

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
27 September 2007 (27.09.2007)

PCT

(10) International Publication Number
WO 2007/109508 A1

(51) International Patent Classification:
A61F 2/00 (2006.01)

(21) International Application Number:
PCT/US2007/064079

(22) International Filing Date: 15 March 2007 (15.03.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/782,911 16 March 2006 (16.03.2006) US
60/852,932 19 October 2006 (19.10.2006) US

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

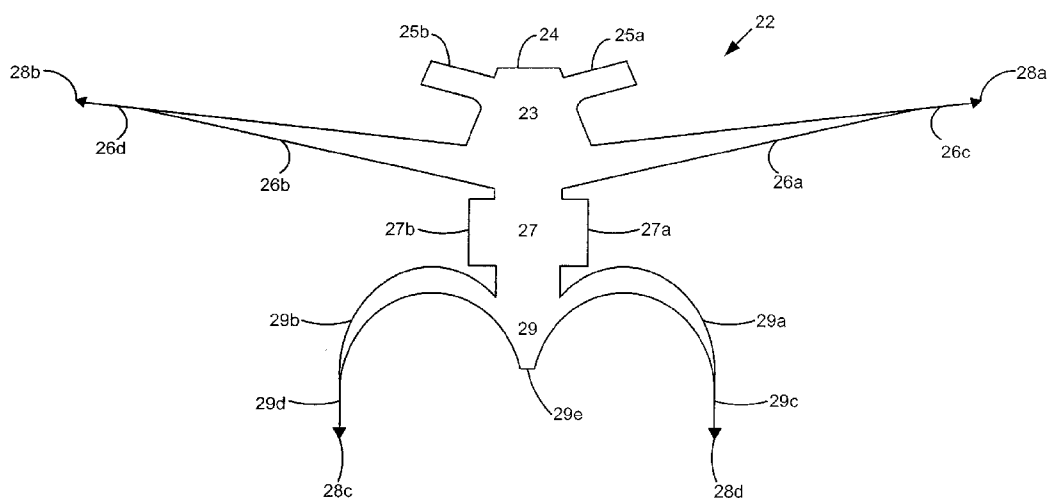
(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SYSTEM AND METHOD FOR TREATING TISSUE WALL PROLAPSE



(57) Abstract: The invention disclosed herein includes an apparatus and a method for treatment of vaginal prolapse conditions. The apparatus is a graft having a central body portion with at least one strap extending from it. The strap has a bullet needle attached to its end portion and is anchorable to anchoring tissue in the body of a patient. The invention makes use of a delivery device adapted to deploy the graft in a patient. The inventive method includes the steps of making an incision in the vaginal wall of a patient, opening the incision to gain access inside the vagina and pelvic floor area, inserting the inventive apparatus through the incision, and attaching the straps of the apparatus to anchoring tissue in the patient.

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SYSTEM AND METHOD FOR TREATING TISSUE WALL PROLAPSE

CROSS-REFERENCE TO RELATED APPLICATIONS

[1001] This application claims priority from U.S. Provisional Patent Application Serial No. 60/782,911, filed on March 16, 2006, and U.S. Provisional Patent Application Serial No. 60/852,932, filed October 19, 2006, both of which are expressly incorporated by reference in their entirety.

BACKGROUND OF THE INVENTION

Field of the Invention

[1002] The present invention relates in general to a system and method in the field of prolapse treatment. More particularly, the present invention relates to an apparatus with multiple components, and a method for surgically correcting tissue wall prolapse using the same. Specifically, one embodiment of the present invention is a kit that has a pre-cut shaped mesh graft, and a graft delivery device.

Discussion of the Related Art

[1003] As is known to those skilled in the art, the treatment of vaginal wall prolapse has been hampered by high failure rates. Reasons for failure include the inherent weakness of the tissue being re-approximated and the inability of the repair to withstand the forces applied by the abdominal cavity bearing down from above. In the last decade, one advance in repair has been the addition of grafts to reinforce vaginal prolapse repairs. While this technique has gained acceptance, there lacks a consensus regarding how to affix the graft under the vaginal wall to best maintain durability and vaginal caliber.

[1004] Some known procedures can cause patient discomfort and/or pain and there is a risk that the graft will become dislodged with time. Additionally, when a graft is sewn into place with standard sutures over the pelvic floor muscles, it may cause pain from suture entrapment. Further, sutures are prone to pullout because the sutures are placed into tissue that is thin and inherently weak. Finally, the placement of the sutures varies among surgeons. Accordingly, it is difficult to teach proper graft placement.

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[1005] With the introduction of new techniques, improved devices have been made commercially available. In general, these systems utilize medical mesh with wings at the corners so that the mesh may be drawn through the pelvic floor musculature and pelvic ligaments to secure the mesh.

[1006] An accepted access point for securing the wings of these systems has been through the obturator membrane and ischiorectal fossa. Access is generally made via these structures because the apex of the vagina is located deep within the pelvis. However, the problem with accessing the apex via these structures is that this anatomy is unfamiliar to surgeons. Further, safety remains a concern for surgeons because these systems require the passage of sharp needles long distances through these unfamiliar anatomic paths with unseen neurovascular structures potentially nearby. Thus, extensive training and anatomy education is required to properly learn the technique.

[1007] In general, the embodiments disclosed in the above-referenced patents and publications have the disadvantage that they are difficult or dangerous to use without extensive training. Also, they are only partially effective to treat prolapse. Other disadvantages include increased risk and ineffective results over time. Given these disadvantages, patients suffering prolapse either must wait long periods of time for treatment or forego treatment altogether because of the risk involved and the necessary high-level of surgeon skill. This further leads to a procedure with a relatively high cost.

[1008] Therefore, what is needed is a relatively simple apparatus and method for the treatment of vaginal wall prolapse. Specifically, what is needed is an apparatus and method that reduce patient discomfort and that are easily repeatable and highly effective over time.

SUMMARY OF THE INVENTION

[1009] The invention disclosed herein includes an apparatus and a method for treatment of vaginal prolapse conditions. The apparatus is a graft having a central body portion with at least one strap extending therefrom. The strap has a bullet needle attached to its end portion and is anchorable to anchoring tissue in the body of a patient. The invention makes use of a

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delivery device adapted to deploy the graft in a patient. The inventive method includes the steps of making an incision in the vaginal wall of a patient, opening the incision to gain access inside the vagina and pelvic floor area, inserting the inventive apparatus through the incision, and attaching the straps of the apparatus to anchoring tissue in the patient.

BRIEF DESCRIPTION OF THE DRAWINGS

[1010] Fig. 1 illustrates a top view of a graft according to an embodiment of the present invention.

[1011] Figs. 2a, 2b, and 2c illustrate top views of various wings and bullet needles of the graft according to an embodiment the present invention.

[1012] Figs. 3a and 3b illustrate a side cut away view of a graft placement device.

[1013] Figs. 4a and 4b are cut-away views of a portion of the graft placement device of Fig. 3a.

[1014] Figs. 5a, 5b, 5c, and 5d illustrate a side view of a portion of the graft placement device of Fig. 3a and a bullet needle.

[1015] Fig. 6 illustrates a side cut-away view of a portion of the graft placement device of Fig. 3a.

[1016] Figs. 7a, 7b, 7c and 7d are schematic illustrations of a vaginal area of a patient.

[1017] Fig. 8 is a schematic illustration of various parts of the female anatomy with some components of the present invention in place.

[1018] In describing the illustrated embodiments of the invention that is illustrated in the drawings, specific terminology may be used for the sake of clarity. However, it is not intended that the invention be limited to the specific terms so selected and it is to be understood that each specific term includes all technical equivalents that operate in a similar manner to accomplish a similar purpose.

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DETAILED DESCRIPTION

[1019] This invention, which includes elements of a method and device, represents a novel way of treating vaginal wall prolapse. The present invention overcomes the above-mentioned limitations of the art. The invention has two main components: a graft and a graft placement device or delivery device. The graft itself can have several sizes and shapes and be made of a variety of materials. See, e.g., U.S. Pat. Nos. 6,102,921 and 6,638,284 incorporated in their entirety by reference. In one embodiment, a synthetic polypropylene mesh graft version is used. One embodiment of the inventive graft is designed to cover the entire vaginal vault and provide anchoring to the arcus tendineus, the sacrospinous ligament, and/or the levator ani muscle of the patient.

[1020] Whereas several known methods use long needles to aid in graft placement (which hamper their adoption), the disclosed apparatus uses a graft that includes bullet needles attached thereto. The bullet needles are configured to attach the graft to the accepted anatomic structures without having to pass through the previously mentioned unfamiliar pathways such as the ischiorectal fossa or the obturator membrane. The graft is, therefore, able to, as a result of its design, reach the desired attachment points directly through the vaginal canal.

[1021] The graft may be placed using a placement device or delivery device. One embodiment of the delivery device is a device such as a Boston Scientific Corporation "Laurus" or "Capio" device, which can be good a predicate device for the delivery device component of this kit. The graft delivery device acts as a suture-capturing device also but in the disclosed invention the suture can be a mesh wing, such as a strap, arm, or leg.

[1022] Using the components described above, in one embodiment, the inventive method includes the following steps: making an incision in the vaginal wall; opening the incision to gain access inside the vagina and Pelvic Floor; taking a suture-capturing device in hand; attaching a mesh wing with a bullet needle to a suture capturing device; inserting the wing, needle and suture device through the incision and inside the vagina; pushing the wing and bullet needle through the ligaments or muscle; pulling the wing back out of the incision with

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the suture device; releasing the bullet needle and wing from the suture device; attaching another wing and its bullet needle to the suture capturing device, and repeating the process at another location within or through the vagina; repeating the process with the other wings and bullet needles until all of the wings are attached to the commonly accepted apical and lateral support structures. These are generally the sacrospinous ligament, proximal arcus tendineus, and levator ani muscle. This wing securement allows the custom adjustment for each patient, which would not occur with conventional suture fixation. The excess mesh wing material should then be trimmed away and discarded. After the remaining mesh is secured, the incision is closed.

[1023] As mentioned above, one embodiment of the present invention has two main components. The first component is a graft. As best shown in Fig. 1, in one embodiment the graft has a unique shape. While the graft 22 can be shaped as shown in Fig. 1, the graft may be of any suitable shape and generally will incorporate a central body portion and at least two longitudinal side portions, e.g., arms. For example, the graft of the present invention may be produced in a substantially oval shape or trapezium shape with extension arms and legs extending away from the central body portion of the graft. The graft can be positioned over the pubocervical fascia and secured via the surrounding ligaments and/or muscles.

[1024] In the embodiment illustrated in Fig. 1, the graft 22 has protrusions referred to as arms, legs, and wings (or generally "wings"). The inventive graft 22 includes an upper portion 23, first edge 24, first wing 25a, second wing 25b, third wing 26a, and fourth wing 26b. A central body portion 27, a first arm 27a, and a second arm 27b also make up the graft 22. The graft 22 further includes a lower portion 29, a first leg 29a, a second leg 29b, a third connecting segment 29c, a fourth connecting segment 29d, and a tail 29e. In one embodiment, the mesh does not include wings 25a and 25b.

[1025] The inventive wings, legs, and arms are intended to be used for attachment via the arcus tendineus near the ischial spine for the anterior vaginal wall, the sacrospinous ligament on the posterior vaginal wall, and/or the levator ani muscle. These anatomical structures are deep in the pelvis making them excellent for support but otherwise difficult to access without

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a graft delivery device as will be described more fully below. Once such a device reaches the preferred location, the device helps the surgeon to wedge the graft into place.

[1026] In some embodiments, the graft material itself is similar to the mesh material made by Boston Scientific Corporation called "POLYFORM." In other embodiments, a mesh as described in U.S. Patent Application Pub. No. 2005/0261545 or a mesh as described in U.S. Patent Application Pub. No. 2005/0222591, both of which are incorporated by reference in their entirety, is used as the material for the graft. There are also many types of available mesh grafts such as the mesh described in PCT/US 02/31681 to Ethicon, which is also incorporated by reference. One embodiment of a mesh includes a plurality of open pores bounded by strands made of nonwoven polymeric material, for example, a polypropylene having monofilament fibers, wherein the junctions between the strands are without open interstices and the majority of open pores of the mesh have an area of less than 15 mm^2 . In some embodiments, the pore size has an area of less than 10 mm^2 . In other embodiments, the pore size of the central body portion of the mesh is greater than the pore size of the longitudinal side portions. In some embodiments, the pore size range in these portions is between 3 mm and 8 mm wide. A mesh according to one embodiment of the invention is also light and very flexible having a weight of less than $.0080 \text{ g cm}^2$. The materials and mesh arrangement are such so as to minimize the chance of infection after implantation.

[1027] While any conventional prosthetic material currently used for the treatment of pelvic organ prolapse can be employed when performing the inventive method, there are many so-called biografts that can be used as well such as animal or human donor tissue or any other xenograft material such as pig dermis, bovine dermis, allograft, or homograft of skin. It is important to note that this novel system and method does not preclude using any number of materials as the graft and will be amenable to the use of future materials as they become available. However, while any of the above-mentioned materials are suitable for reinforcing the vaginal wall according to the disclosed method and with the disclosed apparatus, a synthetic polypropylene mesh is preferred.

[1028] On each arm and leg, respectively, is a first bullet needle 28a, second bullet needle 28b, third bullet needle 28c, and fourth bullet needle 28d. In one embodiment, the

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graft 22 also includes a first needle-connecting segment 26c and a second needle-connecting segment 26d.

[1029] Figs. 2a-2c show various embodiments of the bullet needle and the leg or arm. In Fig. 2a, for example, the bullet needle 28a is relatively small and generally round and is connected to the arm 26a via a thread or very thin segment of mesh, e.g., by needle-connecting segment 26c. In Fig. 2b, the bullet needle 128a is bigger (than 28a) and is round and is connected to the arm 126a via a segment of mesh. In Fig 2c, for example, the bullet needle 228a is bigger and flatter (than 28a and 128a) and is connected to the arm 226a via a wider segment of mesh. In one embodiment, the bullet needles may be formed from stainless steel. In another embodiment, the “needle” is formed of the graft material. For example the “needle” could be formed of more dense graft material. In such an embodiment, the stainless steel needles may be replaced altogether.

[1030] While in some embodiments the inventive wing, leg, or arm of the graft is affixed to a relatively small rounded bullet needle, in some embodiments the wing, leg, or arm is also tapered to allow atraumatic passage of it through the tissue and promote gripping of the wider portion of the arm or leg to the surrounding tissue. Further, instead of using the needle method for attaching the graft, it is also possible for the graft to be attached by other fastening means. Such fastening means including a medical adhesive or glue, microwave or radio frequency welding, staples, tacks, and a hook and loop type fastener.

[1031] One of the novel concepts in the disclosed invention is the adaptation of a previously-patented suture-passing device for the graft delivery device, e.g., as described in U.S. Patent Nos. 5,364,408; 5,540,704; 5,458,609; 5,575,800, and 5,662,664 all incorporated by reference in their entirety. See also, e.g., U.S. Pat. Application Publication No. 2006/0052801, also incorporated in its entirety by reference. In one embodiment, the disclosed delivery device is based in part on the “Capio” device, which is sold by Boston Scientific Corp. The Capio device was originally patented as the Laurus device and is generally used elsewhere for suture passage in limited access cavities. An embodiment of the device is a trocar capped by a curvilinear needle guide and deployable bullet needle that passes to a catch mechanism. A plunger at the other end of the device deploys it.

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[1032] The disclosed graft can be placed using such a graft delivery device, such as the graft placement device as shown in Figs. 3a- 6, which is the second component of the inventive apparatus. The modification of such a graft placement device allows the surgeon to use this device to pass the graft's wings, e.g., the arms and legs, directly through the desired anchoring structures without having to traverse these pathways. Further, the disclosed graft placement device itself is easier to use than the graft delivery devices currently in use in prolapse surgery. Therefore, the disclosed graft placement device requires less skill to deliver the graft wings to their target locations.

[1033] Detailed drawings of an illustrative embodiment of the graft delivery device are shown in Figs. 3a, 3b, 4a, 4b, 5a-5d, and Fig. 6 wherein the graft delivery device 30 includes an outer housing 32, with finger grips 34a and 34b, and a deployment catch 36. In some embodiments, the outer housing 32 is made of injection molded plastic such as polycarbonate, as are many other of the components described herein. A deployment sleeve 38, slidably disposed within the outer housing 32, has a retention catch 40 and is attached to a pushrod 42, constructed for example, of stainless steel. A driver shaft 44 includes a button 46 and has a hole 48a, into which is bonded an elongate rigid shaft 50a. The rigid shaft 50a, which may be made of music wire, passes through outer housing ribs 52a, 52b, and 52c, and terminates slidably disposed within a hollow cylinder 54a. The hollow cylinders 54a and 54b, which can be made from stainless hypodermic tubing, are held in recesses in the outer housing ribs 52b and 52c. An elongate flexible tubular member 56a, that may be made of polypropylene or other suitable material, is also slidably disposed within the hollow cylinder 54a. As shown in Fig. 4b, needle guide 58a may also be constructed from stainless hypodermic tubing, and has pivot pins 60a and 60b pivotally disposed within outer housing bosses 62a and 62b. A driving link 64a is attached by a link pin 66 to the pushrod 42 and to the needle guide 58a by a pivot pin 68a, with the entire mechanism preferably made of stainless steel so as to maximize the biocompatibility as well as the strength of the actuating members.

[1034] Referring again to Figs. 3a and 3b, the device 30 has a driver retainer 70 that is slidably disposed within the outer housing 32, and is fixably attached to rigid shafts 50a and

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50b, with a hole 72 to allow the pushrod 42 to pass slidably therethrough. A driver spring 74, which can be wound from stainless steel wire, is compressed between the driver retainer 70 and the outer housing rib 52b. A deployment spring 76, also made of stainless steel wire is compressed between an end 77 of the deployment sleeve 38 and outer housing rib 52a. A needle catch 78a is housed within a recess 80a in the outer housing 32. Referring now to Fig. 4b, a retraction line 82a that is preferably made of Kevlar, is slidably threaded through the flexible tubular member 56a and is attached to a needle carrier 84a by means of a crimp 86a or other means that would bind the retraction line 82a to the needle carrier 84a. The distal end of the retraction line 82a is attached to the rigid shaft 50a by means of another crimp 98a or other means.

[1035] Referring to Fig. 3b, arm 124 of deployment sleeve 38 is pushed so that the sleeve slides within the outer housing 32, compressing spring 76, and in turn sliding pushrod 42. As illustrated in Fig. 4b, when the pushrod 42 slides relative to the outer housing 32, it forces the needle guide 58a to pivot about the pin 60a that is retained in outer housing boss 62a.

[1036] Referring again to Fig. 4b, a retraction line 82a that is preferably made of Kevlar, is slidably threaded through the flexible tubular member 56a and is attached to a needle carrier 84a by means of a crimp 86a or other means that would bind the retraction line 82a to the needle carrier 84a. The distal end of the retraction line 82a is attached to the rigid shaft 50a by means of another crimp 98a or other means. The needle carrier 84a is slidably disposed within the needle guide 58a, and holds a needle 88a (or e.g. bullet needle 28a), typically constructed of surgical grade stainless steel in a recess 90a, such needle having a suture 92a attached thereto. The suture material is preferably polyglycolic acid, but may be made of polypropylene, nylon, silk, catgut, or any other materials known in the art selected for its biocompatibility and tensile strength to be used in the body for the approximation of tissue. The suture 92a exits the needle guide 58a by means of a groove and is stored in a recess 96 in outer housing 32. In one preferred embodiment, suture 92a would be, e.g., thread 26c which is connected to arm 26a as shown in Fig. 2a.

[1037] It should be understood that in the interest of clarity only one half of an embodiment of a graft placement device of the present invention is shown in Figs. 5a, 5b, 5c,

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5d, and 6. The other half is quite similar in function and structure to the half described herein. The upper portion of the device is similar in construction and materials to the previously disclosed embodiments, and is not repeated here. The graft placement device 196 includes an outer housing 198 having bosses 200 into which a pin 202 is rotatably inserted. The pin 202 is secured to an arm 204, which is attached to a needle carrier 206. A pin 208 on needle carrier 206 is rotatably inserted into a hole 210 in a link 212. Another pin 214 is secured to a pushrod 216 and is rotatably inserted into another hole 218 in the link 212. The pushrod 216 is attached to a sleeve 220 slidably disposed within the outer housing 198. Fig. 6 shows a detail view of a needle 222 (similar to bullet needle 28a) held in a recess 224 in the needle carrier 206. A thread 226, like thread 26c, is attached to the needle 222 and is threaded through a slot 228 in the needle carrier 206. In some embodiments all components in this mechanism are constructed of surgical grade stainless steel, chosen for its biocompatibility and strength.

In Use

[1038] Using the components briefly described above, a placement method includes the following steps: making an incision in the vaginal wall; opening the incision to gain access inside the vagina and Pelvic Floor; taking a suture-capturing device, such as a graft placement device, in hand; attaching the mesh wing with bullet needle to the suture capturing device, such as a graft placement device; inserting the wing, needle and suture device through the incision and inside the vagina; pushing the wing and bullet needle through the ligaments or muscles; pulling the wing back out of the incision with the suture device; releasing the bullet needle and wing from the suture device; attaching another wing and its bullet needle to the suture device and repeating the process at another location within the vagina; repeating the process with the other wings and bullet needles until all of the wings are attached to some internal structure such as the commonly accepted apical and lateral support structures. These support structures are generally the sacrospinous ligament, the proximal arcus tendineus, and the levator ani muscle. This wing securement allows the custom adjustment for each patient, which would not occur with conventional suture fixation; the wings should then be tightened as necessary so that the graft control body is covering the internal top wall of the vagina. The excess mesh wing material should then be

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trimmed away and discarded. After the remaining mesh is secured, the vaginal incision is closed.

[1039] Use and operation of the disclosed graft placement device will now be described beginning with reference to Fig. 5a. The device 196 is introduced into the abdomen. Sleeve 220 slides within the housing 198 in the direction indicated by the arrow. As shown in Fig. 5b, as the sleeve 220 moves, it pushes the pushrod 216 which causes the link 212 to cause the needle carrier 206, along with the needle 222 and the thread 226, to rotate about the axis defined by the pin 202. Referring to Fig. 5c, it may be seen that the needle 222 is driven into a catch 230 through an opening 232 in the outer housing 198. Accordingly, in reference to Fig. 5d, it is seen that as the pushrod 216 is retracted, the link 212 is also retracted, causing the needle carrier 206 to rotate about the pivot pin 202 and back through the opening 232 into the outer housing 198, the same position as shown in Fig. 5a.

[1040] An alternative embodiment mesh delivery device may resemble the device disclosed in U.S. Pat. No. 6,936,952, which is incorporated by reference. As mentioned above, there are specific anatomic structures, deep in the pelvis, typically used for graft fixation, which are chosen due to their advantageous location and resistance to displacement. Nevertheless because these structures are difficult to access, an incision must be made in the vaginal wall. See, e.g., Figs. 7a and 7b. Once the incision is made, a delivery device such as a graft placement device is used to put a graft in place. The placement device uses a needle, that can be affixed to each one of the mesh arms or legs of the implant. The needle and graft are loaded into a needle guide located on the delivery device. In some embodiments of the inventive method, once the graft and the needle are loaded in the graft placement device, the remainder of the body of the graft with the remaining arms and legs hangs from the needle. After the appropriate dissection of the paravaginal tissue is made and the anchoring structures are located and cleared of any connective tissue, the graft placement device is moved into place over the desired structure. The plunger is then compressed and the needle deployed. Once the needle and mesh pass through the desired anchoring structure, the entire device is gently retracted out of the vagina. This leaves the arm or leg of the graft loosely encircling the anchoring point. The delivery device is then again held in position to engage

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the subsequent needles from each of the remaining needles passing each wing around its respective anchoring point. The graft can be delivered as a single piece or cut into two separate pieces for delivery into the anterior and posterior wall of the vagina separately. The arm or leg can then be adjusted. This is done by pulling the graft as cephalad as necessary causing the graft to lie flat in its respective compartment. The ends of each arm or leg are then cut to release the needle. The excess mesh and needle are then disposed of.

[1041] Turning to Fig. 7a, posterior vaginal wall 213 is shown with the epithelium 214 of the posterior vaginal wall in place. In one embodiment of the inventive method, a longitudinal incision is performed in order to mobilize the epithelium 214 off the underlying fascia 215. Dissection is carried out laterally to the levator ani muscles on each side. In the upper part of the vagina, dissection is continued in a lateral and cranial direction through the rectal pillars on both sides towards the sacrospinous ligaments on each side. This creates a safe space through which to deploy the device, and forms bilateral tunnels from the posterior vaginal wall dissection to each sacrospinous ligament. The fascia of the recto-vaginal septum can be plicated (not shown). As illustrated in Fig. 7c, a graft, e.g. graft 216 designed for a posterior vaginal wall repair is placed over the recto-vaginal septum fascia 215 with each extension arm 217, 218 placed into the tunnel extending from the posterior vaginal wall dissection to the sacrospinous ligament. After the remaining mesh is secured, the vaginal incision is closed, as illustrated in Fig. 7d. The positioning of the graft 216 is depicted in Fig. 8, which shows its location relative to the sacrospinous ligament 233, the rectum 234 and the vagina 235. In other embodiments, similar methods can be used to access and attach the graft to the levator ani muscle.

[1042] The device and method described here can also be implemented with other modifications that allow it to be performed in conjunction with other procedures such as uterine preservation procedures.

[1043] While the preferred embodiments and best modes of utilizing the present invention have been disclosed above, other variations are also possible. For example, the materials, shape and size of the components may be changed. Various alternatives are

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contemplated as being within the scope of the following claims that particularly point out and distinctly claim the subject matter regarded as the invention.

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What is claimed is:

1. A method of treating pelvic conditions, comprising:
making an incision in the vaginal wall;
inserting a graft having at least one wing coupled to a bullet needle through the incision; and
pushing the wing and bullet needle through bodily tissue using a graft placement device.
2. The method of claim 1, further comprising pulling the wing back out of incision using the graft placement device.
3. The method of claim 1, further comprising releasing the bullet needle and wing from the graft placement device.
4. The method of claim 1, further comprising suturing the incision closed.
5. The method of claim 1, wherein opening the incision comprises dissection of the paravaginal tissue by pulling back the muscle and flesh.
6. The method of claim 1, further comprising loading one of the bullet needles into a graft insertion device such that the remainder of the graft hangs from the graft insertion device, the one of the bullet needles being attached to the terminus of one of the wings.
7. The method of claim 1, wherein pushing the wing and bullet needle through anchoring tissue using a graft placement device comprises pushing the wing and bullet needle through any of the commonly accepted apical and lateral support structures.
8. The method of claim 1, further comprising trimming away the excess wing material.
9. The method of claim 1, further comprising adjusting the graft by pulling the graft and causing the graft to lie substantially flat in its respective compartment.

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10. The method of claim 1, further comprising cutting the graft into at least two separate pieces.
11. A apparatus for treatment of pelvic conditions, comprising:
a graft having a central body portion and at least one wing extending therefrom, the wing being anchorable to anchoring tissue and having a end portion; and
a bullet needle attached to the end portion.
12. The method of claim 11, further comprising a delivery device releasably connectable to the bullet needle and adapted to deploy the graft in a patient.
13. The apparatus of claim 11, wherein the graft is made from polypropylene mesh.
14. The apparatus of claim 11, wherein the graft is sized and shaped to cover the entire vaginal vault of a patient.
15. The apparatus of claim 11, wherein the wing is configured to be anchorable to the sacrospinous ligaments of the patient.
16. The apparatus of claim 11, wherein the wing is configured to be anchorable to the arcus tendineus of the patient.
17. The apparatus of claim 11, wherein the wing is formed of a material and the bullet needle is formed from the material of the wing.
18. The apparatus of claim 11, wherein the bullet needle is connected to the end portion of the wing via a suture.
19. The apparatus of claim 11, wherein the graft comprises a mesh having a plurality of open pores bounded by nonwoven polymeric fibers, and wherein the majority of the open pores of the central body portion are larger than the majority of the open pores of the wings.

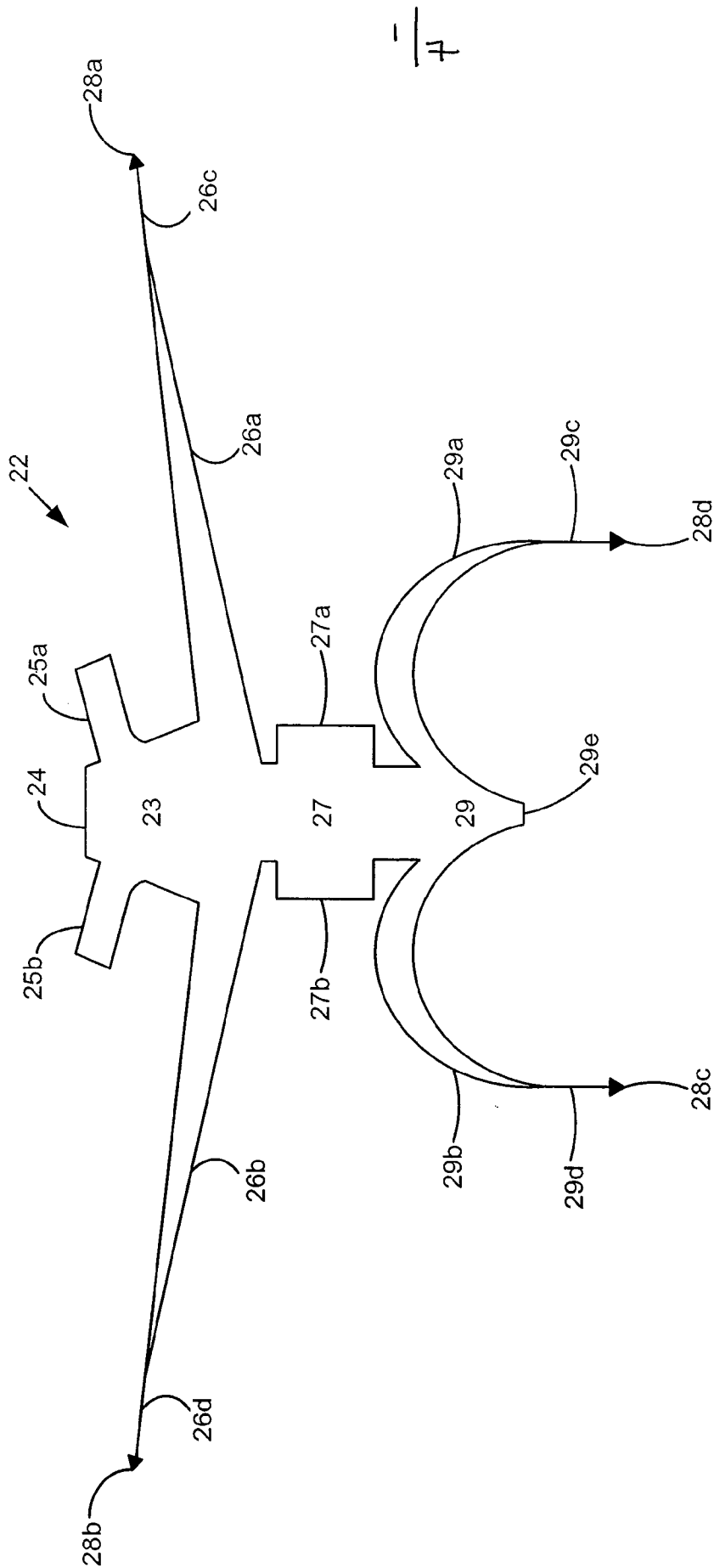


FIG. 1

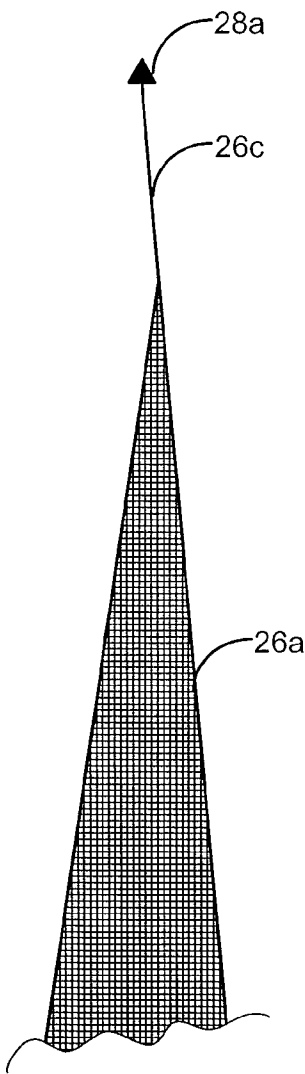


FIG. 2a

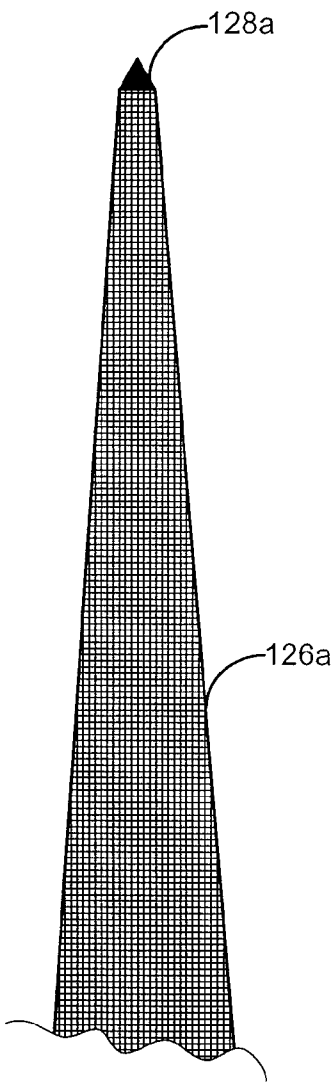


FIG. 2b

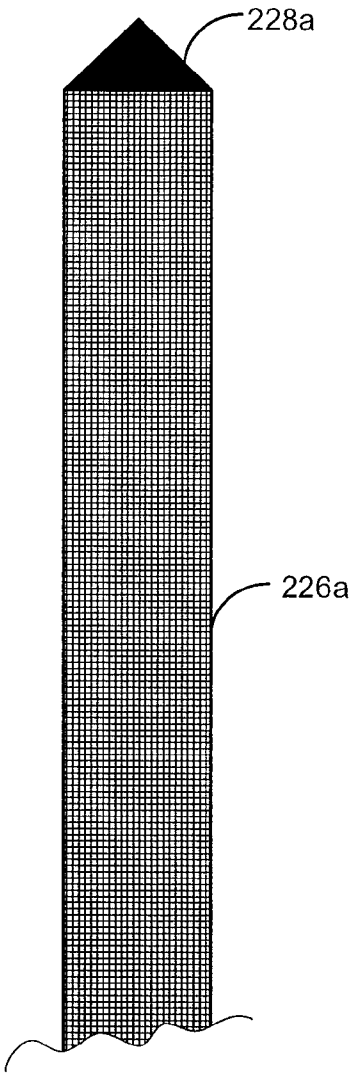


FIG. 2c

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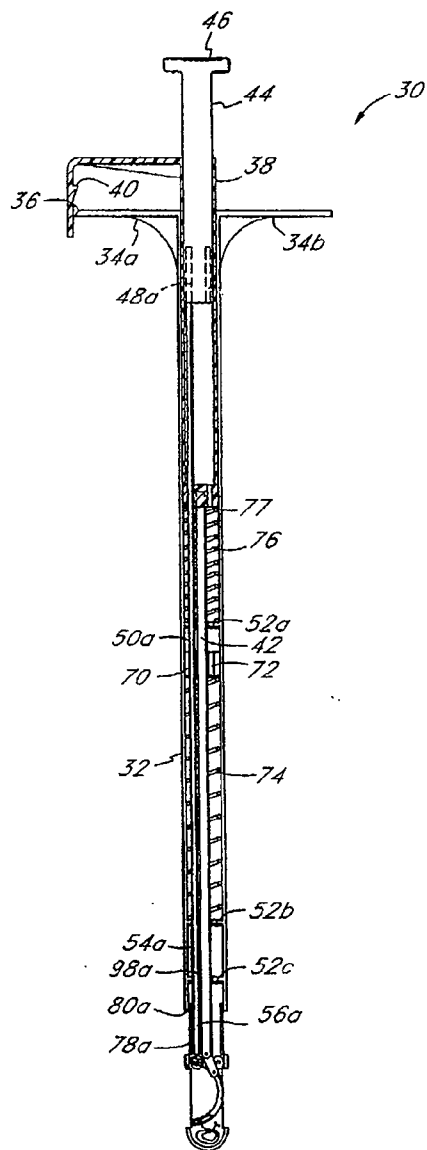


FIG. 3a

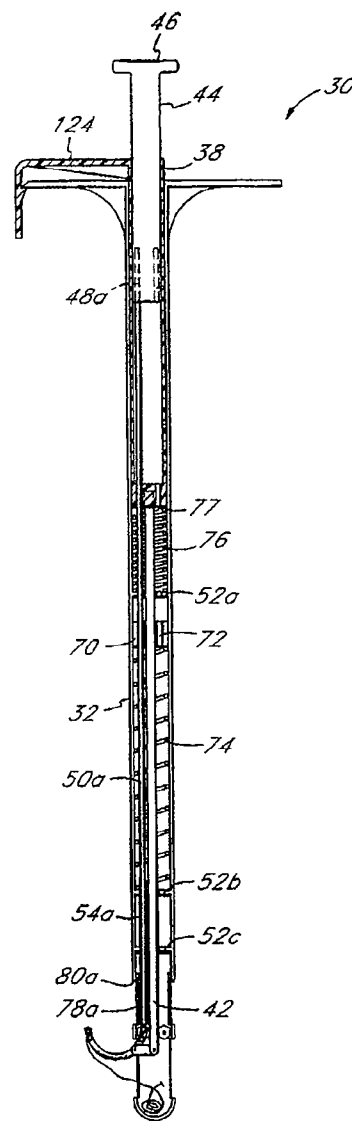
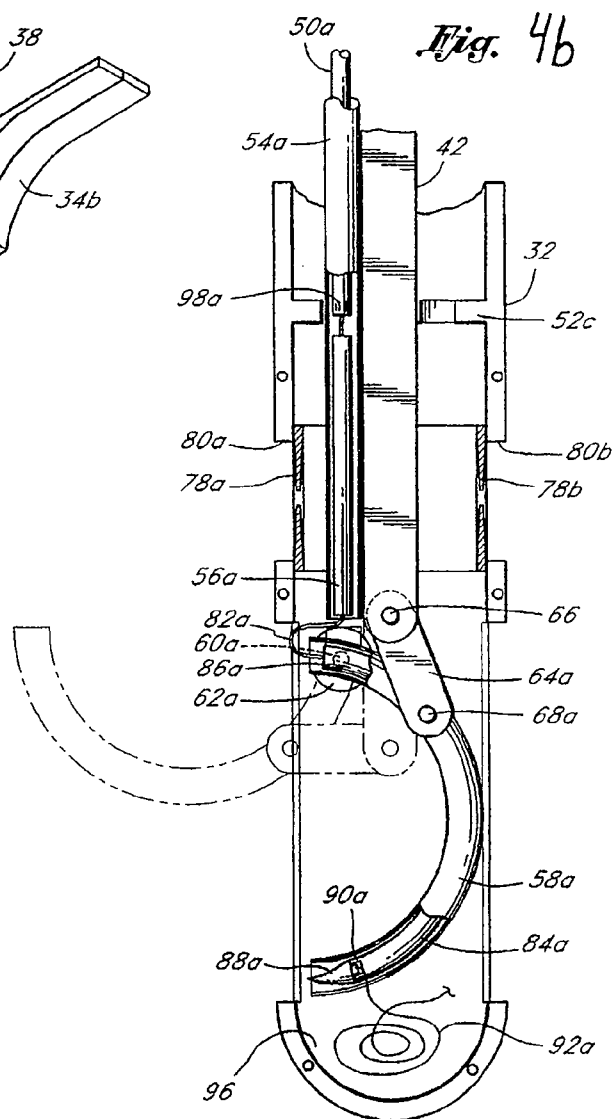
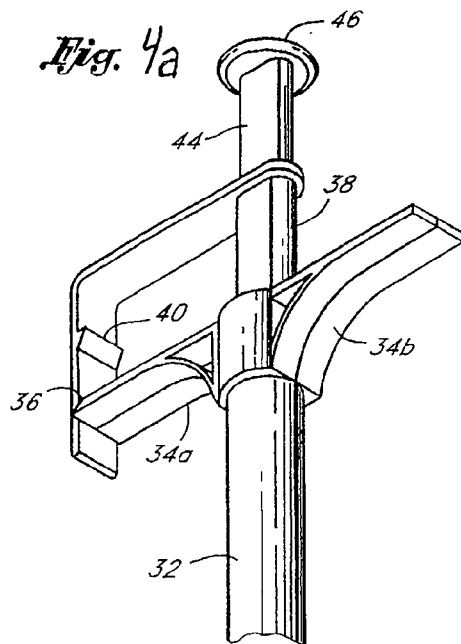
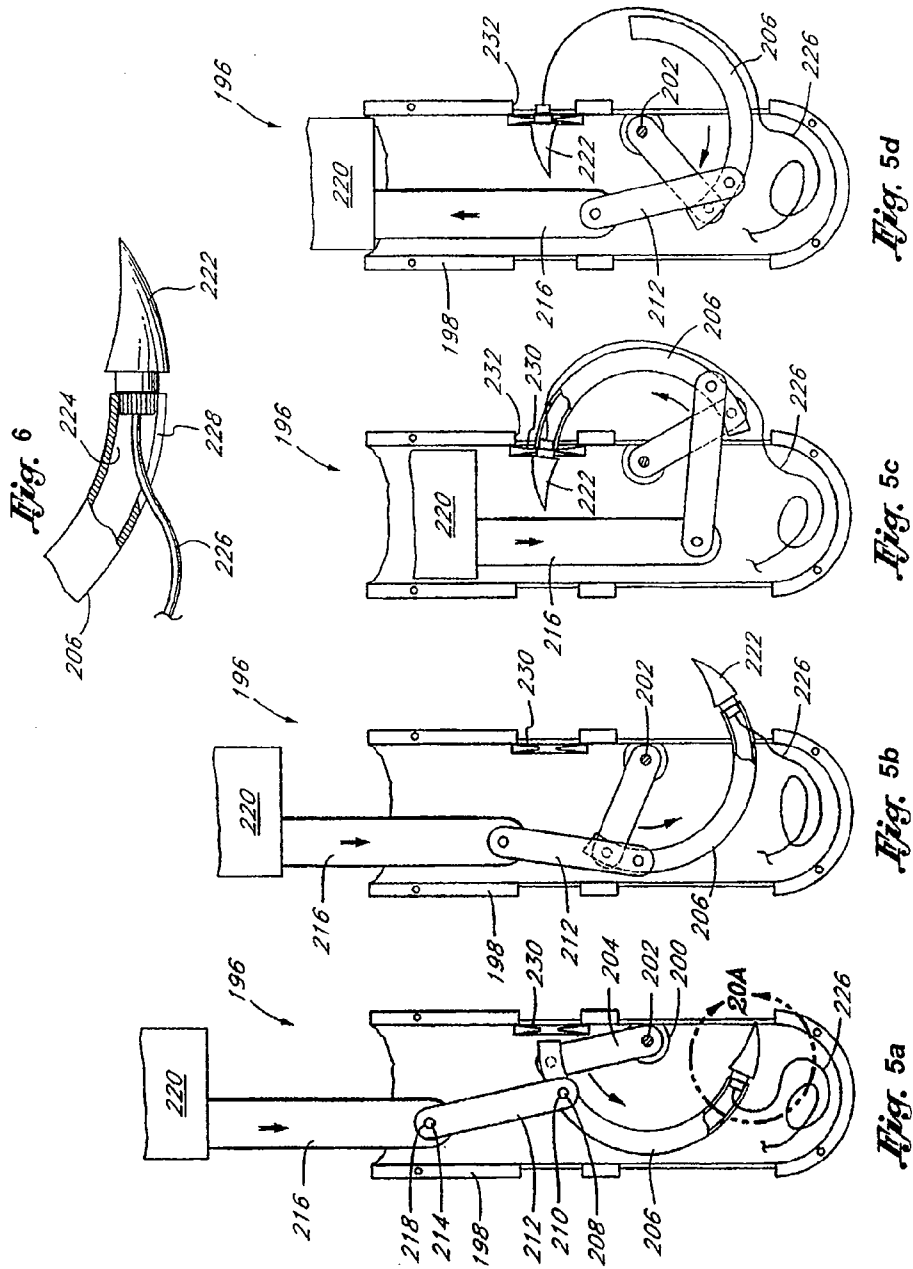


FIG. 3b

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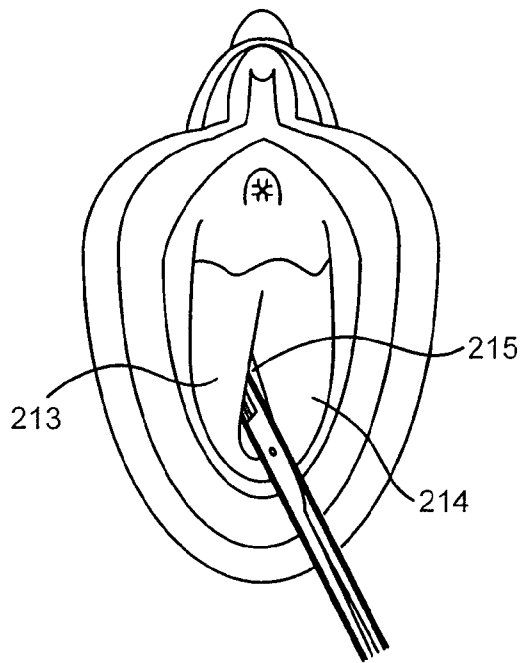


FIG. 7a

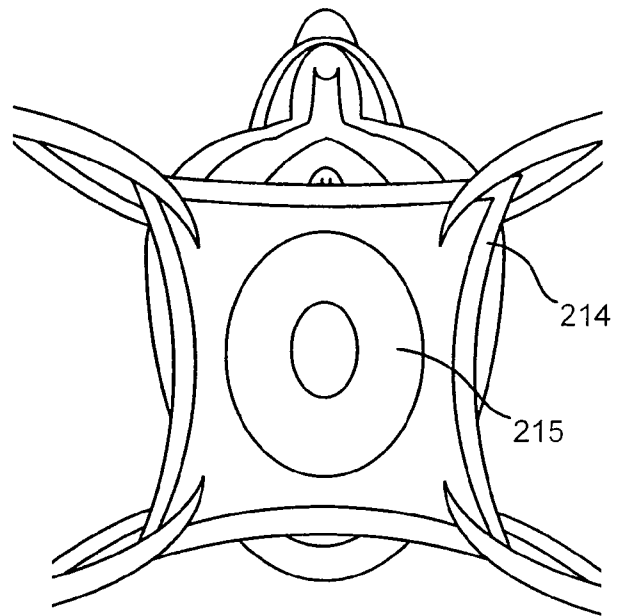


FIG. 7b

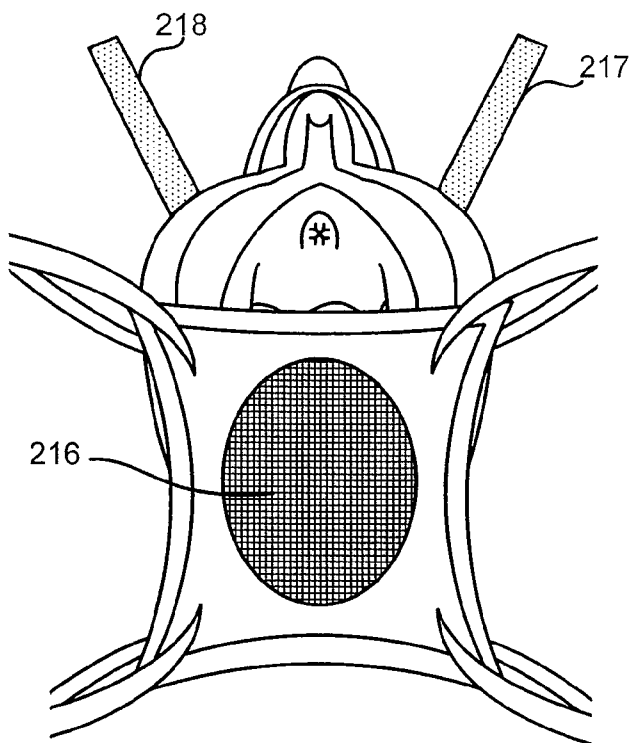


FIG. 7c

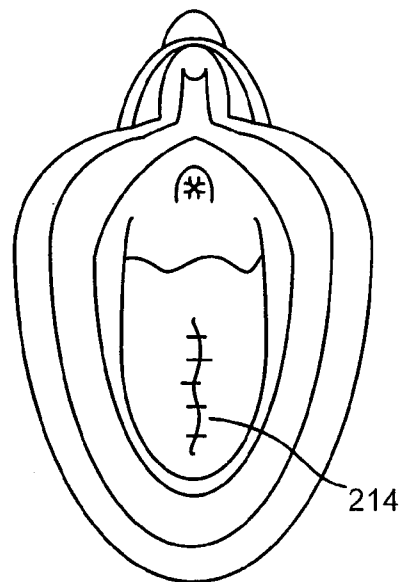


FIG. 7d

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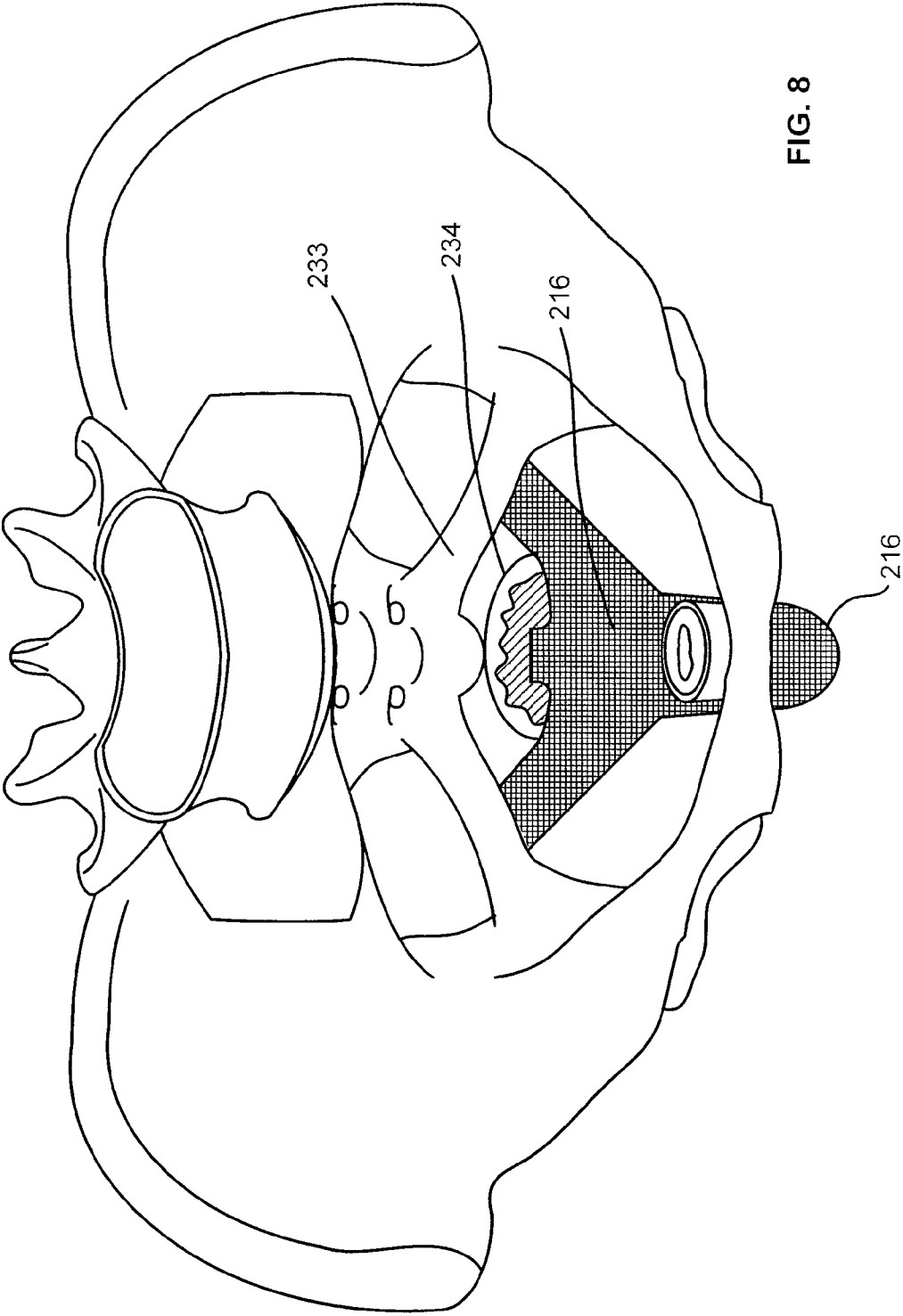


FIG. 8

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/064079

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F 2/00

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)
A61F

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, X	WO 2007/014240 A (BOSTON SCIENT SCIMED INC [US]) 1 February 2007 (2007-02-01) page 29, line 18 - page 30, line 12; figure 10 page 12, line 14	11-16, 18
P, X	WO 2007/016698 A (BARD INC C R [US]; EVANS DOUG [US]) 8 February 2007 (2007-02-08) page 17, line 16 - page 18, line 2; figure 18 page 3, line 23 - page 4, line 1	11-14
E	WO 2007/087132 A (BOSTON SCIENT SCIMED INC [US]; CHU MICHAEL S H [US]) 2 August 2007 (2007-08-02) page 8, line 17 - line 20; figure 5	11-17
	----- -/--	

☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:

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- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *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

21 August 2007

Date of mailing of the international search report

28/08/2007

Name and mailing address of the ISA/

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Authorized officer

Neumann, Elisabeth

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/064079

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2004/039453 A1 (ANDERSON KIMBERLY A [US] ET AL) 26 February 2004 (2004-02-26) paragraph [0087]; claims 4,18,34; figures -----	11,13-15
A	US 2005/234291 A1 (GINGRAS PETER [IE]) 20 October 2005 (2005-10-20) paragraphs [0033], [0034], [0148] - [0150]; figures 3C-3E -----	19

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2007/064079

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. ☒ Claims Nos.: 1-10
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

Information on patent family members

International application No

PCT/US2007/064079

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2007014240 A	01-02-2007	US 2007021649 A1	25-01-2007
WO 2007016698 A	08-02-2007	NONE	
WO 2007087132 A	02-08-2007	US 2007173864 A1	26-07-2007
US 2004039453 A1	26-02-2004	NONE	
US 2005234291 A1	20-10-2005	NONE	