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Attorneys for Plaintiff
SPRINGBOARD MEDICAL VENTURES LLC

IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

SPRINGBOARD MEDICAL VENTURES LLC, a California corporation,

Plaintiff,

v.

AMERICAN MEDICAL SYSTEMS, INC., a Delaware corporation,

Defendant.

Case No. **SACV08-01074 JVS (MLGx)**

COMPLAINT FOR PATENT INFRINGEMENT; TRADE SECRET MISAPPROPRIATION; STATUTORY UNFAIR COMPETITION; AND BREACH OF CONTRACT

DEMAND FOR JURY TRIAL

Plaintiff Springboard Medical Ventures LLC ("Springboard") hereby complains of Defendant American Medical Systems, Inc. ("AMS") and alleges as follows:

THE PARTIES

1. Plaintiff Springboard is a limited liability company organized and existing under the laws of the State of California, having a principal place of business at 27601 Forbes Road, Ste. 60, Laguna Niguel, CA 92677.

2. On information and belief, Defendant AMS is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 10700 Bren Road West, Minnetonka, MN 55343.

3. On information and belief, AMS conducts business throughout the United States, including in this Judicial District, and has committed the acts complained of in this Judicial District and elsewhere.

JURISDICTION AND VENUE

4. This action arises under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, more particularly, 35 U.S.C. § 271 and § 281; for unfair competition arising under California Business & Professions Code §§ 17200, *et seq.* and the common law of the State of California; for trade secret misappropriation arising under California Civil Code §§ 3426, *et seq.*; and for breach of contract arising under the statutory and common law of the State of Minnesota.

5. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 1338(b), and 1367(a).

6. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(c) and 1400(b).

ALLEGATIONS FOR ALL CLAIMS FOR RELIEF

7. Dr. Theodore V. Benderev, a founder of Springboard, has been a practicing urologist in Mission Viejo, California, for nearly twenty-one years. He

is currently a Clinical Professor at the University of California at Irvine and the Medical Director of the Incontinence and Pelvic Support Institute.

8. Dr. Benderev has developed novel inventions for the fixation of urologic slings, and has obtained numerous patents related to the treatment of urinary incontinence. Dr. Benderev has developed a design for a product, known as the "Dart System," containing an advanced fixation and anchoring system for devices for incontinence and other pelvic prolapse surgeries that embodies the technology he developed and patented.

9. Dr. Benderev contacted AMS about potentially licensing his patented and proprietary technology as a next generation female pelvic disorder product. Prior to disclosing any of his confidential information to persons at AMS, Dr. Benderev and Springboard entered into two written Confidential Disclosure Agreements ("CDAs") with AMS. The first CDA was signed by an AMS representative and was effective beginning November 12, 2001. The second CDA was signed by an AMS representative and was effective beginning October 29, 2003. The second CDA was signed the same day as a meeting between Dr. Benderev and an AMS executive team at AMS's headquarters in Minnetonka, Minnesota. True and correct copies of these CDAs are Attached hereto as Exhibits A and B.

10. During the October 29, 2003 meeting, Dr. Benderev disclosed confidential information regarding his patented and proprietary technology. Mr. Kohrs, AMS's President and Chief Executive Officer, signed the disclosed documentation, confirming his receipt of Dr. Benderev's propriety and confidential information. Dr. Benderev and persons from AMS also met at other times and had other discussions with Dr. Benderev regarding his proprietary and patented technology.

11. After receiving these disclosures from Dr. Benderev, AMS proceeded to develop and test devices, including the MiniArc, embodying the patented

technology and proprietary and confidential information of Springboard. On information and belief, AMS thereafter sought and obtained FDA approval for these products, including the MiniArc. AMS then commercially launched these products for sale and has continued to sell these products, including the MiniArc. AMS has publicized these products and instructed physicians regarding the use of these products.

12. All of AMS's activities with respect to urologic slings, including the MiniArc, that embody Springboard's patented technology and proprietary and confidential information have been done without the authorization or approval of Springboard.

FIRST CLAIM FOR RELIEF

(Infringement of U.S. Patent No. 7,410,460)

13. Springboard repeats, realleges, and incorporates by reference the allegations set forth in paragraphs 1 through 12 of this Complaint.

14. On August 12, 2008, the United States Patent and Trademark Office duly and lawfully issued U.S. Patent No. 7,410,460 ("the '460 patent") entitled, "System For Securing Sutures, Grafts And Soft Tissue To Bone And Periosteum" to Theodore V. Benderev. A true and correct copy of the '460 patent is attached hereto as Exhibit C.

15. Springboard is the owner of the '460 patent.

16. On information and belief, AMS has in the past and is currently infringing the '460 patent by making, using, selling, importing, offering to sell and/or inducing others to use urologic slings, such as the MiniArc, embodying the patented invention. AMS's acts constitute direct and indirect infringement of the '460 patent in violation of 35 U.S.C. § 271.

17. On information and belief, the infringement by AMS has been willful, intentional and deliberate. Specifically, given the course of dealings between Springboard and AMS, AMS knew or should have known that there was an

objectively high likelihood that AMS's actions constituted infringement of a valid patent, and AMS nevertheless continued with its infringing activities. This is an exceptional case within the meaning of 35 U.S.C. § 285.

18. On information and belief, Springboard has been and will continue to be injured by AMS's infringement of the '460 patent, and such acts will continue unless AMS is enjoined therefrom.

19. On information and belief, AMS has derived and received, and will continue to derive and receive, gains, profits and advantages from the aforesaid acts of infringement in an amount that is not presently known to Springboard. By reason of the aforesaid infringing acts, Springboard has been damaged, and is entitled to monetary relief in an amount to be proven at trial.

20. Because of the aforesaid infringing acts, Springboard has suffered and continues to suffer great and irreparable injury, for which Springboard has no adequate remedy at law.

SECOND CAUSE OF ACTION

(TRADE SECRET MISAPPROPRIATION)

21. Springboard repeats, realleges, and incorporates by reference the allegations set forth in paragraphs 1 through 20 of this Complaint.

22. This is a cause of action for Misappropriation of Trade Secrets under the Uniform Trade Secrets Act, Cal. Civ. Code § 3426 *et seq.*, based upon AMS's wrongful and improper use and disclosure of proprietary information owned by Springboard.

23. This proprietary Springboard information is a trade secret because it derives independent economic value from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use.

24. AMS gained access to Springboard's proprietary information, *inter alia*, during the presentation by Dr. Benderev on October 29, 2003, subject to the second CDA that Mr. Kohrs executed on behalf of AMS.

25. Springboard took reasonable precautions under the circumstances to protect its trade secrets, and parties with access to the information were subject to obligations to maintain its secrecy.

26. On information and belief, AMS has used and/or disclosed Springboard's trade secrets without Springboard's consent or permission, in developing AMS's urologic slings, including the MiniArc.

27. On information and belief, AMS has used and/or disclosed Springboard's trade secrets without Springboard's consent or permission, in breach of its duty to maintain secrecy pursuant to the second CDA.

28. On information and belief, AMS has disclosed Springboard's trade secrets, maliciously and in willful and conscious disregard of the rights of Springboard.

29. On information and belief, AMS's willful, improper, and unlawful use and/or disclosure of Springboard's trade secrets has resulted in the unjust enrichment of AMS.

30. On information and belief, the aforementioned acts of AMS in wrongfully misappropriating Springboard's trade secrets, were willful and malicious, warranting an award of exemplary damages, as provided by Civ. Code § 3426.3(c), and an award of reasonable attorneys fees, as provided by Civ. Code § 3426.4.

THIRD CAUSE OF ACTION
(BREACH OF CONTRACT)

31. Springboard repeats, realleges, and incorporates by reference the allegations set forth in paragraphs 1 through 30 of this Complaint.

32. The second CDA requires AMS to use Springboard's proprietary information only for limited purposes.

33. On information and belief, AMS breached the terms of the second CDA by using and disclosing Springboard's proprietary information without

///

Springboard's consent or permission, in developing AMS's devices, including the MiniArc.

34. Springboard has fully performed all of its obligations and has satisfied all of its conditions for performance under the second CDA.

35. By reason of the above actions, and as a foreseeable, direct, and proximate result of AMS's breach of the second CDA, Springboard has suffered irreparable injury to its rights and pecuniary damages.

36. On information and belief, AMS has derived, received, and will continue to derive and receive from the aforesaid breach of contract, gains, profits, and advantages, many of which are not presently known to Springboard.

37. By reason of the above actions, and a foreseeable, direct, and proximate result of AMS's breach of the second CDA, Springboard has been, and will continue to be, greatly damaged in an amount not presently ascertained but to be determined at trial.

38. Springboard is therefore entitled to damages as provided by law.

FOURTH CAUSE OF ACTION

(STATUTORY UNFAIR COMPETITION)

39. Springboard repeats, realleges, and incorporates by reference the allegations set forth in paragraphs 1 through 38 of this Complaint.

40. This is a cause of action for Statutory Unfair Competition under California Bus. & Prof. Code § 17200, *et seq.*

41. The acts of AMS alleged herein, including, but not limited to, AMS's misuse of Springboard's proprietary information for the purpose of developing AMS's own urologic slings to compete with Springboard constitutes unlawful, unfair, and fraudulent business practices in violation of California Bus. & Prof. Code § 17200, *et seq.*

42. On information and belief, AMS's acts of unfair competition are continuing in nature, have caused Springboard to suffer injury in fact, and Plaintiff

has lost money and property as the result of Defendant's conduct, and therefore AMS should be enjoined from continuing to engage in the unfair competition alleged herein.

43. On information and belief, based on the acts of unfair competition alleged herein, Springboard is also entitled to any other and further equitable relief deemed necessary by the Court, and an award of attorneys' fees upon prevailing in the request for relief in this cause of action.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Springboard prays for a judgment in its favor against Defendant AMS for the following relief:

A. For an Order adjudging AMS to have directly and indirectly infringed the '460 patent under 35 U.S.C. § 271;

B. For a permanent injunction pursuant to 35 U.S.C. § 283 enjoining AMS, its officers, directors, agents, servants, employees and attorneys, and all those persons in active concert or participation with the Defendant, from directly or indirectly infringing the '460 patent;

C. For an accounting of all gains, profits, and advantages derived by AMS's infringement of the '460 patent and a recovery of Springboard's compensatory damages pursuant to 35 U.S.C. § 284;

D. For an Order adjudging AMS to have willfully infringed the '460 patent under 35 U.S.C. § 271;

E. For increased damages of treble the amount of actual damages pursuant to 35 U.S.C. § 284;

F. For an assessment of pre-judgment and post-judgment interest and costs against AMS, together with an award of such interest and costs, pursuant to 35 U.S.C. § 284;

G. For an Order adjudging this an exceptional case pursuant to 35 U.S.C. § 285;

H. For an award of Springboard's attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285;

I. For an Order adjudging AMS to have misappropriated Springboard's trade secrets in violation of the Uniform Trade Secrets Act, Cal. Civ. Code § 3426 *et seq.*, and that the Defendant's actions in doing so be adjudged willful and malicious;

J. For an Order adjudging AMS to have competed unfairly with Springboard under California Business and Professions Code § 17200 *et seq.*, and that AMS's actions in doing so be adjudged intentional, willful and done knowingly;

K. For an Order adjudging AMS to have breached its October 29, 2003 contract with Springboard;

L. For damages sufficient to compensate Springboard for AMS's trade secret misappropriation under, *inter alia*, California Civil Code § 3426.3;

M. For damages sufficient to compensate Springboard for AMS's breach of contract;

N. For a permanent injunction enjoining AMS, its officers, directors, agents, servants, employees and attorneys, and all those persons in active concert or participation with it, from engaging in any act or practice which constitutes unfair competition against Springboard;

O. For a permanent injunction enjoining AMS, its officers, directors, agents, servants, employees and attorneys, and all those persons in active concert or participation with it, from engaging in any further use and/or misappropriation of Springboard's trade secrets;

P. For a permanent injunction enjoining AMS, its officers, directors, agents, servants, employees and attorneys, and all those persons in active concert or participation with it, from engaging in any further breach of its contracts with Springboard;

Q. For exemplary damages under California Civil Code § 3426.3;

R. For an award of Springboard's reasonable attorneys' fees under, *inter alia*, California Civil Code § 3426.4 and § 1021.5;

S. For AMS to account to Springboard for any and all gains, profits, and advantages derived by AMS as a consequence of the acts complained of herein;

T. For AMS to make restitution of all money and other benefits resulting from the acts complained of herein;

U. For an award to Springboard of any and all other specific, general, and compensatory damages according to proof; and

V. For such other and further relief as this Court may deem just and proper.

Dated: 9/25/08

By: _____
KNOBBE, MARTENS, OLSON & BEAR, LLP
John B. Sganga, Jr.
William R. Zimmerman
Payson LeMeilleur
Jonathan E. Bachand

ROBINSON, CALCAGNIE & ROBINSON
Mark P. Robinson Jr.
Kevin F. Calcagnie

Attorneys for Plaintiff
SPRINGBOARD MEDICAL VENTURES LLC

DEMAND FOR TRIAL BY JURY

SPRINGBOARD MEDICAL VENTURES LLC hereby demands a trial by jury on all issues so triable.

Dated: 9/25/08

By:
KNOBBE, MARTENS, OLSON & BEAR, LLP
John B. Sganga, Jr.
William R. Zimmerman
Payson LeMeilleur
Jonathan E. Bachand

ROBINSON, CALCAGNIE & ROBINSON
Mark P. Robinson Jr.
Kevin F. Calcagnie

Attorneys for Plaintiff
SPRINGBOARD MEDICAL VENTURES LLC

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EXHIBIT A

CONFIDENTIAL DISCLOSURE AGREEMENT

This Agreement, effective November 12, 2001, between American Medical Systems, Inc., a Delaware Corporation, 10700 Bren Road West, Minnetonka, Minnesota 55343 ("AMS") and Theodore V. Benderev, M.D., Springboard Medical Ventures, LLC and Pelvicare Incorporated 28202 Cabot Rd., Suite 300, Laguna Niguel, California 92677 (collectively "Discloser").

WHEREAS, AMS currently markets penile prostheses, artificial urinary sphincters, urological stent products, male and female slings, and other urological products; and

WHEREAS, AMS would like to evaluate certain information regarding product ideas conceived by Discloser or products developed or under development by Discloser which relate to Incontinence, Pelvic Support and Urinary Drainage Devices (the "Products").

NOW, THEREFORE, in consideration of the foregoing, the parties hereto agree as follows:

1. For purposes of this Agreement, the term "Confidential Information" shall mean all information, which Discloser deems to be confidential and proprietary, relating to the Products (including, but not limited to, data, know-how, technical and nontechnical materials, and specifications) which Discloser shall deliver to AMS pursuant to this Agreement. All Confidential Information which is delivered to AMS in writing shall be stamped or marked "Confidential" on the cover page thereof. All Confidential Information which is disclosed by Discloser orally shall be confirmed in writing or by e-mail by the Discloser to be Confidential Information within fifteen (15) days of oral disclosure.

2. AMS, for itself and for its subsidiaries and affiliates, agrees to maintain in confidence the Confidential Information received from Discloser with the same degree of care it holds its own confidential and proprietary information. AMS will divulge Confidential Information of Discloser only to its employees, agents and consultants who have a need to know as part of AMS' use of the Confidential Information hereunder and who are under appropriate confidentiality restrictions. As used in this Agreement, "subsidiaries and affiliates" shall mean any corporation, firm, partnership or other entity which directly or indirectly controls, is controlled by, or is under common control with, AMS where "control" shall mean the ownership or control of more than fifty percent (50%) of all of the voting power of the shares (or other securities or rights) entitled to vote for the election of directors or other governing authority.

3. In the event that any samples or models relating to Products are furnished to AMS in connection with its evaluation hereunder, AMS agrees to use such samples and models only for its evaluation, to keep confidential the results of any tests conducted thereon and to return such samples or models, as well as any documents or other materials embodying Confidential Information, at the conclusion of its evaluation or upon Discloser's request, except that AMS may retain one copy of any such documents for archival purposes.

4. The preceding obligations of AMS of non-disclosure and the limitation upon the right to use the Confidential Information (including samples and test results) shall not apply to the extent that AMS can demonstrate, through written records, that the Confidential Information is: (a) in the possession or control of AMS without restriction on disclosure and use prior to the time of disclosure hereunder; (b) at the time of disclosure or thereafter becomes public knowledge through no fault or omission of AMS or any subsidiary or affiliate of AMS; (c) lawfully

[redacted] third party under no obligation of confidentiality to Discloser; or (d) was [redacted] by AMS without using or referring to the Confidential Information.

[redacted] Subject to the provisions of Paragraph 4 hereof, all proprietary rights (including but [redacted] to patent rights and trade secrets) in and to the Confidential Information and the [redacted] products shall remain Discloser's exclusive property.

6. The Confidential Information being disclosed to AMS pursuant to this Agreement is with the express understanding that neither AMS nor Discloser will be obligated to enter into any further agreement relating to the Products or the Confidential Information, and nothing in this Agreement shall be construed as granting any license to AMS relating thereto.

7. This Agreement shall be governed by the internal laws (but not laws relating to choice of law) of the State of Minnesota. This Agreement sets forth the entire agreement and understanding between the parties hereto as to the subject matter hereof and has priority over all documents, verbal consents or understanding made between the parties with respect to the subject matter hereof. None of the terms of this Agreement shall be amended or modified except pursuant to a written document signed by the parties hereto.

8. All obligations of AMS under this Agreement shall terminate three (3) years from the date of this Agreement.

9. Discloser represents to AMS that Discloser has the full authority and right to enter into this Agreement and to disclose to AMS the Confidential Information and that such disclosure will not violate the rights of any third party.

AMERICAN MEDICAL SYSTEMS, INC.

By: Eva Snitkin

Name: Eva Snitkin
Director, Business Development

Date: 1/13/03

By: T.V.B.

Name: Theodore V. Benderev, M.D.
Pelvicare Incorporated
President
Springboard LLC

Date: 1-15-03

-2-

Exhibit A

EXHIBIT B

CONFIDENTIAL DISCLOSURE AGREEMENT

This Agreement, effective October 29, 2003; thereby superceding and replacing, as of the effective date, a similar agreement executed on November 12, 2001; between American Medical Systems, Inc., a Delaware Corporation, 10700 Bren Road West, Minnetonka, Minnesota 55343 ("AMS") and Theodore V. Benderev, M.D., Springboard Medical Ventures, LLC and Pelvicare Incorporated 27601 Forbes Road, Suite 42, Laguna Niguel, California 92677 (collectively "Discloser").

WHEREAS, AMS currently markets penile prostheses, artificial urinary sphincters, urological stent products, male and female slings, and other urological products; and

WHEREAS, AMS would like to evaluate certain information regarding product ideas conceived by Discloser or products developed or under development by Discloser which relate to Incontinence, Pelvic Support and Urinary Drainage Devices (the "Products").

NOW, THEREFORE, in consideration of the foregoing, the parties hereto agree as follows:

1. For purposes of this Agreement, the term "Confidential Information" shall mean all information, which Discloser deems to be confidential and proprietary, relating to the Products (including, but not limited to, data, know-how, technical and nontechnical materials, and specifications) which Discloser shall deliver to AMS pursuant to this Agreement. All Confidential Information which is delivered to AMS in writing shall be stamped or marked "Confidential" on the cover page thereof. All Confidential information which is disclosed by Discloser orally shall be confirmed in writing or by e-mail by the Discloser to be Confidential information within fifteen (15) days of oral disclosure.

2. AMS, for itself and for its subsidiaries and affiliates, agrees to maintain in confidence the Confidential Information received from Discloser with the same degree of care it holds its own confidential and proprietary information. AMS will divulge Confidential Information of Discloser only to its employees, agents and consultants who have a need to know as part of AMS' use of the Confidential Information hereunder and who are under appropriate confidentiality restrictions. As used in this Agreement, "subsidiaries and affiliates" shall mean any corporation, firm, partnership or other entity which directly or indirectly controls, is controlled by, or is under common control with, AMS where "control" shall mean the ownership or control of more than fifty percent (50%) of all of the voting power of the shares (or other securities or rights) entitled to vote for the election of directors or other governing authority.

3. In the event that any samples or models relating to Products are furnished to AMS in connection with its evaluation hereunder, AMS agrees to use such samples and models only for its evaluation, to keep confidential the results of any tests conducted thereon and to return such samples or models, as well as any documents or other materials embodying Confidential Information, at the conclusion of its evaluation or upon Discloser's request, except that AMS may retain one copy of any such documents for archival purposes.

4. The preceding obligations of AMS of non-disclosure and the limitation upon the right to use the Confidential Information (including samples and test results) shall not apply to the extent that AMS can demonstrate, through written records, that the Confidential Information is: (a) in the possession or control of AMS without restriction on disclosure and use prior to the time of disclosure hereunder; (b) at the time of disclosure or thereafter becomes public

knowledge through no fault or omission of AMS or any subsidiary or affiliate of AMS; (c) lawfully obtained by AMS from a third party under no obligation of confidentiality to Discloser; or (d) was independently derived by AMS without using or referring to the Confidential Information.

5. Subject to the provisions of Paragraph 4 hereof, all proprietary rights (including but not limited to patent rights and trade secrets) in and to the Confidential Information and the Products shall remain Discloser's exclusive property.

6. The Confidential Information being disclosed to AMS pursuant to this Agreement is with the express understanding that neither AMS nor Discloser will be obligated to enter into any further agreement relating to the Products or the Confidential Information, and nothing in this Agreement shall be construed as granting any license to AMS relating thereto.

7. This Agreement shall be governed by the internal laws (but not laws relating to choice of law) of the State of Minnesota. This Agreement sets forth the entire agreement and understanding between the parties hereto as to the subject matter hereof and has priority over all documents, verbal consents or understanding made between the parties with respect to the subject matter hereof. None of the terms of this Agreement shall be amended or modified except pursuant to a written document signed by the parties hereto.

8. All obligations of AMS under this Agreement shall terminate three (3) years from the date of this Agreement.

9. Discloser represents to AMS that Discloser has the full authority and right to enter into this Agreement and to disclose to AMS the Confidential Information and that such disclosure will not violate the rights of any third party.

AMERICAN MEDICAL SYSTEMS, INC.

By: _____

Name: M. James Call
Executive Vice President and CFO

Date: 10/29/03

By: _____

Name: Theodore V. Benderev, M.D.
Pelvicare Incorporated
President
Springboard LLC

Date: 10-29-03

-2-

EXHIBIT C

US007410460B2

(12) **United States Patent**
Benderev

(10) **Patent No.: US 7,410,460 B2**
(45) **Date of Patent: *Aug. 12, 2008**

(54) **SYSTEM FOR SECURING SUTURES, GRAFTS AND SOFT TISSUE TO BONE AND PERIOSTEUM**

(76) Inventor: **Theodore V. Benderev**, 26975 Magnolia Ct., Laguna Hills, CA (US) 92653

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 749 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **10/679,131**

(22) Filed: **Oct. 3, 2003**

(65) **Prior Publication Data**

US 2004/0106847 A1 Jun. 3, 2004

Related U.S. Application Data

(63) Continuation-in-part of application No. 10/465,330, filed on Jun. 19, 2003, now Pat. No. 7,387,634, which is a continuation-in-part of application No. 09/733,455, filed on Dec. 8, 2000, now Pat. No. 7,326,213, which is a continuation-in-part of application No. 09/197,938, filed on Nov. 23, 1998, now Pat. No. 6,200,330.

(51) **Int. Cl.**
A61F 2/02 (2006.01)
A61B 17/12 (2006.01)

(52) **U.S. Cl.** **600/30**; 600/37

(58) **Field of Classification Search** 600/29–30, 600/37; 606/75, 151, 152, 213, 215–216, 606/219–220, 228, 232; 128/897–898
See application file for complete search history.

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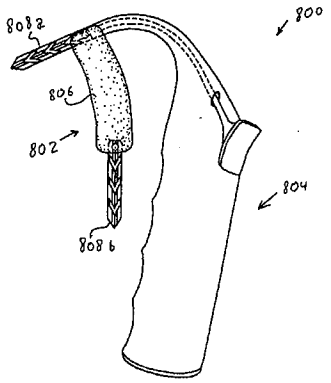
Primary Examiner—John P Lacyk
(74) *Attorney, Agent, or Firm*—Stetina Brunda Garred & Brucker

(57) **ABSTRACT**

Self-anchoring slings and deployment mechanisms for use therewith in selectively positioning a sling into position within the body. According to a preferred embodiment, the sling comprises an elongate sling portion having opposed ends. Formed upon each respective opposed end is an anchor member operative to be advanced through soft tissue at a selected target site in a first direction but resist movement in an opposed direction. Such anchor members are operative to extend in opposed directions to thus enable a sling to be securely affixed into position and resist sag or otherwise lose its ability to support a given structure. The deployment system is operative to selectively anchor the respective anchor members into position within a tissue mass. Although suitable for a wide variety of applications, it is believed that the system and sling of the present invention are particularly well suited for the deployment of suburethral slings via a trans-obturator route.

23 Claims, 11 Drawing Sheets



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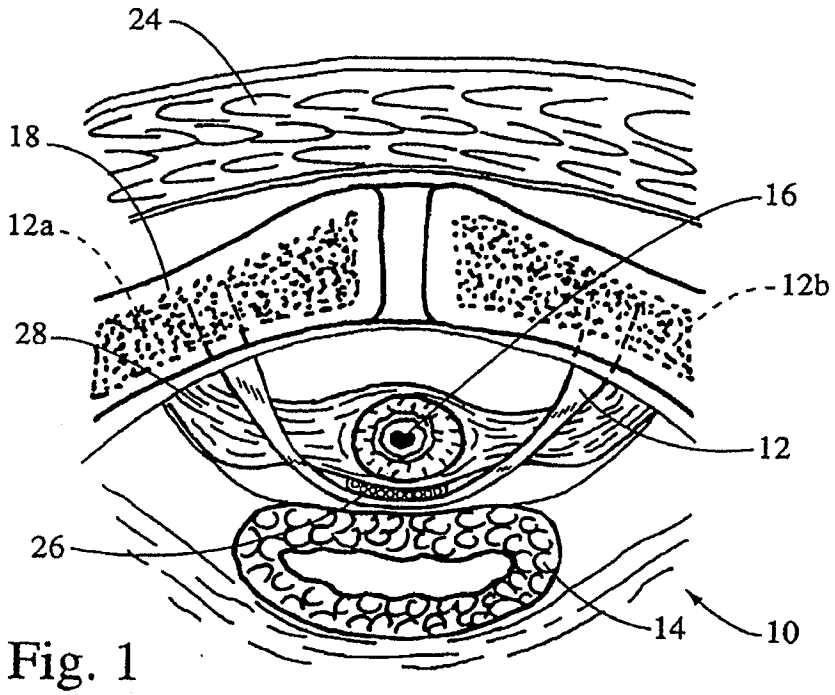


Fig. 1

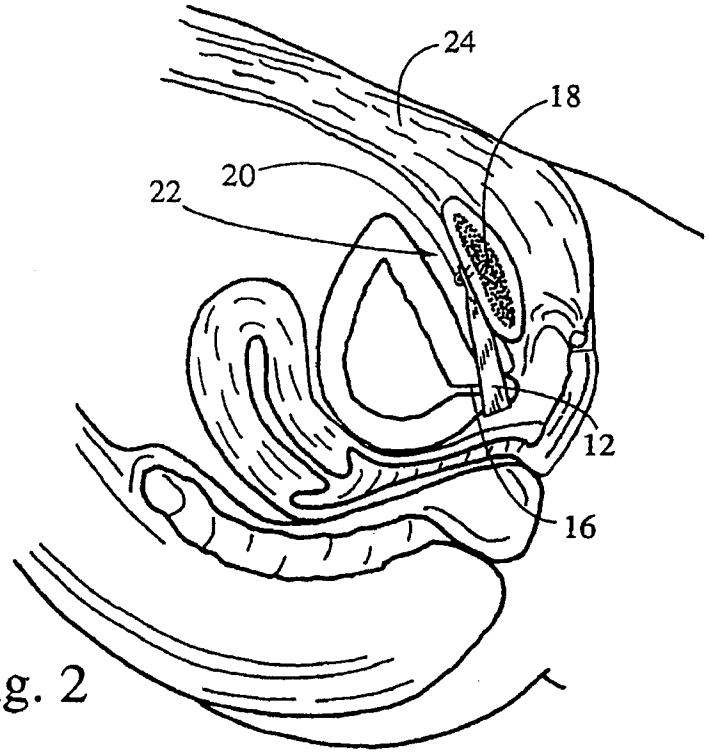
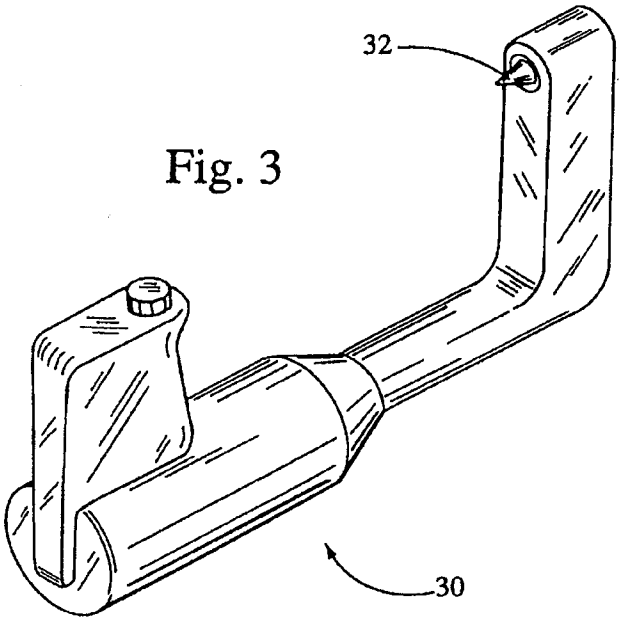


Fig. 2

Fig. 3



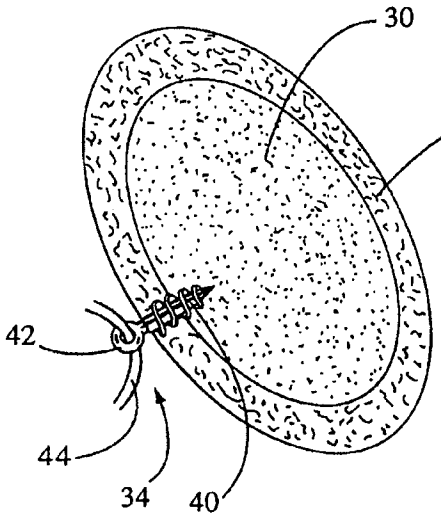
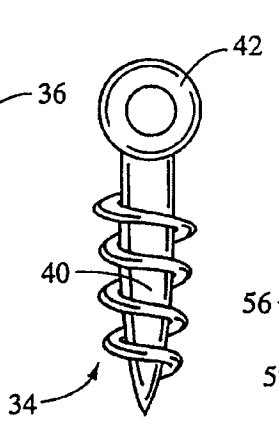


Fig. 4



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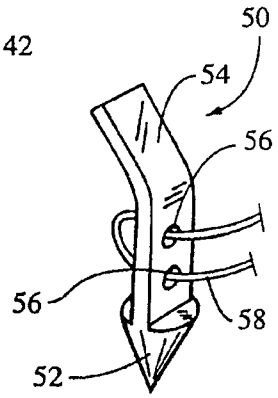


b

Fig. 5

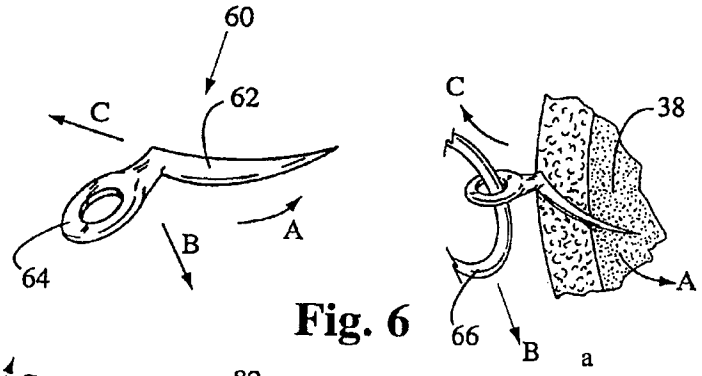


Fig. 6

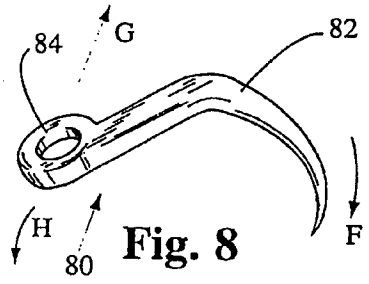


Fig. 8

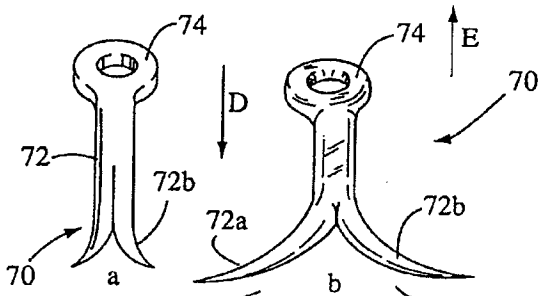


Fig. 7

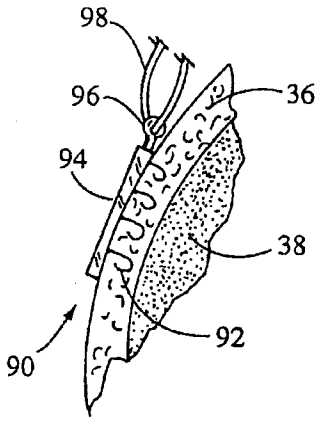


Fig. 9

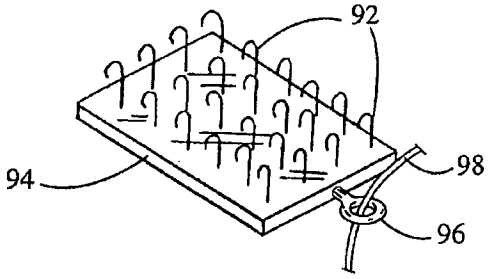


Fig.10

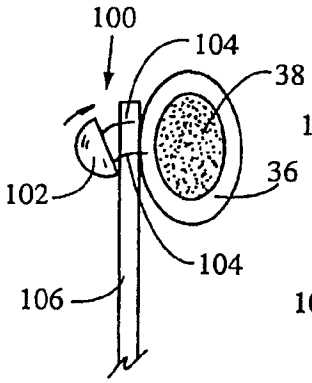


Fig. 11

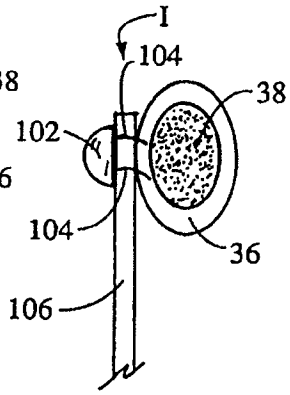


Fig. 12

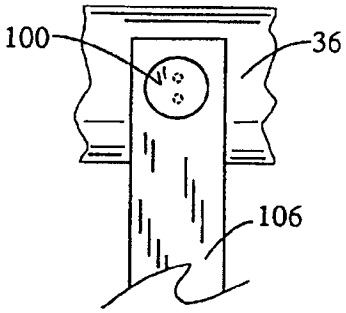


Fig. 13

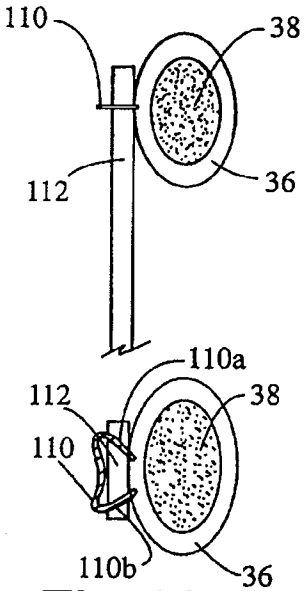


Fig. 14

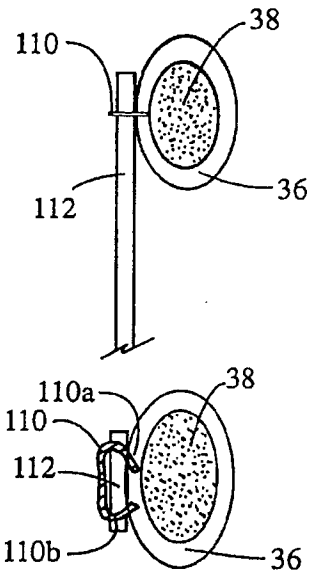


Fig. 15

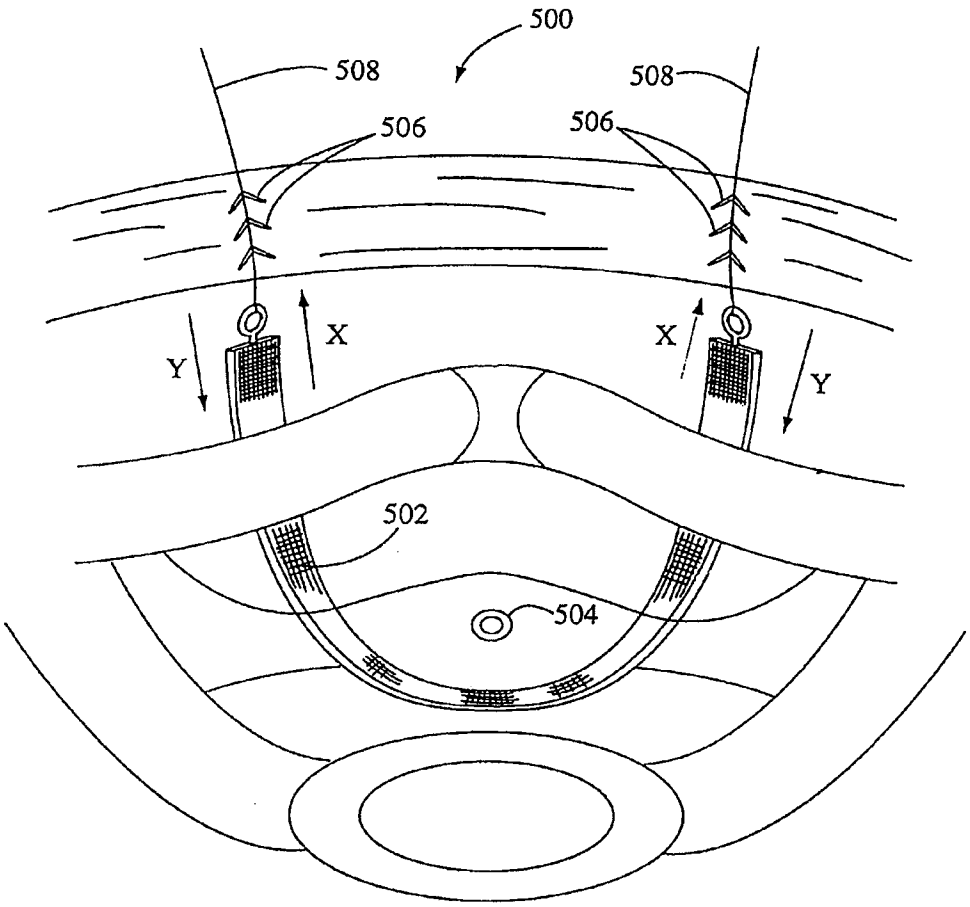


Fig.16

Fig. 16a

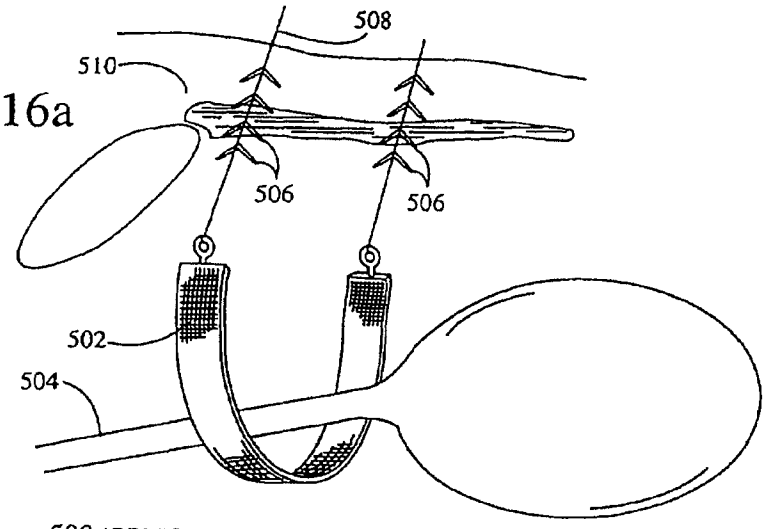
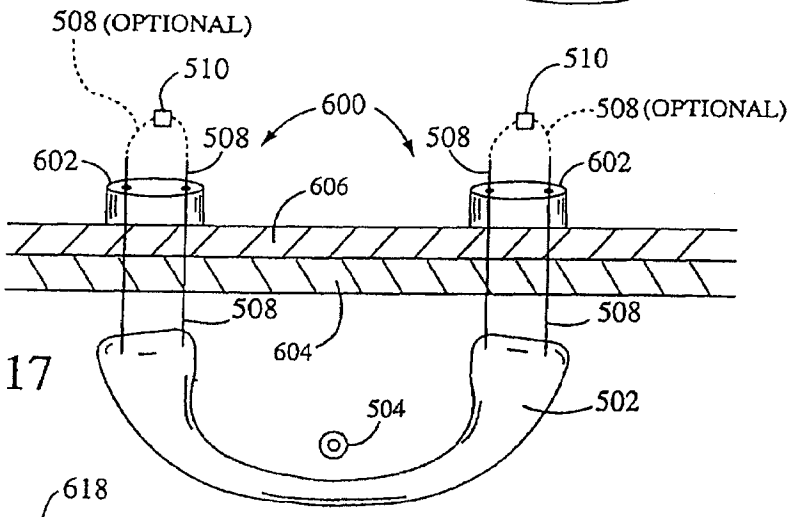


Fig. 17



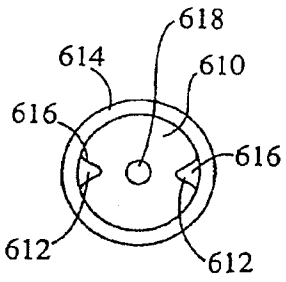


Fig. 17a

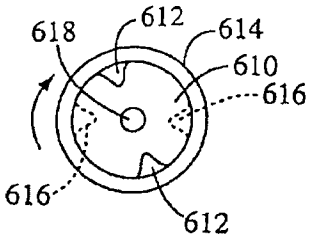


Fig. 17b

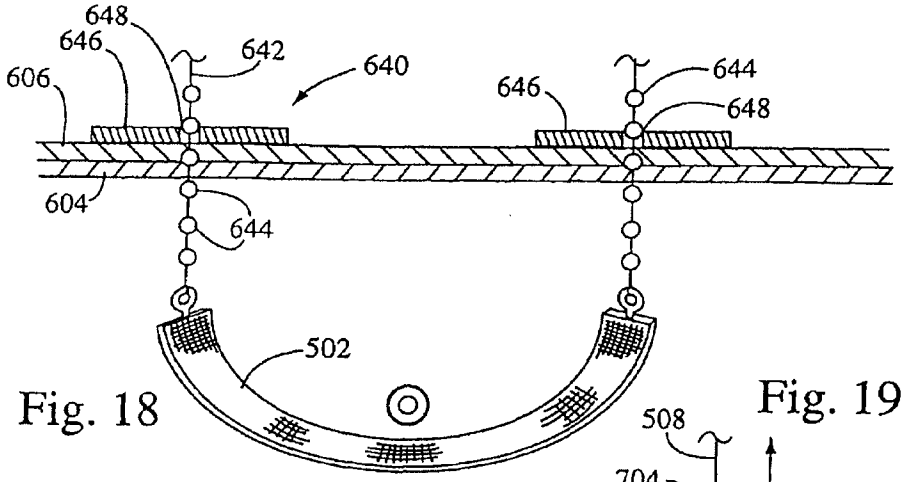


Fig. 18

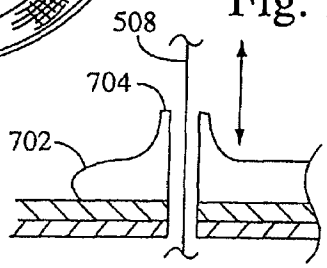


Fig. 19a

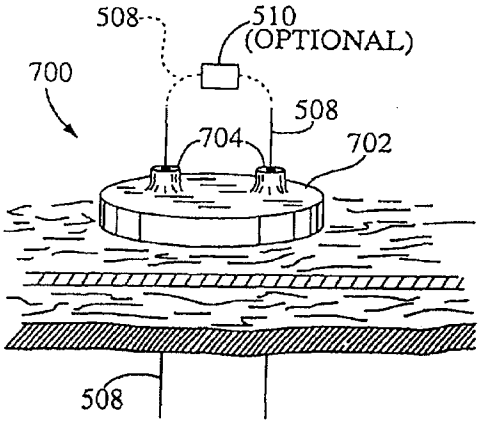


Fig. 19

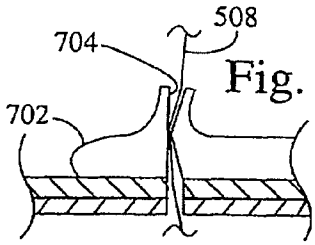


Fig. 19b

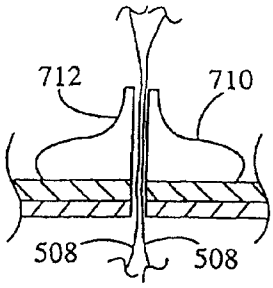


Fig. 19c

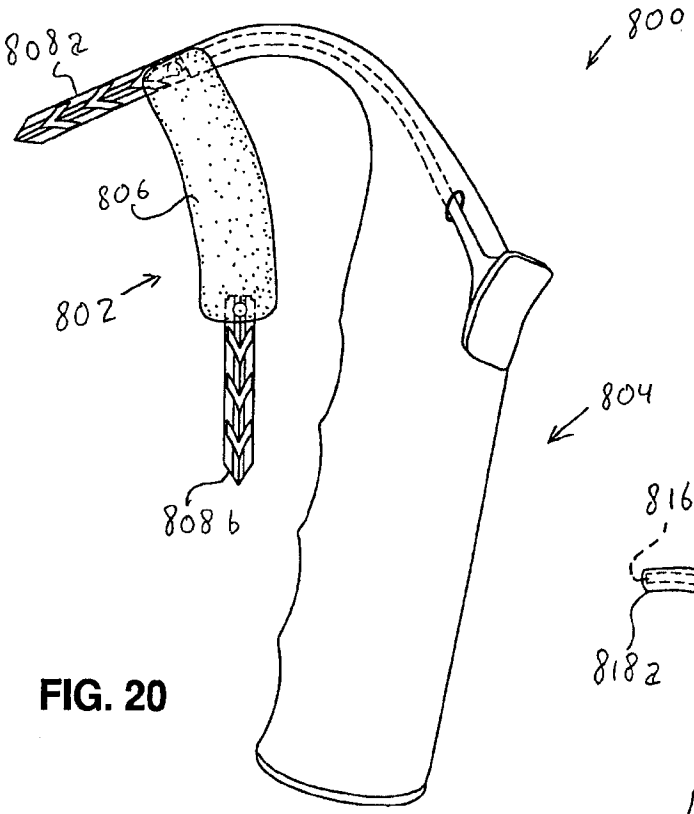


FIG. 20

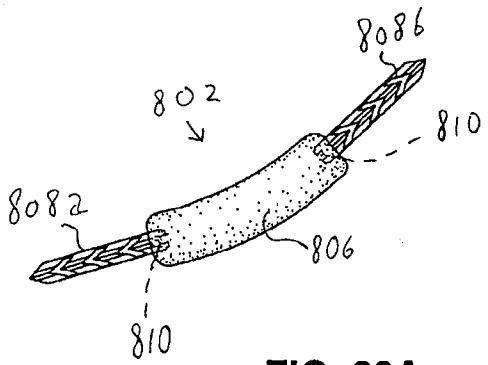


FIG. 20A

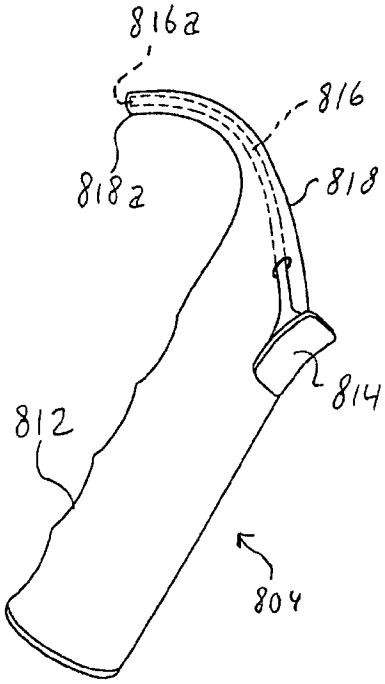


FIG. 20B

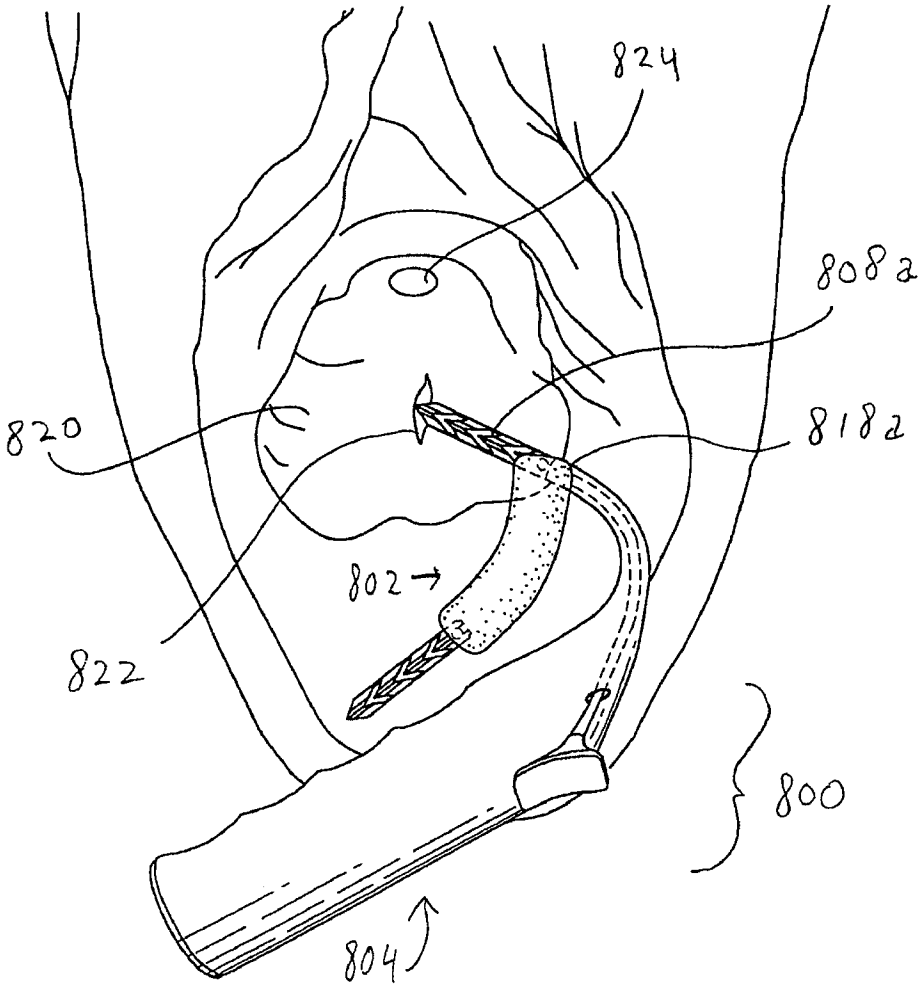


FIG. 21

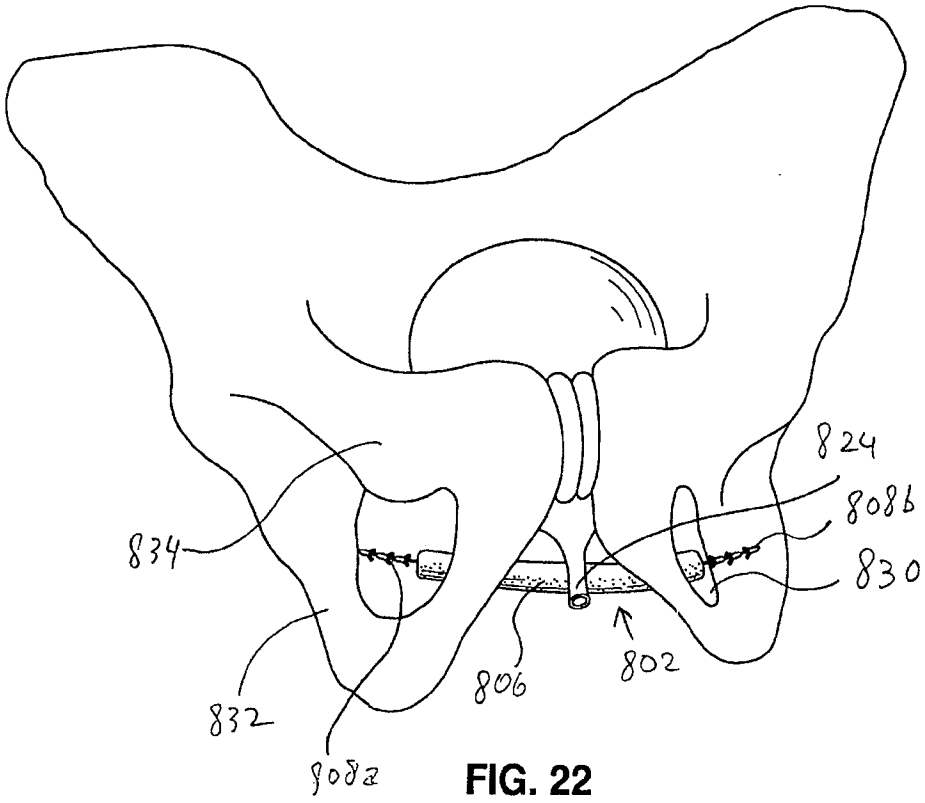


FIG. 22

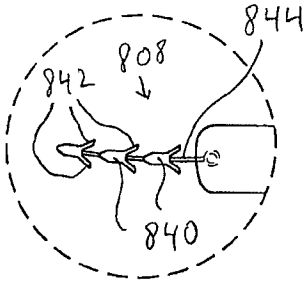


FIG. 22A

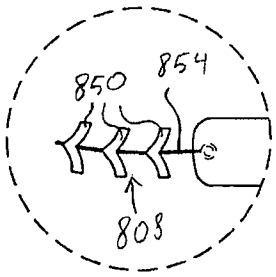


FIG. 22B

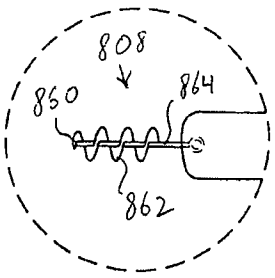


FIG. 22C

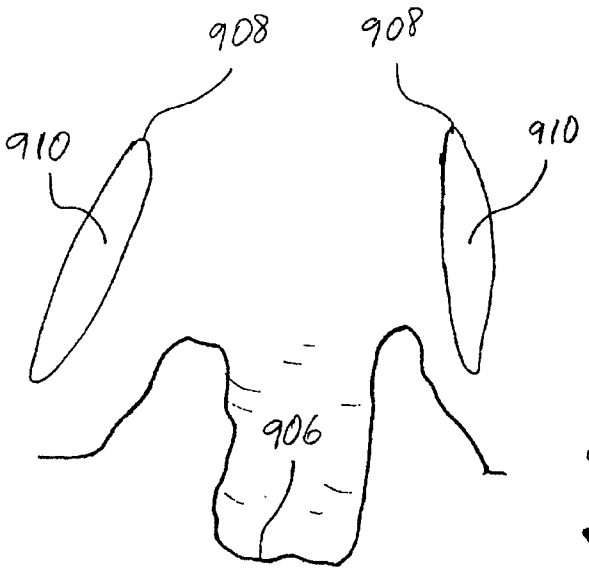


Fig. 23

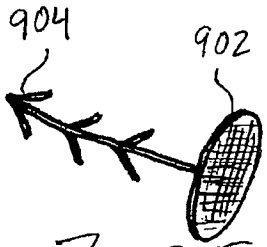


Fig. 25

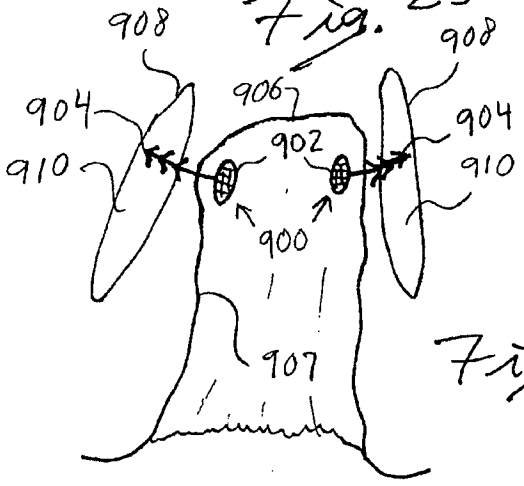


Fig. 24

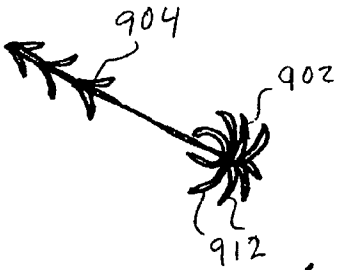


Fig. 26

SYSTEM FOR SECURING SUTURES, GRAFTS AND SOFT TISSUE TO BONE AND PERIOSTEUM

CROSS-REFERENCE TO RELATED APPLICATIONS

The following patent application is a continuation-in-part of U.S. patent application Ser. No. 10/465,330 entitled SYSTEMS FOR SECURING SUTURES, GRAFTS AND SOFT TISSUE TO BONE A PERIOSTEUM, filed Jun. 19, 2003 now U.S. Pat. No. 7,387,634, which is a continuation-in-part of U.S. patent application Ser. No. 09/733,455 entitled SYSTEM AND METHOD FOR SECURING SUTURES TO BONE AND TISSUE, filed Dec. 8, 2000, which is a continuation-in-part of U.S. patent application Ser. No. 09/197,938 entitled SYSTEMS FOR SECURING SUTURES, GRAFTS AND SOFT TISSUE TO BONE AND PERIOSTEUM, now issued as U.S. Pat. No. 6,200,330, and further relies upon Disclosure Document No. 463,908 entitled Transvaginal Rectus-Fascia Anchor, filed Oct. 21, 1999; Disclosure Document No. 479243 entitled Adjustable Soft Tissue Attachment Device and System, filed Sept. 5, 2000; Disclosure Document entitled Transvaginal Rectus-Fascia Attachment, filed Mar. 1, 2000, disclosure document number not assigned; Disclosure Document entitled Transvaginal Attachment Delivery Tool, filed on or about Mar. 1, 2000, disclosure document number not assigned; Disclosure Document No. 463,825 entitled Transvaginal Anchor Delivery Tool, filed on Oct. 21, 1999; Disclosure Document No. 458,659 entitled Transvaginal Adjustable System, filed Jul. 6, 1999; and Disclosure Document No. 480,805 entitled Adjustable Suture Soft Tissue Attachment System, filed Oct. 6, 2000, the teachings of all of which are incorporated herein by reference.

STATEMENT RE: FEDERALLY SPONSORED RESEARCH/DEVELOPMENT

Not Applicable

BACKGROUND OF THE INVENTION

The use of surgical suture anchors for use in attaching soft tissue to bone is well known in the art. In this regard, such anchoring mechanisms have found widespread applicability for a number of surgical procedures, and in particular orthopedic, gynecologic and urologic procedures. Exemplary of such devices include bone screws or anchors that are implantable within bone which further have formed thereon an eyelet or other type of assembly to which may be affixed suture lines or a segment of soft tissue. Exemplary of such devices include those devices disclosed in U.S. Pat. No. 5,370,662, and 5,443,482 to Stone, et al. and U.S. Pat. No. 4,738,255 to Gobel, et al.

Generally, prior art anchor systems take one of two forms. The first configuration typically comprises a self-tapping bone screw, typically made of titanium, having an eyelet formed thereon to which the sutures or other material may be attached. In the alternative prior art configuration, the device comprises an anchor member, which may take the form of an arrowhead or similar conical configuration, which further includes a shaft or attachment member extending therefrom, the latter being formed to have one or more apertures to which the sutures or other material may be attached.

With respect to the surgical installation of such devices, bone-screw mechanisms must necessarily be screwed in position, typically by a battery-powered screw driver, at a target site upon a particular bone. Anchor devices of the other aforementioned variety typically must be "shot" into position at a particular site within a bone, typically via a spring-loaded delivery mechanism. Exemplary of such bone-anchor insertion devices include the In-Fast and In-Tac bone screw and bone anchor fixation devices previously produced by Influence, Inc. of San Francisco, Calif., now a division of American Medical Systems, Inc.

Although such prior art anchor devices generally provide sufficient support to the various sutures and grafts affixed thereto, such fixation devices suffer from numerous drawbacks. In this regard, it is difficult for the surgeon to accurately deploy the insertion device such that the anchor is correctly inserted at the target site. Moreover, substantial difficulty arises in removing and adjusting such devices. This latter task is especially problematic with respect to bone-screw devices insofar as the surgeon attempting to remove the same must take great care to insure that the removal device, also typically comprising a battery-powered screw driver, properly unscrews the anchor member from its seated position. Other prior art anchor devices are even further problematic insofar as the same are often irretrievable once deployed, especially in situations where the same are deployed too deeply into the bone mass.

Additional problems exist with prior art bone fixation systems insofar as the same have a tendency to become dislodged over time from their seated position. In this regard, due to the repetitive application of stress or strain upon the bone anchor via the suture or soft tissue attached thereto, such anchors can eventually become loose and slip out of engagement from their fixed position. This tendency is especially likely to the extent repetitive and persistent application of strain and stress is applied in one specific direction or orientation. In this regard, many fixation techniques are susceptible to failure with misplacement or pull-out of anchors and eventual dislodgement of the structure/graft supported thereby with coughing, vomiting or other violent activity. Moreover, even to the extent such bone anchoring systems remain securely in position, recent study tends to indicate that such bone fixation devices may actually have a tendency to cut the sutures sought to be held thereby.

Separate and apart from the drawbacks associated with the use of prior art bone anchoring systems is the fact that often times anchor systems provide far more structural support than is necessary for a given surgical application. In this respect, numerous surgical procedures requiring the fixation of sutures and/or soft tissue require only a minimal degree of tension. Exemplary of, and perhaps most well-known of such procedures include pelvic prolapse surgery, also known as colpopexy, colporrhaphy or vaginofixation, and transvaginal sling surgery, the latter of which is performed to treat incontinence. The former procedures typically involve the anchoring of all or a portion of the prolapsed vagina to adjacent or nearby structures such as the sacrum whereas sling surgery essentially involves the formation of a graft positioned beneath the urethra with the opposed ends thereof being secured to either one of the abdominal fascia, Cooper's ligament or pubic bone. While such slings typically require little to no tension once fixed into position, due to the lack of alternative means for affixing the opposed ends of such sling into position relative to the pubic bone, such prior art bone anchor devices must necessarily be deployed. As a result, time spent in surgery is increased and the patient undergoing such procedures in subjected to a far more traumatic experience and has a possibly greater susceptibility of becoming infected by virtue of the deployment of such anchor devices than would otherwise occur to the extent alternative, less traumatic affixation devices could be deployed. Along these

lines, a substantial risk exists simply by utilizing a retropubic route to gain access to the surgical site where such sling is affixed into position. In this regard, accessing such surgical site via a retropubic route can increase the risk of bleeding and/or intestinal injury due to the proximity of blood vessels existing within and above the pubocervical fascia and the intestines.

Accordingly, there is a need in the art for systems, devices and methods for affixing sutures, grafts, soft tissues, synthetic materials, and the like to bone and soft tissue that are easier to deploy, manipulate and can remain more firmly seated into position than prior art devices, especially in the performance of suburethral sling, colporrhaphy and colpopexy procedures. There is additionally a need for such devices that can be utilized in a wide variety of surgical applications and may be further customized for use for particular applications such that an optimal degree of support or leverage can be provided thereby. There is further a need in the art for affixation systems, devices and methods that can provide for means for affixing sutures, grafts, soft tissues, synthetic materials, and the like into position that are less traumatic, easier to deploy and adjust, and may be readily removed and repositioned at a particular site than prior art systems and devices.

BRIEF SUMMARY OF THE INVENTION

The present invention specifically addresses and alleviates the above-identified deficiencies in the art. In this regard, the present invention is directed to novel devices, systems and methods for the attachment of sutures, grafts and other types of tissues and materials to bone, periosteum, ligaments, fascia and other soft tissue as may be warranted in a given surgical procedure. The devices of type present invention are particularly well suited for the secure placement of one or both of the opposed ends of a suburethral sling for use in suburethral sling surgery, but are by no means limited to such particular application.

In a first preferred embodiment, the invention comprises an implant implantable within bone, ligaments, fascia and other soft tissue at a desired location. The implant comprises a piton portion designed to pierce into and engage with the bone, or tissue, and a support structure coupled therewith, the latter of which may take the form of a post, hook or eyelet to which the suture, graft, or tissue may be attached. The implants of the present invention may further include a handle member formed thereon to facilitate the insertion and removal of the implant from its fixed or seated position within the bone/tissue.

The piton portion of the implant is specifically designed to become more firmly embedded within the bone or other tissue when pressure is applied to the support structure in a first direction, but may be dislodged or removed when the implant is pulled in an opposed or second direction. The piton member may be further selectively sized and adapted for use in a particular application, and may be particularly designed to penetrate up to certain depths and/or be capable of supporting a specific quantity of mass or weight. In this regard, the implants may be designed to have two or more piton members, that each respectively provide means for securely attaching such implant to a desired side. Such implants may be further configured such that multiple implants may be deployed upon a length of a suture, such that the suture may be selectively pulled and anchored into position along a desired pathway. In this respect, the piton members may be formed such that the same are operative to facilitate movement through tissue in one direction, yet perform an anchoring function in an opposite direction.

Such embodiment further advantageously allows for post-operative adjustment whereby the suture with piton members attached thereto can be selectively pulled along the desired pathway to the extent necessary to adjust the suture position and/or introduce a greater degree of tension thereto. Along these lines, such embodiment has the additional advantage of being completely removable from the patient's body by virtue of its ability to selectively move through and out of tissue.

In a second preferred embodiment, the invention comprises a disc anchoring system that is operative to serve as a platform to which sutures, graphs and the like may be secured or, alternatively, serve as a support for forming a suture "bridge". According to one preferred version, the affixation device comprises a disc or anchor plate which is positionable upon a layer to tissue, such as a layer of muscle, fascia, or ligament, and in particular, the rectus fascia layer. The anchoring plate is preferably formed to be generally circular in nature and comprised of an inner plate member encased within an annular outer plate member. The inner and outer plate members are further preferably formed such that at least one, and preferably two, diametrically opposed apertures are formed respectively therein for receiving suture lines insertable therethrough. The inner plate and outer annular member are formed relative one another such that the inner plate is rotational relative the outer annular ring and operative to transition between a first open configuration, wherein said apertures formed upon the respective plates are open to receive suture lines therethrough and a second closed configuration, wherein rotation of the inner plate relative to the annular ring causes the apertures to close and lock, (i.e., crimp) any suture line extending therethrough to become rigidly secured in position. To the extent desired, those portions of the sutures extending through the anchor plate may be affixed to one another to thus form a bridge or adjoining suture link.

In an alternative configuration, the disc anchoring system comprises a disc or anchor plate which is likewise positionable upon a layer of tissue (e.g., muscle, fascia, or ligament) that includes at least one, and preferably two to four, channels for receiving suture lines insertable therethrough. The channel or channels are configured such that the same are crimpable such that when the suture line or lines are ideally positioned therein or impart the necessary degree of support to an object (i.e., sling, graft, etc.), the crimping of such channel or channels affixes such length of suture or sutures into position. To achieve that end, it is contemplated that any of a variety of conventional crimping devices may be deployed to impart the necessary crimp in the channel or channels. As per the aforementioned embodiment, to the extent multiple suture lines extend through such plate, the same may be tied, linked, crimped or otherwise joined to one another to form a suture bridge.

The disc anchoring system may further take the form of a system whereby a suture, having a plurality of protuberances formed therealong, is engageable with an anchor plate, the latter having an aperture formed therein for receiving the suture line. As respective ones of the protuberances extend through and rest against the anchor plate, the suture line may thus be maintained in a fixed position relative a desired target site. Such embodiment advantageously provides for post-operative adjustment should it become necessary to reposition the suture or increase the tension within the suture line secured by the disc anchoring system.

In all embodiments, the disc anchoring systems are particularly well suited for the use in pubovaginal sling surgery where it is necessary to secure a sling such that the sling extends a desired distance from the urethra or exerts a desired

degree of supportive pressure thereto, which thus necessitates that such sling be selectively secured into position via the suture extending through the anchor plate. It will be recognized, however, that such disc anchoring systems may be utilized for a wide variety of medical applications and further, may be formed to be permanently affixed into position or formed from a bio-absorbable material to the extent such anchoring systems need only remain resident for a limited duration. Still further, it is contemplated that each of the aforementioned disc anchoring system may incorporate a load-bearing object, such as a washer, mesh or other like structure, as part of or in conjunction with the disc anchoring system to facilitate the distribution of stress and strain imparted thereto. As with the disc system, such load distributing apparatus may be formed to be permanently secured into position or formed from an absorbable material.

In a third preferred embodiment, the invention comprises an affixation device designed to secure sutures, grafts, tissues, synthetic materials, and the like to periosteum (i.e., the thick fibrous membrane covering the surface of bones) and other soft tissue. According to a preferred embodiment, the affixation device includes a backing or base member having at least one, and preferably a multiplicity of hook members that are sized and adapted to hook into and ensnare with the periosteum or tissue. The hook members may be specifically designed to become partially embedded within the periosteum tissue, to thus provide relatively loose connection that is easier to remove, or adjust, and may be designed to penetrate deeper within the periosteum tissue to thus provide a more secure method of attachment. An attachment member formed upon the base member is further provided to which may be attached a suture or a portion of a graft.

In an alternative preferred embodiment, the invention comprises an implantable tack consisting of a hub member having at least one, and preferably two or more hook members formed thereon, the latter being designed to extend through the graft or tissue and become ensnared with and embedded in the periosteum such that the graft or tissue becomes interposed between and affixed into position relative the tack and periosteum. The affixation devices according to such embodiments are specifically designed for selective attachment and detachment, and are further designed to provide more atraumatic means for the attachment of the suture or graft to a target location via the periosteum and soft tissue. Such a fixation device, however, may be adapted such that the same are designed to pierce into and become embedded with the bone, as per the other aforementioned embodiments.

In yet another embodiment of the present invention, there is provided a novel surgical staple that is also designed to secure a graft or other types of tissues and materials to the bone, periosteum, or other soft tissue at a specific site or location. The staples of the present invention are preferably formed from plastically deformable materials having opposed ends that are designed to penetrate through the graft/tissue and hook into the bone, periosteum or soft tissue at a selected site of fixation. Once secured in position, the staples are operative to assume an expanded configuration such that the hooks formed thereby become more firmly embedded within the bone/tissue at the target site of fixation to thus further secure attachment of the graft thereto. Preferably, such staples may be fabricated from a shape-memory material, such as nitinol, which thus enables the staple to assume the compressed configuration when at room temperature, but transition to the operative, expanded configuration when warmed to body temperature, as will occur when the device is deployed. Such materials further enable the staples of the present invention to be removed, as may be necessary, during a given procedure or later procedures. Conversely, such staples may be formed from material that enable the same to compress or contract once secured into position to thus provide for a more secure means of attachment.

The present invention further comprises novel surgical approaches for the secure placement of a transvaginal sling during transvaginal sling surgery. More particularly, such surgical procedure involves securing such sling into position, namely, beneath the urethra, with the opposed ends thereof being secured to the posterior portion of the pubic bone, whether it be either the pubic bone itself or the periosteum surrounding the same, in the retropubic space. The opposed ends of the sling may be attached to either the periosteum over the pubic bone or to the pubic bone itself using the novel affixation devices of the present invention. Advantageously, such surgical procedure eliminated the needs to form an abdominal incision, which typically must be made utilizing conventional surgical procedures. The novel affixation method of the present invention during such surgery further provides for the ingrowth of the opposed ends of the graft to a target site near or on the pubic bone or the periosteum thereabout that eliminates any intervening pelvic fascia that would otherwise become interposed between the anchor and opposed ends of the sling sought to be secured into position.

As an alternative to the aforementioned approaches, the present invention further comprises novel systems and surgical techniques that can deploy anchoring systems for the placement of radio opaque markers, such as the TINED lead system of radio opaque markers produced by Medtronic, Inc., and pelvic floor reconstruction for support of pelvic organs, such as through the use of slings affixed thereto, that are fixed into position via trans-obturator placement, as opposed to conventional retropubic surgical placement. Such surgical techniques, devices and systems utilized therewith are positioned utilizing a single percutaneous incision made in the vaginal epithelium which enables a sling to be anchored into position in a target tissue, such as rectus and/or pubocervical fascia, via sling placement toward or through the obturator foramen. To achieve that end, there is preferably provided a deployment system operative to selectively deploy and securely place into position a self-anchoring sling comprised of an elongate sling having opposed ends. Formed on each opposed end of such sling are dedicated anchor mechanisms that are each operative to penetrate into and become embedded within a target site of soft tissue, such as the obturator membrane situated within or around the obturator foramen.

Each respective anchor mechanism is operatively configured such that each anchor mechanism is advanceable in a first direction through the soft tissue at the target site but selectively adjustable to resist movement in an opposed direction, (i.e., such anchor mechanisms are configured such that the opposed ends of the sling are capable of being advanced in opposed directions but resisting or preventing contraction or other similar type of motion drawing the ends towards one another). To facilitate such movement, it is contemplated that the anchor mechanisms may take the form of screws, arrowheads, prongs, and in particular generally Y-shaped or chevron shaped prongs, or any other structure that is capable of being advanced in one direction yet resists or is biased against movement in an opposed direction. In further refinements such anchor mechanisms may further be selectively configured to penetrate to a desired depth within a tissue mass, as well as may be selectively configured to assume a first compressed or deployment configuration such that the same will be operative to be positioned within a specific target site, and a second operative configuration whereby the anchor mechanism expands or otherwise assumes a locking configuration

that enables the anchor to become affixed into position. In this regard, it is contemplated that the anchor mechanism may be formed to have an outwardly expanding spring bias such that once released from a confined position automatically expands or anchors in an automatic fashion.

With respect to the deployment of such slings, it is contemplated that the same will be deployed through a manually operable deployment mechanism. Preferably, such deployment mechanism will include a handle having a deployment member extending distally therefrom. With respect to the latter, the deployment member will preferably be configured for insertion through and under the vaginal wall to thus enable the slings with anchor mechanisms formed thereon to be deployed via a trans-obturator or other route. To facilitate that end, it is contemplated that the deployment member may be provided with a sharpened distal end capable of forming an incision within the vagina and thereafter be extensable under the vaginal wall to thus deploy the slings of the aforementioned variety within or near the obturator foramen. In use, the sling having the anchoring mechanisms formed upon the opposed ends thereof will be coupled to or mounted upon the deployment member such that a respective one of the anchor mechanisms can be positioned by the deployment member at a specified site within the target tissue (e.g., the pubocervical fascia or within the obturator foramen). In this regard, it is contemplated that the deployment member may be configured such that the anchor mechanisms will be deployed in a sequential manner such that a first anchor is deployed in one target site and the other opposed anchor member deployed at a second site such that the sling disposed intermediate the anchor members can be selectively positioned to provide an optimal degree of support to the urethra. In order to manipulate such device, it is contemplated that the deployment system will include an actuation member that enables the surgeon to manually direct the advancement of the anchor mechanism coupled with or mounted upon the deployment member of the mechanism to thus enable the self-anchoring sling to be controllably fixed into position. To facilitate such placement, it is contemplated that the deployment member may be selectively curved or shaped to gain access more readily within a particular anatomical site, such as the obturator foramen.

Related to the foregoing techniques and further encompassed within the scope of the present invention are surgical techniques, slings and anchoring devices for performing vaginal reconstruction surgery, such as vaginal prolapse surgery. According to such technique, the prolapsed vagina in inverted such that the same attains its proper anatomical orientation and, as per the aforementioned technique regarding the deployment of anchoring mechanisms within the obturator foramen, at least one, and preferably an opposed pair of anchoring mechanisms are deployed through the vaginal wall and into the obturator foramen, thus causing the vaginal wall to remain anchored in its proper anatomic orientation. To that end, it is contemplated that the anchoring mechanisms are operative to penetrate into and become embedded within a target site of soft tissue within or around the obturator foramen in a second platform or mesh portion which remains embedded or compressed against the vaginal wall to thus support and retain such structure into position. To facilitate that end, it is contemplated that such anchor members will include a platform surface formed from mesh or other like material to thus provide sufficient surface area to support the vaginal wall into proper positioning.

It is therefore an object of the present invention to provide surgical implantation devices to facilitate the attachment of sutures, grafts, tissues and the like to bone, periosteum and soft tissue that are easier to implant and remove than prior art devices, and are further capable of providing greater support or leverage to the structures coupled therewith than prior art devices.

Another object of the present invention is to provide surgical implantation devices for the attachment of sutures, grafts, tissues and the like to bone, periosteum and soft tissue that can be utilized in a wide variety of surgical procedures, and in particular colpopexy, colporrhaphy, suburethral sling or other pelvic support surgery, and that may be further designed to provide an optimal degree of support for a given quantity of mass or weight as may be necessary for a given surgical procedure.

Another object of the present invention is to provide devices for the affixation of sutures, grafts, tissues and the like to periosteum and soft tissue at a specific site or location that does not require any anchoring mechanism to be inserted into the bone.

Another object of the present invention is to provide devices for the attachment of sutures, grafts, tissues and the like to bone, periosteum and soft tissue at a specific location that are less traumatic than other prior art affixation devices.

Another object of the present invention is to provide devices for the attachment of sutures, grafts, tissues and the like to bone periosteum and soft tissue at a specific location that are easily attachable to and detachable from a point of fixation than prior art devices and re-attachable as may be necessary for a given procedure or future procedures.

Still further objects of the invention include methods and devices for securing sutures, grafts, tissues and the like to bone, periosteum and soft tissue that are of simple construction, may be easily and readily utilized for a variety of surgical procedures, may be readily adapted for use in a wide variety of surgical procedures, and provide an equal, if not greater degree of support or leverage than prior art devices.

Another object of the present invention is to provide a self-anchoring sling that enables the sling to be securely affixed into position within a site of soft tissue such that the same resists sag or otherwise lessens its ability to provide support that can further preferably be deployed via a trans-obturator route, and preferably via a system and method that enables the same to be deployed via a single access route, such as a single vaginal incision, to thus eliminate risks associated with sling delivery via a retro-pubic route.

Another object of the present invention to provide a novel surgical procedure for the formation and affixation of a suburethral sling whereby the opposed ends of the sling are secured near or at the posterior side of the pubic bone in the retropubic space with the opposed ends of the sling being secured to either the periosteum, Cooper's ligament, fascia or the pubic bone itself.

It is another object of the present invention to provide a novel surgical procedure for performing vaginal prolapse surgery, as well as provide devices for performing vaginofixation such that the vagina is surgically positioned according to its proper physiological orientation by anchoring the same in or around a target site of soft tissue, preferably situated at or near the obturator foramen.

BRIEF DESCRIPTION OF THE DRAWINGS

These, as well as other features of the present invention will become more apparent upon reference to the drawings wherein:

FIG. 1 is a frontal, cross-sectional view of the rectus fascia, pubic bone, urethra and vagina further depicting a sling mem-

ber positioned about the urethra or in which the respective ones of opposed ends of the sling are secured to the pubic bone.

FIG. **2** is a side cross-sectional view of the anatomical structures depicted in FIG. **1** and further depicting the fastening arrangement by which the sling is anchored to the posterior portion of the pubic bone.

FIG. **3** is a prior art surgical instrument utilized to secure the anchor member depicted in FIG. **2** to the posterior of the pubic bone.

FIG. **4** is a cross-sectional view of the pubic bone having a prior art anchor device secured thereto.

FIGS. **5***a* and **5***b* are perspective views of prior art anchor devices.

FIGS. **6** and **6***a* are a perspective view of a surgical implant constructed in accordance with a preferred embodiment of the present invention for use in attaching sutures, grafts, tissues and the like to bone, periosteum, and soft tissue, and a side view of the same being inserted into bone.

FIG. **7***a* is a perspective view of a surgical implant constructed in accordance with a second preferred embodiment of the present invention for use in attaching sutures, grafts, tissues and the like to bone, periosteum, and soft tissue. Such figure depicts the surgical implant assuming a pre-insertion configuration.

FIG. **7***b* is a perspective view of the surgical implant of FIG. **7***a* with the implant assuming an expanded, anchoring configuration.

FIG. **8** is a perspective view of a surgical implant constructed in accordance with a third preferred embodiment of the present invention for use in attaching sutures, grafts, tissues and the like to bone, periosteum, and soft tissue.

FIG. **9** is a cross-sectional view of the pubic bone and periosteum thereof having an affixation device affixed with the latter, said affixation device being constructed in accordance with a fourth preferred embodiment of the present invention useful for securing sutures, grafts, tissues and the like to bone, periosteum and soft tissue.

FIG. **10** is a perspective view of the affixation device depicted in FIG. **9**.

FIG. **11** is a cross-sectional view of the pubic bone and periosteum formed thereabout having an opposed end of a graft being secured thereto with an implantable tack, the latter being constructed in accordance with a fifth preferred embodiment of the present invention.

FIG. **12** is a cross-sectional view of the pubic bone and periosteum formed thereabout showing the graft depicted in FIG. **11** being secured thereto via the implantable tack.

FIG. **13** is a frontal view of the graft depicted in FIGS. **11** and **12** as secured to the periosteum via the implantable tack of the present invention.

FIG. **14** is a cross-sectional view further depicting an expanded view of the pubic bone with periosteum formed thereabout having an opposed end of the surgical sling affixed to the periosteum via a surgical staple, the latter being constructed in accordance with a sixth preferred embodiment of the present invention, the staple assuming a first insertion mode.

FIG. **15** is a side-view depicting the surgical staple depicted in FIG. **14** securing an opposed end of the sling to the periosteum, the staple assuming a second, affixation configuration.

FIG. **16** is a cross-sectional view of a suture having a plurality of affixation devices secured thereto, the latter constructed in accordance with a preferred embodiment of the present invention, for use in securing the suture along a desired pathway through tissue.

FIG. **16***a* is a perspective side view of FIG. **16**.

FIG. **17** is a frontal, partially cross-sectional view of a sling being secured beneath a urethra and selectively secured into position to layers of muscle/rectus fascia via an anchoring plate fixation device as constructed in accordance to a preferred embodiment of the present invention.

FIGS. **17***a* and **17***b* are top views of the fixation device utilized in FIG. **17**, the fixation device being shown in a first operative configuration in a second locking or closed configuration.

FIG. **18** is a perspective view of an anchoring system constructed in accordance with another preferred embodiment of the present invention.

FIG. **19** is a perspective view of an anchoring system constructed in accordance with another preferred embodiment of the present invention.

FIG. **19***a* is a partial cross-sectional view of the system depicted in FIG. **19** shown with a suture line extending through a channel defined thereby.

FIG. **19***b* is the cross-sectional view of FIG. **19***a* wherein the channel of said anchoring system is shown in a crimped configuration, the crimp maintaining the suture disposed within the channel in fixed position.

FIG. **19***c* is a cross-sectional view of the anchoring system depicted in FIG. **19** with one channel extending therethrough, said channel having two suture lines extended therethrough.

FIG. **20** is a perspective view of a sling deployment system comprised of a self-anchoring sling member comprised of an elongate sling having anchoring mechanisms formed on the opposed sides thereof, a respective one of the anchoring mechanisms being coupled with a manually operable sling deployment mechanism constructed in accordance with a preferred embodiment of the present invention.

FIG. **20***a* is a perspective view of the sling member depicted in FIG. **20**.

FIG. **20***b* is a perspective view of the sling deployment mechanism depicted in FIG. **10**.

FIG. **21** is a perspective illustration of the sling deployment system and components thereof as depicted in FIGS. **20**, **20***a* and **20***b* wherein a respective anchor mechanism of the sling component is advanced into an incision made in a vaginal wall.

FIG. **22** is a perspective view of the self-anchoring sling depicted in FIGS. **20**, **20**(*a*) and **21** as positioned within the obturator foramen and operative to support the patient's urethra.

FIG. **22***a* is a perspective view of an embodiment anchoring mechanism as incorporated within the self-anchoring slings of the present invention as constructed in accordance with a preferred embodiment.

FIG. **22***b* is a perspective view of an embodiment anchoring mechanism as incorporated within the self-anchoring slings of the present invention as constructed in accordance with another preferred embodiment.

FIG. **22***c* is a screw-type anchor for use with the self-anchoring slings of the present invention as constructed in accordance with yet a further preferred embodiment.

FIG. **23** is a frontal view of a prolapsed vagina and the positioning of the obturator foramen relative thereto.

FIG. **24** depicts the vaginofixation of the prolapsed vagina in FIG. **23** utilizing a fixation device constructed in accordance with a preferred embodiment of the present invention.

FIG. **25** is an enlarged perspective view of the fixation device depicted in FIG. **24**.

FIG. **26** is a perspective view of the fixation device of FIG. **25** as constructed in accordance with an alternative preferred embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

The detailed description as set forth below in connection with the appended drawings is intended as a description of the presently preferred embodiments of the invention, and is not intended to represent the only form in which the present invention may be constructed or utilized. The description sets forth the functions and sequences of steps for constructing and operating the invention in connection with the illustrated embodiments. It is understood, however, that the same or equivalent functions and sequences may be accomplished by different embodiments and that they are also intended to be encompassed within the scope of this invention.

Referring now to the drawings, and particularly FIGS. **6-15**. there are shown various embodiments of the devices and systems of the present invention for securing sutures, grafts, tissues and synthetic materials, and the like to bone, periosteum and other soft tissue. As is well known in the practice of medicine, a wide variety of surgical procedures often necessitate the use of anchoring devices for purposes of attaching suture lines and grafts to bone. Exemplary of such anchoring devices include those disclosed in U.S. Pat. Nos. 5,370,662 and 5,443,482, the teachings of which are expressly incorporated herein by reference as frequently deployed in orthopedic, gynecologic, and urologic surgical procedures.

Among the more well-known surgical procedures incorporating the use of such anchoring devices include transvaginal sling surgery. As illustrated in FIGS. **1** and **2**, such surgical procedure **10** involves the formation of a sling **12**, which may comprise a harvested graft from a donor, or the patient's own tissue or an elongate strip of fabricated synthetic material or some combination thereof, that is introduced via an opening made to the vaginal wall **14** selectively positioned beneath the urethra **16**. Once properly positioned, the sling **12** is secured into position. Unlike conventional transvaginal sling surgery, however, the sling **12** as depicted in FIGS. **1** and **2** is secured within the retropubic space via an anchoring mechanism **20**, more clearly depicted in FIG. **2**. As will be appreciated by those skilled in the art, the method by which the opposed ends **12***a*, **12***b* of the sling **12** are secured, namely to the posterior side of the pubic bone **18**, represents a novel approach insofar as such sling **12** is stitched into position in the retropubic space **22**, as opposed to the suprapubic space which is conventionally utilized. Unlike alternative methods of performing suburethral sling procedures, such transvaginal sling surgical procedure advantageously dispenses with the need to form an incision in the patient's lower abdomen **24** to thus enable the surgeon to gain access to the various anatomical structures, such as the abdominal fascia, pubic bone, or Cooper's ligament, to which the opposed ends of such sling are to be attached. As is well known, performing such abdominal incision increases operative time, increases the chances of infection, delays recovery time, and leaves undesirable scarring. Moreover, such sling procedure as depicted does not require that the sutures or opposed ends of the grafts be caused to penetrate through the intervening pubocervical fascia **28**, depicted in FIG. **1**, present in the retropubic space **22** which, as will be appreciated by those skilled in the art, prevents ingrowth of the opposed ends **12***a*, **12***b* of the sling **12** sought to be secured in position.

As a result of the support imparted by the sling **12** to the urethra **16** during such times as the patient makes provocative gestures, as occurs during coughing, such sling **12** serves as support that prevents incontinence occurring during such provocative event. To insure that the sling **12** is positioned such that the same imparts an optimal degree of support to the urethra **16**, it is contemplated that a tension/pressure monitor **26**, as depicted in FIG. **1**, may be utilized during the performance of such surgical procedure. Such tension/pressure monitors **26** may take any of a variety of forms such as those disclosed in Applicant's co-pending U.S. patent application Ser. No. 09/157,466, the teachings of which are expressly incorporated herein by reference.

In order to provide an anchoring mechanism necessary to secure the sling into position during transvaginal sling procedures, however, there must be deployed the aforementioned anchoring device **20**. As depicted in FIG. **3**, there is shown one such anchor deployment device **30**, also known in the practice of medicine as a bone screw inserter, which allows for bone-screw fixation. Perhaps the most well-known of such devices include the In-Fast and In-Tac bone screw and bone anchor fixation devices previously produced by Influence, Inc. of San Francisco, Calif. Such affixation devices are formed to have a generally "U" shape as shown that enables the distal-most end **32** thereof to be easily inserted into the vagina and be correctly positioned on the posterior portion of the pubic bone. As will be appreciated by those skilled in the art, the distal-most end **32** of such fixation deployment devices **30** are designed to deploy an anchoring device by screwing or embedding the same into bone at a specific site.

As more clearly seen in FIG. **4**, once deployed, the anchor devices **34** are advanced through the periosteum **36** and become embedded into the bone. To provide means for affixing the suture lines or grafts thereto, there is typically formed on the anchor devices a post, hook or eyelet, as shown. Among the more well-known designs of such anchoring devices currently in use include those depicted in FIGS. **5***a* and **5***b*. The first such prior art device **34** depicted in FIG. **5***a* comprises a self-tapping bone screw **40**, typically made of titanium, having an eyelet **42** formed thereon to which the sutures **44** or other material may be attached, as shown in FIG. **4**. In the alternative prior art configuration **50** depicted in FIG. **5***b*, the anchor fixation device comprises an anchor portion **52**, which may take the form of a conical member having a shaft or attachment member **54** extending therefrom, the latter being formed to have one or more apertures **56** thereon to which sutures **58** or other material may be attached. Such devices are typically "shot" into position via spring-loaded insertion devices, such as the In-Tac device discussed above.

Although such prior art anchor devices, such as those depicted in FIGS. **5***a* and **5***b*, generally provide sufficient support to the various sutures and grafts affixed thereto, such fixation devices **34**, **50** suffer from numerous drawbacks. With respect to the bone-screw fixation devices **34**, such devices are difficult to deploy and fix into position. In this regard, such screw fixation devices **34** require the battery-operated inserters **30** depicted in FIG. **3** that must necessarily drill the fixation device **34** into position. Removing such devices **34** is further problematic insofar as the same must necessarily be unscrewed from their position, which as those skilled in the art will appreciate requires meticulous precision.

Anchor devices **50** are also problematic insofar as the same are not only difficult to deploy, typically via a spring-loaded gun mechanism, but are often times irretrievable once deployed. In this regard, once such fixation device **50** is sufficiently embedded within the bone, the anchor portion **52** thereof cannot be reversibly extracted from its embedded position within the bone. As such, to the extent such anchoring devices **50** have been inappropriately deployed (e.g., deployed at a wrong location), there is little, if any, recourse to retrieve the same. Additionally, such prior art bone screws **34** and anchors **50** have the ability to become loosened and

dislodged from their position once a sufficient amount of pressure is applied thereto over time. The probability of becoming dislodged is further increased in those situations where a persistent strain is applied to such devices in a single direction, as can occur when a suture or graft is hung upon the anchoring device. In such circumstances, surgical intervention is necessary to not only retrieve the dislodged screw or anchor, but also deploy yet another of such devices as per the original surgical procedure.

Referring now to FIGS. **6-8**, there are shown three embodiments **60**, **70**, **80** of a surgical implant insertable into bone (as well as periosteum, ligaments, and other soft tissue) which are useful in providing means to secure sutures, grafts, tissues, synthetic materials, and the like to bone, as may be necessary for a given surgical procedure. Each of the embodiments depicted have the advantage of being easy to insert and remove, as well as provide an equal, if not greater, degree of support than prior art devices. Such novel implants further have the ability to remain more firmly seated into position once embedded in bone than such prior art devices.

Referring now to FIG. **6**, there is shown a first embodiment **60** of the surgical implant. As illustrated, the implant **60** comprises a piton member **62** having an eyelet **64** formed thereon. The piton member **62** preferably comprises an arcuate blade having proximal and distal ends, the latter being designed to be inserted into bone such that as the same is advanced therein, there is defined a penetration pathway as indicated by the latter "A". Once inserted into the bone tissue at the target site of fixation, the eyelet portion **64** of the implant will extend therefrom as illustrated in FIG. **6***a*, which will thus provide the necessary structure to which the sutures **66**, grafts and the like may be attached. Although the embodiment shown depicts the use of an eyelet **64**, it will be recognized that other substitute support or attachment structures, such as posts, hooks and the like, including even sledged-on fixation of the suture or graft to the piton, may be utilized as may be necessary for a given application.

As will be appreciated by those skilled in the art, by inserting the implant in the direction indicated by the letter "A", it will be appreciated that to the extent a force is applied thereto, such as by suture **60** or graft, via a vector having an orientation in the general direction of letter "B", such force will necessarily cause the implant to wedge deeper and become more secure into position within the bone **38**, and will thus cause the same to become more rigidly affixed into position unlike prior art devices which have a tendency to become loose and potentially dislodged with the application of greater amounts of pressure and strain thereto.

Such implant further provides the advantage of being easy to remove. In this regard, due to its orientation within the bone, to the extent a pulling force is applied to the implant in the direction indicated by the letter "C", such implant **60** will be caused to become easily dislodged from its seated position to the extent it becomes necessary to remove and/or reposition such implantable fixation device. Such ease of removal advantageously provides for a simpler, less traumatic procedure than those procedures involving prior art screw and anchor fixation devices.

Referring now to FIGS. **7***a* and **7***b*, there is shown a second embodiment **70** of a surgical implant designed to be embedded within bone or soft tissue to which may be attached sutures, grafts and the like. Such embodiment **50**, similar to the embodiment **60** depicted in FIG. **6**, is specifically designed such that the same becomes more firmly seated into position within the bone to the extent a force is applied in a first direction, as indicated by the letter "D". FIG. **7***a* depicts the surgical implant **70** assuming an insertion configuration which enables the same to be implanted into bone at a target site selected by the surgeon. Such implant is provided with a piton member **72** having opposed flanges **72***a*, **72***b* formed at the distal end thereof that are designed to spread apart in the directions "Y" and "Z" and become more deeply embedded within the bone to the extent a pressure is applied in a direction indicated by the letter "D". Although the specific embodiment **70** shown depicts that the opposed flanges **72***a*, **72***b* flare outwardly, it is to be understood that such flanges can be designed to curve inwardly. Moreover, although such embodiment depicts two opposed flanges, it should be recognized that such implant may have three or more flanges and that each respective flange may be designed to flare outwardly, as shown, or hook inwardly as may be needed to a specific application.

Once firmly embedded within the bone, the eyelet portion **74** of such implant may be utilized to attach sutures and the like. Of additional advantage, similar to the embodiment shown in FIG. **6**, is the fact that such implant **70** may further be easily removed to the extent a pulling or opposed force is applied in the direction indicated by the letter "E". As such, to the extent it becomes necessary to remove or otherwise reposition such anchoring device, such anchoring device **70** may be easily dislodged by application of such force. As will be appreciated, such design allows for easier and less traumatic removal than prior art anchor and screw fixation devices.

Referring now to FIG. **8**, there is shown a third embodiment **80** of a surgical tissue implant useful as a fixation device to attach sutures, tissues, and grafts to bone, periosteum, and soft tissue. As per the other embodiments, such implant **80** includes a piton member **82**, preferably formed as a sickle-shaped member, having an eyelet **84** formed on the proximal end thereof. Such implant **80** is designed to be embedded into the bone or other tissue in the direction indicated by the letter "F". Once so secured into position, forces may be applied thereto, via eyelet **84** in the direction indicate by the letter "G", which will thus work to further embed the piton member **82** into the bone via the penetration pathway defined by the distal end of the piton member **82** so that the implant becomes more secure therewithin. Likewise, to the extent it becomes necessary to remove such device **80**, such device may be removed by pulling or otherwise rearwardly retracting the implant in the direction indicated by the letter "H" which, as discussed in the other embodiments, provides for simpler and less traumatic procedure than prior art methodology.

Although each of the aforementioned embodiments **60**, **70**, **80** are particularly well-suited for insertion into bone, it should be recognized by those skilled in the art that the same may be utilized to affix sutures, grafts, tissues, synthetic materials and the like to connective tissue, and in particular, periosteum as per the further embodiments discussed more fully below. In this respect, each of the aforementioned embodiments **60**, **70**, **80** may be designed such that the piton portion thereof pierces into and becomes embedded within such tissue and remains firmly seated thereat so that the attachment mechanism formed thereon can provide a service to which the sutures, grafts and the like may be attached.

As will further be appreciated, in each of the embodiments **60**, **70**, **80** depicted in FIGS. **6-8**, the orientation of each of the implants as the same are embedded into the bone or tissue is crucial for the necessary operation thereof. In this regard, it will be appreciated that the implant must be oriented such that the resultant tension or strain applied thereto will cause the piton portion thereof to advance in the penetration pathway defined thereby. Otherwise, to the extent tension is applied in an opposed direction, such implant may be caused to dislodge from its seated position. As a consequence, it will be appre-

ciated that the implants of the present invention must be selectively positioned, and that the surgeon must take great care in making certain that the ultimate tension applied thereto is oriented to facilitate the attachment of the implant to the bone, as opposed to casing the same to become dislodged therefrom.

Referring now to drawings **16** and **16***a*, there is shown an additional surgical tissue implant **500** useful as a fixation mechanism to attach sutures, tissues, and grafts to soft tissue. In the embodiment depicted, which is shown being deployed for use in securing a sling **502** into position to provide support to a urethra **504**, the implant **500** comprises a plurality of dual-prong anchoring mechanisms **506** disposed linearly about a suture-like cord or line **508**, which enables such line to advance through the tissue in one direction, but resists rearward movement in the opposite direction. As shown, the implants can be configured to have a generally V-orientation such that the suture **508** bisects such implant and extends therethrough. As will be recognized, each respective implant will have an eyelet or other aperture through which the suture, which may be a suture line or suture-like cord, may be extended. As will be further recognized, although depicted as having a generally V-orientation, it will be appreciated that the anchoring mechanisms **506** may be arranged in a staggered configuration, extend along only one side of the suture **508**, or otherwise be radially disposed about a length of the suture **508**. Accordingly, it will be recognized that numerous other designs are contemplated that fall within the scope of the present invention.

By linearly disposing the implants along the suture line, the suture line may be advanced in a direction indicated by the letter "X", but yet resist movement in the direction indicated by the letter "Y". Advantageously, such arrangement enables the suture line **508** to be pulled into a desired position such that the sling **502** supported thereby can be caused to provide a selective degree of support to the urethra **504** or otherwise maintain a desired distance therefrom. Furthermore, to the extent the suture line **508** with implants **506** or the sling **502** supported thereby are inappropriately positioned, it will be recognized by those skilled in the art that, if necessary, the suture line **508** can be cut and the suture with implants affixed thereto extracted completely from the patient's body (and replaced, if necessary or desired). Such design further advantageously permits for the adjustment of the suture line and/or the sling supported thereby not only intro-operatively, but also post-operatively insofar as the suture line **508** can be extended further, for example, in the direction indicated by the letter "X", as may be desired to the extent it is necessary to add extra tension to the suture line **508**. Moreover, as discussed above, the suture line **508** can be removed entirely from a patient's body. In such circumstances, a second suture line **508** having such implants attached can be substituted in its place.

An example of the application of such system is illustrated in the side-perspective view of FIG. **16***a*. As illustrated, the sling **502** is positioned about the urethra **504** and supported upwardly by the suture-like cord **508** having the fixation devices **506** linearly disposed upon the length thereof. In this regard, each respective suture, cord, etc. **508** supporting each respective side of the sling **502** may be selectively caused to remain securely embedded at a desired position within the rectus fascia **510** or other soft tissue. As will be appreciated by those skilled in the art, due to the ability of the suture lines or suture-like cords **508** with the novel implant fixation devices **506** affixed thereto, the surgeon can incrementally increase the pressure exerted by the sling **502** against the urethra **504** or the distance by which the sling **502** extends from the urethra **504** merely by incrementally advancing the suture line/cord **508** through the rectus fascia **510**. As will be appreciated, there has not heretofore been available any mechanism available which provides a surgeon with the ability to merely advance a suture through tissue and have the same remain firmly secured into position. Rather, and as discussed more fully in the background, surgeons have had to identify a target site to which such sling can be anchored and thereafter tie the same into position such that the sling maintains the desired degree of support or distance from the urethra. As is widely recognized, malposition of the sling has been deemed the cause for creating a significant problem and substantially high morbidity for those patients having undergone sling surgery.

In a similar, yet further advanced variation of the embodiment depicted in FIGS. **16** and **16***a*, there is shown in FIGS. **20-22***c* a system **800** comprised of the combination of a deployment mechanism **804** and surgical implant **802**, the latter being configured as per tissue implant **500** that enables a sling portion **806** to be secured into position via the use of anchor mechanisms **808***a*, **808***b*, the latter of which are operative to advance through tissue in one direction but resist rearward movement in an opposite direction. In this regard, and as more clearly depicted in FIG. **20***a*, implant **802** will preferably be comprised of an elongate sling portion **806**, which as those skilled in the art will appreciate may take any of a variety of natural tissues, synthetic material or some combination thereof operative to become implanted within the body and support a specified anatomical structure. Affixed on the opposed ends of the sling **806** are dedicated anchor mechanisms **808***a*, **808***b* which are affixed to the respective ends of the sling **806** via a coupling apparatus **810**, which may likewise comprise any of a variety of attachment mechanisms known in the art.

Each respective anchor mechanism **808***a*, **808***b* may be configured per a variety of embodiments, discussed more fully below, that can enable each mechanism to be advanced into a target site of tissue in one direction yet resist movement when pulled in an opposed direction. In this regard, each respective anchor mechanism **808***a*, **808***b*, will be preferably formed upon the opposed ends of the sling **806** such that the anchor mechanisms **808***a*, **808***b* can be advanced through a target site of tissue in dissimilar directions, such as opposed directions, to thus enable the sling **806** to stretch beneath and ultimately support the target anatomical structure as previously discussed above with reference to FIGS. **1** and **16** (as well as FIG. **22** more fully below). To achieve that end, anchor mechanisms **808***a*, **808***b* may be provided with generally arrowhead-shaped members, V-shaped members, Y-shaped members, or any structure well-known in the art that facilitates the ability of the anchor mechanisms **808***a*, **808***b* to cut through and become positioned or embedded within a target site of tissue such that the same can become resident or fixed in position. In this regard, it is contemplated that the anchor mechanisms **808***a*, **808***b*, may be provided with a textured surface or otherwise be provided with materials to facilitate the ingrowth of tissue about the same to thus enable the anchor mechanisms to remain firmly seated into position once implanted into the body. Illustrative of such an embodiment would include the use of a mesh material cut such that the strands of the fabric of such mesh facilitate movement when advanced in a first direction but resist rearward movement due to the frayed, outwardly-flaring strands of the mesh that would be oriented to cause such loose ends to resist or become biased against rearward movement.

To facilitate the ability of the implant **802** to be accurately and securely placed into position within the body, a deploy-

ment mechanism **804**, more clearly depicted in FIG. **20***b*, may be utilized. Although the implant **802** may be surgically implanted into position utilizing a variety of well-known surgical techniques, it is believed that deployment mechanism **804** may be useful to more quickly, accurately and atraumatically position and securely affix such implant **802** into position. As illustrated, the mechanism **804** comprises a manually operable handle **812** having a deployment member **818** extending distally therefrom. An actuator mechanism **814** is disposed within the handle **812** and includes an elongate shaft portion **816** disposed axially within the deployment member **818** such that the distal-most end thereof **816***a* is caused to selectively protrude through a distal-most opening **818***a* of the deployment member **818**. The actuator **814**, and more particularly the shaft **816** thereof may be selectively coupled to an anchor mechanism such as **808***a* depicted in FIG. **20** to thus direct and position the anchor mechanism **808***a* at a target site within the body. Such deployment member **818** may be configured to have a variety of sizes and shapes, and may be specifically configured for deployment of an implant **802** at a particular target site within the body. For use in deploying implants, such as **802**, to provide suburethral support for the treatment of incontinence, it is contemplated that the deployment member **818** will have a generally arcuate shape and may further be preferably configured to deploy the implant **802** within the obturator foramen of a patient via a trans-obturator route, discussed more fully below.

To facilitate the interconnection between the implant **802**, and more particularly an anchor mechanism **808** thereof, with the deployment mechanism **804**, it is contemplated that such anchor mechanism **808** may be pre-loaded in a cartridge, not shown, the latter being selectively interconnectable with the deployment member **818**. In such embodiment, it is contemplated that such cartridge will be operative to form a rigid casing about the anchor mechanism **808** to thus enable the anchor mechanism to be easily affixed into position on the deployment member **818** and thereafter surgically guided into position such that once a target site has been accessed, the anchor mechanism **808** can be selectively deployed from the cartridge. To help enable the cartridge to reach such desired target site, it is contemplated that such cartridge may be provided with a cutting apparatus or sharpened cutting edge to thus enable the same to cut and advance through tissue. To that end, it will be readily appreciated by those skilled in the art that many possible designs and configurations will be readily apparent to effectuate that end.

Referring now to FIG. **21**, there is shown the use of the system **800** to deploy the implant **802** via the deployment mechanism **804**. In the procedure illustrated, such implant **802** is being deployed through an incision **822** formed within the vaginal wall **820** to thus enable a urethra **824** to ultimately become supported thereby. To that end, it is contemplated that such deployment may take one of two forms. According to a first embodiment, the anchor mechanisms **808** housed within the deployment mechanism are compressed to assume a first deployment configuration and, once released therefrom, assume an expanded configuration that enables the same to remain fixed in position. Alternatively, the anchor mechanisms may simply assume a single state and deploy directly into tissue at a desired surgical site. As will be appreciated, however, other techniques will be readily apparent to those skilled in the art for use in deploying the anchor mechanisms of the present invention.

In this regard, the procedure depicted in FIG. **21** represents deployment of a suburethral sling via a trans-obturator route. As is well-known, most slings are currently delivered via a retropubic route, and although the implants **802** and deployment mechanisms **804** can readily be adapted and utilized for such procedures, current methodology suggests that implant or sling deployment made via a trans-obtruator route substantially minimizes well-known risks associated with bleeding and/or intestinal or bladder injury associated with surgical sling implant procedures utilizing a retropubic route to gain access to the surgical site. In this regard, current medical literature strongly suggests that a trans-obturator route substantially avoids the blood vessels existing within and above the pubocervical fascia, bladder and the intestines. Moreover, securing slings into position according to conventional methodology utilizing retropubic access often times results in sling dislodgement or misplacement, especially so when conventional sling anchoring fails due to the pull or dislodgement of anchors and/or mesh when the patient engages in a violent provocative event, such as coughing, vomiting or some other violent activity.

As shown, the deployment mechanism **804** is selectively positioned such that an anchor mechanism **808***a* of the sling is advanced into the incision **822** via distally-extending deployment member **818**. The actuator **814**, and more particularly the shaft **816** extending therefrom, is operative to advance the anchor member **808***a* away from the distal end **818***a* of the member and through the soft tissue until the same becomes within a target site of tissue. To facilitate the ability of the mechanism to gain access to the target site, it is contemplated that the distal-most end **818***a* of deployment member **818** may be provided with a sharpened cutting surface to thus enable the same to be advanced through tissue via single incision **822**. In an alternative approach, the distal-most end **818***a* wil cooperate with anchor mechanism **808***a* to thus enable the implant to be advanced into and positioned through percutaneous incision **822** made in the vaginal wall **820**. Along these lines, it is contemplated that once an anchor mechanism **808***a* is sufficiently positioned, the second anchor mechanism **808***b* will be affixed to the distal-most end of the deployment member **818** of mechanism **804** and likewise be secured into position by selectively advancing the anchor mechanism **808***b* through the same incision but in an opposed direction relative the first anchor mechanism **808***a*, the latter having been secured into position and thus operative to resist rearward movement.

As will be readily appreciated by those skilled in the art, by merely advancing the anchor mechanisms **808***a*, **808***b*, in generally opposed directions, the anchor mechanisms will thus be operative to stretch out the sling portion **806** such that the same can selectively and accurately be positioned about a target anatomical structure. In this respect, it is contemplated that the sling portion **806** can be positioned such that the same maintains a specified degree of tension or support to an anatomical structure, such as the urethra **824** or some part of the vagina as in a colporrhaphy or colpopexy, or may otherwise be positioned such that the same maintains a desired spatial relationship and orientation relative an anatomical structure. Of additional advantage is the fact that each respective opposed anchor mechanism **808** of the implant **802** can be positioned within the body via a single incision or point of access, which thus eliminates the need for a second incision or access point to be formed in the body, as is known per conventional sling placement which typically requires that separate access points or incisions be made for each fixation point, (i.e., the points at which the opposed ends of the sling are fixed into position within the body).

As a consequence, and shown more clearly in FIG. **22**, the implant **802** may be selectively positioned such that the sling **806** component thereof properly supports the urethra **824** as is desired to achieve a favorable outcome. In the placement of

the implant **802** as depicted, however, the same illustrates the fixation of the implant **802**, and more particularly the sling **806** thereof, within the obturator foramen of pelvis **830**, as defined by the pubis **834** and ishium **832** regions thereof. In this regard, each respective anchor mechanism **808***a*, **808***b* becomes embedded within a target tissue site, such as the pubocervical fascia, toward or through the obturator foramen and ultimately positioned in the desired locale relative the bladder **828** and, more particularly, urethra **824** extending therefrom.

As discussed above, anchor mechanisms **808***a*, **808***b* will preferably be formed or attached to the opposed ends of the sling **806** to thus enable the opposed ends to be stretched out and positioned in the desired manner. To achieve that end, it is important that the anchor mechanisms **808***a*, **808***b* be configured to thus enable the same the be easily advanced into position, to thus achieve the desired goal of fast, accurate and atraumatic placement, but at the same time provide the necessary degree of anchoring support to thus define a secured point of fixation from which the sling **806** can extend and ultimately impart the desired degree of support. FIGS. **22***a*-**22***c* depict various embodiments of the anchor mechanism **808** that are contemplated to achieve those objectives.

Referring now to FIG. **22***a*, there is shown an enlarged view of an anchor mechanism **808** similar to that depicted in FIG. **22**. As illustrated, the anchor mechanism comprises a plurality of anchor bodies **840** each having opposed, outwardly extending anchor members or arms **842** which thus define a generally Y-shaped body. Each respective anchor mechanism **840** is disposed upon elongate cord **844**, which may take the form of a suture or other implantable material well-known to those skilled in the art. To facilitate the ability to manipulate anchor mechanism **808**, elongate cord **844** may be formed to have a desired stiffness, and may be formed as a cable having reinforced material therein operative to provide some structural rigidity as may be desired in some applications.

FIG. **22***b* represents a similar embodiment whereby a plurality of generally chevron-shaped anchor members **850** are disposed upon the length of an elongate cord **854**. Each respective chevron-shaped member **850** is provided with outwardly-extending members or arms **852** that provide a means to anchor the same into tissue. Both the embodiments depicted in FIGS. **22***a* and **22***b*, similar to those discussed above in relation to the embodiment depicted in FIGS. **16** and **16***a*, essentially comprise a plurality of dual-pronged anchor mechanisms disposed linearly about a cord-like suture of various malleability to thus enable the same to advance through tissue in one direction, either by pushing or pulling, but resist rearward movement in an opposite direction. In this respect, the generally Y-shaped and generally chevron-shaped embodiments depicted in FIGS. **22***a* and **22***b* are similar to the generally V-oriented embodiment depicted in FIGS. **16** and **16***a* to thus enable a plurality of anchoring members to be disposed upon a length of cord, suture and the like, to be linearly disposed there along. It will be recognized, however, that numerous other designs are contemplated that fall within the scope of the present invention. As discussed above, such anchor mechanism may comprise selectively oriented segments of mesh material that are selectively oriented such that the loose or frayed fiber ends of the mesh extend in a rearward configuration to thus resist rearward movement.

Referring now to FIG. **22***c*, there is shown a similar type embodiment whereby the anchor mechanism **808** is defined by a screw mechanism **862**, having a distal-most end **860** operative to advance into tissue along a central axis **864**, the latter of which may be a cord or cable having a requisite stiffness. Alternatively, screw mechanism **862** and central axis **864** may comprise a firm yet malleable material suitable for implantation within the body. In such embodiment, it is contemplated that the screw-anchor mechanism **862** can be advanced into a target site of tissue by either blunt advancement or rotational advancement, the latter being facilitated by use of a deployment system **804** whereby the deployment member **818** is operative to selectively position the same within a tissue mass.

As will be appreciated, alternative anchoring mechanisms are contemplated and will be readily known to those skilled in the art. Along these lines, it is contemplated that the anchor mechanisms may be formed to be operatively transitional between a first compressed state whereby one or more of the anchor members, and more particularly the outwardly extending prongs thereof as depicted in FIGS. **22***a*, **22***b* are advanced into position within a target site of soft tissue and a second operative configuration whereby the anchor members and/or prongs thereof expand to become fixed into position at the appropriate target site of soft tissue.

Although not shown, in order to achieve such selective placement of the anchoring mechanisms capable of operatively transitioning between such first and second configurations, it is contemplated that such anchor mechanisms may be selectively positioned via the use of conventional deployment techniques and devices, such as catheters, needles, and/or guide wires. Exemplary of the latter, as utilized to position such operatively transitional anchor mechanisms for use in sling surgery, would be accomplished via the introduction of the guide wire through and then under the vaginal wall and then into the tissue adjacent to the vagina. Once properly positioned, an expansion is then effectuated along the guide wire within the vaginal, via the use of conventional coaxial or balloon systems or other well-known spreading devices that, following deployment, are thereafter removed. As per the procedures discussed above, it is understood that once a first anchor mechanism is deployed, a similar procedure must necessarily be followed to deploy the second respective anchor mechanism such that the sling disposed therebetween is operatively positioned to impart the desired support or positioning at a specified anatomical site.

Another example for use in deploying such operatively transitional anchor mechanisms would include the use of an elongate sheath that is focused as a portion of the deployment member **818** is operative to retain a multiplicity of anchor mechanisms, and in particular a plurality of anchor bodies, such as **840** depicted in FIG. **2**, within an elongate lumen thereof. It is contemplated that such sheath will have a sharpened distal end to thus enable the same with anchor bodies retained therein to be selectively positioned such that the prongs or other attachment elements thereof do not cut, engage with or otherwise become prematurely deployed. Along these lines, it is contemplated that such sheath deployment member would ideally be utilized to selectively position a multiplicity of anchor members positioned along a suture line or other cord-like structure, and may further include mechanisms to facilitate the deployment of such anchor mechanisms to either extend from or be withdrawn within the lumen of such sheath. It is likewise contemplated that such sheath can be used to deploy a plurality of linearly-arranged radio opaque markers, such as the TINED lead system of radio opaque markers produced by Medtronics, Inc. which have a configuration similar to that of the anchor bodies depicted in FIG. **22**A. In use, it is contemplated that such sheath may be provided with an elongate slot formed along a portion the length thereof that enables the cord-like structure having one or more anchor mechanisms formed thereon to be

pulled or pushed into the sheath as well as allow the sheath to be removed following the placement of the anchor mechanism deployed thereby.

Referring now to FIG. **17**, there is shown yet another embodiment of a device **600** for attaching sutures, grafts, tissues and the like into position in the human body. As illustrated, such embodiment comprises an anchoring disc or plate **602** which may be secured to or rest upon an anatomical structure, and more particularly a layer of muscle **604** or rectus fascia **606** as shown. As illustrated, which again is in the context of securing a sling **502** into position such that the urethra **504** is supported thereby, suture lines or suture-like cords **508** on each opposed end of the sling **502** are secured by dedicated anchoring plates **602**, the latter being supported by a layer of muscle and/or layer of rectus fascia. As shown, the anchoring plates **602** are operative to secure the suture lines **508** into position such that the same are allowed to selectively advance therethrough and remain secured in position thereby without requiring that the sutures **508** be ties (i.e., at the fascia level **606**).

To achieve that objective, there is shown in FIGS. **17***a* and **17***b* the mechanism by which the anchoring plate **602** is operative to secure the suture lines **508** thereto. As shown in **17***a*, the anchoring plate **602** comprises the combination of a first inner plate member **610** having at least one, and preferably two diametrically opposed apertures **612** formed therein. Encased about the first plate member **610** is a second annular plate member **614** which also includes at least one, and preferably two, apertures **616** formed therein, such apertures **616** being selectively alignable with the apertures **612** formed upon the first inner plate **610**. The first inner plate member **610** is rotationally mounted within the outer anchoring plate member **614**, such that the same is operative to transition between a first open configuration, wherein the apertures **612** of the first inner plate **610** are alignable with those formed on the outer annular plate **614**, and a second closed configuration, as shown in FIG. **17***b*, wherein the apertures formed on the inner and outer plates **612**, **615**, respectively, are not aligned with one another, such that a closure is formed.

In use, the anchoring plate **602** may be secured into position, via prongs or some other type of anchoring mechanism (not shown) to a desired site. Alternatively, it will be appreciated that such anchoring plate **602** may only need be placed on the rectus fascia and, as discussed more fully below, due to the downward force exerted upon the anchoring plate **602** via the sutures held thereby, such anchoring plate will be caused to remain resident at the desired deployment site. Once positioned, the inner and outer plate members **610**, **614** are maintained in the first operative configuration such that the apertures **612**, **616**, respectively formed thereon form the opening or openings through such anchoring plate **602**. The suture lines **508** may then be extended through apertures defined by the first and second plate members such that the sling **502** held thereby is maintained in a desired orientation or provides a desired degree of support to the urethra **504**. Once so positioned, the inner and outer plate members **610**, **614** are rotated relative one another such that second closed configuration is maintained, which thus serves to secure the suture lines **508** into position. To facilitate that end, a knob **618** or other turning mechanism formed upon the inner plate may be provided to facilitate the insertionability to secure the suture lines **508** into position. As discussed above, such design advantageously dispenses with the need to tie down the suture lines or cords at the fascia level. To the extent desired, such anchoring system further enables the suture lines, and more particularly the suture lines extending through the anchor plate, to be secured to one another to thus form a suture "bridge". As shown in phantom, each respective suture line extending through the anchor plate can be linked to one another as shown. To achieve that end, it will be appreciated that such suture lines may be either tied, fused, crimped, linked or joined to one another via any of a wide variety of methods and devices well known to those skilled in the art.

Referring now to FIG. **18**, there is shown a further refinement of the system utilized to secure a suture line at a desired location such that a sling, graft or other object supported thereby is maintained at a desired location. As illustrated, such system **640** comprises the combination of a suture-like cord **642** having a plurality of protuberances **644** formed therealong and an anchoring plate **646**. The suture-like cord **642** with protuberances **644** is formed such that the same is extensible through tissue. As will be appreciated by those skilled in the art, attached to an opposed end of such suture-like cord **642** with protuberances **644** is a graft, sling **502** or some other object to be held thereby. The suture-like cord **642** is extensible through the anchoring plate **646**, the latter being secured at a desired target site, which may include a bone, periosteum, soft tissue, or a layer of rectus fascia **606** as shown. The suture **642** is extensible through such anchoring plates **646** such that respective ones of the protuberances **644** engage with a locking aperture **648** formed on such plate **646**. As illustrated, each respective protuberance **644** can be pulled through such aperture **648** and thereafter caused to lock the suture **642** into position. As will be appreciated, as the sutures **642** pull through the anchoring plate **646**, the suture line **642** will become progressively shorter and thus raise the object (i.e., sling **502**) held thereby to the desired location. Advantageously, such system accommodated movement in both directions, and by pulling the suture in the rearward direction can cause the suture to experience an increase in slack, which thus consequently can lower or lessen the tension in the object supported thereby. As per the embodiment depicted in FIG. **17**, these suture-like cords with protuberances, to the extent multiple cords are utilized, may be linked to one another to thus form a suture bridge, as may be desired for certain applications.

Referring now to FIGS. **19-19***c*, and initially to FIG. **19**, there is shown an additional embodiment **700** of an anchoring system for securing a suture-like cord or line **508** at a desired location. As per the embodiments depicted in FIGS. **17** and **18**, the embodiment shown includes an anchor plate **702** having at least one, and preferably two to four, channels **704** extending therethrough for receiving suture-like cords **508**. As per the aforementioned embodiments, the anchor plate **702** may likewise be secured into position with a fastener mechanism or, alternatively, merely be positioned at a desired site upon fascia or soft tissue with the ultimate tension imparted thereto by the sutures **508** held thereby causing the same to remain resident at such site. As to the embodiment shown, the anchoring plate **702**, once positioned, is operative to receive the suture line or lines **508** through the channels **704** defined thereby. As more clearly illustrated in the cross-sectional view of FIG. **19***a*, the suture-like cord **508** can be pulled upwardly or downwardly until the same attains the desired position and/or imparts the desired tension to an object held thereby. Once such proper position and/or tension is attained, the channel **704** within which the suture-like cord **508** is disposed may be crimped, as depicted in FIG. **19***b*, such that the suture line **508** is compressively held thereby. As will be appreciated by those skilled in the art, the channel **704** defined by the anchor plate **702** will be formed from a suitable deformable material well-known to those skilled in the art which can not only be easily crimped, but once so crimped, will impart the necessary compressive force to hold the suture

508 in position. It will likewise be recognized that the crimp made to the channel 704 may be formed by any of a variety of surgical crimping mechanisms well-known and commercially available.

In an alternative configuration depicted in FIG. 19*c*, the anchor plate 710 is designed such that the same only has one channel 712 formed therethrough through which one or more suture-like cords 508 may be received. As may be desired for certain procedures, particularly where it is advantageous to simplify such procedures, the channel 712 defined in the anchor plate 710 will preferably be centrally disposed upon the anchor plate such that the same is adapted to receive multiple suture-like cords therethrough (e.g., four (4) suture lines to accommodate two (2) opposed ends of a sling). Once the cord or cords 508 have been received therethrough and optimally positioned, the channel 712 may be crimped such that the cords are compressively held as desired. Any length of the sutures extending therethrough may be linked or connected to one another to thus form a suture bridge, which is again in phantom in FIG. 19.

As will be recognized by those skilled in the art, by providing such a simplistic, atraumatic mechanism for securing sutures, grafts and the like into position substantially reduces suture erosion, greatly minimizes operative time, patient recovery time and further minimizes the risk of infection by minimizing the degree of invasiveness typically associated with securing slings and the like into an optimal position.

As will further be readily appreciated by those skilled in the art, the aforementioned anchoring systems, particularly those mechanisms depicted in FIGS. 17-19*c*, such may be formed from a bio-absorbable material, such that the anchoring system becomes absorbed over time. As will be appreciated by those skilled in the art, to the extent the anchoring system is fabricated to become absorbed over time, the aforementioned discussion regarding the suture bridge may be deemed optimal should it become necessary to maintain the suture lines at a desired location following absorption of such anchoring system.

Alternatively, the anchoring systems may be formed from a non-absorbable material such that the same remains permanently embedded within the body. Moreover, it will be recognized that those mechanisms depicted in FIGS. 17-19*c* may further incorporate a tension spreading mechanism, such a washer or mesh of fabric, that may be deployed with or integrated as part of such anchoring system. In this respect, it will be appreciated that due to the fact that the suture holding mechanisms depicted in FIGS. 17-19*c* will necessarily have a stress and strain imparted thereto via the sutures held thereby, such plate may dissipate the stress and strain over a larger surface area via the incorporation of such tension spreading mechanism. As per the anchor plates themselves, such tension spreading mechanism may be formed from an absorbable or non-absorbable material and may be formed integral with or separate from the anchor plate.

Referring now to remaining drawings 9-15, and initially to FIG. 9, there are depicted further embodiments of the present invention that are directed to devices for attaching sutures, grafts, tissues and the like to periosteum 36 (i.e., the thick fibrous membrane covering the surface of bones), as well as other types of soft tissue. In this regard, each of the embodiments herein preferably do not penetrate or otherwise become embedded within the bone 38, but rather are attachable to the periosteum 36 at a specific site thereof. However, it should be expressly understood that such embodiments may be modified or otherwise adapted to penetrate and become embedded within the bone 38, as may be necessary or ideal for a given medical procedure.

As will be appreciated by those skilled in the art, a wide variety of surgical procedures requiring fixation of sutures, grafts and the like, such as transvaginal sling surgery, particularly when performed in accordance with the procedure depicted in FIGS. 1 and 2, frequently do not necessitate the use of devices, such as those depicted in FIG. 5, that must necessarily be screwed or anchored within the bone. Quite unexpectedly, it has recently been reported at a meeting sponsored by the American Uro-Gynecologic Society that by utilizing the periosteum 36 as a point of affixation, such affixation can be made more or equally secure than prior art bone screws and anchors, but at the same time achieving satisfactory, if not superior, structural support. In this regard, deployment of such prior art bone-screw/anchor devices is generally considered an excessive measure insofar as such devices are known to frequently provide an excess amount of support than what is typically required or suitable for such particular purpose. However, due to the fact that no feasible alternative had been available until now, such bone screw and anchor devices are utilized, which can substantially complicate such surgical procedures as well as cause the patient to endure unnecessary trauma, possibly delayed recovery time, and possibly higher risk of infection.

In the first of such embodiments depicted in FIGS. 9 and 10, there is provided an affixation device 90 comprised of at least one, and preferably a multiplicity of piton members 92 mounted upon a base member. Each one of the multiplicity of pitons 92, which may take the form of a hook as shown, is designed to ensnare with and become embedded in a target site of soft tissue of the periosteum 36, as depicted in FIG. 9, but not penetrate or otherwise disrupt the outer surface of the bone 38 therebeneath. In this respect, the piton members 92 may be designed such that with light pressure the same only penetrate within a certain limited depth of the periosteum 36 or tissue, such that the same provide a moderate degree of fixation and can be easily removed, or with greater pressure the same penetrate deeper so that the device 90 can become more securely embedded within the periosteum 36 or tissue to thus provide for a more secure base or attachment. Formed on the base member 94 is an attachment means, which may comprise a post or eyelet 96 as shown, to which may be attached the suture 98 or graft. As will be appreciated, the affixation device 90 need only be placed against the periosteum 36 at a target location such that the piton members 92 thereof become embedded there within. Because the piton members 92 of the affixation device are caused to only become embedded within the periosteum 36, such novel fixation device may be easily removed and repositioned as may be necessary in a given surgical procedure to insure that an optimal degree of support or positioning is attained.

Once so optimally positioned, the suture 98 or graft may be attached to the device 90 as per conventional surgical procedures. Alternatively, due to the ease by which the affixation device 90 may be detached and reattached, the surgeon is provided with the option of securing the suture 98 or graft to such affixation device 90 and thereafter positioning the affixation device 90 at a target site for best positioning. Advantageously, although the affixation device 90 is specifically designed to provide for easy dislodgment and repositioning, it is believed that once the same is secured into position, due to the eventual overgrowth of tissue about such device 90, the affixation device will continue to provide firmer and stronger support over time.

Referring not to FIGS. 11-13, there is shown another embodiment 100 of an affixation device useful in the attachment of sutures, grafts, tissues and the like to periosteum, soft tissue, and bone. In the embodiment shown, such affixation

device **100** comprises a tack member having a hub portion **102** and at least one, and preferably two or more, prong members **104** formed thereon. As illustrated, the implantable tack **100** may be utilized to affix a graft **106** or other like tissue to the periosteum **36** by merely interposing the graft **106** between the periosteum and the tack **100** and compressing such tack **100** there against such that the prongs **104** thereof extend therethrough and become embedded in the periosteum **36** as systematically shown in FIGS. **11** and **12**.

As will be recognized, the prong portions **104** of such tack **100** will be specifically designed and configured to extend through a given layer of tissue or graft material **106** and become embedded into the periosteum **36**, but not otherwise extend to or penetrate the bone **38** lying therebeneath (although the embodiment may be modified for such applications). It will further be appreciated that such prongs **104** may vary in number and may take any of a variety of shapes and configurations necessary to achieve that end. As discussed above, it is contemplated that the prong members **104** may be designed to penetrate within the soft tissue, periosteum **36**, or even bone **38** at specified depths to thus provide for selective degrees of attachment thereto. In this regard, it is specifically contemplated that such prong members **104** may be formed to have a straight, hook or arcuate shape such that the same facilitate the affixation of a graft **106** to the target site of fixation. For example, in FIG. **12** it will be recognized that due to the arcuate shape of the prong members **104** of the implantable tack **100**, when a force is applied in a direction indicated by the letter "I", such force will actually cause the prong members **104** of such implantable tack **100** to penetrate further within the periosteum **36** to thus cause the affixation to become more secure with increased tension. Furthermore, by utilizing a hub member **102** as part of the implantable tack **100**, as illustrated in FIG. **13**, such implantable tack **100** can be easily accessed and removed in later surgical procedures. To facilitate such removal, a grip, protrusion or an aperture formed upon the hub may be provided. For example, it is contemplated that an attachment material, such as a synthetic mesh "extension" or sleeve, may be formed upon the hub **102**.

Referring now to FIGS. **14** and **15**, there is shown yet another preferred embodiment **110** of the present invention that comprises a novel surgical staple for securing sutures, tissues or grafts **112**, to the periosteum **36**. As illustrated, the staple **110** is operative to penetrate through a segment of tissue or graft **112** and become embedded within the periosteum **36** such that the graft or tissue is caused to become affixed therewith. As illustrated in the top view portion of FIG. **14**, the staple is operative to assume a first insertion configuration whereby the prongs **110***a*, **110***b* or such staple **110** are advanced through the graft **112** and ultimately into the periosteum **36**. Thereafter, as illustrated in the top view of FIG. **15**, the prongs **110***a*, **110***b* are caused to embed within the periosteum **36** to enhance the attachment therewith. As may be necessary for a certain application, such prongs **110***a*, **110***b* may even be caused to embed within the bone **38** lying there underneath to thus provide a more secure attachment.

To facilitate the ability of the staple **110** to secure the graft **112** to the periosteum **36** in the aforementioned manner, it is contemplated that such staple **110** may be formed of resilient, self-expanding or self-contracting material which is biased to the operative configuration shown in FIG. **15** such that when unconstrained, the opposed ends of the staple **110** will become further embedded into the periosteum. Similarly, such staple may be fabricated from a plastically deformable material which is initially formed to assume the insertion configuration depicted in FIG. **14**, but can subsequently be deformed to assume the operative configuration depicted in FIG. **15**. As a still further alternative, such staple **110** may be formed from a shape-memory material, such as nitinol, which thus enables the staple to assume the insertion configuration depicted in FIG. **14** when at room temperature, but transition to the operative, more secure configuration depicted in FIG. **15** when warmed to body temperature, as will occur such staple is deployed. As a further advantage, to the extent it becomes necessary to remove or otherwise reposition such staple **110**, it will be recognized by those skilled in the art that removal of such staple **110** may be facilitated by merely cooling the same down by any of a variety of well-known methods, including applying cold saline thereto.

All of the affixation devices discussed herein, although having widespread applicability and substantial advantage over prior art anchor devices, and more particularly bone screws and bone anchors, are particularly well suited in gynecologic, urologic and orthopedic surgical applications. It is believed that such affixation devices are particularly well suited for transvaginal sling surgery insofar as much of the medical literature tends to indicate that in a vast majority of patients, the sling that is utilized in such procedures should be placed with little to no tension at all, with the tension vector emanating therefrom being oriented in a direction well-suited to the piton portion of those embodying as depicted in FIGS. **6-8**. Indeed, considerable authority exists that optimal placement of the sling in transvaginal sling surgery occurs when the sling merely comes near or into contact with the urethra. Affixation by attaching the sling merely to the periosteum and not to the bone is thus believed to provide more than sufficient leverage or support to the sling in such applications, but yet have the further advantage of being exceptionally easy to secure and re-secure into position in a much less traumatic manner than the prior art devices.

Exemplary of such applications, as illustrated in FIGS. **23-26** is the use of the anchor mechanisms disclosed herein in vaginofixation. Such procedure, also known as colpopexy or colporrhaphy is closely related to the aforementioned surgical techniques related to transvaginal sling placement insofar as the same relies upon fixation devices, anchors and various sling-like materials that are operative to position and maintain the vagina in its proper orientation. In this regard, FIG. **23** illustrates vaginal prolapse whereby the vaginal apex **906** is shown extending outwardly from the vagina of a patient. Such Figure further illustrates the relative positioning of the obturator foramen **908**, and more particularly the membrane **910** extending about the obturator foramen **908**, the latter as discussed above now being widely considered as the optimal zone within which to anchor slings and the like for the treatment of urinary incontinence.

Referring now to FIG. **24**, there is shown the use of an anchor mechanism **900** constructed in accordance with a preferred embodiment of the present invention shown positioning the vagina according to its proper orientation whereby the apex of the vagina **906** is shown extending upwardly within the body. To achieve that end, the fixation device **900** is shown securing the vaginal wall **907** to the membrane **910** extending about the obturator foramen. To accomplish that end, the fixation device **900** is provided with a harpoon or barbed portion **904** operative to extend through the vaginal wall **907** and into a mass of soft tissue, such as membrane **910**. To secure vaginal wall **907** in proximity to such soft tissue, there is preferably provided a large platform or head portion **902** that preferably possesses sufficient surface area to hold the vaginal wall **907** according to its proper orientation such that the vaginal apex **906** remains properly positioned within the patient's body. As will be appreciated by those skilled in the art, the barbed portion **904** will be configured as per any of

the aforementioned embodiments such that the barb **904** will be operative to be inserted into a mass of soft tissue into a first direction but resist rearward movement when pulled in the opposite direction. It is further contemplated that such fixation device **900** may be deployed through any surgical technique known in the art whether it be manually or by deployment via a surgical instrumentsuch as those discussed above or otherwise known in the art. For example, such fixation device **900** may be deployed via a coaxial system whereby a conventional guide wire is first deployed to identify the location the obturator membrane with the device **900** being deployed thereafter. Advantageously, such procedure eliminates the risks associated with blindly deploying such fixation device **900**.

With respect to the preferred embodiments of such anchoring mechanism **900** for use in vaginofixation, two such embodiments are depicted in FIGS. **25** and **26** respectively. Referring initially to FIG. **25**, (which is an enlarged figure of the fixation device depicted in FIG. **24**), such fixation device includes a head portion **902** having a sufficient surface area operative to compress and hold a portion of vaginal wall tissue. As will be appreciated by those skilled in the art, such head portion **902** may preferably be formed from mesh or other biocompatible material to facilitate the ability of the device to secure a tissue mass (i.e., vaginal wall) securably into position. The anchor portion **904**, as discussed above, may take any of a variety of self-anchoring mechanisms discussed herein. As depicted, such anchor portion **904** includes a plurality of linearly-arranged arrows or V-shaped members operative to extend into tissue in a first direction but resist movement in an opposite direction.

Referring now to FIG. **26**, there is depicted an alternative embodiment whereby the head portion **902** is comprised of a plurality of wire or claw members operative to grab and securably hold a portion of soft tissue. The anchor portion **904** is configured as per the embodiment discussed above with respect to FIG. **25** and may include any anchoring mechanism operative to be advanced into tissue in a first direction but resist movement in an opposite direction, as would be achieved by the linearly arranged arrow members as depicted. As should be readily understood, however, the head portion **902** depicted in FIGS. **25** and **26** may take a variety of alternative configurations as will be readily appreciated by those skilled in the art. In this respect, so long as the anchor portion **902** is operative to attach to and securably hold a mass of soft tissue, the same should be deemed to fall within the scope of the present invention. Also, head portion **902** may further include a member formed thereon, such as a post, eyelet, or other structure, to facilitate manipulation or attachment thereto.

Although the invention has been described herein with specific reference to a presently preferred embodiment thereof, it will be appreciated by those skilled in the art that various modifications, deletions, and alterations may be made to such preferred embodiment without departing from the spirit and scope of the invention. For example, it will be recognized that the piton portion of any of the surgical implants disclosed herein may take any of a variety of forms such that the same are caused to become more thoroughly seated in a position via the application of force in one direction, but yet become more easily withdrawn when pulled rearwardly in a second direction. It is further contemplated that such embodiments may be formed from plastically deformable or shape-memory material to thus facilitate fixation of such devices at a selected target site. Moreover, it should be recognized that the affixation devices disclosed herein designed to affix sutures, grafts, tissues, synthetic materials, and the like to periosteum may further be modified so that the same additionally penetrate into and become embedded within the bone lying thereunderneath. Specifically, with respect to the embodiment depicted in FIG. **10**, one or more of the hooks may be sized and adapted to penetrate into the bone, similar to the prongs formed on the implantable tack depicted in FIGS. **11-13**. Likewise, the prongs of the staple element depicted in FIGS. **14** and **15** may be designed to penetrate and embed within the bone. Accordingly, it is intended that all reasonably foreseeable additions, modifications, deletions and alterations be included within the scope of the invention as defined in the following claims.

What is claimed is:

1. An implant for providing support to an anatomical structure comprising:

a) an elongate segment of material having first and second opposed ends, said segment of material being operatively positionable adjacent said anatomical structure to be supported; and

b) at least one anchor mechanism integrally formed upon a respective one of said ends of said segment of material, said anchor mechanism being operatively configured to be advanceable into a soft tissue mass at a target site in a first direction and resistant to movement in an opposite direction in the soft tissue, the anchor mechanism being configured to become permanently fixed in position within the soft tissue.

2. The implant of claim **1** wherein said implant includes two anchor mechanisms attached to said segment of material, each anchor mechanism being formed on a respective one of said opposed ends of said segment of material.

3. The implant of claim **2** wherein said first and second anchor mechanisms are operatively positioned to be advanced through a mass of soft tissue in generally opposed or generally parallel directions relative one another.

4. The implant of claim **1** wherein said segment of material comprises a sling.

5. The implant of claim **4** wherein said sling is fabricated from a material selected from the group consisting of synthetic material, natural material, tissue harvested from a host, and combinations thereof.

6. The implant of claim **3** wherein each anchor mechanism comprises at least one generally Y-shaped prong having a cord extending therethrough.

7. The implant of claim **6** wherein said anchor mechanism comprises a plurality of linearly arranged Y-shaped prongs, each respective one of said plurality of prongs having a cord extending medially therethrough.

8. The implant of claim **3** wherein each anchor mechanism comprises at least one generally chevron-shaped prong having a cord extending therethrough.

9. The implant of claim **8** wherein said anchor mechanism comprises a plurality of linearly arranged chevron-shaped prongs, each respective one of said plurality of prongs having a cord extending medially therethrough.

10. The implant of claim **3** wherein each respective anchor mechanism comprises a spiral-shaped screw.

11. A method for surgically implanting a sling to provide support to an anatomical structure within a patient comprising the steps:

a) providing an implantable sling comprising an elongate segment of material having first and second opposed ends, each respective opposed end having an anchor mechanism formed thereon such that each respective anchor mechanism is advanceable through said soft tissue at a selected target site in a first direction and resistant to movement in an opposite direction;

b) providing a deployment mechanism for positioning said anchor mechanisms of said implantable sling within said target site of said soft tissue, said deployment mechanism comprising a manually operable handle having a deployment member extending distally therefrom, said deployment member being detachably fastenable to a respective one of said anchor mechanisms of said implantable sling;

c) mounting a respective one of said anchor mechanisms of said implantable sling upon said distal end of said deployment member of said deployment mechanism;

d) advancing said anchor mechanism mounted upon said distal end of said deployment member in step c) toward a site selected from the group consisting of a first target site about a first side of the obturator foramen, a first target site about the rectus fascia and a first target site about the pubocervical fascia of said patient and selectively detaching said anchor mechanism from said deployment member such that said anchor mechanism becomes embedded within a first mass of soft tissue;

e) mounting the respective other anchor mechanism of said implantable sling upon said distal end of said deployment member and advancing said respective other anchor mechanism toward a site selected from the group consisting of a second target site about the respective other side of said obturator foramen, a second target site about the rectus fascia and a second target site about the pubocervical fascia, said second target sites being dissimilar to said first target sites, such that said segment of material is positioned to support the anatomical structure of said patient; and

f) detaching said respective other anchor mechanism from said deployment member and embedding said anchor mechanism within a second mass of soft tissue such that said anchor mechanisms resist movement in the opposite direction and securely position said sling to support the anatomical structure of said patient.

12. The method of claim **11** wherein said anatomical structure is selected from the group consisting of the urethra and the vaginal wall of said patient and in steps (d) and (e) said anchor mechanisms are advanced toward said sites via a single incision made in a vagina.

13. The method of claim **11** wherein in step (a), each respective one of said anchor mechanisms of said implantable sling comprise a plurality of linearly arranged Y-shaped prongs, each respective one of said plurality of prongs having a cord extending medially therethrough; and
wherein in steps (d) and (e), said anchor mechanisms are advanced by extending said cord with said generally Y-shaped anchor members formed thereon through said soft tissue.

14. The method of claim **11** wherein in step (a) said anchor mechanism comprises a plurality of generally chevron-shaped anchor mechanisms having a cord extending medially therethrough; and wherein in steps (d) and (e) said anchor mechanisms are advanced by extending said cord with said generally chevron-shaped anchor mechanisms formed thereon through said soft tissue.

15. The method of claim **11** wherein in step (a), each anchor mechanism on the implantable sling comprises a cord having at least one outwardly extending barbed portion disposed adjacent a distal end of the cord, and wherein the implantable sling comprises a mesh material extending axially aftwardly from the barbed portion in general axial alignment with the barbed portion.

16. The method of claim **15** wherein in step (a), the cord is configured as a cable having reinforcing material therein to provide structural rigidity to the anchor mechanism.

17. The method of claim **15** wherein in step (a), each anchor mechanism comprises a pair of the barbed portions extending outwardly from radially opposed sides of the cord to form a dual-prong configuration and wherein the implantable sling has mesh material extending axially aftwardly from each one of the barbed portions.

18. The method of claim **15** wherein in step (a), the mesh material is oriented such that frayed fiber ends of the mesh material extend in a generally outward direction to resist rearward movement of the anchor mechanisms once implanted within the soft tissue.

19. The method of claim **11** wherein in step (a), each anchor mechanism comprises a cord having at least one outwardly extending barbed portion disposed adjacent a distal end of the cord and wherein the implantable sling has mesh material extending axially aftwardly from the barbed portion in general axial alignment with the barbed portion.

20. The method of claim **19** wherein in step (a), the cord is configured as a cable having reinforcing material therein to provide structural rigidity to the anchor mechanism.

21. The method of claim **19** wherein in step (a), each anchor mechanism comprises a pair of the barbed portions extending outwardly from radially opposed sides of the cord to form a dual-prong configuration and wherein the implantable sling has mesh material extending axially aftwardly from each one of the barbed portions.

22. The method of claim **19** wherein in step (a), the mesh material is oriented such that frayed fiber ends of the mesh material extend in a generally outward direction to resist rearward movement of the anchor mechanisms once implanted within the soft tissue.

23. The method of claim **11** wherein the first and second target sites are about the obturator foramen, and steps (d) and (f) comprise embedding the anchor mechanism within first and second soft tissue masses that include muscle tissue about the obturator foramen.

* * * * *

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

NOTICE OF ASSIGNMENT TO UNITED STATES MAGISTRATE JUDGE FOR DISCOVERY

This case has been assigned to District Judge James V. Selna and the assigned discovery Magistrate Judge is Marc Goldman.

The case number on all documents filed with the Court should read as follows:

SACV08- 1074 JVS (MLGx)

Pursuant to General Order 05-07 of the United States District Court for the Central District of California, the Magistrate Judge has been designated to hear discovery related motions.

All discovery related motions should be noticed on the calendar of the Magistrate Judge

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NOTICE TO COUNSEL

A copy of this notice must be served with the summons and complaint on all defendants (if a removal action is filed, a copy of this notice must be served on all plaintiffs).

Subsequent documents must be filed at the following location:

[ ] **Western Division**
312 N. Spring St., Rm. G-8
Los Angeles, CA 90012

[X] **Southern Division**
411 West Fourth St., Rm. 1-053
Santa Ana, CA 92701-4516

[ ] **Eastern Division**
3470 Twelfth St., Rm. 134
Riverside, CA 92501

Failure to file at the proper location will result in your documents being returned to you.

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Newport Beach, CA 92660
Telephone/Facsimile: (949)720-1288 / (949) 720-1292

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

SPRINGBOARD MEDICAL VENTURES LLC, a California corporation PLAINTIFF(S) v. AMERICAN MEDICAL SYSTEMS, INC., a Delaware corporation DEFENDANT(S).	CASE NUMBER **SACV08-01074 JVS (MLGx)** **SUMMONS**

TO: DEFENDANT(S): AMERICAN MEDICAL SYSTEMS, INC.

A lawsuit has been filed against you.

Within 20 days after service of this summons on you (not counting the day you received it), you must serve on the plaintiff an answer to the attached ☑ complaint ☐ _____ amended complaint ☐ counterclaim ☐ cross-claim or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff's attorney, John B. Sganga, Jr., whose address is Knobbe, Martens, Olson & Bear, LLP, 2040 Main Street, 14th Floor, Irvine, CA 92614. If you fail to do so, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

Dated: SEP 26 2008

Clerk, U.S. District Court

By: ROLLS ROYCE PASCHAL
Deputy Clerk

(Seal of the Court)

1144

[Use 60 days if the defendant is the United States or a United States agency, or is an officer or employee of the United States. Allowed 60 days by Rule 12(a)(3)].

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA

CIVIL COVER SHEET

I (a) PLAINTIFFS (Check box if you are representing yourself ☐)
SPRINGBOARD MEDICAL VENTURES LLC

DEFENDANTS
AMERICAN MEDICAL SYSTEMS, INC.

(b) Attorneys (Firm Name, Address and Telephone Number. If you are representing yourself, provide same.) **(See attachment for additional Counsel)**
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2040 Main Street, 14th floor, Irvine, CA 92614
Telephone/Facsimile: (949) 760-0404 / (949) 760-9502

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an X in one box only.)

☐ 1 U.S. Government Plaintiff ☑ 3 Federal Question (U.S. Government Not a Party)

☐ 2 U.S. Government Defendant ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES - For Diversity Cases Only
(Place an X in one box for plaintiff and one for defendant.)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated or Principal Place of Business in this State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated and Principal Place of Business in Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. ORIGIN (Place an X in one box only.)

☑ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify): ☐ 6 Multi-District Litigation ☐ 7 Appeal to District Judge from Magistrate Judge

V. REQUESTED IN COMPLAINT: JURY DEMAND: ☑ Yes ☐ No (Check 'Yes' only if demanded in complaint.)

CLASS ACTION under F.R.C.P. 23: ☐ Yes ☑ No ☐ MONEY DEMANDED IN COMPLAINT: $ to be determined

VI. CAUSE OF ACTION (Cite the U.S. Civil Statute under which you are filing and write a brief statement of cause. Do not cite jurisdictional statutes unless diversity.)
35 U.S.C. 271 PATENT INFRINGEMENT

VII. NATURE OF SUIT (Place an X in one box only.)

OTHER STATUTES
☐ 400 State Reapportionment
☐ 410 Antitrust
☐ 430 Banks and Banking
☐ 450 Commerce/ICC Rates/etc.
☐ 460 Deportation
☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 480 Consumer Credit
☐ 490 Cable/Sat TV
☐ 810 Selective Service
☐ 850 Securities/Commodities/ Exchange
☐ 875 Customer Challenge 12 USC 3410
☐ 890 Other Statutory Actions
☐ 891 Agricultural Act
☐ 892 Economic Stabilization Act
☐ 893 Environmental Matters
☐ 894 Energy Allocation Act
☐ 895 Freedom of Info. Act
☐ 900 Appeal of Fee Determination Under Equal Access to Justice
☐ 950 Constitutionality of State Statutes

CONTRACT
☐ 110 Insurance
☐ 120 Marine
☐ 130 Miller Act
☐ 140 Negotiable Instrument
☐ 150 Recovery of Overpayment & Enforcement of Judgment
☐ 151 Medicare Act
☐ 152 Recovery of Defaulted Student Loan (Excl. Veterans)
☐ 153 Recovery of Overpayment of Veteran's Benefits
☐ 160 Stockholders' Suits
☐ 190 Other Contract
☐ 195 Contract Product Liability
☐ 196 Franchise

REAL PROPERTY
☐ 210 Land Condemnation
☐ 220 Foreclosure
☐ 230 Rent Lease & Ejectment
☐ 240 Torts to Land
☐ 245 Tort Product Liability
☐ 290 All Other Real Property

TORTS PERSONAL INJURY
☐ 310 Airplane
☐ 315 Airplane Product Liability
☐ 320 Assault, Libel & Slander
☐ 330 Fed. Employers' Liability
☐ 340 Marine
☐ 345 Marine Product Liability
☐ 350 Motor Vehicle
☐ 355 Motor Vehicle Product Liability
☐ 360 Other Personal Injury
☐ 362 Personal Injury-Med Malpractice
☐ 365 Personal Injury-Product Liability
☐ 368 Asbestos Personal Injury Product Liability

IMMIGRATION
☐ 462 Naturalization Application
☐ 463 Habeas Corpus-Alien Detainee
☐ 465 Other Immigration Actions

TORTS PERSONAL PROPERTY
☐ 370 Other Fraud
☐ 371 Truth in Lending
☐ 380 Other Personal Property Damage
☐ 385 Property Damage Product Liability

BANKRUPTCY
☐ 422 Appeal 28 USC 158
☐ 423 Withdrawal 28 USC 157

CIVIL RIGHTS
☐ 441 Voting
☐ 442 Employment
☐ 443 Housing/Accommodations
☐ 444 Welfare
☐ 445 American with Disabilities - Employment
☐ 446 American with Disabilities - Other
☐ 440 Other Civil Rights

PRISONER PETITIONS
☐ 510 Motions to Vacate Sentence Habeas Corpus
☐ 530 General
☐ 535 Death Penalty
☐ 540 Mandamus/ Other
☐ 550 Civil Rights
☐ 555 Prison Condition

FORFEITURE / PENALTY
☐ 610 Agriculture
☐ 620 Other Food & Drug
☐ 625 Drug Related Seizure of Property 21 USC 881
☐ 630 Liquor Laws
☐ 640 R.R. & Truck
☐ 650 Airline Regs
☐ 660 Occupational Safety /Health
☐ 690 Other

LABOR
☐ 710 Fair Labor Standards Act
☐ 720 Labor/Mgmt. Relations
☐ 730 Labor/Mgmt. Reporting & Disclosure Act
☐ 740 Railway Labor Act
☐ 790 Other Labor Litigation
☐ 791 Empl. Ret. Inc. Security Act

PROPERTY RIGHTS
☐ 820 Copyrights
☑ 830 Patent
☐ 840 Trademark

SOCIAL SECURITY
☐ 861 HIA (1395ff)
☐ 862 Black Lung (923)
☐ 863 DIWC/DIWW (405(g))
☐ 864 SSID Title XVI
☐ 865 RSI (405(g))

FEDERAL TAX SUITS
☐ 870 Taxes (U.S. Plaintiff or Defendant)
☐ 871 IRS-Third Party 26 USC 7609

FOR OFFICE USE ONLY: Case Number: **SACV08-01074 JVS (MLGx)**

AFTER COMPLETING THE FRONT SIDE OF FORM CV-71, COMPLETE THE INFORMATION REQUESTED BELOW.

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

VIII(a). IDENTICAL CASES: Has this action been previously filed in this court and dismissed, remanded or closed? ☑ No ☐ Yes
If yes, list case number(s): _____

VIII(b). RELATED CASES: Have any cases been previously filed in this court that are related to the present case? ☑ No ☐ Yes
If yes, list case number(s): _____

Civil cases are deemed related if a previously filed case and the present case:

(Check all boxes that apply) ☐ A. Arise from the same or closely related transactions, happenings, or events; or
☐ B. Call for determination of the same or substantially related or similar questions of law and fact; or
☐ C. For other reasons would entail substantial duplication of labor if heard by different judges; or
☐ D. Involve the same patent, trademark or copyright, and one of the factors identified above in a, b or c also is present.

IX. VENUE: (When completing the following information, use an additional sheet if necessary.)

(a) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which EACH named plaintiff resides.
☐ Check here if the government, its agencies or employees is a named plaintiff. If this box is checked, go to item (b).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
ORANGE	

(b) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which EACH named defendant resides.
☐ Check here if the government, its agencies or employees is a named defendant. If this box is checked, go to item (c).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
	MINNESOTA

(c) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which EACH claim arose.
Note: **In land condemnation cases, use the location of the tract of land involved.**

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
ORANGE	

* Los Angeles, Orange, San Bernardino, Riverside, Ventura, Santa Barbara, or San Luis Obispo Counties
Note: In land condemnation cases, use the location of the tract of land involved

X. SIGNATURE OF ATTORNEY (OR PRO PER): _____ Date 9/25/08

Notice to Counsel/Parties: The CV-71 (JS-44) Civil Cover Sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law. This form, approved by the Judicial Conference of the United States in September 1974, is required pursuant to Local Rule 3-1 is not filed but is used by the Clerk of the Court for the purpose of statistics, venue and initiating the civil docket sheet. (For more detailed instructions, see separate instructions sheet.)

Key to Statistical codes relating to Social Security Cases:

Nature of Suit Code	Abbreviation	Substantive Statement of Cause of Action
861	HIA	All claims for health insurance benefits (Medicare) under Title 18, Part A, of the Social Security Act, as amended. Also, include claims by hospitals, skilled nursing facilities, etc., for certification as providers of services under the program. (42 U.S.C. 1935FF(b))
862	BL	All claims for "Black Lung" benefits under Title 4, Part B, of the Federal Coal Mine Health and Safety Act of 1969. (30 U.S.C. 923)
863	DIWC	All claims filed by insured workers for disability insurance benefits under Title 2 of the Social Security Act, as amended; plus all claims filed for child's insurance benefits based on disability. (42 U.S.C. 405(g))
863	DIWW	All claims filed for widows or widowers insurance benefits based on disability under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405(g))
864	SSID	All claims for supplemental security income payments based upon disability filed under Title 16 of the Social Security Act, as amended.
865	RSI	All claims for retirement (old age) and survivors benefits under Title 2 of the Social Security Act, as amended. (42 U.S.C. (g))

Civil Case Cover Sheet Attachment Page

I(b) Plaintiff's Attorneys continued

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