* to be fused, the next step is the formation of bone screw receiving holes **6** prior to installation of the bone screws **30** themselves in the vertebrae **50***a*. While the procedure is described as first attaching the plate **2** to the upper vertebrae **50***a*, the plate **2** can be attached to any of the vertebrae in any order. Different sized plates are used so that, as indicated above, the physician will select the appropriate sized plate in which the bone screw receiving holes **6, 8** are aligned with the three adjacent vertebrae **50***a*, **50***b* and **50**c. Pilot holes are formed by a pilot hole forming apparatus **60** shown in FIGS. **31** and **32**. Unlike with known prior art and screw plating systems, the bone screws **30** may be inserted without the prior formation of an opening into the vertebrae as the bone screws **30** are preferably sharp pointed, self-tapping, and have at their tip a diminishing major diameter to assist the screw entering and pulling into the bone. However, while a hole into the bone of the vertebrae may be formed prior to screw insertion, it is preferable that the hole be of a smaller diameter than the root diameter of the screw and for a different purpose than with the prior art. With the prior art

the hole drilled had to be of a diameter equal to but preferably larger than the root (minor) diameter of the screw, as the screws were not self-tapping. It is desirous to create pilot holes to assure that a proper path for the bone screws **30** is maintained, and also to prevent damage to the vertebral bone during insertion of the bone screws **30**. In addition, the pilot hole forming apparatus **60** creates a more compact vertebral bone mass for reception of the self-tapping bone screw **30** used in this insertion.

As shown in FIGS. **31** and **32**, pilot hole forming apparatus **60** includes a hollow cylindrical housing **62** having a bottom provided with a through hole **63**. Housing **62** contains a central shaft **64** which extends through the through hole **63** in the bottom of housing **62**. The leading end **66** of shaft **64** tapers gradually to a sharp point **65**. Shaft **64** is provided with a ring member **78** having a diameter which closely corresponds to the inner diameter of housing **62** to guide the travel of shaft **64** within housing **62**. A compression spring **67** is interposed between the ring member **78** and the bottom of housing **62**. Compression spring **67** provides a bias force which normally urges the sharp point **65** into a retracted position within housing **62**. The upper end of shaft **64** has an enlarged head **68** extending outside of the housing **62** which is intended to be manually depressed or struck by a percussion instrument in order to drive the sharp point **65** out of housing **62** and into a vertebral body **50***a*. Shaft **64** is given a length, taking into account the length that spring **67** will have when fully compressed, to determine the maximum depth of the pilot hole formed in a vertebral body. The depth is selected to assure that the pilot hole does not reach the posterior cortex of the vertebral body, which borders the spinal canal.

Certain structural features of hole forming apparatus **60** are shown in greater detail in FIG. **32**. In particular, it can be seen that the bottom end of housing **62** has a projecting portion **69** dimensioned to fit precisely in a bone screw receiving hole **6** or **8** of plate **2**. The bottom **71** of the projecting portion **69** is flat in a plane perpendicular to the axis of housing **62**. When the projecting portion **69** of housing **62** is snugly inserted into a bone screw receiving hole **6**, **8** and the flat bottom **71** is placed flush against the upper surface of plate **2**, it is assured that the leading end **66** of shaft **64** will form a pilot hole in the vertebral bone having an axis perpendicular to the plane of the associated portion of plate **2**, thereby assuring that the bone screw **30** will be subsequently installed so that its axis is also perpendicular to the plane which is parallel to the upper and lower surfaces of the associated portion of plate **2**.

When a plate is used which has a threaded bone screw receiving hole, the lower end of the pilot hole forming apparatus **60** is threaded so as to engage the thread in the bone screw receiving hole **6**, **8** thereby fixing the plate and the pilot hole forming apparatus together, assuring a stable fit between the pilot hole forming apparatus and the plate **2**. It should be noted that the diameter of the leading end **66** of the shaft **64** is small since it has to fit within the small space left between the inside wall of the pilot hole forming apparatus. Since it is only a pilot hole for a self-tapping bone screw **30** that is being formed, the small diameter is satisfactory.

Referring to FIG. **37**, if for any reason it should be desired to form the pilot hole in the vertebral body **50** by drilling, rather than by the use of the pilot hole forming apparatus **60**, use can be made of a drill guide **80**, having a lower end as shown in FIG. **37**. The drill **80** guide consists of a tubular member **82** and a small diameter lower end **84** which is dimensioned to achieve a precise interference fit in the associated bone screw receiving hole **6**, **8** of plate **2**. Along the small diameter lower end **84**, drill guide **80** has an axial end surface in a plane perpendicular to the longitudinal axis of the drill guide **80** so that when the small diameter portion **84** is fitted into the bone screw receiving hole **6** and the surface surrounding the small diameter portion **84** is flush against the upper surface of plate **2**, the axis of the drill guiding bore **86** in drill guide **80** will be precisely perpendicular to the upper and lower surfaces of the associated portion of plate **2**. As with the case described above, the bottom end of the drill guide **80** can be threaded so as to engage to the threaded opening of plate **2**.

After the bone screw receiving holes **6**, **8** are formed in the vertebral body **50***a* through the upper two bone screw securing holes **6** of plate **2** by means of either hole forming apparatus **60** or drill guide **80**, bone screws **30** are threaded into the vertebrae **50** while holding the plate **2** firmly against the vertebrae **50** with compression tool **100** or plate holder **800**. This locks the plate to the vertebrae **50***a*.

It is then possible, if desired, to compress the fusion graft in the next adjacent vertebrae **50***b* before attaching bone screws **30** to the adjacent vertebrae **50***b* through the central bone screw receiving holes of plate **2**. Once the initial bone screws are in place in the vertebrae **50***a*, the plate holder **100** or **800** may be removed from the plate **2**. The compression of the fusion graft construct between the two adjacent vertebrae **50***a* and **50***b* is achieved as follows:

Compression post **54** is driven through the central locking hole **12** of plate **2** by means of insertion tool **90**, shown in FIGS. **33**, **34** and **35**, into the vertebral bone of vertebra **50***b*, where it will be used in a subsequent step to apply a compression force between vertebrae **50***a* and **50***b*. Compression post **54** consists of a shaft **56** having a sharp point **57** at its lower end, an enlarged central collar **58** which serves as a depth stop, and a circumferential groove **59** proximate its upper end, defining an enlarged head **55**.

Compression post insertion tool **90** consists of a shaft **92** having a closed hollow portion **94** at its lower end **96** for receiving compression post **54** and an enlarged percussion cap **98** at its other end. Compression post insertion tool **90** also includes in its lower end **96** a second opening **95** having a recess **99** in its inside wall for permitting engagement of the enlarged head **55** on the compression post **54** within the depression **97**. The second opening **95** is in communication with the hollow portion **94** of the insertion tool **90**, as shown in FIG. **35**.

Referring to FIG. **38**, the bore **132** in the second compression arm **130** of compression tool **100** is then applied over compression post **54** in vertebrae **50***b*, and the plate engaging element **108** is inserted in the bore **106** of the first compression arm **104** of compression tool **100**. The hook **110** of the plate engaging element **108** shown in FIG. **36** is fitted into the notch **18** at the end of the plate **2** which is fixed by the bone screws **30** inserted into the vertebra **50***a*, as shown in FIG. **38**. As indicated above, however, the compression tool **100** can be rotated so that the first compression arm **104** is now at the bottom and is able to fit over the compression post **54** in vertebrae **50***c*.

Since the plate is attached to vertebrae **50***a* by means of bone screws **30** and compression post **54** is fixed to the adjacent vertebrae **50***b*, movement of the first and second compression arms **104** and **130** in the direction of vertebrae **50***a* by rotation of handle **140** results in compression of the bone graft construct **51** between the adjacent vertebrae **50***a* and **50***b*. The distance of several millimeters is sufficient for compression of the bone graft construct **51**. Once the desired compression is obtained, bone screw pilot holes can be

formed in vertebral body **50***b* by means of pilot hole forming apparatus **60**, as described above, for insertion of bone screws **30** into bone screw receiving holes **8** of bone plate **2**, fixing the plate **2** to the adjacent vertebrae **50***b*. Compression tool **100** can then be withdrawn by activation of the release.

FIG. **39** illustrates the use of compression tool **100** to induce compression between the lower two vertebral bodies **50***b* and **50***c* after bone screws **30** have been installed in the middle vertebral body **50***b* as just described. As shown in FIG. **39**, compression post **54** remains in place in the middle vertebral body **50***b* and an additional compression post **54** is driven into the lower vertebral body **50***c* by means of pilot hole forming tool **60** distal to the plate itself in the recess between the end projections **4** to allow for the lower compression post **64** to be moved towards vertebrae **50***b* upwardly as shown. The original compression post **64** is inserted in bore **106** in the first compression arm **104** and the additional compression post **54** is inserted into the bore **132** of the second compression arm **130** of compression tool **100**. Again, as discussed above, the turning of the handle **140** results in the two compression arms **104**, **130** moving towards one another, resulting in the compression post **54** in vertebrae **50***c* moving towards the upper compression post **54** in vertebrae **50***b*, once again compressing the fusion graft construct **51** between vertebrae **50***b* and **50***c*. The upper compression post **54** in vertebrae **50***b* can not move since the vertebrae **50***b* has been fixed to the plate by the insertion of the bone screws **30** in the bone screw receiving holes **8** of the plate **2**. Thus, only the lower compression post **54** and vertebrae **50***c* can move. As before, the pilot holes associated with vertebrae **50***c* are formed and the bone screws **30** are inserted through bone screw receiving holes **6**. The compression tool **100** is then removed. Compression post **54** is then extracted from the vertebrae by inserting it in the second opening **95** of the compression post insertion/removal tool **90**, so that it engages the enlarged head **55** of the end of compression post **54** by depression **97**, as shown in FIG. **34**.

It is recognized that other variations in the order of compression may be employed. For example, during the compression of the fusion graft construct **51** between vertebrae **50***b* and **50***c*, the hook **110** of plate engagement element **108** may engage the notch **18** in the end of the plate **2**, and the other compression arm of the compression tool **100** may engage the compression post **54** in the third adjacent vertebrae **50***c*. It should also be noted that plate **2** has a recess end cut out portion between the lobes at the end of the plate for insertion of the compression post **54** in the vertebrae. Otherwise, there may not be room below the end of the plate **2** for insertion of the compression post **54**.

It will be noted that the above-described procedure will be performed with the bone screws **30** fully inserted into vertebral bodies **50***a*, **50***b* and **50***c* and lordosis is maintained during compression of the bone graft construct **51**.

As indicated above, the procedure for attaching the plate **2** to the vertebrae **50***a*, **50***b* and **50***c* was illustrated without the locking screws **20**, **21** in place on the plate **2**. FIG. **40** is a perspective view showing the plate **2** of FIGS. **1–5**, at a stage of a surgical procedure when bone screws **30** have been fully installed in three adjacent vertebrae **50***a*, **50***b* and **50***c*, and locking screws **20**, **21** have been rotated through an angle of about 90N to lock three bone screws **30** in place; the left-hand locking screw **20** as viewed has been rotated through an angle of about 60N to lock three bone screws **30** in place and the central locking screw **21** has been rotated through an angle of about 90N to lock two other bone screws **30** in place. At this time, one of the camming surfaces **44** of each locking screw **20**, **21** rests atop the screw head **32** of a respective bone screw **30**.

Installation of the locking cap **300** can also be performed with a tool **220** such as shown in FIGS. **41** and **42** having a suitably shaped tip **222** with a length corresponding to the depth of hole **306** in a locking cap **300**. The end **222** of tool **220** is flared just proximal to the most distal end so that it creates a friction fit with the screw cap **300** for ease of manipulation, and prevents the screw cap **300** from falling off the tool **200**.

FIG. **43** is a cross-sectional view in the plane of the center of the two end locking screw holes **6** of plate **2**, with two bone screws **30** in their installed positions and locking element **21** in its locking position. FIG. **44** is an enlarged view of one of the bone screws **30** in plate **2** of FIG. **43**. In a preferred embodiment, the axis of each screw **30** is generally perpendicular to tangents to the upper and lower surfaces of plate **2** at points which are intersected by the longitudinal axis of the associated bone screw **30**. Thus, because of the curvature of plate **2** in the plane of FIG. **43**, bone screws **30** can be directed so as to converge toward one another at a desired angle. Preferably, such angle will be greater than 14°. More preferably, such angle will be greater than 14° and less than 30°. The axis of the two bone screws **30** shown in FIG. **43** may subtend an angle of about 45N. Alternatively, the curvature of the plate from side to side may be so as to conform to the surface of the anterior aspect of the human adult cervical spine and the axis of the paired screw hole may deviate from being perpendicular to the plate when viewed on end to achieve optimal convergence.

Because the bone screws **30**, once inserted, are locked to the plate, a "claw" of a rigid triangular frame structure is obtained at each pair of bone screws **30** such that the attachment of plate **2** to the vertebral bodies **50***a*, **50***b* and **50***c* would be highly secure due to the trapping of a wedged mass of bone material between the angled bone screws triangle, even if any thread stripping should occur. The "claw" may be further formed by three angled bone screws in a tripod configuration or by four bone screws in a four sided claw configuration.

A plating system according to each of the above embodiments can be installed in the same manner as described above, and using the same instruments and tools, as illustrated and described above with respect to the first embodiment. In the case of the embodiment shown in FIG. **22**, the compression operations would be performed by means of slot **232** instead of the middle locking screw hole **12**.

2. The Single Locking Plate Systems

The single locking plate system will now be described. FIGS. **47–52** are views of a first embodiment of a single locking plate system. The contour of plate **600** is the same as the plate **2** shown in FIGS. **1–5**. Plate **600** contains bone screw receiving holes **602** which are internally threaded **603** for receiving corresponding locking elements in the form of a locking cap **610**, shown in FIGS. **56–59**. For example, in plate **600**, the bone screw hole **602** has an outer diameter of approximately 5 mm with a preferred range of 4–6 mm; and a threaded inner diameter of approximately 4.8 mm, with a range of 3.5–5.8 mm for this use. Attaching means other than threads may be used, such as bayonet type attachment elements.

The bottom of each bone screw receiving hole **602** has an inwardly stepped portion of properly selected dimensions for retaining an associated bone screw **170**, as shown in FIGS. **53–55**. As described in greater detail below, in this embodiment, a single locking element in the form of a locking cap **610** having threads **608** shown in FIGS. **56–59**, is associated with each of the bone screws receiving holes **602**.

The difference between the bone screw **170** used in the single locking embodiment of the plate from the bone screw used in association with the multiple locking plate is essentially due to the fact that whereas in the multiple locking plate embodiment the locking elements slide over a portion of the top **39** of the screw head **32**, in the single locking embodiment the locking cap **610** fits over the head **172** of the bone screw **170**. Therefore, the head **172** of the bone screw **170** of the present embodiment need not be smooth. This permits the head **172** of this embodiment bone screw **170** to be thicker and stronger.

FIG. **65** shows two bone screws **170** and associated threaded locking caps **610** in their fully installed positions. In these positions, head portions **174** and **176** of each bone screw **170** form an interference fit with corresponding portions of an associated bone screw receiving hole **602**. Rim **612** of each threaded locking cap **610** forms an interference fit with upper portion **178** of the head of its associated bone screw **170**. Because the thread **608** of each locking cap **610** mates precisely with the internal thread in an associated bone screw receiving hole **602**, each threaded locking cap **610** is additionally subjected to a clamping force between associated head portion **178** and the internal threads **603** of associated bone screw receiving hole **602**. The rounded head **614** of each threaded locking cap **610** assures that the upper surface of an assembled plating system will be free of sharp edges, or projections.

Referring to FIGS. **80** and **81** tools for use in inserting both the bone screws and the locking cap in the single locking plate **600** are shown. In the first embodiment of the driving tool **1000** shown in FIG. **80**, the tool **1000** has an outer tubular housing **1002**. Within the housing **1002** is a torks type or hexagonal driver **1004** that has a projecting end **1006** that corresponds to the recess **306** in the cap **610** for engagement with the cap **610**. As indicated above, the driver **1004** is configured so that it makes a firm attachment for the locking cap **610** for holding the locking cap **610** firmly to the driver. The hex driver **1004** is hollow so as to be able to permit the shaft **1010** of a Phillips or torks screw driver to fit through the hollow portion **1012** for engagement by its tip **1012** with the corresponding recess **180** of bone screw **170** for engagement by the end **1006** of the driver **1004**. The shaft **1010** of the driver **1000** is longer than the tubular housing and driver **1004** has an upper end (not shown) extending from the top end of the tubular housing **1002** so that it can be rotated by the handle.

The housing **1002** has a diameter that permits the locking cap **610** to be held within the inner end of the tubular housing **1002** by a friction fit or to the driver **1004**. It is appreciated that other methods of holding the locking cap **610** within the end of the tubular housing **1000** may also be employed.

As shown in FIG. **80**, the operation of the bone screw and locking element driver **1000** is as follows: the cap **610** is inserted onto the end of the cap driver **1004**, and then the cap driver **1004** with the shaft **1010** of the bone screw driver passing through the central longitudinal opening of the cap driver. As shown, the bone screw driver shaft **1010** passes through the recess **306** in the cap **610** and engages the recess **180** in the head of the bone screw **170**. The bone screw **170** is shown being installed in a bone screw receiving hole in the plate **600**. The handle (not shown) of the bone screw driver is rotated, thereby screwing the bone screw **170** in place. Since the diameter of the bone screw driver is less than the width of the recess **306** of the cap **610**, the bone screw driver shaft **1010** is able to rotate without rotation of the cap **610**.

The hollow tubular housing **1002** rests on the top surface of the plate **600** and assists in the alignment of the shaft **1010** in relationship to the plate. Once the bone screw **170** is inserted, the cap driver **1004** is depressed until the threads **608** on the outside of the cap **610** engages the threads **603** of the bone screw receiving hole. The cap driver **1004** is then turned until the cap **610** is securely locked in place.

In FIG. **81**, an alternative embodiment of the combination bone screw and locking cap driver is shown. In this embodiment, a housing is not used. Instead, the driver shaft **1010** holds the cap **610** by friction and the handle **620** for the bone screw driver shaft **1010** is rotated. A ball spring assembly **622** holds the cap driver **1002** up until the bone screw has been screwed into the bone screw receiving hole. Driver **1010** has an elongated portion that once the bone screw has been installed, the ball spring **622** is depressed and the handle **624** associated with the cap driver is permitted to descend for rotation of the cap **610**. A tubular housing can be employed to assist in aligning of the cap **610** in the bone screw receiving hole, as indicated above.

The drivers shown in FIGS. **80** and **81** simplify the procedure, and reduce the number of instruments that are necessary to be used during the installation procedure. The procedure is quick and reliable, giving the physician more assurance that small watch parts will not be lost or difficult to manipulate.

FIG. **52** is a top view of the plate **600** partially installed, with threaded locking caps **600** installed in bone screw receiving holes **602**.

FIGS. **53–55** show a bone screw **170** for use with the single locking plating system according to the invention. Bone screw **170** differs from bone screw **30** previously described in detail, only with regard to the stepped configuration of head **172**. Preferably, bone screw **170** includes a lower portion **174** which is contiguous with the screw shank and has a reduced diameter equal to the maximum diameter of the shank **176**. Portion **178** of head **172** also has smaller diameter than lower portion **174**. The thread **182** has the same configuration as for the bone screw **30** discussed above. However, either embodiment of bone screws can be used with any of the plates.

As in the case of the multiple locking plating system described above, the bone screws **170** for use in the single locking plating system are preferably solid, where the screws adjoin the lower plate surface, where screws used with prior art plates are most prone to breakage, the only recess in the heads being for engagement of the tip **222** of driving tool **220** and with the recess being above the critical area. Therefore, these bone screws **170** remain robust. The screw heads are not deeply slitted into portions and the locking caps do not impose a radial outer force on the associated bone screw heads so the screw heads do not spread apart so as to be stressed and weakened.

Referring to FIGS. **71**, **73** and **75** another alternative embodiment of the single locking plate system of the present invention is shown and referred to by the number **500**. The plate **500** has the same contour as the plate **2** shown in FIGS. **1–5**, but associated with each of the bone screw openings **502**, are threaded openings **524** offset from the bone screw openings **502** for receiving the locking element **506**, **508**, shown in FIGS. **72** and **74** as a threaded locking set screw or cap **506** or screw **508**.

It is appreciated that other configurations of single locking plates may be employed. Referring to FIG. **82**, a single locking plate **900** is shown in which there are a pair of bone screw receiving holes **910** at its ends **930** and a number of bone screw receiving holes **950** along the longitudinal axis

EXHIBIT E

US006936050B2

(12) **United States Patent**
Michelson

(10) **Patent No.: US 6,936,050 B2**
(45) **Date of Patent: Aug. 30, 2005**

(54) **MULTILOCK ANTERIOR CERVICAL PLATING SYSTEM**

(76) Inventor: **Gary K. Michelson**, 438 Sherman Canal, Venice, CA (US) 90291

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 260 days.

(21) Appl. No.: **10/409,805**

(22) Filed: **Apr. 9, 2003**

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Related U.S. Application Data

(62) Division of application No. 10/386,275, filed on Mar. 11, 2003, which is a division of application No. 09/618,036, filed on Jul. 17, 2000, now Pat. No. 6,620,163, which is a division of application No. 09/022,293, filed on Feb. 11, 1998, now Pat. No. 6,193,721.

(60) Provisional application No. 60/037,139, filed on Feb. 11, 1997.

(51) **Int. Cl.**[7] **A61B 17/70**

(52) **U.S. Cl.** **606/61**; 606/69; 606/70; 606/71; 606/76; 606/77

(58) **Field of Search** 606/61, 69, 70, 606/71, 76, 77

(56) **References Cited**

U.S. PATENT DOCUMENTS

74,489	A	2/1868	Bidwell
824,867	A	7/1906	Houghton
1,105,105	A	7/1914	Sherman
2,423,511	A	7/1947	Luben et al.

(Continued)

FOREIGN PATENT DOCUMENTS

DE	4409833	10/1995
DE	4414781	11/1995
EP	0 554 915	8/1993
EP	1106144	6/2001
FR	2 740 321	4/1997
WO	WO 90/02526	3/1990
WO	WO 94/17744	8/1994
WO	WO 94/26193	11/1994
WO	WO 95/11632	5/1995
WO	WO 95/31941	11/1995
WO	WO 95/35067	12/1995
WO	WO 96/08206	3/1996
WO	WO 96/39975	12/1996

OTHER PUBLICATIONS

Advertisement for Codman Anterior Cervical Plate System by Codman; Johnson & Johnson; Professional, Inc.; undated.

AESCULAP Scientific Information Booklet; *Anterior Cervical Fusion and Interbody Stabilization with the Trapezial Osteosynthetic Plate Technique* by Wolfhard Casper; Feb. 1986.

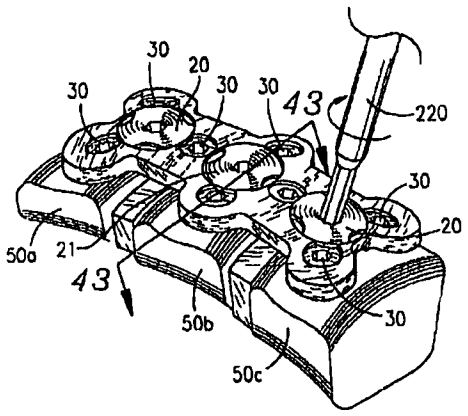
(Continued)

Primary Examiner—David O. Reip
(74) *Attorney, Agent, or Firm*—Martin & Ferraro, LLP

(57) **ABSTRACT**

Anatomically contoured anterior cervical plates with bone ingrowth surfaces, providing for intersegmental compressive preloading, and a rigid and locked interface to all of the bone screws, with those engaging the vertebrae deployed in highly convergent pairs. The bone screws have a tapered self-tapping leading end, an increasing root diameter with a generally constant outer diameter with a thread that is narrow and sharp throughout and an enlarged head portion capable of an interference fit to the receiving holes of the plate. Instrumentation consists of plate holders, a compression apparatus and a pilot hole forming device that interlocks with the plate. Methods for spinal compression and bone hole preparation are provided.

39 Claims, 20 Drawing Sheets



U.S. PATENT DOCUMENTS

2,757,457	A	8/1956	Ziegelski, Sr.
3,244,170	A	4/1966	McElvenny
3,386,437	A	6/1968	Treace
3,604,414	A	9/1971	Borges
3,709,219	A	1/1973	Halloran
3,750,652	A	8/1973	Sherwin
3,840,014	A	10/1974	Ling et al.
3,960,147	A	6/1976	Murray
4,069,586	A	1/1978	Skelton
4,102,339	A	7/1978	Weber et al.
4,338,926	A	7/1982	Kummer et al.
RE31,628	E	7/1984	Allgower et al.
4,488,543	A	12/1984	Tornier
4,493,317	A	1/1985	Klaue
4,503,848	A	3/1985	Caspar et al.
4,542,539	A	9/1985	Rowe, Jr. et al.
4,651,724	A	3/1987	Berentey et al.
4,733,657	A	3/1988	Kluger
4,794,918	A	1/1989	Wolter
4,896,661	A	1/1990	Bogert et al.
5,549,612	A	8/1996	Yapp et al.
5,558,674	A	9/1996	Heggeness et al.
5,562,663	A	10/1996	Wisnewski et al.
5,562,672	A	10/1996	Huebner et al.
5,578,034	A	11/1996	Estes
5,601,553	A	2/1997	Trebing et al.
5,607,426	A	3/1997	Ralph et al.
5,616,142	A	4/1997	Yuan et al.
5,643,265	A	7/1997	Errico et al.
5,662,652	A	9/1997	Schafer et al.
5,672,175	A	9/1997	Martin
5,676,666	A	10/1997	Oxland et al.
5,676,703	A	10/1997	Gelbard
5,735,853	A	4/1998	Olerud
5,735,899	A	4/1998	Schwartz et al.
5,755,796	A	5/1998	Ibo et al.
5,766,254	A	6/1998	Gelbard
D402,032	S	12/1998	Stone
5,849,012	A	12/1998	Abboudi
D406,646	S	3/1999	Stone
5,876,402	A	3/1999	Errico
5,876,446	A	3/1999	Agrawal et al.
5,954,722	A	9/1999	Bono
6,022,350	A	2/2000	Ganem
6,030,389	A	2/2000	Wagner et al.
6,152,927	A	11/2000	Farris et al.
6,342,055	B1	1/2002	Eisermann et al.

OTHER PUBLICATIONS

Article from Plastic and Reconstructive Surgery; *Comparison of Compression and Torque Measurements of Self-Tapping and Pretapped Screws* by John T. Phillips, M.D., F.R.C.S. (C), and Berton A. Rahn, M.D., D.D.S.; Mar. 1989.

Article from The Journal of Prosthetic Dentistry; *Bone–implant interface structures after nontapping and tapping insertion of screw–type titanium alloy endosseous implants* by Keiichi Satomi, D.D.S.; Yasumasa Akagawa, D.D.S., Ph.D.; and Hiroshima Tsuru, D.D.S., Ph.D.; Mar. 1988; vol. 59, No. 3.

Article from The Surgeon; *The Anterior Plating of the Cervical Spine with the Titanium Hollow Screw System* by E. Morshcer, F. Sutter, H. Jenny and S. Olerud; (1986).

Brochure by SYNTHES Spine for *Cervical Spine Locking Plate*; 1991.

ORION Brochure; *Anterior Cervical Plate System, Surgical Technique*, as described by Gary L. Lowery, M.D., Ph.D.; 1996.

CODMAN Brochure; *Anterior Cervical Plate System*; Sep. 1995.

AcroMed; *AcroPlate Anterior Cervical System: Ordering Information for Implants and Instruments*; 1994.

AcroMed; *Kaneda Anterior Spinal Instrumentation System, Technique Manual.*

AcroMed; *University Plate Titanium Anterior System: Ordering Information for Implants and Instruments*; 1994.

Caspar et al.; *Experimental and Clinical Studies, Anterior Cervical Fusion and Caspar Plate Stabilization for Cervical Trauma*; Neurosurgery; vol. 25; No. 4; 1989; pp. 491–502.

Caspar, Wolfhard; *Anterior Cervical Fusion and Interbody Stabilization with the Trapezial Osteosynthetic Plate Technique*AESCULAP Scientific Information Booklet.

Cloward Instrument Corporation; *Brochure, New Cloward Cervical Dislocation Reducer*; Catalog No.C–17–1000.

Cloward Instrument Corporation; *Brochure, New Cloward Lumbar Vertebra Spreader*; Catalog. No. C61–1025/C61–1026.

Cloward Instrument Corporation; *Catalog, Cloward Instruments*; 1993; 1–38.

Foley et al.; *Aline Anterior Cervical Plating System: Surgical Technique*: Surgical Dynamics; 1998; pp. 1–16.

Stryker Implants; *alpha plate*; 1997.

Synthes Spine; *New Additions, Cervical Spine Locking Plate System*, 1995; pp, 1–17.

Synthes Spine; *Product Profile*; 1993; pp. 1–8.

Synthes Spine; *The Titanium, Anterior Thoracolumbar Locking Plate System, Technique Guide*; 1994; pp. 1–13.

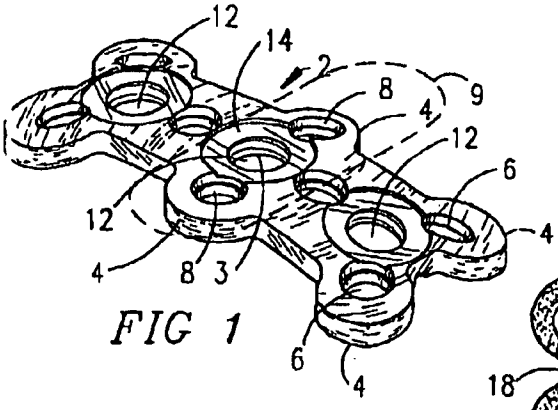


FIG 1

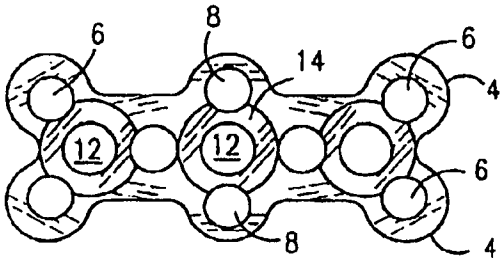


FIG 2

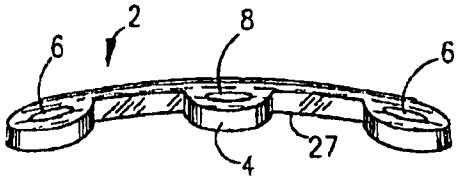


FIG 3

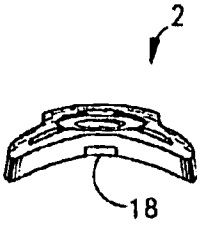


FIG 4

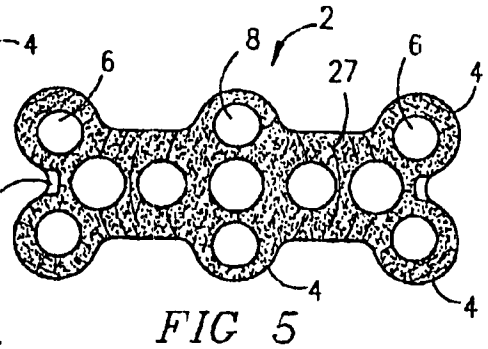


FIG 5

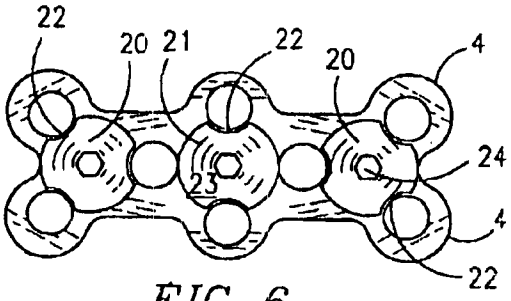


FIG 6

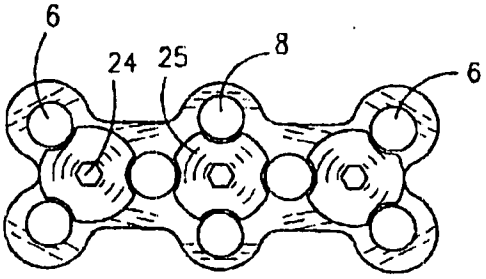


FIG 7

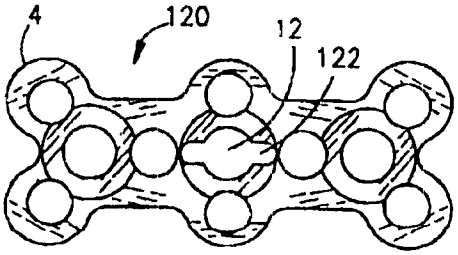


FIG 8

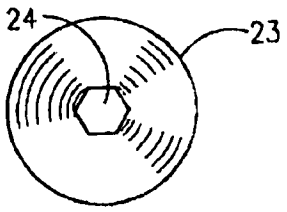


FIG 9

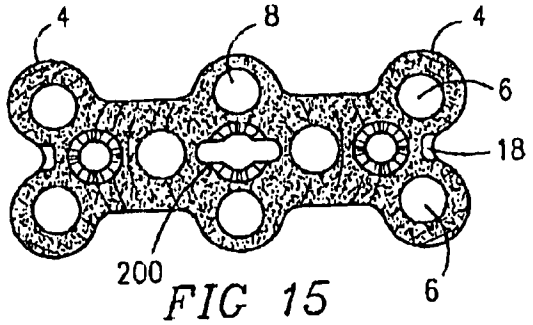


FIG 15

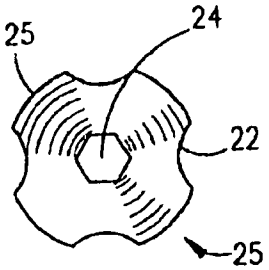


FIG 10

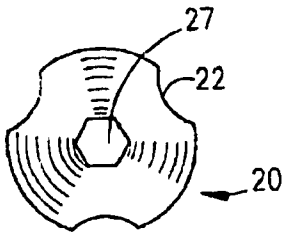


FIG 11

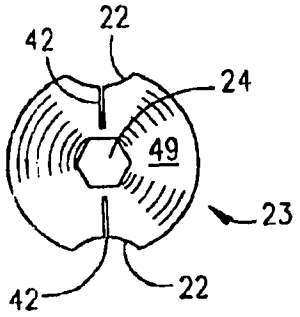


FIG 16

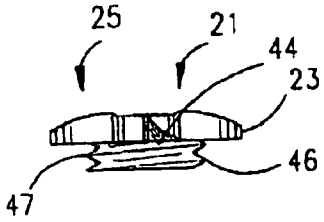


FIG 12

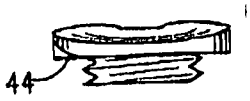


FIG 13

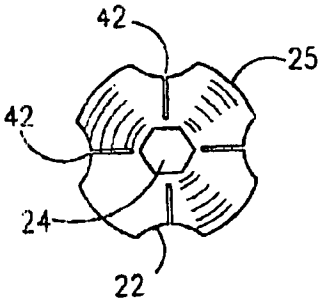


FIG 17

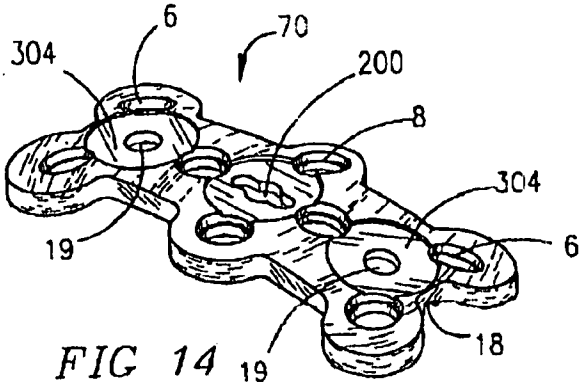


FIG 14

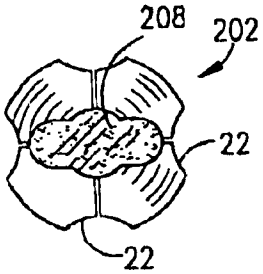


FIG 18

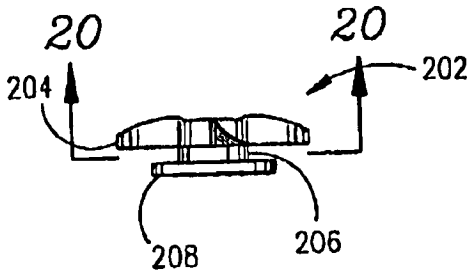


FIG 19

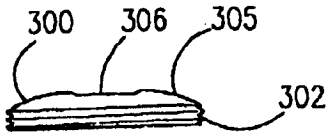


FIG 23

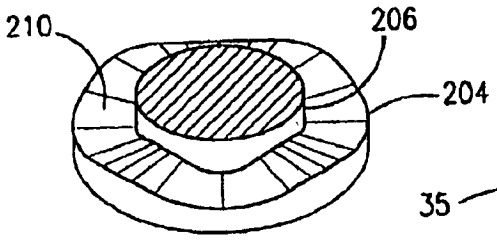


FIG 20

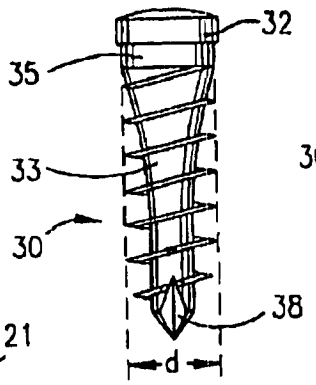


FIG 24A

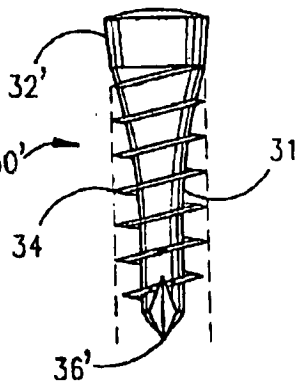


FIG 25

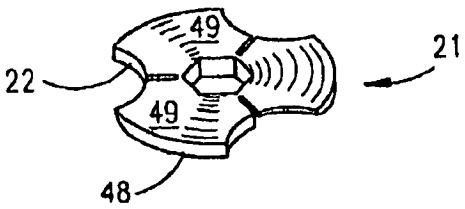


FIG 21

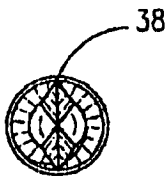


FIG 26

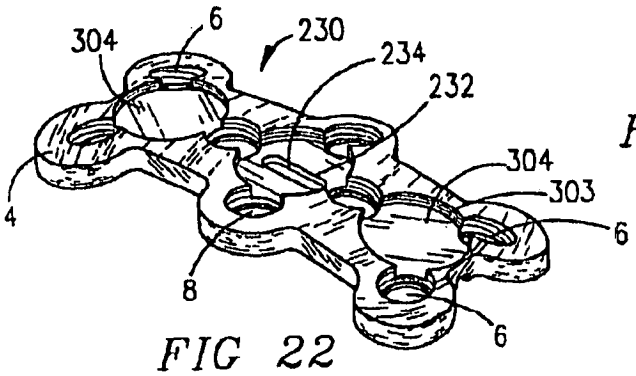


FIG 22

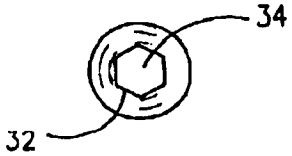


FIG 27

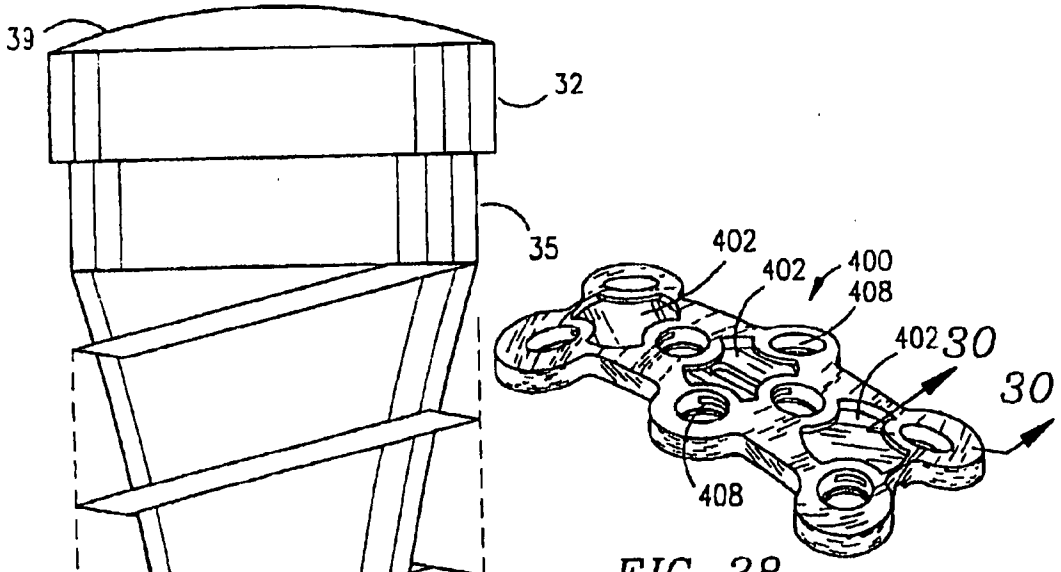


FIG 28

FIG 24B

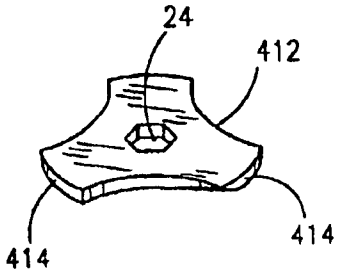


FIG 29

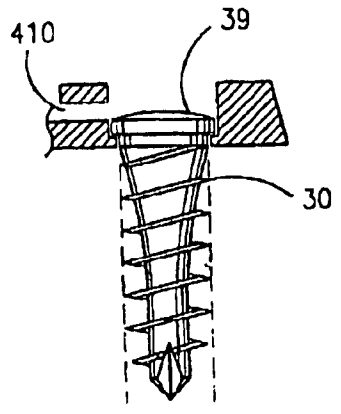


FIG 30

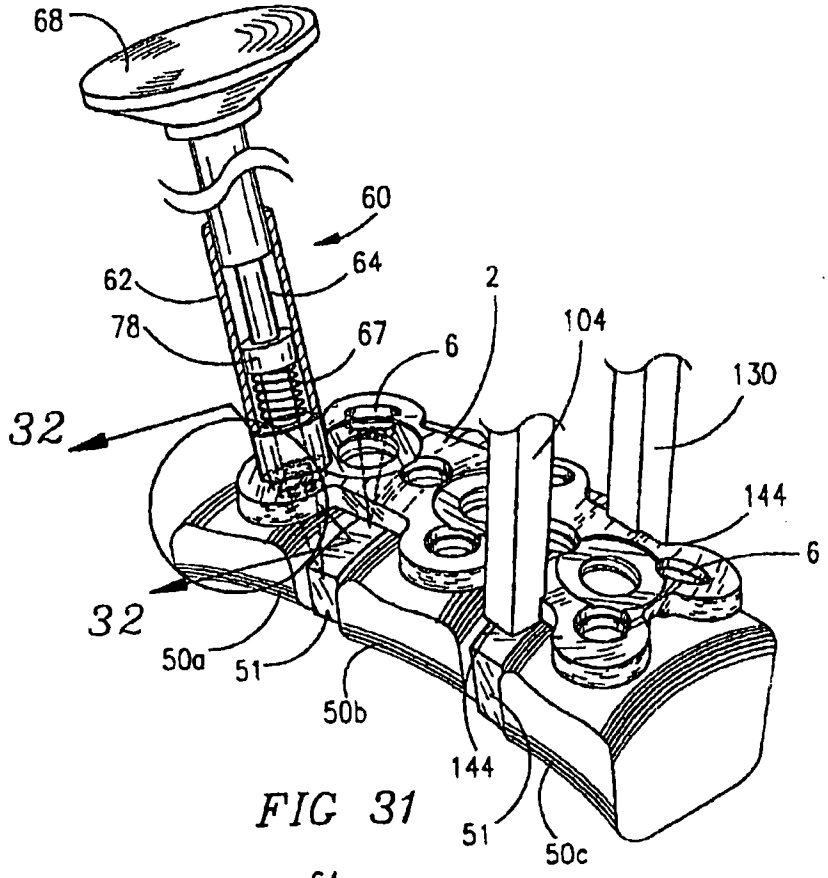


FIG 31

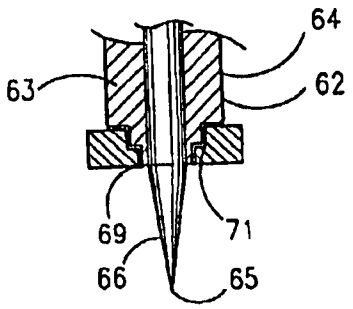


FIG 32

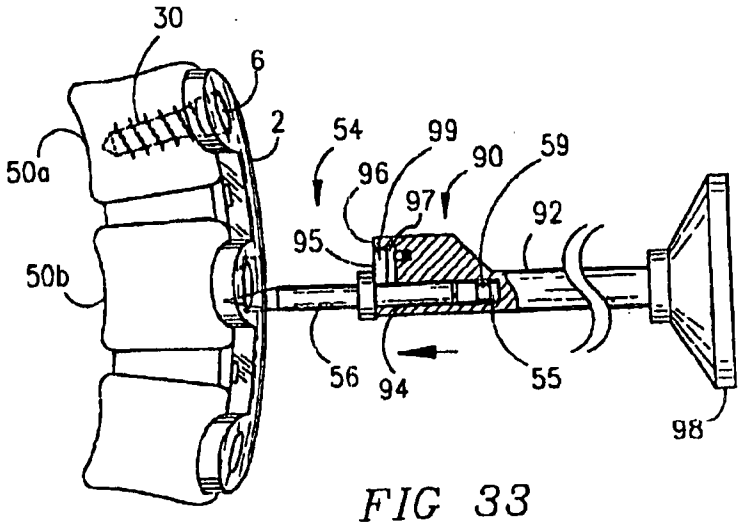


FIG 33

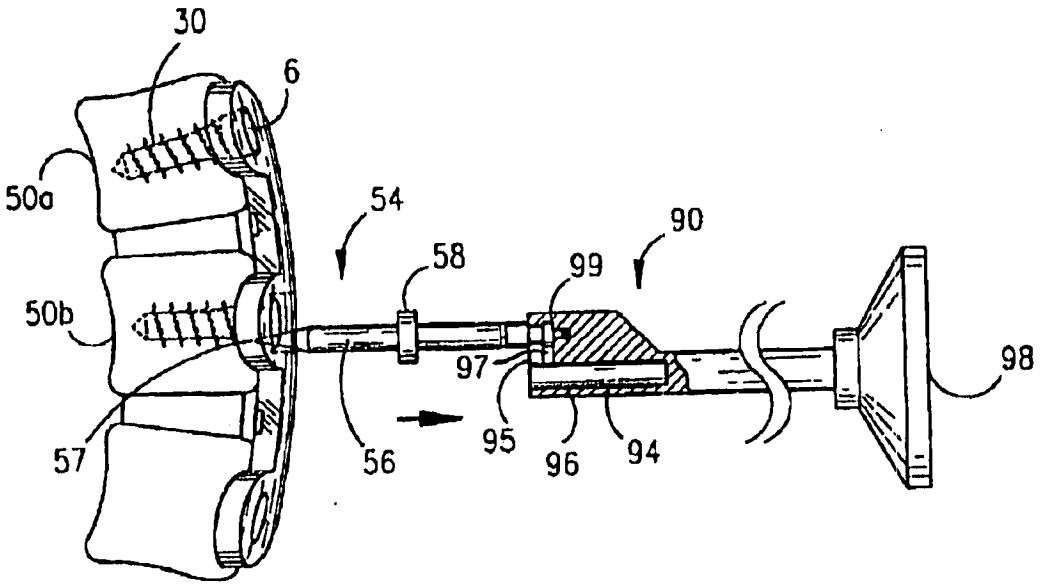


FIG 34

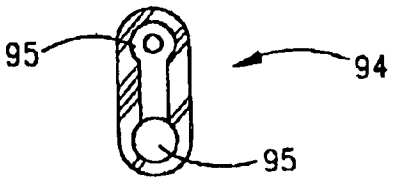


FIG 35

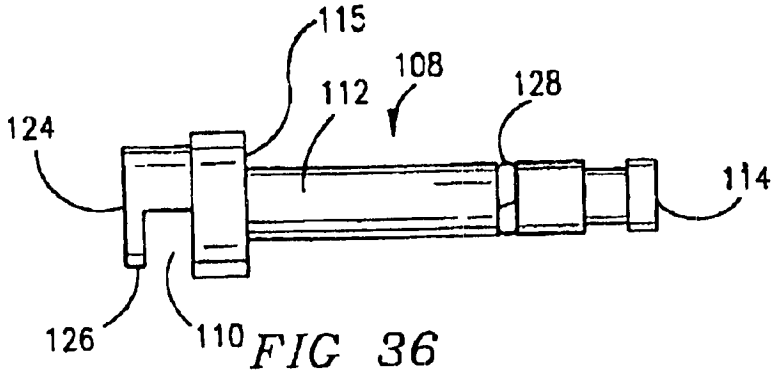


FIG 36

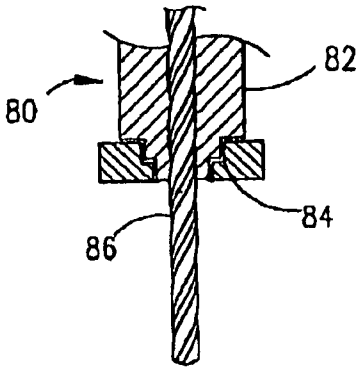
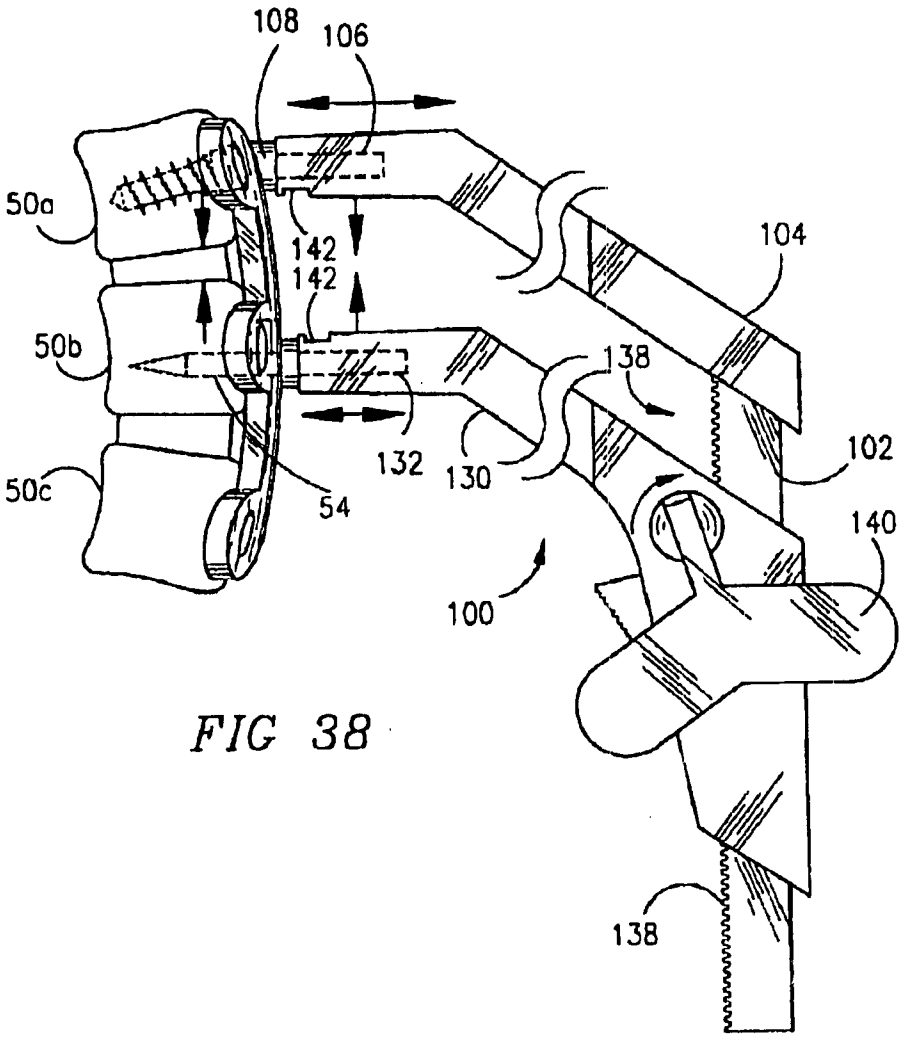

80
82
84
86

FIG 37


108
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130
102
50c
54
140
100
138

FIG 38

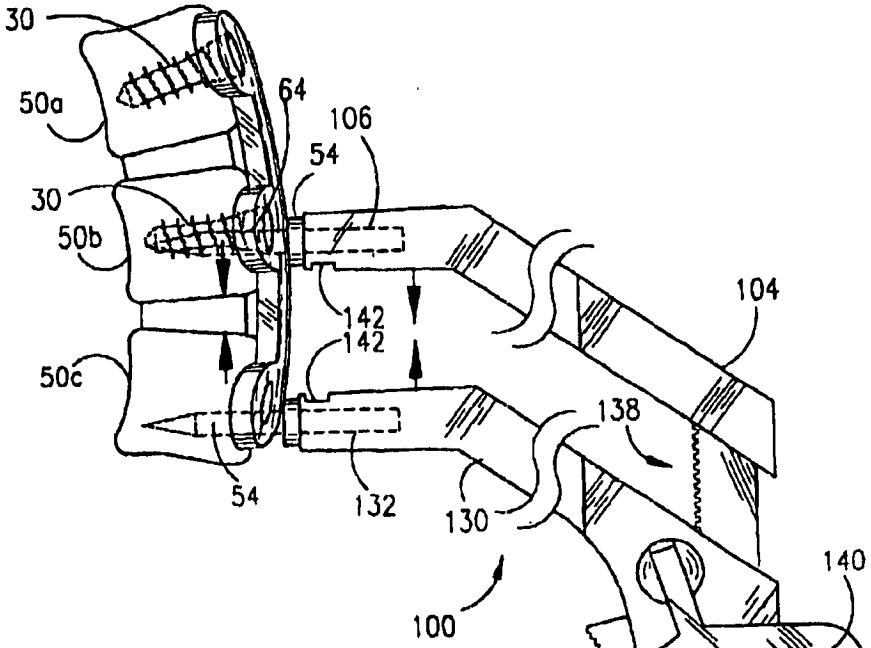


FIG 39

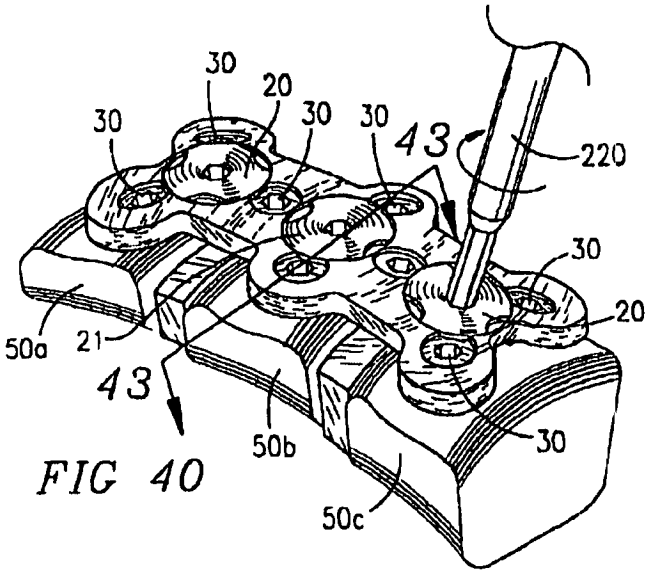


FIG 40

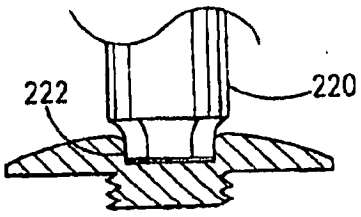


FIG 41

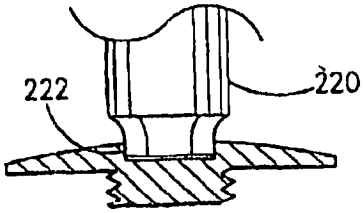


FIG 42

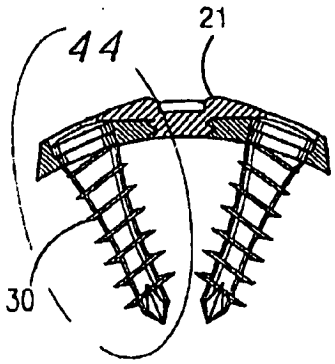


FIG 43

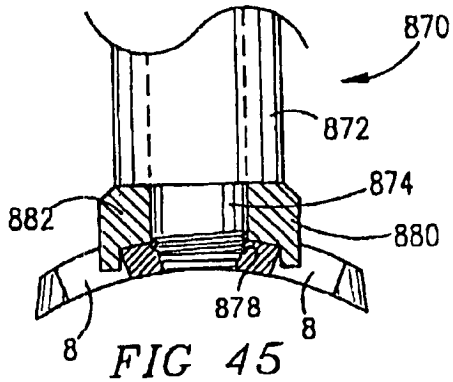


FIG 45

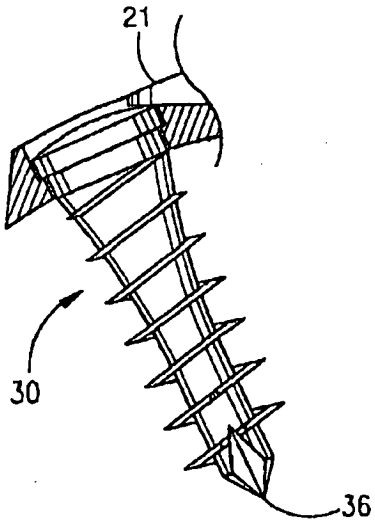


FIG 44

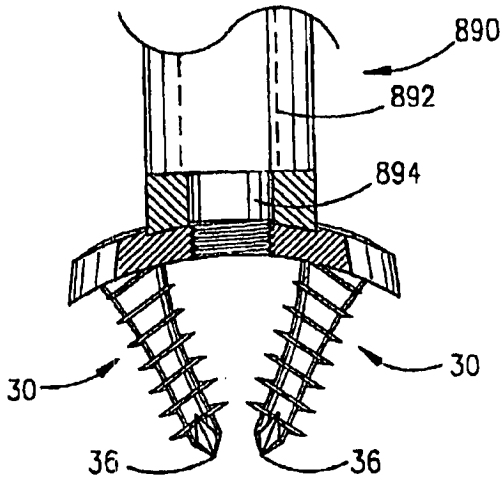


FIG 46

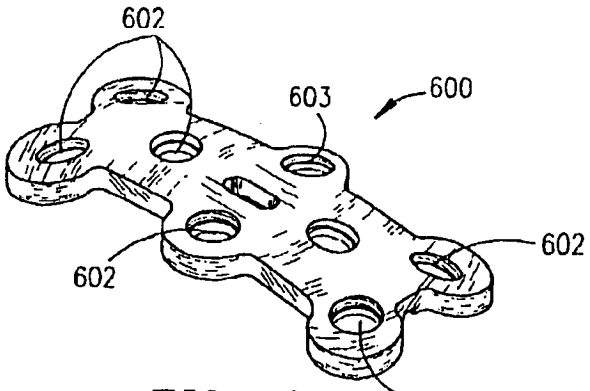


FIG 47

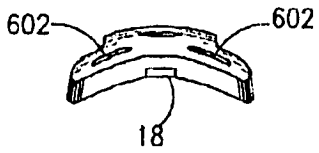


FIG 50

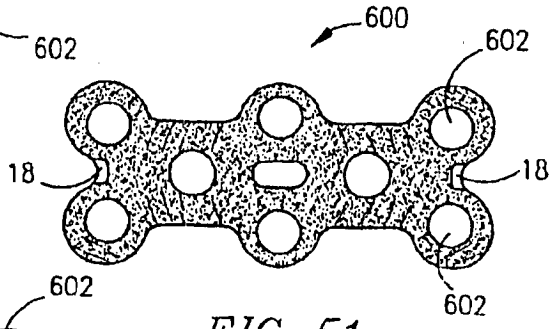


FIG 51

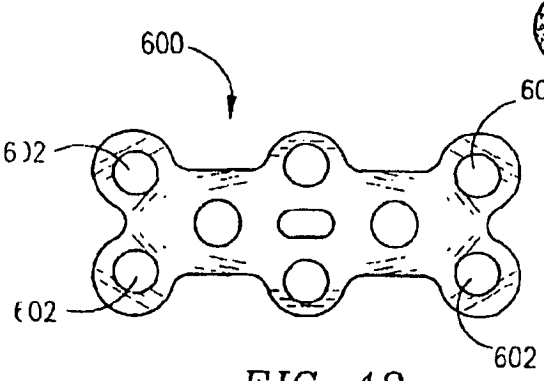


FIG 48

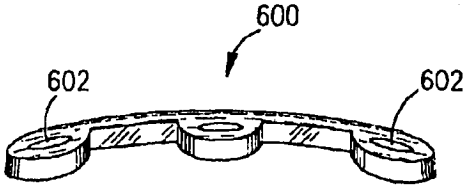


FIG 49

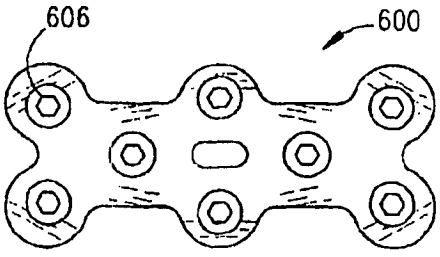


FIG 52

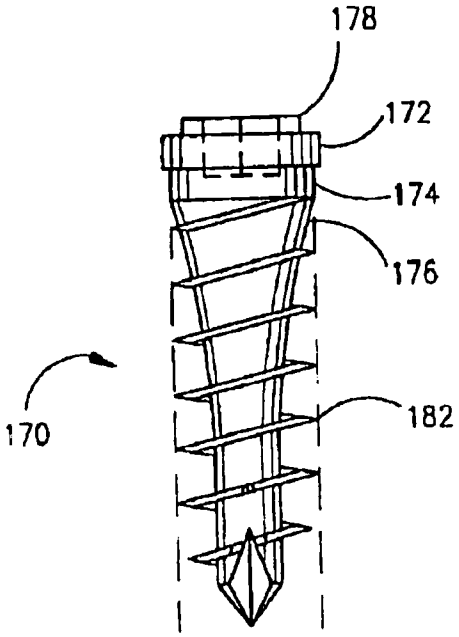


FIG 53

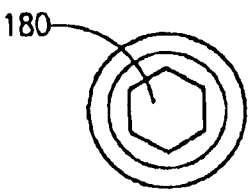


FIG 54

FIG 55

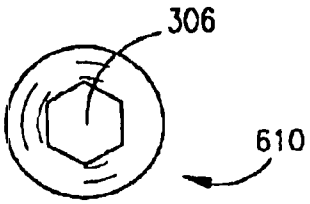


FIG 56

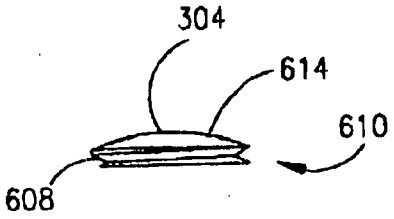


FIG 57

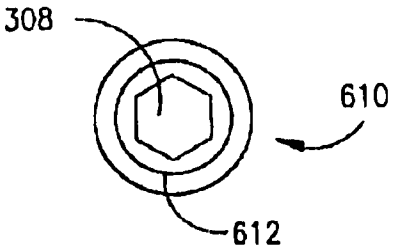


FIG 58

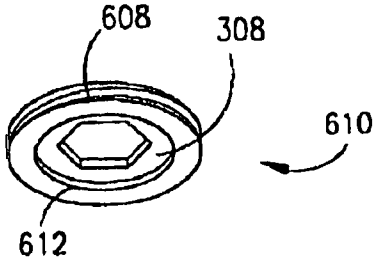


FIG 59

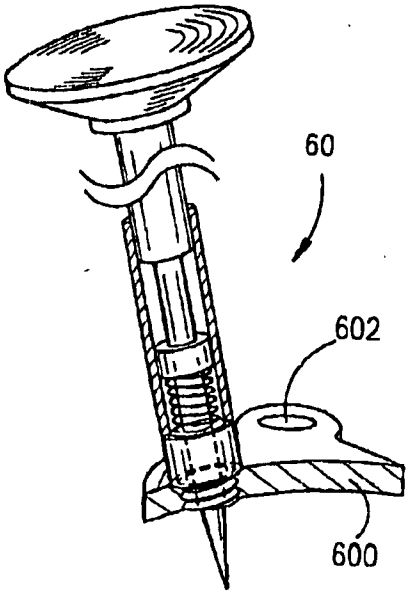


FIG 61

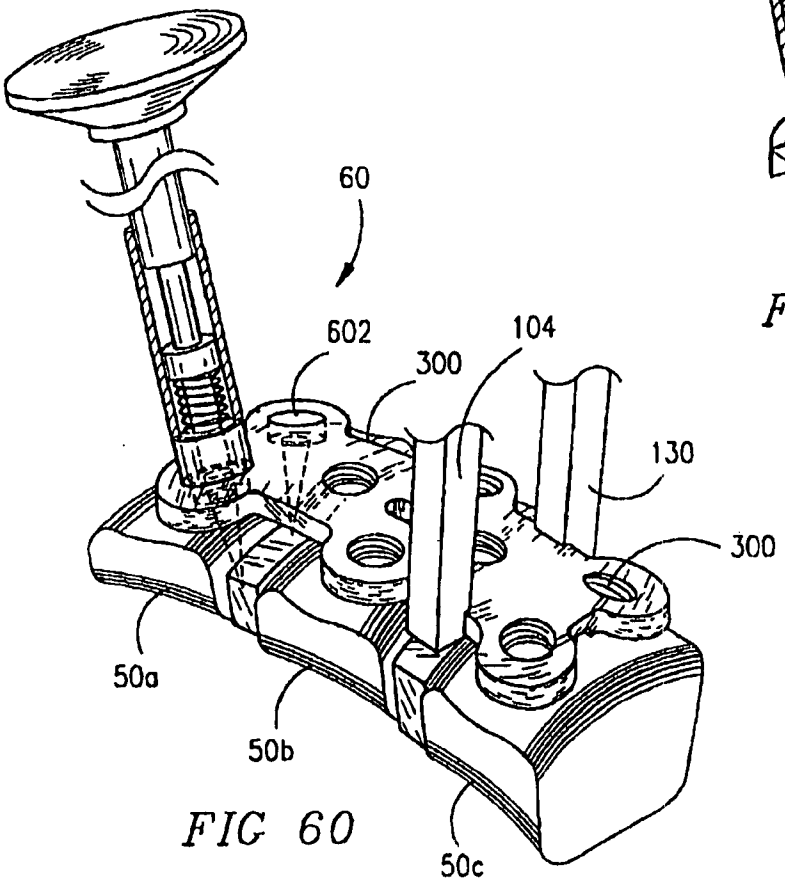


FIG 60

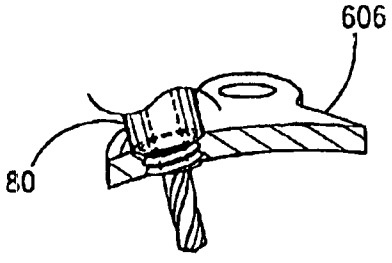


FIG 62

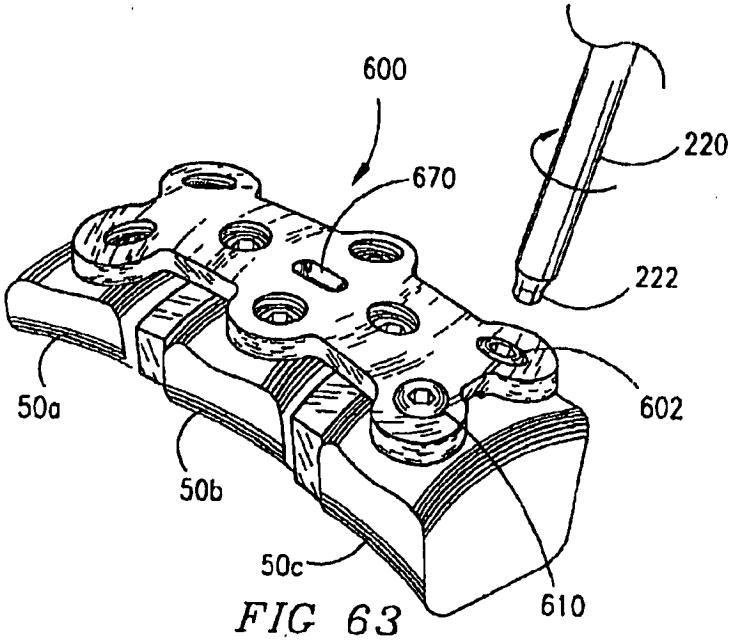


FIG 63

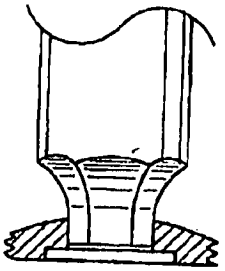


FIG 64

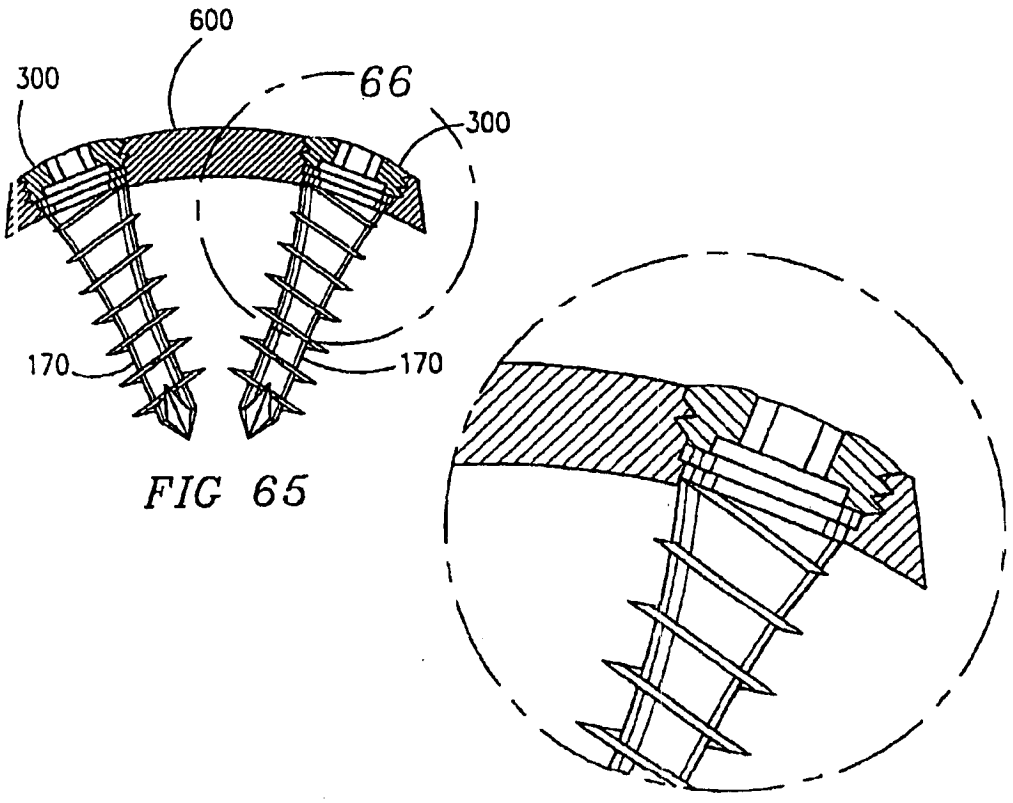


FIG 65

FIG 66

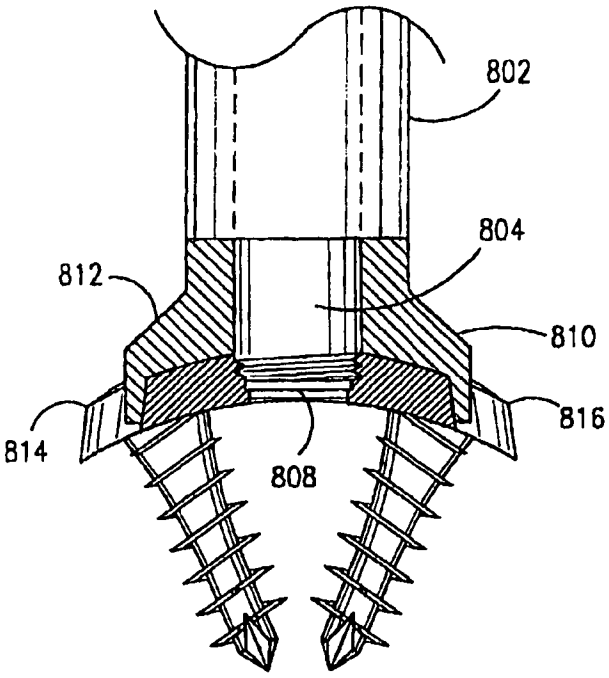


FIG 68

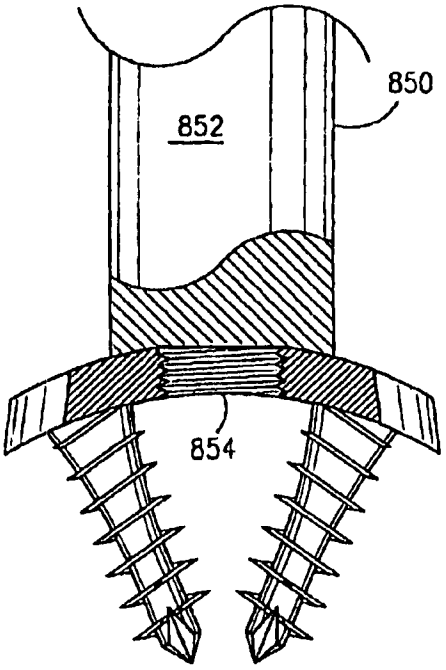


FIG 69A

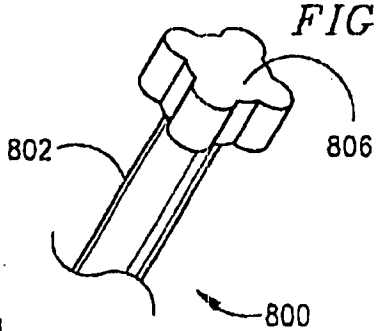
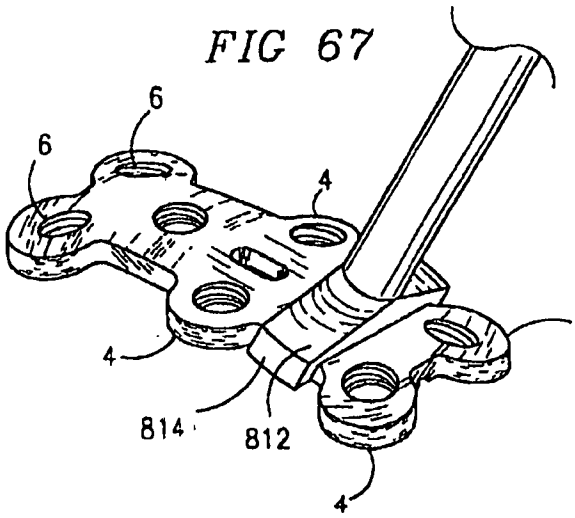


FIG 67



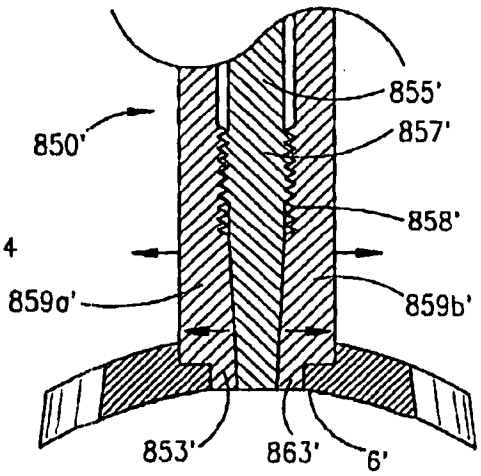


FIG 69B

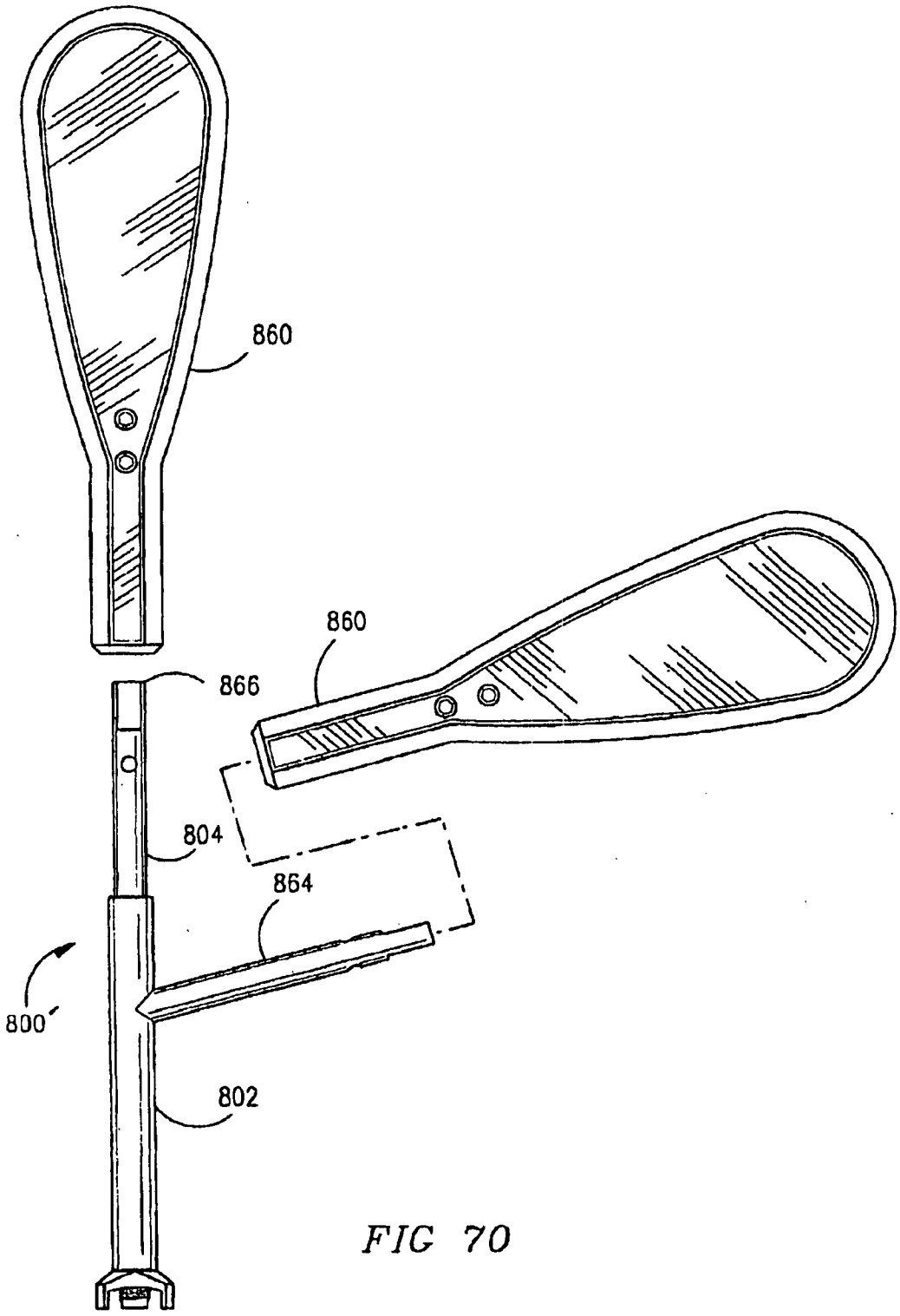


FIG 70

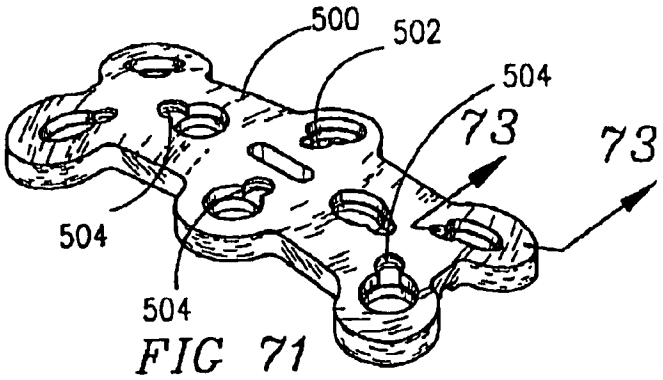


FIG 71

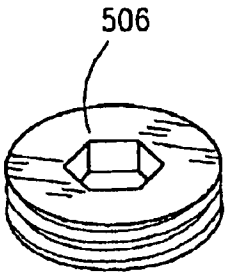


FIG 72

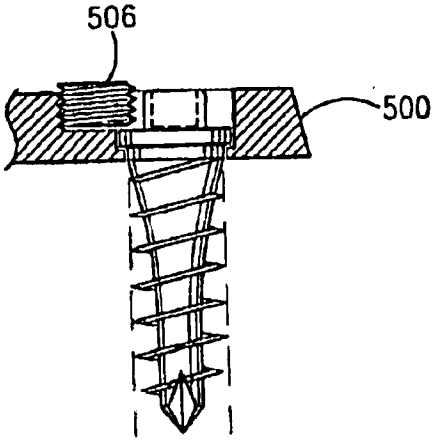


FIG 73

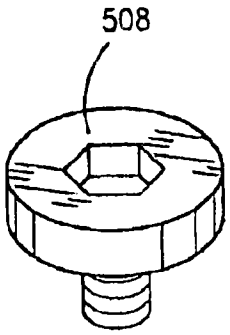


FIG 74

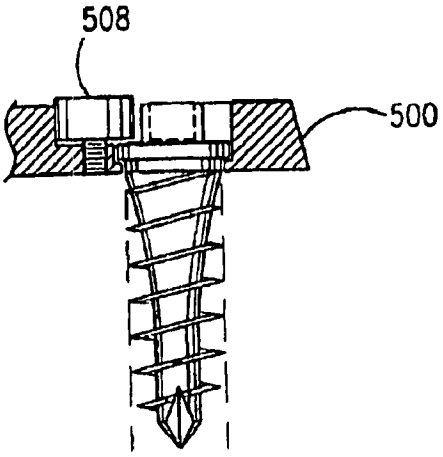


FIG 75

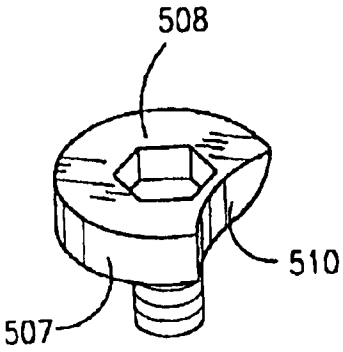


FIG 76

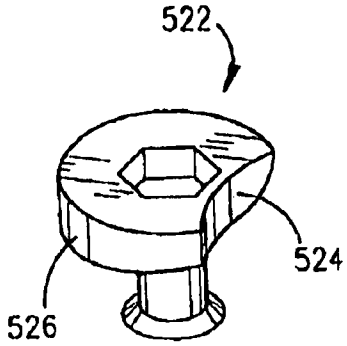


FIG 78

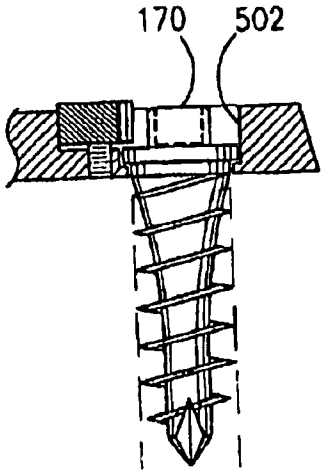


FIG 77

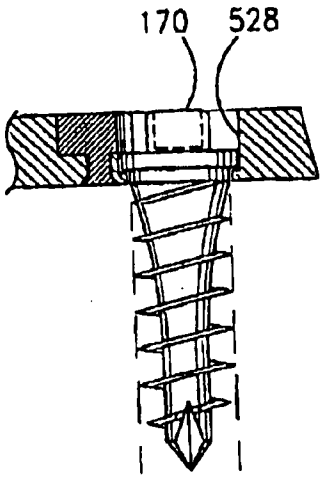


FIG 79

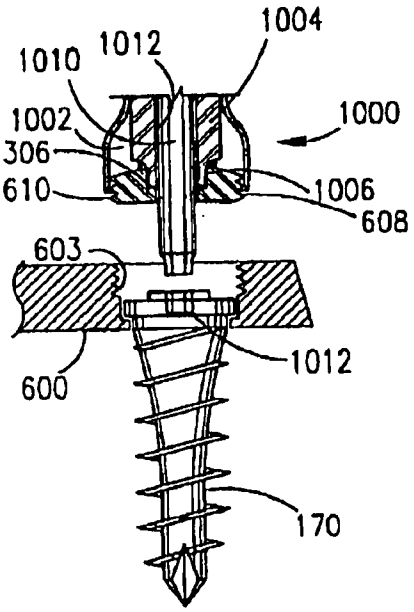

1004
1010
1012
1002
1000
306
610
1006
608
603
1012
600
170

FIG 80

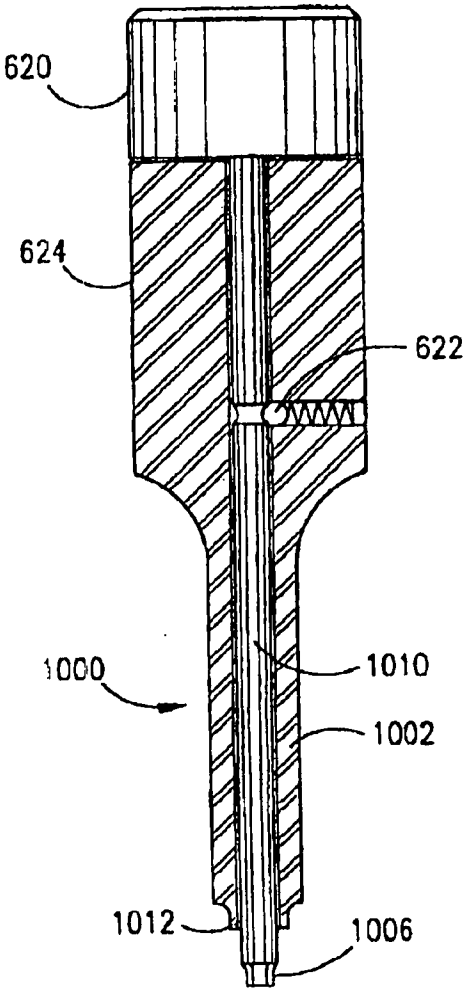

620
624
622
1000
1010
1002
1012
1006

FIG 81

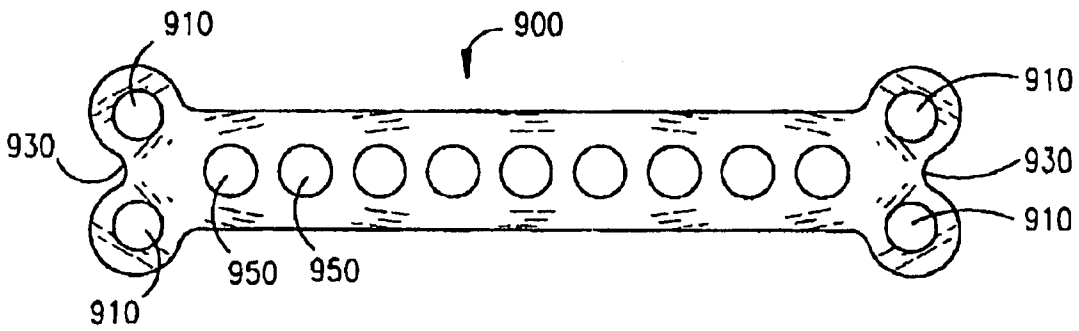


FIG 82

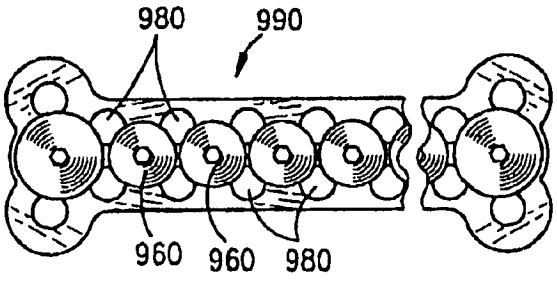


FIG 83

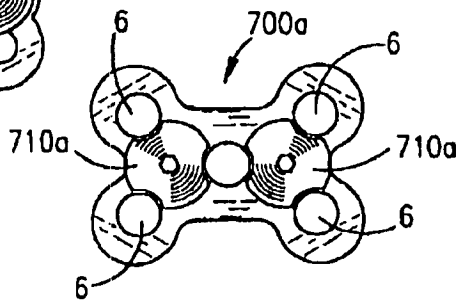


FIG 84A

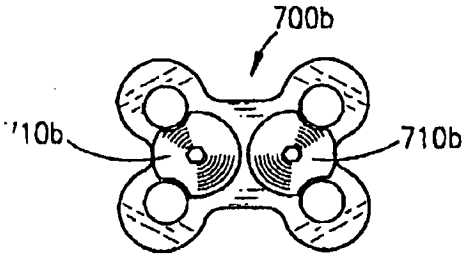


FIG 84B

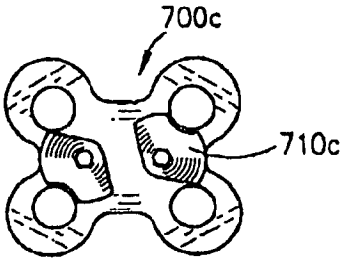


FIG 84C

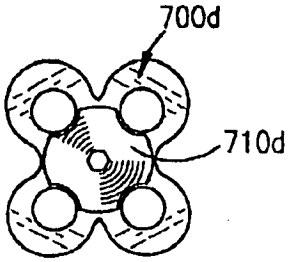


FIG 84D

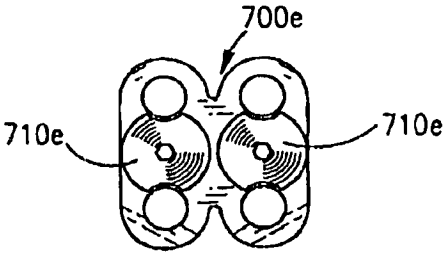


FIG 84E

MULTILOCK ANTERIOR CERVICAL PLATING SYSTEM

RELATED APPLICATIONS

This application is a divisional of application Ser. No. 10/386,275, filed Mar. 11, 2003; which is a divisional of application Ser. No. 09/618,036, filed Jul. 17, 2000, now U.S. Pat. No. 6,620,163; which is a divisional of application Ser. No. 09/022,293, filed Feb. 11, 1998, now U.S. Pat. No. 6,193,721; which claims the benefit of U.S. provisional application Ser. No. 60/037,139, filed Feb. 11, 1997; all of which are incorporated herein by reference. Application Ser. No. 09/022,344, filed Feb. 11, 1998, and titled SKELETAL PLATING SYSTEM, now U.S. Pat. No. 6,139,550, is incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to implants, method, and instrumentation for fusion of the human cervical spine from the anterior aspect, and in particular to plate systems for aligning and maintaining adjacent cervical vertebrae in a selected spatial relationship during spinal fusion of those vertebrae.

2. Description of the Related Art

It is current practice in the art to use cervical plating systems for this purpose. Such systems are composed essentially of plates and screws for aligning and holding vertebrae in a desired position relative to one another. The earliest such devices consisted of stainless steel plates and screws and required that the screws passed entirely through the vertebrae and into the spinal canal in order to engage the strong bone tissue (the posterior cortex) of the vertebral bodies. This required the ability to observe or visualize this area radiographically, which is not always possible, especially in the lower cervical spine where the vertebrae may be hidden radiographically by the shoulders.

In order to form holes in the vertebral bodies for insertion of each screw, a drilling operation was performed, followed by a tapping operation. Each of these operations involved the passage of an instrument entirely through the associated vertebral body and into the spinal column. Thus, these instruments come into close proximity to the spinal cord and the dural sac which are in close proximity to the back surfaces of the vertebral bodies. Any procedure which introduces an object into the spinal canal presents serious risks which are of concern to the surgeon.

The conventional technique of forming a bone screw receiving hole in vertebral bodies by drilling has a number of significant disadvantages. For example, drilling removes bone material, leaving a void and resulting in a loss of bone material. Drilling also causes microfracturing of the bone at the drill bit-bone interface and the resulting fracture lines tend to propagate in directions perpendicular to the wall of the hole. More specifically, the bone material is essentially a type of ceramic which exhibits a brittle pattern of fracture formation and propagation in response to drilling. Furthermore, drilling generates heat which can result in thermal necrosis of the bone material precisely at the interface between the bone and a subsequently installed screw, where necrosis is most harmful. Any bone which does experience necrosis will subsequently be resorbed by the body as part of the bone repair process and this can lead to the loosening of the screw.

Another problem with drilling is that the path of the drill bit is difficult to control and since the drill bit operates by

rotation, it can wind up soft tissue about the associated plate. In addition, unless great care is taken, the drill bit may be driven significantly past the posterior cortex and cause irreparable harm within the spinal canal. Finally, a drill bit may bind and fracture within the vertebral body and can then cause serious injury as the still rotating portion of the drill bit passes into the wound, while the portion of the bit which has broken off may either protrude dangerously from the vertebral body or may be broken off flush with the upper surface of the body so as to be irretrievably embedded therein. In any event, the steps that must be taken to retrieve the broken-off portion of a drill bit will inevitably prolong and complicate the surgical procedure.

In known plating systems, there have been problems with loosening and failure of the hardware, breakage of the screws and plates, and backing out of screws into the patient's throat area. These occurrences generally require further surgical procedures to replace the broken parts or the plates and screws entirely, and to repair any damage that may have been caused.

Other problems which have been encountered with known systems result from the failure of the screws to achieve a sufficient purchase in the bone and the stripping of the screws. Also, the use of the known plating systems may result in a loss of lordosis, which is the normal curve of the cervical spine when viewed from the side.

Known plating systems additionally experience problems in connection with those procedures where bone grafts are placed between vertebral bodies to achieve an interbody fusion which heals by a process called "creeping substitution". In this process, bone at the interface between the graft and a vertebra is removed by a biological process which involves the production of powerful acids and enzymes, as a prelude to invasion of the interface by living tissue and the deposition, or growth, of new bone. While the plates allow for proper alignment of the vertebrae and their rigid fixation, they can therefore, at the same time unfortunately, hold the vertebrae apart while the resorption phase of the creeping substitution process forms gaps in the bone at the fusion site with the result that the desired fusion does not occur. Such failure is known as pseudoarthrosis. When such a failure occurs, the hardware itself will usually break or become loosened from the spine, thus requiring a further surgical procedure to remove the broken components and another surgical procedure to again attempt fusion.

In response to the problems described above, a second generation of plating systems has been developed and/or proposed. These include a system disclosed in U.S. Pat. No. 5,364,399 to Lowery and Pat. No. 5,423,826 to Morscher, as well as cervical spine locking plating systems offered by SYNTHES Spine, the DANEK ORION plate, the CODMAN SHURTLEFF plate, and the SMITH NEPHEW RICHARDS plate, among others. The systems' forming members of this second generation have a number of common properties. They are all made of either a titanium alloy or pure titanium rather than stainless steel, to minimize adverse tissue reactions and are MRI compatible, which stainless steel is not. The screws and the plates have been given increased thickness in order to achieve increased strength. The screws have larger diameters to improve their purchase without requiring that they engage the posterior cortex of the vertebral bodies. Some mild longitudinal contouring of the plates is employed to allow for some lordosis, and/or limited transverse contouring to better follow the generally curved aspect of the front of the vertebral bodies. Mechanisms are employed for securing the vertebral bone screws to their associated plates in a manner to prevent

the screws from backing out. While this second generation of plating systems represents a significant improvement over earlier systems, certain existing problems persist, while new problems have been created.

For example, since the screws no longer extend into the posterior cortex, it is common for the threads in the tapped screw hole to become stripped and for the screws to fail to gain a suitable purchase. In addition, screw breakage continues to be experienced and occurs most commonly at the junction of the screw to the posterior aspect of the plate. The screws employed in both the SYNTHES system and the SMITH NEPHEW RICHARDS system are particularly vulnerable to this problem because those screws are hollow at the level where they attach to the plate to permit the internal reception of locking screws.

In an attempt to prevent screw to plate junction breakage of the screw, more recent designs of screws have an increasing root diameter from tip to head, which thus far has resulted in a near useless stubby and blunt thread near the screw head with little holding power and little tactile feedback to the surgeon to signal the completion of tightening prior to stripping of the screw within the bone. Based on empiric studies testing these prior art screws, the use of a pretapped hole, rather than a self-tapping screw, was found to be preferred for pullout strength and thus these screws have not been self-tapping and thus the screw holes must be pre-tapped. Since the thread cutting portion of a tap is necessarily sharp and rotated to work, there is a serious risk of damage to the surrounding soft tissues when it is used. This is compounded by the fact that the plates employed in these systems do not provide sufficient long axis contouring to make full allowance for lordosis and do not have sufficient transverse contouring to prevent rocking of the plate about its longitudinal axis and to conform to the anterior shape of the vertebral bodies, so that these plates do not prevent soft tissue from creeping in from the sides and beneath the screw holes thus exposing these tissues to damage by the drill and the tap. While it is possible, at the time of surgery, to make some change in the contouring of these plates, this is generally limited to contouring of the longitudinal axis and quite often causes distortion of the plate's bone screw holes and screw hole to plate junctions in a manner which has an adverse effect on the screw-plate interlock. Lack of proper contouring prevents these plates from having an optimally low profile relative to the spine.

In some of the second generation cervical plating systems, screw backout continues to occur, because these plates could not be designed to allow for the locking of all of the screws. Specifically, while the designers of these plates recognized the importance of securing the bone screws to the plates, they were unable to lock all of the screws and had to settle for leaving some of the screws unlocked.

Furthermore, several of these second generation systems utilize tiny and delicate "watchmaker" parts to achieve interlocking. These parts are characterized by the need to engage them with particularly delicate small ended screw drivers. These interlocking components are easily rendered ineffective by any effort to alter the contours of a plate during surgery.

Despite the improvement of these second generation plating systems over the first problems, the problems still persist, the most important of which is pseudoarthroses, and particularly "distraction pseudoarthroses". Although these second generation plates have clearly led to an increase in fusion rate, when a failure to produce fusion occurs, it is generally accompanied by bone resorption along a line at the graft-to-vertebra junction, which can be seen on a radiograph.

In the case of the weak first generation plates and screws, the plates might hold the vertebrae apart, preventing fusion, but only until the hardware would break, relieving the distraction, and then allowing the fusion to occur. The second generation systems of plates are too strong to allow this to occur, thus requiring further surgical procedures for the correction of the pseudoarthroses.

Compression plates are well known and are widely used in orthopedic surgery for the stabilization of tubular bones, and sometimes also flat bones. Such plates may rely on some external compression means or may be self-compressing, relying on the ability of the screw head to slide within a ramped slot such that the tightening of the bone screws through the plate imparts a linear motion perpendicular to the screw axes. U.S. Pat. No. 5,180,381 discloses an attempt to employ such a mechanism in connection with anterior spinal fixation.

However, it has been found that all of the proposed self-compressing plating systems have in common the need for a screw to engage both a proximal and a distal cortex, (bone casing of very dense bone material), so as to anchor the screw tip in a manner to allow the plate to move relative to the screw when tightened rather than allowing the plate to drag the screw off axis. However, as already discussed earlier herein, when a screw is to engage the posterior cortex of the vertebral body, it is necessary for the drill and the tap which form the screw hole, as well as the screw tip itself, to all enter the spinal canal, thereby exposing the spinal cord to damage.

While the system disclosed in U.S. Pat. No. 5,180,381 avoids such danger by engaging the vertebral body end plate instead of the posterior vertebral body cortex, the path of the screw is of necessity quite short, so that there is very little opportunity for the screw threads to achieve additional purchase within the vertebral body. It would therefore appear that to the extent that the device disclosed in U.S. Pat. No. 5,180,380 is able to achieve its stated objectives, it would pull the front of the spine together more than the back and would not appear to compress the back of the vertebral bodies at all, thus producing an undesirable iatrogenic loss of the normal cervical lordosis. Such a situation is disruptive to the normal biomechanics of the cervical spine and potentially quite harmful.

The creation of compression between adjacent vertebrae would offer a number of advantages, including reduced distraction pseudoarthrosis, increased surface area of contact between the graft and vertebrae as slightly incongruent surfaces are forced together, increased osteogenic stimulation, since compressive loads stimulate bone formation, and increased fusion graft and spinal segment stability.

Among the new problems created by these second generation systems is a tendency for the small "watchmaker" parts used to lock the bone screws to the plate to fall off of the driver used for attaching those parts, or out of the associated plates and to become lost in the wound. In addition, these small parts are quite fragile and require specialized additional instruments for their insertion and/or manipulation. Furthermore, incorrect bone screw placement relative to the axis of a plate hole may render the screw locking mechanism unworkable or may cause sharp and jagged shavings of titanium to be formed as a locking screw is driven into contact with an improperly seated bone screw. The means for establishing bone screw to plate hole alignment and preparation are less than reliable. Furthermore, most of these second generation systems lack a reliable and effective means for positioning and holding the plate during attachment.

Specific features of various prior art systems will be summarized below.

The system disclosed in U.S. Pat. Nos. 5,364,399 and 5,423,826, cited earlier herein, includes a thin stainless steel plate which allows for side-by-side or offset bicortical screw placement, the plate having a combination of screw holes and slots.

The "Acromed" system includes a titanium plate and screws which require bicortical screw placement. This system does not include any locking means for the bone screws.

The system disclosed in U.S. Pat. No. 5,180,381 includes an "H" shaped plate having a combination of ramped slots and a hole which requires bicortical screw placement at a 45N angle to the plane of the plate. This patent discloses that this angular positioning is for the purpose of producing compression.

The SYNTHES Morscher plate system employs hollow, slotted screw heads. The screws are placed unicortically so that the heads, when properly aligned, come to rest in the upper portion of the plate holes. The upper portion of each screw is internally threaded to receive a tiny screw which is screwed into the bone screw head in order to increase the interference fit between the bone screw head and the wall of the associated plate hole.

In the system disclosed in U.S. Pat. Nos. 5,364,399 and 5,423,826, use is made of pairs of unicortical bone screws that may be locked in place at both ends of the associated plate by locking screws which have a small diameter shank and a large head. At each end of a plate two bone screws may be locked in place by a single locking screw which is situated between the bone screws. Generally, the plate is provided, between its two ends, with a diagonal slot or slots for receiving one or more additional screws, each additional screw being securable in a bone graft or a respective vertebra which is spanned by the plate. There is no locking screw associated with these intermediate bone screws to lock the bone screws to the plate.

The Codman Shurtleff plating system utilizes the side of a preinstalled rivet having a head rotatable to press against the side of the head of a bone screw so as to secure that one screw to the plate. The plates of this system also are provided with holes for receiving intermediate screws, but these screws are not associated with any locking means.

While the designers of the last-mentioned systems recognized the importance of locking the bone screws in position on their associated plates, they did not provide for any locking of the intermediate bone screws in their associated holes.

In an earlier version of the Codman Shurtleff system, the locking mechanism was a lever pivotable about a shaft passing entirely through the plate and then flared so as to retain the shaft within the plate. The lever was rotated after the bone screw had been inserted to engage the head of the bone screw and thus secure the bone screw to the plate.

Based on a consideration of the features of all of the known cervical plating systems, it appears that there remains a need for an improved system having the following combination of features:

1) The plate should be sufficiently strong to perform its intended function without mechanical failure;
2) The plate should be preformed in three dimensions so as to anatomically conform in both the longitudinal and transverse planes to the anterior cervical spine;
3) The plate should be constructed so that all of the bone screws are generally perpendicular to the plate when viewed from the side, but pairs of screws are highly convergent corresponding to any vertebral level when viewed from the bottom, or on end;
4) Each pair of screws engages in a respective vertebra and the high convergence of screws in a pair allows the length of the screws which engage the bone to be longer and still remain within that vertebra and provide a safer and stronger engagement with the vertebrae;
5) The system should include bone screws which are capable of achieving enhanced purchase within the bone of the vertebral body and without the need to penetrate the posterior vertebral cortex and enter the spinal canal;
6) Use should be made of a screw which is self-tapping, thereby eliminating the need for separate tapping steps;
7) A reliable means should be provided for engaging and manipulating the plate during installation;
8) The plate should be engageable with an instrument means which can reliably produce bone screw holes which are coaxial with the screw holes in the plate;
9) It should be possible to prepare the vertebral bone to receive the bone screws so as to produce a stronger connection and a reduced danger of thread stripping by means of a pilot hole punch creating a pilot hole for the bone screws;
10) Alternatively to the use of a pilot hole punch, a relatively (compared to the overall root diameter of the screw) small diameter drill may be used to create the pilot hole.
11) Means should be provided for locking each and every bone screw in position relative to the plate, and the locking means should be of sufficient size and strength to reliably perform its intended functions;
12) Bone screw locking means should preferably be retainable by the plate prior to bone screw insertion, or should be reliably attachable to a driver to prevent any small parts from becoming loose in the wound; and
13) The system should be capable of effecting compression of the vertebral segments to be fused while maintaining and/or restoring lordosis.

OBJECTS OF THE INVENTION

It is an object of the present invention to provide an improved anterior cervical plating system, installation instrumentation, and installation method which has the above described features and which avoids many of the shortcomings of previously known systems.

One object of the present invention is to provide a locking mechanism where a plurality of bone screws used for attaching the plate to the vertebrae can be easily and reliably locked in place at the same time by a single operation.

Another object of the present invention is to provide a vertebral plate in which the locking mechanisms for locking the bone screws may be pre-installed by the manufacturer prior to the insertion of the bone screws by the physician so that the physician does not have to attach the locking mechanism to the plate as a separate procedure during the operation.

Another object of the invention is to provide an anterior cervical plating system which allows for the intersegmental compression of the spinal segment (compression of the adjacent vertebrae and the fusion graft in the disc space between the adjacent vertebrae) in lordosis, and similarly, where desired, multisegmental compression.

A further object of the invention is to provide bone screws which provide for tactile feedback to the surgeon to assure sufficient tightening of the screws while avoiding stripping and are less prone to failure by breakage or by loosening.

Another object of the invention is to provide bone screws which achieve optimal purchase within the bone, without the need to penetrate the posterior cortex of the vertebrae.

A further object of the invention is to provide plates which are textured or otherwise treated to promote bone growth from vertebrae to vertebra beneath the plate.

Another object of the invention is to provide a plate which is constructed to reliably engage an instrument for forming all bone screw holes coaxial with the holes formed in the plate, the instrument having integral depth limiting means which completely eliminates the danger of perforation of the posterior vertebral wall or entry into the spinal canal.

Yet another object of the invention is to provide a system in which the bone screws and locking mechanisms, when fully installed, have a low profile.

It is another object of the present invention to provide for an anterior cervical plating system which is at least in part bioresorbable.

It is another object of the present invention to provide for an anterior cervical plating system comprising at least in part of bone ingrowth materials and surfaces.

It is another object of the present invention to provide for an anterior cervical plating system comprising at least in part of bone growth promoting substances.

It is another object of the present invention to provide instruments for reliably and easily performing the installation of the plates of the present invention.

It is still another object of the present invention to provide an improved method of installing the plates of the present invention.

The above and other objects and features of the invention will become more readily apparent from the following description of preferred embodiments of the invention, provided with reference to the accompanying drawings, which illustrate embodiments of the invention solely by way of non-limiting example.

SUMMARY OF THE INVENTION

The plating system of the first preferred embodiment of the present invention comprises a plate having a length sufficient to span a disc space and to overlap, at least in part, at least two adjacent cervical vertebrae, a substantial portion of the lower surface of the plate preferably being biconcave, that is concave curved along a substantial portion of the longitudinal axis of the plate and concave curved along a substantial portion of the transverse axis of the plate. The lower surface of the plate may also textured and/or treated to induce bone growth along the lower surface of the plate which contacts the cervical vertebrae. The plate is provided with a plurality of bone screw receiving holes which extend through the plate, from the upper surface to the lower surface of the plate, and at least one locking element is associated with the bone screw receiving hole. The plate and its component parts, may be made of any implant quality material suitable for use in the human body, and the plate and associated component may be made of a bioresorbable material.

Bone screws are each insertable into a respective bone screw receiving hole for attaching the plate to a vertebra. A locking element, is engageable to a locking element receiving recess and has a head formed to lock the bone screws to the plate. In the preferred embodiment, a single locking element locks a number of different bone screws in place. The locking elements are pre-installed prior to use by the surgeon in a manner so as to not impede installation of the bone screws.

As a result, the problems previously associated with the locking screws of the type applied after the insertion of the bone screws, including the problems of instrumentation to position and deliver to the plate the locking means, backing out, breakage, stripping and misthreading associated with the prior art more delicate locking screws resembling "watchmaker's parts", are eliminated.

In an alternative embodiment of the present invention, a locking element fits within a respective bone screw receiving hole to lock a respective one of the bone screws in place. According to this second embodiment of the invention, each of the bone screws is locked to the plate by means of an individual locking element which bears against at least a portion of the bone screw. Since no other holes need be formed in the plate to attach the locks to the plate, the plate remains quite strong.

The locking elements can be in many forms to achieve their intended purpose, such as, but not limited to, screws, threaded caps, rivets, set screws, projecting elements, and the like.

Also, a novel bone screw is disclosed so as to prevent pulling out of the bone screw during use. This is achieved by a design which includes a screw in which the outer diameter or crest diameter of the thread is maintained substantially constant along the entire length of the shaft of the bone screw, from below the head to above the tip, where threads of a lesser outer diameter facilitate insertion. The screw tip is fluted at its distal end to be self-tapping. The thread also has an extremely thin and sharp profile to cut into and preserve the integrity of the vertebral bone stock.

The plating system does not require that the head of the bone screw be hollow, or that additional holes be placed through the plate in addition to those provided for the passage of the bone screws. It will be appreciated that bone screws are weakened when their heads are hollow and that plates are weakened when they are provided with additional holes.

Additionally, the plate of the disclosed systems permit the proper aligning of the holes in the plate for the bone screws and for the plate to be easily applied to the vertebrae in compression. The plates include appropriate slots and engagement means for engaging compression instrumentation, described in detail below, for applying a compression force between adjacent vertebrae to which the plate is attached, in a reliable and easy manner.

An improved locking screw driver is provided. The driver provides for a wedged interference fit with a recess in the head of the bone screws and the head of the locking elements. The same driver is usable for both bone screws and locking elements. The driver ensures that the locking element cannot fall off the driver and become lost in the wound. The driver has a tapered end to facilitate insertion into the complimentary recess in the head of the screws and is used to engage and pick up the locking elements. Alternatively, the receiving socket can be tapered to the same purpose.

Alternatively, a combination bone screw and locking screw driver is disclosed in which the bone screw driver passes through a longitudinal opening in the locking screw driver so that both the bone screw and the locking screw can be loaded prior to insertion of the bone screw and both can be tightened with one instrument, without removing it from position.

Also, instruments are provided for forming pilot holes to assist in the ease and accuracy of the installment of the bone screws, and for creating a creating a compression force between adjacent vertebrae during installation of the plate and for holding the plate during installation.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a top perspective view of a first embodiment of a cervical spine multiple locking plate.

FIG. **2** is a top plan view of the cervical spine multiple locking plate shown in FIG. **1**.

FIG. **3** is a side elevational view of the cervical spine multiple locking plate shown in FIG. **1**.

FIG. **4** is an end view of the cervical spine multiple locking plate shown in FIG. **1**.

FIG. **5** is a bottom plan view of the cervical spine multiple locking plate shown in FIG. **1**.

FIG. **6** is a top plan view of the cervical spine multiple locking plate shown in FIGS. **1–5**, with locking elements installed in an open configuration.

FIG. **7** is a top plan view of a modification of the plate of FIGS. **1–6** with a four bone screw locking element in place.

FIG. **8** is a top plan view of a further embodiment of a cervical locking plate of FIG. **1** with an elongated central slot for increased compression capability.

FIG. **9** is a top plan view of a locking element for use with the plates of FIGS. **1–6**.

FIG. **10** is a top plan view of a locking element for use with the central opening of the plate of FIGS. **7** and **22**.

FIG. **11** is a top plan view of a locking cap for use in the end openings shown in FIGS. **1, 6,** and **7**.

FIG. **12** is a side elevational view of the locking element of FIG. **16**.

FIG. **13** is a side elevational view of another embodiment of the locking element of FIG. **16**.

FIG. **14** is a top perspective view of an alternative embodiment of cervical spine multiple locking plate for use with locking rivets.

FIG. **15** is a bottom plan view of the cervical spine multiple locking plate of FIG. **14**.

FIG. **16** is a top plan view of a two bone screw locking element.

FIG. **17** is a top plan view of an alternative embodiment of a four bone screw locking element having head slits for increased flexibility of the locking tabs.

FIG. **18** is a bottom plan view of a rivet type locking element for use with the central opening of the plate of FIG. **14**.

FIG. **19** is a side elevational view of a rivet locking element.

FIG. **20** is a top perspective view of the bottom portion of the head of rivet of FIG. **19** viewed along lines **20—20**.

FIG. **21** is a top perspective view of the head portion of a three bone screw locking element.

FIG. **22** is a top perspective view of a third embodiment of a cervical spine multiple locking plate utilizing locking elements in the form of threaded caps.

FIG. **23** is a side elevational view of a locking element for use with the plate of FIG. **22**.

FIG. **24A** is a side elevational view of a bone screw in accordance with the present invention.

FIG. **24B** is an enlarged side elevational view of the bone screw of FIG. **24A**.

FIG. **25** is a side elevational view of an alternative embodiment of a bone screw in accordance with the present invention.

FIG. **26** is a bottom end view of the bone screw shown in FIG. **24A**.

FIG. **27** is a top end view of the bone screw shown in FIG. **24A**.

FIG. **28** is a top perspective view of a fourth embodiment of a cervical spine multiple locking plate.

FIG. **29** is a top perspective view of a locking element for use with the plate of FIG. **28**.

FIG. **30** is a partial side sectional view of the plate of FIG. **28** along lines **30—30** with a bone screw in place.

FIG. **31** is a top perspective view of the plate of FIG. **1** positioned against the anterior aspect of three successive vertebral bodies in the cervical spine, a plate holder, and an instrument for forming bone screw receiving holes in to the vertebral bodies.

FIG. **32** is a cross-sectional view of a portion of the bone forming device shown in FIG. **31** viewed along lines **32—32**.

FIG. **33** is a side elevational view in partial cross section illustrating a compression post tool and a compression post engaged to it for insertion into a vertebral body.

FIG. **34** is a side elevational view in partial cross section of the compression post tool engaged for removal of the compression post from the vertebral body.

FIG. **35** is a bottom end view of the compression post tool of FIG. **34**.

FIG. **36** is a side elevational view of a plate engaging hook for use with the compression apparatus shown in FIG. **38**.

FIG. **37** is a cross-sectional view through the plate of an alternative embodiment of a hole forming instrument in the form of a drill guide and drill for use during the plate installation procedure.

FIG. **38** is a side elevational view showing intersegmental compression of the spine and compression apparatus.

FIG. **39** is a view similar to that of FIG. **38** showing the compression apparatus in a further stage of the plate installation procedure.

FIG. **40** is a top perspective view showing the locking of the bone screws to the plate.

FIG. **41** is a partial side sectional view of a locking element attached to a driver instrument.

FIG. **42** is a partial side sectional view of another embodiment of the locking element attached to a driver instrument.

FIG. **43** is a partial cross-sectional view showing a cervical plate, locking element, and bone screws along lines **43—43** of FIG. **40**.

FIG. **44** is an enlarged portion of detail along line **44** of FIG. **43**.

FIG. **45** is a side view in partial cross section of a plate holder attached to a plate.

FIG. **46** is a side view in partial cross section of another embodiment of a plate holder attached to a plate.

FIG. **47** is a top perspective view of a first embodiment of a single locking plate.

FIG. **48** is a top plan view of the plate shown in FIG. **47**.

FIG. **49** is a side elevational view of the plate shown in FIG. **47**.

FIG. **50** is an end view of the plate shown in FIG. **47**.

FIG. **51** is a bottom plan view of the plate shown in FIG. **47**.

FIG. **52** is a top plan view of the plate shown in FIG. **47**, with locking elements in place.

FIG. **53** is a side elevational view of a bone screw used with the plate shown in FIG. **47**.

FIG. **54** is a top end view of the bone screw shown in FIG. **53**.

FIG. **55** is a bottom end view of the bone screw of FIG. **53**.

FIG. **56** is a top plan view of a locking cap for use with the single locking plate of FIG. **47**.

FIG. **57** is a side elevational view of the locking cap shown in FIG. **56**.

FIG. **58** is a bottom plan view of the locking cap shown in FIGS. **56** and **57**.

FIG. **59** is a bottom perspective view of the locking cap of FIGS. **56–58**.

FIG. **60** is a top perspective view of the single locking plate of FIG. **47** shown being held by a plate holder against three vertebral bodies, with the hole forming instrument for punching a pilot hole into the vertebral bodies for receiving a bone screw.

FIG. **61** is a side elevational view in partial cutaway of the hole forming instrument threaded to a bone screw receiving hole.

FIG. **62** is a perspective side sectional view of the drill and drill guide threadably engaged to the plate for drilling a hole for insertion of a bone screw.

FIG. **63** is a top perspective view of a single locking plate installed along a segment of the spine with two locking caps installed in two bone screw receiving holes.

FIG. **64** is a side elevational view in partial cross section of a locking cap engaged to a driver for installing the locking cap.

FIG. **65** is a partial cross sectional view of the plate, bone screws and locking caps along line **65—65** of FIG. **63**.

FIG. **66** is an enlarged fragmentary view of area **66** of FIG. **65**.

FIG. **67** is a perspective view of a cervical locking plate being held by an alternative plate holder instrument.

FIG. **68** is an end sectional view showing the plate holder of FIG. **67** engaging a plate.

FIG. **69A** is an end sectional view of an alternative embodiment of the plate holder.

FIG. **69B** is an end sectional view of another alternative embodiment of the plate holder.

FIG. **70** is a plate holder instrument with an offset and removable handle.

FIG. **71** is a top perspective view of a second embodiment of a cervical single locking plate having individual locking elements to lock each bone screw.

FIG. **72** is a top perspective view of a threaded locking element for use with the cervical single locking plate of FIG. **71** FIG. **73** is a partial side sectional view of the plate of FIG. **71** viewed along lines **73—73** with the locking element of FIG. **72** in place to hold a bone screw, but not fully tightened.

FIG. **74** is a top perspective view of an alternative locking element for use with a first modification of the cervical single locking plate of FIG. **71**.

FIG. **75** is a side sectional view of the first modification of the plate of FIG. **71** with the locking element of FIG. **74**.

FIG. **76** is a perspective view of an alternative locking element for use with the first modification of the plate of FIG. **71**.

FIG. **77** is a partial side sectional view of the first modification of the plate of FIG. **71** with the locking element of FIG. **76** in place.

FIG. **78** is a top perspective view of another alternative locking element in the form of a rivet for use with a second modification of the locking plate of FIG. **71**.

FIG. **79** is a partial side sectional detail view of the plate of FIG. **71** modified to use a locking element of FIG. **78** shown in place.

FIG. **80** is a partial cross sectional view of a plate and bone screw with the end of a tool shown for use in inserting both the bone screws and locking caps.

FIG. **81** is a side elevational view of another embodiment of the tool of FIG. **80**.

FIG. **82** is a further embodiment of a cervical spine single locking plate for use in stabilizing multiple segments of the spine.

FIG. **83** is a further embodiment of a cervical spine multiple locking plate for use in stabilizing multiple segments of the spine.

FIGS. **84A–84E** are various embodiments of cervical spine multiple locking plates for use in stabilizing a single segment of the spine.

DETAILED DESCRIPTION OF THE DRAWINGS

The present invention will be described first in association with the preferred embodiment of the plate system in which a plurality of bone screws are locked in place with one locking element. This is referred to as the multiple locking plate system. The multiple locking plates will be described, then the locking elements for locking the bone screws to the plate, then the bone screws associated with the multiple locking plates, and finally the instrumentation and method of installation of the multiple locking plates. Thereafter the plate systems in which a single locking element locks a single bone screw will be described. This is referred to as the single locking plate system. The locking elements, bone screws, instrumentation, and method of installation associated with the single locking plate will then be discussed.

1. Multiple Locking Plate System

The preferred embodiment of the multiple locking anterior cervical locking plate **2** according to the present invention (here shown by way of example for use in a two level fusion (three adjacent vertebrae)) is shown in FIGS. **1–5**. Plate **2** has a generally elongated form whose outline generally departs from rectangular due to the presence of lobes or lateral projections **4** at the corners and at the center of the sides of plate **2**. Each lobe **4** has a rounded outline and contains a respective circular bone screw receiving hole **6**. Two additional intermediate circular bone screw receiving holes **8** are located inwardly of the sides of plate **2** and are centered on the longitudinal center line of plate **2**. Lobes **4** give plate **2** additional strength in the region surrounding each bone screw receiving hole **6**. It is recognized that other shapes for the plate **2** may be employed.

The intermediate paired bone screw receiving holes **8** are for use with a two level (three vertebrae) fusion. The intermediate bone screw receiving holes **8** may be eliminated for a single level (two vertebrae) fusion, or additional intermediate bone screw receiving holes **8** may be added if additional levels are to be fused.

Plate **2** is further provided with three locking element holes **12**, each of which in the preferred embodiment is internally threaded **3**, and each of which is surrounded by a shallow countersunk region **14**. As will be described in greater detail below, in the preferred embodiment, bone

screws are inserted in the bone screw receiving holes and a single pre-installed locking element associated with each of the locking element holes **12** locks a number of bone screws **30** in position at one time.

The number of paired bone screw holes generally correspond to the number of vertebrae to be fused. A plate for a one level fusion could have but a single locking element hole **12**, while plates for fusing more than two levels (three vertebrae) could have additional middle locking element holes **12** corresponding to additional paired bone screw holes. In the embodiment illustrated in FIGS. **1–6**, each end locking element **20** will lock three bone screws **30** in place, while the locking screw **21** in the central locking hole **12** locks two bone screws **30** in place. As shown in FIG. **7**, central locking element **25** can also be configured so that four bone screws **30** are locked at one time.

As shown particularly in FIGS. **3**, **4** and **5**, plate **2** is shaped so that its bottom surface **27** (the surface which will be in contact with the vertebral bodies) has a biconcave curvature, being concave both in the longitudinal plane (corresponding to its length) and in the plane transverse thereto, corresponding to its width. The concave curvature in the longitudinal plane conforms to the proper shape of the anterior aspect of the spine with the vertebrae aligned in appropriate lordosis. That longitudinal curve is an arc along the circumference of a circle (referred to herein as the "radius of curvature") 15.0 cm to 30.0 cm in radius and more preferably 20.0–25.0 cm in radius. Viewed on end in FIG. **4**, the plate **2** has a radius of curvature of a circle 15–25 mm in radius, but preferably 19–21 mm in radius. While the plate **2** may have a thickness between 2 to 3 mm, a thickness of between 2.25 and 2.5 mm is preferred.

Having the bottom surface **27** of plate **2** contoured so that it is able to lie flush against the associated vertebral bodies is in contrast to conventional plates which have larger radii of curvature that contact the vertebral bodies only along the longitudinal centerline of the plate, thereby permitting side-to-side rocking of the plate relative to the vertebral bodies. The contour of the plate of the present invention provides effective resistance to rocking of the plate **2** relative to the vertebral bodies about the longitudinal center line of the plate, thereby reducing stress on the plate **2** and bone screws **30**, and preventing the soft tissues from becoming engaged beneath the plate.

Other advantages produced by the above curvature are that the plate **2** will conform more closely to the facing bone surface; the plate **2** will project from the spine by a smaller distance; soft tissue will be prevented from sliding underneath the edges of the plate **2**, where it could be subject to damage; and the angle of the bone screws **30**, perpendicular to the plate when viewed from the side, when installed will be at a substantial converging angle, trapping the vertebral bone between the bone screws **30**, and thus more strongly anchoring the plate to the spine.

As shown in FIG. **5**, the bottom surface **27** of plate **2**, preferably has a porous, roughened, and/or textured surface layer and may be coated with, impregnated with, or comprise of fusion promoting substances (such as bone morphogenetic proteins) so as to encourage the growth of bone along the underside of the plate **2** from vertebrae to vertebrae. The textured bottom surface **27** also provides a medium for retaining fusion promoting substances with which the bottom surface **27** layer can be impregnated prior to installation. The bottom surface **27** of plate **2** may be given the desired porous textured form by rough blasting or any other conventional technology, such as etching, plasma spraying, sintering, and casting for example. If porous, the bottom surface **27** is formed to have a porosity or pore size in the order of 50–500 microns, and preferably 100–300 microns. Fusion promoting substances with which the porous, textured bottom surface **27** can be impregnated include, but are not limited to, bone morphogenetic proteins, hydroxyapatite, or hydroxyapatite tricalcium phosphate. The plate **2** may comprise of at least in part a resorbable material which can further be impregnated with the bone growth material so that as the plate **2** is resorbed by the body of the patient, the bone growth material is released, thus acting as a time release mechanism. Having the plate **2** being made from a material that is resorbable and having bone growth promoting material present permits the vertebrae to be fused in a more natural manner as the plate becomes progressively less load bearing thereby avoiding late stress shielding of the spine.

As further shown in FIGS. **4** and **5**, at least one end of plate **2** has a recess **18** that can cooperate with a compression apparatus, described in detail later in reference to FIGS. **36** and **38**.

FIG. **6** is a top plan view of the plate **2** of FIG. **1** with locking elements **20**, **21** inserted into the locking element receiving holes. In the preferred embodiment, the locking elements **20**, **21** are in the form of screws that cooperate with the threaded interior **3** of the locking holes **12**. Each of these locking elements **20**, **21** is shown in its initial open orientation, where the orientation of the cutouts **22** in the head **23** of each locking element **20**, **21** is oriented so as to permit introduction of bone screws **30** into adjacent bone screw receiving holes **6**,**8** without interference by the head **23** of the locking element **20**, **21**. It is appreciated that other configurations of the head **23** are possible so as to permit introduction of bone screw into adjacent bone screw receiving holes without interference by the head **23**.

FIG. **8** is a top view of another embodiment of plate **2** of FIGS. **1–5**, and is generally referred to as plate **120**. Plate **120** is provided with a longitudinally extending elongated slot **122** along its longitudinal axis which is superimposed on the middle locking hole **12**. Elongated slot **122** allows additional relative movement between plate **120** and a compression post **54** associated with a compression tool during the compression procedure, as discussed below.

Referring to FIGS. **14** and **15**, an alternative embodiment of a multiple locking plate referred to by the number **70** is shown. In plate **70**, rather than the threaded locking hole **12**, a central opening **200** for receiving a removable rivet **202**, of the type shown in FIGS. **17–20**, is provided. FIG. **15** is a bottom plan view of the plate **70** shown in FIG. **14**. The contour of the plate **70** is the same as that of the plate **2** shown in FIGS. **1–5**. The rivet **202** is removable and fits within the unthreaded opening **200**, comparable to the locking hole **12** and slot **122** described above. Other embodiments may employ a rivet that is not removable, but is manufactured as part of the plate **70** as would be used in the end locking holes **19** of FIGS. **14** and **15**.

Referring to FIG. **22**, another alternative embodiment of a multiple locking plate is shown and is generally referred to by the number **230**. The plate **230** uses threaded caps, such as cap **300** shown in FIGS. **9** and **23**, for a locking element or preferably one with cut outs as described having an appearance in a top view such as the locking element in FIGS. **10–11**, for example. The central locking hole **232** has an elongated slot **234** for providing an increased compression capability, as will be discussed further herein.

Referring to FIGS. **10–13**, a first embodiment of a locking element **20**, **21**, **25** in the form of locking screws according to the present invention for use with plate **2** is shown. FIG.

10 is a top plan view which illustrates the head 23 of the central locking element 25 shown in FIG. 7. The shaft 46 of locking element 25 is threaded 47 to mate with the threading 3 within the associated locking hole 12 of plate 2. As shown in FIG. 21, each segment 49 on each side of cutouts 22 of the locking element 21 has a bearing surface 48 formed at the lower surface of locking element head 23. As shown in FIG. 16, the locking element head 23 can be provided with two slots 42 for providing flexibility to the locking element head 23 to assist in the locking element's ability to ride over the top of the bone screw head 32 during the bearing action when the locking element is rotated. Alternatively, it is appreciated that the bearing surface can be cammed, ramped or wedged. The cammed, ramped or wedged features can also be used with the other locking elements described herein.

Referring to FIGS. 6 and 10–13, it will be appreciated that when the locking elements 20, 21 are rotated in the clockwise direction with respect to the view of FIG. 6, a respective bearing surface 48 (as best seen in FIG. 21) will ride upon the curved top surface 39 of a respective bone screw head 32 in order to positively lock the associated bone screws 30 and the locking elements 20, 21 in place.

Alternatively, as shown in FIGS. 12 and 13 in place of a bearing surface 48, a ramp or wedge shaped surface 44 may be used to increase the force applied to the bone screw head 32. When locked, the leading end of the ramped portion of the locking element would be lower than the prominence of the bone screw head 32 so that more force is needed to lift the locking element and untighten it than is needed for the locking element to remain tight and locked. However, the locking element heads 23 need not have slots, be cammed, or have a ramped surface to achieve the locking of the bone screw 30 in place. Pressure, friction, interference fits, or other engagement means capable of preventing the locking element from moving from its locked position may be employed.

The rivet 202, shown in FIGS. 17–20 is intended for use in association with plate 70 shown in FIGS. 14–15, is shown in detail in cross section in FIGS. 19 and 20. The rivet 202 has a head 204, a shaft 206, and an elongated bottom segment 208 for fitting within the corresponding opening 200 in the plate 70. The lower surface 210 of the head 204 of the rivet 202 has an irregular surface which may be cammed, such as on the bottom of locking element 20, 21, for engaging the top surface 39 of the bone screw head 32. For use in the end locking holes 19, the upper surface of the elongated bottom segment 208 can have an irregular surface for cooperating with the irregular surface of the bottom of the plate 70 to hold the rivet 202 in the locked position against the bone screw head 32, as shown in FIG. 15. While the rivet of FIG. 18 is a separate, removable component from the plate, the rivets, and particularly those for use with the end locking holes, can be formed as part of the plate during the manufacturing process of the plate and rivet can be non-removable.

Each of the above embodiments provides tight attachment of the locking element relative the bone screw 30 and relevant plate.

In the alternative embodiment of multiple locking plate 23 shown in FIG. 22, the locking element can be in the form of threaded locking cap 300 shown in FIG. 23. The threaded locking cap 300 has a thread 302 on its outer circumference corresponding to the thread 303 on the inner circumference of the locking element depressions 304 in the top of the plate 230 shown in FIG. 22. The locking cap 300 is relatively thin, particularly compared to its width. The top 305 of locking cap 300 is provided with a noncircular through hole 306 for receiving a similarly configured driving tool.

Referring to FIGS. 28, 29, and 30 another embodiment of the multiple locking plate generally referred to by the number 400 and a locking element in the form of a thin locking member 412 are shown. Plate 400 has an opening in its top surface for insertion of the thin locking member 412, a recess 402 associated with each of the bone screw receiving holes 408 and a slot 410 in the side wall of the bone screw receiving holes 408 to permit the thin locking member 412, having a series of thin projections or blades 414, thinner than the slot 410, that give this locking member 412 an appearance similar to that of a propeller. The thin locking member 412 is able to be rotated within the plate so as to not cover the bone screw holes, thus allowing the thin locking member 412 to be pre-installed prior to the installation of the bone screws by the surgeon. Limited rotation of the thin locking member 412 allows the blades 414 to protrude through the slot 410 and to cover a portion of the top of the associated bone screws 30. The blades 414 of the thin locking member 412 are flexible and, when rotated, slide over the top surface 39 of the bone screw head 32 to lock the bone screw 30 in place. As with the other embodiments discussed, each of the embodiments of the locking element is capable of locking more than one bone screw 30. It is appreciated that the various multiple locking plates and locking element combinations are capable of locking as many as four bone screws at once, but are equally effective for locking a lesser number or none at all, that is securing itself to the plate.

It will be noted that one characteristic of each of the above described locking element embodiments is to have a driver engagement means, in these cases for example, a recess 24 as large as the recess 34 in the bone screws 30 so that the same tool can be used to turn both the bone screws 30 and the locking elements. Also, the locking elements are sufficiently strong and have sufficient mass so as to be able to withstand being locked without breakage.

All of the shown examples of the multiple locking elements that have a number of cutout portions have an arc with a radius greater than that of the bone screw head. In addition, the head 23 of each locking element 20, 21 is provided at its center with a noncircular recess 24, such as shown in FIG. 9 which is engageable by an appropriate manipulation tool, such as shown in FIGS. 40–42. In the embodiment of head 23 shown in FIG. 9, the associated tool would have a hex head, but as discussed with regard to FIGS. 80 and 81, other shapes of recesses in the head 23 may be used. The thread of each locking hole 12 and of each locking element 20, 21 has a close tolerance so that they will reliably retain their orientations so as to permit introduction of bone screws 30 into bone screw receiving holes 6, 8 without interference.

It is appreciated that while various forms of locking elements have been disclosed, in light of the teaching, other equivalent means can be used for the purpose of locking the bone screws 30 in place. In FIG. 83, an alternative multiple locking plate 990 is shown having additional intermediate bone screw receiving holes 980 and associated locking elements 960 for locking bone screws 30 in place. Plate 990 allows for a more close spacing and more pairs of bone screw holes than the number of vertebrae to be engaged.

In FIGS. 84A–84E various plates 700*a–g* used for a single level fusion are shown. Each of these plates 700*a–g* is designed to span one spinal segment consisting of one disc space and two adjacent vertebrae (containing the bone graft), and have bone screws inserted into the end of the vertebrae through the bone screw receiving holes 6 associated with the

two adjacent vertebrae and then locked in place. As shown in FIGS. **84–84E**, one locking element **710**, or two locking elements can be used to lock four bone screws in place. In FIGS. **84A–84E**, each of the plates **700***a–e* is shown with the locking elements in their open orientation, before being rotated to lock the bone screws.

Each of the above described plates can have the same generally biconcave contour as already described for conforming to the anterior aspect of the spine.

FIGS. **24A** and **24B** provide a side view of one embodiment of a bone screw **30** according to the present invention. FIG. **27** is a top view of the bone screw **30**. At the center of bone screw head **32** is a profiled recess **34** which may have the same form as the recess **24** of each locking element **20, 21** in which case it may be turned with the same tool as that employed for turning locking elements **20, 21**. It is appreciated that the driver engaging portion of the bone screw **30** could be slotted, and be either male or female (as is shown).

In the embodiment of bone screw **30** shown in FIGS. **24A** and **24B**, the bone screw head **32** is stepped, with the first lower head portion **35** being contiguous with the screw shank **33** and has a smaller diameter than the upper portion of the bone screw head **32**. When this embodiment of bone screw **30** is employed, each bone screw receiving hole **6, 8** of the plate **2** has a countersunk region **14** matching the diameter of the upper portion of the bone screw head **32** and dimensioned for an interference fit. The lower portion **35** of the bone screw head **32** is dimensioned to achieve an interference fit with its associated portion of bone screw receiving holes **6, 8**. The larger diameter upper portion of bone screw head **32** assures that the bone screw **30** cannot be advanced completely through bone screw receiving holes **6, 8** of plate **2**. The bone screw **30** passes completely through the upper surface of the plate **2** without engaging the upper surface in any way.

As shown in FIG. **44**, the head **32** of screw **30** passes unobstructed through the upper surface of the plate until the lower surface of enlarged screw head **32** engages the upper face of the narrowed bone screw receiving portion at the midsubstance or below the midsubstance of the plate. This is considered optimal for allowing for the greatest screw to plate stability, even absent the lock, against all forces except those reverse the path of insertion, while still providing for the greatest plate strength beneath the bone screw head **23**. That is, since the plate is of only generally 2–3 mm in thickness, a sheer vertical circumferential wall is best able to constrain the motion of a screw if the head is similarly configured and there is little tolerance between them. Placing the support of the head near the mid thickness of the plate is preferred as it allows the head to remain large to accommodate the recess for the driver without being weakened, while placing the support of the head away from the upper surface of the plate allows the screw head to be deep into the plate. Placing the support of the head at approximately the mid thickness of the plate assures plenty of plate material beneath the head to support while providing adequate head length above and below the contact point to prevent the contact point from acting as a fulcrum by providing adequate lever arms to prevent unwanted motion.

In the alternative embodiment of bone screw **30'**, as shown in FIG. **25**, bone screw head **32'** is tapered in the direction from the top of the bone screw head **32'** toward screw tip **36'**. Again, the bone screw head **32'** is dimensioned to achieve an interference fit in the associated bone screw receiving hole **6,8** when the bone screw **30'** has been fully installed. When this embodiment of bone screw **30'** is employed, bone screw receiving holes **6, 8** need not be provided with a countersunk region **4**.

In each of the above embodiments of the bone screws, the bone screws **30** and **30'** present a unique combination of a tapered screw shaft **33** and a helical thread **31**. The diameter of screw shaft **33** generally increases from a distal portion of the shaft near the screw tip **36** toward the proximal portion of the shaft near screw head **32**. In the preferred embodiment, the rate of increase in diameter is also greater near the bone screw head **32**. Such a shape avoids stress risers and provides increased strength at the screw-plate junction, where it is needed the most. The tapering of screw shaft **33** may have a concave form, as shown in FIG. **24A**, or may be linear. The distal portion of the screw shaft **33** may assume a constant diameter.

Referring again to FIGS. **24A** and **24B**, the thread **31** of the bone screw **30** has a substantially constant outer, or crest, diameter "d" from the proximal portion of the shaft below the bone screw head **32** to the distal portion of the shaft near the bone screw tip **36**. In the screw tip **36**, the crest diameter of thread **31** may be reduced for preferably one to two turns to facilitate the insertion and penetration of the bone screw **30** into the bone.

In the preferred embodiment, the thread **31** of each bone screw **30** has an outer diameter slightly smaller than the diameter of the lowest portion **35** of the bone screw head **32**, which is adjacent the trailing, or upper, end of the associated thread **31**. In addition, the thread **31** is relatively thin, in the direction of the longitudinal axis of the screw, and tapers outwardly, and has a cross section of a triangle.

An example of the dimensions of a bone screw for use in human anterior cervical spinal surgery for insertion into the vertebrae is as follows: the threaded portion of said screw has a length from about 10 mm to about 22 mm (12–18 mm preferred) and a head length from about 1 mm to about 3 mm (2–2.5 mm preferred). The threaded portion should have a maximum outside diameter from about 3.6 mm to about 5.2 mm (3.8–4.5 mm preferred) and the head has a diameter from about 3.8 mm to about 6 mm (4–5.5 mm preferred). The thread pitch is from about 1.25 mm to about 2.5 mm (1.5–2.0 mm preferred) and has a sharp and thin threaded profile. The apex of the two faces of the thread have an angle of less than about 21 degrees (15 degrees preferred) and the base of the thread is less than about 0.60 mm thick (0.25 mm–0.35 mm preferred). The screw has a root diameter that increases from proximately above the tip of the shank, along the longitudinal axis to proximately below the head portion of the screw. Preferably, the tip of the screw tip is fluted by at least one cut out section so as to make the screw self-tapping.

Even though the thread **31** of the bone screw **30** has a thin profile, the thread will nevertheless be stronger than the bone into which it is introduced so that this thread will efficiently cut a thin helical groove in the bone tissue. The volume of bone that will be displaced by the thickness of the thread is minimized by the thin form of the thread, yet the substantial crest diameter of the screw thread maximizes the surface area of the threads in contact with the bone. While enlarging the screw shaft **33** diameter near the bone screw head **32** increases its strength where needed, reducing the screw shaft **33** diameter away from the bone screw head **32** where such strength is not required allows for the maximum area of engagement for the thread **31** to the bone.

In the preferred embodiment, as shown in FIGS. **24A** and **26**, bone screw tip **36** is provided with cutting flutes **38**, to make the bone screw **30** self-tapping. Unlike the prior art bone screws, used for anterior cervical spinal surgery which are not self-tapping, the thread form of the present invention screw is itself more like a tap than a conventional screw in

that the threads are very sharp and fluted. Additional embodiments of the bone screws **30** is shown in FIGS. **53–55**.

By way of example, plates for fusing three adjacent vertebrae (2 interspaces, or two spinal segments) are shown. Each set of the bone screw receiving holes associated with a vertebrae is considered to be a segment of the plate so that for example, in FIG. **1** three segments are shown—an upper, a central, and a lower segment. While the present discussion is in association with plates for use in fusing three vertebrae across two interspaces, it should be understood that longer and shorter plates having the appropriate number and location of bone screw receiving holes corresponding to the number of vertebrae to be fused are contemplated, and would take the form of the plates shown with fewer or more intermediate segments, such as the segment along line **9** of FIG. **1**, or the intermediate segments of the plates shown in FIGS. **82–84F**.

Referring to FIGS. **31–42**, an outline of the steps of the method for installing the plates of the present invention is set forth below. A detailed description of the instrumentation and method for installing the plates of the present invention follows the outline.

Step 1

Having completed the interbody fusions, the surgeon removes any bone spurs or localized irregularities along the front of the spine of the area to be fused.

Step 2

The correct length plate is selected by the surgeon by measuring the distance on the spine by a caliper, ruler, template, and the like. That plate having a length sufficient to span the distance of the spine to be fused and to partially overlap a portion of each of the end vertebrae to be fused.

Step 3

Utilizing a plate holder, the plate is placed into the wound and positioned to confirm positioning, length, and screw hole alignment relative to the segments of the spine to be fused.

Step 4

As shown in FIG. **31**, with the plate thus positioned and securely held, the plate may be attached to any of the vertebrae to be fused (by example only, here shown as the top vertebra).

Sub-Step 4A

The pilot (guide) hole punch **60** is attached to the plate **2** as per FIG. **32**, or alternatively, while not preferred the drill guide may be used as per FIG. **37**. In either event, the pilot hole forming means rigidly aligns with and is captured by the plate bone screw receiving hole wall.

Sub-Step 4B

The pilot hole is then formed by impacting the pilot hole punch of FIG. **32** or drilling with the drill of FIG. **37**. In the alternative while not preferred, the formation of the pilot hole can be done away with altogether and the correct screw selected so as to have a length less than the distance along its path to the posterior vertebral cortex can be directly inserted.

The determination of the appropriate screw length is made by measuring or templating from radiographs, MRI's, or CT scans, or determined directly by measuring the depth of the disc space.

Step 5

The correct screw is then attached to the screw driver which regardless of the specific form of the screw driver engagement means, is designed to have an interference fit so as to remain firmly bound to the driver during transport to the insertion site. FIGS. **41, 42, 63, 64, 80** and **81** show various ways of achieving such a fit of the driver and screw. In addition to a wedging at the screw and driver interface, clips, and springs and other means are well known for temporarily and reversibly securing the screw to the driver, such as is shown in FIG. **80** where a slotted inwardly springing sleeve holds a threaded cap peripherally until, as it is screwed into the plate, it is automatically pushed back releasing the threaded cap.

Once a first bone screw has been fully inserted into a vertebra through the plate, it is preferable to insert the other of the transverse pair in the manner already described as per FIG. **33**.

In a similar manner, it is possible to insert the remaining bone screws as per the surgeon's preference into each of the vertebrae to be included into the fusion, just the end vertebrae of the fusion construct, or additionally place screws into the fusion grafts.

However, as shown in FIGS. **33, 34, 38** and **39**, it is possible with the present invention at the surgeon's option to place any portion or all of the fusion construct under compression and to do so intersegmentally or across the entire length of the fusion construct even when multi-segmented.

It is appreciated that the same procedure could be generally used for any of the plate systems of the present invention.

As shown in FIG. **31**, the vertebrae **50***a–c* are separated from one another by fusion graft blocks **51** which were previously installed in the spinal disc space between adjacent vertebrae **50** forming a fusion bone graft construct. Plate **2** is shown in FIG. **31** with the locking elements **20, 21** removed in order to simplify the illustration. It will be understood, however, that in the preferred embodiment the locking elements **20, 21** can be, and preferably are, pre-installed in the positions shown in FIG. **6** prior to positioning plate **2** upon vertebral bodies of the vertebrae **50**, thereby saving the surgeon time and trouble.

Plate **2** may be held in position by any known plate holding means, but preferably by the holding tools shown in FIGS. **45, 46** or **70** by the notches **142** in the sides of the compression arms **104, 130** of a vertebral compressor tool **100** shown in FIG. **39**, or as a further alternative, by the unitary plate holder similar to the FIG. **70** design.

As shown in FIG. **45**, plate holder **870** has a hollow tubular housing **872**, with a central rod **874** having a thread **878** at one end for engaging one of the threaded locking holes **12** in the plate **2**. The bottom end of the housing **872** has projections **880, 882** that extend outwardly and then downwardly to fit into the bone screw receiving holes **8** of the plate **2** preventing the housing **872** from rotating. The central rod **874** is located in the housing **872** such that it can be rotated by rotating a handle (not shown) which is fixed to the central rod **874** at its upper end.

In FIG. **46** an alternative embodiment of the plate holder **890** is shown. A single solid member **890** has a threaded projection **894** at its bottom end for attachment to the central threaded locking hole **12** in the plate. The bottom surface of the holder **890** of this embodiment is contoured so as to match the contours of the top surface of the plate adjacent to the locking hole **12**, shown as a depression **14** (FIG. **1**).

Referring to FIGS. **67–68**, an embodiment of a plate holder for holding any of the plates while being positioned on the vertebrae is shown and generally referred to by the number **800**. The plate holder **800** has a hollow tubular housing **802**, with a central rod **804** having a handle **806** at one end and a thread **808** at its other end for engaging one of the threaded locking holes **12** in the plate **600**. The bottom

end of the housing **802** has projections **810, 812** that extend outwardly and then downwardly **814, 816** to fit along the side edge of the plate **2** between the end and intermediate lobes **4**, preventing the housing **802** from rotating. The central rod **804** is located in the housing **802** such that it can be rotated by rotating the handle **806** which is fixed to the central rod **804** at its upper end. This central rod **804** can also be attached to the housing **802** so that it can move up and down to some extent, by any number of conventional ways, such as by having the central rod **804** have an annular depression with a length of approximately 3–5 mm, and a set screw projecting inward from the housing to engage the central rod **804**. Once the plate **600** is in the proper place and the plate is attached to one of the vertebrae by bone screws **30**, the central rod **804** is disconnected from the opening in the plate **600** and the holder **800** is removed.

FIG. **69**A is an alternative embodiment of the plate holder **850**. A single solid member **852** has a threaded projection **854** at its bottom end for attachment to the central threaded locking hole **12** in the plate. The solid member **852** could also be threaded into a bone screw receiving hole **6**. The bottom surface of the holder **850** of this embodiment is contoured so as to match the contours of the top surface of the plate adjacent to the locking hole **12**, shown as a depression **14** (FIG. **1**).

FIG. **69**B is another embodiment of the plate holder **850'**. A housing **851'** having an end **853'** configured to engage a bone screw receiving hole **6** contains a rod **855'** having an uneven diameter and having a threaded portion **857'**. As rod **855'** is rotated by a handle similar to handle **806** shown in FIG. **68**, rod **855'** screws downward into the housing **851'** into matching threads **858'**. As the end of rod **855'** is driven down, it spreads portions **859***a'* and **859***b'* (**859***c'* and **859***d'* not shown) wedging plate holder **850'** into a bone screw receiving hole of the plate. Plate holder **850'** is best used with non-threaded bone screw receiving holes, but works for all types of bone screw receiving holes.

Referring to FIG. **70**, an alternative embodiment of the plate holder referred to by the number **800'** is shown in which there is a removable handle **860** that is used for first attaching the plate holder **800'** to the plate, by rotating the shaft **804**, and then for holding the plate holder **800'** off to the side by extension **864**, during the attachment procedure reducing the interference of the plate holder **800'** with the surgical procedure.

Referring to FIG. **38**, a compression tool **100** is shown with a toothed gear bar **102** having a first compression arm **104** secured to its free end. Compression arm **104** has at its distal end a bore **106** for removably holding either a plate engaging element **108**, shown in FIG. **36**, having a hook **110** at one end for engaging a depression or notch **18** in the end of plate **2**, or for removably holding a compression post **54** shown in FIGS. **33–34**. As shown in FIG. **36**, plate engaging element **108** includes a shaft **112** that will be inserted into the corresponding bore **106** of compression arm **104**, and a flange **115** for resting against the bottom face of bore **106** to accurately limit the depth of insertion of plate engaging element **108** into the bore **106**. A ring spring **128**, preferably of metal, is located in an annular depression of the shaft **112**, for holding the plate engaging element **108** in the bore **106**.

Referring to FIGS. **38–39**, compression tool **100** includes a second moveable compression arm **130** movable along toothed bar **102** parallel to first compression arm **104**. The distal end of the second compression arm **130** also has a bore **132**, the same as bore **106**, that can receive a removable compression post **54**. Bores **106** and **132** are the same so that either compression arm **104, 130** can be used to hold the removable compression post **54**, permitting the compression tool **100** to be used in any orientation. By permitting the plate engaging element **108** and the compression post **54** to both rotate and slide in the bores **106, 132** of the two compression arms **104,130**, with the plate engaging hook **110** able to work even at an angle to the plate allows for the apparatus to be readily attachable to the spine through the compression post **54** and plate.

Compression arm **130** has a driving assembly consisting of a toothed wheel (not visible) which is engaged with the tooth gear **138** of bar toothed gear **102** and is connected to compression arm **130** such that compression arm **130** is movable along the length of toothed gear bar **102** by means of the rotation of handle **140**, which is connected to the toothed wheel When the handle **140** is turned in the direction of the arrow shown in FIG. **38**, compression arm **130** is moved toward compression arm **104**. The driving assembly has a self lock release mechanism whereby the movement of the two compression arms **104,130** away from one another is prevented, without the activation of the release. On the inward distal end of each compression arm, on facing sides, is a notch **142** or recess for holding the plate **2** along its sides between the central lobes **4** and end lobes **4**, as shown in FIG. **38**.

While the toothed gear bar **102** and compression arms **104, 130** have been described as being straight, it is possible that the toothed gear bar **102** and compression arms **104, 130** may be arcuately or otherwise shaped, so as to induce lordosis in the vertebrae, if so desired.

As shown in FIG. **31**, in the event that the compression tool **100** is used to hold the plate **2**, the ends **144** of the compression arms **104, 130** will be located in line with the fusion graft construct **51** which was placed in the disc space when plate **2** is properly positioned. A gap will exist between plate **2** and each fusion graft construct **51**, providing a space to accommodate the free ends of arms **104, 130** should they extend beyond the bottom surface of the plate **2**. As will be described below, the same compression tool **100** can also be used for compressing a plurality of cervical vertebral bodies with bone grafts interposed during the attachment of plate **2** to the vertebrae **50**.

Referring to FIG. **31**, plate **2** is held by a suitable holder, in this case shown as the compression arms **104** and **130**. Once the appropriate length plate **2** has been properly positioned so that the bone screw receiving holes **6** are aligned with each of the respective vertebrae **50***a–c* to be fused, the next step is the formation of bone screw receiving holes **6** prior to installation of the bone screws **30** themselves in the vertebrae **50***a*. While the procedure is described as first attaching the plate **2** to the upper vertebrae **50***a*, the plate **2** can be attached to any of the vertebrae in any order. Different sized plates are used so that, as indicated above, the physician will select the appropriate sized plate in which the bone screw receiving holes **6, 8** are aligned with the three adjacent vertebrae **50***a*, **50***b* and **50***c*. Pilot holes are formed by a pilot hole forming apparatus **60** shown in FIGS. **31** and **32**. Unlike with known prior art and screw plating systems, the bone screws **30** may be inserted without the prior formation of an opening into the vertebrae as the bone screws **30** are preferably sharp pointed, self-tapping, and have at their tip a diminishing major diameter to assist the screw entering and pulling into the bone. However, while a hole into the bone of the vertebrae may be formed prior to screw insertion, it is preferable that the hole be of a smaller diameter than the root diameter of the screw and for a different purpose than with the prior art. With the prior art the hole drilled had to be of a diameter equal to but

preferably larger than the root (minor) diameter of the screw, as the screws were not self-tapping. It is desirous to create pilot holes to assure that a proper path for the bone screws **30** is maintained, and also to prevent damage to the vertebral bone during insertion of the bone screws **30**. In addition, the pilot hole forming apparatus **60** creates a more compact vertebral bone mass for reception of the self-tapping bone screw **30** used in this insertion.

As shown in FIGS. **31** and **32**, pilot hole forming apparatus **60** includes a hollow cylindrical housing **62** having a bottom provided with a through hole **63**. Housing **62** contains a central shaft **64** which extends through the through hole **63** in the bottom of housing **62**. The leading end **66** of shaft **64** tapers gradually to a sharp point **65**. Shaft **64** is provided with a ring member **78** having a diameter which closely corresponds to the inner diameter of housing **62** to guide the travel of shaft **64** within housing **62**. A compression spring **67** is interposed between the ring member **78** and the bottom of housing **62**. Compression spring **67** provides a bias force which normally urges the sharp point **65** into a retracted position within housing **62**. The upper end of shaft **64** has an enlarged head **68** extending outside of the housing **62** which is intended to be manually depressed or struck by a percussion instrument in order to drive the sharp point **65** out of housing **62** and into a vertebral body **50***a*. Shaft **64** is given a length, taking into account the length that spring **67** will have when fully compressed, to determine the maximum depth of the pilot hole formed in a vertebral body. The depth is selected to assure that the pilot hole does not reach the posterior cortex of the vertebral body, which borders the spinal canal.

Certain structural features of hole forming apparatus **60** are shown in greater detail in FIG. **32**. In particular, it can be seen that the bottom end of housing **62** has a projecting portion **69** dimensioned to fit precisely in a bone screw receiving hole **6** or **8** of plate **2**. The bottom **71** of the projecting portion **69** is flat in a plane perpendicular to the axis of housing **62**. When the projecting portion **69** of housing **62** is snugly inserted into a bone screw receiving hole **6, 8** and the flat bottom **71** is placed flush against the upper surface of plate **2**, it is assured that the leading end **66** of shaft **64** will form a pilot hole in the vertebral bone having an axis perpendicular to the plane of the associated portion of plate **2**, thereby assuring that the bone screw **30** will be subsequently installed so that its axis is also perpendicular to the plane which is parallel to the upper and lower surfaces of the associated portion of plate **2**.

When a plate is used which has a threaded bone screw receiving hole, the lower end of the pilot hole forming apparatus **60** is threaded so as to engage the thread in the bone screw receiving hole **6, 8** thereby fixing the plate and the pilot hole forming apparatus together, assuring a stable fit between the pilot hole forming apparatus and the plate **2**. It should be noted that the diameter of the leading end **66** of the shaft **64** is small since it has to fit within the small space left between the inside wall of the pilot hole forming apparatus. Since it is only a pilot hole for a self-tapping bone screw **30** that is being formed, the small diameter is satisfactory.

Referring to FIG. **37**, if for any reason it should be desired to form the pilot hole in the vertebral body **50** by drilling, rather than by the use of the pilot hole forming apparatus **60**, use can be made of a drill guide **80**, having a lower end as shown in FIG. **37**. The drill **80** guide consists of a tubular member **82** and a small diameter lower end **84** which is dimensioned to achieve a precise interference fit in the associated bone screw receiving hole **6, 8** of plate **2**. Along the small diameter lower end **84**, drill guide **80** has an axial end surface in a plane perpendicular to the longitudinal axis of the drill guide **80** so that when the small diameter portion **84** is fitted into the bone screw receiving hole **6** and the surface surrounding the small diameter portion **84** is flush against the upper surface of plate **2**, the axis of the drill guiding bore **86** in drill guide **80** will be precisely perpendicular to the upper and lower surfaces of the associated portion of plate **2**. As with the case described above, the bottom end of the drill guide **80** can be threaded so as to engage to the threaded opening of plate **2**.

After the bone screw receiving holes **6, 8** are formed in the vertebral body **50***a* through the upper two bone screw securing holes **6** of plate **2** by means of either hole forming apparatus **60** or drill guide **80**, bone screws **30** are threaded into the vertebrae **50** while holding the plate **2** firmly against the vertebrae **50** with compression tool **100** or plate holder **800**. This locks the plate to the vertebrae **50***a*.

It is then possible, if desired, to compress the fusion graft in the next adjacent vertebrae **50***b* before attaching bone screws **30** to the adjacent vertebrae **50***b* through the central bone screw receiving holes of plate **2**. Once the initial bone screws are in place in the vertebrae **50***a*, the plate holder **100** or **800** may be removed from the plate **2**. The compression of the fusion graft construct between the two adjacent vertebrae **50***a* and **50***b* is achieved as follows:

Compression post **54** is driven through the central locking hole **12** of plate **2** by means of insertion tool **90**, shown in FIGS. **33, 34** and **35**, into the vertebral bone of vertebra **50***b*, where it will be used in a subsequent step to apply a compression force between vertebrae **50***a* and **50***b*. Compression post **54** consists of a shaft **56** having a sharp point **57** at its lower end, an enlarged central collar **58** which serves as a depth stop, and a circumferential groove **59** proximate its upper end, defining an enlarged head **55**.

Compression post insertion tool **90** consists of a shaft **92** having a closed hollow portion **94** at its lower end **96** for receiving compression post **54** and an enlarged percussion cap **98** at its other end. Compression post insertion tool **90** also includes in its lower end **96** a second opening **95** having a recess **99** in its inside wall for permitting engagement of the enlarged head **55** on the compression post **54** within the depression **97**. The second opening **95** is in communication with the hollow portion **94** of the insertion tool **90**, as shown in FIG. **35**.

Referring to FIG. **38**, the bore **132** in the second compression arm **130** of compression tool **100** is then applied over compression post **54** in vertebrae **50***b*, and the plate engaging element **108** is inserted in the bore **106** of the first compression arm **104** of compression tool **100**. The hook **110** of the plate engaging element **108** shown in FIG. **36** is fitted into the notch **18** at the end of the plate **2** which is fixed by the bone screws **30** inserted into the vertebra **50***a*, as shown in FIG. **38**. As indicated above, however, the compression tool **100** can be rotated so that the first compression arm **104** is now at the bottom and is able to fit over the compression post **54** in vertebrae **50***c*.

Since the plate is attached to vertebrae **50***a* by means of bone screws **30** and compression post **54** is fixed to the adjacent vertebrae **50***b*, movement of the first and second compression arms **104** and **130** in the direction of vertebrae **50***a* by rotation of handle **140** results in compression of the bone graft construct **51** between the adjacent vertebrae **50***a* and **50***b*. The distance of several millimeters is sufficient for compression of the bone graft construct **51**. Once the desired compression is obtained, bone screw pilot holes can be formed in vertebral body **50***b* by means of pilot hole forming

apparatus **60**, as described above, for insertion of bone screws **30** into bone screw receiving holes **8** of bone plate **2**, fixing the plate **2** to the adjacent vertebrae **50***b*. Compression tool **100** can then be withdrawn by activation of the release.

FIG. **39** illustrates the use of compression tool **100** to induce compression between the lower two vertebral bodies **50***b* and **50***c* after bone screws **30** have been installed in the middle vertebral body **50***b* as just described. As shown in FIG. **39**, compression post **54** remains in place in the middle vertebral body **50***b* and an additional compression post **54** is driven into the lower vertebral body **50***c* by means of pilot hole forming tool **60** distal to the plate itself in the recess between the end projections **4** to allow for the lower compression post **64** to be moved towards vertebrae **50***b* upwardly as shown. The original compression post **64** is inserted in bore **106** in the first compression arm **104** and the additional compression post **54** is inserted into the bore **132** of the second compression arm **130** of compression tool **100**. Again, as discussed above, the turning of the handle **140** results in the two compression arms **104**, **130** moving towards one another, resulting in the compression post **54** in vertebrae **50***c* moving towards the upper compression post **54** in vertebrae **50***b*, once again compressing the fusion graft construct **51** between vertebrae **50***b* and **50***c*. The upper compression post **54** in vertebrae **50***b* can not move since the vertebrae **50***b* has been fixed to the plate by the insertion of the bone screws **30** in the bone screw receiving holes **8** of the plate **2**. Thus, only the lower compression post **54** and vertebrae **50***c* can move. As before, the pilot holes associated with vertebrae **50***c* are formed and the bone screws **30** are inserted through bone screw receiving holes **6**. The compression tool **100** is then removed. Compression post **54** is then extracted from the vertebrae by inserting it in the second opening **95** of the compression post insertion/removal tool **90**, so that it engages the enlarged head **55** of the end of compression post **54** by depression **97**, as shown in FIG. **34**.

It is recognized that other variations in the order of compression may be employed. For example, during the compression of the fusion graft construct **51** between vertebrae **50***b* and **50***c*, the hook **110** of plate engagement element **108** may engage the notch **18** in the end of the plate **2**, and the other compression arm of the compression tool **100** may engage the compression post **54** in the third adjacent vertebrae **50***c*. It should also be noted that plate **2** has a recess end cut out portion between the lobes at the end of the plate for insertion of the compression post **54** in the vertebrae. Otherwise, there may not be room below the end of the plate **2** for insertion of the compression post **54**.

It will be noted that the above-described procedure will be performed with the bone screws **30** fully inserted into vertebral bodies **50***a*, **50***b* and **50***c* and lordosis is maintained during compression of the bone graft construct **51**.

As indicated above, the procedure for attaching the plate **2** to the vertebrae **50***a*, **50***b* and **50***c* was illustrated without the locking screws **20**, **21** in place on the plate **2**. FIG. **40** is a perspective view showing the plate **2** of FIGS. **1–5**, at a stage of a surgical procedure when bone screws **30** have been fully installed in three adjacent vertebrae **50***a*, **50***b* and **50***c*, and locking screws **20**, **21** have been rotated through an angle of about **90**N to lock three bone screws **30** in place; the left-hand locking screw **20** as viewed has been rotated through an angle of about 60N to lock three bone screws **30** in place and the central locking screw **21** has been rotated through an angle of about 90N to lock two other bone screws **30** in place. At this time, one of the camming surfaces **44** of each locking screw **20**, **21** rests atop the screw head **32** of a respective bone screw **30**.

Installation of the locking cap **300** can also be performed with a tool **220** such as shown in FIGS. **41** and **42** having a suitably shaped tip **222** with a length corresponding to the depth of hole **306** in a locking cap **300**. The end **222** of tool **220** is flared just proximal to the most distal end so that it creates a friction fit with the screw cap **300** for ease of manipulation, and prevents the screw cap **300** from falling off the tool **200**.

FIG. **43** is a cross-sectional view in the plane of the center of the two end locking screw holes **6** of plate **2**, with two bone screws **30** in their installed positions and locking element **21** in its locking position. FIG. **44** is an enlarged view of one of the bone screws **30** in plate **2** of FIG. **43**. In a preferred embodiment, the axis of each screw **30** is generally perpendicular to tangents to the upper and lower surfaces of plate **2** at points which are intersected by the longitudinal axis of the associated bone screw **30**. Thus, because of the curvature of plate **2** in the plane of FIG. **43**, bone screws **30** can be directed so as to converge toward one another at a desired angle. Preferably, such angle will be greater than 14°. More preferably, such angle will be greater than 14° and less than 30°. The axis of the two bone screws **30** shown in FIG. **43** may subtend an angle of about 45N. Alternatively, the curvature of the plate from side to side may be so as to conform to the surface of the anterior aspect of the human adult cervical spine and the axis of the paired screw hole may deviate from being perpendicular to the plate when viewed on end to achieve optimal convergence.

Because the bone screws **30**, once inserted, are locked to the plate, a "claw" of a rigid triangular frame structure is obtained at each pair of bone screws **30** such that the attachment of plate **2** to the vertebral bodies **50***a*, **50***b* and **50***c* would be highly secure due to the trapping of a wedged mass of bone material between the angled bone screws triangle, even if any thread stripping should occur. The "claw" may be further formed by three angled bone screws in a tripod configuration or by four bone screws in a four sided claw configuration.

A plating system according to each of the above embodiments can be installed in the same manner as described above, and using the same instruments and tools, as illustrated and described above with respect to the first embodiment. In the case of the embodiment shown in FIG. **22**, the compression operations would be performed by means of slot **232** instead of the middle locking screw hole **12**.

2. The Single Locking Plate Systems

The single locking plate system will now be described. FIGS. **47–52** are views of a first embodiment of a single locking plate system. The contour of plate **600** is the same as the plate **2** shown in FIGS. **1–5**. Plate **600** contains bone screw receiving holes **602** which are internally threaded **603** for receiving corresponding locking elements in the form of a locking cap **610**, shown in FIGS. **56–59**. For example, in plate **600**, the bone screw hole **602** has an outer diameter of approximately 5 mm with a preferred range of 4–6 mm; and a threaded inner diameter of approximately 4.8 mm, with a range of 3.5–5.8 mm for this use. Attaching means other than threads may be used, such as bayonet type attachment elements.

The bottom of each bone screw receiving hole **602** has an inwardly stepped portion of properly selected dimensions for retaining an associated bone screw **170**, as shown in FIGS. **53–55**. As described in greater detail below, in this embodiment, a single locking element in the form of a locking cap **610** having threads **608** shown in FIGS. **56–59**, is associated with each of the bone screws receiving holes **602**.

The difference between the bone screw **170** used in the single locking embodiment of the plate from the bone screw used in association with the multiple locking plate is essentially due to the fact that whereas in the multiple locking plate embodiment the locking elements slide over a portion of the top **39** of the screw head **32**, in the single locking embodiment the locking cap **610** fits over the head **172** of the bone screw **170**. Therefore, the head **172** of the bone screw **170** of the present embodiment need not be smooth. This permits the head **172** of this embodiment bone screw **170** to be thicker and stronger.

FIG. **65** shows two bone screws **170** and associated threaded locking caps **610** in their fully installed positions. In these positions, head portions **174** and **176** of each bone screw **170** form an interference fit with corresponding portions of an associated bone screw receiving hole **602**. Rim **612** of each threaded locking cap **610** forms an interference fit with upper portion **178** of the head of its associated bone screw **170**. Because the thread **608** of each locking cap **610** mates precisely with the internal thread in an associated bone screw receiving hole **602**, each threaded locking cap **610** is additionally subjected to a clamping force between associated head portion **178** and the internal threads **603** of associated bone screw receiving hole **602**. The rounded head **614** of each threaded locking cap **610** assures that the upper surface of an assembled plating system will be free of sharp edges, or projections.

Referring to FIGS. **80** and **81** tools for use in inserting both the bone screws and the locking cap in the single locking plate **600** are shown. In the first embodiment of the driving tool **1000** shown in FIG. **80**, the tool **1000** has an outer tubular housing **1002**. Within the housing **1002** is a torks type or hexagonal driver **1004** that has a projecting end **1006** that corresponds to the recess **306** in the cap **610** for engagement with the cap **610**. As indicated above, the driver **1004** is configured so that it makes a firm attachment for the locking cap **610** for holding the locking cap **610** firmly to the driver. The hex driver **1004** is hollow so as to be able to permit the shaft **1010** of a Phillips or torks screw driver to fit through the hollow portion **1012** for engagement by its tip **1012** with the corresponding recess **180** of bone screw **170** for engagement by the end **1006** of the driver **1004**. The shaft **1010** of the driver **1000** is longer than the tubular housing and driver **1004** has an upper end (not shown) extending from the top end of the tubular housing **1002** so that it can be rotated by the handle.

The housing **1002** has a diameter that permits the locking cap **610** to be held within the inner end of the tubular housing **1002** by a friction fit or to the driver **1004**. It is appreciated that other methods of holding the locking cap **610** within the end of the tubular housing **1000** may also be employed.

As shown in FIG. **80**, the operation of the bone screw and locking element driver **1000** is as follows: the cap **610** is inserted onto the end of the cap driver **1004**, and then the cap driver **1004** with the shaft **1010** of the bone screw driver passing through the central longitudinal opening of the cap driver. As shown, the bone screw driver shaft **1010** passes through the recess **306** in the cap **610** and engages the recess **180** in the head of the bone screw **170**. The bone screw **170** is shown being installed in a bone screw receiving hole in the plate **600**. The handle (not shown) of the bone screw driver is rotated, thereby screwing the bone screw **170** in place. Since the diameter of the bone screw driver is less than the width of the recess **306** of the cap **610**, the bone screw driver shaft **1010** is able to rotate without rotation of the cap **610**.

The hollow tubular housing **1002** rests on the top surface of the plate **600** and assists in the alignment of the shaft **1010** in relationship to the plate. Once the bone screw **170** is inserted, the cap driver **1004** is depressed until the threads **608** on the outside of the cap **610** engages the threads **603** of the bone screw receiving hole. The cap driver **1004** is then turned until the cap **610** is securely locked in place.

In FIG. **81**, an alternative embodiment of the combination bone screw and locking cap driver is shown. In this embodiment, a housing is not used. Instead, the driver shaft **1010** holds the cap **610** by friction and the handle **620** for the bone screw driver shaft **1010** is rotated. A ball spring assembly **622** holds the cap driver **1002** up until the bone screw has been screwed into the bone screw receiving hole. Driver **1010** has an elongated portion that once the bone screw has been installed, the ball spring **622** is depressed and the handle **624** associated with the cap driver is permitted to descend for rotation of the cap **610**. A tubular housing can be employed to assist in aligning of the cap **610** in the bone screw receiving hole, as indicated above.

The drivers shown in FIGS. **80** and **81** simplify the procedure, and reduce the number of instruments that are necessary to be used during the installation procedure. The procedure is quick and reliable, giving the physician more assurance that small watch parts will not be lost or difficult to manipulate.

FIG. **52** is a top view of the plate **600** partially installed, with threaded locking caps **600** installed in bone screw receiving holes **602**.

FIGS. **53–55** show a bone screw **170** for use with the single locking plating system according to the invention. Bone screw **170** differs from bone screw **30** previously described in detail, only with regard to the stepped configuration of head **172**. Preferably, bone screw **170** includes a lower portion **174** which is contiguous with the screw shank and has a reduced diameter equal to the maximum diameter of the shank **176**. Portion **178** of head **172** also has smaller diameter than lower portion **174**. The thread **182** has the same configuration as for the bone screw **30** discussed above. However, either embodiment of bone screws can be used with any of the plates.

As in the case of the multiple locking plating system described above, the bone screws **170** for use in the single locking plating system are preferably solid, where the screws adjoin the lower plate surface, where screws used with prior art plates are most prone to breakage, the only recess in the heads being for engagement of the tip **222** of driving tool **220** and with the recess being above the critical area. Therefore, these bone screws **170** remain robust. The screw heads are not deeply slitted into portions and the locking caps do not impose a radial outer force on the associated bone screw heads so the screw heads do not spread apart so as to be stressed and weakened.

Referring to FIGS. **71**, **73** and **75** another alternative embodiment of the single locking plate system of the present invention is shown and referred to by the number **500**. The plate **500** has the same contour as the plate **2** shown in FIGS. **1–5**, but associated with each of the bone screw openings **502**, are threaded openings **524** offset from the bone screw openings **502** for receiving the locking element **506**, **508**, shown in FIGS. **72** and **74** as a threaded locking set screw or cap **506** or screw **508**.

It is appreciated that other configurations of single locking plates may be employed. Referring to FIG. **82**, a single locking plate **900** is shown in which there are a pair of bone screw receiving holes **910** at its ends **930** and a number of bone screw receiving holes **950** along the longitudinal axis

of the plate **900**. The additional bone screw receiving holes **950** permit a single plate to be able to be aligned with a number of different sized vertebrae disc spaces, and bone fusion grafts. As indicated above, the plate of the present invention shown in FIGS. **1–5**, requires that a properly sized plate be selected by the surgeon so that each pair of bone screw receiving holes **6**, **8** line up with the appropriate vertebrae. This requires a number of different sized plates to be available for optimum attachment of the bone screw receiving holes to each of the vertebrae. With the plate **900** of FIG. **82**, the close spacing and increased number of central openings permit the surgeon to locate at least one appropriate opening to be aligned with each of the intermediate vertebrae, and/or bone grafts.

The procedure for installation of the single locking plates is substantially the same as described herein in detail for the multiple locking plates. The central longitudinal slot **670** in the single locking plates is used for the compression procedure. The same instrumentation is used to create the plate hole either by means of a punch or a drill. FIGS. **60–69** show the various steps in the procedure for installation of the single locking plates, comparable to the steps employed in the installation of the multiple locking plates.

Referring to FIGS. **76–79** the heads **507** and **526** of the locking elements **508** and **522** have a recess **510** and **524** corresponding to the radius of the bone screw openings **502** and **528** so that the locking element **508** and **522** may be installed in place prior to the insertion of the bone screw **170** into the bone screw receiving hole **502** and **528**. When the locking elements **508** and **522** are rotated, a portion of its head extends over the top of the head of bone screw **170** to lock it in place. As with the above embodiments, the bottom surface of the locking screws **508** and **522** can have a camming or other configuration for engagement with the top surface **39** of the associated bone screw **170**.

While the plate instrumentation and method have been described in association with attaching a plate to the vertebrae of the spine, it should be appreciated that the plates can be adopted for specification to other parts of the body. See, for example, application Ser. No. 09/022,344, filed Feb. 11, 1998, and titled Skeletal Plating System, now U.S. Pat. No. 6,139,550, incorporated by reference above. However, the dimensions of the plate, the specific contours and placement of the bone screw receiving holes would have to be modified.

Similarly, the bone screws described in this application could be used in other parts of the body, again being modified so as to serve their intended purposed, depending on the size of the body part in which they are to be installed.

While particular embodiments of the present invention have been shown and described, it will be obvious to those skilled in the art that changes and modifications may be made without departing from this invention in its broader aspects and, therefore, the aim in the appended claims is to cover all such changes and modifications as fall within the true spirit and scope of this invention.

While specific innovative features may have been presented in reference to specific examples, they are just examples, and it should be understood that various combinations of these innovative features beyond those specifically shown are taught such that they may now be easily alternatively combined and are hereby anticipated and claimed.

What is claimed is:

1. A plate system adapted for application to the anterior human cervical spine and for contacting at least a portion of the anterior aspects of at least two cervical vertebral bodies, said plate system comprising:

a plate having a longitudinal axis and a length sufficient to span a disc space and overlap portions of at least two adjacent cervical vertebral bodies, said plate having a lower surface for placement against the vertebral bodies and an upper surface opposite said lower surface, said lower surface being concave along a substantial portion of the longitudinal axis of said plate, said plate having a recess;

at least two bone screw receiving holes extending through said plate from said upper surface through said lower surface, each of said bone screw receiving holes having a central longitudinal axis and being adapted to receive a bone screw to attach said plate to the cervical spine; and

a lock for preventing the inadvertent backing out of the screws from within said bone screw receiving holes, said lock having a threaded shaft member with a longitudinal axis and a cover portion adapted to cover at least a portion of at least two of said bone screw receiving holes, said cover portion of said lock having a non-circular perimeter lying generally in a plane transverse to the longitudinal axis of said threaded shaft member, at least a portion of the perimeter of said cover portion being received in said recess, said threaded shaft member being adapted to engage said plate to secure said cover portion of said lock over a portion of said plate and a portion of at least two bone screw receiving holes.

2. The plate system of claim **1**, wherein at least two of said bone screw receiving holes lie along a line transverse to the longitudinal axis of said plate to overlie one of the cervical vertebral bodies.

3. The plate system of claim **1**, wherein at least a portion of said lower surface of said plate is other than smooth.

4. The plate system of claim **1**, wherein said lock is removably coupled to said plate.

5. The plate system of claim **1**, further comprising at least a third bone screw receiving hole, said cover portion of said lock being configured to cover at least three of said bone screw receiving holes.

6. The plate system of claim **5**, further comprising at least a fourth bone screw receiving hole, said cover portion of said lock being configured to cover at least four of said bone screw receiving holes.

7. The plate system of claim **1**, wherein said lock comprises of a screw.

8. The plate system of claim **1**, in combination with at least two bone screws each having a central longitudinal axis and being adapted to engage each of the at least two vertebral bodies, respectively, each of said bone screws having a leading end for insertion into the vertebral bodies and a trailing end opposite said leading end.

9. The plate system of claim **8**, comprising at least in part of a bioresorbable material.

10. The plate system of claim **1**, wherein at least a first pair of said bone screw receiving holes is transversely oriented side-by-side in said plate to overlie the anterior aspect of a cervical vertebral body, said cover portion of said lock being adapted to cover at least in part a portion of each of said transversely oriented side-by-side bone screw receiving holes.

11. The plate system of claim **1**, in combination with an interbody implant.

12. The plate system of claim **1**, in combination with a bone graft.

13. The plate system of claim **1**, in combination with a bone growth promoting material.

14. The plate system of claim 13, wherein said bone growth promoting material is at least in part other than bone.

15. The plate system of claim 13, wherein said bone growth promoting material is at least in part bone.

16. The plate system of claim 13, wherein said bone growth promoting material includes at least one of bone morphogenetic protein, hydroxyapatite, and hydroxyapatite tricalcium phosphate.

17. The plate system of claim 1, wherein at least a portion of said lower surface of said plate comprises a bone ingrowth material.

18. The plate system of claim 1, wherein at least a portion of said lower surface of said plate includes a bone ingrowth surface.

19. The plate system of claim 1, wherein at least a portion of one of said plate and said lock is a bioresorbable material.

20. A plate system adapted for application to the anterior human cervical spine and for contacting at least a portion of the anterior aspects of at least two cervical vertebral bodies, said plate system comprising:

a plate having a longitudinal axis and a length sufficient to span a disc space and overlap portions of at least two adjacent cervical vertebral bodies, said plate having a lower surface for placement against the vertebral bodies and an upper surface opposite said lower surface, said lower surface being concave along a substantial portion of the longitudinal axis of said plate;

at least two bone screws each having a central longitudinal axis and one each being adapted to engage one each of the at least two vertebral bodies, each of said bone screws having a leading end for insertion into the vertebral bodies and a trailing end opposite said leading end;

at least two bone screw receiving holes extending through said plate from said upper surface through said lower surface, each of said bone screw receiving holes having a central longitudinal axis and being adapted to receive a bone screw to attach for engaging said plate to the cervical spine; and

a lock comprising at least in part a threaded shaft member having a longitudinal axis to cooperatively engage said plate and a cover portion adapted to cover at least a portion of said trailing ends of at least two bone screws to prevent the inadvertent backing out of said at least two bone screws from said plate, said cover portion of said lock having a maximum dimension and a minimum dimension transverse to the longitudinal axis of said shaft, the minimum dimension being less than and generally perpendicular to the maximum dimension, the maximum dimension of said cover portion of said lock being generally transverse to the longitudinal axis of said plate to retain at least two bone screws to said plate.

21. The plate system of claim 20, wherein said plate includes a recess configured to receive at least a portion of a perimeter of said cover portion.

22. The plate system of claim 20, wherein at least two of said bone screw receiving holes lie along a line transverse to the longitudinal axis of said plate to overlie one of the cervical vertebral bodies.

23. The plate system of claim 20, wherein at least a portion of said lower surface of said plate is other than smooth.

24. The plate system of claim 20, wherein said lock is removably coupled to said plate.

25. The plate system of claim 20, further comprising at least a third bone screw receiving hole, said cover portion of said lock being configured to cover at least three of said bone screw receiving holes.

26. The plate system of claim 25, further comprising at least a fourth bone screw receiving hole, said cover portion of said lock being configured to cover at least four of said bone screw receiving holes.

27. The plate system of claim 20, wherein said lock comprises of a screw.

28. The plate system of claim 20, in combination with at least two bone screws each having a central longitudinal axis and being adapted to engage each of the at least two vertebral bodies, respectively, each of said bone screws having a leading end for insertion into the vertebral bodies and a trailing end opposite said leading end.

29. The plate system of claim 28, comprising at least in part of a bioresorbable material.

30. The plate system of claim 20, wherein at least a first pair of said bone screw receiving holes is transversely oriented side-by-side in said plate to overlie the anterior aspect of a cervical vertebral body, said cover portion of said lock being adapted to cover at least in part a portion of each of said transversely oriented side-by-side bone screw receiving holes.

31. The plate system of claim 20, in combination with an interbody implant.

32. The plate system of claim 20, in combination with a bone graft.

33. The plate system of claim 20, in combination with a bone growth promoting material.

34. The plate system of claim 33, wherein said bone growth promoting material is at least in part other than bone.

35. The plate system of claim 33, wherein said bone growth promoting material is at least in part bone.

36. The plate system of claim 33, wherein said bone growth promoting material includes at least one of bone morphogenetic protein, hydroxyapatite, and hydroxyapatite tricalcium phosphate.

37. The plate system of claim 20, wherein at least a portion of said lower surface of said plate comprises a bone ingrowth material.

38. The plate system of claim 20, wherein at least a portion of said lower surface of said plate includes a bone ingrowth surface.

39. The plate system of claim 20, wherein at least a portion of one of said plate and said lock is a bioresorbable material.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,936,050 B2
DATED : August 30, 2005
INVENTOR(S) : Gary K. Michelson

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title page,

Item [56], **References Cited**, U.S. PATENT DOCUMENTS, please insert the following:

-- 4,898,161	2/1990	Grundei
4,957,495	9/1990	Kluger
4,959,065	09/1990	Arnett et al.
5,000,166	3/1991	Karpf
5,019,079	05/1991	Ross
5,041,113	08/1991	Biedermann et al.
5,052,373	10/1991	Michelson
5,053,036	10/1991	Perren et al.
5,059,194	10/1991	Michelson
5,127,912	07/1992	Ray et al.
5,147,361	09/1992	Ojima et al.
5,167,662	12/1992	Hayes et al.
5,180,381	01/1993	Aust et al.
5,190,544	03/1993	Chapman et al.
5,209,751	5/1993	Farris et al.
5,217,497	6/1993	Mehdian
5,234,430	08/1993	Huebner
5,300,073	04/1994	Ray et al.
5,338,197	08/1994	Kwan
5,364,399	11/1994	Lowery et al.
5,380,328	01/1995	Morgan
5,397,363	03/1995	Gelbard
5,423,826	06/1995	Coates et al.
5,456,685	10/1995	Huebner
5,478,340	12/1995	Kluger
5,478,348	12/1995	Bajada
5,492,442	02/1996	Lasner
5,520,690	05/1996	Errico et al.
5,527,314	06/1996	Brumfield et al.
5,531,554	07/1996	Jeanson et al.

UNITED STATES PATENT AND TRADEMARK OFFICE

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DATED : August 30, 2005
INVENTOR(S) : Gary K. Michelson

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title page (cont'd),

5,531,746	07/1996	Errico et al.
5,545,163	08/1996	Miller et al.
5,545,165	08/1996	Biedermann et al. --.

Signed and Sealed this

Eighteenth Day of October, 2005

JON W. DUDAS
Director of the United States Patent and Trademark Office