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(54) Title: IMPLANTS AND PROCEDURES FOR SUPPORTING ANATOMICAL STRUCTURES

(57) Abstract: Implants for the treatment of pelvic support conditions and methods of implementing the same. The implants comprise relatively soft, flexible bodies and relatively strong arms extending in predetermined orientations therefrom. Methods and devices for placing the implants minimize trauma to the pelvic floor and provide well- anchored support to pelvic organs without interfering with sexual or other bodily functions.

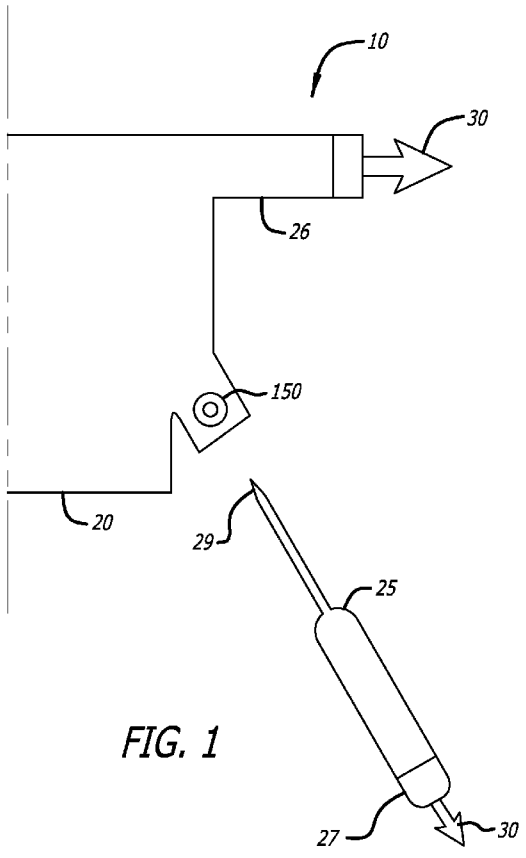

FIG. 1

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IMPLANTS AND PROCEDURES FOR SUPPORTING ANATOMICAL STRUCTURES

RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Application Serial No. 61/142,604 filed January 5, 2009, entitled *Implantable Anchors For Use With Mesh Within The Body*, and is related to U.S. Application Serial No. (Not yet assigned), filed January 5, 2010, entitled *Implants And Procedures For Supporting Anatomical Structures For Treating Conditions Such As Incontinence*, and U.S. Application Serial No. (Not yet assigned), filed January 5, 2010, entitled *Implants And Procedures For Supporting Anatomical Structures For Treating Conditions Such As Pelvic Organ Prolapse*, all of which are hereby incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The present invention pertains to the field of medical devices for anchoring and supporting anatomical structures and, more particularly, to implantable mesh that are operative to treat pelvic organ prolapse and incontinence.

BACKGROUND OF THE INVENTION

[0003] Pelvic floor disorders are a class of abnormalities that affect the pelvic region of millions of men and women. In women, for example, the pelvic region includes various anatomical structures such as the uterus, the rectum, the bladder, and the vagina. These anatomical structures are supported and held in place by a complex collection of tissues, such as muscles and ligaments. When these tissues are damaged, stretched, or otherwise weakened, the anatomical structures of the pelvic region shift and in some cases protrude into other anatomical structures. For example, when the tissues between the bladder and the vagina weaken, the bladder may shift and protrude into the vagina, causing a pelvic floor disorder known as cystocele. Other pelvic floor disorders include vaginal prolapse, vaginal hernia, rectocele, enterocele, uterocele, and/or urethrocele.

[0004] Pelvic floor disorders often cause or exacerbate urinary incontinence (UI). One type of UI, called stress urinary incontinence (SUI), effects primarily women and is often 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 (or "coapt") properly, causing urine to leak out of the urethra during stressful activity. In hypermobility, the pelvic floor is distended, weakened, or damaged. When the afflicted woman sneezes, coughs, or otherwise strains the pelvic region, the bladderneck and proximal urethra rotate and descend. As a result, the urethra does not close with sufficient response time, and urine leaks through the urethra.

[0005] UI and pelvic floor disorders, which are usually accompanied by significant pain and discomfort, are often treated by implanting a supportive sling or mesh in or near the pelvic floor region to support the fallen or shifted anatomical structures or more generally, to strengthen the pelvic region by promoting tissue in-growth. Often, treatments of stress incontinence are made without treating the pelvic floor disorders at all, potentially leading to an early recurrence of the stress incontinence.

[0006] Existing systems, methods, and kits for treatment typically employ delivery devices to position a supportive surgical implant into a desired position in the pelvic region. However, some of these systems and methods require a medical operator to create multiple incisions and deliver the implant using complex procedures. Moreover, many existing surgical implants are not suitably sized or shaped to properly fit within a patient and treat pelvic floor disorders. Accordingly, medical operators and patients need improved systems, methods, and surgical kits for the treatment of pelvic floor disorders and/or urinary incontinence.

OBJECTS AND SUMMARY OF THE INVENTION

[0007] The present invention provides improved methods and devices for supporting pelvic organs in the treatment of conditions such as incontinence and various pelvic floor disorders including but not limited to cystocele, enterocele and rectocele.

[0008] Devices of the present invention include implants having soft, flexible support bodies and anchors that are sturdy and durable.

[0009] Other devices of the present invention include introducers that allow an implant to be deeply implanted so as not to cause damage to the pelvic floor and to preserve the natural length of the vagina.

[0010] Methods of the present invention include the use of multiple implants for treating multiple disorders, including treating pelvic floor disorders and incontinence.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] These and other aspects, features and advantages of which embodiments of the invention are capable of will be apparent and elucidated from the following description of embodiments of the present invention, reference being made to the accompanying drawings, in which

[0012] FIG. 1 is a partial plan view of an implant according to an embodiment of the present invention.

[0013] FIG. 2A-2C are partial plan views of an implant according to an embodiment of the present invention.

[0014] FIG. 3 is a plan view of an implant according to an embodiment of the present invention.

[0015] FIG. 4 is a perspective view of an anchor according to an embodiment of the present invention.

[0016] FIG. 5 is a cross-sectional, perspective view of an anchor according to an embodiment of the present invention.

[0017] FIG. 6 is a perspective view of an anchor according to an embodiment of the present invention.

[0018] FIG. 7 is a perspective view of an anchor according to an embodiment of the present invention.

[0019] FIG. 8A and 8B are cross-sectional views of an anchor according to an embodiment of the present invention.

[0020] FIGS. 9A-9F is a series of drawings showing a process of assembling an implant according to an embodiment of the present invention.

[0021] FIG. 10A is a plan view of an anchor according to an embodiment of the present invention.

[0022] FIGS. 10B-10D is a series of drawings showing a process of assembling an implant according to an embodiment of the present invention.

[0023] FIGS 11A-11D are plan views of one end of an implant according to certain embodiments of the present invention.

[0024] FIGS. 12A-12C is a series of drawings showing a process of assembling an implant according to one embodiment of the present invention.

[0025] FIG. 13 is a perspective view of a locking member according to an embodiment of the present invention.

[0026] FIG. 14 is a plan view of a locking member according to an embodiment of the present invention.

[0027] FIG. 15A is a side elevation view and a cut-away view of a delivery system according to an embodiment of the present invention.

[0028] FIG. 15B is a cross-sectional view of a delivery system according to an embodiment of the present invention.

[0029] FIG. 16 is a cross-sectional view of a delivery system according to an embodiment of the present invention.

[0030] FIG. 17 is a cross-sectional view of a delivery system taken along section line B-B of FIG. 14.

[0031] FIG. 18 is a perspective view of and implant and a delivery system according to an embodiment of the present invention.

DESCRIPTION OF EMBODIMENTS

[0032] Specific embodiments of the invention will now be described with reference to the accompanying drawings. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. The terminology used in the detailed description of the embodiments illustrated in the accompanying drawings is not intended to be limiting of the invention. In the drawings, like numbers refer to like elements.

[0033] Unless otherwise defined, all terms (including technical and scientific terms) used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. It will be further understood that terms, such as those defined in commonly used dictionaries, should be interpreted as having a meaning that is consistent with their meaning in the context of the relevant art and will not be interpreted in an idealized or overly formal sense unless expressly so defined herein.

[0034] The implant according to the present invention may, for example, be employed to provide support for organs in treatment for conditions such as incontinence and various pelvic floor disorders including but not limited to cystocele, enterocele and recetocel. In this regard, the implant is operative to provide a single-incision solution for implanting a surgical support member within the body specifically for pelvic organ prolapse applications. The implant, the implant delivery system, and the associated methods for implanting the implant provide a strong anchor with a delivery method that is safe, fast, and easy to deploy for surgeons of various experience levels. The present

invention allows for easy and controlled deployment of an anchor deep within the body, preferably under palpation control, while providing the ability to easily adjust the mesh tension prior to locking the implant in place.

[0035] Broadly speaking, as shown in FIG. 1, an implant 10 according to certain embodiments of the present invention includes a supporting member 20 having one or more arms 26 extending from the support member 20 and associated with an anchor 30 that secures the implant 10 to tissue within the body, e.g. the obturator member (OM), the obturator internus fascia, the obturator internus muscle, the arcus tendineus levator ani, the levator ani muscle, the sacrospinous ligaments (SSL), the illiococcygeus muscle, or the arcus tendineus facia pelvis (white line). The implant 10 further includes a tether 25 which is associated with the anchor 30 at a distal end 27 and associated with the support member at a proximal end 29. The portion of the proximal end 29 of the tether 25 is inserted through a locking member 150 that is integrated into the support member 20. For the sake of clarity, FIG. 1 shows only one side of the implant 10. It is understood that the side not shown is a mirror image of the side shown. FIGS. 2A-2C show alternative configurations of the supporting member 20 and the arms 26. Suitable supporting members 20 are further described in the Assignee's U.S. Patent Application No.: 11/936,063, the contents of which are herein incorporated by reference. In certain embodiments of the present application, the supporting member 20 has a simpler shape that is approximately rectangular, oval, or circular and in which the arms 26 are less pronounced or even absent.

[0036] The support member 20 and the tether 25 may be fabricated of a synthetic material, such as surgical mesh and the like, natural tissues, such as tissues harvested from either an animal, cadaverous source or the patient himself, and/or combinations of synthetic and natural materials. In a preferred embodiment, the support member 20 and the tether 25 are fabricated of a mesh or weave.

[0037] In certain embodiments, a support member suture 50, shown in FIG. 18, is advantageously attached to the support member 20. The support member suture 50 is looped through, tied to, or otherwise associated with the support member 20. Preferably, the support member suture 50 is affixed to the support member 20 at a

proximate mid-point of the support member 20. As would be understood by one of ordinary skill in the art, it may also be advantageous to employ a plurality of the support member sutures 50 at predetermined positions on or within the support member 20 in order to provide markers along a dimension of the support member 20. In order to distinguish the various individual sutures, the sutures may be provided in different colors, lengths, or other indicating means that would allow a user to distinguish one suture from another. Indicating marks may also be provided along a length of the suture that can be employed to determine a depth of the suture within the body.

[0038] FIGS. 3-7 show an anchor 30 according to one embodiment of the present invention. The anchor 30 has a distal portion 60 and a proximal portion 70 associated with one another by mid-portion 80. A proximal end of the distal portion 60 of the anchor 30 is associated with or attached to a distal end of the mid-portion 80. Conversely, a distal end of the proximal portion 70 is associated with or attached to a proximal end of the mid-portion 80 of the anchor 30. The mid-portion 80 of anchor 30 is formed as a shaft or spacer that serves to provide space between the distal portion 60 and the proximal portion 70 to, for example, accommodate a depth of tissue through which the distal portion 60 has penetrated.

[0039] The distal portion 60 of the anchor 30 employs a piercing tip 62 for penetrating tissue and a tissue-retention protrusion 64 proximal of the piercing tip 60 that anchors or secures the distal portion 30 within tissue. The distal portion 60 may have, for example, an arrowhead-like shape as shown in FIGS. 3-6. Alternatively, distal portion 60 may have a more complex shape configured to employ more than two, for example as shown in FIG. 7, four tissue-retention protrusions 64. The distal portion 60 may further employ a conical or cone-like shape having a circular tissue-retention protrusion 64. One of ordinary skill in the art would recognize that alternative shapes and configurations of the distal portion 60 are possible while still achieving the desired objective. For example, distal portion 60 may employ resilient, spring loaded and/or self-tensioning tissue-retention protrusions 64.

[0040] The proximal portion 70 of anchor 30 comprises a shoulder 72 for providing a back-stop for the support member 20 or the tether 25 and a guide member 74 for

engagement with a delivery system, as discussed in greater detail below. The proximal portion 70 may further employ recesses 76 and eyelet 78. The anchor suture 40 passes through the eyelet 78 and is, for example, secured back to itself to form a loop. The recesses 76 may be positioned on one or both sides of the eyelet 78 and configured so as to accept the anchor suture 40 such that the presence of the anchor suture 40 does not add to or change an outer dimension of the guide member 74.

[0041] The anchor 30 may be formed from a variety of materials, including but not limited to metal alloys, such as titanium, stainless steel, or cobalt-chome alloys, polymeric materials, such as polyethylene (PE), polypropylene (PP), polysulfone, polyether ether ketone (PEEK), polyether imide (PEI), and biodegradable materials, such as polylactic acid (PLA) and polyglycolic acid (PGA) based materials. The anchor 30 may be formed of a single material or a combination thereof. For example, as illustrated in FIGS. 8A and 8B, the anchor 30 may be formed of a combination of primary material 90, such as titanium, and a biodegradable material 92 assembled or molded over the primary material 90.

[0042] Turning next to FIGS. 9A-9F, FIGS. 9A-9F show the steps of assembling the implant 10 according to various embodiments of the present invention. For the sake of clarity, FIGS. 9A-9F show only the assembly of one arm 26 of the implant 10. First, a tool 90 is used to form an opening 110 through the arm 26 proximate an end of the arm 26 by penetrating, stretching, or spreading the mesh or knitted material of the arm 26 of the support member 20. The tool 90 has a tapered or pointed end and a cross-section shape in the form of a circle, rectangle, oval or most any other shape. The distal portions 60 of the anchors 30 are then inserted through the openings 110 in the arm 26 until the arm 26 rests against the shoulders 72 of the proximal portions 72 of the anchors 30. In a preferred embodiment, the openings 110 are formed interior of the outer perimeter of the arm 26 such that there is sufficient material of arm 26 so that the openings 110 do not substantially expand or rip through the outer perimeter of the support member 20.

[0043] In an alternative embodiment of the present invention, as shown in FIG. 10A-10D, the shoulder of the anchor 31 is formed of a plastic or metal pin 73 that is inserted

through a receiving hole 75 formed through the proximal portion of the anchor 31. During assembly of the implant 10, once the openings 110 are formed through the arm 26, the guide 74 and/or proximal portion 70 of anchor 31 is placed through the opening 110 and the pin 73 is inserted through the receiving hole 75 to form an element functionally similar to the shoulder 72 previously described. As one of ordinary skill in the art would recognize, this embodiment provides the advantage that a smaller opening 110 may be formed when assembling the implant 10. The smaller opening 110, in turn, provides the advantage of the arm 26 having a greater resistance to tearing and deformation.

[0044] In certain other embodiments of the present invention, the assembled implant 10 as described above may be subjected to additional fabrication steps. For instance, as shown in FIGS. 11 and 12, after insertion of the anchor 30 through the opening 110 of arm 26, a portion of the arm 26 between the opening 10 and the outer perimeter of the arm 26 is folded over the shoulder of the anchor 30 back on to itself to form a folded portion 22. The folded portion 22 may then be bonded, sutured, welded, or tacked to it self to form bond 24 to better maintain the fold. Formation of the folded portion 22 serves, in part, to decrease resistance to penetration of the anchor 30 into tissue. The fold 22 may additionally help insure that the anchor 30 remains inserted through the arm 26 during handling and implantation of the implant 10, as well as provide a more visually appealing appearance to the implant 10. As shown in FIGS. 11 and 12, the shape of the portion of the arm 26 that forms the fold 22 may be manipulated so as to, for example, result in the arm 26 having a tapered end. A tapered end may be formed by forming a portion of the arm 26 so as to have a width that narrows at a fold line 26, as shown in FIG. 11A. A tapered end may also be formed through a secondary folding of the extremities or corners of the fold 22 towards one another, as shown in FIG. 11B. Alternatively, as shown in FIG. 11C, once the folded portion 22 is formed a suture may be threaded through the fold 22 and cinched and bound to itself so as to form a tapered end of the anchor 30. A tapered end may also be formed in the implant 10 by cutting or trimming the corners of the fold 22 after the fold 22 has been formed, as shown in FIG. 11D.

[0045] FIGS. 12A-12C show yet another embodiment of the implant 10 in which, prior to formation of the fold 22, the arm 26 is twisted 180 degrees or more. Again, this method of assembly decreases resistance to penetration of the anchor and helps ensure that the anchor 30 remains inserted through the arm 26 during handling and implantation. One of ordinary skill in the art will, however, recognize that other methods of assembling the support member 20 and the anchor 30 to achieve the desired characteristics of the implant 10 are known in the art.

[0046] It will be understood that, while the above described assembly has been made only with reference to the assemble of the arm 26 with the anchor 30 the, assembly of the tether 25 with the anchor 30 is substantially identical.

[0047] Turning now to the locking member 150, FIGS. 13 and 14 show different embodiments of locking member 150 according to the present invention. FIG. 13 shows a circular locking member 150 having an aperture 132 from which flexible teeth 152 extend inward. The teeth 152 provide for one-way movement of the tether 25 in the direction of arrow 154 through the apertures 132 but lock against movement of the tether 25 through the aperture 132 in the direction of the arrow 156.

[0048] FIG. 14 shows another embodiment in which the locking member 150 incorporates an aperture 132 and a slide lock 133 having engagement members 134. The slide lock 133 is incorporated into and integral with the locking member 150 such that the slide lock 133 slides laterally away from and towards the aperture 132. In the open or unlocked state, shown in FIG. 14, the slide lock 133 is withdrawn or cleared from the aperture 132 and the tether 25 passes through the aperture 132 freely. In the locked or closed state, not shown, the slide lock 133 is displaced so as to extend across the aperture 132 and thereby engage the tether 25 with the engagement members 134. In the closed position, the engagement members 134 snag or penetrate the tether 25 so as to prevent movement of the tether through the aperture 132. In order to maintain the slide lock in the closed state, the slide lock may incorporate resilient portions that slide into receiving elements or other structural features that prevent the slide lock from further movement absent disengagement of the resilient portions from the receiving elements. One of ordinary skill in the art will recognize that there are various known

structures and configurations possible for achieving the above described embodiment, for example, the slide lock 133 may slide within a channel formed in the locking member 150 and the resilient portions may engage openings or recesses formed within the channel so as to lock the slide lock into a fixed position.

[0049] It will be understood by one of ordinary skill in the art that while the locking member 150 has been described as being incorporated or otherwise attached to the support member 20, alternative configurations are contemplated. For example, in certain embodiments of the present invention, the support member 20 incorporates an eyelet in place of the locking member 150. The tether 25 passes first through the eyelet of the support member 20 and then passes through an independent locking member 150 positioned on a backside of the support member 20. The locking member 150 is sized and/or shaped so as to be incapable of passing through the eyelet and therefore provides a secure back-top against which the support member 20 rests.

[0050] Turning now to the delivery system of the present invention. Broadly speaking, the delivery system is configured to receive a portion of the anchor 30 of the assembled arm 26 or tether 25. FIG. 15A shows a delivery system 120 having a handle 125 and a shaft 140. The handle 125 is preferably ergonomically shaped to facilitate grasping and manipulating. The handle 125 is preferably marked, colored, textured or otherwise configured so as to indicate to a user the orientation of the delivery system 120. The shaft 140 protrudes from or is an extension of the handle 125. The shaft 125 is, for example, formed of stainless steel or other metal in the general shape of a needle. A curved distal portion 142 of the shaft 140 includes a cavity 144 and a slot 146.

[0051] Optionally, as shown in FIG. 15B, the delivery system 120 may further employ a sheath 148. The sheath 148 is a slit tube or u-shaped channel that functions, in part, to protect the support member 20 or tether 25 and various associated sutures from exposure to tissue during implantation. The sheath 148 also functions to limit the depth of penetration of the anchor 30 in to the target tissue. This function is achieved by configuring the sheath 148 to be a distance D shorter than a length of the implant 10 and shaft 140 when assembled and have an outer diameter greater than that of the

shaft 140 and the anchor. Because the sheath 148 is displaceable along the axis of the shaft 140, indicated by arrow E of FIG. 15B, the user, after first piercing the target tissue with the distal portion 60 of the anchor 30, may move the sheath to determine or measure the approximate depth of that the anchor 30 within the target tissue.

[0052] Referring now to FIGS. 16 and 17, FIG. 16 shows the implant 10 and delivery system 120 assembled ready for implantation of the arm 26 or the tether 25 of the implant 10. FIG. 17 shows a cross-sectional view of the assembled arm 26 or the tether 25 and the delivery system 120 viewed along section line B-B of FIG. 16. As will be noted, the shape of the cavity 144 corresponds to the shape of the guide 74 of the anchor 30. That is to say that the guide 74 of the anchor 30 of the implant 10 and the cavity 144 of the shaft 140 of the delivery system 120 are complementary elements, the cavity 144 forming a female receiving element for the male guide 74. Preferably, the cavity 144 and the guide 74 are formed in the shape of a square, rectangle, oval, triangle, star, or other shape that resists the guide 74 rotating within the cavity 144. In certain embodiments of the present invention, the cavity 144 and the guide 74 form a friction fit such that the guide 74 is maintained within the cavity 144 during handling and deployment of the implant 10 but is readily released from the cavity 144 upon engagement of the distal portion 60 of the anchor 30 within tissue. A portion of the slot 146 penetrates radially through the shaft 140 into the cavity 174 and extends axially along a length of the distal portion 142 of the shaft 140. Preferably, the slot 146 extends axially along the shaft 140 to a greater extent than the cavity 174. The slot 146 thereby receives and forms a channel through which the anchor suture 40 of anchor 30 is positioned along an axis of the shaft 140.

[0053] A method for deploying or implanting the anchor 30 assembled with the arm 26 or the tether 25 will now be described. First, a single incision or entry point is made in the patient followed by blunt dissection as necessary or desired. A first arm 26 or tether 25 incorporating the anchor 30 that is engaged with the delivery system 120 is inserted through an entry point in the body and the anchor 30 is forced into or through a portion of the target tissue, e.g. the obturator member (OM), the obturator internus fascia, the obturator internus muscle, the arcus tendineus levator ani, the levator ani muscle, the sacrospinous ligaments (SSL), the illiococcygeus muscle, or the arcus

tendineus facia pelvis (white line). The delivery system 120 is retracted away from the anchor 30 that has penetrated the target tissue thereby breaking the engagement between the delivery system 120 and the anchor 30. During this process and particularly while the delivery system 120 is being retracted, the anchor suture 40 corresponding to the implanted anchor 30 is secured such that the delivery system 120 is retracted while an end of the anchor suture 40 is maintained extending out from the entry point. The arm 26 or tether 25 incorporating the anchor 30 that is opposite the implanted anchor 30 is engaged with the delivery system 120 and implanted as described with regard to the first side. In certain embodiments of the present invention, the tethers 25 are implanted before the arms 26 of the support member 20 in order to provide a less cluttered work space for the potentially deeper implantation of the tethers 25.

[0054] Substantially concurrent with the implantation of the second side of the implant 10, the support member 20 of the implant 10 is positioned so as to support at least a portion of the desired organ. The support member suture 50, shown in FIG. 18, may be used to determine the position and/or tension of the implanted support member 20. The tension of the support member 20 spanning between the two sides of the implant 10 is initially adjusted by pushing the delivery system 20 engaged with the anchor 30 of the second arms 26 of the implant 10 further into the target tissue. The delivery system 120 is then retracted from the second arm 26 of the implant 10. An end of the second anchor suture 30 is also maintained such that it extends out from the entry point.

[0055] The tethers 25 are then passed through the locking members 150 of the support member 20, and the support member 20 is pushed up the tethers 25 towards the anchors 30 associated with each tether into the desired position.

[0056] Should it be determined that greater tension is desired or if it is otherwise desirable to reengage of the delivery system 120 with one of the anchors 30, the present invention provides a particularly advantageous means for achieving such. As shown in FIG. 18, the end of the anchor suture 40 of the relevant anchor 30 that extends from the entry point is tensioned and secured. The slot 146 of the delivery system 120

is then positioned such that the anchor suture 40 passes through the slot 146, and serves as a guide for the delivery system 120 to the relevant anchor 30. The delivery system 120 is advanced towards the relevant anchor 30 along the anchor suture 40. The guide 74 of the anchor 30 is thereby received by the cavity 144 of the delivery system 120 and, if desired, the friction fit between the anchor 30 and the delivery system 120 is reestablished. It is then possible to adjust the tension of the support member 20 of the implant 10 by pushing the delivery system 120 so as to drive the anchor further into the target tissue. The implant can be retracted by pulling on the anchor suture 40 or the support member suture 50 thus releasing all or a portion of the tension present in the implant 10.

[0057] Upon completion of the implantation of the implant 10 the single entry point is closed. The anchor sutures 40 and support member sutures 50 can be left in place for possible use in a follow-up procedures or may be removed from the patient.

[0058] The implant 10 according to the present invention may employ the anchors 30 or the anchors described in the Assignee's pending U.S. Application Serial No. (Not yet assigned), filed January 5, 2010, entitled *Implants and Procedures for Supporting Anatomical Structures*, and U.S. Application Serial No. (Not yet assigned), filed January 5, 2010, entitled *Implants and Procedures for Supporting Anatomical Structures*, all of which are incorporated herein by reference, exclusively or a combination thereof. It will be understood by one of skill in the art that the different anchors of the present invention will each lend themselves to implantation within potentially different target tissues having different characteristics and locations within the body.

[0059] While the present invention has been described for use in treating pelvic floor disorders and incontinence, it would be understood by one of skill in the art that the present invention can be used support other organs within the body or as a means of fixation of tissue or implants within the body.

[0060] Although the invention has been described in terms of particular embodiments and applications, one of ordinary skill in the art, in light of this teaching, can generate additional embodiments and modifications without departing from the spirit of or exceeding the scope of the claimed invention. Accordingly, it is to be understood that

the drawings and descriptions herein are proffered by way of example to facilitate comprehension of the invention and should not be construed to limit the scope thereof.

What is claimed is:

1. A system for supporting an anatomical structure comprising:

a tether having a proximal area and a distal area, said distal area associated with an anchor;

a support member having an aperture through which a portion of said distal area of said tether passes; and

an engagement member configured to receive said portion of said distal area of said tether and transfer a tension on said support member to said tether.

2. The system of claim 1 wherein the support member is mesh.

3. The system of claim 1 wherein the support member comprises an arm.

4. The system of claim 1 wherein at least one removable filament extends from the support member.

5. The system of claim 1 wherein at least one removable filament extends from said anchors.

6. The system of claim 1 wherein said engagement member resides within said aperture of said support member.

7. The system of claim 1 wherein said engagement member comprises displaceable teeth.

8. The system of claim 1 wherein said engagement member comprises flexible teeth.

9. The system of claim 1 wherein said anchor comprises a proximal protrusion for engagement with a delivery system.

10. The system of claim 1 wherein said engagement member comprises a ring through which said portion of said distal area of said tether passes after said portion passes through said aperture of said support member.

11. A system for implanting an implant for supporting an anatomical structure comprising:

an implant comprising;

a tether having a proximal area and a distal area, said distal area associated with an anchor;

a support member having an aperture through which a portion of said distal area of said tether passes; and

an engagement member configured to receive said portion of said distal area of said tether and transfer a tension on said support member to said tether; and

a delivery tool comprising a handle and a shaft, said shaft having a cavity formed within a distal portion, the cavity having a cross-sectional shape complementary to a cross-sectional shape of a proximal protrusion of the anchor.

12. The system of claim 11 wherein the distal portion of the delivery tool comprises a slot that extends axially along the shaft.

13. The system of claim 11 wherein a removable filament extends from the proximal protrusion of the anchor through the slot of the delivery tool when the proximal protrusion of the anchor is inserted within the cavity of the delivery tool.

14. The system of claim 11 further comprising a sheath having a lumen through which the shaft is displaceable.

15. The system of claim 11 wherein the sheath is a slit tube.

16. The system of claim 12 wherein the sheath is a U-shaped channel.

17. A method for supporting an anatomical structure comprising:

making a single entry point in the body of the patient;

securing a plurality of anchors within said body through said single entry point;

feeding a tether extending from one of said plurality of anchors through an aperture within a support member;

tensioning the support member between at least two of said plurality of anchors secured within said body;

locking said support member in position relative to said tether; and

closing said single entry point.

18. The method of claim 17 wherein the step of securing a plurality of anchors within said body through said single entry point comprises:

engaging one of said plurality of anchors with a tool;

advancing said tool engaged with said anchor to a target tissue;

piercing said target tissue with said anchor; and

withdrawing said tool from said anchor.

19. The method of claim 18 further comprising the steps of:

introducing a removable filament extending from said anchor outside of said entry point into a guide slot of said tool;

advancing said tool towards said anchor along said removable filament;

reengaging said tool with said anchor from which said removable filament extends; and

forcing said anchor further into said target tissue with said tool thereby increasing a tension upon said support member.

20. The method of claim 17 wherein the step of locking said support member in position relative to said tether comprises mechanically engaging said tether.

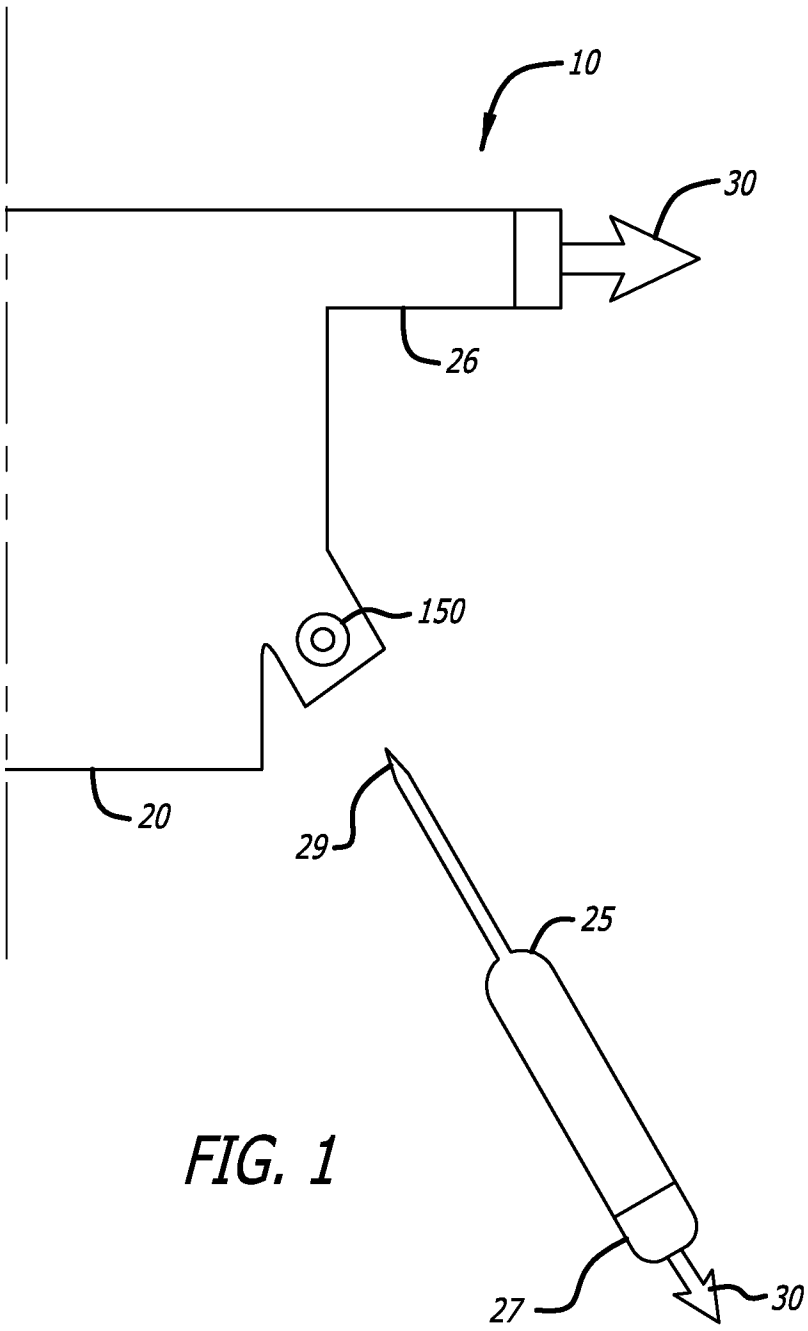

FIG. 1

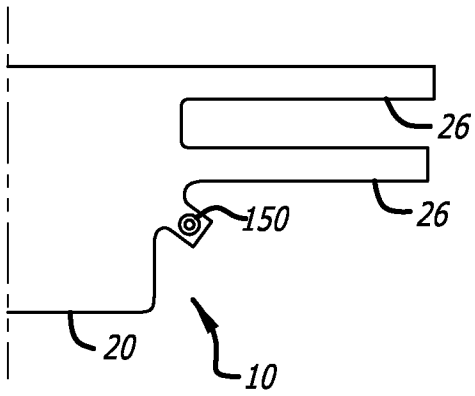

FIG. 2A

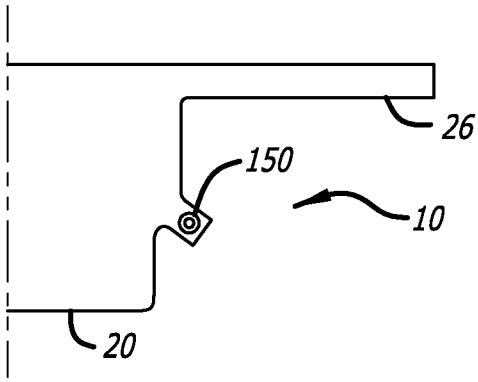

FIG. 2B

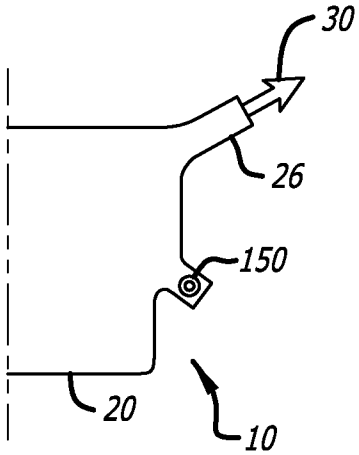

FIG. 2C

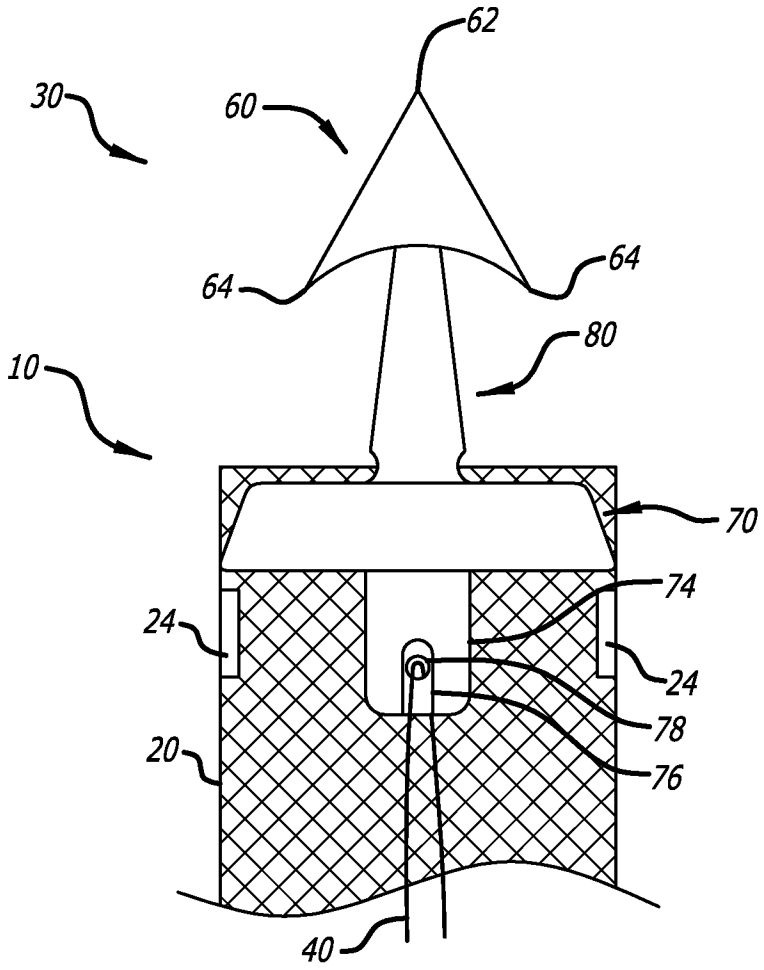

FIG. 3

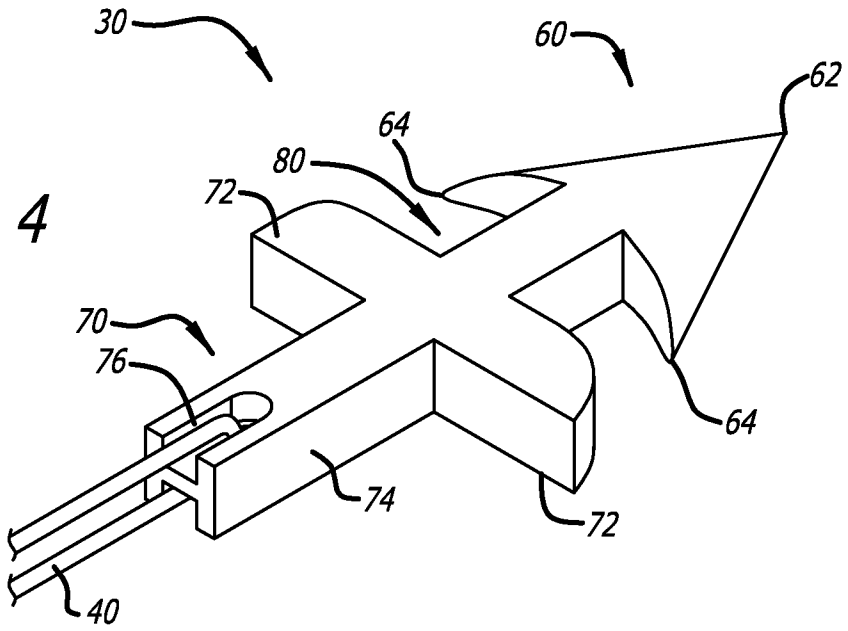

FIG. 4

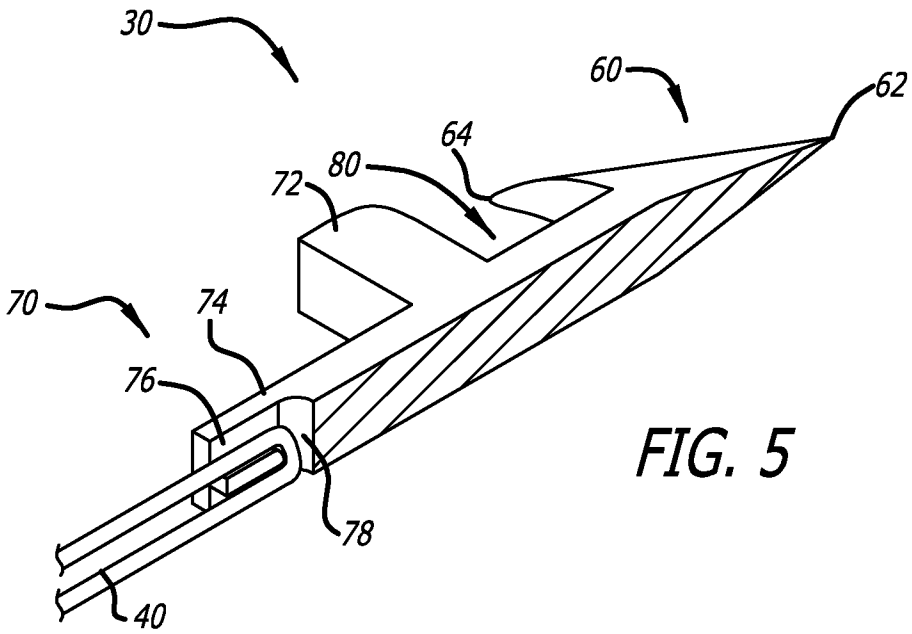

FIG. 5

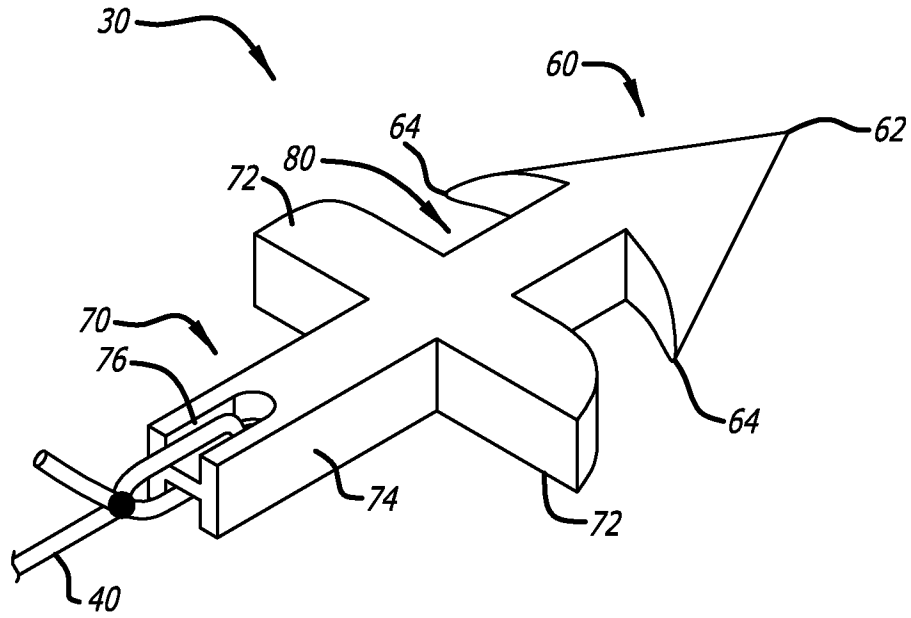

FIG. 6

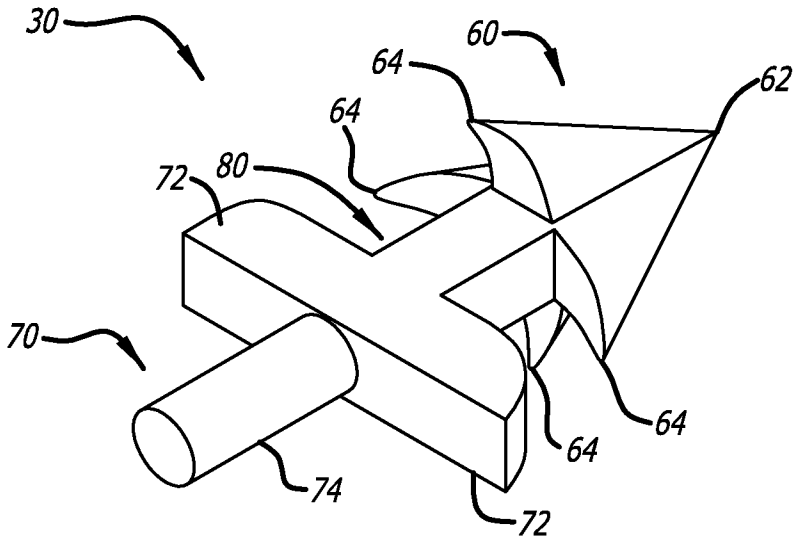

FIG. 7

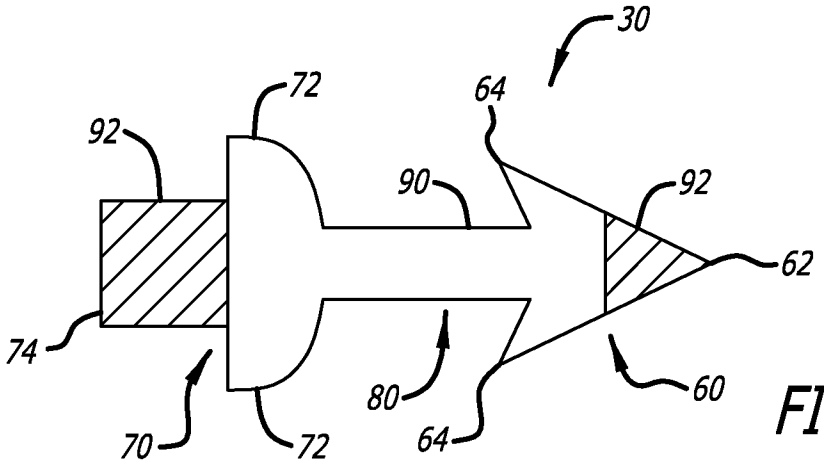
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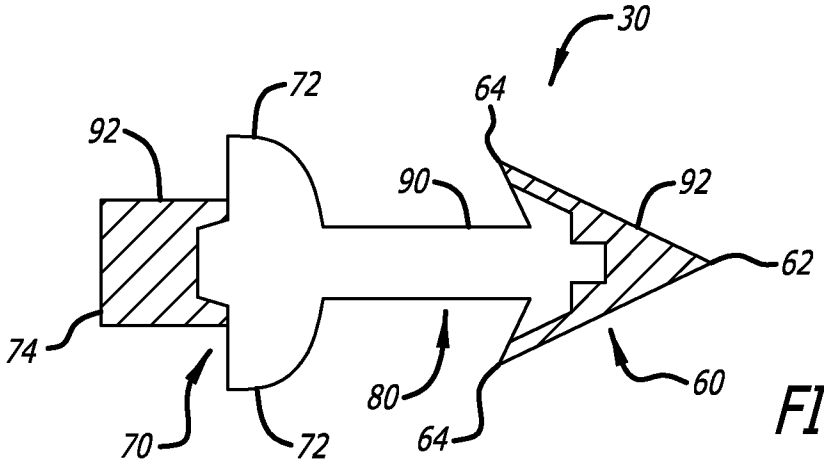
FIG. 8A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64

FIG. 8B

FIG. 9A

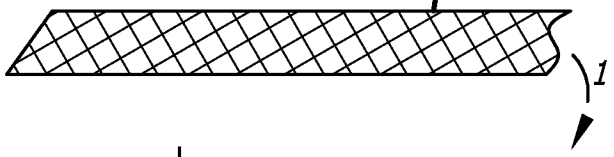


FIG. 9B

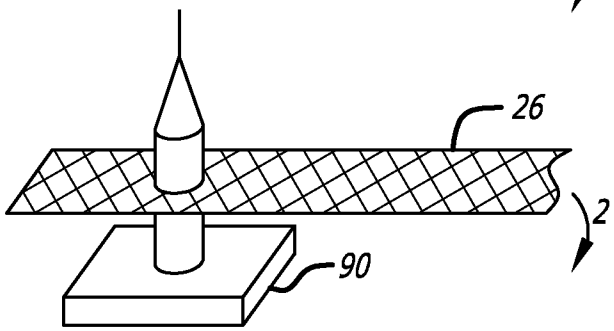


FIG. 9C

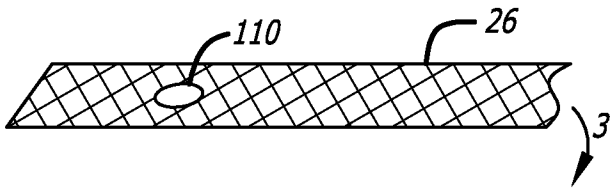


FIG. 9D

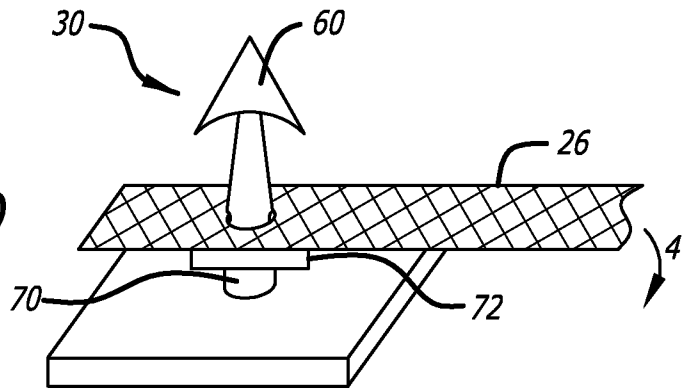


FIG. 9E

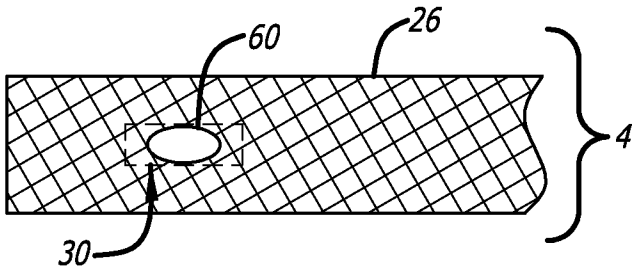
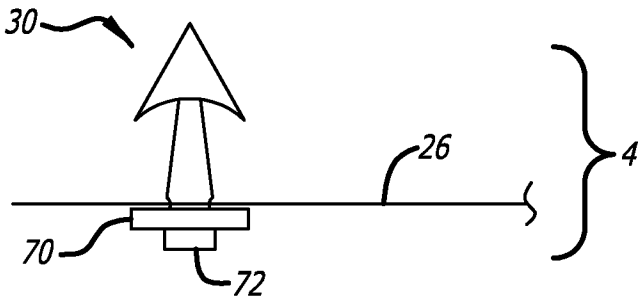


FIG. 9F



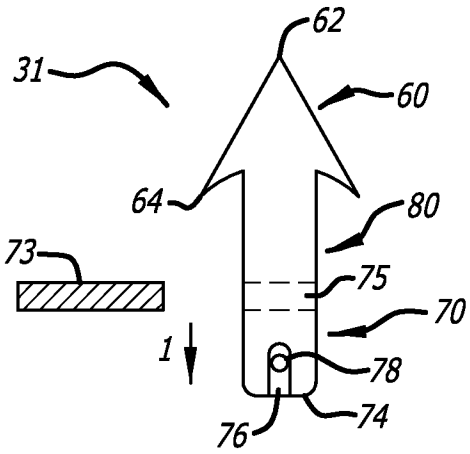
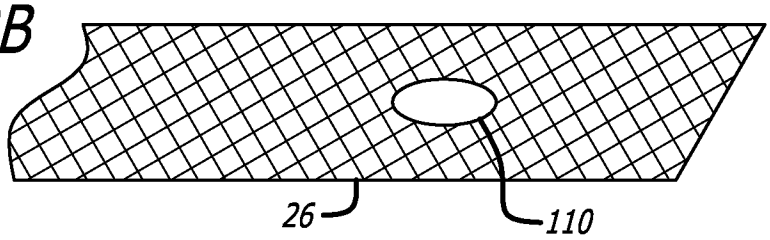


FIG. 10A

FIG. 10B



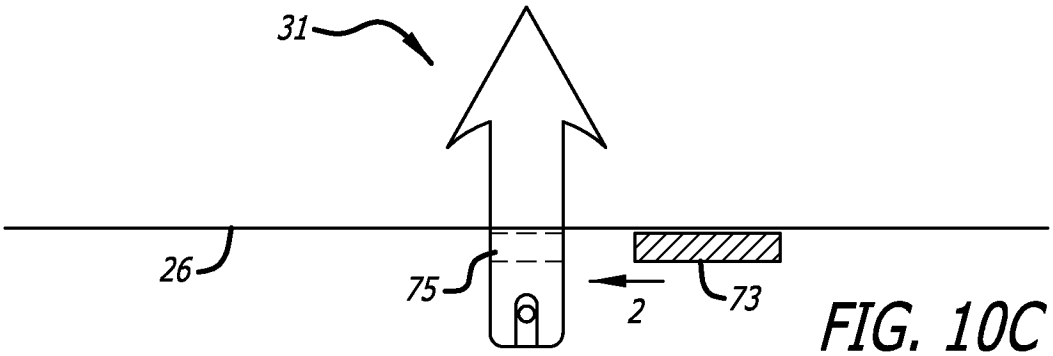


FIG. 10C

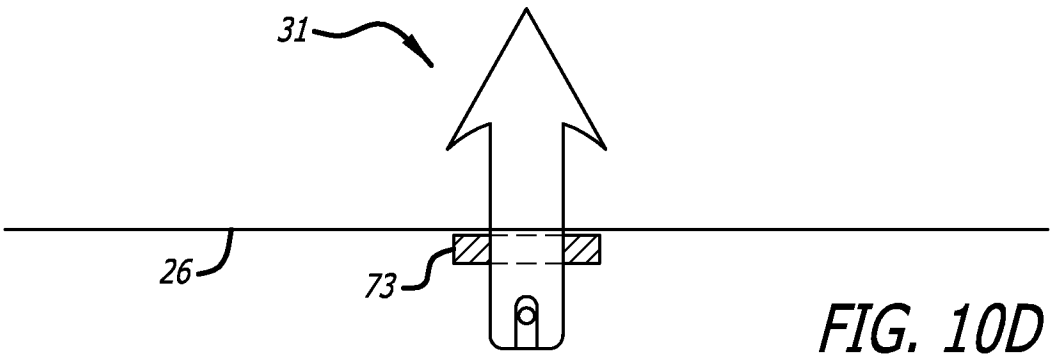


FIG. 10D

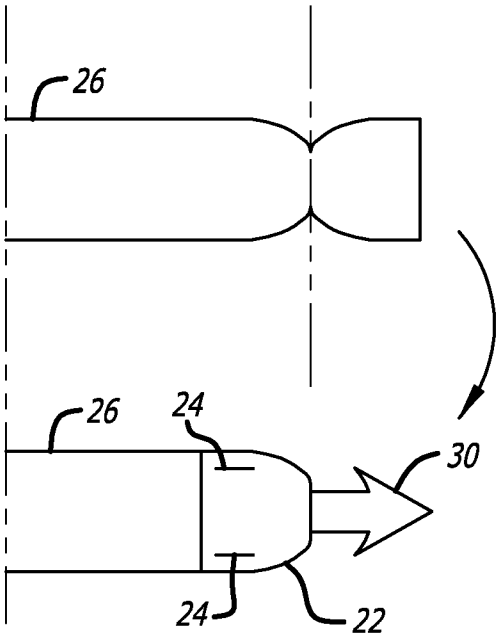


FIG. 11A

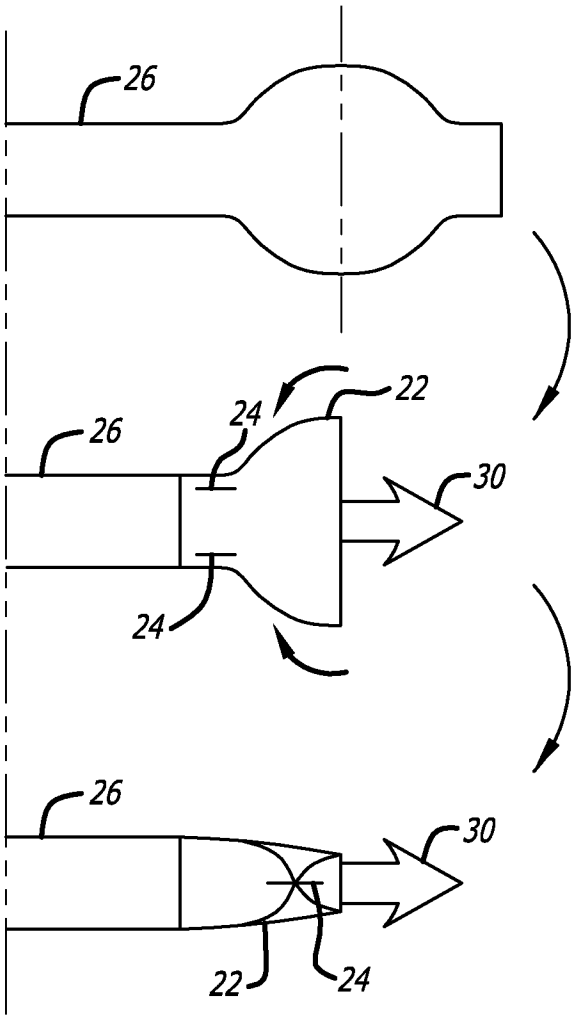


FIG. 11B

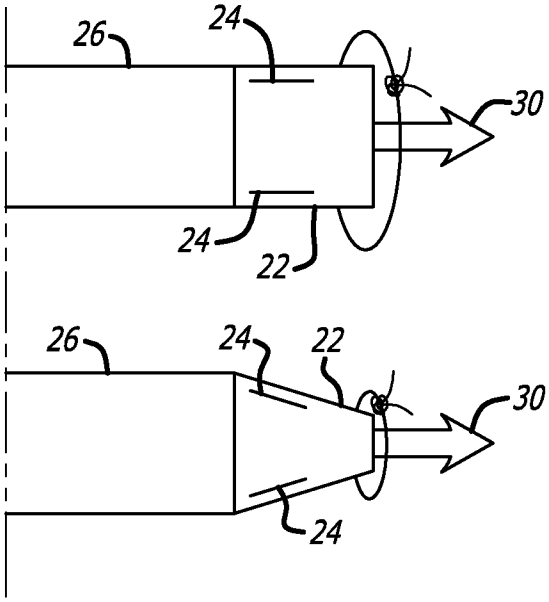


FIG. 11C

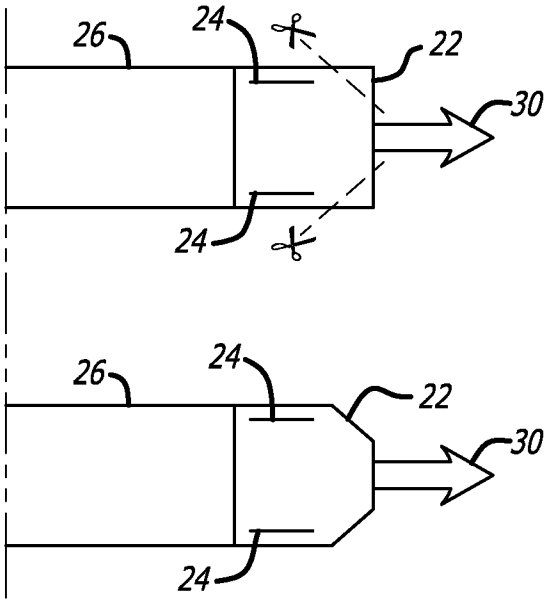


FIG. 11D

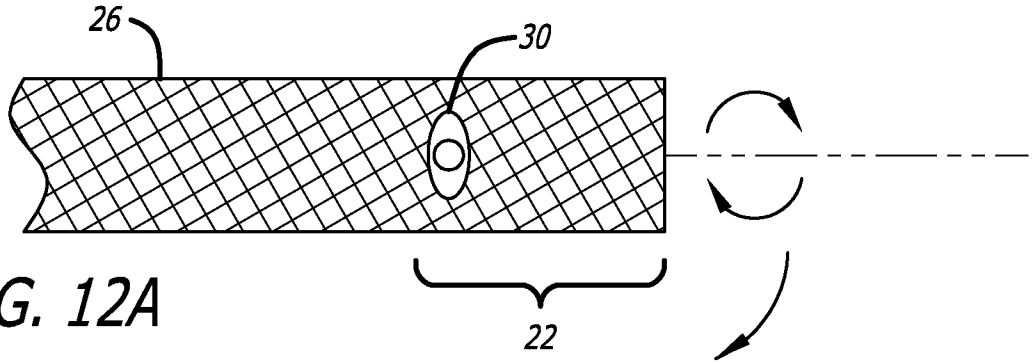


FIG. 12A

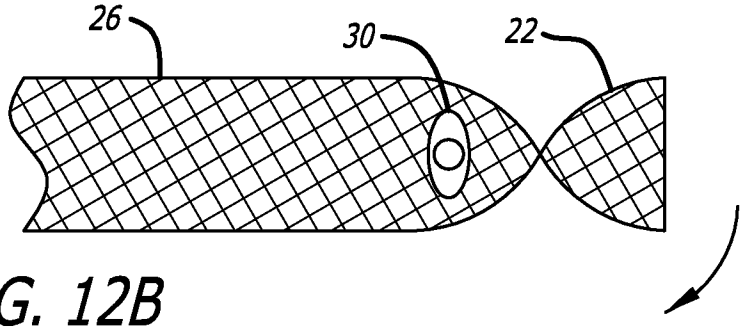


FIG. 12B

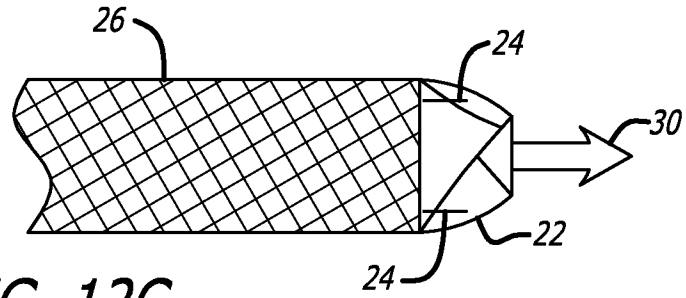


FIG. 12C

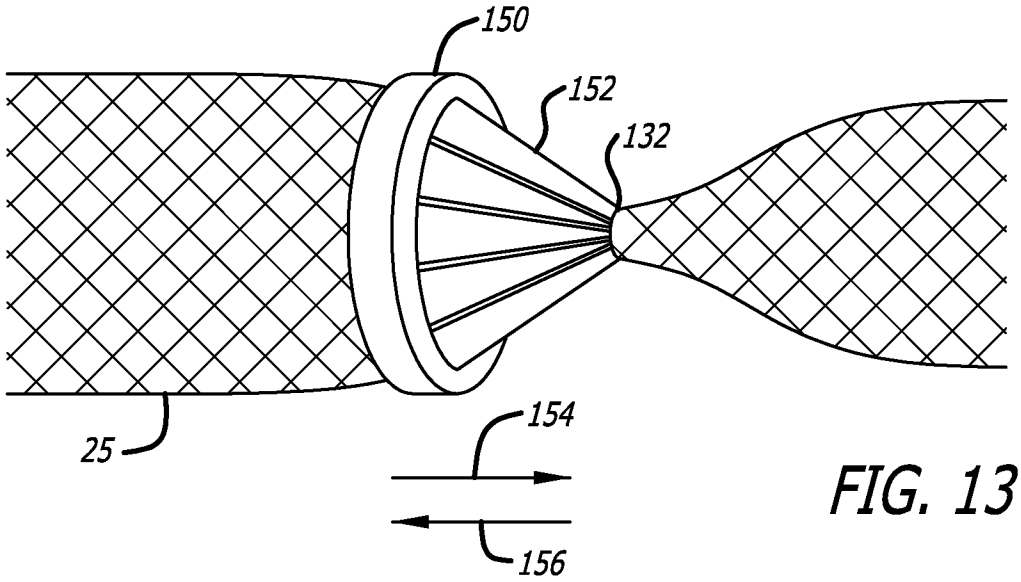


FIG. 13

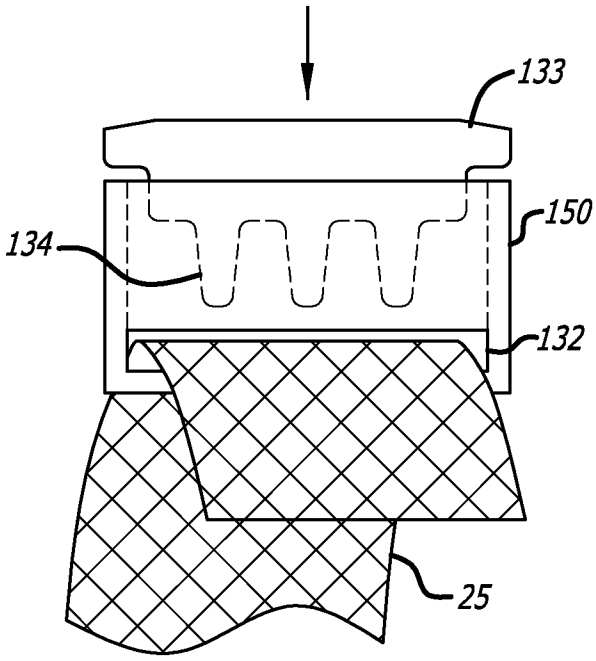


FIG. 14

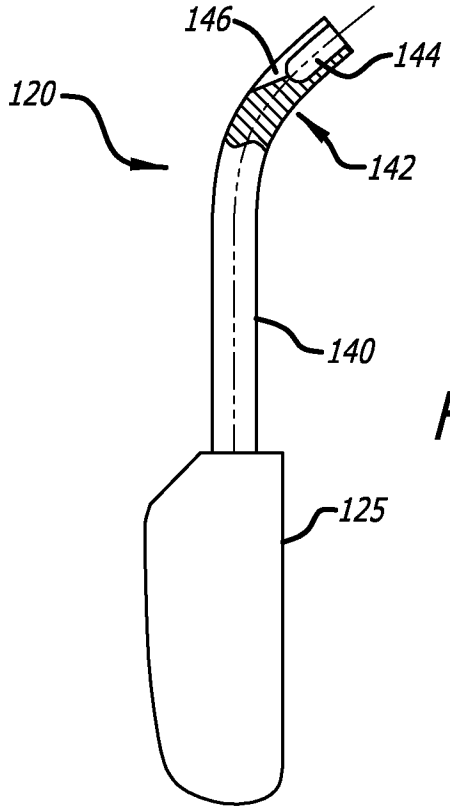


FIG. 15A

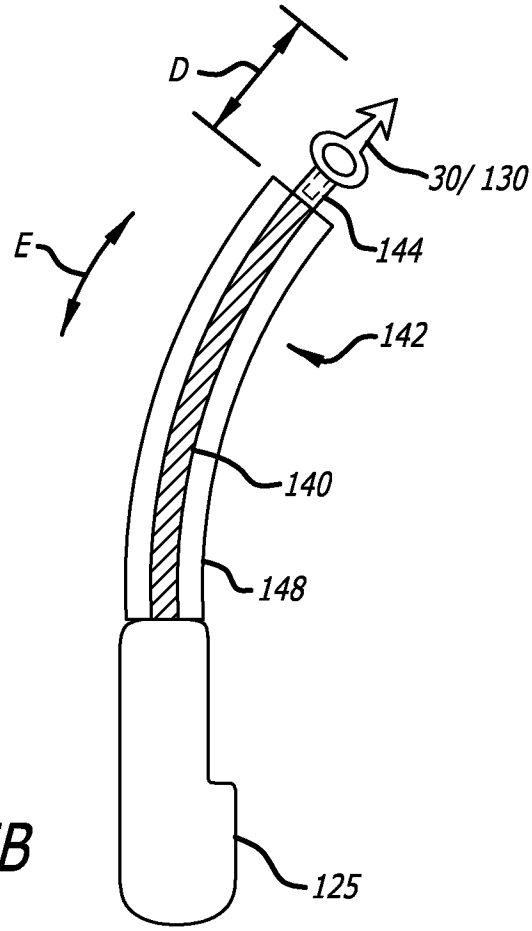


FIG. 15B

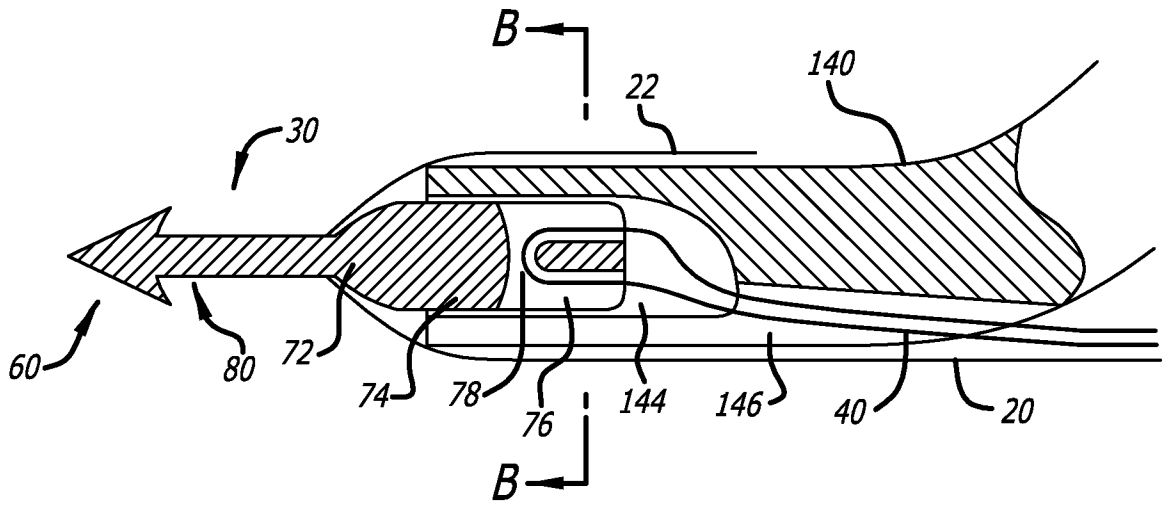


FIG. 16

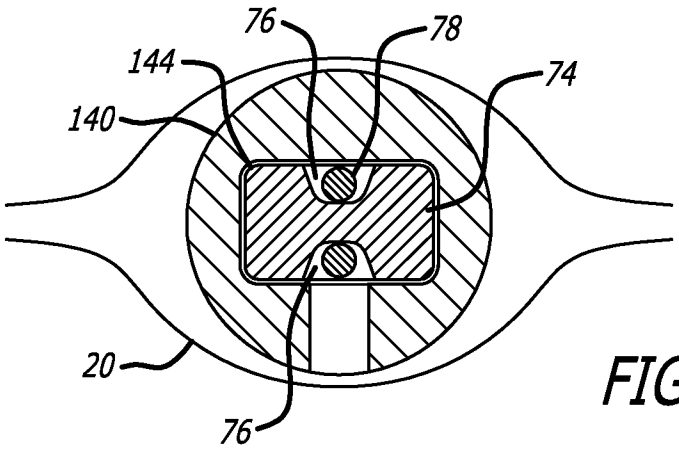


FIG. 17

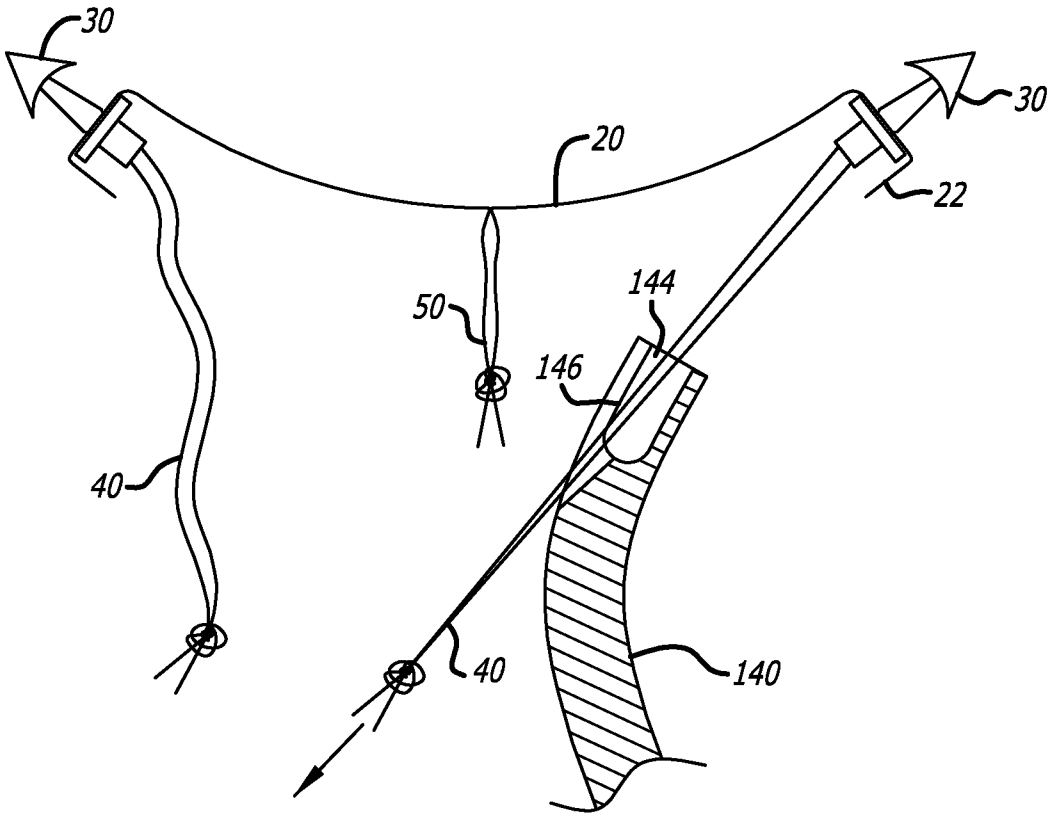


FIG. 18

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/020161

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 02/00 (2010.01)
USPC - 600/37
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(8) - A61F 02/00 (2010.01)
USPC - 600/30,37; 606/93,151,157,217; 128/898

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 practicable, search terms used)
USPTO EAST System (US, USPG-PUB, EPO, DERWENT), MicroPatent, IP.com, DialogPro
EAST and MicroPatent

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 2006/0089525 A1 (MAMO et al) 27 April 2006 (27.04.2006) entire document	1-6, 9-10, 17-18, 20 ---------- 7-8, 11-16, 19
Y	US 5,902,015 A (ALLCOCK) 11 May 1999 (11.05.1999) entire document	7-8
Y	US 2007/0299299 A1 (ROSENBLATT) 27 December 2007 (27.12.2007) entire document	11-16, 19
Y	US 6,595,911 B2 (LOVUOLO) 22 July 2003 (22.07.2003) entire document	12-13, 15, 19

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

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent 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	Date of mailing of the international search report
08 February 2010	26 FEB 2010
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)