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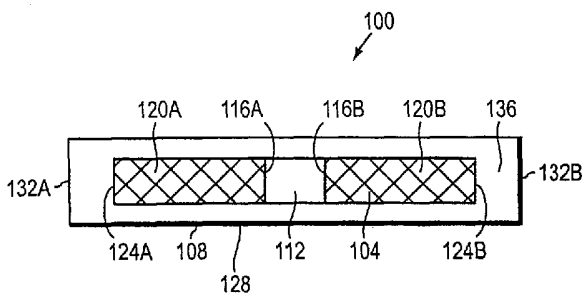
(54) Title: BIOABSORBABLE CASING FOR SURGICAL SLING ASSEMBLY



(57) Abstract: The invention provides a surgical sling assembly for implanting in tissue to provide anatomical support in a patient. The surgical sling assembly includes a sling and a biocompatible casing enclosing at least a portion of the sling. The biocompatible casing is absorbed by the patient's tissues after the surgical sling assembly is positioned within the patient's tissue to provide anatomical support.

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BIOABSORBABLE CASING FOR SURGICAL SLING ASSEMBLY

Technical Field

The invention generally relates to surgical sling assemblies, and related methods, for providing anatomical support in a patient's body. More particularly, the invention relates to surgical sling assemblies, and related methods, that include bioabsorbable casings.

Background Information

Stress urinary incontinence (SUI) affects primarily women and is generally caused by two conditions, intrinsic sphincter deficiency (ISD) and hypermobility. These conditions may occur independently or in combination. In ISD, the urinary sphincter valve, located within the urethra, fails to close properly (coapt), causing urine to leak out of the urethra during stressful activity. Hypermobility is a condition in which the pelvic floor is distended, weakened, or damaged, causing the bladder neck and proximal urethra to rotate and descend in response to increases in intra-abdominal pressure (*e.g.*, due to sneezing, coughing, straining, etc.). The result is that there is an insufficient response time to promote urethral closure and, consequently, urine leakage and/or flow results.

A popular treatment of SUI is the use of a surgical sling that is placed under a patient's bladder neck or mid-urethra to provide a urethral platform. Placement of the surgical sling limits the endopelvic fascia drop while providing compression to the urethral sphincter to improve coaptation. Typically, a protective sleeve encloses the sling during the placement procedure. Once the surgical sling assembly, which includes the sling and the sleeve, is correctly positioned in the patient's periurethral tissues, the sleeve is physically removed from about the sling and withdrawn from the patient's body, leaving behind only the sling in the patient's tissues.

The current steps and procedures used to physically remove the sleeve from about the sling which it encloses are, however, problematic. For instance, while physically removing the sleeve from about the sling, friction between the sleeve and the sling may cause the sling to be dragged away from its preferred position adjacent the mid-urethra, to twist, or to otherwise become misplaced. Ultimately, the utility of the sling is hampered and patient discomfort is increased.

Improved surgical sling assemblies, and related methods, for treating SUI are, therefore, needed.

Summary of the Invention

The present invention provides a surgical sling assembly, and related methods, for providing anatomical support in a patient's body (*e.g.*, a surgical sling assembly for treating urinary incontinence in a patient). The surgical sling assembly, and related methods, of the invention have the advantage of obviating the need to physically remove a sleeve from about a sling.

In one aspect of the invention, a surgical sling assembly for implanting in tissue to provide anatomical support in a patient includes a sling and a biocompatible casing. The biocompatible casing encloses at least a portion of the sling and includes a bioabsorbable material. The biocompatible casing is absorbed by the patient's tissues after the surgical sling assembly is positioned within the patient's tissue to provide anatomical support. As the term is used herein, bioabsorbable means removal of a substance in a patient's tissue by physiologic or pathologic means.

In one embodiment of this aspect of the invention, the biocompatible casing includes a sleeve. Alternatively, the biocompatible casing includes a coating. The bioabsorbable material may be an alginate, a sugar based formulation, a starch, a gelatin, cellulose, polyvinyl alcohol, polyglycolic acid, polylactic acid, polydioxinone, or a lubricious material. In one embodiment, the surgical sling assembly is positioned within a patient's periurethral tissues to treat urinary incontinence. In one such embodiment, the biocompatible casing is absorbed by the patient's tissues in less than ten minutes after the surgical sling assembly is positioned within the patient's periurethral tissues. In one such particular embodiment, the biocompatible casing is absorbed by the patient's tissues in eight to ten minutes after the surgical sling assembly is positioned within the patient's periurethral tissues.

In another aspect, the invention relates to a method for providing anatomical support in a patient. The method includes providing a surgical sling assembly as described above and positioning the sling within the patient's tissues.

In one embodiment of this aspect of the invention, the sling is positioned within a patient's periurethral tissues to treat urinary incontinence.

The foregoing and other objects, aspects, features, and advantages of the invention will become more apparent from the following description and from the claims.

Brief Description of the Drawings

In the drawings, like reference characters generally refer to the same parts throughout the different views. Also, the drawings are not necessarily to scale, emphasis instead generally being placed upon illustrating the principles of the invention.

FIG. 1 depicts a top view of a sling assembly according to an illustrative embodiment of the invention.

FIG. 2 depicts a top view of a sling according to an illustrative embodiment of the invention.

FIG. 3 depicts a top view of a sling assembly according to another illustrative embodiment of the invention.

FIG. 4 depicts a perspective view of a delivery system used to deliver a sling assembly to the patient's periurethral tissues in accordance with an illustrative embodiment of the invention.

FIG. 5 depicts the placement of a sling assembly, including a bioabsorbable casing, in a patient's periurethral tissues, according to an illustrative embodiment of the invention.

FIG. 6 depicts the placement of a sling in a patient's periurethral tissues, after the casing of FIG. 5 has been absorbed by the patient's tissues, according to an illustrative embodiment the invention.

Description

In general, the invention pertains to surgical sling assemblies, and related methods, for providing anatomical support in a patient's body (*e.g.*, a surgical sling assembly for the treatment of urinary incontinence). All of the embodiments have in common a sling at least partially enclosed within a bioabsorbable casing.

FIG. 1 depicts a surgical sling assembly 100 according to an illustrative embodiment of the invention. In the illustrative embodiment, the surgical sling assembly 100 includes a sling 104 and a casing 108. The sling 104 is, for example, generally rectangular in shape and flat, or sheet-like. In a preferred embodiment, the sling 104 is a mesh sling. In one embodiment, the sling 104 is knit from fibers, such as, for example, polymeric fibers. However, in alternative embodiments, the sling 104 may be made of any suitable materials, including, for example, native mammalian tissue or any combination of the above materials. In the illustrative embodiment, the sling 104 includes a mid-length portion 112, which has end points 116A, 116B, and two end-length portions 120A, 120B. The two end-length portions 120A, 120B extend from the end points 116A, 116B of the mid-length portion 112 to sling ends 124A, 124B, respectively. The two end-length portions 120A, 120B are, in one embodiment, of substantially equal length, such that the mid-length portion 112 is generally centered along the long axis of the sling 104. Alternatively, in another embodiment, the two end-length portions 120A, 120B are of different lengths and the mid-length portion 112 is eccentric (not shown).

FIG. 2 depicts a sling 104 according to an illustrative embodiment of the invention. In the illustrative embodiment, the end-length portions 120A, 120B are tanged (*i.e.*, rough) portions of the sling 104 that, as described below, engage the patient's periurethral tissues and secure the sling 104 in position. For example, in one embodiment, fiber ends extend/project from the tanged end-length portions 120A, 120B. For its part, the mid-length portion 112 is, in the illustrative embodiment, a de-tanged (*i.e.*, a smooth) portion of the sling 104 that is preferably placed under the patient's mid-urethra. For example, in one embodiment, the de-tanged mid-length portion 112 is heat sealed to remove any sharp fiber ends and to ensure that its surfaces remain smooth.

The casing 108 encloses at least a portion of the sling 104. In one embodiment, as illustrated in FIG. 1, the casing 108 encloses the entire sling 104. In another embodiment, the casing 108 encloses only the tanged end-length portions 120A, 120B of the sling 104. In yet another embodiment, the casing 108 encloses the tanged end-length portions 120A, 120B and a portion of one or both sides of the de-tanged mid-length portion 112.

According to the illustrative embodiment shown in FIG. 1, the casing 108 is a sleeve 128, *e.g.*, a flattened tube. The sleeve 128 may include one or more layers of the same or different materials that are laminated together. In one embodiment, the sleeve 128 includes a first sleeve-end 132A, a second sleeve-end 132B, and a lumen 136 extending from the first sleeve-end 132A to the second sleeve-end 132B. Throughout the process of delivering the sling 104 to the patient's periurethral tissues, the sling 104 is located within the lumen 136 of the sleeve 128, between the first sleeve-end 132A and the second sleeve-end 132B, as illustrated. As such, the tanged end-length portions 120A, 120B of the sling 104 are protected by the sleeve 128, thereby preventing the tanged end-length portions 120A, 120B from catching on the patient's tissues during the delivery procedure. The casing 108 maintains the sling 104 in a flat configuration and prevents it from twisting, turning, or otherwise becoming distorted, or even destroyed, during implantation of the sling 104 in the patient's body.

FIG. 3 depicts a surgical sling assembly 100 according to another embodiment of the invention. As shown, the casing 108 is, in this alternative embodiment, a coating 138. In one embodiment, the coating 138 is applied to the sling 104 by, for example, dipping the sling 104 in, or spraying the sling 104 with, a solution of a bioabsorbable material that later assumes the characteristics of a gel or solidifies. In another embodiment, the coating 138 is a polymer (*e.g.*, a thermoplastic) that is melted, freeze dried, or vacuum dried on to the sling 104. Alternatively, the coating 138 may be applied in a variety of other manners. Moreover, more than one coating 138, of the same or different materials, may be applied, in the same or different manners, to the sling 104. The coating 138 is of sufficient rigidity to prevent the tanged end-length portions 120A, 120B of the sling 104 from catching on the patient's tissues during the delivery procedure.

In one embodiment, the casing 108 (*e.g.*, the sleeve 128 or the coating 138) is made of a biocompatible material. As used herein, the term "biocompatible" means a material that is non-toxic and that does not induce inflammation or any other adverse reaction in the patient's body that would have a significantly adverse effect on the patient's health.

Moreover, in one embodiment, the casing 108 is made of a bioabsorbable material. Accordingly, as explained below, the casing 108 is absorbed by the patient's

tissues after the surgical sling assembly 100 is positioned within the patient's periurethral tissues. Advantageously, an operator (*e.g.*, a physician) need not, therefore, remove the casing 108 from about the sling 104 after the sling 104 is implanted in the patient's tissues. Exemplary bioabsorbable materials from which the casing 108 may be made include, but are not limited to, alginates, sugar based formulations, starches, gelatins, cellulose, polyvinyl alcohol, polyglycolic acid (PGA), polylactic acid (PLA), polydioxinone (PDO), and other synthetic and natural polymers including combinations thereof. In another embodiment, the bioabsorbable material is a lubricious material that, during the delivery procedure, reduces the friction between the sling assembly 100 and the patient's periurethral tissues and thereby facilitates placement of the sling assembly 100.

In another aspect, the invention provides a method for treating urinary incontinence. FIG. 4 depicts an exemplary delivery system 148 that is used to deliver the sling assembly 100 to the patient's periurethral tissues in accordance with an illustrative embodiment of the invention. As shown, the delivery system 148 includes a delivery apparatus 152, connectors such as guide tubes 156A, 156B, and the sling assembly 100. In other embodiments, the guide tubes 156A, 156B may be replaced by other types of connectors (not shown). In one embodiment, each of the guide tubes 156A, 156B includes a proximal opening 160, a distal opening 164, and a lumen 168 extending from the proximal opening 160 to the distal opening 164. The exemplary delivery apparatus 152 includes a handle 172 and a cannula 176. In one embodiment, a first end 180A of the sling assembly 100 is coupled to a proximal portion 182A of the first guide tube 156A, and a second end 180B of the sling assembly 100 is coupled to a proximal portion 182B of the second guide tube 156B.

In an exemplary method of treating urinary incontinence, the operator loads the first guide tube 156A onto the cannula 176 illustrated in FIG. 4. Specifically, with continued reference to FIG. 4, a distal end 184 of the cannula 176 is inserted through the proximal opening 160A of the first guide tube 156A. The distal end 184 of the cannula 176 is advanced through the lumen 168A of the first guide tube 156A until it exits from the distal opening 164A of the first guide tube 156A. Illustratively, the operator then introduces the distal end 184 of the cannula 176 into the patient's tissues transvaginally at a first site until the distal end 184 of the cannula 176 emerges once

again from the patient's tissues at a second site, such as at the abdominal wall. The operator grasps and stabilizes a distal portion 186A of the first guide tube 156A that emerges from the patient's tissues at the second site. While the operator stabilizes the grasped portion of the first guide tube 156A, the cannula 176 is backed out of the patient's tissues, leaving behind the first guide tube 156A in the patient's tissues. The operator then loads a second guide tube 156B onto the cannula 176 of the delivery apparatus 152 and repeats the above-described procedure on the opposite side of the patient's periurethral tissue.

With both guide tubes 156A, 156B in place in the patient's tissues, the operator performs a cystoscopy to confirm that the guide tubes 156A, 156B have not penetrated the urinary bladder. Once so confirmed, the operator grasps the distal portions 186A, 186B of the guide tubes 156A, 156B, respectively, where they emerge from the patient's tissues at the abdominal wall and withdraws the guide tubes 156A, 156B. The operator then adjusts the position of the sling assembly 100 in the patient's periurethral tissue.

Referring now to FIG. 5, an exemplary method of treating urinary incontinence includes implanting the sling assembly 100, including the sling 104 and the casing 108, in a patient's

periurethral tissues 140 and positioning the sling assembly 100 adjacent the patient's urethra 144. In one particular embodiment, an operator places the de-tanged mid-length portion 112 of the sling 104 adjacent the urethra 144. Referring again to FIG. 4, once the sling assembly 100 is correctly positioned, the operator uncouples the ends 180A, 180B of the sling assembly 100 from the guide tubes 156A, 156B. The sling assembly 100, including the sling 104 and the casing 108, is left behind in the patient's periurethral tissues 140, as illustrated in FIG. 5.

In alternative embodiments, rather than using a transvaginal approach as described above, the operator approaches the patient's periurethral tissues 140 using a supra-pubic approach (*i.e.*, percutaneously through the abdominal wall, abdominal fascia, and rectus fascia), a transobturator approach (*i.e.*, around the ischiopubic ramus percutaneously through the obturator membrane and periurethral endopelvic fascia to a vaginal incision), or a pre-pubic approach (*i.e.*, from the abdominal wall along the

anterior surface of the pubic bone). Other alternative operable methodologies for placing a sling 104 with a casing 108 according to the invention in a patient's body, to provide anatomical support, are also contemplated within the scope of the invention.

Referring now to FIG. 6, after a pre-determined period of time, such as, for example, less than ten minutes after placement of the surgical sling assembly 100 in the patient's periurethral tissues 140, the casing 108 is absorbed by the patient's tissues. Preferably, the casing 108 is absorbed by the patient's tissues between eight to ten minutes after placement of the surgical sling assembly 100 in the patient's periurethral tissues 140. However, in alternate embodiments, the casing 108 is absorbed by the patient's tissues after any period of time following placement of the surgical sling assembly 100 in the patient's periurethral tissues 140. Only the sling 104 is left behind in the patient's periurethral tissues 140. Because the operator need not physically remove the casing 108 from about the sling 104 in order to implant the sling 104, the sling 104 is not at risk of shifting, twisting, or of otherwise being misplaced, as would be the case if the casing 108 was physically removed. Advantageously, the de-tanged mid-length portion 112 of the sling 104 remains adjacent the urethra 144. Tissue compression and eventual tissue in-growth at the tanged end-length portions 120A, 120B permanently secure the sling 104 in position. The sling 104 provides the requisite support to assist in maintaining continence.

The sling assembly 100 described above may terminate in any suitable configuration or structure such as loops, apertures, male and female connectors, guide tubes, and the like. Exemplary configurations and structures are disclosed in United States patent application Serial Nos. 10/093,371, 10/093,398, 10/093,424, 10/093,450, 10/093,498, and 10/094,352 filed in the United States Patent Office on March 7, 2002, which are based on and claim priority to provisional patent application Serial No. 60/274,843 filed in the United States Patent Office on March 9, 2001 and provisional patent application Serial No. 60/286,863 filed in the United States Patent Office on April 26, 2001, provisional patent application Serial No. 60/403,555 filed in the United States Patent Office on August 14, 2002, provisional patent application Serial No. 60/418,827 filed in the United States Patent Office on October 15, 2002, provisional patent application Serial No. 60/418,642 filed in the United States Patent Office on October 15, 2002, provisional patent application Serial No. 60/434,167 filed in the

United States Patent Office on December 17, 2002, United States patent application Serial No. 10/325,125 filed in the United States Patent Office on December 19, 2002, provisional patent application Serial No. 60/449,465 filed in the United States Patent Office on February 24, 2003, and provisional patent application Serial No. 60/465,722 filed in the United States Patent Office on April 25, 2003, all the disclosures of which are hereby incorporated herein by reference in their entirety.

Moreover, the sling assembly 100 of the invention may be employed with any suitable delivery system. Such delivery systems include, for example, those delivery systems configured for supra-pubic, pre-pubic, transvaginal, or transobturator approaches. Without limitation, delivery systems and methodologies that may be employed in combination with the sling assembly 100 of the invention can be found, for example, in United States patent application Serial Nos. 10/093,371, 10/093,398, 10/093,424, 10/093,450, 10/093,498, and 10/094,352 filed in the United States Patent Office on March 7, 2002, which are based on and claim priority to provisional patent application Serial No. 60/274,843 filed in the United States Patent Office on March 9, 2001 and provisional patent application Serial No. 60/286,863 filed in the United States Patent Office on April 26, 2001, provisional patent application Serial No. 60/403,555 filed in the United States Patent Office on August 14, 2002, provisional patent application Serial No. 60/418,827 filed in the United States Patent Office on October 15, 2002, provisional patent application Serial No. 60/418,642 filed in the United States Patent Office on October 15, 2002, and provisional patent application Serial No. 60/434,167 filed in the United States Patent Office on December 17, 2002, all the disclosures of which are hereby incorporated herein by reference in their entirety.

Additionally, the sling 104 of the invention may have any suitable size or shape configuration and may include any complimentary features. Without limitation, various applicable sling configurations are disclosed in United States patent application Serial No. 09/916,983 filed in the United States Patent Office on July 27, 2001, United States patent application Serial No. 10/092,872 filed in the United States Patent Office on March 7, 2002, provisional patent application Serial No. 60/388,109 filed in the United States Patent Office on June 12, 2002, provisional patent application Serial No. 60/403,555 filed in the United States Patent Office on August 14, 2002, provisional patent application Serial No. 60/449,465 filed in the United States Patent Office on

February 24, 2003, provisional patent application Serial No. 60/465,722 filed in the United States Patent Office on April 25, 2003, and United States patent application Serial No. 10/460,112 filed in the United States Patent Office on June 12, 2003, all the disclosures of which are hereby incorporated herein by reference in their entirety.

Variations, modifications, and other implementations of what is described herein will occur to those of ordinary skill in the art without departing from the spirit and the scope of the invention. The invention is not to be defined only by the preceding illustrative description.

Claims

1. A surgical sling assembly for implanting in tissue to provide anatomical support in a patient, comprising:

a sling; and

a biocompatible casing enclosing at least a portion of the sling, the biocompatible casing comprising a bioabsorbable material, wherein the biocompatible casing is absorbed by the patient's tissues after the surgical sling assembly is positioned within the patient's tissue to provide anatomical support.

2. The sling assembly of claim 1, wherein the biocompatible casing comprises a sleeve.

3. The sling assembly of claim 1, wherein the biocompatible casing comprises a coating.

4. The sling assembly of claim 1, wherein the bioabsorbable material comprises an alginate.

5. The sling assembly of claim 1, wherein the bioabsorbable material comprises a sugar based formulation.

6. The sling assembly of claim 1, wherein the bioabsorbable material comprises a starch.

7. The sling assembly of claim 1, wherein the bioabsorbable material comprises a gelatin.

8. The sling assembly of claim 1, wherein the bioabsorbable material comprises cellulose.

9. The sling assembly of claim 1, wherein the bioabsorbable material comprises polyvinyl alcohol.

10. The sling assembly of claim 1, wherein the bioabsorbable material comprises polyglycolic acid.

11. The sling assembly of claim 1, wherein the bioabsorbable material comprises polylactic acid.

12. The sling assembly of claim 1, wherein the bioabsorbable material comprises polydioxinone.

13. The sling assembly of claim 1, wherein the bioabsorbable material comprises a lubricious material.

14. The sling assembly of claim 1, wherein the surgical sling assembly is positioned within a patient's periurethral tissues to treat urinary incontinence.

15. The sling assembly of claim 14, wherein the biocompatible casing is absorbed by the patient's tissues in less than ten minutes after the surgical sling assembly is positioned within the patient's periurethral tissues.

16. The sling assembly of claim 15, wherein the biocompatible casing is absorbed by the patient's tissues in eight to ten minutes after the surgical sling assembly is positioned within the patient's periurethral tissues.

17. A method for providing anatomical support in a patient, comprising:

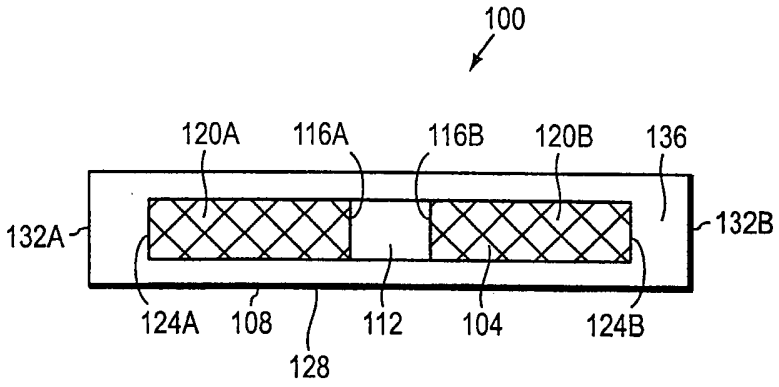
providing a surgical sling assembly, comprising:

a sling; and

a biocompatible casing enclosing at least a portion of the sling, the biocompatible casing comprising a bioabsorbable material, wherein the biocompatible casing is absorbed by the patient's tissues after the surgical sling assembly is positioned within the patient's tissue to provide anatomical support; and

positioning the sling within the patient's tissue.

18. The method of claim 17, wherein positioning the sling comprises positioning the sling within a patient's periurethral tissues to treat urinary incontinence.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128
112
104
124B

FIG. 1

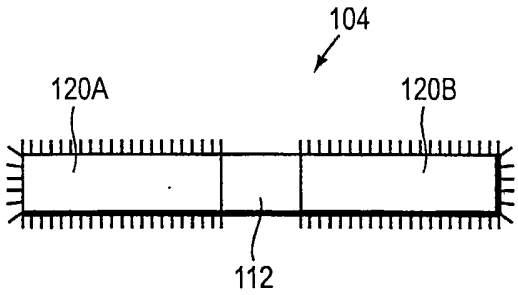


FIG. 2

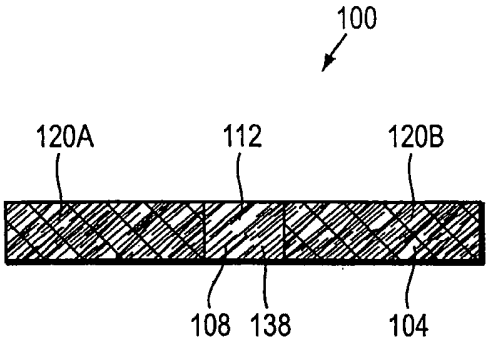
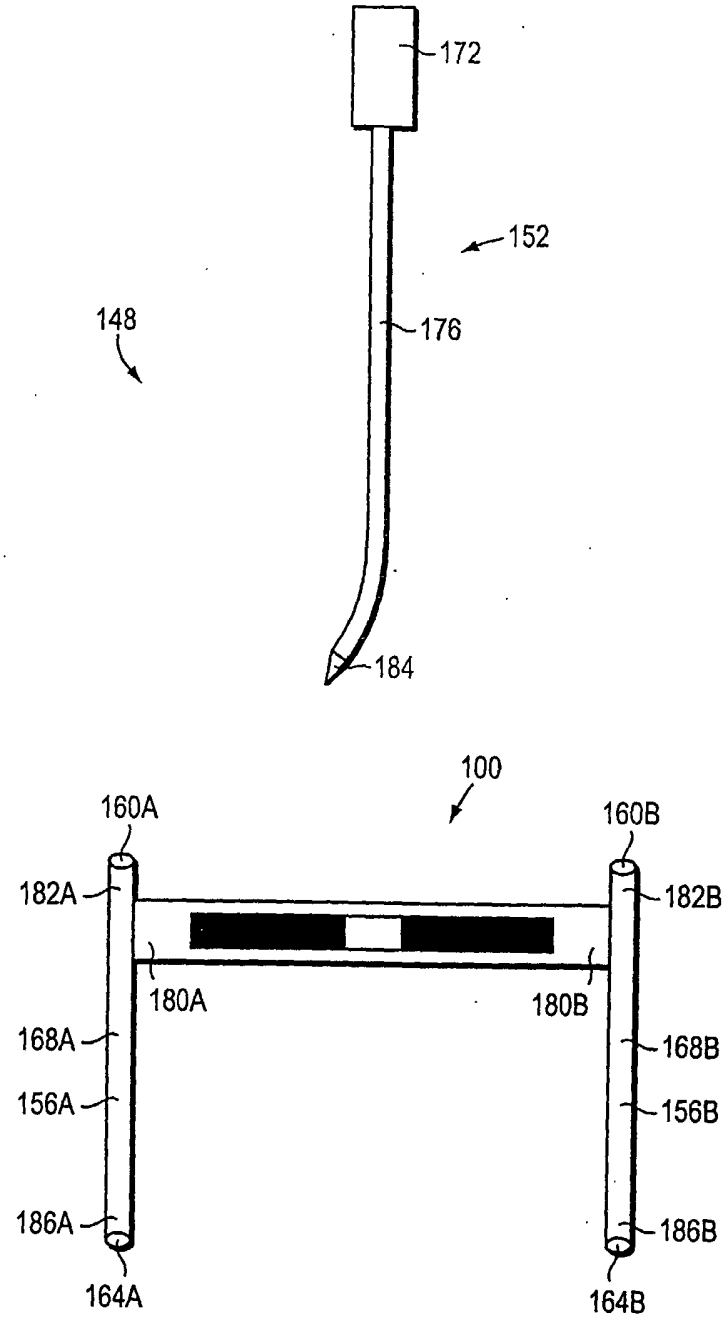


FIG. 3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164A
164B

FIG. 4

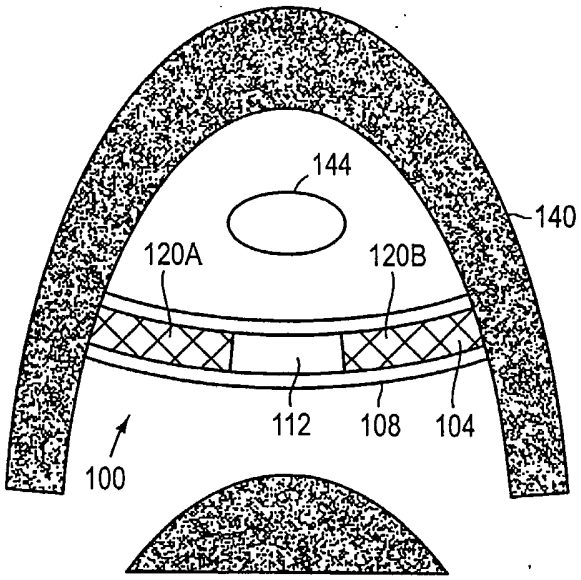

FIG. 5

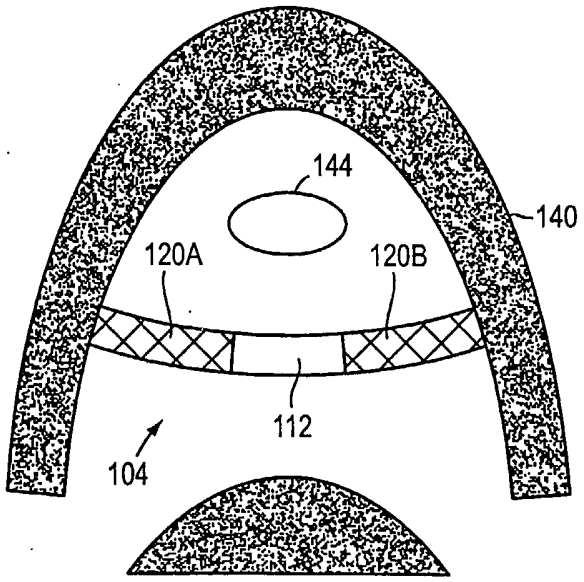

FIG. 6

INTERNATIONAL SEARCH REPORT

Application No
PCT/US2004/023842

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61L31/10 A61L31/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, BIOSIS, WPI Data, COMPENDEX, PAJ, EMBASE, CHEM ABS Data, INSPEC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 042 534 A (GELLMAN BARRY N ET AL) 28 March 2000 (2000-03-28) column 2, line 5 - line 38 column 7, line 61 - column 8, line 24 claims	1-16
X	WO 02/32321 A (YEUNG JEFFREY E ; YEUNG TERESA T (US)) 25 April 2002 (2002-04-25) page 32, line 5 - line 11 figure 72 claims	1-16

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 November 2004	14/12/2004

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Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

Application No
PCT/US2004/023842

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/156489 A1 (GELLMAN BARRY N ET AL) 24 October 2002 (2002-10-24) paragraphs '0135!, '0136! paragraphs '0164! - '0166! paragraph '0178! paragraph '0186! claims	1-16
X	US 6 306 079 B1 (TRABUCCO ARNALDO F) 23 October 2001 (2001-10-23) column 3, line 9 - line 10 column 6, line 15 - line 20 figure 5 claims	1-16
X	DATABASE BIOSIS 'Online! BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 2002, SCHOSTAK M ET AL: "Transvaginal bone anchors in female stress urinary incontinence: Poor results." XP002307616 Database accession no. PREV200300173905 abstract & GYNECOLOGIC AND OBSTETRIC INVESTIGATION, vol. 54, no. 3, 2002, pages 154-158, ISSN: 0378-7346	1-16

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Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 17-18
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Application No
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