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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

WARSAW ORTHOPEDIC, INC.; MEDTRONIC SOFAMOR DANEK U.S.A., INC.; MEDTRONIC PUERTO RICO OPERATIONS CO.; and OSTEOTECH, INC., Plaintiffs, vs. NUVASIVE, INC., Defendant. AND RELATED COUNTERCLAIMS.	CASE NO. 3:12-cv-02738-CAB (MDD) **SECOND AMENDED AND SUPPLEMENTAL COMPLAINT FOR PATENT INFRINGEMENT** **JURY TRIAL DEMANDED**

Plaintiffs Warsaw Orthopedic, Inc. ("Warsaw"), Medtronic Sofamor Danek U.S.A., Inc. ("Sofamor Danek USA"), Medtronic Puerto Rico Operations Co. ("MPROC"), and Osteotech, Inc. ("Osteotech") (collectively "Plaintiffs") bring this First Amended Complaint for Patent Infringement and Jury Demand against Defendant NuVasive, Inc. ("NuVasive"), alleging as follows:

PARTIES, JURISDICTION, AND VENUE

1. Plaintiff Warsaw is an Indiana corporation, with its principal place of business in Warsaw, Indiana.

2. Plaintiff Sofamor Danek USA is a Tennessee corporation, with its principal place of business in Memphis, Tennessee. Sofamor Danek USA researches, develops, and distributes medical devices and instruments for use in connection with spine surgery.

3. Plaintiff MPROC is a Cayman Islands corporation, with its principal place of business in Humacao, Puerto Rico. MPROC manufactures and sells medical devices and instruments for use in connection with spine surgery.

4. Plaintiff Osteotech is a Delaware corporation, with its principal place of business in Eatontown, New Jersey. Osteotech makes and sells biologic and regenerative therapy products for use in the repair of the musculoskeletal system.

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

6. This action arises under the patent laws of the United States, 35 U.S.C. § 1 et seq., and seeks damages and injunctive relief pursuant to 35 U.S.C. §§ 271, 281, 283–285.

7. This Court has subject matter jurisdiction over the action pursuant to 28 U.S.C. §§ 1331 and 1338(a) because 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 judicial District pursuant to 28 U.S.C. §§ 1391(b), 1391(c), 1391(d) and/or 1400(b).

COUNT I

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

11. United States Patent No. 8,021,430 (the "'430 patent," a copy of which is attached hereto as Exhibit A), entitled "Anatomic Spinal Implant Having Anatomic Bearing Surfaces," issued on September 20, 2011. Plaintiff Warsaw is the owner of the '430 patent by written assignment. Warsaw has granted to Plaintiff MPROC, via written agreements, the exclusive license under the '430 patent to use, make, have made, import, offer for sale, and sell. MPROC has granted to Plaintiff Sofamor Danek USA, via written agreements, the exclusive sub-license under the '430 patent to import, offer for sale, and sell. As a result of these agreements and Warsaw's ownership of the '430 patent, Plaintiffs Warsaw, MPROC, and Sofamor Danek USA have standing to bring suit for infringement of the '430 patent.

12. NuVasive is infringing and has infringed the '430 patent by making, using, offering for sale, and selling infringing products, including but not limited to its CoRoent XL family of spinal implants (e.g., CoRoent XL Thoracic, CoRoent XL Standard, CoRoent XL Lordotic, CoRoent XL Wide Lordotic, CoRoent XL Wide Standard, CoRoent XL Coronal Tapered Lordotic, CoRoent XL Coronal Tapered Standard, and CoRoent Keeled) for use in its eXtreme Lateral Interbody Fusion ("XLIF") surgical procedure, as well as its CoRoent Large family of spinal implants (e.g., CoRoent Large Wide and Narrow) for use in transforaminal or posterior surgical approaches, within the United States.

13. NuVasive's infringement of the '430 patent has been without permission,

consent, authorization, or license of Plaintiffs.

14. NuVasive's infringement of the '430 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

15. Paragraphs 1–9 are incorporated into this count by reference.

16. United States Patent No. 5,676,146 C2 (the "'146 patent," a copy of which is attached hereto as Exhibit B), entitled "Surgical Implant Containing A Resorbable Radiopaque Marker And Method Of Locating Such Within A Body," issued on December 25, 2007. The original application issued as a patent on October 14, 1997, and reexamination certificates for the '146 patent issued on April 18, 2000 and December 25, 2007.

17. Plaintiff Osteotech was the owner of the '146 patent from original issuance until April 15, 2011. Osteotech obtained its ownership by written assignment. As owner of the '146 patent during this time period, Osteotech has standing to sue for infringement of the '146 patent that occurred between original issuance of the patent and April 15, 2011.

18. Plaintiff Warsaw is the current owner of the '146 patent by written assignment from Osteotech. As a result of this assignment, Warsaw has been the owner of the '146 patent since April 15, 2011. The April 15, 2011 assignment from Osteotech to Warsaw did not transfer to Warsaw the right to sue for damages for infringement that took place before the assignment.

19. Warsaw has granted to Plaintiff Sofamor Danek USA, via written agreements, an exclusive license under the '146 patent to import, offer for sale, and sell. As a result of these agreements and Warsaw's ownership of the '146 patent, Plaintiffs Warsaw and Sofamor Danek USA have standing to bring suit for infringement of the '146 patent that occurred from April 15, 2011 to the present, and going forward.

20. NuVasive is infringing and has infringed the '146 patent from 2008 to the present by making, using, offering for sale, and selling infringing products, including but not limited to its Osteocel Plus bone graft product, within the United States.

21. NuVasive is inducing and has induced direct infringement of the '146 patent by surgeons in violation of 35 U.S.C. § 271(b) by actively taking steps to facilitate purchase of Osteocel Plus and instructing surgeons to use Osteocel Plus in spine surgery with knowledge that such use infringes one or more claims of the '146 patent, and with the specific intent to induce that infringement.

22. NuVasive is instructing and has instructed surgeons to use Osteocel Plus in spine surgery, including in, but not limited to, its anterior cervical discectomy and fusion ("ACDF"), XLIF, anterior lumbar interbody fusion ("ALIF"), posterior cervical fusion ("PCF"), posterior laminoplasty, transforaminal lumbar interbody fusion ("TLIF"), Interlaminar Lumbar Instrumented Fusion ("ILIF"), posterior lumbar interbody fusion ("PLIF"), and posterior fixation surgical techniques.

23. Following NuVasive's instructions, surgeons have implanted, and continue to implant, Osteocel Plus into patients' bodies during spine surgery, an act that constitutes direct infringement of at least one claim of the '146 patent.

24. Upon information and belief, NuVasive has had knowledge of the '146 patent at least as early as 2008 given that the Grafton and Grafton Plus products that compete with Osteocel Plus are marked with the '146 patent. Upon information and belief, NuVasive's products have been used in spine surgery in conjunction with Grafton products with NuVasive sales representatives present during the surgery. NuVasive also has had knowledge of the '146 patent at least as early as August 21, 2012, when it was served with Plaintiffs' original Complaint for Patent Infringement and Jury Demand.

25. NuVasive has acted with the specific intent to induce direct infringement of the '146 patent by, among other things, actively continuing to sell Osteocel Plus and actively continuing to instruct surgeons to use Osteocel Plus in spine surgery as

alleged with knowledge of the ’146 patent.

26. NuVasive is also contributing and has contributed to the infringement of the ’146 patent in violation of 35 U.S.C. § 271(c) by offering for sale, selling, promoting, teaching, and encouraging the use of Osteocel Plus in spine surgery. NuVasive markets Osteocel Plus as especially made or especially adapted for implantation within patients’ bodies during surgery. Osteocel Plus is not a staple article of commerce suitable for substantial non-infringing use because it is especially designed for surgical implantation and its location and/or orientation is necessarily apparent using x-ray or other radiographic techniques. The use of Osteocel Plus in surgery necessarily and directly infringes at least one claim of the ’146 patent.

27. NuVasive’s infringement of the ’146 patent has been without permission, consent, authorization, or license of Plaintiffs.

28. NuVasive’s infringement of the ’146 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

29. Paragraphs 1–12 are incorporated into this count by reference.

30. United States Patent No. 8,251,997 (the “’997 patent,” a copy of which is attached hereto as Exhibit C), entitled “A Method For Inserting An Artificial Implant Between Two Adjacent Vertebrae Along A Coronal Plane,” issued on August 28, 2012 from U.S. Application No. 13/306,583 (“the ’583 application”). The ’997 patent relates generally to novel methods for performing surgical procedures in the human spine. Plaintiff Warsaw is the owner of the ’997 patent by written assignment. Warsaw has granted to Plaintiff Sofamor Danek USA, via written agreements, the exclusive license under the ’997 patent to use, make, have made, import, offer for sale, and sell. As a result of these agreements and Warsaw’s ownership of the ’997 patent, Plaintiffs Warsaw and Sofamor Danek USA have standing to bring suit for infringement of the ’997 patent.

31. NuVasive is inducing and has induced direct infringement of the '997 patent by surgeons in violation of 35 U.S.C. § 271(b) by actively taking steps to facilitate purchase of its CoRoent XL family of implants and at least its MaXcess 4 Retractor and instructing and training surgeons to use the CoRoent XL family of implants and at least the MaXcess 4 Retractor in NuVasive's minimally invasive spinal surgical procedure, XLIF, that is performed through the side of patients' bodies with knowledge that such use infringes one or more claims of the '997 patent, and with the specific intent to induce that infringement.

32. NuVasive is instructing and training and has instructed and trained surgeons to use its CoRoent XL family of implants and at least its MaXcess 4 Retractor in its XLIF surgical technique. NuVasive includes such instruction in, for example, published surgical techniques and CoRoent XL and MaXcess 4 Retractor marketing literature, and on its website, available at http://www.nuvasive.com/patient-solutions/indications/lumbar-degenerative-disc-disease. NuVasive also provides such instruction during training courses.

33. Following NuVasive's instructions, surgeons have implanted, and continue to implant, the CoRoent XL family of implants into patients' bodies using at least the MaXcess 4 Retractor while performing NuVasive's XLIF surgical technique, an act that constitutes direct infringement of at least one claim of the '997 patent.

34. NuVasive has had knowledge of the claims of the '997 patent at least as early as August 3, 2012, when notice was provided to NuVasive of a filing with the United States Patent & Trademark Office of an Opposition and Petition Under 37 C.F.R. § 1.183 in the inter partes reexamination of U.S. Patent 7,207,949 (Control No. 95/001,202), which noted that the claims of the '583 application were allowed and the patent would issue shortly.

35. Upon information and belief, NuVasive has been monitoring patents in the '997 patent family at least as early as 2008.

36. NuVasive has acted with the specific intent to induce direct infringement

of the '997 patent by, among other things, actively marketing, selling, supporting, and warranting the CoRoent XL family of implants and at least the MaXcess 4 Retractor and actively continuing to instruct surgeons to use the CoRoent XL family of implants and at least the MaXcess 4 Retractor while performing NuVasive's XLIF surgical technique as alleged with knowledge of the '997 patent.

37. NuVasive is also contributing and has contributed to the infringement of the '997 patent in violation of 35 U.S.C. § 271(c) by offering for sale, selling, promoting, teaching, and encouraging the use of its CoRoent XL family of implants and at least its MaXcess 4 Retractor in its XLIF surgical technique. NuVasive markets its CoRoent XL family of implants and MaXcess 4 Retractor as especially made or especially adapted for use in its XLIF surgical technique.

38. The CoRoent XL family of implants is not a staple article of commerce suitable for substantial non-infringing use. The CoRoent XL family of implants is especially designed for use in NuVasive's XLIF surgical technique, a procedure performed from the lateral aspect of the spine. For example, NuVasive markets "the CoRoent® XL family of implants [as] [d]esigned specifically for the eXtreme Lateral Interbody Fusion (XLIF®) procedure." The structural configurations of the CoRoent XL family of implants render them unsuitable for insertion from the anterior or posterior aspect of the spine. These structural configurations include at least the dimensions, surface configurations, and insertion mechanisms. The use of the CoRoent XL family of implants in NuVasive's XLIF surgical technique necessarily and directly infringes at least one claim of the '997 patent.

39. The MaXcess 4 Retractor is not a staple article of commerce suitable for substantial non-infringing use. The MaXcess 4 retractor is especially designed for use in NuVasive's XLIF surgical technique, a procedure performed from the lateral aspect of the spine. For example, NuVasive markets its MaXcess 4 Retractor as the "fourth generation XLIF access system" "designed to deliver reproducible XLIF outcomes." The structural configurations of the MaXcess 4 Retractor render it unsuitable for use

in surgery performed from the anterior or posterior aspect of the spine. These structural configurations include at least the blade length that is especially adapted for use in lateral spine surgery. The use of the MaXcess 4 Retractor in NuVasive's XLIF surgical technique necessarily and directly infringes at least one claim of the '997 patent.

40. NuVasive's infringement of the '997 patent has been without permission, consent, authorization, or license of Plaintiffs.

41. NuVasive's infringement of the '997 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

42. Paragraphs 1–9 are incorporated into this count by reference.

43. United States Patent No. 8,444,696 (the "'696 patent," a copy of which is attached hereto as Exhibit D), entitled "Anatomic Spinal Implant Having Anatomic Bearing Surfaces," issued on May 21, 2013. Plaintiff Warsaw is the owner of the '696 patent by written assignment. Warsaw has granted to Plaintiff MPROC, via written agreements, the exclusive license under the '696 patent to use, make, have made, import, offer for sale, and sell. MPROC has granted to Plaintiff Sofamor Danek USA, via written agreements, the exclusive sub-license under the '696 patent to import, offer for sale, and sell. As a result of these agreements and Warsaw's ownership of the '696 patent, Plaintiffs Warsaw, MPROC, and Sofamor Danek USA have standing to bring suit for infringement of the '696 patent.

44. NuVasive is infringing and has infringed the '696 patent by making, using, offering for sale, and selling infringing products, including but not limited to its CoRoent XL family of spinal implants (e.g., CoRoent XL Thoracic, CoRoent XL Standard, CoRoent XL Lordotic, CoRoent XL Wide Lordotic, CoRoent XL Wide Standard, CoRoent XL Coronal Tapered Lordotic, CoRoent XL Coronal Tapered Standard, CoRoent XL Keeled, and CoRoent XL Fixation) for use in its eXtreme

Lateral Interbody Fusion ("XLIF") surgical procedure, as well as its CoRoent Large family of spinal implants (e.g., CoRoent Large Wide, CoRoent Large Narrow, and CoRoent Large Tapered) for use in transforaminal or posterior surgical approaches, within the United States.

45. NuVasive's infringement of the '696 patent has been without permission, consent, authorization, or license of Plaintiffs.

46. NuVasive's infringement of the '696 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 '430 patent;

2. Adjudge that NuVasive has directly infringed and is directly infringing and has induced and contributed to and is inducing and contributing to the infringement of the '146 patent;

3. Adjudge that NuVasive has induced and contributed to and is inducing and contributing to the infringement of the '997 patent;

4. Adjudge that NuVasive has infringed and is infringing the '696 patent;

5. Preliminarily and permanently enjoin NuVasive and its affiliates, subsidiaries, officers, directors, employees, agents, representatives, licensees, successors, and assigns, and all of those acting for it and on its behalf, or acting in concert with it, from further infringement of the '430, '146, '997, and '696 patents;

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

7. Order an accounting to the extent necessary to provide complete monetary relief to Plaintiffs;

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

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

DATED: May 23, 2013

Respectfully submitted,

KIRKLAND & ELLIS LLP

/s/ Nimalka R. Wickramasekera
Luke L. Dauchot
Alexander F. MacKinnon
Nimalka R. Wickramasekera

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JURY TRIAL DEMAND

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

DATED: May 23, 2013

Respectfully submitted,

KIRKLAND & ELLIS LLP

/s/ Nimalka R. Wickramasekera
Luke L. Dauchot
Alexander F. MacKinnon
Nimalka R. Wickramasekera

Attorneys for Plaintiffs/Counterclaim Defendants, WARSAW ORTHOPEDIC, INC.; MEDTRONIC SOFAMOR DANEK U.S.A., INC.; MEDTRONIC PUERTO RICO OPERATIONS CO.; OSTEOTECH, INC.; MEDTRONIC, INC.; and MEDTRONIC SOFAMOR DANEK DEGGENDORF, GMB

EXHIBIT A

US008021430B2

(12) **United States Patent**
Michelson

(10) **Patent No.: US 8,021,430 B2**
(45) **Date of Patent: *Sep. 20, 2011**

(54) **ANATOMIC SPINAL IMPLANT HAVING ANATOMIC BEARING SURFACES**

(75) Inventor: **Gary Karlin Michelson**, Venice, CA (US)

(73) Assignee: **Warsaw Orthopedic, Inc.**, Warsaw, IN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **12/807,489**

(22) Filed: **Sep. 7, 2010**

(65) **Prior Publication Data**

US 2011/0004310 A1 Jan. 6, 2011

Related U.S. Application Data

(60) Continuation of application No. 10/926,766, filed on Aug. 26, 2004, now Pat. No. 7,789,914, which is a continuation of application No. 10/237,751, filed on Sep. 9, 2002, now Pat. No. 7,503,933, which is a continuation of application No. 09/412,090, filed on Oct. 4, 1999, now Pat. No. 6,447,544, which is a continuation of application No. 08/813,283, filed on Mar. 10, 1997, now Pat. No. 6,302,914, which is a division of application No. 08/482,146, filed on Jun. 7, 1995, now Pat. No. 5,609,635.

(51) **Int. Cl.**
A61F 2/44 (2006.01)

(52) **U.S. Cl.** **623/17.16**

(58) **Field of Classification Search** 623/17.11–17.16
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,372,622	A	3/1945	Fassio
2,677,369	A	5/1954	Knowles
3,298,372	A	1/1967	Feinberg
3,605,123	A	9/1971	Hahn
3,848,601	A	11/1974	Ma et al.
3,867,728	A	2/1975	Stubstad et al.
3,875,595	A	4/1975	Froning
3,905,047	A	9/1975	Long
3,948,262	A	4/1976	Zaffaroni

(Continued)

FOREIGN PATENT DOCUMENTS

CA	1 328 957	5/1994

(Continued)

OTHER PUBLICATIONS

Brandt, L., et al.; A Dowell Inserter for Anterior Cervical Interbody Fusion; J. Neurosurg. 61:793-794 (Oct. 1984).

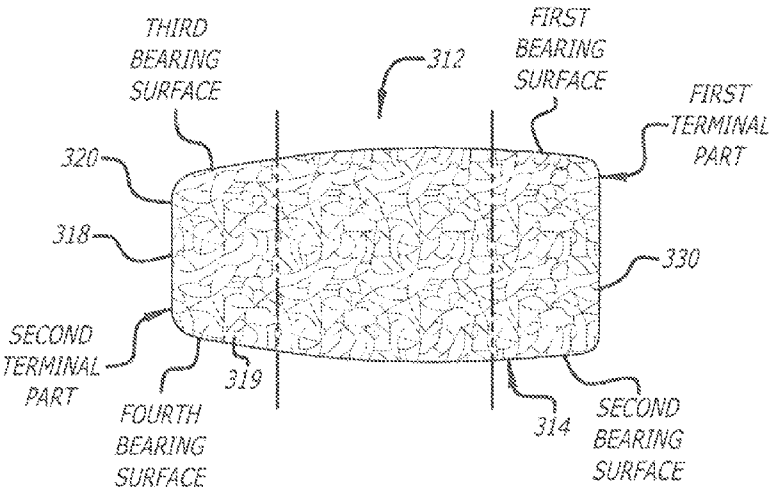
(Continued)

Primary Examiner — Alvin J Stewart
(74) *Attorney, Agent, or Firm* — Martin & Ferraro, LLP

(57) **ABSTRACT**

The present application is directed to an interbody spinal implant having a structural configuration that provides for maintaining the normal anatomic relationship of two adjacent vertebrae of the spine. The spinal implant is sized to fit within the disc space created by the removal of disc material between two adjacent vertebrae and conform wholly, or in part, to the disc space created. The spinal implant of the present invention has first and second sides with upper and lower bearing surfaces that form a support structure for bearing against the end plates of the adjacent vertebrae. The upper and lower bearing surfaces of the first and second sides are shaped to create an anatomic fit with the endplates of the adjacent vertebrae.

32 Claims, 11 Drawing Sheets



U.S. PATENT DOCUMENTS

3,952,334	A	4/1976	Bokoros et al.
3,987,499	A	10/1976	Scharbach et al.
D245,259	S	8/1977	Shen
4,070,514	A	1/1978	Entherly et al.
4,168,326	A	9/1979	Broemer et al.
4,309,777	A	1/1982	Patil
4,349,921	A	9/1982	Kuntz
4,401,112	A	8/1983	Rezaian
4,405,319	A	9/1983	Cosentino
4,439,152	A	3/1984	Small
4,501,269	A	2/1985	Bagby
4,507,115	A	3/1985	Kambara et al.
4,535,485	A	8/1985	Ashman et al.
4,542,539	A	9/1985	Rowe, Jr. et al.
4,545,374	A	10/1985	Jacobson
4,547,390	A	10/1985	Ashman et al.
4,553,273	A	11/1985	Wu
4,554,914	A	11/1985	Kapp et al.
4,566,466	A	1/1986	Ripple et al.
4,599,086	A	7/1986	Doty
4,604,995	A	8/1986	Stephens
4,608,052	A	8/1986	Van Kampen et al.
4,634,720	A	1/1987	Dorman et al.
4,636,217	A	1/1987	Ogilvie et al.
4,636,526	A	1/1987	Dorman et al.
4,645,503	A	2/1987	Lin et al.
4,655,777	A	4/1987	Dunn
4,661,536	A	4/1987	Dorman et al.
4,693,721	A	9/1987	Ducheyne
4,698,375	A	10/1987	Dorman et al.
4,714,469	A	12/1987	Kenna
4,721,103	A	1/1988	Freedland
4,743,256	A	5/1988	Brantigan
4,759,766	A	7/1988	Buettner-Janz et al.
4,759,769	A	7/1988	Hedman et al.
4,763,644	A	8/1988	Webb
4,820,305	A	4/1989	Harms et al.
4,834,757	A	5/1989	Brantigan
4,863,476	A	9/1989	Shepperd
4,863,477	A	9/1989	Monson
4,865,603	A	9/1989	Noiles
4,877,020	A	10/1989	Vich
4,878,915	A	11/1989	Brantigan
4,904,261	A	2/1990	Dove et al.
4,911,718	A	3/1990	Lee et al.
4,936,848	A	6/1990	Bagby
4,955,908	A	9/1990	Frey et al.
4,961,740	A	10/1990	Ray et al.
5,015,247	A	5/1991	Michelson
5,026,373	A	6/1991	Ray et al.
5,055,104	A	10/1991	Ray
5,062,845	A	11/1991	Kuslich et al.
5,071,437	A	12/1991	Steffee
5,122,130	A	6/1992	Keller
5,123,926	A	6/1992	Pisharodi
5,171,278	A	12/1992	Pisharodi
5,190,548	A	3/1993	Davis
5,192,327	A	3/1993	Brantigan
5,246,458	A	9/1993	Graham
5,250,061	A	10/1993	Michelson
5,258,031	A	11/1993	Salib et al.
5,258,043	A	11/1993	Stone
5,304,191	A	4/1994	Gosselin
5,306,308	A	4/1994	Gross et al.
5,306,309	A	4/1994	Wagner et al.
5,360,430	A	11/1994	Lin
5,370,697	A	12/1994	Baumgartner
5,397,364	A	3/1995	Kozak et al.
5,425,772	A	6/1995	Brantigan
5,443,514	A	8/1995	Steffee
5,445,639	A	8/1995	Kuslich et al.
5,458,638	A	10/1995	Kuslich et al.
5,458,643	A	10/1995	Oka et al.
5,484,437	A	1/1996	Michelson
5,489,307	A	2/1996	Kuslich et al.
5,489,308	A	2/1996	Kuslich et al.
5,499,984	A	3/1996	Steiner et al.
5,522,899	A	6/1996	Michelson
5,534,028	A	7/1996	Bao et al.
5,554,191	A	9/1996	Lahille et al.
5,571,109	A	11/1996	Bertagnoli
5,571,190	A	11/1996	Ulrich et al.
5,607,424	A	3/1997	Tropiano
5,609,635	A	3/1997	Michelson
5,609,636	A	3/1997	Kohrs et al.
5,609,637	A	3/1997	Biedermann et al.
5,658,335	A	8/1997	Allen
5,658,337	A	8/1997	Kohrs et al.
5,665,122	A	9/1997	Kambin
5,669,909	A	9/1997	Zdeblick et al.
5,683,463	A	11/1997	Godefroy et al.
5,766,252	A	6/1998	Henry et al.
5,769,897	A	6/1998	Härle
5,776,199	A	7/1998	Michelson
5,782,919	A	7/1998	Zdeblick et al.
5,800,547	A	9/1998	Schäfer et al.
5,824,094	A	10/1998	Serhan et al.
5,861,041	A	1/1999	Tienboon
5,888,223	A	3/1999	Bray
5,888,224	A	3/1999	Beckers et al.
5,893,890	A	4/1999	Pisharodi
5,980,522	A	11/1999	Koros et al.
5,984,967	A	11/1999	Zdeblick et al.
6,059,829	A	5/2000	Schläpfer et al.
6,149,686	A	11/2000	Kuslich et al.
6,159,214	A	12/2000	Michelson
6,302,914	B1	10/2001	Michelson
6,447,544	B1	9/2002	Michelson
6,558,423	B1	5/2003	Michelson
6,613,091	B1	9/2003	Zdeblick et al.
7,056,342	B2	6/2006	Michelson
7,503,933	B2	3/2009	Michelson
7,789,914	B2	9/2010	Michelson

FOREIGN PATENT DOCUMENTS

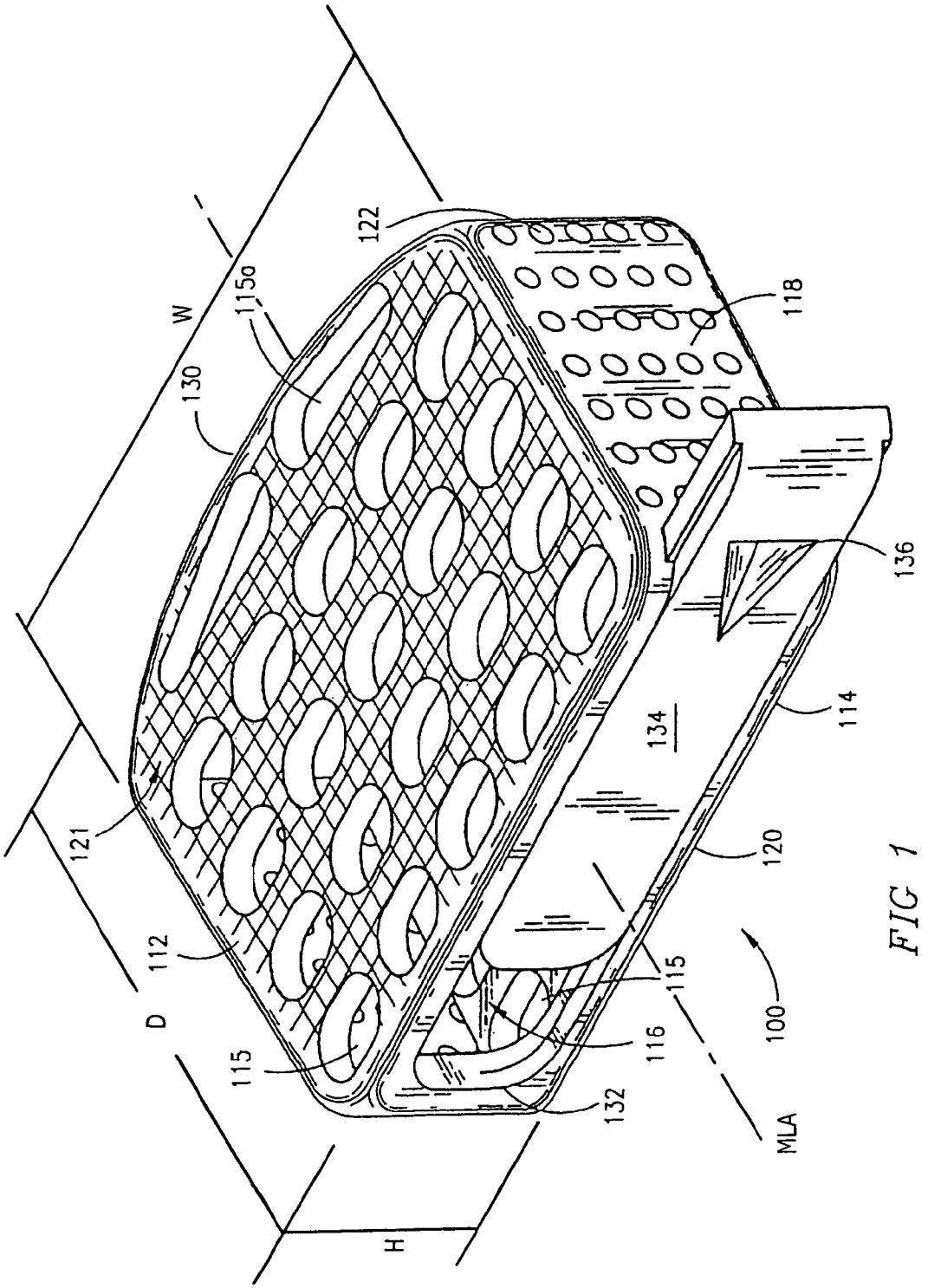
CA	2 151 481		3/1995
DE	29 10 627		9/1980
DE	36 08 163	A1	9/1987
DE	36 20 549		12/1987
EP	0 179 695		4/1986
EP	0 260 044		8/1988
EP	0 493 698	A1	7/1992
EP	0 599 419	A2	6/1994
EP	0 627 204	A2	12/1994
EP	0 425 542		3/1995
EP	0 646 366		4/1995
FR	2 703 580		10/1994
JP	60-31706		11/1979
JP	60-43984		10/1985
JP	62-155846		7/1987
JP	5-208029		8/1993
SU	1107854		8/1984
WO	WO 90/00037		1/1990
WO	WO 93/01771		2/1993
WO	WO 96/22747		8/1996

OTHER PUBLICATIONS

The Official Communication from the Canadian Intellectual Property Office dated Jan. 31, 2002 from corresponding Canadian Patent Application No. 2,223,964.

European Search Report dated Jan. 12, 2000 for European Patent Application No. 96918001 in the name of Gary Karlin Michelson.

Tech. Mitt. Krupp, Nickel-Titanium Spacers for Partial Stiffening of the Spinal Column—Problems Involved, Manufacture, Pretesting, and Clinical Use; vol. 42 (1984), No. 1, pp. 24-38; including translation pp. 5-27.


W
130
115a
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120
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112
D
115
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115
100
132
MLA
H

FIG 1

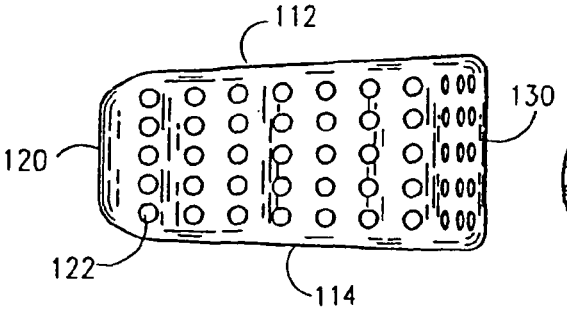


FIG 3

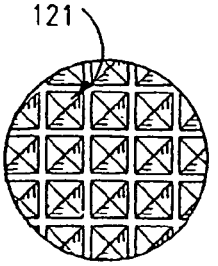


FIG 7

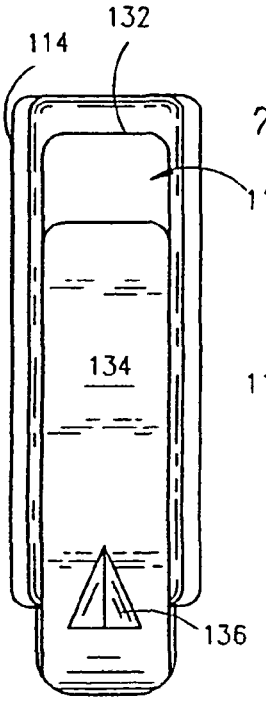


FIG 5

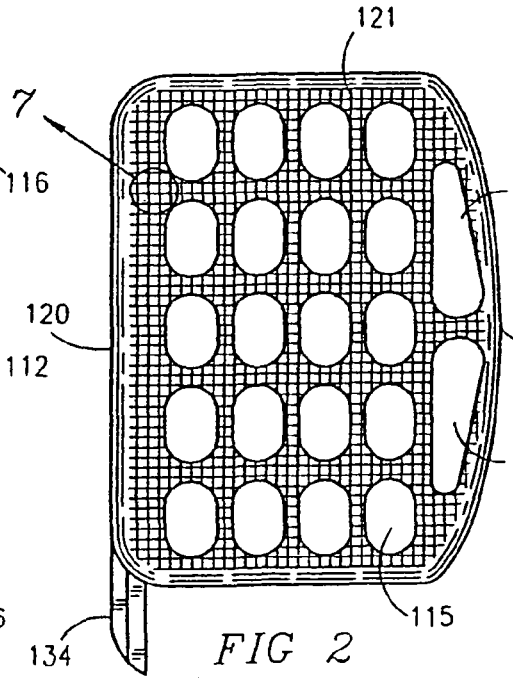
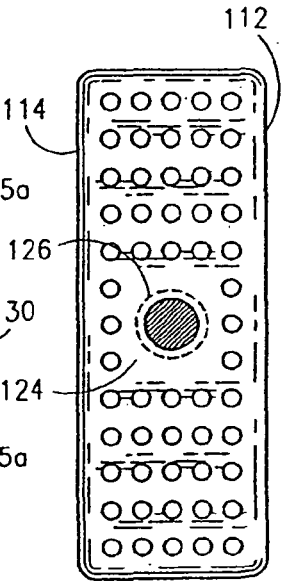


FIG 2



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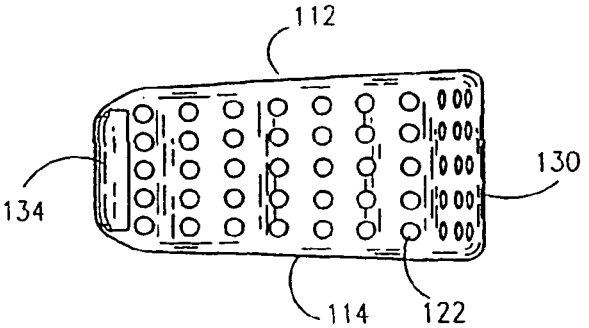


FIG 4

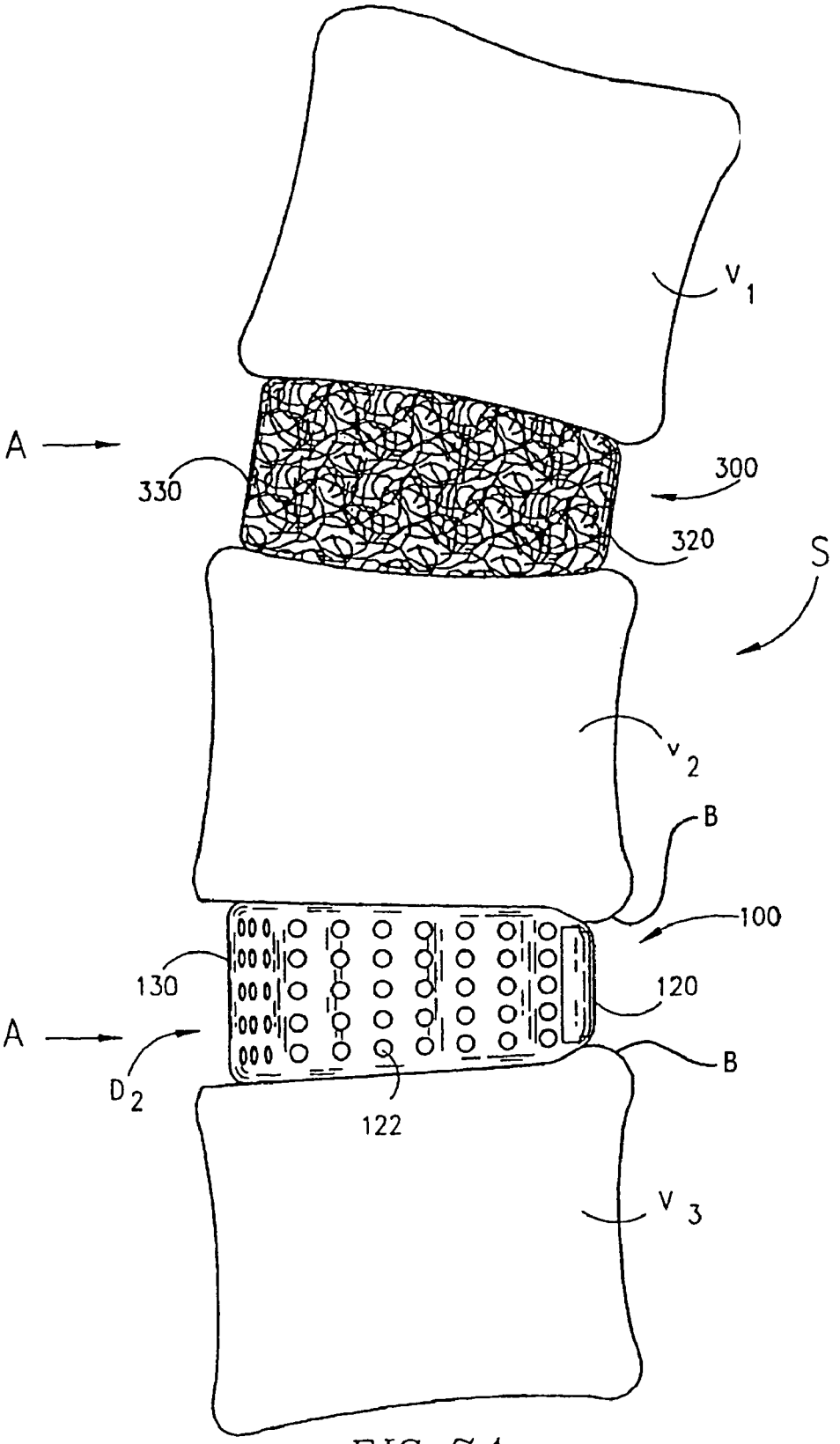


FIG 7A

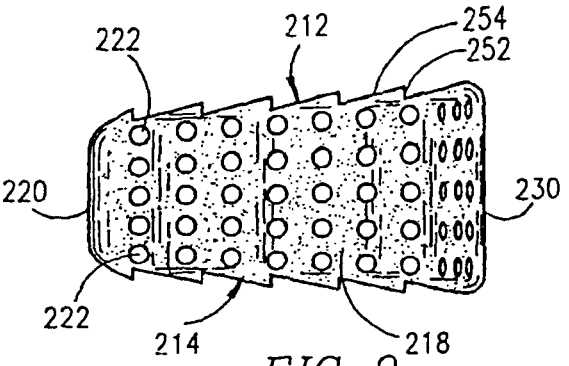
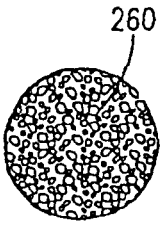


FIG 9



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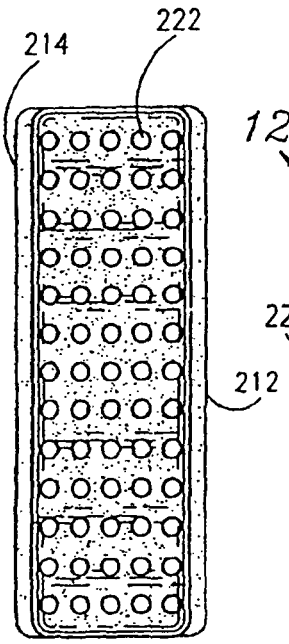

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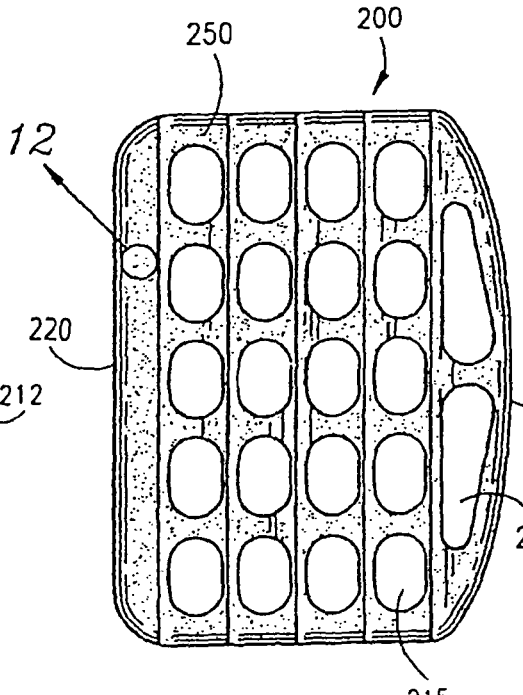


FIG 8

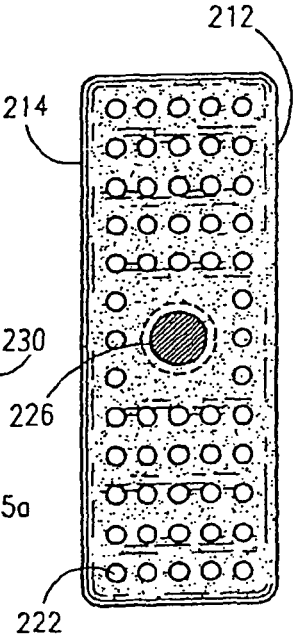


FIG 11

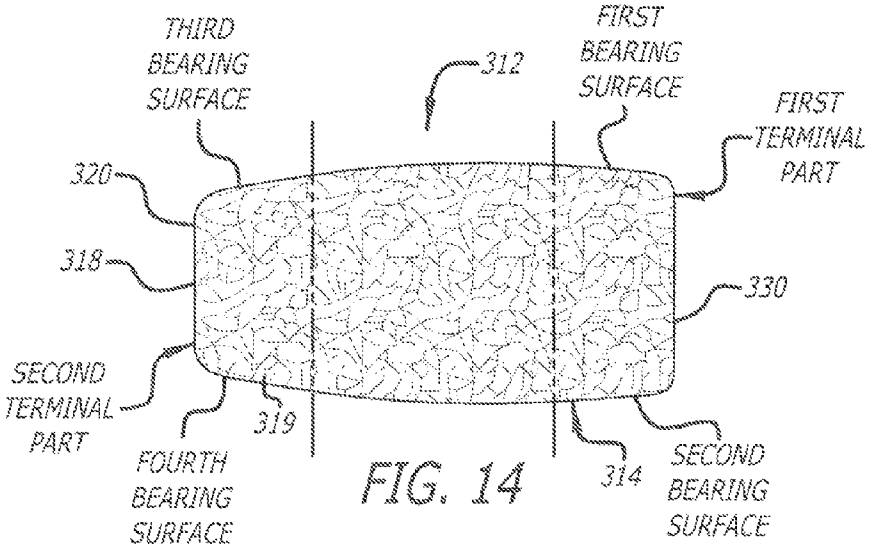

THIRD BEARING SURFACE
312
FIRST BEARING SURFACE
FIRST TERMINAL PART
320
318
330
SECOND TERMINAL PART
319
FOURTH BEARING SURFACE
314
SECOND BEARING SURFACE

FIG. 14

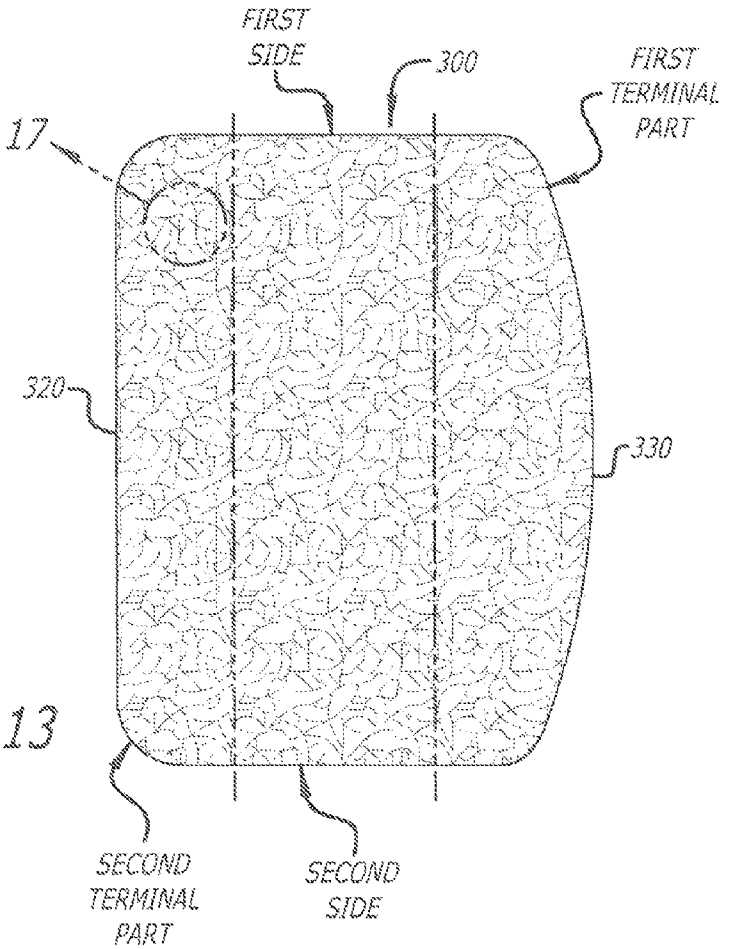

FIRST SIDE
300
FIRST TERMINAL PART
17
320
330
SECOND TERMINAL PART
SECOND SIDE

FIG. 13

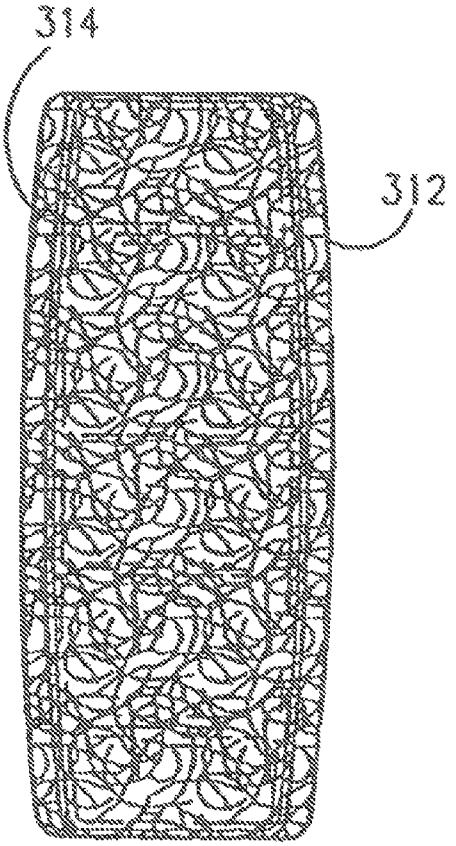


FIG 15

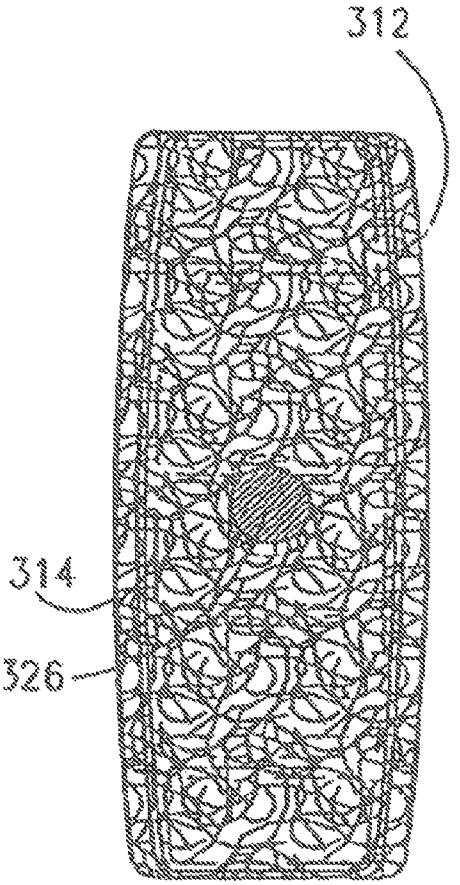
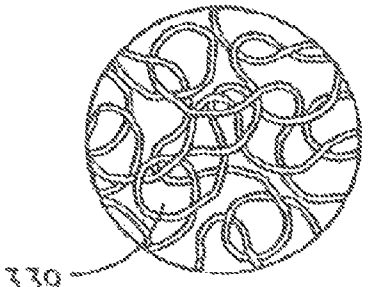


FIG 16



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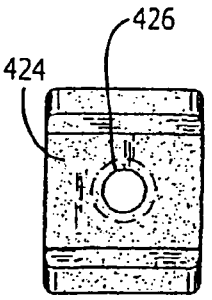


FIG 21

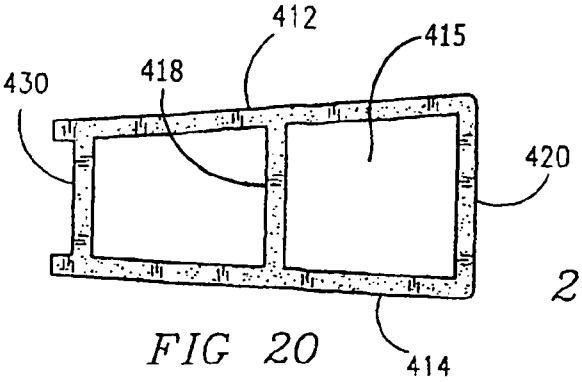


FIG 20

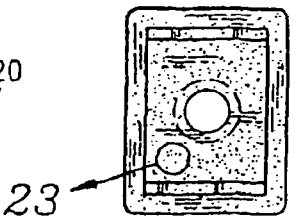


FIG 22

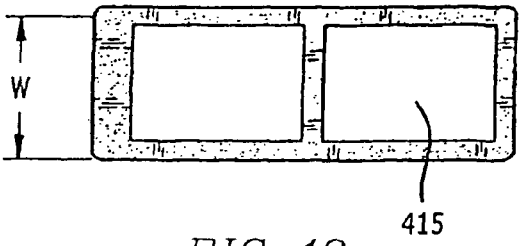
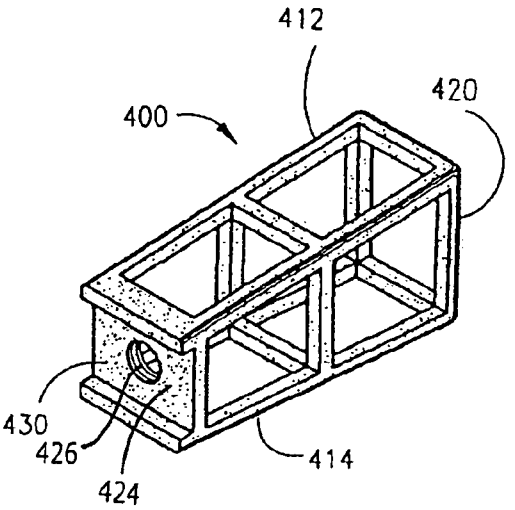


FIG 19



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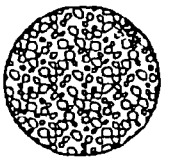

FIG 23

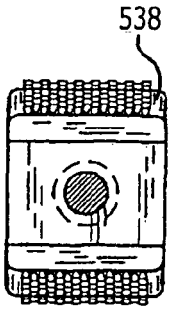

FIG 26

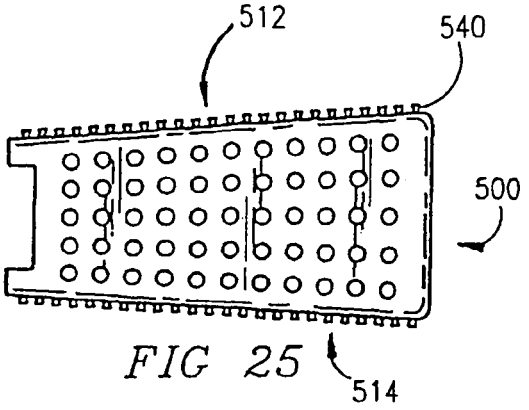

FIG 25

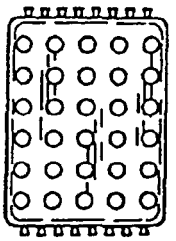

FIG 27

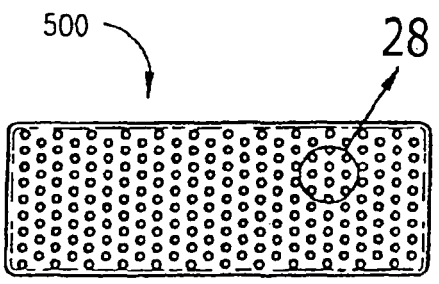

FIG 24

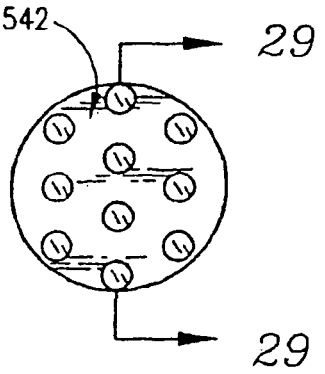

FIG 28

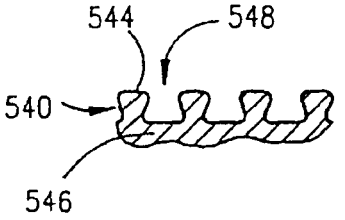

FIG 29

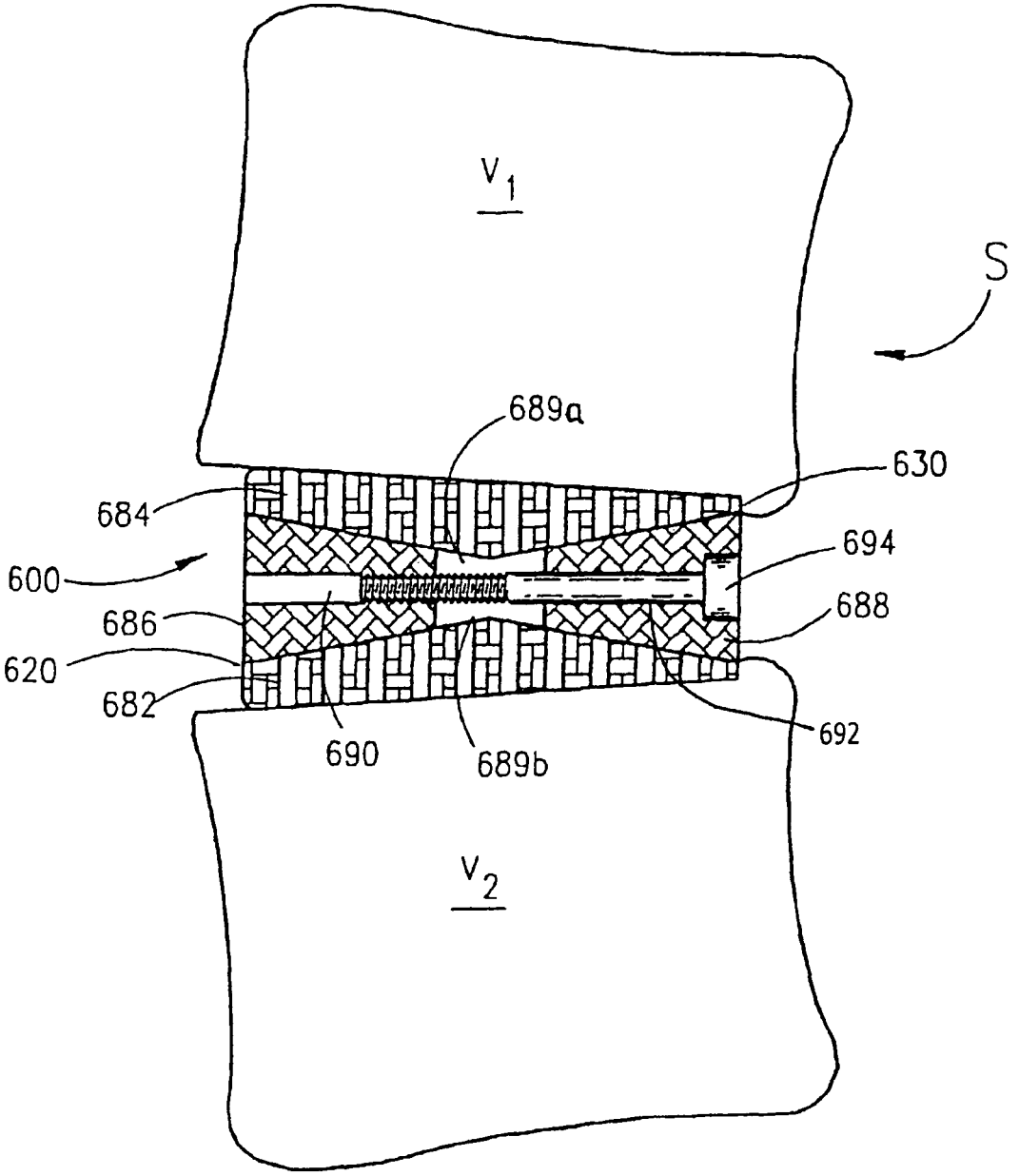

FIG 30

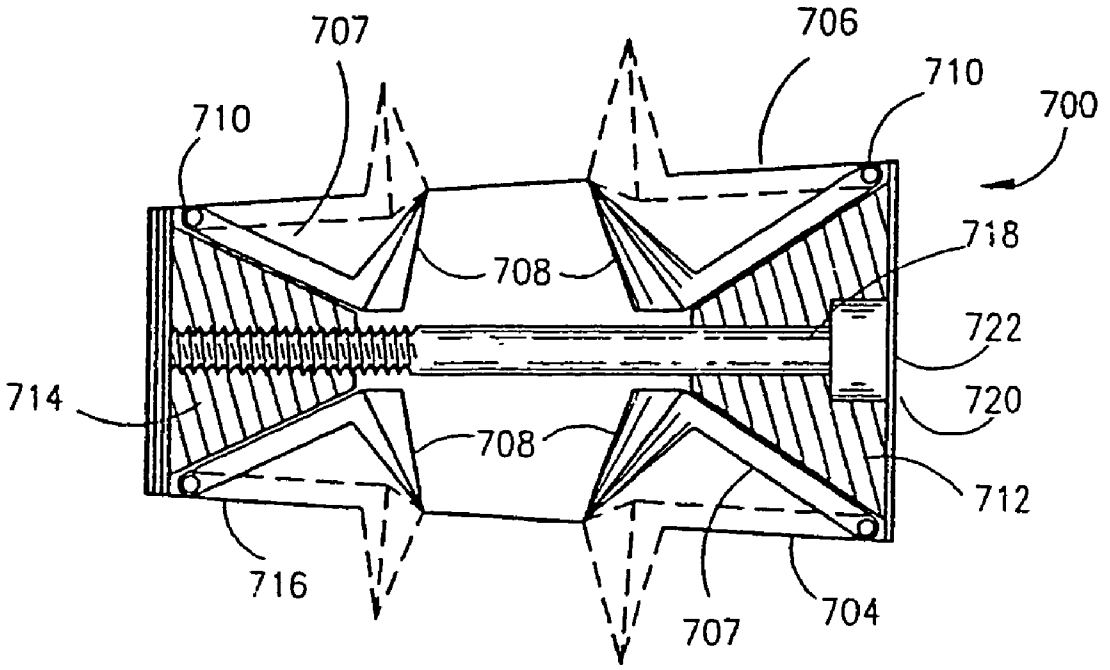

FIG 31

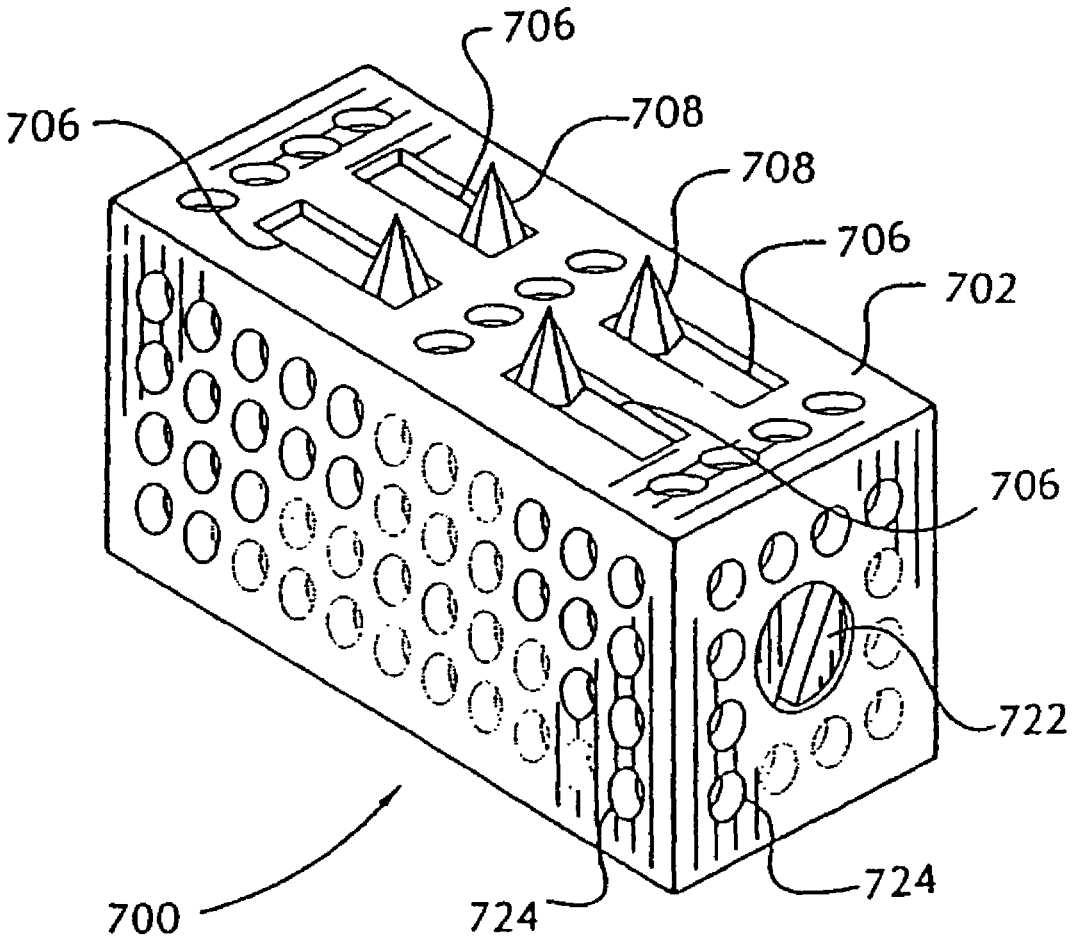

FIG 32

ANATOMIC SPINAL IMPLANT HAVING ANATOMIC BEARING SURFACES

This application is a continuation of application Ser. No. 10/926,766, filed Aug. 26, 2004, now U.S. Pat. No. 7,789,914; which is a continuation of application Ser. No. 10/237,751, filed Sep. 9, 2002 now U.S. Pat. No. 7,503,933; which is a continuation of application Ser. No. 09/412,090, filed Oct. 4, 1999, now U.S. Pat. No. 6,447,544; which is a continuation of application Ser. No. 08/813,283, filed Mar. 10, 1997, now U.S. Pat. No. 6,302,914; which is a divisional of application Ser. No. 08/482,146, filed Jun. 7, 1995, now U.S. Pat. No. 5,609,635; all of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to interbody spinal fusion implants, and in particular to spinal fusion implants configured to restore and maintain two adjacent vertebrae of the spine in correct anatomical angular relationship.

2. Description of the Prior Art

Both the cervical and lunbar areas of the human spine are, in a healthy state, lordotic such that they are curved convex forward. It is not uncommon that in degenerative conditions of the spine that lordosis is lost. This effectively shortens the spinal canal which decreases its capacity. Further, the absence of lordosis moves the spinal cord anteriorly where it may be compressed against the posterior portions of the vertebral bodies and discs. Finally, such a loss of lordosis disturbs the overall mechanics of the spine which may cause cascading degenerative changes throughout the adjacent spinal segments.

The surgical treatment of those degenerative conditions of the spine in which the spinal discs are in various states of collapse, and out of lordosis, commonly involves spinal fusion. That is the joining together of adjacent vertebrae through an area of shared bone. When the shared bone is in the area previously occupied by the intervertebral disc that is referred to as an interbody fusion. Further history in this regard is provided in application Ser. No. 08/263,952 entitled Artificial Spinal Fusion Implants ("Parent Application") incorporated herein by reference.

The Parent Application taught the use of artificial spinal fusion implants that were capable of being placed between adjacent vertebrae, and which implants were capable of containing and providing fusion promoting substances including bone at the fusion site. These devices were further capable of restoring the height of the disc space and of supporting the spine, and were self-stabilizing as well as being stabilizing to the spinal area where implanted.

SUMMARY OF THE INVENTION

The present invention is directed to interbody spinal fusion implants having a structural configuration that provides for the maintaining and creating of the normal anatomic angular relationship of two adjacent vertebrae of the spine to maintain and create spinal lordosis. The spinal fusion implants of the present invention are sized to fit within the disc space created by the removal of disc material between two adjacent vertebrae and conform wholly or in part to the disc space created. The spinal fusion implants of the present invention have upper and lower surfaces that form a support structure for bearing against the end plates of the adjacent vertebrae. In the preferred embodiments, the upper and lower surfaces are disposed in a converging angular relationship to each other

such that the implants of the present invention have an overall "wedged-shape" in an elevational side view. The angular relationship of the upper and lower surfaces places and maintains the vertebrae adjacent to those surfaces in an angular relationship to each other, creating and maintaining the desired lordosis.

The implants of the present invention may have surface irregularities to increase their surface area, and/or to further engage the adjacent vertebrae and to enhance stability. The lordotic implants of the present invention may have surface irregularities that are uniform in height along the longitudinal axis of the upper and lower vertebrae engaging surfaces, or may increase in height from one end of the implant to the other. That is, the implant body and the surface formed and the projections may be similarly wedged. The outer contour of the surface projections may be more or less rectangular while the underlying implant may be wedge-shaped; or the reverse wherein the underlying implant body is more or less rectangular while the contour of the surface projections are wedge-shaped from one end of the implant to the other.

The implants of the present invention have various faces which may be curved so as to conform to the shape of the vertebral surfaces adjacent to the area of the disc removal. Specifically the upper and/or lower surfaces may be convex, and/or the front and/or rear surfaces may be convex. The surfaces of the implants of the present invention may have openings which may or may not pass all the way through them, and a central chamber in communication to the surface through holes. The openings may be of random sizes, and/or shapes, and/or distributions. The implants themselves may be composed of materials, and/or have surface treatments, to encourage microscopic bone ingrowth into the implants.

In the performing of a posterior lumbar interbody fusion, it is not possible to replace the removed portions of the disc, if a total nuclear discectomy has been performed, with a single large implant as the delicate dural sac containing the spinal cord, and the nerve roots cover at all times at least some portion of the posterior disc space. As set forth in the Parent Application, the use of "modular implants" is appropriate in such cases. The modular implants being approximately as long as the depth of the disc material removed, but being considerably narrower, such that they can be introduced into the disc space from the posterior aspect to either side of the dural sac, and then aligned side to side within the disc space so that a number of them each having a length consistent with the depth of the disc removed in that area would in combination have a width equal to the width of the disc material removed.

The modular implants of the present invention may be generally wedge-shaped and may have upper and lower surfaces conforming to the contours of the vertebral endplates, which contours include but are not limited to being relatively flat or convex. As the disc spaces in the lumbar spine are generally lordotic, said implants in the preferred embodiment would be taller anteriorly, that is at the implant's insertion end, and less tall posteriorly, that is at the implant's trailing end. To introduce an implant that is taller at its insertion end than the space available at the posterior aspect of the disc space, even when that disc space is optimally distracted, is problematic.

The modular implants of the present invention provide two solutions to the problem. In the first embodiment, the modular implants may have a reduced size at their insertion end, including but not limited to a bullet nose, a convexity, and a chamfer to a smaller front surface. This then provides that the implant has an area small enough to be introduced into the posterior aspect of the disc space when the disc space is

adequately distracted and the contour of that specialized leading portion of the implant is such that it then allows for a ramping up of the adjacent vertebrae relative to the implant as the implant is advanced forward into the disc space.

The implants of the present invention provide a second solution to this same problem. In the preferred embodiment of the modular implant, the implant is again wedge-shaped in the side elevational view and is taller at its insertion end than at its trailing end. However, the implant incorporates at its trailing end a means for engaging insertion instrumentation such as the box and threaded opening configuration disclosed in the Parent Application. Since in the preferred embodiment these implants are wedge-shaped in the side elevational view when upright but are generally rectangular when viewed from the top plan view, these implants are therefore designed to be introduced into the disc space on their side such that the side walls of the implants are adjacent to the end plates of the adjacent vertebrae. The implants have a side-to-side dimension that is less than the dimension through the insertion end of the implant when upright. It is possible to easily insert these implants with them on their side and then to use the insertion instrument engaged to the implant to rotate the implants ninety degrees into the fully upright position, once they have been fully inserted. Once inserted, the upper and lower surfaces are adjacent to the endplates of the adjacent vertebrae and create and maintain the desired angular relationship of the adjacent vertebrae as the upper and lower walls are angled with respect to each other.

In an alternative embodiment of the present invention, a mechanical implant which may be inserted in a collapsed position and which may then be adjusted to increase in height so as to provide for the optimal restoration of the height of the space between the adjacent vertebrae is disclosed. The mechanical implant may be wedge-shaped, and have upper and lower surfaces, the contours of which generally conform to the contacted areas of the adjacent vertebral endplates and which contours may include but are not limited to being relatively flat, or convex. Further, the mechanical implant may be wedge-shaped or generally rectangular, but capable of increasing in both height and the extent of wedging when adjusted. This may easily be achieved by having one of the two wedge mechanisms employed in the example given being larger, or steeper than the other. Alternatively, a single wedge may be utilized, and if it is desired to achieved increased height at one end of the implant while restricting the height at the other, then the end of the implant may incorporate a hinge means and the height expansion at the other end achieved by drawing a wedge member, bar, ball, or other means from the far end toward the hinged end so as to drive said upper and lower surfaces apart in a wedged fashion.

In an alternative embodiment of the present invention, an implant having a mechanically deployable bone engaging means is taught. Such an implant is generally wedge-shaped in the side elevational view and has upper and lower surfaces generally conforming to the contour of the vertebral endplates where contacted by the implant, and which upper and lower surfaces may be but are not limited to being either flat or convex. The use of such deployable bone engaging means are particularly of value in that the largest possible implant may be inserted into a disc space and the vertebral engaging means, which if fixed to the surface would have blocked the insertion of the implant, may then be deployed after the insertion such that the distance from the tip of the upper and lower boite engagement means exceeds the height of the space available for insertion. Such a feature is of particular value when the implant itself is wedge-shaped as the considerable compressive loads across the lumbar spine would tend to drive a wedge-shaped implants out of the disc space.

OBJECTS OF THE PRESENT INVENTION

It is an object of the present invention to provide a spinal fusion implant that is easily inserted into the spine, having a tapered leading end;

It is another object of the present invention to provide a spinal fusion implant that tapers in height from one end to the other consistent with the taper of a normal spinal disc;

It is yet another object of the present invention to provide a spinal fusion implant that is capable of maintaining anatomic alignment and lordosis of two adjacent vertebrae during the spinal fusion process;

It is still another object of the present invention to provide a spinal fusion implant that is self stabilizing within the spine;

It is yet another object of the present invention to provide a spinal fusion implant that is capable of providing stability between adjacent vertebrae when inserted;

It is further another object of the present invention to provide a spinal fusion implant that is capable of spacing apart and supporting adjacent vertebrae in an angular relationship during the spinal fusion process;

It is still further another object of the present invention to provide a spinal fusion implant that fits between to adjacent vertebrae and preserves the end plants of those vertebrae; and

It is another object of the present invention to provide a spinal fusion implant having a shape which conforms to the endplates of the adjacent vertebrae; and

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 view of the lordotic interbody spinal fusion implant of the present invention with a slidable door shown in a partially open position providing access to the internal chamber of the implant.

FIG. **2** is a top plan view of the lordotic interbody spinal fusion implant of the present invention.

FIG. **3** is a left side elevational view of the lordotic interbody spinal fusion implant of the present invention.

FIG. **4** is a right side elevational view of the lordotic interbody spinal fusion implant of the present invention.

FIG. **5** is a front end view of the lordotic interbody spinal fusion implant of the present invention showing the slidable door in a partially open position.

FIG. **6** is a rear end view of the lordotic interbody spinal fusion implant of the present invention showing the means for engaging insertion instrumentation.

FIG. **7** is an enlarged fragmentary view along line **7** of FIG. **2** illustrating the bone engaging surface configuration of the lordotic interbody spinal fusion implant of the present invention.

FIG. **7**A is an elevational side view of a segment of the spinal column having the lordotic implant of the present invention inserted in the disc space at different disc levels between adjacent vertebrae to restore and maintain the correct anatomical alignment of the adjacent vertebrae.

FIG. **8** is a top plan view of an alternative embodiment of the lordotic interbody spinal fusion implant of the present invention.

FIG. **9** is a left side elevational view of the lordotic interbody spinal fusion implant of FIG. **8**.

FIG. **10** is a front end view of the lordotic interbody spinal fusion implant of FIG. **8**.

FIG. **11** is a rear end view of the lordotic interbody spinal fusion implant of FIG. **8** showing the means for engaging insertion instrumentation.

FIG. **12** is an enlarged fragmentary view along line **12** of FIG. **8** illustrating the surface configuration the lordotic interbody spinal fusion implant of the present invention.

FIG. **13** is a top plan view of an alternative embodiment of the lordotic interbody spinal fusion implant of the present invention made of a mesh-like material.

FIG. **14** is a left side elevational view of the lordotic interbody spinal fusion implant of FIG. **13**.

FIG. **15** is a front end view of the lordotic interbody spinal fusion implant of FIG. **13**.

FIG. **16** is a rear end view of the lordotic interbody spinal fusion implant of FIG. **13** showing the means for engaging insertion instrumentation.

FIG. **17** is an enlarged fragmentary view along line **17** of FIG. **13** illustrating the surface configuration of the lordotic interbody spinal fusion implant of the present invention.

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

FIG. **19** is a top plan view of the lordotic interbody spinal fusion implant of FIG. **18**.

FIG. **20** is a left side elevational view of the lordotic interbody spinal fusion implant of FIG. **18**.

FIG. **21** is a rear end view of the lordotic interbody spinal fusion implant of FIG. **18**.

FIG. **22** is a front end view of the lordotic interbody spinal fusion implant of FIG. **18**.

FIG. **23** is an enlarged fragmentary view along line **23** of FIG. **22** illustrating the surface configuration the lordotic interbody spinal fusion implant of the present invention.

FIG. **24** is a top plan view of an alternative embodiment of the lordotic interbody spinal fusion implant of the present invention.

FIG. **25** is a left side elevational view of the lordotic interbody spinal fusion implant of FIG. **24**.

FIG. **26** is a rear end view of the lordotic interbody spinal fusion implant of FIG. **24**.

FIG. **27** is a front end view of the lordotic interbody spinal fusion implant of FIG. **24**.

FIG. **28** is an enlarged fragmentary view along line **28** of the lordotic interbody spinal fusion implant of FIG. **24** illustrating the surface configuration of the lordotic interbody spinal fusion implant of the present invention.

FIG. **29** is a sectional view along lines **29--29** of FIG. **28** the lordotic interbody spinal fusion implant of the present invention.

FIG. **30** is a side elevational view of a segment of the human spinal column shown with an alternative embodiment of the lordotic spinal fusion implant of the present invention that is adjustable and expandable shown in sectional view inserted in the disc space levels to restore and maintain the correct anatomical alignment of the adjacent vertebrae.

FIG. **31** is a side cross sectional view of, an alternative embodiment of the lordotic implant of the present invention having movable projections, in the form of spikes **708**, which are movable from a first position within the implant **700** to a second position extending to the exterior of the implant.

FIG. **32** is a perspective view of the embodiment of FIG. **31**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIGS. **1** through **7** the lordotic interbody spinal fusion implant of the present invention for use in the disc space between two adjacent vertebrae, generally referred to by the numeral **100**, is shown. The implant **100** has a generally rectangular configuration, having an upper surface **112** and a lower surface **114**. In the preferred embodiment, the upper and lower surfaces **112** and **114** of implant **100** are disposed in a converging angular relationship toward each other such that the implant **100** appears "wedge-shaped" from a side elevational view as shown in FIGS. **3** and **4**. The upper and lower surfaces **112** and **114** have an interior surface which form a support structure for bearing against the endplates of the adjacent vertebrae between which the implant **100** is inserted. The angular relationship of the upper and lower surfaces **112** and **114** places and maintains the vertebrae adjacent to those surfaces in an angular relationship, creating and maintaining the desired lordosis of the spine.

The upper and lower surfaces **112** and **114** of the implant **100** may be flat or curved to conform to the shape of the end plates of the adjacent vertebrae between which the implant **100** is inserted. The implant **100** conforms to the shape of the nucleus pulposus and a portion of the annulus fibrosus removed from the vertebrae. The upper and lower surfaces **112** and **114** comprise surface roughenings that provide a surface suitable for engaging the adjacent vertebrae to stabilize the implant **100** within the disc space once surgically implanted. The surface roughenings of the upper and lower surfaces **112** and **114** comprise a surface knurling **121** and/or grooves.

Referring to FIG. **7**, an enlarged fragmentary view of the surface knurling **121** of the implant **100** is shown as a diamond-shaped bone engaging pattern. The implant **100** may have surface knurling **121** throughout the entire upper and lower surfaces **112** and **114**, throughout only a portion of the upper and lower surfaces **112** and **114**, or any combination thereof, without departing from the scope of the present invention. It is also appreciated that the surface knurling **121** may have various configuration other than the configuration shown.

In this embodiment, the implant **100** is hollow and comprises a plurality of openings **115** of passing through the upper and lower surfaces **112** and **114** and into a central hollow chamber **116**. The openings **115** provide for bone growth to occur from the vertebrae through the openings **115** to the internal chamber **116**. While the openings **115** have been shown in the drawings as being circular, it is appreciated that the openings **115** may have any shape, size, configuration or distribution suitable for use in a spinal implant without departing from the scope of the present invention. For example, the openings may have a tear-drop configuration as shown in opening **115***a* in FIGS. **1** and **2**. The upper and lower surfaces **112** and **114** of the implant **100** are supported and spaced apart by a side wall **118**, which may also comprise a plurality of openings **122**.

The implant **100** has an insertion end **120** and a trailing end **130** both of which may be curved or flat. The trailing end **130** of the implant may be convex to conform to the curvature of the vertebrae and has a means for engaging an implant insertion instrument comprising a depressed portion **124** with a central threaded opening **126** for receiving the engaging end of a driving instrument. The insertion end **120** of the implant **100** comprises an access opening **132** and a slidable door **134** which closes the opening **132**. The slidable door **134** covers the opening **132** into the chamber **116** and permits the insertion of autogenous bone material into the chamber **116**.

In use, the slidable door **134** is placed in the open position for loading material into the chamber **116**. The slideable door **134** has a depression **136** for facilitating the opening and closing of the door **134**. The internal chamber **116** 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 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 fusion enhancing material that is packed within the chamber **116** of the implant **100** serves to promote bone ingrowth between the implant **100** and the adjacent vertebrae. Once the bone ingrowth occurs, the implant **100** will be a permanent fixture preventing dislodgement of the implant as well as preventing any movement between the adjacent vertebrae.

The slidable door **134** is then closed prior to implantation. In the closed position, the slideable door conforms to the curvature of the insertion end **120** of the implant **100**. Various methods of packing the implant **100** with the autogenous bone material may be used to obtain a completely packed implant **100**.

The method of inserting the implant **100** is set forth in detail in application Ser. No. 08/263,952, incorporated herein by reference. The threaded end of a driving instrument is attached to the threaded opening **126** in the trailing end **130** of the implant **100** and the fitting of the driving instrument into the depressed portion **124** prevents movement of the implant **100** in relationship to the driving instrument. The implant **100** is then placed at the entrance to the disc space between the two adjacent vertebrae V. The driver instrument is then tapped with a hammer sufficiently hard enough to drive the implant **100** into the disc space.

The size of the implant **100** is substantially the same size as the disc material that it is replacing and thus will be larger or smaller depending on the amount of disc material removed to create the disc space in which it is to be used. In the preferred embodiment in regard to the lumbar spine the implant **100** has a width W approximately 28-48 mm wide, approximately 36 mm being preferred. The implant **100** has a height H conforming to the restoration of the anatomic height of the disc space the average height would range from 8-16 mm, with 10-12 of which being the preferred average height. The depth D along mid-longitudinal axis MLA would at its maximum range from 20 to 34 mm with 26 to 32 being the preferred maximum depth. In the cervical spine the width of the implant is in the range of approximately 14-28 mm, with the preferred width being 18-22 mm. The implant has a height in the range of approximately 5-10 mm with the preferred height being 6-8 mm. The implant has a depth in the range of approximately 11-21 mm with the preferred depth being 11-13 mm.

Referring to FIG. **7**A, a side elevational view of the lateral aspect of a segment of the spinal column S is shown with the implant **100** inserted in the disc space D_2 between two adjacent vertebrae V_2 and V_3. The implant **100** is inserted in the direction of arrow A into the disc space D_2 and maintains the two vertebrae V_2 and V_3 in angular relationship to each other such that the natural lordosis of that segment of the spinal column S is restored. The forward advancement of the implant **100** is blocked by the natural bone processes B in the endplates of the vertebrae V_2 and V_3. Backing out of the implant **100** is prevented by the bone engaging surface knurling **121** of the upper and lower surfaces **112** and **114**.

Referring to FIGS. **8-12**, an alternative embodiment of the lordotic interbody spinal fusion implant of the present invention, generally referred to by the numeral **200**, is shown. The implant **200** has a similar overall configuration as the implant **100** described above. In the preferred embodiment, the implant **200** is solid and comprises a plurality of channels **215** passing from the upper surface **212** to the lower surface **214** through the implant **200**. The channels **215** provide for bone ingrowth and facilitate the incorporation of the implant **200** into the spinal fusion mass. The channels may also be loaded with fusion promoting materials such as those described above, prior to implantation. It is appreciated that the channels **215** need not pass all the way through the implant **200**, but can have a configuration similar to wells, which may hold fusion promoting materials and permit bone ingrowth into the upper and lower surfaces **212** and **214** of the implant **200**.

In addition to the channels **215**, the implant **200** may have small openings **222** on the side wall **218** which may or may not pass through the entire implant **200**. The same openings **222** may be in communication with the channels **215** such that bone ingrowth may occur from the openings **222** to the channels **215** to lock the implant **200** into the fusion mass. If the openings **222** do not pass through the entire implant **200**, they may function as small wells for holding fusion promoting materials or described above.

In the preferred embodiment of implant **200**, the channels **215** have a diameter in the range of 0.1 mm to 6 mm, with 2-3 mm being the preferred diameter. The openings **222** have a diameter in the range of 0.1 mm to 6 mm, with 1-3 mm being the preferred diameter range. It is appreciated that although the channels **215** and openings **222** are shown having a generally rounded configuration, it is within the scope of the present invention that the channels **215** and openings **222** may have any size, shape, configuration, and distribution suitable for the intended purpose.

The implant **200**, has a plurality of ratchetings **250** on the upper and lower surface **212** and **214** for engaging the bone of the adjacent vertebrae. The ratchetings **250** comprise a bone engaging edge **252** and angled segment **254**.

Referring specifically to FIG. **9**, the implant **200** has a wedge-shaped elevational side view in which the trailing end **230** is taller than the insertion end **220**. The plurality of ratchetings **250** are oriented in the direction of the insertion end **220** to provide for a one-way insertion of the implant **200** as the bone engaging edge **252**, or ridge, engages the vertebrae and prevents the implant from backing out once implanted. Alternatively, the trailing end ratchetings could be of a lessor height such that the overall shape of the ratchetings as a group is convex.

Referring to FIG. **11**, the trailing end **230** of implant **200** has means for engaging insertion instrumentation comprising a thread opening **226** as described above for implant **100**.

Referring to FIG. **12**, an enlarged fragmentary view along line **12** of FIG. **8** illustrating the surface configuration the implant **200** is shown. The upper and lower surfaces **212** and **214** of implant **200**, in addition to the ratcheting **250** comprise a porous texture **260** to present an irregular surface to the bone to promote bone ingrowth. The porous texture **260** is also able to hold fusion promoting materials and provides for an increased surface area to engage the bone in the fusion process and to provide further stability. The porous texture **260** may also be present on the side walls **218**. It is appreciated that the outer surface and/or the entire implant **200**, may comprise any other porous material or roughened surface sufficient to hold fusion promoting substances and/or allow for bone ingrowth and/or engage the bone during the fusion process. The implant **200** may be further coated with bioac-

tive fusion promoting substances including, but not limited to, hydroxyapatite compounds, osteogenic proteins and bone morphogenic proteins or may be from bioabsorbable material.

Referring to FIGS. **13-17**, an alternative embodiment of the lordotic interbody spinal fusion implant, generally referred to by the numeral **300**, is shown. The implant **300** is made of a mesh-like material comprising strands, which may be made of metal, that are pressed together and molded. The upper and lower surfaces **312** and **314** may be convex and conform to the natural surface curvature of the end plates of the vertebrae. In addition, the entire implant **300** may be molded to a shape that conforms to the shape of the disc space created by the removal of disc material from between two adjacent vertebrae. In this manner, the implant **300** has curved upper and lower surfaces **312** and **314**, a curved side wall **318** and chamfered edges **319**.

As shown in FIGS. **13** and **14**, the implant **300** includes a first terminal part defining a first bearing surface adapted to bear against an endplate of the vertebrae V_1, and an opposite second bearing surface adapted to bear against an endplate of the vertebrae V_2. The implant **300** also includes a second terminal part opposite the first terminal part. The second terminal part defines a third bearing surface adapted to bear against the endplate of the vertebrae V_1 and a fourth bearing surface adapted to bear against the endplate of the vertebrae V_2.

In addition to the first and second terminal parts, the implant **300** also includes a first side extending between the first terminal part and the second terminal part, and a second side opposite the first side and extending between the first terminal part and the second, terminal part.

Referring to FIG. **7**A, the implant **300** is shown inserted in the direction of arrow A into the disc space D_1 between adjacent vertebrae V_1 and V_2. The implant **300** conforms to the endplates of the adjacent vertebrae V_1 and V_2 as the upper and lower surfaces **312** and **314** are convex, and the side walls **318** are curved to conform to the natural curvature of the vertebrae V_1 and V_2. In this manner, the implant **300** has the same dimensions as the disc material removed from between the two adjacent vertebrae V_1 and V_2.

The implant **300** may be made wholly or in part of a solid material and/or a porous material, and/or a mesh-like material. The implant **300** may have a surface comprising of a porous material, a mesh-like material, or have a surface that is roughened. It is appreciated that the implant **300** may be solid or may be partially hollow and include at least one internal chamber in communication with said upper and lower surfaces.

As shown in FIG. **17**, the mesh-like material comprises strands that are formed and pressed together such that interstices **339**, capable of retaining fusion promoting material and for allowing for bone ingrowth, are present between the strands in at least the outer surface of implant **300**. Alternatively, it is appreciated that the implant **300** may be made of a cancellous material, similar in configuration to human cancellous bone, having interstices allowing for bone ingrowth. As the implant **300** may be made entirely or in part of the cancellous material, the interstices may be present in the outer surface of the implant **300** and/or within the entire implant to promote bone ingrowth and hold bone fusion promoting materials.

Referring to FIGS. **18-23** an alternative embodiment of the implant of the present invention, generally referred to by the numeral **400**, is disclosed. The implant **400** has a substantially rectangular shape having upper and lower surfaces **412** and **414**. The upper and lower surfaces **412** and **414** support the adjacent vertebrae and are disposed in a converging angular relationship to each other in the same manner described above.

The implant **400** has a width W that is substantially less than the width of the implants **100-300** such that a series of such implants **400** are used as the interbody spinal implant, each placed closely adjacent to one another to approximate the size of the removed disc. The size of the implant **400** is approximately 26 millimeters in length and is wide enough so that four of them will substantially fill the intervertebral space, depending on which vertebrae are fused.

In the performing of a posterior lumbar interbody fusion, it is not possible to replace the removed portions of the disc, if a total nuclear discectomy has been performed, with a single large implant as the, delicate dural sac containing the spinal cord and nerve roots covers at all times at least some portion of the posterior disc space. The use of modular implants **400** that are inserted separately into the disc space is appropriate in such case. The modular implants **400** being approximately as long as the depth of the disc material removed, but being considerably narrower, such that they could be introduced into the disc space from the posterior aspect to either side of the dural sac, and then realigned side to side with the disc space so that a number of them each having a length consistent with the depth of the disc removed in that area would in combination have a width equal to the width of the disc material removed. As the disc spaces in the lumbar spine are generally lordotic, the insertion end **420** of the modular implants **400** would have to be taller and less tall posteriorly at the trailing end **430**.

To introduce the modular implant **400** that is taller at its insertion end **420** than the space available at the posterior aspect of the disc space, even when that disc space is optimally distracted, is problematic. The modular implants **400** of provide two solutions to the problem. The modular implants **400** may have a reduced size at their insertion end **420**, including but not limited to, a bullet nose, a convexity, and a chamfer to a smaller front surface. This then provides that the implant **400** has an area small enough to be introduced into the posterior aspect of the disc space when the disc space is adequately distracted and the contour of that specialized insertion end of the implant **400** is such that it then allows for a ramping up of the adjacent vertebrae relative to the implant **400** as the implant is advanced forward into the disc space.

Alternatively, or in combination with the above, since in the preferred embodiment the implants **400** are wedge-shaped in the side elevational view when upright but are generally rectangular when viewed from the top plan view, these implants may be introduced into the disc space on their side such that the side walls of the implants are adjacent to the end plates of the adjacent vertebrae. The implants **400** have a side-to-side dimension that is less than the dimension through the insertion end of the implant **400** when upright. It is possible to easily insert the implant **400** first on their side and then to use the insertion instrument engaged to the implant **400** to rotate the implant ninety degrees into the fully upright position, once it has been fully inserted. Once inserted, the upper and lower surfaces **412** and **414** are adjacent to the endplates of the adjacent vertebrae and create and maintain the desired angular relationship of the adjacent vertebrae as the upper and lower surfaces **412** and **414** of the implant **400** are angled with respect to each other.

The implant **400** has large openings **415** in the form of rectangular slots for holding fusion promoting materials to promote bone growth from the vertebrae through the upper and lower surfaces **412** and **414** and into the interior of the implant **400**. As the implant **400** is modular and more than one

is implanted at a time, the large openings **415** are also present in the side walls **418** of the implant **400** to provide for bone growth from one implant to another implant such that after successful fusion, the modular implants **400** are interconnected to form a single unit.

Referring to FIG. **21**, the trailing end **430** of the implant **400** is shown having an insertion instrument engaging means comprising a rectangular slot **424** and threaded opening **426**.

Referring to FIG. **23**, an enlarged fragmentary view along line **23** of FIG. **22** illustrating the surface configuration the implant **400** is shown. The surface configuration of the implant **400** is the same as the porous texture **260** described above.

Referring to FIG. **24**, an alternative embodiment of the lordotic interbody spinal fusion implant of the present invention, generally referred to by the numeral **500**, is shown. The implant **500** is a modular implant and has a similar overall configuration as implant **400**. The implant **500** instead of having slots **415** has an upper and lower surfaces **512** and **514** that are capable of receiving and holding bone, or other materials capable of participating in the fusion process and/or capable of promoting bone ingrowth. In the preferred embodiment, the upper and lower surfaces **512** and **514** comprise a plurality of posts **540** that are spaced apart to provide a plurality of interstices **542** which are partial wells with incomplete walls capable of holding and retaining milled bone material or any artificial bone ingrowth promoting material. The implant **500** may be prepared for implantation by grouting or otherwise coating the surface **538** with the appropriate fusion promoting substances.

Referring to FIGS. **28** and **29**, an enlarged view of the upper surface **512** of the implant **500** and a partial cross section thereof are shown. In the preferred embodiment, the posts **540** have a head portion **544** of a larger diameter than the remainder of the posts **540**, and each of the interstices **542** is the reverse configuration of the posts **544**, having a bottom **546** that is wider than the entrance **548** to the interstices **542**. Such a configuration of the posts **540** and interstices **542** aids in the retention of bone material in the surface **538** of the implant **500** and further assists in the locking of the implant **500** into the bone fusion mass created from the bone ingrowth. As the bone ingrowth at the bottom **546** of the interstices **542** is wider than the entrance **548**, the bone ingrowth cannot exit from the entrance **548** and is locked within the interstice **542**. The surface **538** of the implant **500** provides for an improvement in the available amount of surface area which may be still further increased by rough finishing, flocking or otherwise producing a non smooth surface.

In the preferred embodiment, the posts **540** have a maximum diameter in the range of approximately 0.1-2 mm and a height of approximately 0.1-2 mm and are spaced apart a distance of 0.1-2 mm such that the interstices **542** have a width in the range of approximately 0.1 to 2 mm. The post sizes, shapes, and distributions may be varied within the same implant.

It is appreciated that the implant **500** shares the same structure and features of the implant **400** described above.

FIG. **30** is a side elevational view of a segment of the human spinal column S shown in lordosis with an alternative embodiment of the lordotic spinal fusion implant referred to by the numeral **600**, that is adjustable and expandable shown inserted in a space to restore and maintain the correct anatomical alignment of the adjacent vertebrae. The implant **600** comprises a lower member **682** and an upper member **684** which when fitted together form an essentially rectangular implant. The upper member **684** and the lower member **682** have hollow portions that face one another and receive tapered wedges **686** and **688** that fit within the hollow portion of the upper and lower members **682** and **684**. The upper and lower members **682** and **684** each have a wedged interior surface **689***a* and **689***b* which are angled towards the interior of the implant **600**. The wedges **682** and **684** are such that at their large end, they are higher than the combined hollow space between the upper and lower members **684** and **682**, and shallower at the other end than the hollow space between the upper and lower members.

The wedges **686** and **688** have a central threaded opening **690** and **692** in alignment with each other for receiving threaded screw **694**. As the screw **694** is threaded into the opening **690**, the wedges **686** and **688** abut the interior sloped surfaces **689***a* and **689***b* of the upper and lower members **682** and **684**. As the screw **694** is turned, the wedges **686** and **688** are drawn together, and the sloped portions of the wedges force the upper member **682** away from the lower member **684**. As the interior sloped surfaces **689***a* and **689***b* have a greater slope near the trailing end **630**, than near the insertion end **620**, the upper and lower members **682** and **684** are forced apart more at the insertion end **620** than at the trailing end **630**. As a result, the upper and lower members **682** and **684** are disposed at a converging angular relationship to each other and support the adjacent vertebrae V_1 and V_2 in the same angular relationship.

Referring to FIG. **31**, an alternative embodiment of the implant of the present invention, generally referred to by the numeral **700**, is shown. The implant **700** has movable projections, in the form of spikes **708**, which are movable from a first position within the implant **700** to a second position extending outside of the implant. The implant **700** is of a generally rectangular configuration, having a top surface **702** and a bottom surface **704** of the implant with slots **706** for permitting pivotal member **707** having spikes **708** at their ends to project through said slots **706**. The spikes **708** are pinned at one end **710** within the implant **700**.

The implant **700** has opposing wedge shaped members **712** and **714** having a central threaded opening **716** for receiving a threaded screw **718** having a head **720** and a slot **722**. The wedges **712** and **714** are facing each other so that upon turning of the screw **718**, will the two wedges **712** and **714** are drawn together to cause the spikes **708** to pivot about their end **710** and project to the exterior of the implant **700** through the aligned slots **706**. The implant **700** may comprise a series of holes **724** on its surfaces for promoting bone ingrowth and fusion.

In use, after the removal of the disc material, the implant **700** with the spikes **708** in their withdrawn position, is inserted into the disc space. Then the screw **718** is turned until the spikes **708** are forced to enter the vertebrae and the implant **700** is thus held firmly in place.

While the invention has been described with regards to the preferred embodiment and a number of alternative embodiments, it is recognized that other embodiments of the present invention may be devised which would not depart from the scope of the present invention.

I claim:

1. An implant for insertion between a first vertebra and a second vertebra, the first vertebra having a generally vertically extending first peripheral wall and a first cortical bone endplate and the second vertebra having a generally vertically extending second peripheral wall and a second cortical bone endplate, wherein the implant comprises:

a first terminal part defining a trailing face, a first bearing surface adapted to bear against a portion of the cortical bone endplate proximate to the first peripheral wall, and an opposite second bearing surface adapted to bear

against a portion of the second cortical bone endplate proximate to the second peripheral wall;

an elongated body including a central part extending from said first terminal part, said central part having an upper bearing surface and a lower bearing surface, said elongated body terminating in a second terminal part opposite said first terminal part, said second terminal part including an anti-expulsion feature and having an insertion face extending from said upper bearing surface to said lower bearing surface, said insertion face including a curved surface extending from said upper bearing surface to said lower bearing surface, said central part having a longitudinal axis extending through said trailing face of said first terminal part and said insertion face of said second terminal part, and having a cross section in a first plane extending through said upper bearing surface and said lower bearing surface, and along the longitudinal axis, the first plane bisecting said upper bearing surface in two halves, wherein at least a portion of said cross section is convex at said upper bearing surface and said lower bearing surface; and

a first side and an opposite second side, said first side and said second side extending along said first terminal part, said elongated body, and said second terminal part, portions of said first side and said second side being substantially flat, said substantially flat portions intersecting a second plane that is perpendicular to the first plane and extends through said insertion face and said trailing face, said substantially flat portion of said first side extending along a third plane and said substantially flat portion of said second side extending along a fourth plane, wherein the third and fourth planes are symmetrical about the longitudinal axis and transverse to said insertion face.

2. The implant of claim **1**, wherein said first bearing surface and said second bearing surface include at least one anti-expulsion feature.

3. The implant of claim **1**, wherein said implant may include a chamber in communication with said bearing surfaces.

4. The implant of claim **1**, wherein said implant is adapted to hold bone fusion promoting materials.

5. An implant for insertion between a first vertebra and a second vertebra, the first vertebra having a generally vertically extending first peripheral wall and a first cortical bone endplate and the second vertebra having a generally vertically extending second peripheral wall and a second cortical bone endplate, wherein the implant comprises:

a first terminal part defining a trailing face, a first bearing surface adapted to bear against a portion of the cortical bone endplate proximate to the first peripheral wall, and an opposite second bearing surface adapted to bear against a portion of the second cortical bone endplate proximate to the second peripheral wall;

a second terminal part opposite said first terminal part, said second terminal part including an anti-expulsion feature and having an insertion face extending from a third bearing surface to a fourth bearing surface, said implant having a longitudinal axis extending through said trailing face of said first terminal part and said insertion face of said second terminal part, and having a cross section in a first plane extending through said first bearing surface and said second bearing surface, and along the longitudinal axis, the first plane bisecting said first bearing surface in two halves;

a first side and an opposite second side, said first side and said second side extending from said first terminal part to said second terminal part, portions of said first side and said second side being substantially flat, said substantially flat portions intersecting a second plane that is perpendicular to the first plane and extends through said insertion face and said trailing face, wherein said substantially flat portions of said first side and said second side are symmetrical about the first plane; and

upper and lower bearing surfaces proximate each of said first and second sides, wherein said upper and lower bearing surfaces proximate said first and second sides are, at least in part, convex relative to the second plane.

6. The implant of claim **5**, wherein said first bearing surface and said second bearing surface include at least one anti-expulsion feature.

7. The implant of claim **5**, wherein said third bearing surface and said fourth bearing surface include at least one anti-expulsion feature.

8. The implant of claim **5**, wherein said second terminal part includes a chamfered edge between said third bearing surface and said insertion face.

9. The implant of claim **5**, wherein said second terminal part includes a rounded edge between said third bearing surface and said insertion face.

10. The implant of claim **5**, wherein said implant may include a chamber in communication with said bearing surfaces.

11. The implant of claim **5**, wherein said implant is adapted to hold bone fusion promoting materials.

12. An implant for insertion between a first vertebra and a second vertebra, the first vertebra having a generally vertically extending first peripheral wall and a first cortical bone endplate and the second vertebra having a generally vertically extending second peripheral wall and a second cortical bone endplate, wherein the implant comprises:

a first terminal part defining a trailing face, a first bearing surface adapted to bear against a portion of the cortical bone endplate proximate to the first peripheral wall, and an opposite second bearing surface adapted to bear against a portion of the second cortical bone endplate proximate to the second peripheral wall;

a second terminal part opposite said first terminal part, said second terminal part including an anti-expulsion feature and having an insertion face extending from a third bearing surface to a fourth bearing surface, said implant having a longitudinal axis extending through said trailing face of said first terminal part and said insertion face of said second terminal part, and having a cross section in a first plane extending through said first bearing surface and said second bearing surface, and along the longitudinal axis, the first plane bisecting said first bearing surface in two halves;

a first side and an opposite second side, said first side and said second side extending from said first terminal part to said second terminal part, portions of said first side and said second side being substantially flat, said substantially flat portions intersecting a second plane that is perpendicular to the first plane and extends through said insertion face and said trailing face, wherein said substantially flat portions of said first side and said second side are symmetrical about the first plane; and

upper and lower bearing surfaces proximate each of said first and second sides, wherein a maximum height measured between said upper and lower bearing surfaces proximate said first side is greater than a maximum height measured between said first and second bearing surfaces and a maximum height measured between said third and fourth bearing surfaces.

13. The implant of claim 12, wherein said first bearing surface and said second bearing surface include at least one anti-expulsion feature.

14. The implant of claim 12, wherein said third bearing surface and said fourth bearing surface include at least one anti-expulsion feature.

15. The implant of claim 12, wherein said second terminal part includes a chamfered edge between said third bearing surface and said insertion face.

16. The implant of claim 12, wherein said second terminal part includes a rounded edge between said third bearing surface and said insertion face.

17. The implant of claim 12, wherein said implant may include a chamber in communication with said bearing surfaces.

18. The implant of claim 12, wherein said implant is adapted to hold bone fusion promoting materials.

19. An implant for insertion between a first vertebra and a second vertebra, the first vertebra having a generally vertically extending first peripheral wall and a first cortical bone endplate and the second vertebra having a generally vertically extending second peripheral wall and a second cortical bone endplate, wherein the implant comprises:

a first terminal part defining a trailing face, a first bearing surface adapted to bear against a portion of the cortical bone endplate proximate to the first peripheral wall, and an opposite second bearing surface adapted to bear against a portion of the second cortical bone endplate proximate to the second peripheral wall;

a second terminal part opposite said first terminal part, said second terminal part including an anti-expulsion feature and having an insertion face extending from a third bearing surface to a fourth bearing surface, said implant having a longitudinal axis extending through said trailing face of said first terminal part and said insertion face of said second terminal part, and having a cross section in a first plane extending through said first bearing surface and said second bearing surface, and along the longitudinal axis, the first plane bisecting said first bearing surface in two halves;

a first side and an opposite second side, said first side and said second side extending from said first terminal part to said second terminal part, portions of said first side and said second side being substantially flat, said substantially flat portions intersecting a second plane that is perpendicular to the first plane and extends through said insertion face and said trailing face, wherein said substantially flat portions of said first side and said second side are symmetrical about the first plane; and

upper and lower bearing surfaces proximate each of said first and second sides, said upper and lower bearing surfaces proximate said first and second sides being intersected by a third plane that is perpendicular to the first and second planes, a maximum first distance between said upper and lower bearing services proximate said first side measured perpendicular to the second plane and in the third plane being greater than a maximum second distance between said first and second bearing surfaces measured in a direction parallel to the maximum first distance and a maximum third distance between said third and fourth bearing surfaces measured in a direction parallel to the maximum first distance.

20. The implant of claim 19, wherein said first bearing surface and said second bearing surface include at least one anti-expulsion feature.

21. The implant of claim 19, wherein said third bearing surface and said fourth bearing surface include at least one anti-expulsion feature.

22. The implant of claim 19, wherein said second terminal part includes a chamfered edge between said third bearing surface and said insertion face.

23. The implant of claim 19, wherein said second terminal part includes a rounded edge between said third bearing surface and said insertion face.

24. The implant of claim 19, wherein said implant may include a chamber in communication with said bearing surfaces.

25. The implant of claim 19, wherein said implant is adapted to hold bone fusion promoting materials.

26. An implant for insertion between a first vertebra and a second vertebra, the first vertebra having a generally vertically extending first peripheral wall and a first cortical bone endplate and the second vertebra having a generally vertically extending second peripheral wall and a second cortical bone endplate, wherein the implant comprises:

a first terminal part defining a trailing face, a first bearing surface adapted to bear against a portion of the cortical bone endplate proximate to the first peripheral wall, and an opposite second bearing surface adapted to bear against a portion of the second cortical bone endplate proximate to the second peripheral wall;

a second terminal part opposite said first terminal part, said second terminal part including an anti-expulsion feature and having an insertion face extending from a third bearing surface to a fourth bearing surface, said implant having a longitudinal axis extending through said trailing face of said first terminal part and said insertion face of said second terminal part, and having a cross section in a first plane extending through said first bearing surface and said second bearing surface, and along the longitudinal axis, the first plane bisecting said first bearing surface in two halves;

a first side and an opposite second side, said first side and said second side extending from said first terminal part to said second terminal part, said first and second sides intersecting a second plane that is perpendicular to the first plane and extends through said insertion face and said trailing face, wherein a cross section of said implant at the second plane is generally rectangular; and

upper and lower bearing surfaces proximate each of said first and second sides, wherein said upper and lower bearing surfaces proximate said first and second sides are, at least in part, convex relative to the second plane.

27. The implant of claim 26, wherein said first bearing surface and said second bearing surface include at least one anti-expulsion feature.

28. The implant of claim 26, wherein said third bearing surface and said fourth bearing surface include at least one anti-expulsion feature.

29. The implant of claim 26, wherein said second terminal part includes a chamfered edge between said third bearing surface and said insertion face.

30. The implant of claim 26, wherein said second terminal part includes a rounded edge between said third bearing surface and said insertion face.

31. The implant of claim 26, wherein said implant may include a chamber in communication with said bearing surfaces.

32. The implant of claim 26, wherein said implant is adapted to hold bone fusion promoting materials.

* * * * *

EXHIBIT B

US005676146A

United States Patent [19]

Scarborough

[11] Patent Number: 5,676,146

[45] Date of Patent: Oct. 14, 1997

[54] **SURGICAL IMPLANT CONTAINING A RESORBABLE RADIOPAQUE MARKER AND METHOD OF LOCATING SUCH WITHIN A BODY**

[75] Inventor: **Nelson L. Scarborough**, Ocean, N.J.

[73] Assignee: **Osteotech, Inc.**, Eatontown, N.J.

[21] Appl. No.: **713,694**

[22] Filed: **Sep. 13, 1996**

[51] **Int. Cl.**[6] **A61B 6/00**

[52] **U.S. Cl.** **128/654**; 623/11; 623/16; 623/66

[58] **Field of Search** 623/11, 16, 18, 623/66; 606/77; 128/653.1, 654

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,829,904	8/1974	Ling et al. .	
3,891,997	7/1975	Herbert .	
3,922,726	12/1975	Trentani et al. .	
4,123,806	11/1978	Amstutz et al. .	
4,224,698	9/1980	Hopson .	
4,450,592	5/1984	Niederer et al. .	
5,306,304	4/1994	Gendler	623/11
5,343,877	9/1994	Park	623/16
5,405,402	4/1995	Dye et al. .	
5,425,762	6/1995	Muller .	
5,476,880	12/1995	Cooke et al. .	
5,507,813	4/1996	Dowd et al. .	

Primary Examiner—Ruth S. Smith

Attorney, Agent, or Firm—Dilworth & Barrese

[57] **ABSTRACT**

A surgical implant containing a resorbable radiopaque marker enables the position and/or orientation of the implant to be readily determined by x-ray or other radiographic technique following its surgical implantation in the body.

17 Claims, No Drawings

SURGICAL IMPLANT CONTAINING A RESORBABLE RADIOPAQUE MARKER AND METHOD OF LOCATING SUCH WITHIN A BODY

BACKGROUND OF THE INVENTION

This invention is directed to a surgical implant, more particularly one containing a radiopaque marker which enables the position and/or orientation of the implant to be readily determined by x-ray or other radiographic technique following its surgical implantation in the body.

Osteoprosthetic implants are useful for repairing a variety of skeletal defects and irregularities. It may be necessary to confirm the location of an implant following its placement in the body. However, many osteoprosthetic implants are fabricated from materials, e.g., synthetic resins, that are transparent to radiographic imaging such as x-ray. Osteoprosthetic implants of this type have been provided with a radiopaque marker facilitating the determination of the position of the installed implant employing x-ray or other radiographic technique. See, e.g., U.S. Pat. Nos. 3,829,904, 3,891,997, 3,922,726, 4,123,806, 4,224,698, 4,450,592, 5,405,402, 5,425,762, and 5,476,880. The radiopaque markers in the implants described in these patents takes the form of a metal wire formed from a biologically compatible metal such as stainless steel.

SUMMARY OF THE INVENTION

In accordance with the present invention, an implant for repairing skeletal defects and irregularities is provided which comprises an implant fabricated from a radiolucent material and possessing a resorbable radiopaque marker, e.g., nondemineralized or partially demineralized bone particles. Unlike the metal wire radiopaque marker in the synthetic prostheses of the patents identified above, the implant of this invention has a radiopaque marker component which is resorbable in its entirety and may contribute to the healing of bone through natural processes.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The implant can be manufactured from any of several radiolucent resorbable or non-resorbable materials including demineralized bone sheet, particles, etc., collagen and collagen derivatives, plastic such as polyethylene cetabular cups.

In one embodiment of the present invention, the resorbable implant is manufactured from elongate demineralized bone particles as disclosed in U.S. Pat. No. 5,507,813, the contents of which are incorporated herein by reference. According to the method described in U.S. Pat. No. 5,507,813, elongate bone particles are obtained by milling from a section of whole bone, the particles are demineralized with acid in accordance with known and conventional procedures to provide substantially completely demineralized bone particles which are characteristically radiolucent and the bone particles are then formed into a shaped material possessing a definite geometrical configuration, e.g., a sheet possessing a square or rectangular shape. The sheet is formed by a wet-laying process the steps of which are as follows: slurrying a quantity of the demineralized elongate bone particles in a suitable liquid, e.g., water, organic protic solvent, aqueous solution such as physiological saline, etc., and optionally containing one or more biocompatible ingredients such as adhesives, fillers, plasticizers, flexibilizing agents, biostatic/biocidal agents, surface active agents, medically/surgically useful substances, etc., applying the slurry to a porous support, e.g., a flat perforate sheet, mesh screen or three-dimensional mold, through which excess slurry liquid drains thereby providing a coherent, shaped wetted mass of demineralized bone particles and, optionally, drying the wetted mass. The sheet material thus formed is relatively rigid when dry and, upon contact with a biocompatible liquid, e.g., water, saline solution, etc., becomes pliable and flexible thus making it readily conformable to a desired bone repair site.

The radiopaque marker which is to be incorporated into the resorbable implant of this invention is advantageously provided as native bone obtained from either human or animal bone, e.g., by cutting, milling, grinding or other suitable technique. The radiopaque marker can also be partially demineralized bone, the extent of demineralization being not so great as to substantially impair its radiopaque character. For example, partially demineralized bone containing not less than about 50 weight percent of its original mineral content can be utilized as the radiopaque component of the implant of this invention. The radiopaque marker can also be a resorbable calcium-based mineral, e.g., hydroxyapatite, tricalcium phosphate, etc., or other resorbable inorganic material. The radiopaque marker is preferably provided in particulate form with an average particle size of from about 0.1 mm to about 10 mm and preferably from about 1 mm to about 5 mm. The radiopaque marker can be shaped in the form of spherical, quasi-spherical, cuboid, rectangular or any other shape which may be useful.

The radiopaque marker can be incorporated into the resorbable implant at any stage in the manufacture of the latter, e.g., in the case of a bone sheet manufactured in accordance with aforementioned U.S. Pat. No. 5,507,813, by introduction into the slurry from which the bone sheet is made. The radiopaque marker can also be incorporated into the milled bone particles prior to their demineralization and formation into the bone sheet. However, as will be recognized, the radiopaque marker in this embodiment must be able to survive or be resistant to the demineralization process. In the case of a radiopaque marker made up of bone particles, by making such particles larger and/or thicker than the elongate bone particles intended for demineralization, it is possible to limit the extent of their demineralization so that they still contain sufficient inorganic matter to render them radiopaque while the elongate bone particles undergo complete, or nearly complete, demineralization. Another method of imparting resistance to demineralization to bone particles intended to function as the radiopaque marker is to coat the particles with a substance that is less susceptible to acid attack.

When incorporating the radiopaque marker into the resorbable implant, the marker can be arranged within the implant in a predetermined pattern, e.g., a geometric pattern such as a grid. This can be readily accomplished by use of a template placed over the implant during a processing step so that marker material that is poured or cast over the implant is only imbedded in desired areas. The usefulness of a predetermined pattern for the markers is to render the implant easily distinguishable from other surrounding structures in situ.

In the case of a resorbable implant which is fabricated from demineralized bone, application of the implant to the site of a bone defect, e.g., one resulting from injury, infection, malignancy or developmental malformation, leads to new bone ingrowth by one or more biological mechanisms such as osteogenesis, osteoconduction and/or osteoin-

duction or by one or more physical mechanisms such as providing a physical barrier to soft tissue ingrowth, presenting a support or scaffolding for new bone growth, etc.

Upon implantation of the implant into the body at a defect site, the implant can be viewed by using any of several known and conventional radiographic techniques such as x-ray imaging. In the case of x-ray imaging, the radiopaque marker is displayed on the exposed and developed x-ray film as white spots allowing the location and/or the orientation of the implant to be accurately determined.

The implant of this invention can be utilized in a wide variety of orthopaedic, neurosurgical and oral and maxillofacial surgical procedures such as the repair of simple and compound fractures and non-unions, external and internal fixations, joint reconstructions such as arthrodesis, general arthroplasty, cup arthroplasty of the hip, femoral and humeral head replacement, femoral head surface replacement and total joint replacement, repairs of the vertebral column including spinal fusion and internal fixation, tumor surgery, e.g. deficit filling, discectomy, laminectomy, excision of spinal cord tumors, anterior cervical and thoracic operations, repair of spinal injuries, scoliosis, lordosis and kyphosis treatments, intermaxillary fixation of fractures, mentoplasty, temporomandibular joint replacement, alveolar ridge augmentation and reconstruction, inlay bone grafts, implant placement and revision, sinus lifts, etc. These materials can be sutured or stapled in place for anchoring purposes and serve in guided tissue regeneration or as barrier materials.

The following examples are illustrative of the resorbable implant of this invention.

EXAMPLE 1

A sheet fabricated from demineralized elongate bone particles is manufactured according to the method described in U.S. Pat. No. 5,507,813. While the sheet is being wet-laid nondemineralized bone particles that have been classified to a predetermined range are added thereto. The mineralized particles are uniformly distributed within the wet sheet which is then subjected to the remaining manufacturing operations described in the aforesaid patent. The resultant flexible sheets are then cut into implant-sized pieces.

EXAMPLE 2

A small sheet from Example 1 is rehydrated and implanted into an animal at a calvarial defect site. The site is then sutured closed and the skull is x-rayed. The mineralized particles are displayed on the resultant x-ray film as white spots allowing the location of the implant to be precisely determined.

EXAMPLE 3

The nondemineralized bone particles in Example 1 can be incorporated into the wet-laid sheet in a regular pattern such as a grid with 5 mm spaces between particles. When the sheet processing is completed and a small sheet segment is rehydrated and implanted as in Example 2, the position/orientation of the sheet segment is more easily determined via x-ray imaging due to the regular pattern of the radiopaque nondemineralized particles.

EXAMPLE 4

The nondemineralized particles of Example 1 can be distributed in a flowable osteogenic composition which is comprised of demineralized bone particles and an inert carrier such as glycerol.

What is claimed is:

1. A surgical implant for surgical implantation in the body, the implant being fabricated from radiolucent material and possessing a resorbable radiopaque marker.

2. The implant of claim **1** wherein the radiolucent material is resorbable.

3. The implant of claim **2** wherein the resorbable material is demineralized bone or collagen.

4. The implant of claim **2** wherein the resorbable material is a flexible sheet of demineralized bone.

5. The implant of claim **1** which possesses a definite geometrical configuration.

6. The implant of claim **1** wherein the resorbable radiopaque marker comprises nondemineralized or partially demineralized bone particles.

7. The implant of claim **6** wherein the nondemineralized or partially demineralized bone particles are selected from the group consisting of human and animal bone.

8. The implant of claim **6** wherein the nondemineralized or partially demineralized bone particles are of a predetermined shape selected from the group consisting of spherical, quasi-spherical, cuboid, tube, fiber, spiral and rectangular.

9. The implant of claim **6** wherein the partially demineralized bone particles contain not less than about 20 weight percent residual inorganic matter.

10. The implant of claim **1** wherein the resorbable radiopaque marker is a calcium-based mineral selected from the group consisting of hydroxyapatite, tricalcium phosphate, fluorapatite and their mixtures.

11. The implant of claim **1** wherein the resorbable radiopaque marker is arranged within the implant in accordance with a predetermined pattern.

12. The implant of claim **11** wherein the predetermined pattern is a grid.

13. A method of determining the location and/or orientation of a surgical implant within a body which comprises:

a) surgically implanting within a body an implant fabricated from radiolucent material containing a resorbable radiopaque marker; and,

b) post-surgically determining the location and/or orientation of the implant by a radiographic technique.

14. The method of claim **13** wherein radiolucent material is resorbable.

15. The method of claim **13** wherein the radiographic technique is x-ray imaging.

16. The method of claim **13** wherein the radiopaque marker is arranged within the implant in accordance with a predetermined pattern.

17. The method of claim **16** wherein the predetermined pattern is a grid.

* * * * *

US005676146B1

REEXAMINATION CERTIFICATE (4047th)

United States Patent [19] [11] **B1 5,676,146**

Scarborough [45] Certificate Issued **Apr. 18, 2000**

[54] **SURGICAL IMPLANT CONTAINING A RESORBABLE RADIOPAQUE MARKER AND METHOD OF LOCATING SUCH WITHIN A BODY**

[75] Inventor: **Nelson L. Scarborough**, Ocean, N.J.

[73] Assignee: **Osteotech, Inc.**, Eatontown, N.J.

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[52] **U.S. Cl.** **600/431**; 623/11.11; 623/16.11

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,627,853	12/1986	Campbell et al.	623/16
4,709,703	12/1987	Lazarow et al. .	
4,795,463	1/1989	Gerow .	
5,108,399	4/1992	Eitenmuller et al. .	
5,366,507	11/1994	Sottosanti	623/16
5,441,517	8/1995	Kensey et al. .	

FOREIGN PATENT DOCUMENTS

0405429	1/1991	European Pat. Off. .
296 08 321 U	8/1996	Germany .
WO94/21196	9/1994	WIPO .

Primary Examiner—Ruth S. Smith

[57] **ABSTRACT**

A surgical implant containing a resorbable radiopaque marker enables the position and/or orientation of the implant to be readily determined by x-ray or other radiographic technique following its surgical implantation in the body.

REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

THE PATENT IS HEREBY AMENDED AS INDICATED BELOW.

Matter enclosed in heavy brackets [ ] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

Claims **10**, **11**, **14** are cancelled.

Claims **1**, **8**, **9**, **12**, **13** are determined to be patentable as amended.

Claims **2–7**, **15–17**, dependent on an amended claim, are determined to be patentable.

New claims **18–24** are added and determined to be patentable.

1. A surgical implant for surgical implantation in the body, the implant being fabricated from radiolucent material and possessing a resorbable *particulate* radiopaque marker *arranged within the radiolucent material in a predetermined geometric pattern.*

8. **[**The implant of claim **6]** *A surgical implant for surgical implantation in the body, the implant being fabricated from radiolucent material and possessing a resorbable radiopaque marker, the radiopaque marker including non-demineralized or partially demineralized bone particles* wherein the nondemineralized or partially demineralized bone particles are of a predetermined shape selected from the group consisting of spherical, quasi-spherical, cuboid, tube, fiber, spiral and rectangular.

9. **[**The implant of claim **6]** *A surgical implant for surgical implantation in the body, the implant being fabricated from radiolucent material and possessing a resorbable radiopaque marker, the radiopaque marker including partially demineralized bone particles* wherein the partially demineralized bone particles contain not less than about 20 weight percent residual inorganic matter.

12. The implant of claim **[11]** *1* wherein the predetermined pattern is a grid.

13. A method of determining the location and/or orientation of a surgical implant within a body which comprises:

a) surgically implanting within a body an implant fabricated from *particles of a* radiolucent material **[**containing a resorbable radiopaque marker**]** *uniformly distributed with a radiopaque marker of particles of nondemineralized or partially nondemineralized bone*; and

b) post-surgically determining the location and/or orientation of the implant by a radiographic technique.

18. A surgical implant for surgical implantation in the body comprising nondemineralized or partially demineralized bone particles and demineralized bone particles uniformly distributed in an inert carrier.

19. A surgical implant for surgical implantation in the body according to claim 18 wherein the inert carrier is glycerol.

20. A surgical implant for implantation in the body according to claim 18 wherein the implant includes collagen.

21. A surgical implant for surgical implantation in the body, the implant comprising particles of a radiolucent material in substantially uniform admixture with particles of nondemineralized or partially demineralized bone.

22. A surgical implant for surgical implantation in the body according to claim 21 wherein the radiolucent material is demineralized bone.

23. A surgical implant for surgical implantation in the body according to claim 21 wherein the implant possesses a definite geometrical configuration.

24. A surgical implant comprising radiolucent material and a resorbable particulate radiopaque marker arranged within the radiolucent material, wherein the radiolucent material includes demineralized bone and the radiopaque marker includes non-demineralized or partially demineralized bone.

* * * * *

US005676146C2

(12) EX PARTE REEXAMINATION CERTIFICATE (6066th)
United States Patent
Scarborough

(10) Number: US 5,676,146 C2
(45) Certificate Issued: Dec. 25, 2007

(54) **SURGICAL IMPLANT CONTAINING A RESORBABLE RADIOPAQUE MARKER AND METHOD OF LOCATING SUCH WITHIN A BODY**

(75) Inventor: **Nelson L. Scarborough**, Ocean, NJ (US)

(73) Assignee: **Osteotech, Inc.**, Eatontown, NJ (US)

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A61F 2/00	(2006.01)
A61B 6/00	(2006.01)
A61B 6/12	(2006.01)
A61B 19/00	(2006.01)

(52) **U.S. Cl.** **600/431**; 623/1.34; 623/11.11; 623/16.11

(58) **Field of Classification Search** 600/431; 623/1.34, 11.11, 16.11
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,627,853	A	* 12/1986	Campbell et al.	128/898
4,824,939	A	* 4/1989	Simpson	530/356
5,441,517	A	* 8/1995	Kensey et al.	606/213
5,507,813	A	* 4/1996	Dowd et al.	523/23.63
5,510,396	A	* 4/1996	Prewett et al.	523/113

OTHER PUBLICATIONS

Urist et al., Bone Formation in Implants of partially and Wholly Demineralized Bone Matrix, Clinical Orthopaedics and Related Research, vol. 71, pp. 271–278 (1970).*

Grafton™ Allogenic Bone Matrix (ABM), Advertising Brochure, *Advanced Processing of Human Allograft Bone*, Osteotech, Inc., 1992.

Frenkel et al., *Use of Demineralized Bone Matrix Gel to Enhance Spine Fusion*, 19th Annual Meeting of the Society for Biomaterials, Apr. 28–May 2, 1993, Birmingham, AL, p. 162.

Stevenson et al., *Long Bone Defect Healing Induced By a New Formulation of Rat Demineralized Bone Matrix Gel*, 40th Annual Meeting, Orthopedic Research Society, Feb. 21–24, 1994, New Orleans, LA, p. 205–35.

* cited by examiner

Primary Examiner—David O. Reip

(57) **ABSTRACT**

A surgical implant containing a resorbable radiopaque marker enables the position and/or orientation of the implant to be readily determined by x-ray or other radiographic technique following its surgical implantation in the body.

EX PARTE REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

THE PATENT IS HEREBY AMENDED AS INDICATED BELOW.

Matter enclosed in heavy brackets [ ] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

The patentability of claims **1**–**7**, **9** and **12** is confirmed.

Claims **10**, **11** and **14** were previously cancelled.

Claims **8**, **13**, **18**, **21** and **24** are determined to be patentable as amended.

Claims **15**–**17**, **19**, **20**, **22** and **23**, dependent on an amended claim are determined to be patentable.

New claims **25**–**28** are added and determined to be patentable.

8. **[**A**]** *An osteogenic* surgical implant for surgical implantation in the body, the implant being fabricated from radiolucent material and possessing a resorbable radiopaque **[**marker**]** *material*, the radiopaque **[**marker**]** *material* including nondemineralized or partially demineralized *allograft* bone particles *with an average particle size from about 0.1 mm to about 10 mm and being provided in sufficient quantity for use as a marker,* wherein the nondemineralized or partially demineralized *allograft* bone particles are of a predetermined shape selected from the group consisting of spherical, quasi-spherical, cuboid, tube, fiber, spiral and rectangular.

13. A method of determining the location and/or orientation of **[**a**]** *an osteogenic* surgical implant within a body which comprises:

a) surgically implanting within a body an *osteogenic* implant fabricated from **[**particles of**]** a radiolucent material **[**uniformly distributed with**]** *comprising allograft bone particles and* a radiopaque **[**marker of**]** *material comprising* particles of nondemineralized or partially nondemineralized allograft bone*, the radiopaque material being uniformly distributed within the radiolucent material, wherein the radiopaque material is provided in sufficient quantity for use as a marker*; and

b) post-surgically determining the location and/or orientation of the implant by a radiographic technique.

18. **[**A**]** *An osteogenic* surgical implant for surgical implantation in the body comprising *a radiopaque material comprising* nondemineralized or partially demineralized *allograft* bone particles and *a radiolucent material including* demineralized *allograft* bone particles*, the radiopaque material and radiolucent material being* uniformly distributed in an inert carrier*, wherein the radiopaque material is provided in sufficient quantity for use as a marker*.

21. **[**A**]** *An osteogenic* surgical implant for surgical implantation in the body, the implant comprising particles of a radiolucent material *including demineralized allograft bone particles* in substantially uniform admixture with *a radiopaque material including* particles of nondemineralized or partially demineralized *allograft* bone*, wherein the radiopaque material is provided in sufficient quantity for use as a marker*.

24. **[**A**]** *An osteogenic* surgical implant comprising radiolucent material and a resorbable particulate radiopaque marker arranged within the radiolucent material, wherein the radiolucent material includes demineralized *allograft* bone and the a radiopaque marker includes *particles of* nondemineralized or partially demineralized *allograft* bone*, the particles of nondemineralized or partially demineralized allograft bone being provided in sufficient quantities for use as a marker*.

25. An osteogenic surgical implant for surgical implantation in the body comprising nondemineralized or partially demineralized allograft bone particles and demineralized allograft bone particles uniformly distributed in an inert carrier, the nondemineralized or partially demineralized allograft bone particles being provided in sufficient quantities for use as a marker, the surgical implant being stored in a package for subsequent implantation.

26. An osteogenic surgical implant for surgical implantation in the body, the implant comprising particles of a radiolucent material in a substantially uniform admixture with particles of nondemineralized or partially demineralized bone, wherein the particles of nondemineralized or partially demineralized bone are provided in sufficient quantities for use as a radiopaque marker, the surgical implant being stored in a package for subsequent implantation.

27. An osteogenic surgical implant comprising radiolucent material and a resorbable particulate radiopaque material arranged within the radiolucent material, wherein the radiolucent material includes demineralized allograft bone and the radiopaque material includes nondemineralized or partially demineralized allograft bone particles, wherein the radiopaque material is provided in sufficient quantity for use as a marker, the surgical implant being stored in a package for subsequent implantation.

28. The surgical implant of claim 18 wherein the surgical implant is packaged in the wet state.

* * * * *

EXHIBIT C

US008251997B2

(12) **United States Patent**
Michelson

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(54) **METHOD FOR INSERTING AN ARTIFICIAL IMPLANT BETWEEN TWO ADJACENT VERTEBRAE ALONG A CORONAL PLANE**

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See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

350,420	A	10/1886	Dillon	
1,137,585	A	4/1915	Craig	
2,065,659	A	12/1936	Cullen	
2,181,746	A	11/1939	Siebrandt	
2,243,718	A	5/1941	Moreira	
2,514,665	A	7/1950	Myller	
2,537,070	A	1/1951	Longfellow	
2,543,780	A	3/1951	Hipps et al.	
2,677,369	A	5/1954	Knowles	
2,774,350	A	12/1956	Cleveland	
2,789,558	A	4/1957	Rush	
2,832,343	A	4/1958	Mose	
2,842,131	A	7/1958	Smith	
2,878,809	A	3/1959	Treace	
2,919,692	A *	1/1960	Ackermann	600/567
3,128,768	A	4/1964	Geistauts	
3,298,372	A	1/1967	Feinberg	
3,426,364	A	2/1969	Lumb	
3,486,505	A	12/1969	Morrison	
3,604,487	A	9/1971	Gilbert	
3,605,123	A	9/1971	Hahn	
3,618,611	A	11/1971	Urban	
3,709,219	A	1/1973	Halloran	

(Continued)

FOREIGN PATENT DOCUMENTS

DE 1 961 531 7/1970

(Continued)

OTHER PUBLICATIONS

U.S. Appl. No. 08/219,626, filed Mar. 1994, Michelson.

(Continued)

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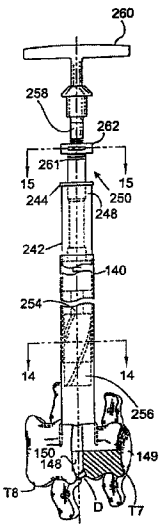
(57) **ABSTRACT**

A method for inserting an artificial implant between two adjacent vertebrae along a coronal plane.

30 Claims, 14 Drawing Sheets



U.S. PATENT DOCUMENTS

3,719,186	A		3/1973	Merig, Jr.
3,720,959	A		3/1973	Hahn
3,750,652	A		8/1973	Sherwin
3,848,601	A	*	11/1974	Ma et al. ..... 606/86 A
3,855,638	A		12/1974	Pilliar
3,867,728	A		2/1975	Stubstad et al.
3,867,932	A		2/1975	Huene
3,867,950	A		2/1975	Fischell
3,875,595	A		4/1975	Froning
3,888,260	A		6/1975	Fischell
3,892,232	A		7/1975	Neufeld
3,905,047	A		9/1975	Long
3,915,151	A		10/1975	Kraus
3,916,907	A		11/1975	Peterson
3,918,440	A		11/1975	Kraus
3,941,127	A		3/1976	Froning
3,942,535	A		3/1976	Schulman
3,948,262	A		4/1976	Zaffaroni
3,952,334	A		4/1976	Bokros et al.
3,987,499	A		10/1976	Scharbach et al.
4,016,651	A		4/1977	Kawahara et al.
4,027,392	A		6/1977	Sawyer et al.
D245,259	S		8/1977	Shen
4,051,905	A		10/1977	Kleine
4,059,115	A		11/1977	Jumashev et al.
4,070,514	A		1/1978	Entherly et al.
4,082,097	A		4/1978	Mann et al.
4,086,701	A		5/1978	Kawahara et al.
4,124,026	A		11/1978	Berner et al.
4,142,517	A		3/1979	Stavropoulos et al.
4,168,326	A		9/1979	Broemer et al.
4,175,555	A		11/1979	Herbert
4,177,524	A		12/1979	Grell et al.
4,181,457	A		1/1980	Holmes
4,197,850	A		4/1980	Schulman et al.
4,206,516	A		6/1980	Pilliar
4,222,128	A		9/1980	Tomonaga et al.
D257,511	S		11/1980	Zahn
4,232,679	A		11/1980	Schulman
4,237,948	A		12/1980	Jones et al.
4,258,716	A		3/1981	Sutherland
4,259,072	A		3/1981	Hirabayashi et al.
4,262,369	A		4/1981	Roux
4,271,832	A		6/1981	Evans et al.
D260,525	S		9/1981	Lassiter
4,289,123	A		9/1981	Dunn
4,293,962	A		10/1981	Fuson
4,309,777	A		1/1982	Patil
4,328,593	A		5/1982	Sutter et al.
4,333,469	A		6/1982	Jeffcoat et al.
4,341,206	A		7/1982	Perrett et al.
4,349,921	A		9/1982	Kuntz
4,356,572	A		11/1982	Guillemin et al.
4,401,112	A		8/1983	Rezaian
4,405,319	A		9/1983	Cosentino
4,414,979	A		11/1983	Hirshorn et al.
4,423,721	A		1/1984	Otte et al.
4,439,152	A		3/1984	Small
4,450,834	A		5/1984	Fischer
4,484,570	A		11/1984	Sutter et al.
4,492,226	A		1/1985	Belykh et al.
4,497,320	A		2/1985	Nicholson et al.
4,501,269	A		2/1985	Bagby
4,507,115	A		3/1985	Kambara et al.
RE31,865	E		4/1985	Roux
4,530,360	A		7/1985	Duarte
4,535,374	A		8/1985	Anderson et al.
4,535,485	A		8/1985	Ashman et al.
4,542,539	A		9/1985	Rowe, Jr. et al.
4,545,374	A		10/1985	Jacobson
4,547,390	A		10/1985	Ashman et al.
4,549,547	A		10/1985	Brighton et al.
4,552,200	A		11/1985	Sinha et al.
4,553,273	A		11/1985	Wu
4,554,914	A		11/1985	Kapp et al.
D281,814	S		12/1985	Pratt et al.
4,570,623	A		2/1986	Ellison et al.
4,570,624	A		2/1986	Wu
4,573,448	A	*	3/1986	Kambin 606/170
4,592,346	A		6/1986	Jurgutis
4,599,086	A		7/1986	Doty
4,600,000	A		7/1986	Edwards
4,602,638	A		7/1986	Adams
4,604,995	A		8/1986	Stephens
4,608,052	A		8/1986	Van Kampen et al.
4,611,581	A		9/1986	Steffee
4,619,264	A		10/1986	Singh
4,628,921	A		12/1986	Rousso
4,634,720	A		1/1987	Dorman et al.
4,636,217	A		1/1987	Ogilvie et al.
4,636,526	A		1/1987	Dorman et al.
4,645,503	A		2/1987	Lin et al.
4,653,486	A		3/1987	Coker
4,653,509	A		3/1987	Oloff et al.
4,655,777	A		4/1987	Dunn
4,661,536	A		4/1987	Dorman et al.
4,664,567	A		5/1987	Edwards
4,665,920	A		5/1987	Campbell
4,677,883	A		7/1987	Lee
4,677,972	A		7/1987	Tornier
4,693,721	A		9/1987	Ducheyne
4,696,290	A		9/1987	Steffee
4,698,375	A		10/1987	Dorman et al.
4,710,075	A		12/1987	Davison
4,713,004	A		12/1987	Linkow et al.
4,714,469	A		12/1987	Kenna
4,721,103	A		1/1988	Freedland
4,723,540	A		2/1988	Gilmer, Jr.
4,736,738	A		4/1988	Lipovsek et al.
4,743,256	A		5/1988	Brantigan
4,743,260	A		5/1988	Burton
4,759,766	A		7/1988	Buettner-Janz et al.
4,759,769	A		7/1988	Hedman et al.
4,769,881	A		9/1988	Pedigo et al.
4,772,286	A		9/1988	Goble
4,781,591	A		11/1988	Allen
4,790,303	A		12/1988	Steffee
4,805,602	A		2/1989	Puno et al.
4,820,305	A		4/1989	Harms et al.
4,830,000	A		5/1989	Shutt
4,832,683	A		5/1989	Idemoto et al.
4,834,757	A		5/1989	Brantigan
4,848,327	A		7/1989	Perdue
4,851,008	A		7/1989	Johnson
4,863,476	A		9/1989	Shepperd
4,863,477	A		9/1989	Monson
4,865,603	A		9/1989	Noiles
4,877,020	A		10/1989	Vich
4,878,915	A		11/1989	Brantigan
4,879,915	A	*	11/1989	Spencer 73/864.74
4,903,882	A		2/1990	Long
4,904,260	A		2/1990	Ray et al.
4,904,261	A		2/1990	Dove et al.
4,911,718	A		3/1990	Lee et al.
4,913,144	A		4/1990	Del Medico
4,936,848	A		6/1990	Bagby
4,943,291	A		7/1990	Tanguy
4,955,885	A		9/1990	Meyers
4,955,908	A		9/1990	Frey et al.
4,957,495	A		9/1990	Kluger
4,960,420	A		10/1990	Goble et al.
4,961,740	A		10/1990	Ray et al.
4,968,316	A		11/1990	Hergenroeder
4,969,888	A		11/1990	Scholten et al.
4,987,904	A		1/1991	Wilson
5,015,247	A		5/1991	Michelson
5,015,255	A		5/1991	Kuslich
5,026,373	A		6/1991	Ray et al.
5,030,236	A		7/1991	Dean
5,047,036	A		9/1991	Koutrouvelis
5,047,055	A		9/1991	Bao et al.
5,055,104	A		10/1991	Ray
5,059,193	A		10/1991	Kuslich
5,062,845	A		11/1991	Kuslich et al.
5,071,437	A		12/1991	Steffee
5,084,050	A		1/1992	Draenert
5,102,414	A		4/1992	Kirsch

5,105,819	A		4/1992	Wollschlager et al.
5,108,422	A		4/1992	Green et al.
5,112,336	A		5/1992	Krevolin et al.
5,116,304	A		5/1992	Cadwell
5,122,130	A		6/1992	Keller
5,123,926	A		6/1992	Pisharodi
5,131,382	A		7/1992	Meyer
5,171,278	A		12/1992	Pisharodi
5,171,279	A		12/1992	Mathews
5,183,471	A		2/1993	Wilk
5,192,327	A		3/1993	Brantigan
5,195,541	A		3/1993	Obenchain
5,217,479	A		6/1993	Shuler
5,242,443	A	*	9/1993	Kambin 606/60
5,246,458	A		9/1993	Graham
5,258,031	A		11/1993	Salib et al.
5,263,953	A		11/1993	Bagby
5,269,772	A		12/1993	Wilk
5,279,292	A		1/1994	Baumann et al.
5,292,252	A		3/1994	Nickerson et al.
5,306,307	A		4/1994	Senter et al.
5,306,309	A		4/1994	Wagner et al.
5,314,427	A		5/1994	Goble et al.
5,314,432	A		5/1994	Paul
5,324,295	A		6/1994	Shapiro
5,352,229	A		10/1994	Goble et al.
5,360,430	A		11/1994	Lin
5,364,399	A		11/1994	Lowery et al.
5,370,662	A		12/1994	Stone et al.
5,370,697	A		12/1994	Baumgartner
5,393,036	A		2/1995	Sheridan
RE34,871	E		3/1995	McGuire et al.
5,395,317	A		3/1995	Kambin
5,395,372	A		3/1995	Holt et al.
5,396,880	A		3/1995	Kagan et al.
5,397,364	A		3/1995	Kozak et al.
5,425,772	A		6/1995	Brantigan
5,435,723	A		7/1995	O'Brien
5,441,527	A		8/1995	Erickson et al.
5,443,514	A		8/1995	Steffee
5,458,638	A		10/1995	Kuslich et al.
5,480,440	A		1/1996	Kambin
5,484,437	A		1/1996	Michelson
5,489,307	A		2/1996	Kuslich et al.
5,489,308	A		2/1996	Kuslich et al.
D368,777	S		4/1996	Goble et al.
5,571,109	A		11/1996	Bertagnoli
5,593,409	A		1/1997	Michelson
5,609,636	A		3/1997	Kohrs et al.
5,658,337	A		8/1997	Kohrs et al.
5,683,463	A		11/1997	Godefroy et al.
5,766,252	A		6/1998	Henry et al.
5,772,661	A		6/1998	Michelson
D397,439	S		8/1998	Koros et al.
5,800,547	A		9/1998	Schafer et al.
5,885,299	A		3/1999	Winslow et al.
6,224,595	B1		5/2001	Michelson
7,207,991	B2		4/2007	Michelson
7,491,205	B1		2/2009	Michelson
8,066,705	B2		11/2011	Michelson

FOREIGN PATENT DOCUMENTS

DE	31 01 333	A1	12/1981
DE	31 32 520	A1	6/1982
DE	35 05 567	A1	6/1982
DE	36 08 163	A1	9/1987
EP	0 077 159		4/1983
EP	0 162 005		11/1985
EP	0 179 695		4/1986
EP	0 551 187	A1	7/1993
EP	0 577 179	A1	1/1994
EP	0 599 419	A2	6/1994
EP	0 627 204	A2	12/1994
ES	283078		5/1985
FR	2 581 336		11/1986
FR	2 703 580		10/1994
GB	1291470		10/1972
GB	1531487		11/1978
GB	2076657	A	12/1981
GB	2126094	A	3/1984
GB	2164277	A	3/1986
JP	60-31706		9/1985
JP	60-43984		10/1985
JP	62-155846		7/1987
JP	63 300758	A	12/1988
JP	4-88929	U	8/1992
SE	106 101		7/1939
SU	1107854		8/1984
SU	1124960		11/1984
SU	1217374		3/1986
SU	1222254		4/1986
SU	1650114	A	5/1991
WO	WO 84/01298		4/1984
WO	WO 90/00037		1/1990
WO	WO 92/14423		9/1992
WO	WO 94/28824		12/1994
WO	WO 96/22747		8/1996

OTHER PUBLICATIONS

U.S. Appl. No. 12/655/178, filed Dec. 2009, Michelson

Adams, et al.; Outline of Orthopaedics, Eleventh Edition; Trunk and Spine; 1990; cover page and p. 194.

Herkowitz, et al., Principles on Bone Fusion; The Spine, Third Edition; Chapter 44; cover page and p. 1739; 1992.

Muschler, et al.; The Biology of Spinal Fusion; Spinal Fusion Science and Technique, Cotler and Cotler (editors); 1990; 2 cover pages and pp. 9-21.

Zindrick, et al., Lumbar Spine Fusion: Different Types and Indications; The Lumbar Spine, vol. 1, Second Edition, 2 cover pages and pp. 588-593 (1996).

Gillingham, F.J., et al.: Automatic Patient Monitoring in the Ward; Brit. J. Surg. vol. 53, No. 10, cover page and pp. 864-866 (Oct. 1966).

Maloney, A.F.J., et al.; Clinical and Pathological Observations in Fatal Head Injuries, Brit. J. Surg., vol. 56, No. 1, cover page and pp. 23-31 (Jan. 1969).

Harris, P., et al.; Spinal Deformity After Spinal Cord Injury; Paraplegia, vol, 6, No. 4, cover page and p. 232-238 (Feb. 1969).

Gillingham, F.J., et al.; Head injuries; Proceedings of the 18th World Congress of the International College of Surgeons, Rome, 2 cover pages and pp. 68-71 (May 28-31, 1972).

Whatmore, W. J.; Sincipitai Encephalomeningoceles; Brit. J. Surg., vol. 60, No. 4, cover page and pp. 261-270 (Apr. 1973).

Whatmore, W. J., et al.; Meningioma Following Trauma; Brit. J. Surge., vol. 60, No. 6, cover page and pp. 496-498 (Jun. 1973).

Bagby, George W.; Wobbler Syndrome in Horses (the Ataxic Horse); Spokane County Medical Society Bulletin; Spring 1979; 2 pages.

Rathke, F.W., et al.; Surgery of the Spine; Atlas of Orthopaedic Operations, vol. 1, p. 137, W.B. Saunders Co., Philadelphia (1979).

Albrektsson, T., et al.; Osseointegrated Titanium Implants; Acta. Orthop. Scand.; vol. 52:155-170 (1981).

Raveh, J., et al.; Neue Rekonstruktionsmoglichkeiten des Unterkiefers bei knochernen Defekten nach Tumorresektionen; Der Chirurg vol. 53:459-467 (1982).

Crock, H. V.; Practice of Spinal Surgery; Springer-Verlag/Wien, New York (1983); 14 pages.

Crock, Henry V.; Practice of Spinal Surgery; Springer-Verlag/Wien, New York (1983); cover page and pp. 64-92.

DeBowes, R.M., et al.; Study of Bovine . . . Steel Baskets; Transactions of the 29th Annual Meeting; Orthopaedic Research Society, vol. 8, cover page and p. 407, Mar. 8-10 (1983).

O'Neill, P., et al.; Spinal Meningoceles in Association with Neurofibromatosis; Neurosurgery, vol, 13, No. 1, cover page and pp. 82-84 (Jul. 1983).

Brandt, L., et al.; A Dowel Inserter for Anterior Cervical Interbody Fusion; J. Neurosurg. 61.793-794 (Oct. 1984).

Whatmore, W.J., et al.; The Coventry Cervical Spreader and Dowel Inserter; ACTA Neurochirurgica, vol. 70, FASC. 1-2; cover page and p. 132; (1984).

Raveh, J., et al.; Use of the Titanium-coated Hollow Screw and Reconstruction Plate System in Bridging of Lower Jaw Defects; J. Oral Maxillofac Surg. 42:281-294 (1984).

Otero-Vich, Jose M.; Anterior Cervical Interbody Fusion with Threaded Cylindrical Bone; J. Neurosurg 63: 2 cover pages and pp. 750-753 (Nov. 1985).
Morscher, E., et al.; Die vordere Verplattung der Halswirbelsäule mit dem Hohlschrauben-Plattensystem aus Titanium, *Der Chirurg*, vol. 57, pp. 702-707 (1986) with English Transiation.
Bagby, G.W.; Basket Implant Facilitates Spinal Fusion; Orthopedics Today, vol. 7, No. 10, (Oct. 1987); 3 pages.
Butts, M. K., et al.; Biomechanical Analysis of a New Method for Spinal Interbody Fixation; 1987 Symposium, American Society of Mechanical Engineers, "Advances in Bioengineering", Boston, MA (Dec, 13, 18, 1987); 7 pages.
Crawley et al.; A Modified Cloward's Technique for Arthrodesis of the Normal Metacarpophalangeal Joint in the Horse; Veterinary Surgery, vol. 17, No. 3, pp. 117-127 (1988).
Raveh, J., et al.; Surgical Procedures for Reconstruction of the Lower Jaw Using the Titanium Coated Hollow Screw Reconstruction Plate System: Bridging of Defects; Otolaryngologic Clinics of North America; vol. 20, No. 3; pp. 535-558; (Aug. 1987).
Whatmore, W. J.; Proceedings of the Society of British Neurological Surgeons; Journal of Neurology, Neurosurgery, and Psychiatry, 50:1093-1100 (1987).
Goldthwaite, N., et al.; Toward Percutaneous Spine Fusion; Ch. 45; Lumbar Spine Surgery: Techniques and Complications; C.V. Mosby Company, 2 cover pages and pp. 512-522 (1987).
Bagby, G.W.; Arthrodesis by the Distraction-Compression Method Using a Stainless Steel Implant; Orthopedics, vol. II, No. 6, pp. 931-934 (Jun. 1988).
Itoman, M., et al.; Banked Bone Grafting for Bone Defect Repair—Clinical Evaluation of Bone Union and Graft Incorporation; J. Jpn. Orthop. Assoc. 62:461-469 (1988).
Kane, W.J.; Direct Current Electrical Bone Growth Stimulation for Spinal Fusion; Spine, vol. 13, No. 3, pp. 363-365 (Mar. 1988).
The SpF-T Spinal Fusion Stimulator: An Efficacious Adjunct that Meets the Diverse Needs of Spine Patients; EBI Medical Systems; (Aug. 1991); 4 pages.
Schmitz et al.; Performance of Alloplastic, Materials and Design of an Artificial Disc; The Artificial Disc, Brock, Mayer, Weigel (editors); cover page and pp. 23-34 (1991).
The Use of Direct Current for Electrically Induced Osteogenesis; The Positive Effect of an Electronegative charge on Bone Growth; EBI Medical Systems (Feb. 1993); 4 pages.
Mylonas, C., et al.; Anterior Cervical Decompression and Fusion Using the Coventry Cervical Spreader and Dowel Inserter; British Journal of Neurosurgery; 7: cover page and pp. 545-549 (1993).
Fusion of the Lumbar Spine; Anterior Monosegmental Fusion L5-S1, Atlas of Spinal Operations, Thieme, cover page and pp. 270-274 (1993).
Spine Basics, Danek Group, Inc., Glossary (1993); 2 pages.
Lumbar Spine Surgery, Techniques & Complications; 1987; pp. 11-15, 27, 30, 35-45, and 265-268.
Cloward, Ralph B.; Surgical Techniques for Lumbar Disc Lesions; Codman; Signature Series 3; 1982; 31 pages.
Cloward, Ralph B.; Ruptured Cervical Intervertebral Discs: Removal of Disc & Osteophytes & Anterior Cervical Interbody Fusion (A.C. I.F.); Codman; Signature Series 4; 1974; 22 pages.
Cloward, Ralph B.; Recent Advances in Surgery of the Cervical Spine; 2 cover pages and pp. 285-293; German Society for Neurosurgery: vol. 2 Cervical Spine Operations; Excerpta Medics; 1971.
Hutter, Charles George; Spinal Stenosis and Posterior Lumbar Interbody Fusion; 2 cover pages and pp. 103-114; Clinical Orthopaedics and Related Research; No. 193; The Association of Bone and Joint Surgeons; 1985.
Lin, Paul M, (editor); Posterior Lumbar Interbody Fusion; 2 cover pages and pp. 114-.122; Charles C. Thomas; Springfield, Illinois; 1982.
Lin, Paul M., et al. (editors); Lumbar Interbody Fusion: Principles and Techniques in Spine Surgery; Techniques and Complications; 5 cover pages and pp. 81, 98, 120, 146, 173, 180-184, 204, 224, 225, and 231; Aspen Publishers, Inc.; 1989.
Tan, S.B., et al.; A Modified Technique of Anterior Lumbar Fusion with Femoral Cortical Allograft; 2 cover pages and pp. 83-93; The Journal of Orthopaedic Surgical Techniques, vol. 5, No. 3, 1990.
Muller, M.E., et al.: Manual of Internal Fixation: Techniques Recommended by the AO Group; Second Edition, Expanded and Revised; cover page, and pp. V, VI, 3-20), 27-41, 53-58, 71-78, 94, 311, and 320; Springer-Verlag; 1979.
Hierholzer, G., et al.; Manual on the AO/ASIF Tubular External Fixator; 2 cover pages and pp. 85-91; Springer-Verlag; 1985.
Heim, Urs, et al.; Small Fragment Set Manual: Technique Recommended by the ASIF-Group; 2 cover pages and pp. 5-7, 10, 20, 21, and 30; Springer-Verlag; 1974.
Harmon, Paul H.; Anterior Excision and Vertebral Body Fusion Operation for Intervertebral Disk Syndromes of the Lower Lumbar Spine: Three- to Five-Year Results in 244 Cases; pp. 107-127; Clinical Orthopaedics and Related Research, No. 26, J.B. Lippincott Company, 1963.
Harmon, Paul H.; A Simplified Surgical Technic for Anterior Lumbar Diskectomy and Fusion; Avoidance of Complications; Anatomy of the Retropedtoneal Veins; pp, 130-144; Clinical Orthopaedics and Related Research, No. 37, J.B. Lippincott Company, 1964.
Bullough, P., et al.; Atlas of Spinal Diseases; Figure 5,7; J.B. Lippencott Company; 1988; 3 pages.
Canale, S. Terry; Campbell's Operative Orthopaedics; vol. 3, 9th Edition; 2 cover pages and pp. 2191, 2216, and 2459; Mosby, 1998,.
Baulot et al.; "Complementary Anterior Spondylodesis by Thoracosopy. Technical note regarding an observation, Technical Designs and Experimental Research;" 90(5): 347-351 (1994).
Bolesta and Bohlman; Chapter 68: "Surgical Management of Injuries to the Thoracic and Lumbosacral Spine;" in "Surgery of the Spine, A Combined Orthopaedic and Neurosurgical Approach;" Ed. Findlay and Owen, pp. 1115-1129 and cover page; Oxford, Blackwell Scientific Publications (1992).
Larson et al.; "Lateral Extracavitary Approach to Traumatic Lesions of the Thoracic and Lumbar Spine;" J. Neurosurg.; 45:628-6387 (1976).
Rosenthal et al.; "Removal of a Protruded Thoracic Disc Using Microsurgical Endoscopy. A New Technique." Spine, 19(9):1087-1091 (1994).
Friedman, William; "Percutaneous Discectomy: An Alternative to Chemonuleolysis?" Neurosurgery, 13(5); cover page, contents page and pp. 542-547 (1983).
Hoppenfeld, Stanley; "Percutaneous Removal of Herniated Lumbar Discs;" Clinical Orthopaedics and Related Research, No. 238, 2 cover pages and pp. 92-97 (1989).
Leu et al.; "Percutaneous Fusion of the Lumbar Spine: A Promising Technique;" Spine, vol. 6, No. 3, 2 cover pages and pp. 593-604 (1992).
Verbiest, H.; Chapter 1: "History and Development of Spinal Surgery;" in "Surgery of the Spine, A Combined Orthopaedic and Neurosurgical Approach;" Ed. Findlay and Owen, 2 cover pages and pp. 3-15; Oxford, Blackwell Scientific Publications (1992).
Willberger, B.R.; "Dowel Intervertebral Fusion as Used in Lumbar Disc Surgery;" The Journal of Bone and Joint Surgery, vol. 39A, cover page and pp. 234-292, and 331; 1957.
X-Rays showing surgeries performed using the Acronex Disc; Sep. 7, 1989; 7 pages.
Pictures showing surgery performed using the Brantigan I/F Cage; undated; 11 pages.
Pictures of Brantigan I/F Cage, undated, 7 pages.
Brantigan, John W., et al.; presentation titled "Interbody Lumbar Fusion Using a Carbon Fiber Cage Implant vs. Allograft Bone—an investigational study in the Spanish goat;" undated; 7 pages.
Pictures showing surgery performed using the Brantigan Anterior I/F Cage; undated; 9 pages.
X-Rays and pictures showing surgeries performed on sheep using the Brantigan Anterior I/F Cage; dated Apr. 30, 1990 through Jul. 4, 1992; 477 pages.
X-Rays and picture showing surgery using the BAK Cage; undated; 3 pages.
Drawings and pictures showing surgery on sheep using the BAK Cage; undated; 6 pages.

Medtronic Sofamor Danek USA, Inc. et al., v. *Nuvasive, Inc.*; Defendant Nuvasive, Inc.'s First Amended Answer to Plaintiffs' First Amended Complaint for Patent Infringement and Third Amended Counterclaims; 24 pages; dated Sep. 4, 2009.

Medtronic Sofamor Danek USA, Inc. et al., v. *Nuvasive, Inc.*; Joint Claim Construction Chart, Worksheet, and Hearing Statement Pursuant to Patent L.R. 4.2 for U.S. Patent No. 5,772,661 U.S. Patent No. 5,860,973, and U.S. Patent No. 6,945,933; 5 pages; dated May 27, 2009; Exhibit A, 22 pages; Exhibit B, 24 pages; Exhibit D, 14 pages; Exhibit E, 21 pages.

Medtronic Sofamor Danek USA, Inc. et al.; v. *Nuvasive, Inc.*; Medtronic's Third Supplemental Disclosure of Asserted Claims and Infringement Contentions; 5 pages; dated Nov. 6, 2009; Attachment 16, 2 pages.

Medtronic Sofamor Danek USA, Inc. et al., v. *Nuvasive, Inc.*; Joint Claim Construction Chart, Worksheet, and Hearing Statement Pursuant to Patent L.R. 4.2 for U.S. Patent Nos. 6,592,586: 5,860,973; 6,945,933; 7,582,058; and 7,470,236; 4 pages; dated Nov. 23, 2009; Exhibit B, 21 pages; Exhibit G, 17 pages.

Medtronic Sofamor Danek USA, Inc. et al., v. *Nuvasive, Inc.*; Medtronic Sofamor Danek USA, Inc. et al.'s Opening Claim Construction Brief; 70 pages; dated Jan. 11, 2010.

Medtronic Sofamor Danek USA, Inc. et al., v. *Nuvasive, Inc.*; Medtronic's Fourth Supplemental Disclosure of Asserted Claims and Infringement Contentions; 8 pages; dated Feb. 12; 2010.

Medtronic Sofamor Danek USA, Inc. et al., v. *Nuvasive, Inc.*; Medtronic Sofamor Danek USA, Inc., et al.'s Preliminary Claim Constructions Pursuant to Patent L.R. 4.1; 9 pages; dated Apr. 24, 2009.

Medtronic Sofamor Danek USA, Inc. et al., v. *Nuvasive, Inc.*; Medtronic Sofamor Danek USA, Inc., et al.'s Preliminary Claim Constructions Regarding U.S. Patent Nos. 6,592,586; 5,860,973; 6,945,933; 7,582,058; 7,207,949; and 7,470,236 Pursuant to Patent L.R. 4.1; 11 pages; dated Sep. 30, 2009.

Medtronic Sofamor Danek USA, Inc. et al., v. *Nuvasive, Inc.*; Medtronic Sofamor Danek USA, Inc., et al.'s 1 Responsive Claim Construction Brief; 37 pages; dated Jan. 20, 2010.

Medtronic Sofamor Danek USA, Inc et al., v. *Nuvasive, Inc.*; Declaration of Esha Bandyopadhyay in Support of Medtronic's Responsive Claim Construction Brief; 4 pages; dated Jan. 20, 2010; Exhibit 11, 4 pages; Exhibit 12, 3 pages; Exhibit 13, 2 pages; Exhibit 14, 3 pages; Exhibit 16, 3 pages; Exhibit 17, 2 pages.

Medtronic Sofamor Danek USA, Inc. et al., v. *Nuvasive, Inc.*; Medtronic Sofamor Danek USA, Inc., et al.'s Responsive Claim Constructions Regarding U.S. Patent Nos. 6,592,586; 5,860,973; 6,945,933; 7,582,058; 7,207,949; and 7,470,236 Pursuant to Patent L.R. 4.1; 12 pages; dated Oct. 9, 2009.

Medtronic Sofamor Danek USA, Inc. et al., v. *Nuvasive, Inc.*; Nuvasive, Inc.'s Opening Claim Construction Brief Regarding U.S. Patent Nos. 7,470,236; 7,582,058; 5,860,973; 6,592,586; and 6,945,933; 70 pages; dated Jan. 11, 2010.

Medtronic Sofamor Danek USA, Inc. et al., v. *Nuvasive, Inc.*; Nuvasive, Inc.'s Preliminary Claim Constructions and identification of Extrinsic Evidence Pursuant to Patent L.R. 4.1 for U.S. Patent No. 5,772,661, U.S. Patent No. 5,860,973, and U.S. Patent No. 6,945,933; 24 pages; dated Apr. 24, 2009.

Medtronic Sofamor Danek USA, Inc. et al., v. *Nuvasive, Inc.*; Nuvasive, Inc.'s Preliminary Claim Constructions and Identification of Extrinsic Evidence Pursuant to Patent L.R. 4.1 for U.S. Patent No. 6,592,586, U.S. Patent No. 5,860,973, U.S. Patent No. 6,945,933; U.S. Patent No. 7,207,949, U.S, Patent No. 7,470,236, and U.S. Patent No. 7,582,058; 7 pages; dated Sep. 30, 2009.

Medtronic Sofamor Danek USA, Inc., et al., v. *Nuvasive, Inc.*; Nuvasive, Inc.'s Responsive Claim Constructions Pursuant to Patent L.R. 4.1; 15 pages; dated May 8, 2009.

Medtronic Sofamor Danek USA, Inc. et al., v. *Nuvasive, Inc.*; Nuvasive, Inc.'s Responsive Claim Constructions and Identification of Extrinsic Evidence Pursuant to Patent L.R. 4.1 for U.S. Patent No. 6,592,586, U.S. Patent No. 5,860,973, U.S. Patent No. 6,946,933; U.S. Patent No. 7,207,949, U.S. Patent No. 7,470,236, and U.S. Patent No. 7,582,058; 18 pages; dated Oct. 9, 2009.

Medtronic Sofamor Danek USA, Inc. et al., v. *NuVasive, Inc.*; NuVasive's Preliminary Identification of Prior Art; 12 pages; dated Dec. 24, 2008.

Medtronic Sofamor Danek USA, Inc. et al., v. *NuVasive, Inc.*; NuVasive Inc.'s Supplemental Response to Plaintiffs' Interrogatory No. 6; 26 pages; dated Apr. 17, 2009.

Medtronic Sofamor Danek USA, Inc. et al., v. *Nuvasive, Inc.*; Order Construing Disputed Claim Terms of United States Patent Nos. 5,860,973; 6,945,933; 6,592,586; and 7,470,236; pp. 1-22; Case No. 08cvl 512- MMA(AJB); Apr. 1, 2010.

Medtronic Sofamor Danek USA, Inc., et al. v. *Nuvasive, Inc.*; Plaintiff Medtronic Sofamor Danek USA, Inc., et al.'s Supplemental Objections and Responses to NuVasive, Inc.'s Second Set of Interrogatories (No. 16); 13 pages; dated May 10, 2010,.

Medtronic Sofamor Danek, Inc., v. *Nuvasive, Inc.*; Nuvasive, Inc.'s Corrected Final Invalidity Contentions Regarding U.S. Patent Nos. 5,860,973; 6,592,586; and 6,945,933; 17 pages; dated Jun. 14, 2010; Appendix B.1, 63 pages; Appendix B.2, 61 pages; Appendix B.3, 55 pages; Appendix B.4, 61 pages; Appendix B.5, 51 pages; Appendix B.6, 73 pages; Appendix B.7, 61 pages; Appendix B.8, 53 pages; Appendix B.9, 43 pages; Appendix B,10, 60 pages; Amended Appendix B.11, 78 pages; Appendix B.14, 27 pages; Appendix B.15, 50 pages; Appendix B.16, 35 pages; Appendix B.17, 12 pages; Appendix B.18, 14 pages; Appendix B.19, 13 pages; Appendix B.20, 12 pages; Appendix B.21, 13 pages; Appendix 8.22, 13 pages; Appendix B.23, 13 pages.

Medtronic Sofamor Danek, Inc., v. *Nuvasive, Inc.*; Expert Report of Dr. Barton L. Sachs, M.D.. M.B.A., CPE Regarding Infringement of U.S. Patent Nos. 5,860,973 and 6,945,933 (redacted); 194 pages; Dec. 3, 2010.

Medtronic Sofamor Danek, Inc., v. *Nuvasive, Inc.*; Expert Rebuttal Report of Dr. Barton L. Sachs, M.D., M,B,A., CPE Regarding Validity of U.S. Patent Nos. 5,860,973 and 6,945,933; 144 pages; Jan. 20, 2011.

Warsaw Orthopedic, Inc., v. *Nuvasive, Inc.*; Medtronic's Opposition to Nuvasive iInc.'s Motions for Summary Judgment (Redacted Version); 30 pages; Mar. 9, 2011.

Warsaw Orthopedic, Inc., v. *Nuvasive, Inc.*; Medtronic's Responses to Nuvasive's Statement of Undisputed Facts and Medtronic's Statement of Additional Material Facts (Redacted Version); 77 pages; Mar. 9, 2011.

Warsaw Orthopedic, Inc., v. *Nuvasive, Inc*; Nuvasive's Opposition to Warsaw's Motions for Summary judgment (Redacted Version); 31 pages; Mar. 9, 2011.

Warsaw Orthopedic, Inc., v. *Nuvasive, Inc.*; Nuvasive's Response to Warsaw's Statement of Undisputed Material Facts (Redacted Version); 89 pages; Mar. 10, 2011.

Warsaw Orthopedic, Inc., v. *Nuvasive, Inc,*: Medtronic's Responses to Nuvasive's Statement of Additional Material Facts (Redacted Version); 39 pages; Mar. 16, 2011.

Warsaw Orthopedic, Inc., v. *Nuvasive, Inc.*, Nuvasive's Reply in Support of Motions for Summary Judgment (Redacted Version); 13 pages Mar. 16, 2011.

Warsaw Orthopedic, Inc., v. *Nuvasive, Inc.*; Nuvasive's Reply to Warsaw's Statement of Additional Material Facts (Redacted Version); 67 pages; Mar. 16, 2011.

Warsaw Orthopedic, Inc., v. *Nuvasive, Inc.*; Reply Memorandum in Support of Medtronic's Motion for Summary Judgment (Redacted Version); 14 pages; Mar. 16, 2011.

Medtronic Sofamor Danek, Inc., v. *Nuvasive, Inc.*; Notice and Order Providing Tentative Rulings Re: Parties' Cross Motions for Summary judgment; 1 page; Mar. 21, 2011.

Warsaw Orthopedic, Inc., v. *Nuvasive, Inc.*; Nuvasive, Inc.'s Notice Pursuant to 35 U.S.C. § 282; 11 pages; Jul. 29, 2011.

Warsaw Orthopedic, Inc., v. *Nuvasive, Inc.*; Judgment Following Jury Verdict; 9 pages; Sep. 20, 2011.

Barnes, Walter P.; "The Use of Blade-Guides in Intervertebral-Body Bone-Grafting;" The Journal of Bone & Joint Surgery, vol, 40-A, No. 2; Apr. 1958; cover pages and pp. 461-464.

Brantigan, John W., et al.; "A Carbon Fiber Implant to Aid Interbody Lumbar Fusion: 1-year Clinical Results in the First 26 Patients:" Lumbar Fusion and Stabilization; cover page and pp. 379-395.

Brantigan, John W., et al.; "A Carbon Fiber Implant to Aid Interbody Lumbar Fusion: Two-Year Clinical Results in the First 26 Patients;" SPINE, vol. 18, No. 14; 1993; pp. 2106-2117.
Brantigan, John W., et al.; "A Carbon Fiber Implant to Aid Interbody Lumbar Fusion: Mechanical Testing;" SPINE, vol. 16, No. 6S; Jun. 1991; pp. S277-S282.
Brantigan ALIF Cage, 1993, 121 pages.
Chang, Benjamin B., et al.; "The Right Retroperitoneal Approach for Abdominal Aortic Surgery;" The American Journal of Surgery; vol. 158; Aug. 1989; cover and pp. A2, A3, and 156-158.
Freebody, D., et al.; "AnteriorTransperitoneal Lumbar Fusion;" The Journal of Bone and Joint Surgery; vol. 53B, No. 4; Nov. 1971; pp. 617-627.
Fujimaki, Arihisa, et al.; "The Results of 150 Anterior Lumbar interbody Fusion Operations Performed by Two Surgeons in Australia;" Clinical Orthopaedics and Related Research; No. 165; May 1982; pp. 164-167.
Harmon, Paul H.; "Subtotal Anterior Lumbar Disc Excision and Vertebral Body Fusion;" American Journal of Surgery; vol. 97; May 1959; pp. 649-659.
Hodgson, A.R., et al.; "The Classic Anterior Spinal Fusion;" Clinical Orthopaedics and Related Research; No. 300; Mar. 1994; pp. 16-23.
Hoover, Norman W., et al,; "Methods of Lumbar Fusion;" The Journal of Bone & Joint Surgery; vol. 50-A, No. 1; Jan. 1968; cover page and pp. 194-210.
Mack, Michael J., et al.; "Video-Assisted Thoracic Surgery for the Anterior Approach to the Thoracic Spine;" Ann Thorac Surg; No. 59; 1995; pp. 1100-1106.
McAfee, Paul C.; "Complications of Anterior Approaches to the Thoracolumbar Spine;" Clinical Orthopaedics; vol. 306; Sep. 1994; pp. 110-119.
Nissan, M., et al.; "The Cervical and Lumbar Vertebrae—An Anthropometric Model:" Engineering in Medicine; vol. 13, No. 3; 1984; pp. 111-114.
Panjabi, Manohar M., et al.; "Cervical Human Vertebrae Quantitative Three-Dimensional Anatomy of the Middle and Lower Regions;" SPINE; vol. 16, No. 8; 1991; pp. 861-869.
Panjabi, Manohar M., et al.; "Thoracic Human Vertebrae Quantitative Three-Dimensional Anatomy;" SPINE; vol. 16, No. 8; 1991; pp. 888-901.
Postacchini, Franco, et al,; "Morphometry of the Lumbar Vertebrae;" Clinical Orthopaedics and Related Research; No. 172; Jan.-Feb. 1983; pp. 296-303.
Program for Thorascopy and Laparoscopy of the Spine; Feb. 18-19, 1994; 4 pages.
Scoles, Peter V., et al.; "Vertebral Body and Posterior Element Morphology: The Normal Spine in Middle Life;" Spine; vol. 13, No. 10; Oct. 1988; cover page and pp. 1083-1085.
Texas Back Institute Research Foundation Neuroscience Conference Schedule; First Quarter of 1994; , 1 page.
van Schiak, Jan J.P., et al.; "Morphometry of Lower Lumbar Vertebrae as Seen on CT Scans: Newly Recognized Characteristics:" American Journal of Roentgenology; vol. 145, No. 2; Aug. 1985; pp. 327-335.
Brantigan, John W., et al.; "Interbody Lumbar Fusion Using a Carbon Fiber Cage Implant Versus Allograft Bono;"SPINE, vol. 19, No. 13, 1994; pp. 1436-1444.
Regan, John J., et al.; "Endoscopic Thoracic Fusion Cage;" Atlas of Endoscopic Spine Surgery; 1995; cover page and pp. 350-354.
Fedder, Ira L., et al,; "Video-Assited Spinal Surgery: Laboratory Protocol;" General Principles of Thoracoscopy & Laporascopy; 1995; pp. 18-26.
Cunningham, Bryan W., et al; "Video-Assisted Thoracoscopic Surgery Versus Open Thoracotorny for Anterior Thoracic Spinal Fusion;" SPINE, vol, 23, No. 12; Jun. 15, 1998; pp. 1333-1340.
Mooney, V., et al.; "Is Hydroxyapatite an Effective Bone Graft Substitute When New Bone Formation is Not Physically Stressed?" Orthopaedic Transactions, vol. 18, No. 3; 1994; cover page and pp. 848-849.
Mooney, Vert, et al.; "Comparison of Hydroxyapatite Granules to Autogenous Bone Graft in Fusion Cages in a Goat Model;" Surg. Neurol., vol. 49, 1998; pp. 628-634.
Danek Medical, Inc.; "Orion Anterior Cervical Plate System Brochure;" 1994; 2 pages.
Crock, H.V.; "Anterior Lumbar Interbody Fusion;" Clinical Orthopaedics and Related Research; 1982; 2 cover pages and pp. 157-163.
Crock, H.V.; A Short Practice of Spinal Surgery; Second, revised edition; Springer-Verlag/Wien, New York; 1993; 352 pages.
Kemp, H.B.S., et al.; "Anterior Fusion of the Spine for Infective Lesions in Adults;" The Journal of Bone and Joint Surgery; vol. 55B, No. 4; Nov. 1973; pp. 715-734.
Acromed Acro-flex device; as advertised in *Spine*, vol. 18, No. 13, Oct. 1, 1993; 3 pages.
Acrorned Acro-flex device; as advertised in *Spine*, vol. 19, No. 2, Jan. 1994, 4 pages.
Acromed Acro-flex device; as advertised in *Spione*, vol. 19, No. 3, Feb. 1994; 4 pages.
Berry et al.; "A Morphometric Study of Human Lumbar and Selected Thoracic Vertebrae;" Study of Selected Vertebrae; pp. 362-367; (1986).
Edeland, H.G.; "Suggestions for a Total Elasto-Dynamic Intervertebral Disc Prosthesis;" Biomaterials, Medical Devices, and Artificial Organs; 9(1), cover page and pp. 65-73 (1981).
Edeland, H.G.; "Some Additional Suggestions for an Intervertebral Disc Prosthesis;" Journal of Biomedical Engineering; vol. 7; pp. 57-62; Jan. 1985.
Grant, Pamela J. et al.; "Mapping the Structrual Properties of the Lumbosacral Vertebral Endplates;" SPINE; vol. 26, No. 8; pp. 889-896; 2001.
Hall, Lance T. et al.; "Morphology of the Lumbar Vertebral Endplates;" SPINE; vol. 23, No. 14; pp. 1517-1523; 1998.
Panjabi, Manohar M., et al.; "Human Lumbar Vertebrae Quantitive Three-Dimensional Anatomy;" Spine; vol. 17, No. 3; 1992; pp. 299-306.
Office Action from U.S. Appl. No. 12/655,178; mailed Aug. 11, 2011; 16 pages.
Office Action from U.S. Appl. No. 12/655,178; mailed Mar. 9, 2011; 8 pages.
McAfee, Paul C., et al.; Minimally invasive Anterior Retroperitoneal Approach to the Lumbar Spine, Emphasis on the Lateral BAK; Spine, vol. 23, No. 13, pp. 1476-1484 (1998).
Maiman et al.; "Lateral Extracavitary Approach to Spine for Thoracic Disc Herniation: Report of 23 Cases;" Neurosurg.: 14(2):178-182 (1984).
Rosenthal et al.; "Removal of a Protruded Thoracic Disc Using Microsurgical Endoscopy. A New Technique." Spine, 19(9)1087-1091 (1994).
Sturm et al,: "Far Lateral Lumbar Disc Herniation Treated with an Anteriorlateral Retroperitoneal Approach;" Spine, 17(3):363-365 (1992).
Friedman, William; "Percutaneous Discectomy: An Alternative to Chemonuleolysis?" Neurosurgery, 13(5); cover page, contents page, and pages 542-547 (1983).
Hoppenfeld, Stanley; "Percutaneous Removal of Herniated Lumbar Discs;" Clinicai Orthopaedics and Related Research, No. 238, 2 cover pages and pp. 92-97 (1989).
Leu et al.; "Percutaneous Fusion of the Lumbar Spine: A Promising Technique;" Spine, vol. 6, No. 3; 2 cover pages and pp. 593-604 (1992).
Schreiber et al.; "Percutaneous Nucleotomy: Technique with Discoscopy;" Orthopedics, vol. 14, No. 4, cover page, contents page, and pp. 439-444 (1991).
Verbiest, H.; Chapter 1: "History and Deveioprnent of Spinal Surgery;" in "Surgery of the Spine; A Combined Orthopaedic and Neurosurgical Approach;" Ed. Findlay and Owen, 2 cover pages and pp. 3-15; Oxford, Blackwell Scientific Publications (1992).
Wiltberger, B.R.; "Dowel intervertebral Fusion as Used in Lumbar Disc Surgery;" The Journal of Bone and Joint Surgery, vol. 39A, cover page and pp. 234-292, and 331; 1957.
Steffee; Arthur D., et al.; Presentation titled "Artificial Discs and Joints" dated Oct. 17-22, 1993; showing x-rays of surgery using the AcroFlex Disc dated Nov. 2, 1988; 100 pages.
X-Rays showing surgeries performed using the AcroFLex Disc; Sep. 7, 1989; 7 pages.

X-Rays and pictures showing surgeries performed using the Brantigan Anterior I/F Cage; Nov. 12, 1992; 15 pages.
X-Rays showing surgeries performed using the Brantigan Anterior I/F Cage; May 17, 1991; 24 pages.
X-Rays and pictures showing surgeries performed on sheep using the Brantigan Anterior I/F Cage; dated Apr. 30, 1990 through Jul. 4, 1992, 477 pages.
Medtronic Sofamor Danek USA, Inc. et al., v. *Nuvasive; Inc.*; Defendant Nuvasive, inc.'s First Amended Answer to Plaintiffs' First Amended Complaint for Patent infringement and Third Amended Counterclaims; 24 pages; dated Sep. 4, 2009.
Medtronic Sofamor Danek USA, Inc. et al., v. *Nuvasive, Inc.*; Joint Claim Construction Chart, Worksheet; and Hearing Statement Pursuant to Patent L.R. 4.2 for U.S. Patent No. 5,772,661, U.S. Patent No. 5,860,973, and U.S. Patent No. 6,945,933; 5 pages; dated May 27, 2009; Exhibit A, 22 pages; Exhibit B, 24 pages; Exhibit D, 14 pages; Exhibit E, 21 pages.
Medtronic Sofamor Danek USA, Inc. et al., v. *Nuvasive, Inc.*; Medtronic's Third Supplemental Disclosure of Asserted Claims and Infringement Contentions; 5 pages; dated Nov. 6, 2009; Attachment 16, 2 pages.
Medtronic Sofamor Danek USA, Inc. et al., v. *Nuvasive. Inc.*; Joint Claim Construction Chart, Worksheet, and Hearing Statement Pursuant to Patent L.R. 4.2 for U.S. Patent Nos. 6,592,586; 5,860,973; 6,945,933; 7,582;058; and 7;470;236; 4 pages; dated Nov. 23, 2009; Exhibit B, 21 pages; Exhibit G, 17 pages.
Medtronic Sofamor Danek USA, Inc. et al., v. *Nuvasive, Inc.*; Medtronic Sofarnor Danek USA, Inc. et al.'s Opening Claim Construction Brief; 70 pages; dated Jan. 11, 2010.
Medtronic Sofamor Danek USA, Inc. at al., v. *Nuvasive, Inc.*; Medtronic's Fourth Supplemental Disclosure Claims and Infringement Contentions; 8 pages; dated Feb. 12, 2010.

* cited by examiner

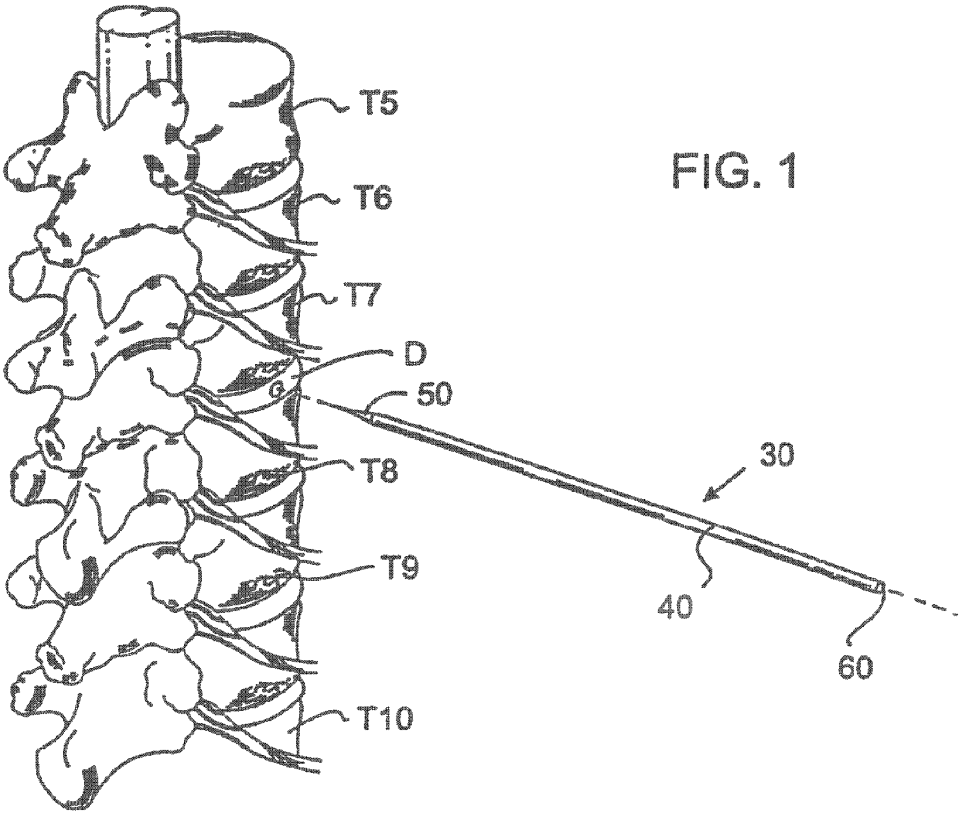

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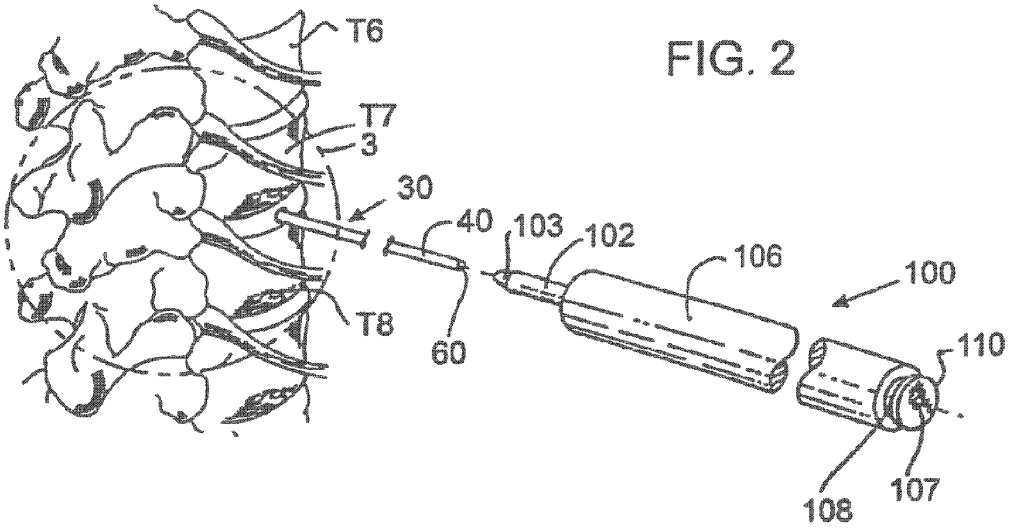
FIG. 1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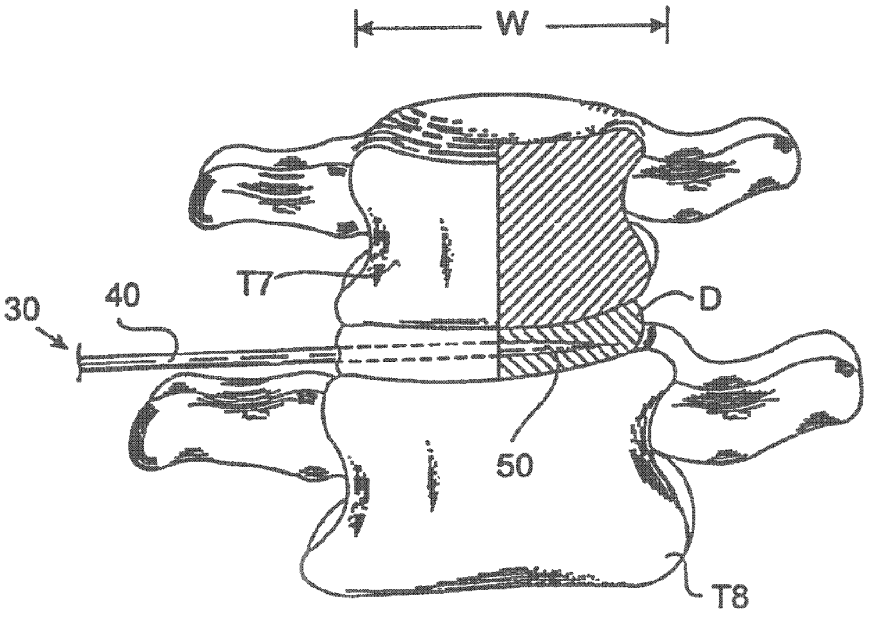


FIG. 3

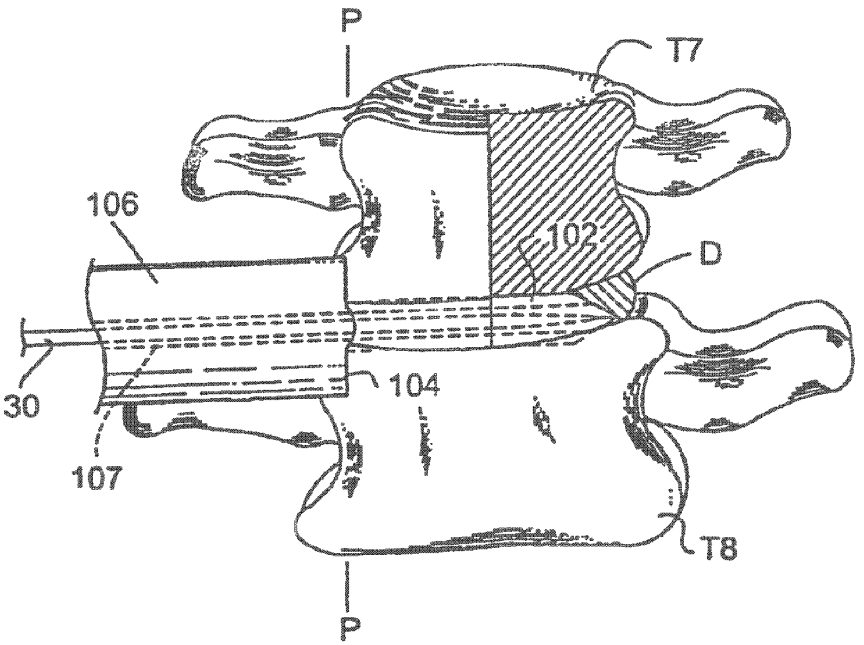


FIG. 4

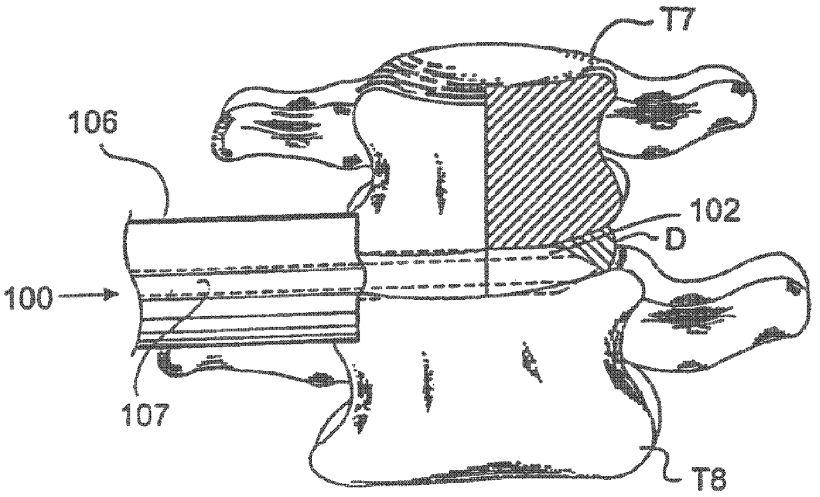


FIG. 5

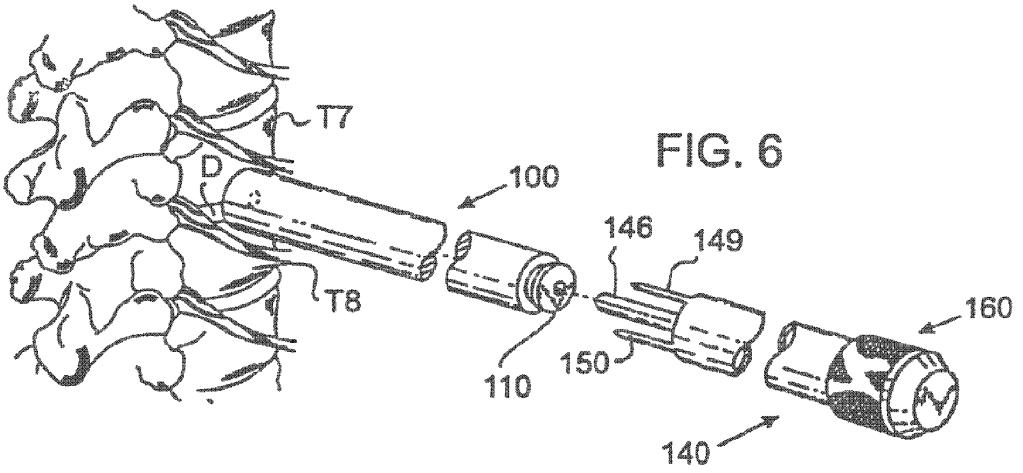


FIG. 6

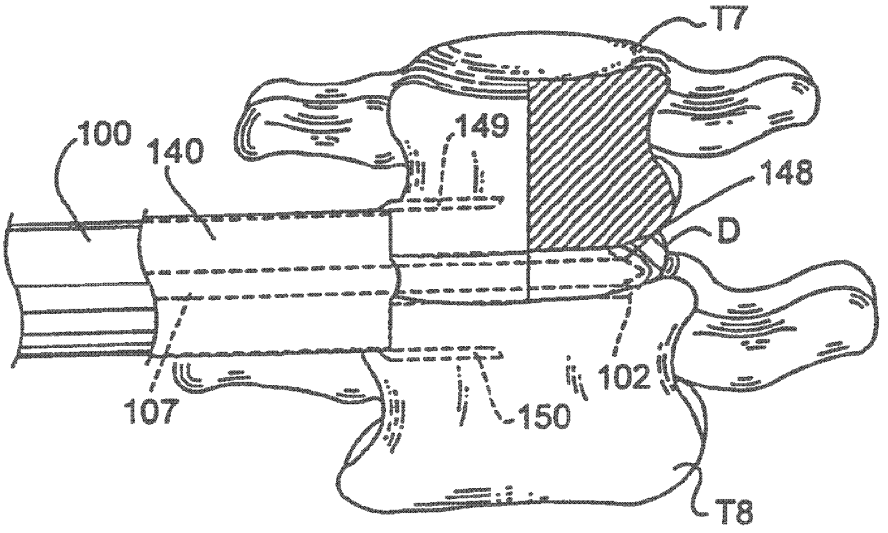


FIG. 7

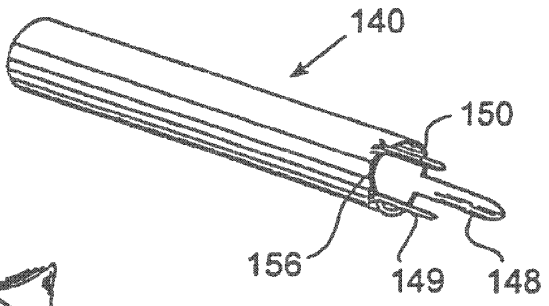


FIG. 7A

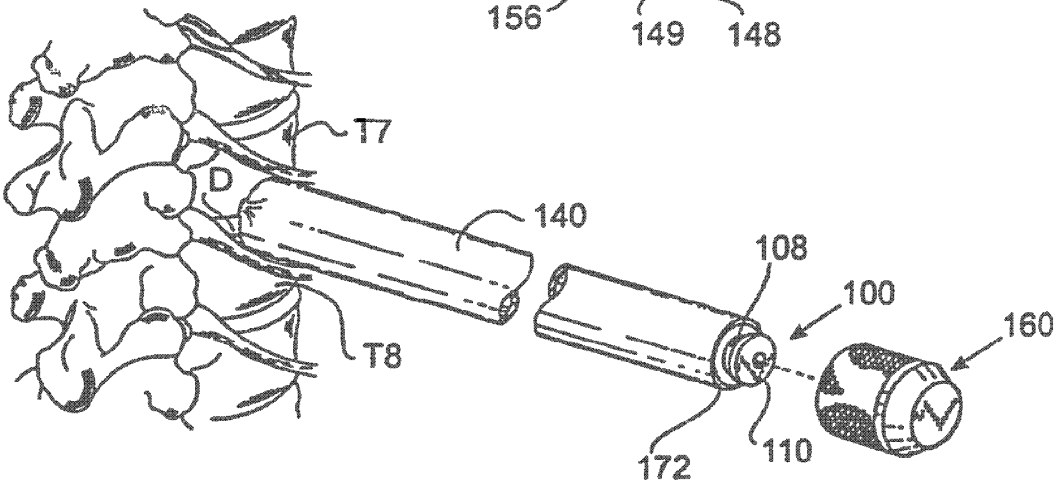
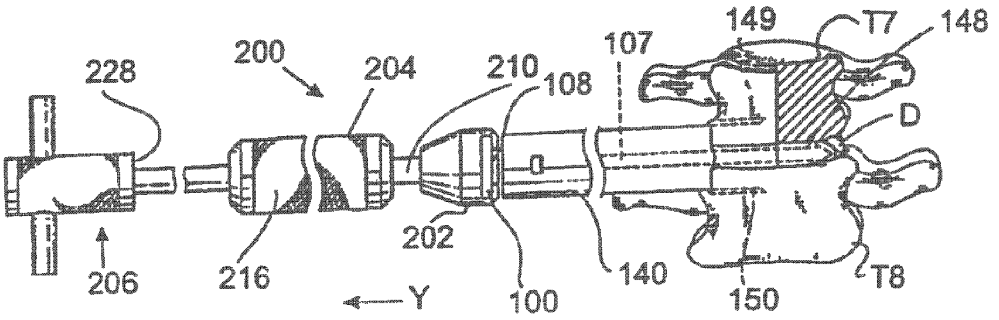


FIG. 8


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

FIG. 9

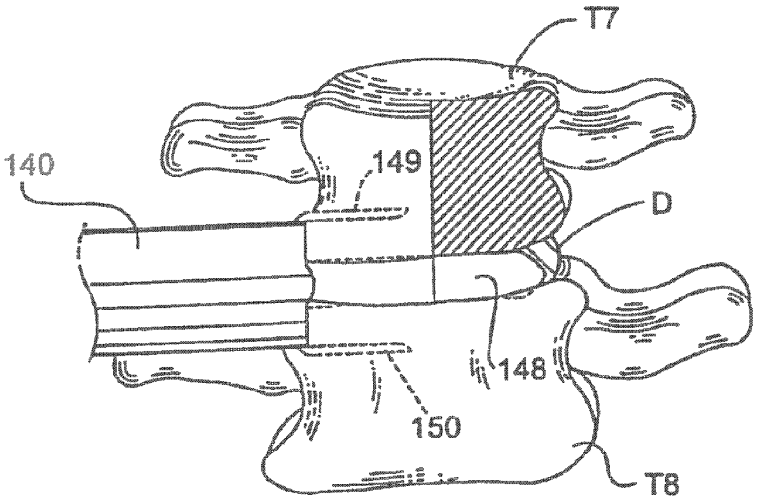

T7
140
149
D
148
150
T8

FIG. 10

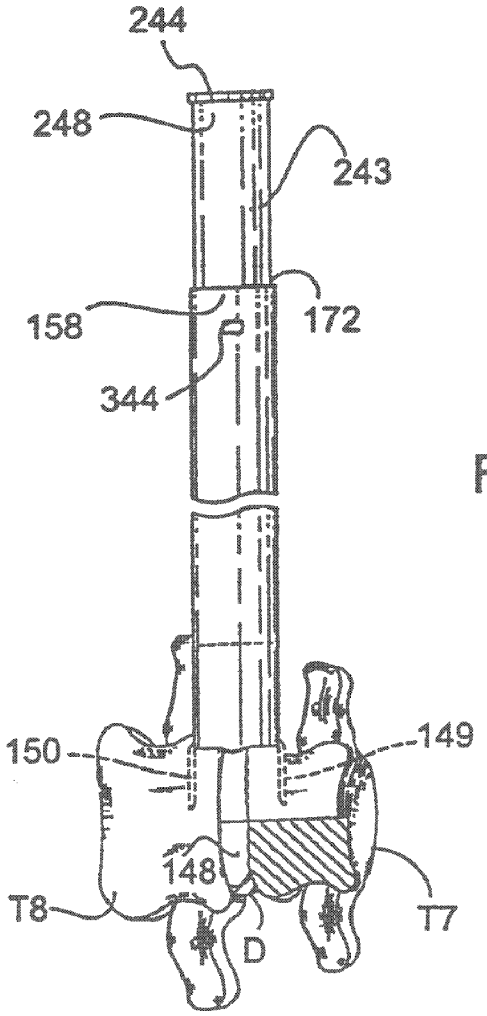
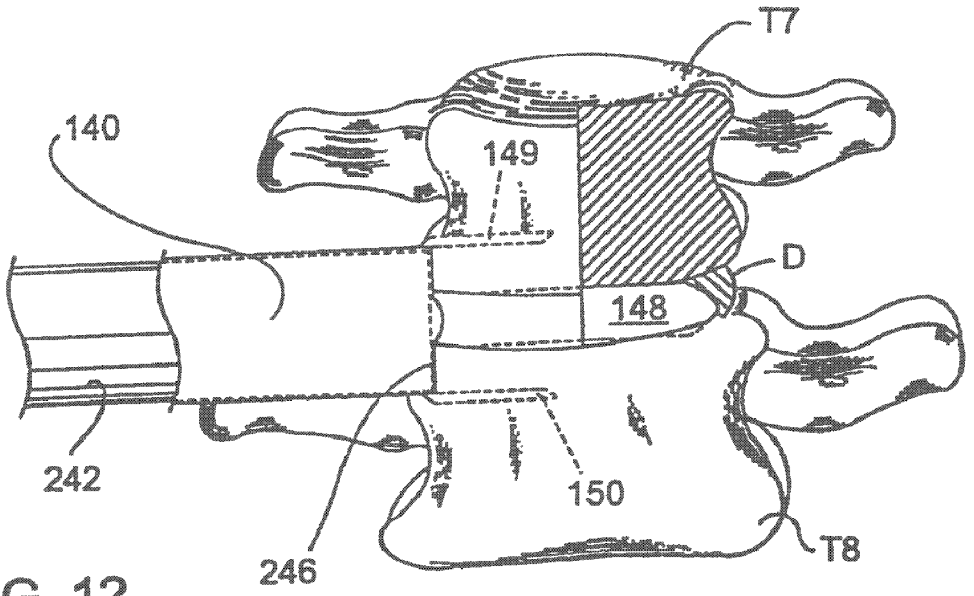

244
248
243
158
172
344
150
149
148
T8
T7
D

FIG. 11


T7
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149
D
148
242
150
T8
246

FIG. 12

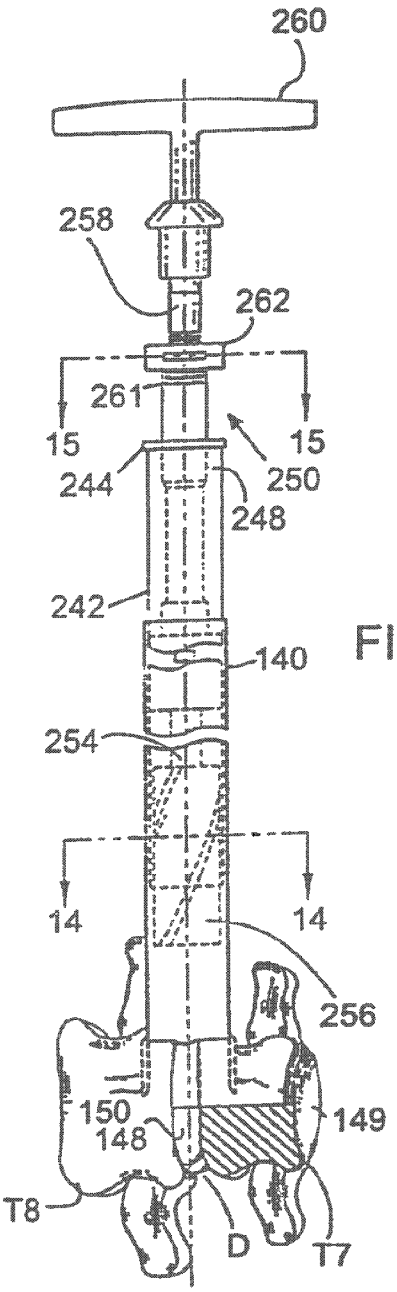


FIG. 13

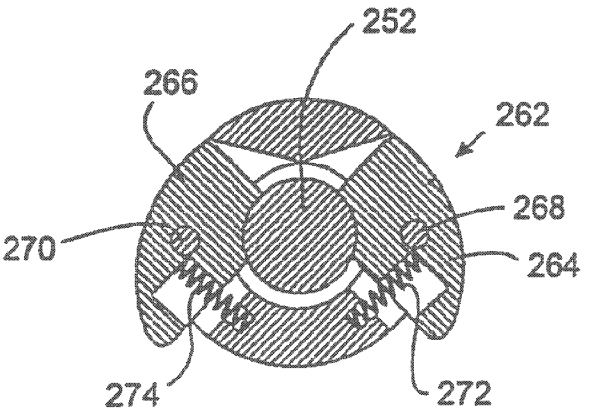


FIG. 15

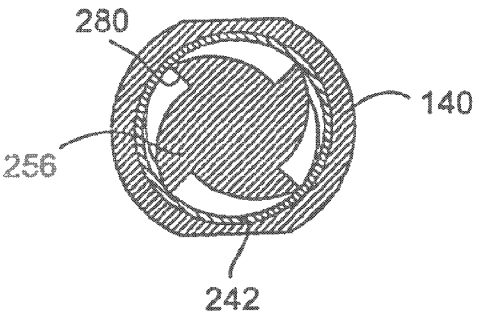
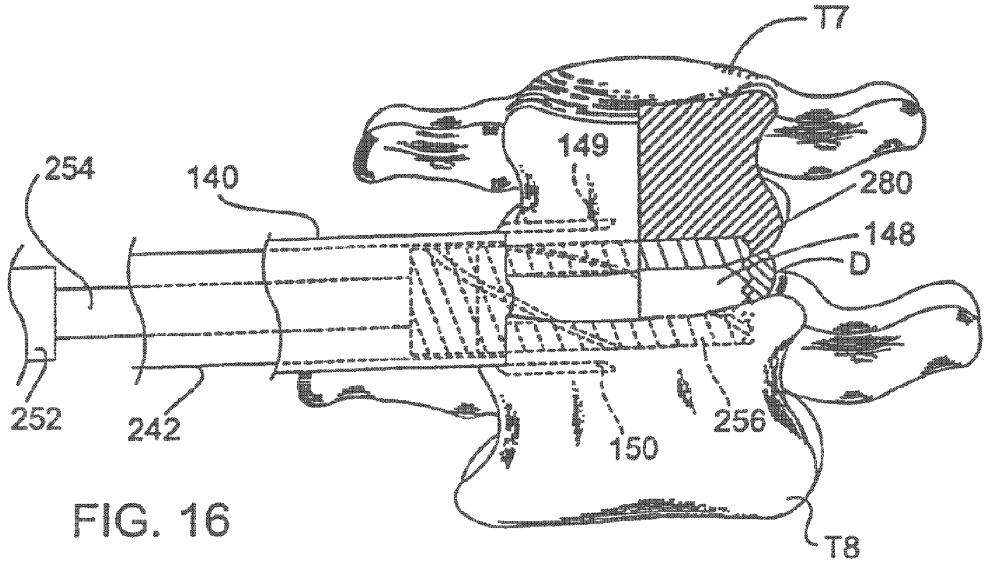


FIG. 14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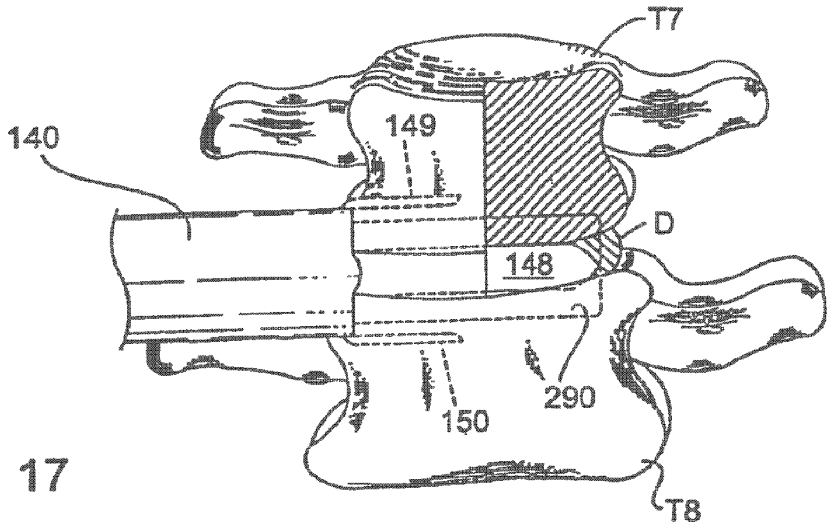
254
140
149
280
148
D
252
242
150
256
T8

FIG. 16


T7
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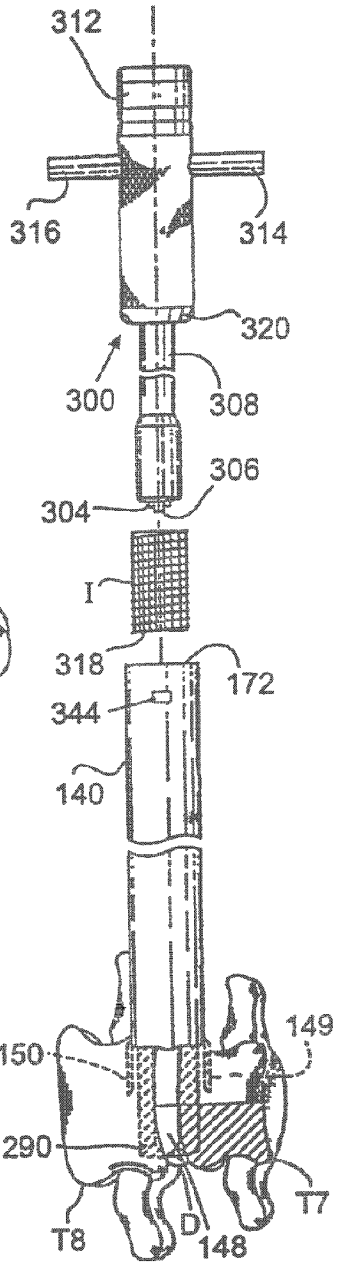
149
D
148
290
150
T8

FIG. 17

FIG. 18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308
306
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I
318
172
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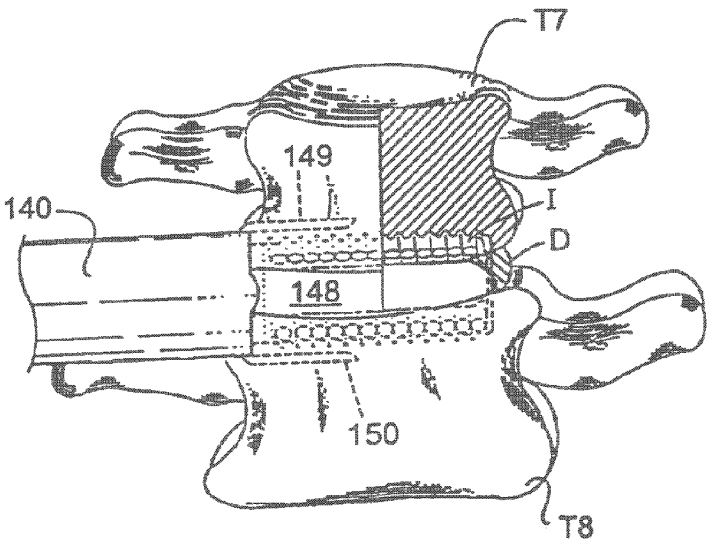
140
149
150
290
T7
T8
D
148


T7
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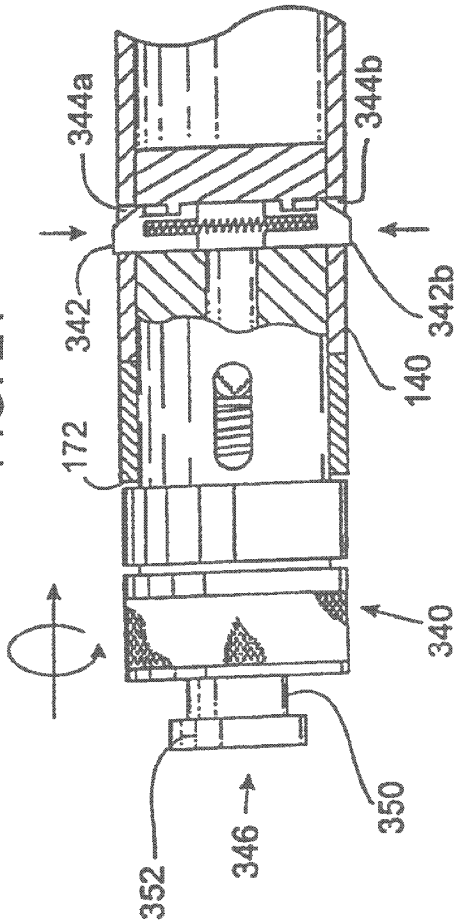
I
D
148
150
T8

FIG. 19


344a
344b
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342b
140
172
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350
346
352

FIG. 21

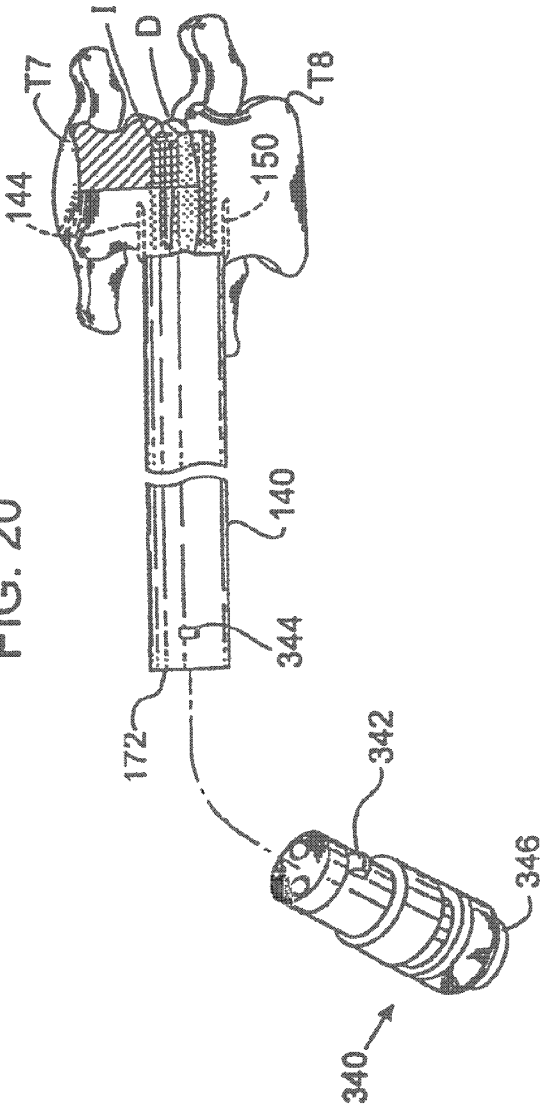

I
D
T7
T8
144
150
140
344
172
342
346
340

FIG. 20

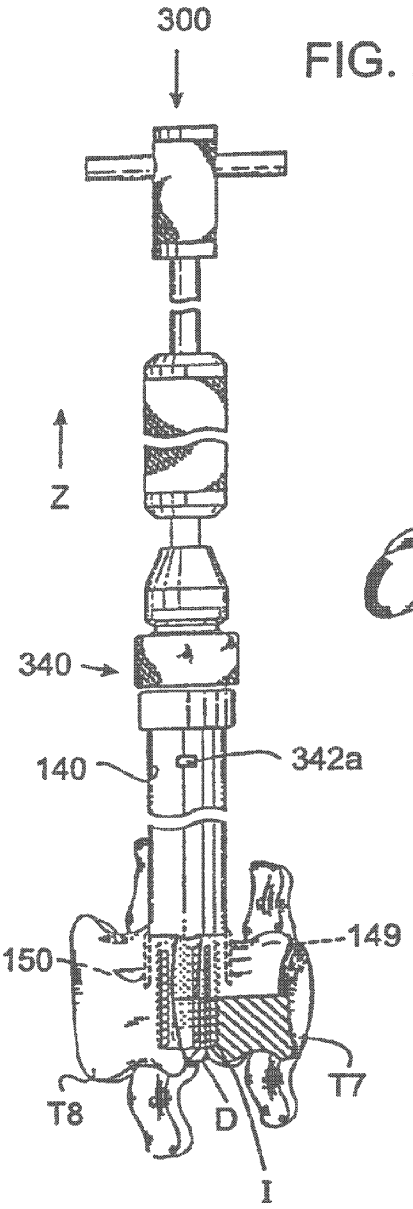


FIG. 22

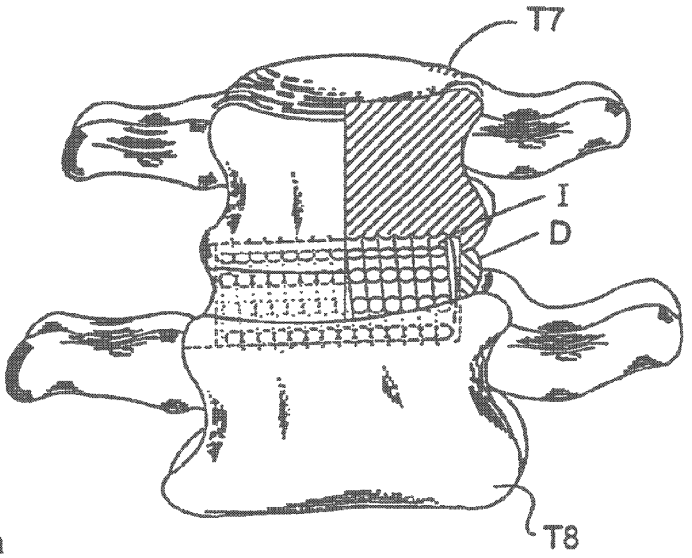


FIG. 23

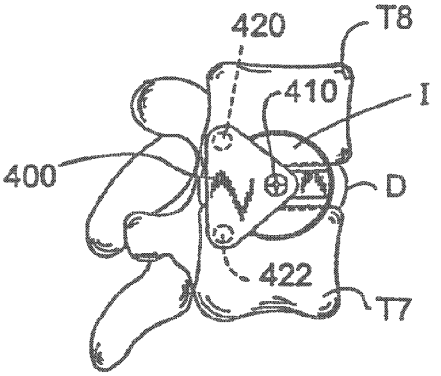


FIG. 24

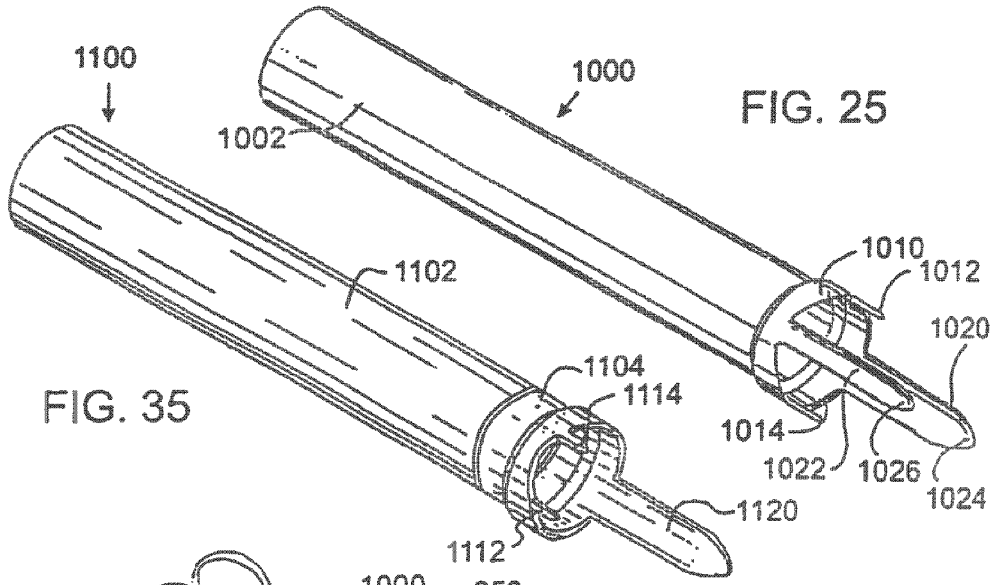


FIG. 35

FIG. 25

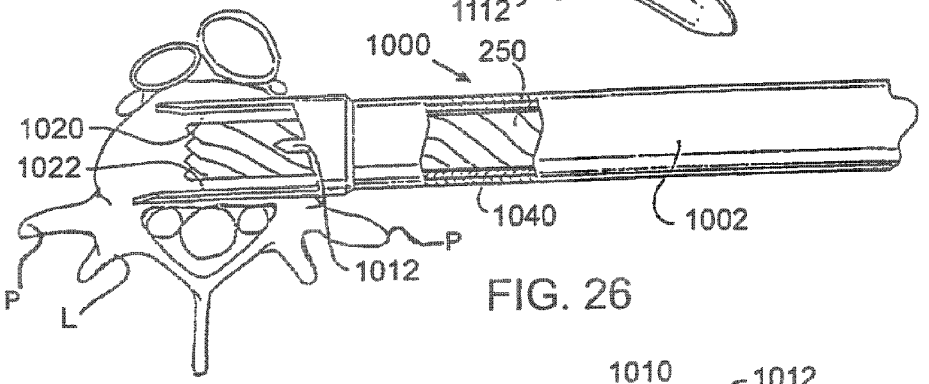


FIG. 26

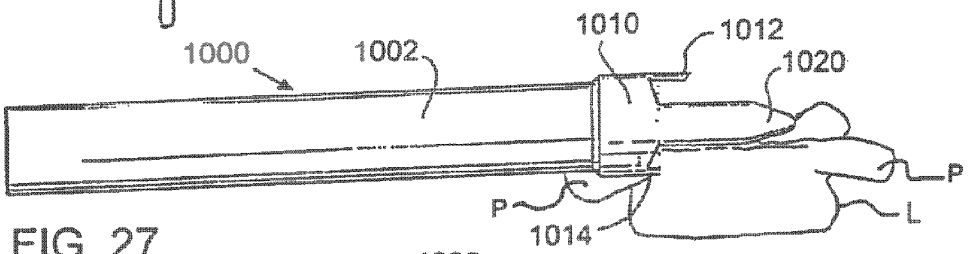


FIG. 27

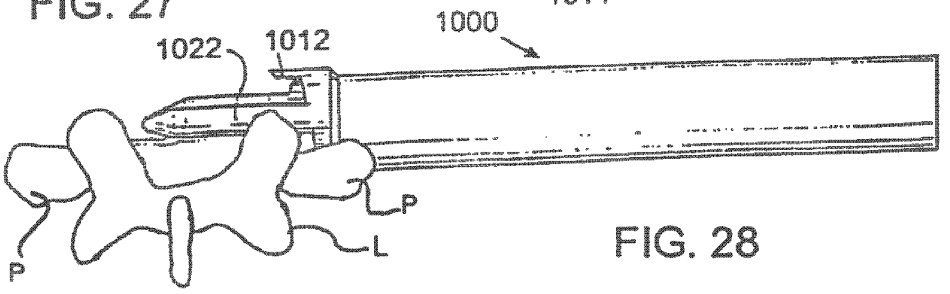
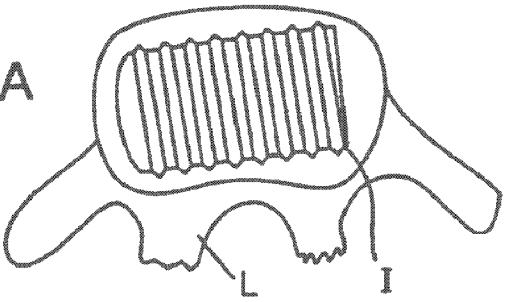


FIG. 28

FIG. 30A



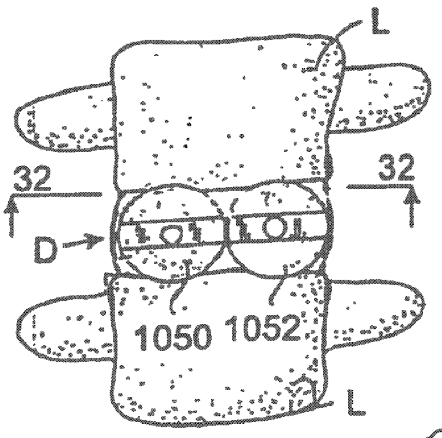


FIG. 31

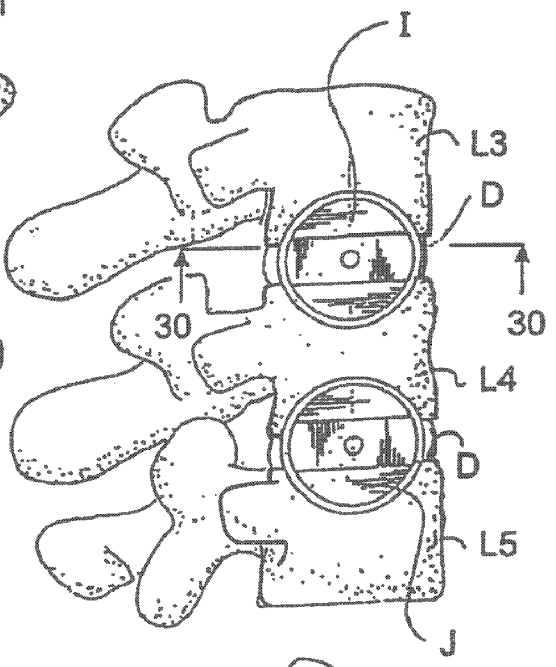


FIG. 29

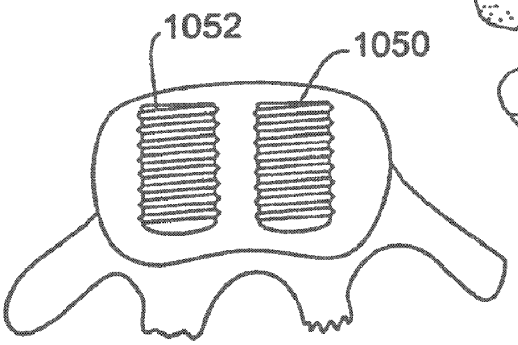


FIG. 32

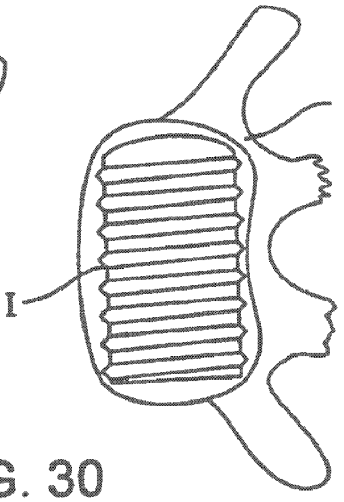


FIG. 30

FIG. 33

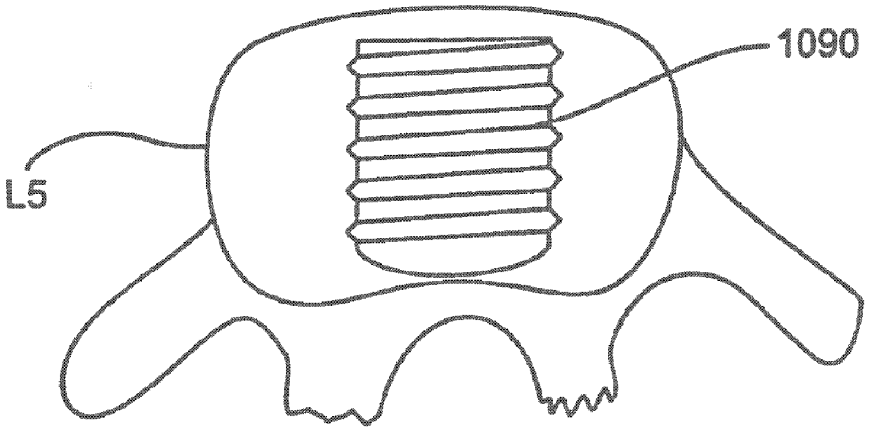
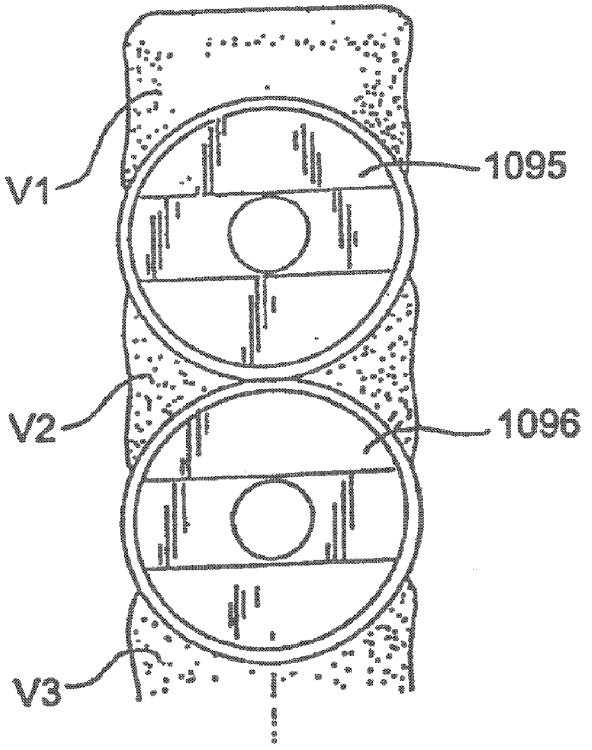


FIG. 34



METHOD FOR INSERTING AN ARTIFICIAL IMPLANT BETWEEN TWO ADJACENT VERTEBRAE ALONG A CORONAL PLANE

This application is a continuation of U.S. application Ser. No. 10/371,757, filed Feb. 21, 2003 (now U.S. Pat. No. 8,066,705); which is a continuation of U.S. application Ser. No. 08/480,461, filed Jun. 7, 1995 (now U.S. Pat. No. 7,491,205); which is a divisional of U.S. application Ser. No. 08/394,836, filed Feb. 27, 1995 (now U.S. Pat. No. 5,772,661); all of which are 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 the Prior 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.

procedures from a lateral approach to the spine (from the side) using fiber optic viewing instruments called thorascopes 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_4 L_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, 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 dosed 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. **7**A 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. **26** 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. **30**A 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 PREFERRED EMBODIMENT

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 (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_7 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 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 hallow 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 distracter **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 **7**A, 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. **7**A, 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 dose 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_6 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 U.S. 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 fiat 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 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 FIGS. **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 snap-fit 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 U.S. 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 **416** 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 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** 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 cave 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, 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 implant 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. **30**A, 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 it **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. **7**A, 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.

I claim:

1. A method comprising:

making an incision in skin of a patient's body to gain access to a disc space between two adjacent vertebrae located within a portion of one of a human thoracic or lumbar spine, said portion of one of the human thoracic or lumbar spine defined by the two adjacent vertebrae having an anterior aspect and a posterior aspect being divided by a first plane through transverse processes of the two adjacent vertebrae, the disc space having a depth measured from an anterior aspect to a posterior aspect of the disc space, each of the two adjacent vertebrae having a vertebral body having a transverse width perpendicular to the depth of the disc space, said incision being proximate an intersection of the skin and a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes;

advancing a first surgical instrument having a length into the body of the patient through said incision until proximate the disc space along said path and anterior to the transverse processes;

advancing a second surgical instrument into the body of the patient through said incision and over at least a portion of the length of said first surgical instrument, said second surgical instrument having a distal end and an opposite proximal end and a length therebetween, said second surgical instrument having a passageway configured to receive a portion of the length of said first surgical instrument therein;

advancing a third surgical instrument into the body of the patient through said incision and over at least a portion of the length of said second surgical instrument, said third surgical instrument having a distal end for insertion over said second surgical instrument and an opposite proximal end;

positioning said third surgical instrument such that said distal end of said third surgical instrument is proximate a lateral aspect of the vertebral bodies of the two adjacent vertebrae; and

inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, a non-bone interbody intraspinal implant through said third surgical instrument into a laterally facing opening in said portion of one of the human thoracic or lumbar spine, said implant having an insertion end for insertion first into the laterally facing opening and a trailing end and a length therebetween, the length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae, the length of said implant being greater than the depth of the disc space, said implant having opposed surfaces oriented toward each of the vertebral bodies of the two adjacent vertebrae when inserted therebetween, said opposed surfaces having bone engaging projections configured to engage the vertebral bodies of the two adjacent vertebrae, said implant having a maximum height between said bone engaging projections of said opposed surfaces and perpendicular to the length of said implant, the length of said implant being greater than the maximum height of said implant.

2. The method of claim **1**, further comprising engaging a spinal fixation device to the adjacent vertebrae after inserting of said implant into the laterally facing opening.

3. The method of claim **2**, wherein said spinal fixation device has a plate configured to cover at least a portion of said trailing end of said implant.

4. The method of claim **1**, further comprising engaging a plate with the adjacent vertebrae to prevent unwanted excursion of said implant from the spine.

5. The method of claim **4**, wherein the engaging of said plate includes attaching a portion of said plate to each of the adjacent vertebrae with a fastening member.

6. The method of claim **4**, wherein the engaging of said plate includes engaging a screw with said plate after inserting of said implant into the laterally facing opening.

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

8. The method of claim **1**, wherein said fusion implant is provided in combination with fusion promoting substances.

9. A method comprising:

making an incision in skin of a patient's body to gain access to a disc space between two adjacent vertebrae located within a portion of one of a human thoracic or lumbar spine, said portion of one of the human thoracic or lumbar spine defined by the two adjacent vertebrae having an anterior aspect and a posterior aspect being divided by a first plane through transverse processes of the two adjacent vertebrae, the disc space having a depth measured from an anterior aspect to a posterior aspect of the disc space, each of the two adjacent vertebrae having a vertebral body having a transverse width perpendicular to the depth of the disc space, said incision being proximate an intersection of the skin and a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes;

advancing a first surgical instrument having a length into the body of the patient through said incision until proximate the disc space along said path and anterior to the transverse processes;

advancing a second surgical instrument into the body of the patient through said incision and over at least a portion of the length of said first surgical instrument, said second surgical instrument having a distal end and an opposite proximal end and a length therebetween, said second surgical instrument having a passageway configured to receive a portion of the length of said first surgical instrument therein;

advancing a third surgical instrument into the body of the patient through said incision and over at least a portion of the length of said second surgical instrument, said third surgical instrument having a distal end for insertion over said second surgical instrument and an opposite proximal end;

positioning a single elongated portion removably attached to said distal end of said third surgical instrument over the disc space, said single elongated portion having a length, a thickness, and a width, the length of said single elongated portion being greater than the width and the thickness of said single elongated portion, the width of said single elongated portion being greater than the thickness of said single elongated portion, said single elongated portion being tapered to facilitate entry between the vertebral bodies of the two adjacent vertebrae;

inserting said single elongated portion into the disc space with the width of said single elongated portion being oriented along a height of the disc space; and

inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, an interbody intraspinal implant through said third surgical instrument into a laterally facing opening in said portion of one of the human thoracic or lumbar spine, said implant having an insertion end for insertion first into the laterally facing opening and a trailing end and a length therebetween, the length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae, the length of said implant being greater than the depth of the disc space, said implant having opposed surfaces oriented toward each of the vertebral bodies of the two adjacent vertebrae when inserted therebetween, said opposed surfaces having bone engaging projections configured to engage the vertebral bodies of the two adjacent vertebrae, said implant having a maximum height between said bone engaging projections of said opposed surfaces and perpendicular to the length of said implant, the length of said implant being greater than the maximum height of said implant.

10. The method of claim **9**, further comprising engaging a spinal fixation device to the adjacent vertebrae after inserting of said implant into the laterally facing opening.

11. The method of claim 10, wherein said spinal fixation device has a plate configured to cover at least a portion of said trailing end of said implant.

12. The method of claim 9, further comprising engaging a plate with the adjacent vertebrae to prevent unwanted excursion of said implant from the spine.

13. The method of claim 12, wherein the engaging of said plate includes attaching a portion of said plate to each of the adjacent vertebrae with a fastening member.

14. The method of claim 12, wherein the engaging of said plate includes engaging a screw with said plate after inserting of said implant into the laterally facing opening.

15. The method of claim 9, further comprising coupling a spinal fixation device to said implant and engaging said spinal fixation device to the adjacent vertebrae.

16. The method of claim 9, wherein said fusion implant is provided in combination with fusion promoting substances.

17. A method comprising:

making an incision in skin of a patient's body to gain access to a disc space between two adjacent vertebrae located within a portion of one of a human thoracic or lumbar spine, said portion of one of the human thoracic or lumbar spine defined by the two adjacent vertebrae having an anterior aspect and a posterior aspect being divided by a first plane through transverse processes of the two adjacent vertebrae, the disc space having a depth measured from an anterior aspect to a posterior aspect of the disc space, each of the two adjacent vertebrae having a vertebral body having a transverse width perpendicular to the depth of the disc space, said incision being proximate an intersection of the skin and a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes;

advancing a first surgical instrument having a length into the body of the patient through said incision until proximate the disc space along said path and anterior to the transverse processes;

advancing a second surgical instrument into the body of the patient through said incision and over at least a portion of the length of said first surgical instrument, said second surgical instrument having a distal end and an opposite proximal end and a length therebetween, said second surgical instrument having a passageway configured to receive a portion of the length of said first surgical instrument therein;

advancing a third surgical instrument into the body of the patient through said incision and over at least a portion of the length of said second surgical instrument, said third surgical instrument having a distal end for insertion over said second surgical instrument and an opposite proximal end, said third surgical instrument having at least two elongated portions for insertion into the patient, each of said elongated portions having a length, a width, and a thickness, said length of each of said at least two elongated portions being greater than the width and the thickness of said at least two elongated portions, each of said at least two elongated portions have a cross section through the width and the thickness and perpendicular to the length of said at least two elongated portions, respectively, each cross section of said at least two elongated portions having a convex exterior surface, said convex surfaces of each of said at least two elongated portions having the same curvature;

positioning said third surgical instrument such that at least part of one of said at least two elongated portions is over one of the two adjacent vertebrae and at least part of another of said at least two elongated portions is over the other of the two adjacent vertebrae; and

inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, an interbody intraspinal implant through said third surgical instrument into a laterally facing opening in said portion of one of the human thoracic or lumbar spine, said implant having an insertion end for insertion first into the laterally facing opening and a trailing end and a length therebetween, the length of said implant being sized to occupy substantially the full transverse width of the vertebral bodies of the two adjacent vertebrae, the length of said implant being greater than the depth of the disc space, said implant having opposed surfaces oriented toward each of the vertebral bodies of the two adjacent vertebrae when inserted therebetween, said opposed surfaces having bone engaging projections configured to engage the vertebral bodies of the two adjacent vertebrae, said implant having a maximum height between said bone engaging projections of said opposed surfaces and perpendicular to the length of said implant, the length of said implant being greater than the maximum height of said implant.

18. The method of claim 17, further comprising engaging a spinal fixation device to the adjacent vertebrae after inserting of said implant into the laterally facing opening.

19. The method of claim 18, wherein said spinal fixation device has a plate configured to cover at least a portion of said trailing end of said implant.

20. The method of claim 17, further comprising engaging a plate with the adjacent vertebrae to prevent unwanted excursion of said implant from the spine.

21. The method of claim 20, wherein the engaging of said plate includes attaching a portion of said plate to each of the adjacent vertebrae with a fastening member.

22. The method of claim 20, wherein the engaging of said plate includes engaging a screw with said plate after inserting of said implant into the laterally facing opening.

23. The method of claim 17, wherein said fusion implant is provided in combination with fusion promoting substances.

24. A method comprising:

making an incision in skin of a patient's body to gain access to a disc space between two adjacent vertebrae located within a portion of one of a human thoracic or lumbar spine, said portion of one of the human thoracic or lumbar spine defined by the two adjacent vertebrae having an anterior aspect and a posterior aspect being divided by a first plane through transverse processes of the two adjacent vertebrae the disc space having a depth measured from an anterior aspect to a posterior aspect of the disc space, each of the two adjacent vertebrae having a vertebral body having a transverse width perpendicular to the depth of the disc space, said incision being proximate an intersection of the skin and a path having an axis lying in a coronal plane passing through a lateral aspect and a medial aspect of the two adjacent vertebrae and anterior to the transverse processes;

advancing a first surgical instrument having a length into the body of the patient through said incision and along said path and anterior to the transverse processes;

advancing a second surgical instrument into the body of the patient through said incision and over at least a portion of said length of said first surgical instrument, said second surgical instrument having a distal end and an opposite proximal end and a length there between, said sec-

ond surgical instrument having a passageway configured to receive a portion of said length of said first surgical instrument therein;

advancing a third surgical instrument into the body of the patient through said incision and over at least a portion of the length of said second surgical instrument, said third surgical instrument having a distal end for insertion over said second surgical instrument and an opposite proximal end, said third surgical instrument having a first, a second, and a third elongated portion for insertion into the patient, each of said elongated portions having a length, a width, and a thickness, the length of said first elongated portion being greater than the width and the thickness of said first elongated portion, the width of said first elongated portion being greater than the thickness of said first elongated portion, the width of said first elongated portion proximate said distal end of said third surgical instrument having a midpoint, the length of said second elongated portion being greater than the width and the thickness of said second elongated portion, the length of said third elongated portion being greater than the width and the thickness of said third elongated portion, each of said first, second, and third elongated portions have a cross section through the width and the thickness and perpendicular to the length thereof, each cross section of said first, second, and third elongated portions having a convex exterior surface, said convex exterior surfaces of each of said second and third elongated portions having the same curvature;

positioning said third surgical instrument such that the midpoint of the width of said first elongated portion is over the disc space and said second elongated portion is over one of the two adjacent vertebrae and said third elongated portion is over the other of the two adjacent vertebrae;

withdrawing said second surgical instrument and said first surgical instrument from the body; and

inserting, from the position anterior to the transverse processes of the two adjacent vertebrae and along said path, an interbody intraspinal implant through said third surgical instrument into a laterally facing opening in said portion of one of the human thoracic or lumbar spine, said implant having an insertion end for insertion first into the laterally facing opening and a trailing end and a length therebetween, the length of said implant being sized to occupy the full transverse width of the vertebral bodies of the two adjacent vertebrae, the length of said implant being greater than the depth of the disc space, said implant having opposed surfaces oriented toward each of the vertebral bodies of the two adjacent vertebrae when inserted therebetween, said opposed surfaces having bone engaging projections configured to engage the vertebral bodies of the two adjacent vertebrae, said implant having a maximum height between said bone engaging projections of said opposed surfaces and perpendicular to the length of said implant, the length of said implant being greater than the maximum height of said implant.

25. The method of claim **24** further comprising engaging a spinal fixation device to the adjacent vertebrae after inserting of said implant into the laterally facing opening.

26. The method of claim **25** wherein said spinal fixation device has a plate configured to cover at least a portion of said trailing end of said implant.

27. The method of claim **24** further comprising engaging a plate with the adjacent vertebrae to prevent unwanted excursion of said implant from the spine.

28. The method of claim **27** wherein the engaging of said plate includes attaching a portion of said plate to each of the adjacent vertebrae with a fastening member.

29. The method of claim **27** wherein the engaging of said plate includes engaging a screw with said plate after inserting of said implant into the laterally facing opening.

30. The method of claim **24** wherein said fusion implant is provided in combination with fusion promoting substances.

* * * * *

EXHIBIT D

US008444696B2

(12) **United States Patent**
Michelson

(10) **Patent No.: US 8,444,696 B2**
(45) **Date of Patent: *May 21, 2013**

(54) **ANATOMIC SPINAL IMPLANT HAVING ANATOMIC BEARING SURFACES**

(75) Inventor: **Gary Karlin Michelson**, Venice, CA (US)

(73) Assignee: **Warsaw Orthopedic, Inc.**, Warsaw, IN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 3 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **13/235,998**

(22) Filed: **Sep. 19, 2011**

(65) **Prior Publication Data**

US 2012/0071982 A1 Mar. 22, 2012

Related U.S. Application Data

(60) Continuation of application No. 12/807,489, filed on Sep. 7, 2010, now Pat. No. 8,021,430, which is a continuation of application No. 10/926,766, filed on Aug. 26, 2004, now Pat. No. 7,789,914, which is a continuation of application No. 10/237,751, filed on Sep. 9, 2002, now Pat. No. 7,503,933, which is a continuation of application No. 09/412,090, filed on Oct. 4, 1999, now Pat. No. 6,447,544, which is a continuation of application No. 08/813,283, filed on Mar. 10, 1997, now Pat. No. 6,302,914, which is a division of application No. 08/482,146, filed on Jun. 7, 1995, now Pat. No. 5,609,635.

(51) **Int. Cl.**
A61F 2/44 (2006.01)

(52) **U.S. Cl.**
USPC **623/17.16**

(58) **Field of Classification Search**
USPC 623/17.11–17.16, 16.11, 14.12, 18.11; 606/246–249, 99
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,372,622	A	3/1945	Fasslo
2,677,369	A	5/1954	Knowles
3,298,372	A	1/1967	Feinberg
3,605,123	A	9/1971	Hahn
3,848,601	A	11/1974	Ma et al.

(Continued)

FOREIGN PATENT DOCUMENTS

WO	WO 93/01771 A1	2/1993
WO	WO 95/08306	3/1995

OTHER PUBLICATIONS

Request for Inter Partes Reexamination of U.S. Patent No. 8,021,430, dated Sep. 14, 2012, 477 pages.

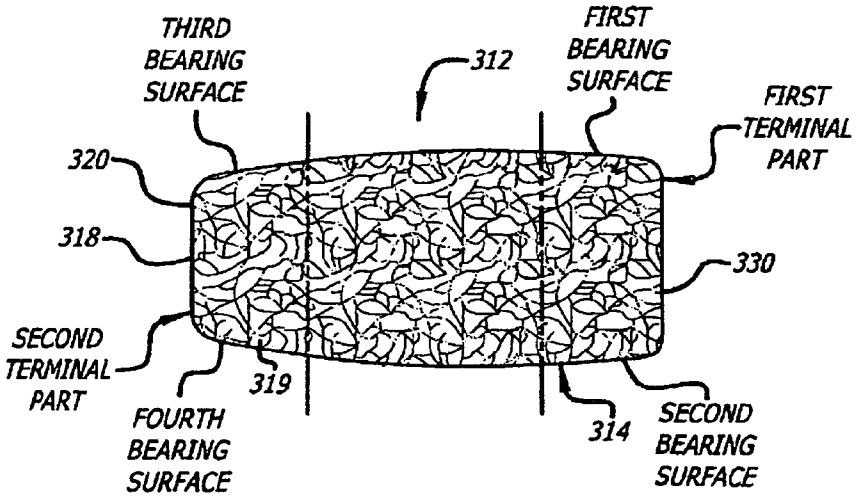
(Continued)

Primary Examiner — Alvin Stewart
(74) *Attorney, Agent, or Firm* — Martin & Ferraro, LLP

(57) **ABSTRACT**

The present application is directed to an interbody spinal implant having a structural configuration that provides for maintaining the normal anatomic relationship of two adjacent vertebrae of the spine. The spinal implant is sized to fit within the disc space created by the removal of disc material between two adjacent vertebrae and conform wholly, or in part, to the disc space created. The spinal implant of the present invention has first and second sides with upper and lower bearing surfaces that form a support structure for bearing against the end plates of the adjacent vertebrae. The upper and lower bearing surfaces of the first and second sides are shaped to create an anatomic fit with the endplates of the adjacent vertebrae.

19 Claims, 11 Drawing Sheets



U.S. PATENT DOCUMENTS

3,867,728	A	2/1975	Stubstad et al.
3,875,595	A	4/1975	Froning
3,905,047	A	9/1975	Long
3,948,262	A	4/1976	Zaffaroni
3,952,334	A	4/1976	Bokros et al.
3,987,499	A	10/1976	Scharbach et al.
D245,259	S	8/1977	Shen
4,070,514	A	1/1978	Eatherly et al.
4,168,326	A	9/1979	Broemer et al.
4,309,777	A	1/1982	Patil
4,349,921	A	9/1982	Kuntz
4,401,112	A	8/1983	Rezaian
4,405,319	A	9/1983	Cosentino
4,439,152	A	3/1984	Small
4,501,269	A	2/1985	Bagby
4,507,115	A	3/1985	Kambara et al.
4,535,485	A	8/1985	Ashman et al.
4,542,539	A	9/1985	Rowe, Jr. et al.
4,545,374	A	10/1985	Jacobson
4,547,390	A	10/1985	Ashman et al.
4,553,273	A	11/1985	Wu
4,554,914	A	11/1985	Kapp et al.
4,566,466	A	1/1986	Ripple et al.
4,599,086	A	7/1986	Doty
4,604,995	A	8/1986	Stephens et al.
4,608,052	A	8/1986	Van Kampen et al.
4,634,720	A	1/1987	Dorman et al.
4,636,217	A	1/1987	Ogilvie et al.
4,636,526	A	1/1987	Dorman et al.
4,645,503	A	2/1987	Lin et al.
4,655,777	A	4/1987	Dunn et al.
4,661,536	A	4/1987	Dorman et al.
4,693,721	A	9/1987	Ducheyne
4,698,375	A	10/1987	Dorman et al.
4,714,469	A	12/1987	Kenna
4,721,103	A	1/1988	Freedland
4,743,256	A	5/1988	Brantigan
4,759,766	A	7/1988	Buettner-Janz et al.
4,759,769	A	7/1988	Hedman et al.
4,763,644	A	8/1988	Webb
4,820,305	A	4/1989	Harms et al.
4,834,757	A	5/1989	Brantigan
4,863,476	A	9/1989	Shepperd
4,863,477	A	9/1989	Monson
4,865,603	A	9/1989	Noiles
4,877,020	A	10/1989	Vich
4,878,915	A	11/1989	Brantigan
4,904,261	A	2/1990	Dove et al.
4,911,718	A	3/1990	Lee et al.
4,936,848	A	6/1990	Bagby
4,955,908	A	9/1990	Frey et al.
4,961,740	A	10/1990	Ray et al.
5,015,247	A	5/1991	Michelson
5,026,373	A	6/1991	Ray et al.
5,055,104	A	10/1991	Ray
5,062,845	A	11/1991	Kuslich et al.
5,071,437	A	12/1991	Steffee
5,122,130	A	6/1992	Keller
5,123,926	A	6/1992	Pisharodi
5,171,278	A	12/1992	Pisharodi
5,190,548	A	3/1993	Davis
5,192,327	A	3/1993	Brantigan
5,246,458	A	9/1993	Graham
5,250,061	A	10/1993	Michelson
5,258,031	A	11/1993	Salib et al.
5,258,043	A	11/1993	Stone
5,304,191	A	4/1994	Gosselin
5,306,308	A	4/1994	Gross et al.
5,306,309	A	4/1994	Wagner et al.
5,360,430	A	11/1994	Lin
5,370,697	A	12/1994	Baumgartner
5,397,364	A	3/1995	Kozak et al.
5,425,772	A	6/1995	Brantigan
5,443,514	A	8/1995	Steffee
5,445,639	A	8/1995	Kuslich et al.
5,458,638	A	10/1995	Kuslich et al.
5,458,643	A	10/1995	Oka et al.
5,484,437	A	1/1996	Michelson
5,489,307	A	2/1996	Kuslich et al.
5,489,308	A	2/1996	Kuslich et al.
5,499,984	A	3/1996	Steiner et al.
5,514,180	A	5/1996	Heggeness et al.
5,522,899	A	6/1996	Michelson
5,534,028	A	7/1996	Bao et al.
5,554,191	A	9/1996	Lahille et al.
5,571,109	A	11/1996	Bertagnoli
5,571,190	A	11/1996	Ulrich et al.
5,607,424	A	3/1997	Tropiano
5,609,635	A	3/1997	Michelson
5,609,636	A	3/1997	Kohrs et al.
5,609,637	A	3/1997	Biedermann et al.
5,645,596	A	7/1997	Kim et al.
5,658,335	A	8/1997	Allen
5,658,337	A	8/1997	Kohrs et al.
5,665,122	A	9/1997	Kambin
5,669,909	A	9/1997	Zdeblick et al.
5,683,463	A	11/1997	Godefroy et al.
5,766,252	A	6/1998	Henry et al.
5,769,897	A	6/1998	Härle
5,776,199	A	7/1998	Michelson
5,782,919	A	7/1998	Zdeblick et al.
5,800,547	A	9/1998	Schäfer et al.
5,824,094	A	10/1998	Serhan et al.
5,861,041	A	1/1999	Tienboon
5,888,223	A	3/1999	Bray
5,888,224	A	3/1999	Beckers et al.
5,893,890	A	4/1999	Pisharodi
5,980,522	A	11/1999	Koros et al.
5,984,967	A	11/1999	Zdeblick et al.
6,059,829	A	5/2000	Schläpfer et al.
6,149,686	A	11/2000	Kuslich et al.
6,159,214	A	12/2000	Michelson
6,302,914	B1	10/2001	Michelson
6,447,544	B1	9/2002	Michelson
6,558,423	B1	5/2003	Michelson
6,613,091	B1	9/2003	Zdeblick et al.
7,056,342	B2	6/2006	Michelson
7,503,933	B2	3/2009	Michelson
7,789,914	B2	9/2010	Michelson
8,021,430	B2	9/2011	Michelson

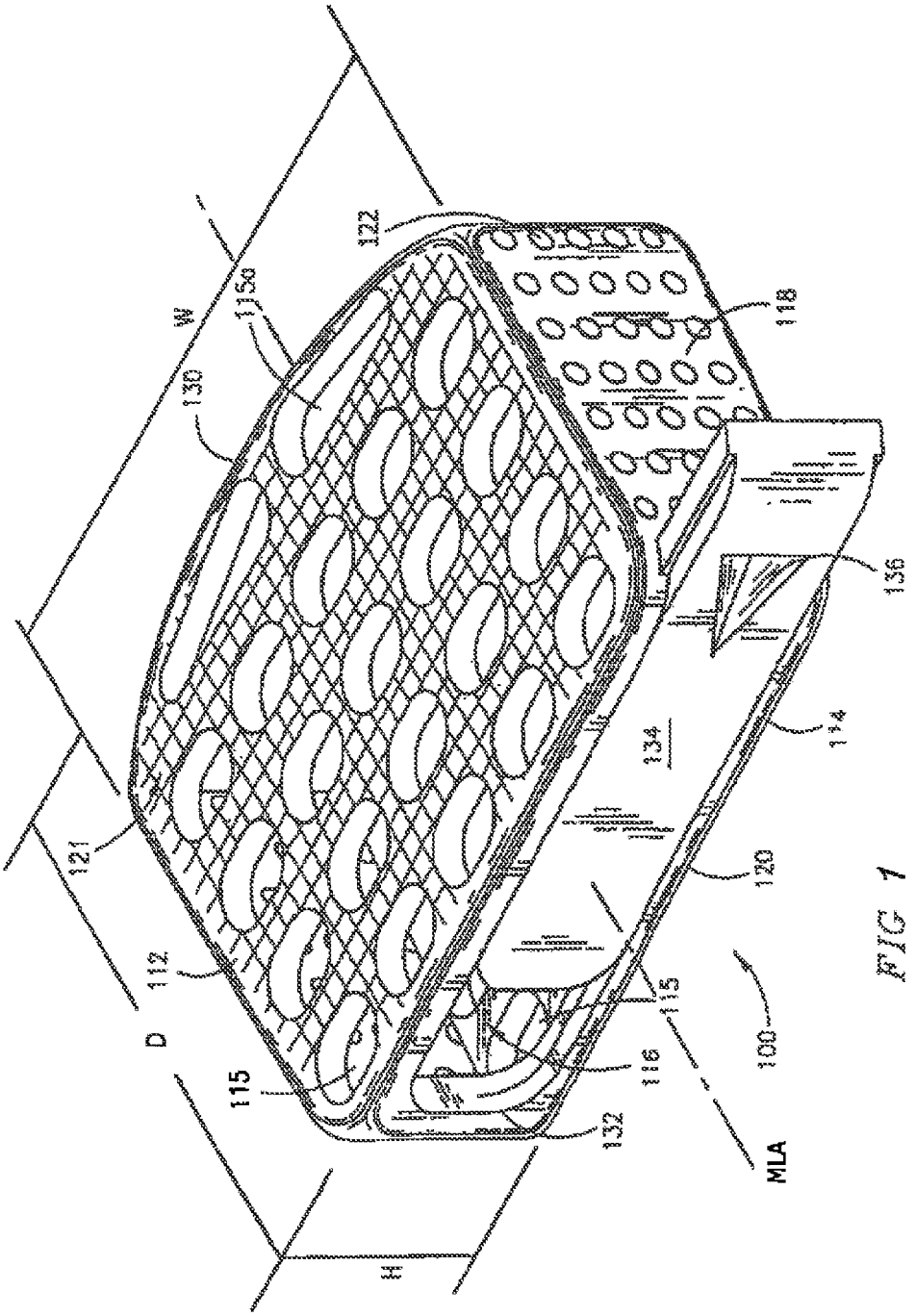
OTHER PUBLICATIONS

Office Action from Reexamination Proceeding No. 95/002,380; mailed Nov. 29, 2012; 18 pages.

Amendment in Reexam Control No. 95/002,380, filed Feb. 19, 2013, 15 pages.

Third Party Comments in Reexam Control No. 95/002,380, filed Mar. 21, 2013, 52 pages.

Decision Expunging Papers in Reexamination Control No. 95/002,380, Mar. 26, 2013, 4 pages.


122
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MLA
H

FIG 1

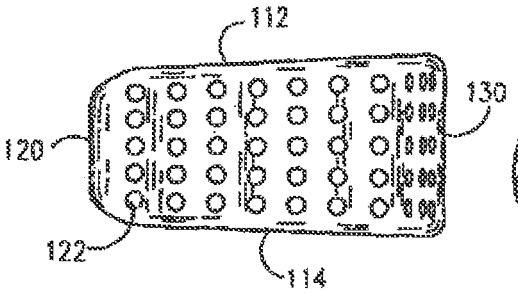

FIG 3

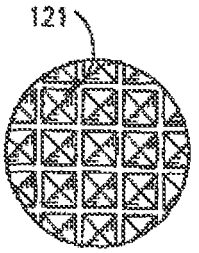

FIG 7

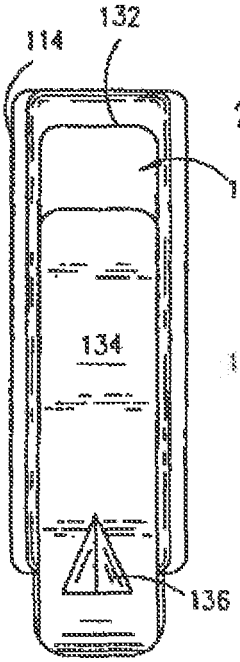

FIG 5

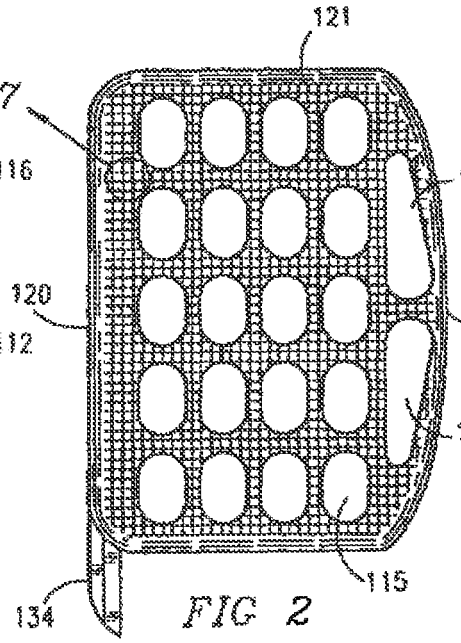

FIG 2

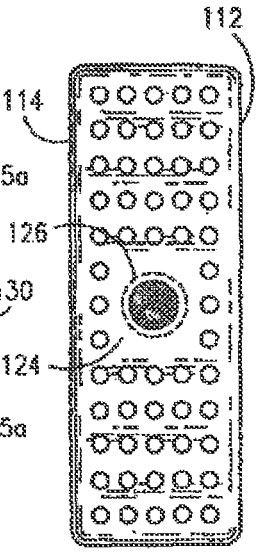

FIG 6

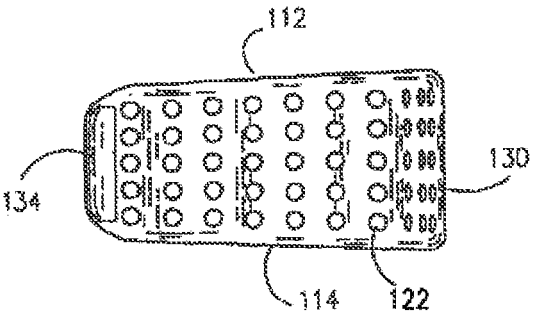

FIG 4

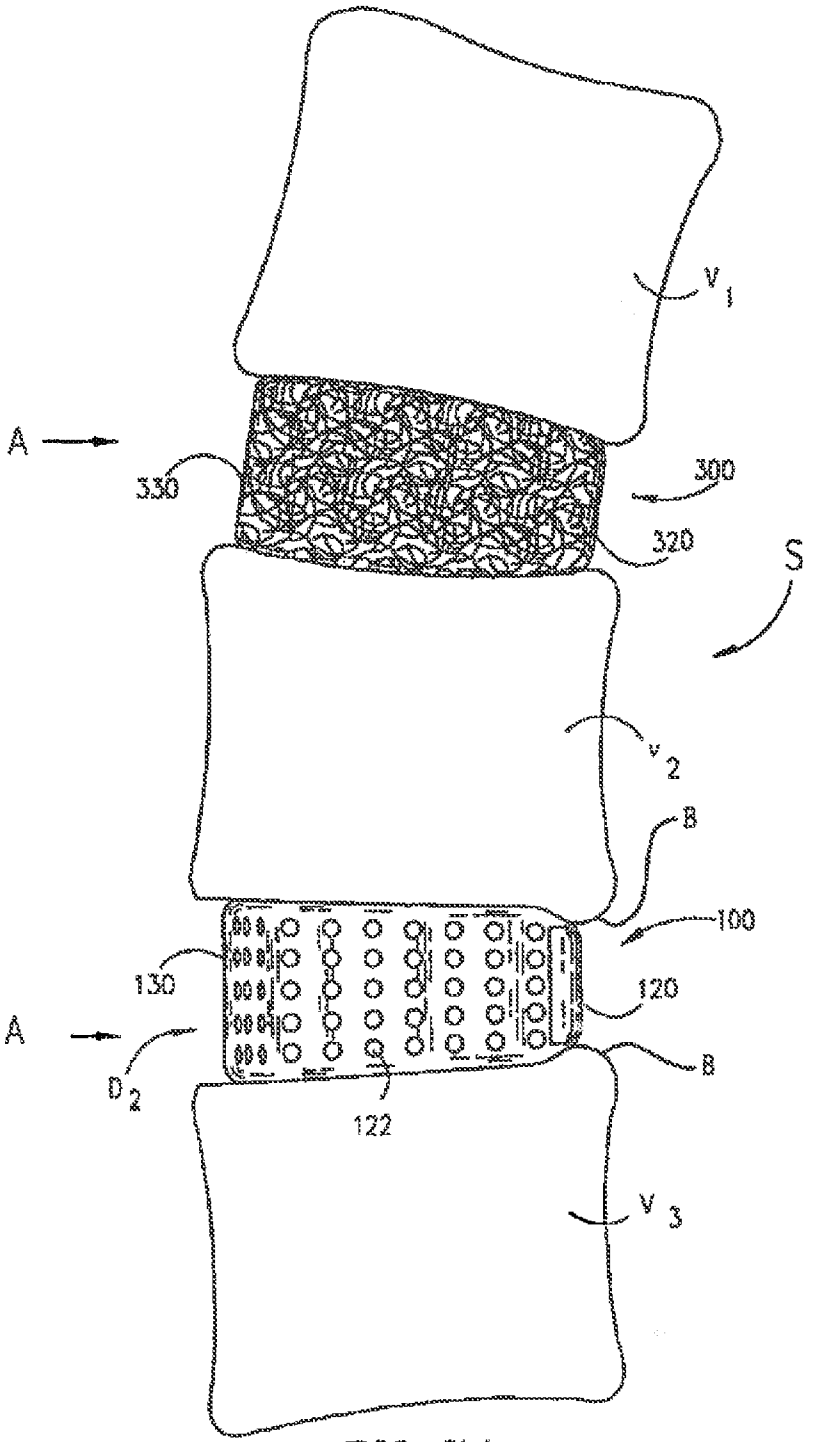

FIG 7A

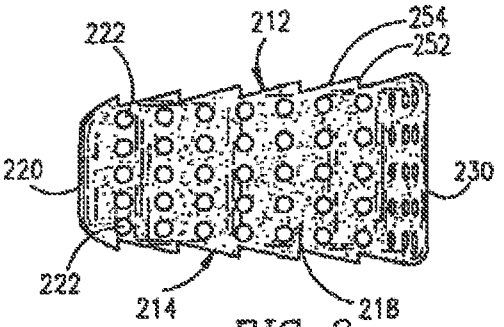

FIG 9

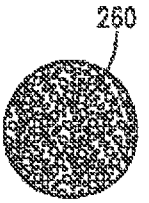

FIG 12

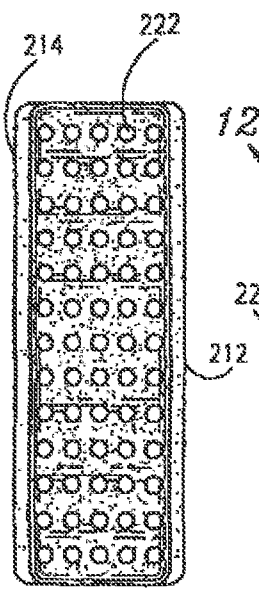

FIG 10

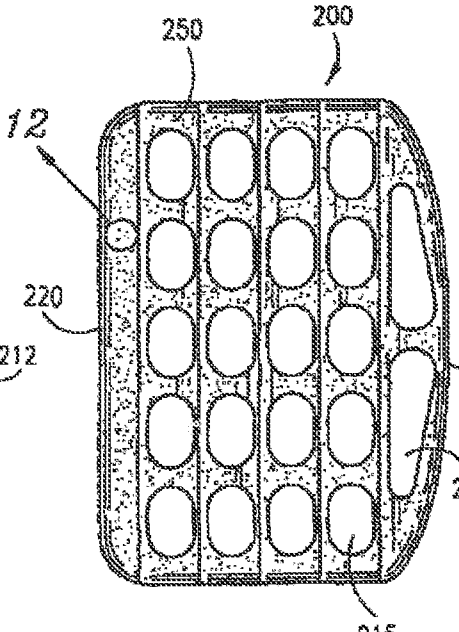

FIG 8

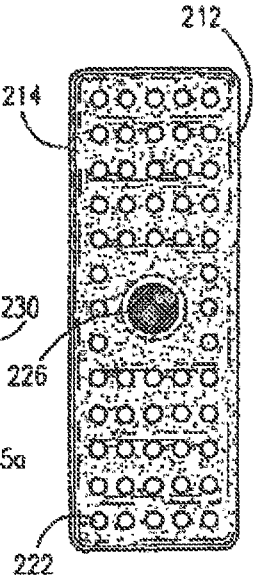

FIG 11

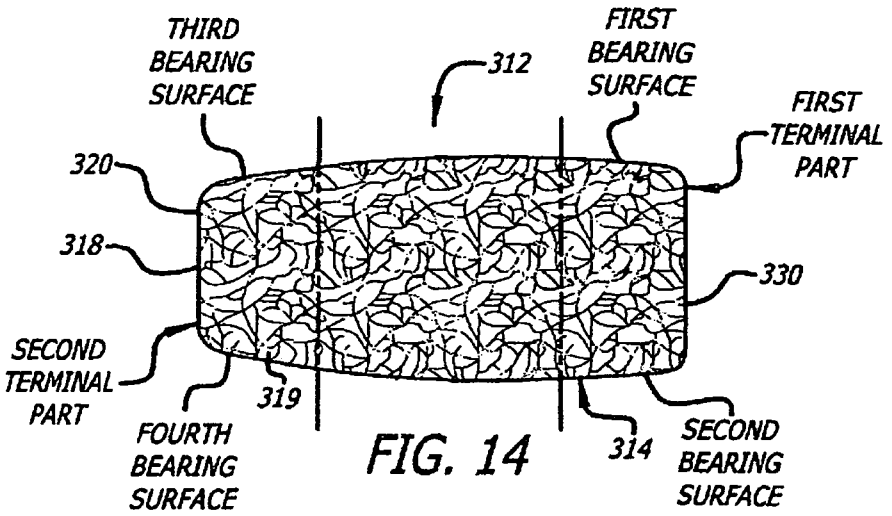
THIRD BEARING SURFACE
312
FIRST BEARING SURFACE
FIRST TERMINAL PART
320
318
330
SECOND TERMINAL PART
319
FOURTH BEARING SURFACE
314
SECOND BEARING SURFACE

FIG. 14

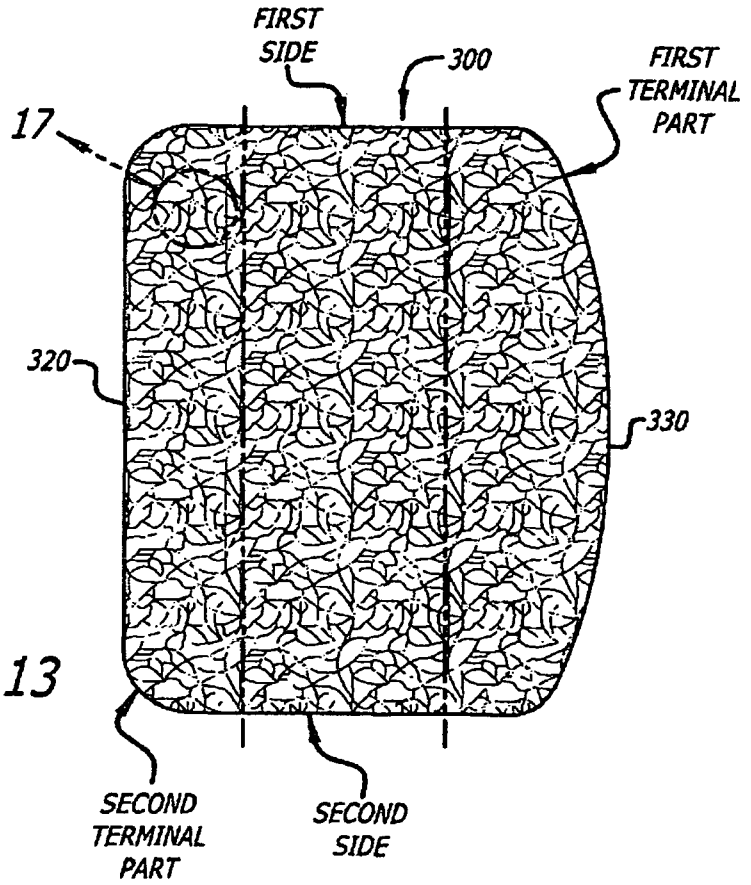
FIRST SIDE
300
FIRST TERMINAL PART
17
320
330
SECOND TERMINAL PART
SECOND SIDE

FIG. 13

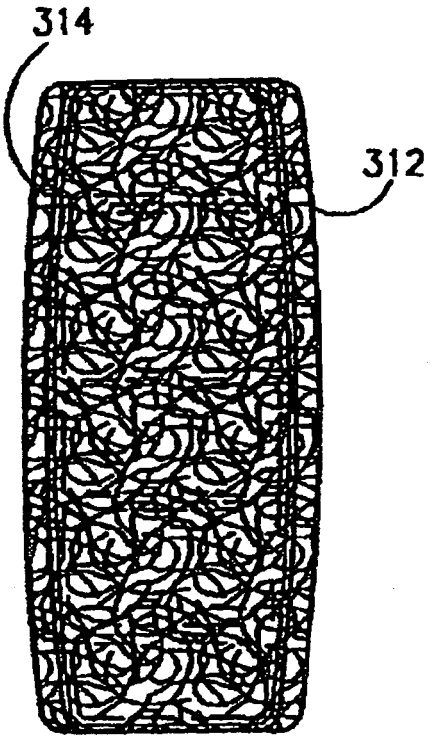

FIG 15

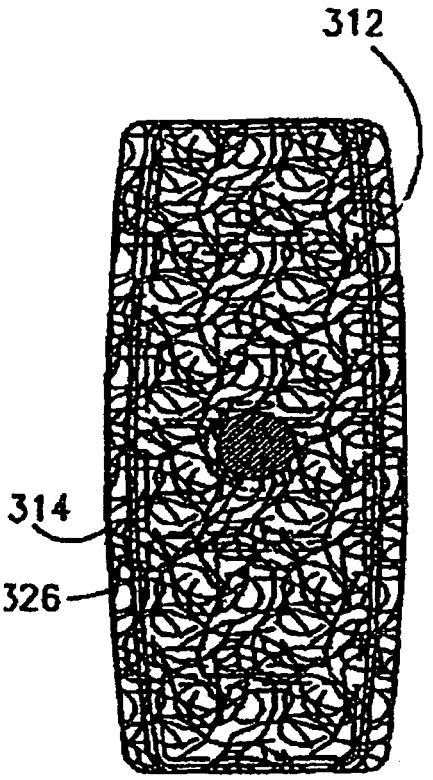

FIG 16

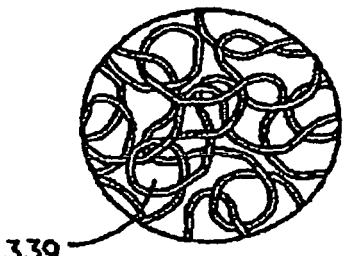

FIG 17

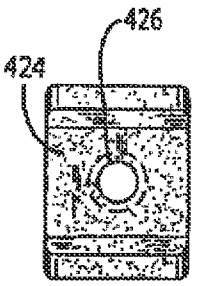

FIG 21

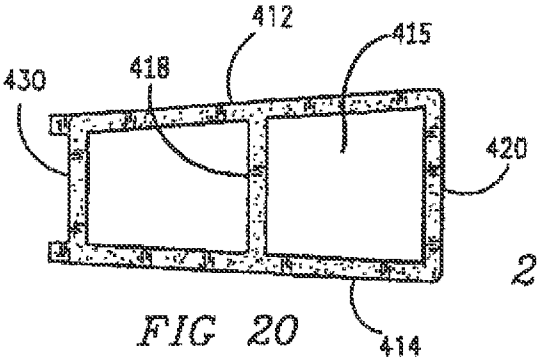

FIG 20

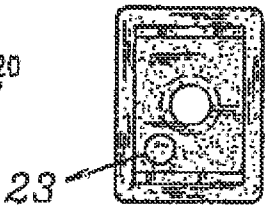

FIG 22

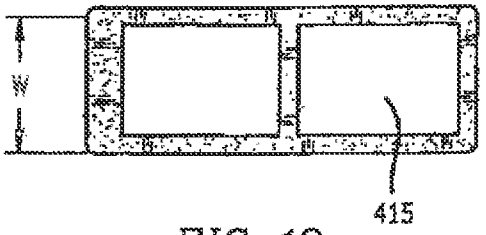

FIG 19

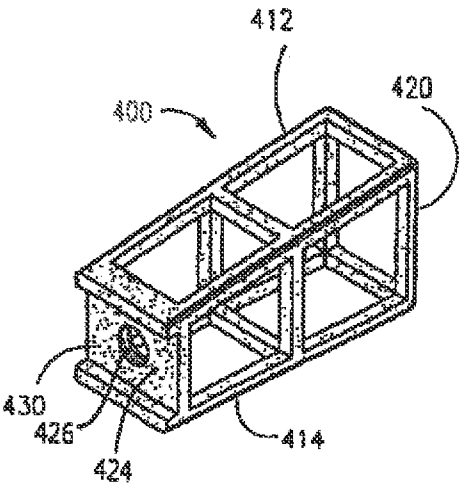

FIG 18

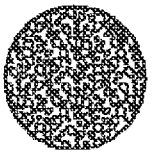

FIG 23

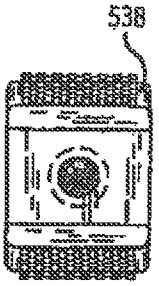

FIG 26

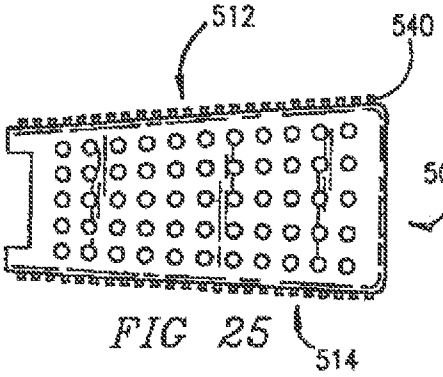

FIG 25

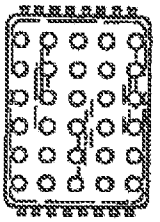

FIG 27

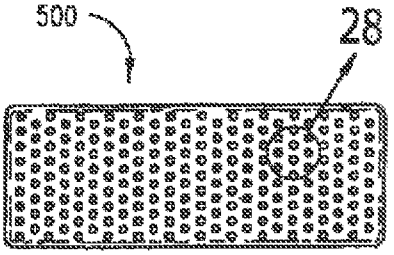

FIG 24

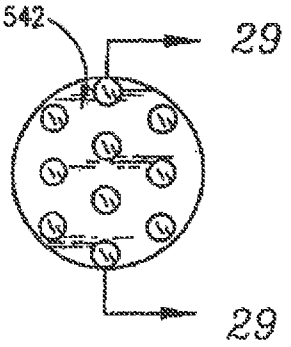

FIG 28

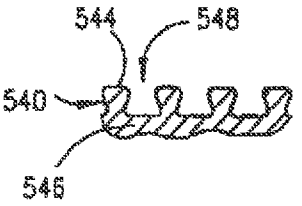

FIG 29

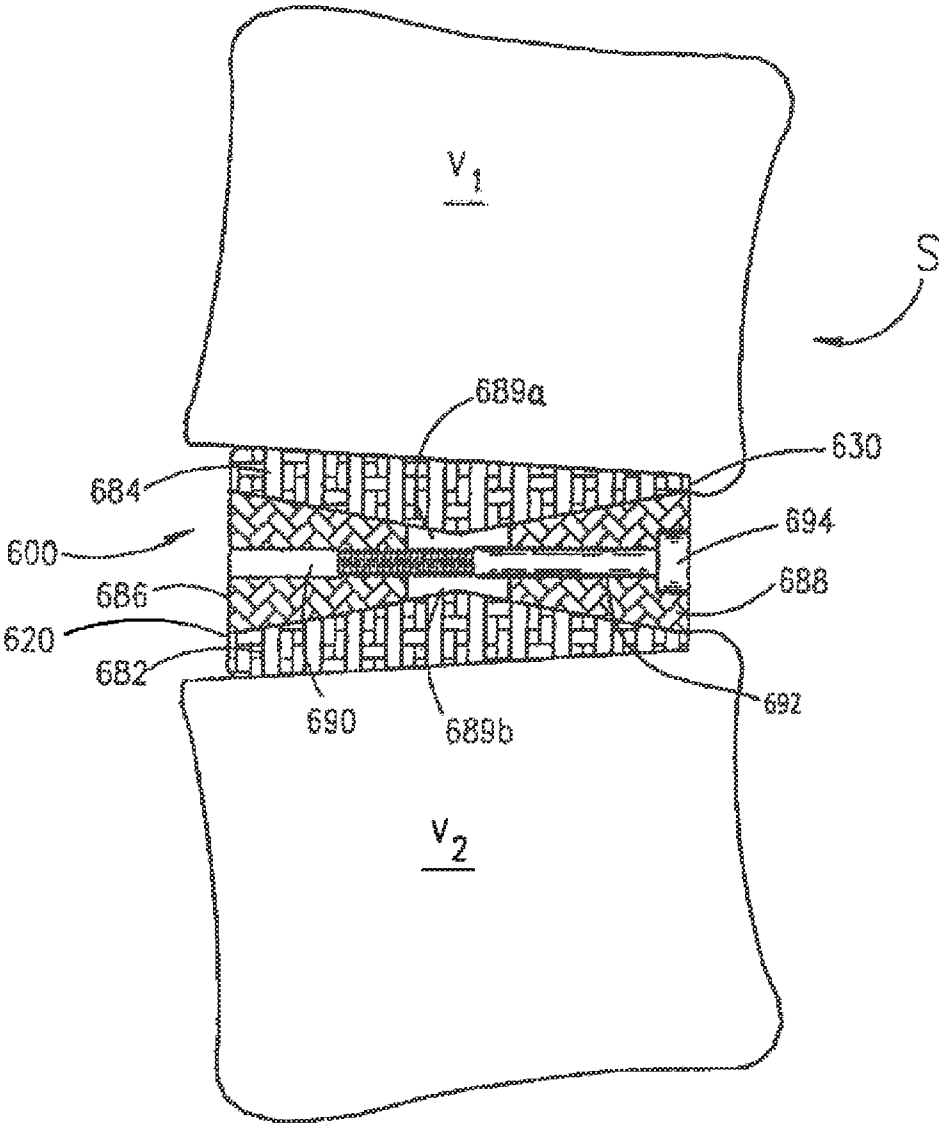

FIG 30

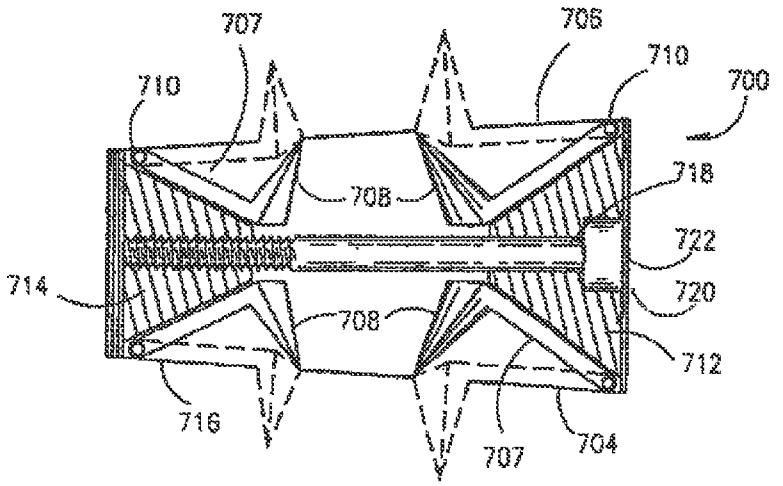

FIG 31

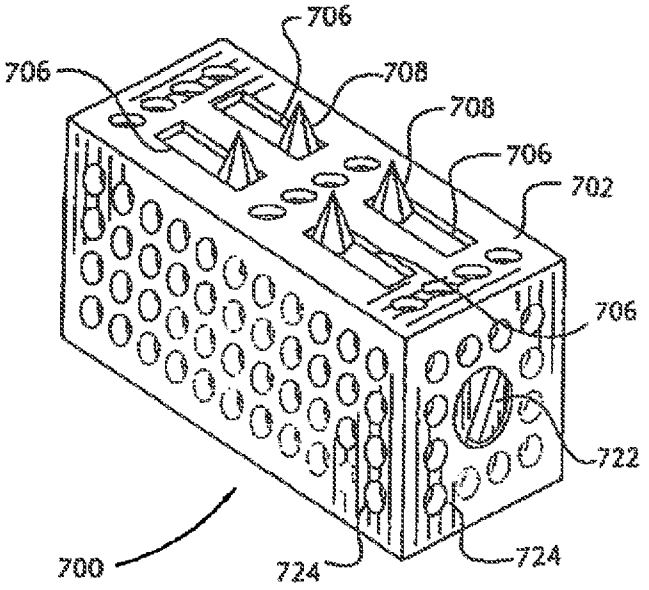

FIG 32

ANATOMIC SPINAL IMPLANT HAVING ANATOMIC BEARING SURFACES

This application is a continuation of application Ser. No. 12/807,489, filed Sep. 7, 2010, now U.S. Pat. No. 8,021,430; which is a continuation of application Ser. No. 10/926,766, filed Aug. 26, 2004, now U.S. Pat. No. 7,789,914; which is a continuation of application Ser. No. 10/237,751, filed Sep. 9, 2002 now U.S. Pat. No. 7,503,933; which is a continuation of application Ser. No. 09/412,090, filed Oct. 4, 1999, now U.S. Pat. No. 6,447,544; which is a continuation of application Ser. No. 08/813,283, filed Mar. 10, 1997, now U.S. Pat. No. 6,302,914; which is a divisional of application Ser. No. 08/482,146, filed Jun. 7, 1995, now U.S. Pat. No. 5,609,635; all of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to interbody spinal fusion implants, and in particular to spinal fusion implants configured to restore and maintain two adjacent vertebrae of the spine in correct anatomical angular relationship.

2. Description of the Prior Art

Both the cervical and lunbar areas of the human spine are, in a healthy state, lordotic such that they are curved convex forward. It is not uncommon that in degenerative conditions of the spine that lordosis is lost. This effectively shortens the spinal canal which decreases its capacity. Further, the absence of lordosis moves the spinal cord anteriorly where it may be compressed against the posterior portions of the vertebral bodies and discs. Finally, such a loss of lordosis disturbs the overall mechanics of the spine which may cause cascading degenerative changes throughout the adjacent spinal segments.

The surgical treatment of those degenerative conditions of the spine in which the spinal discs are in various states of collapse, and out of lordosis, commonly involves spinal fusion. That is the joining together of adjacent vertebrae through an area of shared bone. When the shared bone is in the area previously occupied by the intervertebral disc that is referred to as an interbody fusion. Further history in this regard is provided in application Ser. No. 08/263,952 entitled Artificial Spinal Fusion Implants ("Parent Application") incorporated herein by reference.

The Parent Application taught the use of artificial spinal fusion implants that were capable of being placed between adjacent vertebrae, and which implants were capable of containing and providing fusion promoting substances including bone at the fusion site. These devices were further capable of restoring the height of the disc space and of supporting the spine, and were self-stabilizing as well as being stabilizing to the spinal area where implanted.

SUMMARY OF THE INVENTION

The present invention is directed to interbody spinal fusion implants having a structural configuration that provides for the maintaining and creating of the normal anatomic angular relationship of two adjacent vertebrae of the spine to maintain and create spinal lordosis. The spinal fusion implants of the present invention are sized to fit within the disc space created by the removal of disc material between two adjacent vertebrae and conform wholly or in part to the disc space created. The spinal fusion implants of the present invention have upper and lower surfaces that form a support structure for bearing against the end plates of the adjacent vertebrae. In the preferred embodiments, the upper and lower surfaces are disposed in a converging angular relationship to each other such that the implants of the present invention have an overall "wedged-shape" in an elevational side view. The angular relationship of the upper and lower surfaces places and maintains the vertebrae adjacent to those surfaces in an angular relationship to each other, creating and maintaining the desired lordosis.

The implants of the present invention may have surface irregularities to increase their surface area, and/or to further engage the adjacent vertebrae and to enhance stability. The lordotic implants of the present invention may have surface irregularities that are uniform in height along the longitudinal axis of the upper and lower vertebrae engaging surfaces, or may increase in height from one end of the implant to the other. That is, the implant body and the surface formed and the projections may be similarly wedged. The outer contour of the surface projections may be more or less rectangular while the underlying implant may be wedge-shaped; or the reverse wherein the underlying implant body is more or less rectangular while the contour of the surface projections are wedge-shaped from one end of the implant to the other.

The implants of the present invention have various faces which may be curved so as to conform to the shape of the vertebral surfaces adjacent to the area of the disc removal. Specifically the upper and/or lower surfaces may be convex, and/or the front and/or rear surfaces may be convex. The surfaces of the implants of the present invention may have openings which may or may not pass all the way through them, and a central chamber in communication to the surface through holes. The openings may be of random sizes, and/or shapes, and/or distributions. The implants themselves may be composed of materials, and/or have surface treatments, to encourage microscopic bone ingrowth into the implants.

In the performing of a posterior lumbar interbody fusion, it is not possible to replace the removed portions of the disc, if a total nuclear discectomy has been performed, with a single large implant as the delicate dural sac containing the spinal cord, and the nerve roots cover at all times at least some portion of the posterior disc space. As set forth in the Parent Application, the use of "modular implants" is appropriate in such cases. The modular implants being approximately as long as the depth of the disc material removed, but being considerably narrower, such that they can be introduced into the disc space from the posterior aspect to either side of the dural sac, and then aligned side to side within the disc space so that a number of them each having a length consistent with the depth of the disc removed in that area would in combination have a width equal to the width of the disc material removed.

The modular implants of the present invention may be generally wedge-shaped and may have upper and lower surfaces conforming to the contours of the vertebral endplates, which contours include but are not limited to being relatively flat or convex. As the disc spaces in the lumbar spine are generally lordotic, said implants in the preferred embodiment would be taller anteriorly, that is at the implant's insertion end, and less tall posteriorly, that is at the implant's trailing end. To introduce an implant that is taller at its insertion end than the space available at the posterior aspect of the disc space, even when that disc space is optimally distracted, is problematic.

The modular implants of the present invention provide two solutions to the problem. In the first embodiment, the modular implants may have a reduced size at their insertion end, including but not limited to a bullet nose, a convexity, and a chamfer to a smaller front surface. This then provides that the

implant has an area small enough to be introduced into the posterior aspect of the disc space when the disc space is adequately distracted and the contour of that specialized leading portion of the implant is such that it then allows for a ramping up of the adjacent vertebrae relative to the implant as the implant is advanced forward into the disc space.

The implants of the present invention provide a second solution to this same problem. In the preferred embodiment of the modular implant, the implant is again wedge-shaped in the side elevational view and is taller at its insertion end than at its trailing end. However, the implant incorporates at its trailing end a means for engaging insertion instrumentation such as the box and threaded opening configuration disclosed in the Parent Application. Since in the preferred embodiment these implants are wedge-shaped in the side elevational view when upright but are generally rectangular when viewed from the top plan view, these implants are therefore designed to be introduced into the disc space on their side such that the side walls of the implants are adjacent to the end plates of the adjacent vertebrae. The implants have a side-to-side dimension that is less than the dimension through the insertion end of the implant when upright, it is possible to easily insert these implants with them on their side and then to use the insertion instrument engaged to the implant to rotate the implants ninety degrees into the fully upright position, once they have been fully inserted. Once inserted, the upper and lower surfaces are adjacent to the endplates of the adjacent vertebrae and create and maintain the desired angular relationship of the adjacent vertebrae as the upper and lower walls are angled with respect to each other.

In an alternative embodiment of the present invention, a mechanical implant which may be inserted in a collapsed position and which may then be adjusted to increase in height so as to provide for the optimal restoration of the height of the space between the adjacent vertebrae is disclosed. The mechanical implant may be wedge-shaped, and have upper and lower surfaces, the contours of which generally conform to the contacted areas of the adjacent vertebral endplates and which contours may include but are not limited to being relatively flat, or convex. Further, the mechanical implant may be wedge-shaped or generally rectangular, but capable of increasing in both height and the extent of wedging when adjusted. This may easily be achieved by having one of the two wedge mechanisms employed in the example given being larger, or steeper than the other. Alternatively, a single wedge may be utilized, and if it is desired to achieved increased height at one end of the implant while restricting the height at the other, then the end of the implant may incorporate a hinge means and the height expansion at the other end achieved by drawing a wedge member, bar, ball, or other means from the far end toward the hinged end so as to drive said upper and lower surfaces apart in a wedged fashion.

In an alternative embodiment of the present invention, an implant having a mechanically deployable bone engaging means is taught. Such an implant is generally wedge-shaped in the side elevational view and has upper and lower surfaces generally conforming to the contour of the vertebral endplates where contacted by the implant, and which upper and lower surfaces may be but are not limited to being either flat or convex. The use of such deployable bone engaging means are particularly of value in that the largest possible implant may be inserted into a disc space and the vertebral engaging means, which if fixed to the surface would have blocked the insertion of the implant, may then be deployed after the insertion such that the distance from the tip of the upper and lower boite engagement means exceeds the height of the space available for insertion. Such a feature is of particular value when the implant itself is wedge-shaped as the considerable compressive loads across the lumbar spine would tend to drive a wedge-shaped implants out of the disc space.

OBJECTS OF THE PRESENT INVENTION

It is an object of the present invention to provide a spinal fusion implant that is easily inserted into the spine, having a tapered leading end;

It is another object of the present invention to provide a spinal fusion implant that tapers in height from one end to the other consistent with the taper of a normal spinal disc;

It is yet another object of the present invention to provide a spinal fusion implant that is capable of maintaining anatomic alignment and lordosis of two adjacent vertebrae during the spinal fusion process;

It is still another object of the present invention to provide a spinal fusion implant that is self stabilizing within the spine;

It is yet another object of the present invention to provide a spinal fusion implant that is capable of providing stability between adjacent vertebrae when inserted;

It is further another object of the present invention to provide a spinal fusion implant that is capable of spacing apart and supporting adjacent vertebrae in an angular relationship during the spinal fusion process;

It is still further another object of the present invention to provide a spinal fusion implant that fits between to adjacent vertebrae and preserves the end plants of those vertebrae; and

It is another object of the present invention to provide a spinal fusion implant having a shape which conforms to the endplates of the adjacent vertebrae; and

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 view of the lordotic interbody spinal fusion implant of the present invention with a slidable door shown in a partially open position providing access to the internal chamber of the implant.

FIG. **2** is a top plan view of the lordotic interbody spinal fusion implant of the present invention.

FIG. **3** is a left side elevational view of the lordotic interbody spinal fusion implant of the present invention.

FIG. **4** is a right side elevational view of the lordotic interbody spinal fusion implant of the present invention.

FIG. **5** is a front end view of the lordotic interbody spinal fusion implant of the present invention showing the slidable door in a partially open position.

FIG. **6** is a rear end view of the lordotic interbody spinal fusion implant of the present invention showing the means for engaging insertion instrumentation.

FIG. **7** is an enlarged fragmentary view along line **7** of FIG. **2** illustrating the bone engaging surface configuration of the lordotic interbody spinal fusion implant of the present invention.

FIG. **7**A is an elevational side view of a segment of the spinal column having the lordotic implant of the present invention inserted in the disc space at different disc levels between adjacent vertebrae to restore and maintain the correct anatomical alignment of the adjacent vertebrae.

FIG. **8** is a top plan view of an alternative embodiment of the lordotic interbody spinal fusion implant of the present invention.

FIG. **9** is a left side elevational view of the lordotic interbody spinal fusion implant of FIG. **8**.

FIG. **10** is a front end view of the lordotic interbody spinal fusion implant of FIG. **8**.

FIG. **11** is a rear end view of the lordotic interbody spinal fusion implant of FIG. **8** showing the means for engaging insertion instrumentation.

FIG. **12** is an enlarged fragmentary view along line **12** of FIG. **8** illustrating the surface configuration the lordotic interbody spinal fusion implant of the present invention.

FIG. **13** is a top plan view of an alternative embodiment of the lordotic interbody spinal fusion implant of the present invention made of a mesh-like material.

FIG. **14** is a left side elevational view of the lordotic interbody spinal fusion implant of FIG. **13**.

FIG. **15** is a front end view of the lordotic interbody spinal fusion implant of FIG. **13**.

FIG. **16** is a rear end view of the lordotic interbody spinal fusion implant of FIG. **13** showing the means for engaging insertion instrumentation.

FIG. **17** is an enlarged fragmentary view along line **17** of FIG. **13** illustrating the surface configuration of the lordotic interbody spinal fusion implant of the present invention.

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

FIG. **19** is a top plan view of the lordotic interbody spinal fusion implant of FIG. **18**.

FIG. **20** is a left side elevational view of the lordotic interbody spinal fusion implant of FIG. **18**.

FIG. **21** is a rear end view of the lordotic interbody spinal fusion implant of FIG. **18**.

FIG. **22** is a front end view of the lordotic interbody spinal fusion implant of FIG. **18**.

FIG. **23** is an enlarged fragmentary view along line **23** of FIG. **22** illustrating the surface configuration the lordotic interbody spinal fusion implant of the present invention.

FIG. **24** is a top plan view of an alternative embodiment of the lordotic interbody spinal fusion implant of the present invention.

FIG. **25** is a left side elevational view of the lordotic interbody spinal fusion implant of FIG. **24**.

FIG. **26** is a rear end view of the lordotic interbody spinal fusion implant of FIG. **24**.

FIG. **27** is a front end view of the lordotic interbody spinal fusion implant of FIG. **24**.

FIG. **28** is an enlarged fragmentary view along line **28** of the lordotic interbody spinal fusion implant of FIG. **24** illustrating the surface configuration of the lordotic interbody spinal fusion implant of the present invention.

FIG. **29** is a sectional view along lines **29-29** of FIG. **28** the lordotic interbody spinal fusion implant of the present invention.

FIG. **30** is a side elevational view of a segment of the human spinal column shown with an alternative embodiment of the lordotic spinal fusion implant of the present invention that is adjustable and expandable shown in sectional view inserted in the disc space levels to restore and maintain the correct anatomical alignment of the adjacent vertebrae.

FIG. **31** is a side cross sectional view of, an alternative embodiment of the lordotic implant of the present invention having movable projections, in the form of spikes **708**, which are movable from a first position within the implant **700** to a second position extending to the exterior of the implant.

FIG. **32** is a perspective view of the embodiment of FIG. **31**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIGS. **1** through **7** the lordotic interbody spinal fusion implant of the present invention for use in the disc space between two adjacent vertebrae, generally referred to by the numeral **100**, is shown. The implant **100** has a generally rectangular configuration, having an upper surface **112** and a lower surface **114**. In the preferred embodiment, the upper and lower surfaces **112** and **114** of implant **100** are disposed in a converging angular relationship toward each other such that the implant **100** appears "wedge-shaped" from a side elevational view as shown in FIGS. **3** and **4**. The upper and lower surfaces **112** and **114** have an interior surface which form a support structure for bearing against the endplates of the adjacent vertebrae between which the implant **100** is inserted. The angular relationship of the upper and lower surfaces **112** and **114** places and maintains the vertebrae adjacent to those surfaces in an angular relationship, creating and maintaining the desired lordosis of the spine.

The upper and lower surfaces **112** and **114** of the implant **100** may be flat or curved to conform to the shape of the end plates of the adjacent vertebrae between which the implant **100** is inserted. The implant **100** conforms to the shape of the nucleus pulposus and a portion of the annulus fibrosus removed from the vertebrae. The upper and lower surfaces **112** and **114** comprise surface roughenings that provide a surface suitable for engaging the adjacent vertebrae to stabilize the implant **100** within the disc space once surgically implanted. The surface roughenings of the upper and lower surfaces **112** and **114** comprise a surface knurling **121** and/or grooves.

Referring to FIG. **7**, an enlarged fragmentary view of the surface knurling **121** of the implant **100** is shown as a diamond-shaped bone engaging pattern. The implant **100** may have surface knurling **121** throughout the entire upper and lower surfaces **112** and **114**, throughout only a portion of the upper and lower surfaces **112** and **114**, or any combination thereof, without departing from the scope of the present invention. It is also appreciated that the surface knurling **121** may have various configuration other than the configuration shown.

In this embodiment, the implant **100** is hollow and comprises a plurality of openings **115** of passing through the upper and lower surfaces **112** and **114** and into a central hollow chamber **116**. The openings **115** provide for bone growth to occur from the vertebrae through the openings **115** to the internal chamber **116**. While the openings **115** have been shown in the drawings as being circular, it is appreciated that the openings **115** may have any shape, size, configuration or distribution suitable for use in a spinal implant without departing from the scope of the present invention. For example, the openings may have a tear-drop configuration as shown in opening **115***a* in FIGS. **1** and **2**. The upper and lower surfaces **112** and **114** of the implant **100** are supported and spaced apart by a side wall **118**, which may also comprise a plurality of openings **122**.

The implant **100** has an insertion end **120** and a trailing end **130** both of which may be curved or flat. The trailing end **130** of the implant may be convex to conform to the curvature of the vertebrae and has a means for engaging an implant insertion instrument comprising a depressed portion **124** with a central threaded opening **126** for receiving the engaging end of a driving instrument. The insertion end **120** of the implant **100** comprises an access opening **132** and a slidable door **134** which closes the opening **132**. The slidable door **134** covers the opening **132** into the chamber **116** and permits the insertion of autogenous bone material into the chamber **116**.

In use, the slidable door **134** is placed in the open position for loading material into the chamber **116**. The slidable door **134** has a depression **136** for facilitating the opening and closing of the door **134**. The internal chamber **116** 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 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 fusion enhancing material that is packed within the chamber **116** of the implant **100** serves to promote bone ingrowth between the implant **100** and the adjacent vertebrae. Once the bone ingrowth occurs, the implant **100** will be a permanent fixture preventing dislodgement of the implant as well as preventing any movement between the adjacent vertebrae.

The slidable door **134** is then closed prior to implantation. In the closed position, the slidable door conforms to the curvature of the insertion end **120** of the implant **100**. Various methods of packing the implant **100** with the autogenous bone material may be used to obtain a completely packed implant **100**.

The method of inserting the implant **100** is set forth in detail in application Ser. No. 08/263,962, incorporated herein by reference. The threaded end of a driving instrument is attached to the threaded opening **126** in the trailing end **130** of the implant **100** and the fitting of the driving instrument into the depressed portion **124** prevents movement of the implant **100** in relationship to the driving instrument. The implant **100** is then placed at the entrance to the disc space between the two adjacent vertebrae V. The driver instrument is then tapped with a hammer sufficiently hard enough to drive the implant **100** into the disc space.

The size of the implant **100** is substantially the same size as the disc material that it is replacing and thus will be larger or smaller depending on the amount of disc material removed to create the disc space in which it is to be used. In the preferred embodiment in regard to the lumbar spine the implant **100** has a width W approximately 28-48 mm wide, approximately 36 mm being preferred. The implant **100** has a height H conforming to the restoration of the anatomic height of the disc space the average height would range from 8-16 mm, with 10-12 of which being the preferred average height. The depth D along mid-longitudinal axis MLA would at its maximum range from 20 to 34 mm with 26 to 32 being the preferred maximum depth. In the cervical spine the width of the implant is in the range of approximately 14-28 mm, with the preferred width being 18-22 mm. The implant has a height in the range of approximately 5-10 mm with the preferred height being 6 mm. The implant has a depth in the range of approximately 11-21 mm with the preferred depth being 11-13 mm.

Referring to FIG. **7**A, a side elevational view of the lateral aspect of a segment of the spinal column S is shown with the implant **100** inserted in the disc space D_2 between two adjacent vertebrae V_2 and V_3. The implant **100** is inserted in the direction of arrow A into the disc space D_2 and maintains the two vertebrae V_2 and V_3 in angular relationship to each other such that the natural lordosis of that segment of the spinal column S is restored. The forward advancement of the implant **100** is blocked by the natural bone processes B in the endplates of the vertebrae V_2 and V_3. Backing out of the implant **100** is prevented by the bone engaging surface knurling **121** of the upper and lower surfaces **112** and **114**.

Referring to FIGS. **8-12**, an alternative embodiment of the lordotic interbody spinal fusion implant of the present invention, generally referred to by the numeral **200**, is shown. The implant **200** has a similar overall configuration as the implant **100** described above. In the preferred embodiment, the implant **200** is solid and comprises a plurality of channels **215** passing from the upper surface **212** to the lower surface **214** through the implant **200**. The channels **215** provide for bone ingrowth and facilitate the incorporation of the implant **200** into the spinal fusion mass. The channels may also be loaded with fusion promoting materials such as those described above, prior to implantation. It is appreciated that the channels **215** need not pass all the way through the implant **200**, but can have a configuration similar to wells, which may hold fusion promoting materials and permit bone ingrowth into the upper and lower surfaces **212** and **214** of the implant **200**.

In addition to the channels **215**, the implant **200** may have small openings **222** on the side wall **218** which may or may not pass through the entire implant **200**. The same openings **222** may be in communication with the channels **215** such that bone ingrowth may occur from the openings **222** to the channels **215** to lock the implant **200** into the fusion mass. If the openings **222** do not pass through the entire implant **200**, they may function as small wells for holding fusion promoting materials or described above.

In the preferred embodiment of implant **200**, the channels **215** have a diameter in the range of 0.1 mm to 6 mm, with 2-3 mm being the preferred diameter. The openings **222** have a diameter in the range of 0.1 mm to 6 mm, with 1-3 mm being the preferred diameter range. It is appreciated that although the channels **215** and openings **222** are shown having a generally rounded configuration, it is within the scope of the present invention that the channels **215** and openings **222** may have any size, shape, configuration, and distribution suitable for the intended purpose.

The implant **200**, has a plurality of ratchetings **250** on the upper and lower surface **212** and **214** for engaging the bone of the adjacent vertebrae. The ratchetings **250** comprise a bone engaging edge **252** and angled segment **254**.

Referring specifically to FIG. **9**, the implant **200** has a wedge-shaped elevational side view in which the trailing end **230** is taller than the insertion end **220**. The plurality of ratchetings **250** are oriented in the direction of the insertion end **220** to provide for a one-way insertion of the implant **200** as the bone engaging edge **252**, or ridge, engages the vertebrae and prevents the implant from backing out once implanted. Alternatively, the trailing end ratchetings could be of a lessor height such that the overall shape of the ratchetings as a group is convex.

Referring to FIG. **11**, the trailing end **230** of implant **200** has means for engaging insertion instrumentation comprising a thread opening **226** as described above for implant **100**.

Referring to FIG. **12**, an enlarged fragmentary view along line **12** of FIG. **8** illustrating the surface configuration the implant **200** is shown. The upper and lower surfaces **212** and **214** of implant **200**, in addition to the ratcheting **250** comprise a porous texture **260** to present an irregular surface to the bone to promote bone ingrowth. The porous texture **260** is also able to hold fusion promoting materials and provides for an increased surface area to engage the bone in the fusion process and to provide further stability. The porous texture **260** may also be present on the side walls **218**. It is appreciated that the outer surface and/or the entire implant **200**, may comprise any other porous material or roughened surface sufficient to hold fusion promoting substances and/or allow for bone ingrowth and/or engage the bone during the fusion process. The implant **200** may be further coated with bioac-

tive fusion promoting substances including, but not limited to, hydroxyapatite compounds, osteogenic proteins and bone morphogenic proteins or may be from bioabsorbable material.

Referring to FIGS. **13-17**, an alternative embodiment of the lordotic interbody spinal fusion implant, generally referred to by the numeral **300**, is shown. The implant **300** is made of a mesh-like material comprising strands, which may be made of metal, that are pressed together and molded. The upper and lower surfaces **312** and **314** may be convex and conform to the natural surface curvature of the end plates of the vertebrae. In addition, the entire implant **300** may be molded to a shape that conforms to the shape of the disc space created by the removal of disc material from between two adjacent vertebrae. In this manner, the implant **300** has curved upper and lower surfaces **312** and **314**, a curved side wall **318** and chamfered edges **319**.

As shown in FIGS. **13** and **14**, the implant **300** includes an insertion end **320** and a trailing end **330**. Furthermore, as shown in FIGS. **13** and **14**, the implant **300** includes a first terminal part defining a first bearing surface adapted to bear against an endplate of the vertebrae V_1, and an opposite second bearing surface adapted to bear against an endplate of the vertebrae V_2. The implant **300** also includes a second terminal part opposite the first terminal part. The second terminal part defines a third bearing surface adapted to bear against the endplate of the vertebrae V_1 and a fourth bearing surface adapted to bear against the endplate of the vertebrae V_2.

In addition to the first and second terminal parts, the implant **300** also includes a first side extending between the first terminal part and the second terminal part, and a second side opposite the first side and extending between the first terminal part and the second terminal part.

Referring to FIG. **7**A, the implant **300** is shown inserted in the direction of arrow A into the disc space D_1 between adjacent vertebrae V_1 and V_2. The implant **300** conforms to the endplates of the adjacent vertebrae V_1 and V_2 as the upper and lower surfaces **312** and **314** are convex, and the side was **318** are curved to conform to the natural curvature of the vertebrae V_1 and V_2. In this manner, the implant **300** has the same dimensions as the disc material removed from between the two adjacent vertebrae V_1 and V_2.

The implant **300** may be made wholly or in part of a solid material and/or a porous material, and/or a mesh-like material. The implant **300** may have a surface comprising of a porous material, a mesh-like material, or have a surface that is roughened. It is appreciated that the implant **300** may be solid or may be partially hollow and include at least one internal chamber in communication with said upper and lower surfaces.

As shown in FIG. **17**, the mesh-like material comprises strands that are formed and pressed together such that interstices **339**, capable of retaining fusion promoting material and for allowing for bone ingrowth, are present between the strands in at least the outer surface of implant **300**. Alternatively, it is appreciated that the implant **300** may be made of a cancellous material, similar in configuration to human cancellous bone, having interstices allowing for bone ingrowth. As the implant **300** may be made entirely or in part of the cancellous material, the interstices may be present in the outer surface of the implant **300** and/or within the entire implant to promote bone ingrowth and hold bone fusion promoting materials.

Referring to FIGS. **18-23** an alternative embodiment of the implant of the present invention, generally referred to by the numeral **400**, is disclosed. The implant **400** has a substantially rectangular shape having upper and lower surfaces **412** and **414**. The upper and lower surfaces **412** and **414** support the adjacent vertebrae and are disposed in a converging angular relationship to each other in the same manner described above.

The implant **400** has a width W that is substantially less than the width of the implants **100-300** such that a series of such implants **400** are used as the interbody spinal implant, each placed closely adjacent to one another to approximate the size of the removed disc. The size of the implant **400** is approximately 26 millimeters in length and is wide enough so that four of them will substantially fill the intervertebral space, depending on which vertebrae are fused.

In the performing of a posterior lumbar interbody fusion, it is not possible to replace the removed portions of the disc, if a total nuclear discectomy has been performed, with a single large implant as the, delicate dural sac containing the spinal cord and nerve roots covers at all times at least some portion of the posterior disc space. The use of modular implants **400** that are inserted separately into the disc space is appropriate in such case. The modular implants **400** being approximately as long as the depth of the disc material removed, but being considerably narrower, such that they could be introduced into the disc space from the posterior aspect to either side of the dural sac, and then realigned side to side with the disc space so that a number of them each having a length consistent with the depth of the disc removed in that area would in combination have a width equal to the width of the disc material removed. As the disc spaces in the lumbar spine are generally lordotic, the insertion end **420** of the modular implants **400** would have to be taller and less tall posteriorly at the trailing end **430**.

To introduce the modular implant **400** that is taller at its insertion end **420** than the space available at the posterior aspect of the disc space, even when that disc space is optimally distracted, is problematic. The modular implants **400** of provide two solutions to the problem. The modular implants **400** may have a reduced size at their Insertion end **420**, including but not limited to, a bullet nose, a convexity, and a chamfer to a smaller front surface. This then provides that the implant **400** has an area small enough to be introduced into the posterior aspect of the disc space when the disc space is adequately distracted and the contour of that specialized insertion end of the implant **400** is such that it then allows for a ramping up of the adjacent vertebrae relative to the implant **400** as the implant is advanced forward into the disc space.

Alternatively, or in combination with the above, since in the preferred embodiment the implants **400** are wedge-shaped in the side elevational view when upright but are generally rectangular when viewed from the top plan view, these implants may be introduced into the disc space on their side such that the side walls of the implants are adjacent to the end plates of the adjacent vertebrae. The implants **400** have a side-to-side dimension that is less than the dimension through the insertion end of the implant **400** when upright. It is possible to easily insert the implant **400** first on their side and then to use the insertion instrument engaged to the implant **400** to rotate the implant ninety degrees into the fully upright position, once it has been fully inserted. Once inserted, the upper and lower surfaces **412** and **414** are adjacent to the endplates of the adjacent vertebrae and create and maintain the desired angular relationship of the adjacent vertebrae as the upper and lower surfaces **412** and **414** of the implant **400** are angled with respect to each other.

The implant **400** has large openings **415** in the form of rectangular slots for holding fusion promoting materials to promote bone growth from the vertebrae through the upper

and lower surfaces **412** and **414** and into the interior of the implant **400**. As the implant **400** is modular and more than one is implanted at a time, the large openings **415** are also present in the side walls **418** of the implant **400** to provide for bone growth from one implant to another implant such that after successful fusion, the modular implants **400** are interconnected to form a single unit.

Referring to FIG. **21**, the trailing end **430** of the implant **400** is shown having an insertion instrument engaging means comprising a rectangular slot **424** and threaded opening **426**.

Referring to FIG. **23**, an enlarged fragmentary view along line **23** of FIG. **22** illustrating the surface configuration the implant **400** is shown. The surface configuration of the implant **400** is the same as the porous texture **260** described above.

Referring to FIG. **24**, an alternative embodiment of the lordotic interbody spinal fusion implant of the present invention, generally referred to by the numeral **500**, is shown. The implant **500** is a modular implant and has a similar overall configuration as implant **400**. The implant **500** instead of having slots **415** has an upper and lower surfaces **512** and **514** that are capable of receiving and holding bone, or other materials capable of participating in the fusion process and/or capable of promoting bone ingrowth. In the preferred embodiment, the upper and lower surfaces **512** and **514** comprise a plurality of posts **540** that are spaced apart to provide a plurality of interstices **542** which are partial wells with incomplete walls capable of holding and retaining milled bone material or any artificial bone ingrowth promoting material. The implant **500** may be prepared for implantation by grouting or otherwise coating the surface **538** with the appropriate fusion promoting substances.

Referring to FIGS. **28** and **29**, an enlarged view of the upper surface **512** of the implant **500** and a partial cross section thereof are shown. In the preferred embodiment, the posts **540** have a head portion **544** of a larger diameter than the remainder of the posts **540**, and each of the interstices **542** is the reverse configuration of the posts **544**, having a bottom **546** that is wider than the entrance **548** to the interstices **542**. Such a configuration of the posts **540** and interstices **542** aids in the retention of bone material in the surface **538** of the implant **500** and further assists in the locking of the implant **500** into the bone fusion mass created from the bone ingrowth. As the bone ingrowth at the bottom **546** of the interstices **542** is wider than the entrance **548**, the bone ingrowth cannot exit from the entrance **548** and is locked within the interstice **542**. The surface **538** of the implant **500** provides for an improvement in the available amount of surface area which may be still further increased by rough finishing, flocking or otherwise producing a non smooth surface.

In the preferred embodiment, the posts **540** have a maximum diameter in the range of approximately 0.1-2 mm and a height of approximately 0.1-2 mm and are spaced apart a distance of 0.1-2 mm such that the interstices **542** have a width in the range of approximately 0.1 to 2 mm. The post sizes, shapes, and distributions may be varied within the same implant.

It is appreciated that the implant **500** shares the same structure and features of the implant **400** described above.

FIG. **30** is a side elevational view of a segment of the human spinal column S shown in lordosis with an alternative embodiment of the lordotic spinal fusion implant referred to by the numeral **600**, that is adjustable and expandable shown inserted in a space to restore and maintain the correct anatomical alignment of the adjacent vertebrae. The implant **600** comprises a lower member **682** and an upper member **684** which when fitted together form an essentially rectangular implant. The upper member **684** and the lower member **682** have hollow portions that face one another and receive tapered wedges **686** and **688** that fit within the hollow portion of the upper and lower members **682** and **684**. The upper and lower members **682** and **684** each have a wedged interior surface **689***a* and **689***b* which are angled towards the interior of the implant **600**. The wedges **682** and **684** are such that at their large end, they are higher than the combined hollow space between the upper and lower members **684** and **682**, and shallower at the other end than the hollow space between the upper and lower members.

The wedges **686** and **688** have a central threaded opening **690** and **692** in alignment with each other for receiving threaded screw **694**. As the screw **694** is threaded into the opening **690**, the wedges **686** and **688** abut the interior sloped surfaces **689***a* and **689***b* of the upper and lower members **682** and **684**. As the screw **694** is turned, the wedges **686** and **688** are drawn together, and the sloped portions of the wedges force the upper member **682** away from the lower member **684**. As the interior sloped surfaces **689***a* and **689***b* have a greater slope near the trailing end **630**, than near the insertion end **620**, the upper and lower members **682** and **684** are forced apart more at the insertion end **620** than at the trailing end **630**. As a result, the upper and lower members **682** and **684** are disposed at a converging angular relationship to each other and support the adjacent vertebrae V_1 and V_2 in the same angular relationship.

Referring to FIG. **31**, an alternative embodiment of the implant of the present invention, generally referred to by the numeral **700**, is shown. The implant **700** has movable projections, in the form of spikes **708**, which are movable from a first position within the implant **700** to a second position extending outside of the implant. The implant **700** is of a generally rectangular configuration, having a top surface **702** and a bottom surface **704** of the implant with slots **706** for permitting pivotal member **707** having spikes **708** at their ends to project through said slots **706**. The spikes **708** are pinned at one end **710** within the implant **700**.

The implant **700** has opposing wedge shaped members **712** and **714** having a central threaded opening **716** for receiving a threaded screw **718** having a head **720** and a slot **722**. The wedges **712** and **714** are facing each other so that upon turning of the screw **718**, will the two wedges **712** and **714** are drawn together to cause the spikes **708** to pivot about their end **710** and project to the exterior of the implant **700** through the aligned slots **706**. The implant **700** may comprise a series of holes **724** on its surfaces for promoting bone ingrowth and fusion.

In use, after the removal of the disc material, the implant **700** with the spikes **708** in their withdrawn position, is inserted into the disc space. Then the screw **718** is turned until the spikes **708** are forced to enter the vertebrae and the implant **700** is thus held firmly in place.

While the invention has been described with regards to the preferred embodiment and a number of alternative embodiments, it is recognized that other embodiments of the present invention may be devised which would not depart from the scope of the present invention.

I claim:

1. A spinal fusion implant for insertion between a first vertebra and a second vertebra adjacent the first vertebra, the first vertebra having a generally vertically extending first peripheral wall and a first endplate and the second vertebra having a generally vertically extending second peripheral wall and a second endplate, wherein the implant comprises:

a first terminal part defining a trailing face, a first bearing surface adapted to bear against a portion of the first

endplate, and an opposite second bearing surface adapted to bear against a portion of the second, said trailing face extending between said first bearing surface and second bearing surface, said trailing face having a recessed portion and a threaded opening configured to receive an insertion instrument for inserting said implant between the first vertebra and the second vertebra;

a second terminal part opposite said first terminal part, said second terminal part having an insertion face extending between a third bearing surface and a fourth bearing surface, said implant having a longitudinal axis extending through said trailing face of said first terminal part and said insertion face of said second terminal part, and having a cross section in a first plane extending through said first bearing surface and said second bearing surface, and along the longitudinal axis, said implant having a length between said trailing face of said first terminal part and said insertion face of said second terminal part and parallel to the longitudinal axis, said implant having a width and a height each perpendicular to the length of said implant, the width of said implant being greater than the height of said implant;

a first side and an opposite second side, said first side and said second side extending from said first terminal part to said second terminal part, portions of said first side and said second side being substantially flat, said substantially flat portions intersecting a second plane that is perpendicular to the first plane and extends through said insertion face and said trailing face, wherein said substantially flat portions of said first side and said second side are symmetrical about the first plane;

an opening between said trailing face and said insertion face and between said first and second sides to permit for the growth of bone through said implant from the first vertebra to the second vertebra;

upper and lower bearing surfaces each having a length measured parallel to the longitudinal axis of said implant, said upper and lower bearing surfaces having portions proximate each of said first and second sides and being convex along the entire length of said upper and lower bearing surfaces relative to the second plane and in a direction parallel to the longitudinal axis, said trailing face having a height less than and measured parallel to a maximum height measured between said upper and lower bearing surfaces proximate one of said first and second sides;

ratchetings on each of said upper and lower bearing surfaces adapted to engage the first vertebra and the second vertebra, respectively, each of said ratchetings having a ridge oriented in a direction generally parallel to the width of said implant, said ratchetings on each of said upper and lower bearing surfaces facing one direction; and

said implant being adapted to hold bone fusion promoting materials.

2. The implant of claim **1**, wherein said implant has a plurality of openings between said trailing face and said insertion face and between said first and second sides to permit for the growth of bone through said implant from the first vertebra to the second vertebra.

3. The implant of claim **1**, wherein said convex portions of said upper and lower bearing surfaces are convex along a continuous uninterrupted majority of the lengths of said upper and lower bearing surfaces.

4. A spinal fusion implant for insertion between a first vertebra and a second vertebra adjacent the first vertebra, the first vertebra having a generally vertically extending first peripheral wall and a first endplate and the second vertebra having a generally vertically extending second peripheral wall and a second endplate, wherein the implant comprises:

a first terminal part defining a trailing face, a first bearing surface adapted to bear against a portion of the first endplate, and an opposite second bearing surface adapted to bear against a portion of the second endplate, said trailing face extending between said first bearing surface and second bearing surface, said trailing face having a recessed portion and a threaded opening configured to receive an insertion instrument for inserting said implant between the first vertebra and the second vertebra;

a second terminal part opposite said first terminal part, said second terminal part having an insertion face extending between a third bearing surface and a fourth bearing surface, said implant having a longitudinal axis extending through said trailing face of said first terminal part and said insertion face of said second terminal part, and having a cross section in a first plane extending through said first bearing surface and said second bearing surface, and along the longitudinal axis, said implant having a length between said trailing face of said first terminal part and said insertion face of said second terminal part and parallel to the longitudinal axis, said implant having a width and a height each perpendicular to the length of said implant;

a first side and an opposite second side, said first side and said second side extending from said first terminal part to said second terminal part, portions of said first side and said second side being substantially flat, said substantially flat portions intersecting a second plane that is perpendicular to the first plane and extends through said insertion face and said trailing face, wherein said substantially flat portions of said first side and said second side are symmetrical about the first plane;

an opening between said trailing face and said insertion face and between said first and second sides to permit for the growth of bone through said implant from the first vertebra to the second vertebra;

upper and lower bearing surfaces each having a length measured parallel to the longitudinal axis of said implant, said upper and lower bearing surfaces having portions proximate each of said first and second sides and being convex along the entire length of said upper and lower bearing surfaces relative to the second plane and in a direction parallel to the longitudinal axis, the width of said implant being greater than the height measured between said upper and lower bearing surfaces proximate one of said first and second sides of said implant;

ratchetings on each of said upper and lower bearing surfaces adapted to engage the first vertebra and the second vertebra, respectively, each of said ratchetings having a ridge oriented in a direction generally parallel to the width of said implant, said ratchetings on each of said upper and lower bearing surfaces facing one direction; and

said implant being adapted to hold bone fusion promoting materials.

5. The implant of claim **4**, wherein said implant has a plurality of openings between said trailing face and said insertion face and between said first and second sides to permit for the growth of bone through said implant from the first vertebra to the second vertebra.

6. The implant of claim **4**, wherein said convex portions of said upper and lower bearing surfaces are convex along a

continuous uninterrupted majority of the lengths of said upper and lower bearing surfaces.

7. A lordotic spinal fusion implant for insertion between a first vertebra and a second vertebra adjacent the first vertebra, the first vertebra having a generally vertically extending first peripheral wall and a first endplate and the second vertebra having a generally vertically extending second peripheral wall and a second endplate, wherein the implant comprises:

a first terminal part defining a trailing face, a first bearing surface adapted to bear against a portion of the first endplate, and an opposite second bearing surface adapted to bear against a portion of the second endplate, said trailing face extending between said first bearing surface and second bearing surface;

a second terminal part opposite said first terminal part, said second terminal part having an insertion face extending between a third bearing surface and a fourth bearing surface, said implant having a longitudinal axis extending through said trailing face of said first terminal part and said insertion face of said second terminal part, and having a cross section in a first plane extending through said first bearing surface and said second bearing surface, and along the longitudinal axis, said implant having a length between said trailing face of said first terminal part and said insertion face of said second terminal part and parallel to the longitudinal axis, said implant having a width and a height each perpendicular to the length of said implant;

a first side and an opposite second side, said first side and said second side extending from said first terminal part to said second terminal part, portions of said first side and said second side being substantially flat, said substantially flat portions intersecting a second plane that is perpendicular to the first plane and extends through said insertion face and said trailing face, wherein said substantially flat portions of said first side and said second side are symmetrical about the first plane, said implant being adapted to be inserted between the first vertebra and the second vertebra with said first side and said second side of said implant being oriented toward the first endplate and the second endplate, respectively, and then rotated ninety degrees into an upright position, said trailing face having a recessed portion intersecting each of said first and second sides and being configured to receive an insertion instrument for inserting said implant between the first vertebra and the second vertebra;

an opening between said trailing face and said insertion face and between said first and second sides to permit for the growth of bone through said implant from the first vertebra to the second vertebra;

upper and lower bearing each surfaces having a length measured parallel to the longitudinal axis of said implant, said upper and lower bearing surfaces having portions proximate each of said first and second sides and being convex along the entire length of said upper and lower bearing surfaces relative to the second plane and in a direction parallel to the longitudinal axis, said trailing face having a height less than and measured parallel to a maximum height measured between said upper and lower bearing surfaces proximate one of said first and second sides, said upper and lower bearing surfaces being disposed in a converging angular relationship toward each other such that said implant appears wedge-shaped from a side view, the converging angular relationship of said upper and lower bearing surfaces maintaining the first vertebra and the second vertebra adjacent to said upper and lower bearing surfaces in an angular relationship to maintain the desired lordosis between the first vertebra and the second vertebra;

ratchetings on each of said upper and lower bearing surfaces adapted to engage the first vertebra and the second vertebra, respectively, each of said ratchetings having a ridge oriented in a direction generally parallel to the width of said implant, said ratchetings on each of said upper and lower bearing surfaces facing one direction; and

said implant being adapted to hold bone fusion promoting materials.

8. The implant of claim **7**, wherein said implant has a plurality of openings between said trailing face and said insertion face and between said first and second sides to permit for the growth of bone through said implant from the first vertebra to the second vertebra.

9. The implant of claim **7**, wherein said convex portions of said upper and lower bearing surfaces are convex along a continuous uninterrupted majority of the lengths of said upper and lower bearing surfaces.

10. A spinal fusion implant for insertion between a first vertebra and a second vertebra adjacent the first vertebra, the first vertebra having a generally vertically extending first peripheral wall and a first endplate and the second vertebra having a generally vertically extending second peripheral wall and a second endplate, wherein the implant comprises:

a first terminal part defining a trailing face, a first bearing surface adapted to bear against a portion of the first endplate, and an opposite second bearing surface adapted to bear against a portion of the second endplate, said trailing face extending between said first bearing surface and second bearing surface;

a second terminal part opposite said first terminal part, said second terminal part having an insertion face extending between a third bearing surface and a fourth bearing surface, said implant having a longitudinal axis extending through said trailing face of said first terminal part and said insertion face of said second terminal part, and having a cross section in a first plane extending through said first bearing surface and said second bearing surface, and along the longitudinal axis, said implant having a length between said trailing face of said first terminal part and said insertion face of said second terminal part and parallel to the longitudinal axis, said implant having a width and a height each perpendicular to the length of said implant;

a first side and an opposite second side, said first side and said second side extending from said first terminal part to said second terminal part, portions of said first side and said second side being substantially flat, said substantially flat portions intersecting a second plane that is perpendicular to the first plane and extends through said insertion face and said trailing face, wherein said substantially flat portions of said first side and said second side are symmetrical about the first plane, said implant being adapted to be inserted between the first vertebra and the second vertebra with said first side and said second side of said implant being oriented toward the first endplate and the second endplate, respectively, and then rotated ninety degrees into an upright position, said trailing face having a recessed portion intersecting each of said first and second sides and being configured to receive an insertion instrument for inserting said implant between the first vertebra and the second vertebra;

an opening between said trailing face and said insertion face and between said first and second sides to permit for

the growth of bone through said implant from the first vertebra to the second vertebra;

upper and lower bearing surfaces each having a length measured parallel to the longitudinal axis of said implant, said upper and lower bearing surfaces having portions proximate each of said first and second sides and being convex along the entire length of said upper and lower bearing surfaces relative to the second plane and in a direction parallel to the longitudinal axis, said trailing face having a height less than and measured parallel to a maximum height measured between said upper and lower bearing surfaces proximate one of said first and second sides;

ratchetings on each of said upper and lower bearing surfaces adapted to engage the first vertebra and the second vertebra, respectively, each of said ratchetings having a ridge oriented in a direction generally parallel to the width of said implant, said ratchetings on each of said upper and lower bearing surfaces facing one direction; and

said implant being adapted to hold bone fusion promoting materials.

11. The implant of claim **10**, wherein said implant has a plurality of openings between said trailing face and said insertion face and between said first and second sides to permit for the growth of bone through said implant from the first vertebra to the second vertebra.

12. The implant of claim **10**, wherein said convex portions of said upper and lower bearing surfaces are convex along a continuous uninterrupted majority of the lengths of said upper and lower bearing surfaces.

13. A spinal fusion implant for insertion between a first vertebra and a second vertebra adjacent the first vertebra, the first vertebra having a generally vertically extending first peripheral wall and a first endplate and the second vertebra having a generally vertically extending second peripheral wall and a second endplate, wherein the implant comprises:

a first terminal part defining a trailing face, a first bearing surface adapted to bear against a portion of the first endplate, and an opposite second bearing surface adapted to bear against a portion of the second endplate, said trailing face extending between said first bearing surface and second bearing surface, said trailing face having a recessed portion and an opening configured to receive an insertion instrument for inserting said implant between the first vertebra and the second vertebra;

a second terminal part opposite said first terminal part, said second terminal part having an insertion face extending between a third bearing surface and a fourth bearing surface, said implant having a longitudinal axis extending through said trailing face of said first terminal part and said insertion face of said second terminal part, and having a cross section in a first plane extending through said first bearing surface and said second bearing surface, and along the longitudinal axis, said implant having a length between said trailing face of said first terminal part and said insertion face of said second terminal part and parallel to the longitudinal axis, said implant having a width and a height each perpendicular to the length of said implant, the width of said implant being greater than the height of said implant;

a first side and an opposite second side, said first side and said second side extending from said first terminal part to said second terminal part, portions of said first side and said second side being substantially flat, said substantially flat portions intersecting a second plane that is perpendicular to the first plane and extends through said insertion face and said trailing face, wherein said substantially flat portions of said first side and said second side are symmetrical about the first plane;

an opening between said trailing face and said insertion face and between said first and second sides to permit for the growth of bone through said implant from the first vertebra to the second vertebra;

upper and lower bearing surfaces each having a length measured parallel to the longitudinal axis of said implant, said upper and lower bearing surfaces having portions proximate each of said first and second sides and being convex along the entire length of said upper and lower bearing surfaces relative to the second plane and in a direction parallel to the longitudinal axis, said trailing face having a height less than and measured parallel to a maximum height measured between said upper and lower bearing surfaces proximate one of said first and second sides;

a plurality of raised pyramid-like projections on each of said upper and lower bearing surfaces for engaging the implant to the first vertebra and the second vertebra once implanted; and

said implant being adapted to hold bone fusion promoting materials.

14. The implant of claim **13**, wherein said implant has a plurality of openings between said trailing face and said insertion face and between said first and second sides to permit for the growth of bone through said implant from the first vertebra to the second vertebra.

15. The implant of claim **13**, wherein said convex portions of said upper and lower bearing surfaces are convex along a continuous uninterrupted majority of the lengths of said upper and lower bearing surfaces.

16. A lordotic spinal fusion implant for insertion between a first vertebra and a second vertebra adjacent the first vertebra, the first vertebra having a generally vertically extending first peripheral wall and a first endplate and the second vertebra having a generally vertically extending second peripheral wall and a second endplate, wherein the implant comprises:

a first terminal part defining a trailing face, a first bearing surface adapted to bear against a portion of the first endplate, and an opposite second bearing surface adapted to bear against a portion of the second endplate, said trailing face extending between said first bearing surface and second bearing surface, said implant having a recessed portion configured to receive an insertion instrument for inserting said implant between the first vertebra and the second vertebra;

a second terminal part opposite said first terminal part, said second terminal part having an insertion face extending between a third bearing surface and a fourth bearing surface, said implant having a longitudinal axis extending through said trailing face of said first terminal part and said insertion face of said second terminal part, and having a cross section in a first plane extending through said first bearing surface and said second bearing surface, and along the longitudinal axis, said implant having a length between said trailing face of said first terminal part and said insertion face of said second terminal part and parallel to the longitudinal axis, said implant having a width and a height each perpendicular to the length of said implant;

a first side and an opposite second side, said first side and said second side extending from said first terminal part to said second terminal part, portions of said first side and said second side being substantially flat, said substantially flat portions intersecting a second plane that is

perpendicular to the first plane and extends through said insertion face and said trailing face, wherein said substantially flat portions of said first side and said second side are symmetrical about the first plane, said implant being adapted to be inserted between the first vertebra and the second vertebra with said first side and said second side of said implant being oriented toward the first endplate and the second endplate, respectively, and then rotated ninety degrees into an upright position, said trailing face having a recessed portion intersecting each of said first and second sides and being configured to receive an insertion instrument for inserting said implant between the first vertebra and the second vertebra;

an opening between said trailing face and said insertion face and between said first and second sides to permit for the growth of bone through said implant from the first vertebra to the second vertebra;

upper and lower bearing surfaces each having a length measured parallel to the longitudinal axis of said implant, said upper and lower bearing surfaces having portions proximate each of said first and second sides and being convex along the entire length of said upper and lower bearing surfaces relative to the second plane and in a direction parallel to the longitudinal axis, said trailing face having a height less than and measured parallel to a maximum height measured between said upper and lower bearing surfaces proximate one of said first and second sides, said upper and lower bearing surfaces being disposed in a converging angular relationship toward each other such that said implant appears wedge-shaped from a side view, the converging angular relationship of said upper and lower bearing surfaces maintaining the first vertebra and the second vertebra adjacent to said upper and lower bearing surfaces in an angular relationship to maintain the desired lordosis between the first vertebra and the second vertebra;

a plurality of raised pyramid-like projections on each of said upper and lower bearing surfaces for engaging the implant to the first vertebra and the second vertebra once implanted; and

said implant being adapted to hold bone fusion promoting materials.

17. The implant of claim **16**, wherein said implant has a plurality of openings between said trailing face and said insertion face and between said first and second sides to permit for the growth of bone through said implant from the first vertebra to the second vertebra.

18. The implant of claim **16**, wherein said convex portions of said upper and lower bearing surfaces are convex along a continuous uninterrupted majority of the lengths of said upper and lower bearing surfaces.

19. The implant of claim **16**, wherein said substantially flat portions of said first and second sides are parallel to one another.

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