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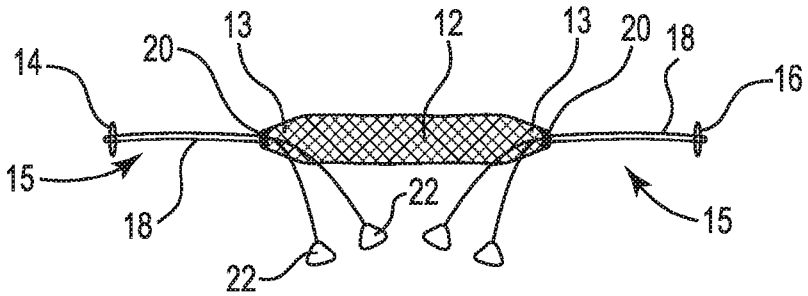

Fig. 3

(57) Abstract: An implant comprising a support portion, extension portions, and end anchors. One or more ends of the implant can include an adjustability feature to provide for both intra- and post-procedural adjustments or tensioning to the implant.

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ADJUSTABLE SURGICAL IMPLANT SYSTEM AND METHOD

Priority

This Application claims priority to and the benefit of U.S. Provisional Patent Application No. 62/191,503, filed July 12, 2015, which is hereby incorporated fully by reference herein.

FIELD OF THE INVENTION

The present invention relates generally to surgical methods and apparatus and, more specifically, to an implant having one or more adjustability features to facilitate adjustability of the implant during and after the surgical procedure.

BACKGROUND OF THE INVENTION

Pelvic health for men and women is a medical area of increasing importance, at least in part due to an aging population. Examples of common pelvic ailments include incontinence (fecal and urinary), pelvic tissue prolapse (e.g., female vaginal prolapse), and conditions of the pelvic floor.

Urinary incontinence can further be classified as including different types, such as stress urinary incontinence (SUI), urge urinary incontinence, mixed urinary incontinence, among others. Other pelvic floor disorders include cystocele, rectocele, enterocele, and prolapse such as anal, uterine and vaginal vault prolapse. A cystocele is a hernia of the bladder, usually into the vagina and introitus. Pelvic disorders such as these can result from weakness or damage to normal pelvic support systems.

In its severest forms, vaginal vault prolapse can result in the distension of the vaginal apex outside of the vagina. An enterocele is a vaginal hernia in which the peritoneal sac containing a portion of the small bowel extends into the rectovaginal space. Vaginal vault prolapse and enterocele represent challenging forms of pelvic disorders for surgeons. These procedures often involve lengthy surgical procedure times.

Urinary incontinence can be characterized by the loss or diminution in the ability to maintain the urethral sphincter closed as the bladder fills with urine. Male or female stress urinary incontinence (SUI) occurs when the patient is physically stressed.

A specific area of pelvic health is trauma of the pelvic floor, e.g., of the levator ("levator ani") or coccygeus muscle (collectively the pelvic floor). The pelvic floor is made up of the levator and coccygeus muscles, and the levator is made up of components that include the puborectalis muscle, the pubococcygeus muscle, and the iliococcygeous muscle. For various reasons, the levator may suffer weakness or injury such as damage to the levator hiatus, ballooning or levator avulsion, any of which that can result in symptoms such as prolapse, fecal incontinence, and other conditions of the pelvis.

Levator defects (weakness or injury) can affect any portion of the levator, and can be especially common in the pubic portion of the levator ani, including the pubococcygeus and puborectalis muscles. Such defects are relatively common, for instance, in women with vaginal prolapse. Defects can also be present at the iliococcygeus muscle. Still other defects are in the form of a paravaginal defect, such as avulsion of the inferiomedial aspects of the levator ani from the pelvic sidewall; avulsion can refer to tissue being detached from the pubic bone, and may precede prolapse conditions. Another levator defect is levator ballooning, which refers to distension of levator muscles.

A different levator defect is a defect of the levator hiatus, which can reduce the stability of the pelvic floor and may result in sexual dysfunction, defecatory dysfunction,

rectal prolapse, and fecal incontinence. Levator hiatus is also believed to play a significant role in the progression of prolapse.

Currently, surgical implants are either non-adjustable or only permit gross adjustment. Further, current surgical implants do not provide post-operative adjustment of the surgical implant. In order to conduct a post-operative adjustment a surgeon typically is required to make an incision and manipulate the implant within a patient through the new incision.

There is a desire to obtain a minimally invasive and highly effective adjustable implant system that can be finely adjusted pre or post operatively to treat incontinence, pelvic organ prolapse and other conditions. There is also a desire to obtain an adjustable implant that can be adjusted post-operatively without the need to create an incision and to manipulate the implant within the patient through the newly formed incision.

SUMMARY OF THE INVENTION

The present patent application describes a surgical device and system that includes adjustability and tensioning features importantly configured so that both intra- and post-procedural adjustments may be made to the implant. Because the adjustable member or suture member is made with small (e.g., 4-0) monofilament strands, the adjustment ends can emerge from a closed incision to allow later adjustment, and then simply trimmed when completed. The self-locking nature of the mechanism allows for this adjustment without the need for opening the incision (e.g., to apply a final locking step).

The present patent application further describes a surgical system that includes a delivery tool adapted to deliver one or more anchors coupled to a support portion by an adjustability feature capable of adjusting a distance between the anchors and the support portion. The support portion may be positioned near a tissue to provide support. The delivery

tool may further include a mechanism adapted to release an anchor attached, coupled to or retain in a needle of the delivery tool.

Pelvic implants and methods for treating pelvic conditions such as incontinence (various forms such as fecal incontinence, stress urinary incontinence, urge incontinence, mixed incontinence, etc.), vaginal prolapse (including various forms such as enterocele, cystocele, rectocele, vault prolapse, etc.), among others. Embodiments of implants include a support portion, and an anchor at a distal end of one or more extension portions. The anchors can be placed at and secured within internal tissue of the pelvic region to support the implant end extension and pelvic tissue that is supported by the implant. As an example, an anchor can be placed at tissue of the obturator foramen (this phrase referring to tissue that lies within or spans the obturator foramen, for example the obturator internus muscle, the obturator membrane, or the obturator externus muscle). Other tissue of the pelvic region can also be locations useful for implanting an anchor. The anchors can be designed to engage a distal end of an insertion tool to allow the insertion tool to place the anchor at a desired tissue location by pushing.

The invention also contemplates a method of treating urinary incontinence in male and female patients. The method includes creating a single medial incision (a transvaginal incision or a perineal incision) under the mid-urethra, dissecting a tissue path on each side of the incision, passing a urinary incontinence sling through the incision whereby the urinary incontinence sling is suspended between the obturator internus muscles and the sling body is positioned between the patient's urethra and vaginal wall (for a female) to provide support to the urethra. For males, a perineal incision can be made to pass the sling through the incision and suspend the sling in a manner comparable to the sling installed in the female patient anatomy. A procedure for treating male urinary incontinence may be performed with or following a prostatectomy, or otherwise.

In addition to treating urinary incontinence, the invention also contemplates methods relating to other types of pelvic floor repairs. Currently, pelvic floor repairs are surgically treated through graft augmented repairs and with kit systems that use needles to deliver a graft through an incision on the anterior and posterior vaginal wall. These current procedures address tissue, muscle and ligament weakness in the pelvic floor such as rectoceles, enteroceles, cystoceles, apical, and uterine descent.

The invention allows pelvic floor reconstruction procedures to become more minimally invasive and easier to use for all pelvic floor surgeon groups. The invention relates to a tissue fixation anchoring system that can be applied to a variety of areas of the pelvic floor: anterior repairs, posterior repairs, apical support, perineal body support (address levator hiatus openings), fecal incontinence, hysterectomy repairs with vault support by means of graft augmentation with tissue anchors into several different anatomical landmarks. These landmarks may be the white line, muscle, and fascial layers, ligament structures (sacrospinous, sacrotuberous, cardinal, round, uterosacrals, perineal and rectal ligaments, etc.) etc. The anchor can be delivered to tissue in combination with a sling, hammock, or suture thread, introduced with an elongate insertion tool directly to tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 depicts a prior art implant device.

Fig. 2 depicts an implant having one adjustability feature, in accordance with embodiments of the present invention.

Fig. 3 depicts an implant having two opposing adjustability features, in accordance with embodiments of the present invention.

Fig. 4 depicts an implant having an adjustability feature and a relatively short implant support portion.

Fig. 5 depicts an example of an adjustability feature and an implant extension portion.

Fig. 6 depicts an example of an adjustability feature of an implant.

Fig. 7 depicts an example delivery tool for delivering an implant in accordance with embodiments of the present invention.

Fig. 8 depicts an implant positioned in a pelvis according to the invention disclosed herein.

Fig. 9 depicts a curved delivery tool for delivering an implant in accordance with embodiments of the present invention.

Fig. 10 depicts a generally straight delivery tool for delivering an implant in accordance with embodiments of the present invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The following description is meant to be illustrative only and not limiting. Other embodiments of this invention will be apparent to those of ordinary skill in the art in view of this description.

The present invention is directed to surgical instruments, assemblies, and implantable articles for treating pelvic floor disorders such as fecal or urinary incontinence, including stress urinary incontinence (SUI), prolapse, etc. According to various embodiments, a surgical implant can be used to treat a pelvic condition, including the specific examples of implanting a support member ("implant") to treat a condition such as vaginal vault prolapse or incontinence (male or female). Described are various features of surgical implants, surgical tools, surgical systems, surgical kits, and surgical methods, useful for installing implants. An implant can be implanted in a male or a female to treat disorders such as urge incontinence, mixed incontinence, overflow incontinence, functional incontinence, fecal incontinence, or

for female conditions including prolapse (e.g. vaginal or uterine), enteroceles (e.g. of the uterus), rectoceles, cystocele, and anatomic hypermobility.

Referring now to Fig. 1, an implant 10 to treat various pelvic conditions such as urinary incontinence is depicted that utilizes a tissue support portion (or "support portion") 12 that can be used to support a pelvic tissue such as the urethra (which includes the bladder neck), vaginal tissue, etc. During use, the tissue support portion 12 may be placed in contact with and, optionally, attached to tissue to be supported, such as with a suture. An implant 10 can additionally include one or more extension portions 13 (otherwise known as "end" portions or "arms") attached to or integral with the tissue support portion 12 to extend ends of the implant 10 to or near anatomical features capable of supporting the pelvic tissue. Further, embodiments of the devices or implant 10 and their corresponding anchors 14, 16, suture loops, suture locks and/or tensioning mechanisms and techniques can be employed in a myriad of surgical procedures, including orthopedic, plastic surgery, cardiovascular, and like procedures to replace or supplement any traditional or other suture tightening and tensioning techniques. The devices and methods of the present invention can significantly reduce the time of surgical procedures by allowing for fast and efficient tensioning and locking securement of the implant without requiring a physician to tie sutures or introduce additional tensioning mechanisms.

As indicated above, the extension portion(s) 13 of an implant 10 may also include one or more opposing anchors or tissue engagement portions 14, 16 that can be employed to attach and stabilize the implant 10 to tissue within the pelvis, adjacent to or proximate tissue near the urethra or other tissue that needs to be supported. As further detailed herein, the anchors 14, 15 can also be used to provide selective adjustment. The anchors or engagement portions 14, 16 can be configured to engage soft tissue and can include various barbs, tines, serrated edges, extending fibers, or other similar structural feature to promote tissue fixation.

The barbs or other features to engage the tissue prevent movement of the anchors 14, 16 once placed, thereby retaining the extension portion 13 or support portion 12 supporting the tissue.

Other embodiments of the anchors 14, 16 can be toggle bolts or anchors adapted to be inserted into or to penetrate and engage a target anchoring site. The toggle anchors 14, 16 can be generally elongate and adapted to be carried by a portion of delivery device (*e.g.*, distal needle end) as further detailed herein, for anchoring within soft tissue, *e.g.*, the obturator membrane. The anchors 14, 16 may flex, pivot, or otherwise displace to facilitate deployment and tissue fixation.

Referring to Figs. 2-4, embodiments of the adjustable implant 10 of the present invention can include at least one adjustability feature or mechanism 15 having one or more members or sutures 18 attached and adjustable relative to the support portion 12 or extension portions 13 and the end anchors 14, 16. Namely, one or more members 18 can connect or loop through the anchors 14, 16 and then back through an eyelet or like feature 20 in the extension portions 13 of the implant 10. As such, the distance between the anchors 14, 16 and the support portion 12 can be adjusted (e.g., shortening or lengthening via pulling one of the strands of the member 18), thereby adjusting the length of the implant 10 to accommodate various patient anatomical differences and to provide for post-deployment tensioning and adjustment. Ends of the members 18 can include one or more features 22 to facilitate this manual manipulation and adjustment. The features 22 can include one or more suture loops, tabs, clips, knots, and the like. In other embodiments the member 18 merely includes one or more free ends, without including features 22.

Referring now to the particular example embodiment of Fig. 2, the adjustability feature 15 can be included on only one end of the implant 10, with attachment to only one of the anchors (e.g., 14). As illustrated the members 18 may extend back toward the extension portion 13 and may include features, tabs or handles 22 to permit a user to adjust the length

of the implant 10 by selectively adjusting members 18. In this particular example embodiment, the non-adjustable side or portion of implant 10 can include one or more members 18 that can be non-adjustably coupled to and extending between an anchor (e.g., 16) and extension portion 13 or support portion 12. The members 18 can be any material including but not limited to suture material (single filament, braided and the like). The unilateral adjustment of the implant 10 reduces the amount of time is required for surgery and also reduces the number of external incisions that may be required for post-operative adjustments.

Fig. 3 illustrates an embodiment of the present invention having more than one adjustability feature. In this embodiment an adjustability feature 15 can be operatively coupled to each end of the implant 10. Each adjustability feature 15 may include one or more members 18 that extend between or loop through anchor 14, 16. Ends of the members 18 may then extend through a portion of the ends of the extension portions 13 or through an eyelet 20. Ends of the members 18 of each adjustability feature 15 may be selectively adjusted to reduce or lengthen the distance between both extension portions 13 and the anchors 14, 16. This example embodiment of the invention permits fine tune adjustment of both ends of the implant 10.

Turning now to Fig. 4, an example embodiment is depicted that demonstrates a relatively shorter support portion 12 such that the adjustability features 15 may be longer, yet the entire length of the implant 10 is easily and selectively adjustable upon deployment and fixation to soft tissue. The length of the support portion 12 and the extension portions or the members 18 may vary and the description herein should not be considered limiting. Additionally, although this example embodiment depicts a unilateral adjustability feature 15 it is also contemplated that bilateral adjustability features 15 may also be employed.

Continuing with the example embodiment of Fig. 4, the eyelet 20 can be used to control adjustment of the length or tension of the implant 10. In example embodiments, the eyelet 20 may include a grommet or like element to allow for selective locking of the member 18 after adjustment. Figure 5 illustrates an adjustability feature 15 and an extension portion 13 of the support portion 12 (not shown). As illustrated in Fig. 5, the eyelet or grommet type of mechanism (as identified in Fig. 6 shown without an extension portion 13 or support portion 12) may be attached or coupled to the extension portion 13 of the implant 10. The eyelet 20 or grommet mechanism may be attached or connected to the extension portion 13 by an adhesive or other mechanical coupling mechanism such as tying, weaving and the like. Other devices, mechanisms, or techniques or also envisioned to facilitate this locking or self-locking technique.

In one example embodiment, the adjustability feature 15 can be configured as illustrated in Figs. 5 and 6 and as described and depicted in U.S. Patent Publication No. 20160038267, which is incorporated by reference herein in its entirety. In this particular embodiment the anchors 14 or 16, acting as a pulley device identified as 30, can include a first aperture 32 and a second aperture 34 extending therethrough with the members 18 able to extending through the first aperture 32 and through the second aperture 34 and the end or features 22 of the members 18 extending through the eyelet 20 to form a pulley mechanism. As particularly illustrated in Fig. 6, the members 18 can be formed by two or more strands such that they form a first suture loop 40a and a second suture loop 40b that extend through eyelet 20, with at least the second suture loop 40b being able to slide freely through the anchor 14, 16 and the first suture loop 40a extending through the second suture loop 40b to form a friction point or cinching area E, which fixes or locks the movement of members 18 after adjustment. The fixation of the members 18 prevents movement of the distance

between the anchor 14, 16 from eyelet 20 and extension portion 13 or support portion 12. Other configurations of the loops 40a and 40b are also contemplated herein.

Prior to adjustment, the members 18 are generally in a slacked state. The second suture loop 40b can resist sliding or spreading even when in this slackened state. This can be attributed to the combination of suture material properties and the dimensions of this design. Once a tension load is applied between the anchor 14, 16 and the eyelet 20 the adjustment length therebetween is fixed immobilizing the suture loop and movement of the anchor 14, 16 relative to the eyelet 20. The fixation, lock or securement of the length between the anchors 14, 16 and the eyelet 20, extension portion 13 or support portion 12 may be achieved by one or both the mechanical binding between the suture loops 40a and 40b as well as friction between the suture members 18 and the anchors 14, 16. As further illustrated in Figs. 5 and 6, a knot B may be formed in one of the suture members 18 to engage or cinch a portion of suture loop 40b between the knot B and a surface or recess of eyelet 20. The fixation may also be released by pulling on tab 22 of loop 40a, which draws knot B away from the eyelet 20 to release the suture member 18 of loop 40b. Other constructs and configurations are also contemplated herein and the disclosed configuration should not be considered limiting.

These embodiments having an adjustability feature 15 provide for both intra- and post-procedural adjustments or tensioning to the implant. Because the adjustable member or suture member 18 can be made with small (e.g., 4-0) monofilament strands, the adjustment ends or tabs 22 can emerge from a closed incision to allow later adjustment. Upon later adjustment, the ends or tabs 22 can be simply trimmed and completed. The self-locking nature of the mechanism allows this adjustment without the need for re-opening of the incision (e.g., to apply a final locking step).

Referring to FIG. 7, embodiments of the present invention can include one or more delivery tools or devices 50. The tool 50 can include a handle portion 52, a needle portion 54,

and an actuator mechanism, switch or button 56. The needle portion 54 can be straight or curved as illustrated in Figs. 9 and 10, and can include a distal end portion 58. The needle portion 54 can include a lumen and the distal end portion 58 can be slotted at slot 60.

The slot 60 at the distal end portion 58 is sized and shaped to slidably and selectively receive and secure the anchor 14, 16 therein. Upon introduction through a target tissue location (e.g., obturator membrane as illustrated in Figs. 9 and 10), the release mechanism 56 can be actuated (pushed, pulled, slid, etc.) to release the anchor 14, 16 from the distal end portion 58. A wire, rod or like member within the lumen of the needle portion 54, and operatively connected to the mechanism 56, can therefore traverse to push or otherwise release the anchor 14, 16 from the distal end portion 58. In other embodiments tool 50 can also receive and deploy the anchor 14 or 16, with a mechanism adapted to slide back and correspondingly retract the needle portion 54 into the handle 52. Markings 62 on the needle portion 54 can provide indicia of tissue depth to assist the physician in deployment of the implant.

One embodiment of deploying and implanting the implant 10 of the present invention to treat a female pelvic disorder includes first prepping the patient by positioning her legs generally in a dorsal lithotomy position. As illustrated in Fig. 8, a target location for each anchor on the externus side of the obturator membrane D, at the superior medial notch of the obturator foramen. Next, the physician locates the superior medial notches of the obturator foramina for visual guidance and can accordingly mark, on each side, with a pen, palpating to confirm positions. A foley catheter can be used to drain the bladder, with the catheter left in place after clamping.

The physician may then create a vaginal incision in order to insert the implant 10 into a space between the vaginal tissue and the urethra. A local anesthesia can be delivered to the anterior wall of the distal vagina near the vaginal incision to a depth determined by the

physician. Then, the physician can locate the path of the delivery tool 50 by evenly spreading the labia minora. The insertion of the delivery tool 50 can be at any position determined by the physician between the 3 and 9 o'clock position on the incision.

Next, the implants 10 and the delivery tool 50 are provided. The anchor 14, 16 is attached to, inserted into or otherwise coupled to the needle tip 58 by sliding the anchor 14, 16 into the slot 60. A retaining mechanism may be formed in the slot 60 to retain the anchor 14, 16 and can include a lip, rib or other retaining mechanism. As a physician inserts the anchor 14, 16 into the slot 60 a click or like response may be detected. The labia minora can be spread, exposing the vaginal incision thereby permitting the physician to insert the delivery tool needle 54 into the incision.

The needle tip 58 can then be advanced along the path through the pelvic tissue, along a direction parallel with or slightly diverted from, the urethra. The physician continues the needle tip 58 toward the obturator foramen until the tip 68 punctures the tissue of the obturator tissue, which may be indicated by an audible popping sound. Additionally, the proper depth may be indicated by markings 62 on the needle 54.

Holding the delivery tool 50 stationary, the physician will push or pull the slider or like mechanism completely forward or backward to release the anchor 14, 16 from the slot 60 of the needle 54. The physician can then ensure the sutures are completely free from the delivery tool 50 and initially retract the needle in a straight line out of the obturator muscle.

The physician can then pull on tabs or suture ends 22 to set the anchor 14, 16 in or against the obturator tissue. The physician can then insert the support portion 12 through the vaginal incision and position proximate the urethra in order to support the urethra. Continuing to pull the tab or suture end 22 will move the extension portion 13 toward the anchor 14 or 16, thereby shortening the space between the anchors 14 and 16 and the eyelet 20. Likewise, pulling the other tab or suture end 22 (for example, tab 22 of loop 40a) may cause knot A to

engage the eyelet to move the extension portion 13 away from the anchor 14, 16, thereby lengthening the space between the anchors 14, 16 and the eyelet 20 or extension portion 13. Lengthening may be needed if tension greater than needed for supporting the tissue is noted (by strong movement of tissue). Similarly, if a correction is required, the anchor 14 or 16 may be fully retrieved by pulling on the tab 22 or the member 18 and reinserting with a hemostat or the delivery tool 50.

Once the implant 10 is in position the physician may close the incision and may leave the members 18 with tabs 22 extending through the incision for post operative adjustment. As during the surgery, the physician may pull on the tabs 22 or ends of the members 18 to adjust the distance between anchors 14, 16 and the extension portion 13 and thereby the amount of support on the urethra. Once the physician is satisfied that no future adjustment will be necessary the physician may cut the members 18 extending from the incision and if necessary stitch the incision closed.

These surgical procedures steps, devices and techniques may be completed on either one or both sides of the urethra. Further additional securement of the fixation may be accomplished by a surgeon knotting the two tabs or ends 22. Further, the present invention may be utilized to support a variety of tissues and organs such as a patient's bladder, bladder neck, urethra, pelvic tissues in the correction of cystocele, rectocele or vaginal vault prolapse. Additionally, the present invention may be utilized for the treatment of disorders other than pelvic disorders. The devices or structures described herein can be employed or introduced into the pelvic region of the patient transvaginally, percutaneously or in any other manner known by those of ordinary skill in the art.

Various systems, devices, structures, techniques and methods, alone or in combination, as disclosed in U.S. Patent Publication Nos. 7,500,945, 7,407,480, 7,351,197, 7,347,812, 7,303,525, 7,025,063, 6,911,003, 6,691,711, 6,648,921, 6,612,977, 6,802,807,

2002/0161382, 2002/0147382, 2002/151762, 2004/0039453, 2008/0057261, 2008/0045782, 2010/0105979, 2011/0144417, and 2011/0201876, pending U.S. Patent Application No. 13/556,167, and International PCT Publication Nos. WO 2008/057261 and WO 2007/097994, can be employed with the present invention, with the above-identified disclosures being incorporated herein by reference in their entirety.

The systems, their various components, structures, features, materials and methods of the present invention may have a number of suitable configurations as shown above. Various methods and tools for introducing, deploying, anchoring and manipulating implants or to treat incontinence and prolapse as disclosed in the previously-incorporated references are envisioned for use with the present invention as well.

A variety of materials may be used to form portions or components of the implants and devices, including Nitinol, polymers, elastomers, porous mesh, thermoplastic elastomers, metals, ceramics, springs, wires, plastic tubing, and the like. The systems, components and methods may have a number of suitable configurations known to one of ordinary skill in the art after reviewing the disclosure provided herein.

All patents, patent applications, and publications cited herein are hereby incorporated by reference in their entirety as if individually incorporated, and include those references incorporated within the identified patents, patent applications and publications.

Obviously, numerous modifications and variations of the present invention are possible in light of the teachings herein. It is therefore to be understood that within the scope of the appended claims, the invention may be practiced other than as specifically described herein.

CLAIMS

1. A surgical device for treating incontinence, comprising:

an implant having a support portion and opposed extension portions; and

at least one adjustability feature operatively coupled to at least one of the extension portions, the adjustability feature having at least one anchor and at least one member operatively coupling the anchor to the extension portion, the anchor being adapted to engage a portion of pelvic tissue such that the distance between the anchor and the extension portion is adjustable to restore continence.

2. The surgical device of claim 1, wherein the member includes at least two tabs extending from the extension portion, the tabs capable of being pulled to adjust the distance between the anchor and the extension portion.

3. The surgical device of claim 1, wherein the adjustability feature includes an eyelet to retain the member, wherein the member extends through the eyelet and terminates in one or more two tabs capable of being pulled to adjust a distance between the anchor and the extension portion.

4. The surgical device of claim 3, wherein the member includes at least one loop, whereby a portion of the member extends through the loop to limit movement of the extension portion.

5. The surgical device of claim 1, wherein the anchor comprises a toggle adapted to receive a portion of the member to create a pulley mechanism.

6. The surgical device of claim 1, further including a delivery tool having a needle adapted to deliver the anchor to a target tissue.

7. The surgical device of claim 1, wherein the anchor is adapted to engage a target tissue site selected from the group consisting of: the obturator foramen, obturator internus, abdominal fascia, sacrospinous ligament, prepubic fascia, rectus fascia, the tendinous arch of the levator ani, Cooper's ligament, and a pubic symphysis cartilage.

8. A system for treating pelvic disorders comprising:

an implant including a single adjustability feature adjustably connected to an anchor and a support portion of the implant, the anchor adapted to engage a target tissue;

a delivery tool having a needle adapted to deliver the anchor to a target tissue; and

wherein the adjustability feature is adapted to adjust a distance between the anchor the support portion.

9. The system of claim 8, wherein the adjustability feature includes a member operatively coupled to and extending between the anchor and the support portion of the implant.

10. The system of claim 8, further including an eyelet coupled to the support portion and in operative communication with the adjustability feature.

11. The system of claim 10, wherein the adjustability feature includes a member operatively coupled to and extending between the anchor and the eyelet, the member adapted to adjust the distance between the anchor and the eyelet.

12. The system of claim 8, wherein the delivery tool includes a needle having a slot for retaining the anchor and delivering the anchor to the target tissue.

13. The system of claim 12, wherein the delivery tool includes a handle having a release mechanism operatively disposed therein to release the anchor once at the target tissue.

14. A method of treating incontinence comprising:

making a vaginal incision;

providing an implant having a support portion to support tissue;

positioning the support portion in the vaginal incision and proximate a tissue ;

providing at least one adjustability feature operatively coupled to the support portion, the adjustability feature having at least one anchor and at least one member operatively coupling the anchor to the support portion;

coupling the anchor and a delivery tool;

inserting a portion of the delivery tool to deliver the anchor to an anchoring tissue site; and

operating the adjustability feature to adjust a distance between the anchor and the support portion.

15. The method of claim 14, wherein the step of operating the adjustability feature comprises pulling a portion of the member to increase or decrease the distance between the support portion and the anchor.

16. The method of claim 14, wherein the step of coupling the anchor to the delivery tool comprises inserting the anchor into a slot of a needle of the delivery tool.

17. The method of claim 16, further comprising the step of activating a release mechanism of the delivery tool to deliver the anchor to the anchoring tissue site.

18. The method of claim 14, further comprising the step of providing ends of the member extending out of the vaginal incision and suturing closed the vaginal incision to permit post operative adjustment of the distance between the anchor and the support portion.

19. The method of claim 18, further comprising the step of cutting the ends of the member extending from the closed vaginal incision.

20. The method of claim 14, further comprising the step of providing a second adjustability feature operatively coupled to the support portion to permit bilateral adjustment of the support portion.

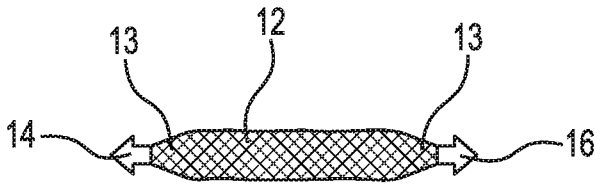

Fig. 1

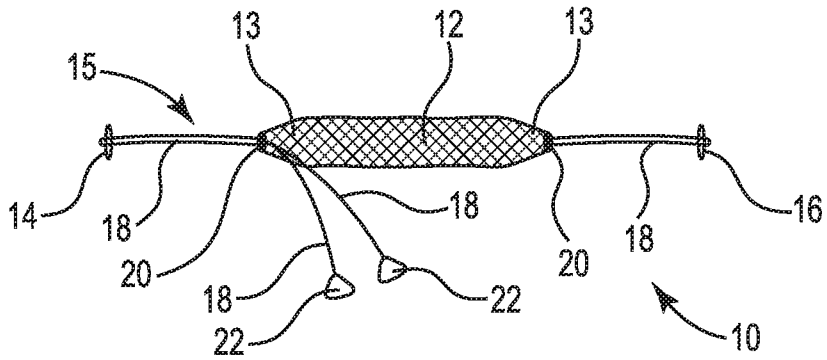

Fig. 2

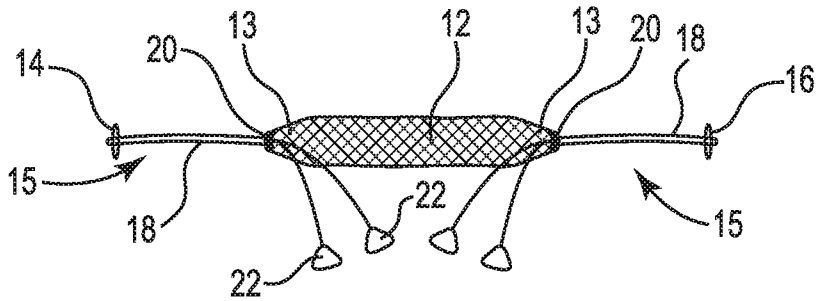

Fig. 3

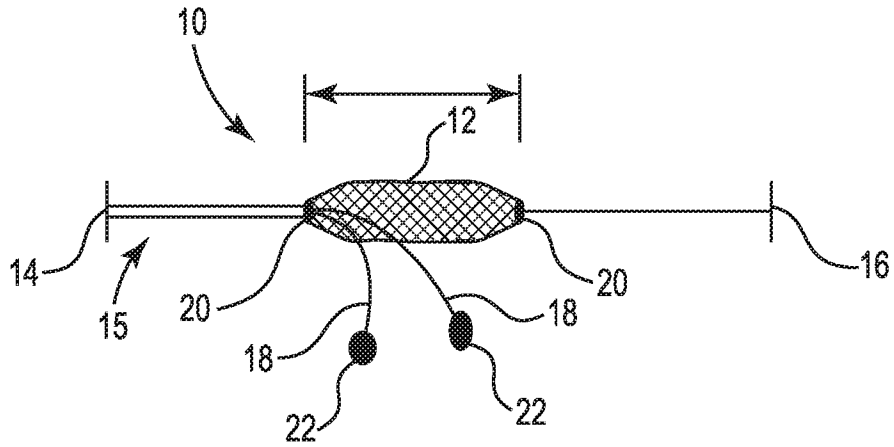

Fig. 4

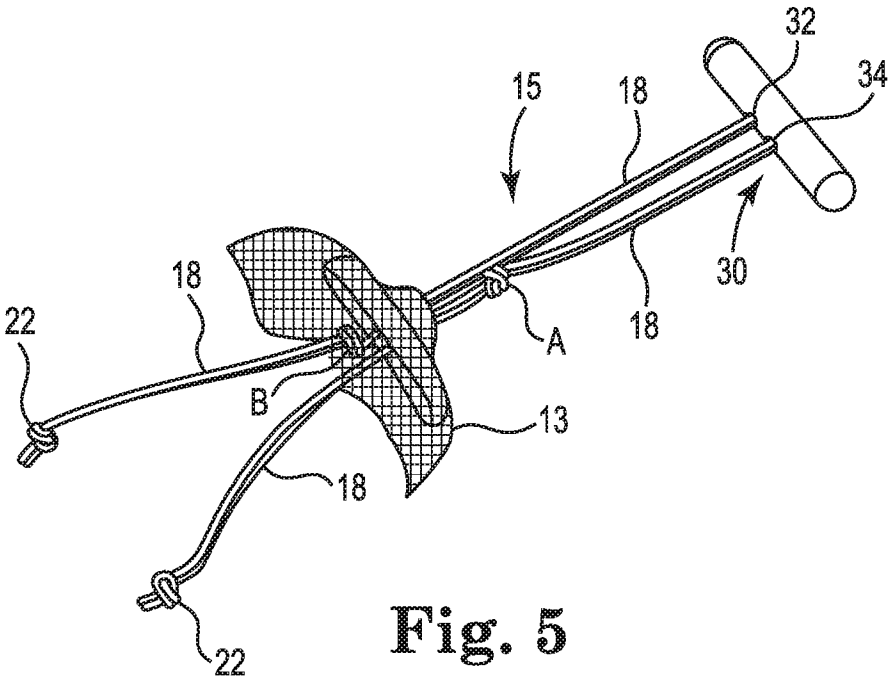
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Fig. 5

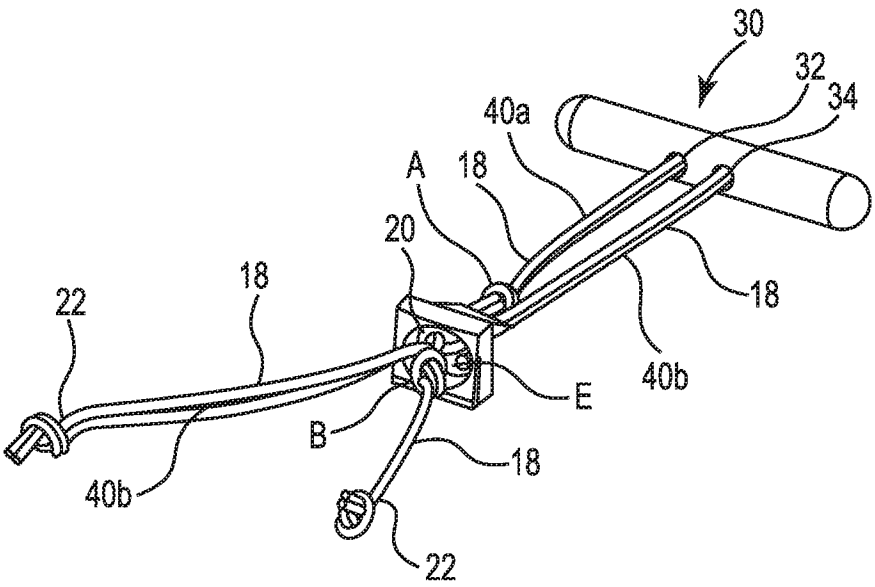
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Fig. 6

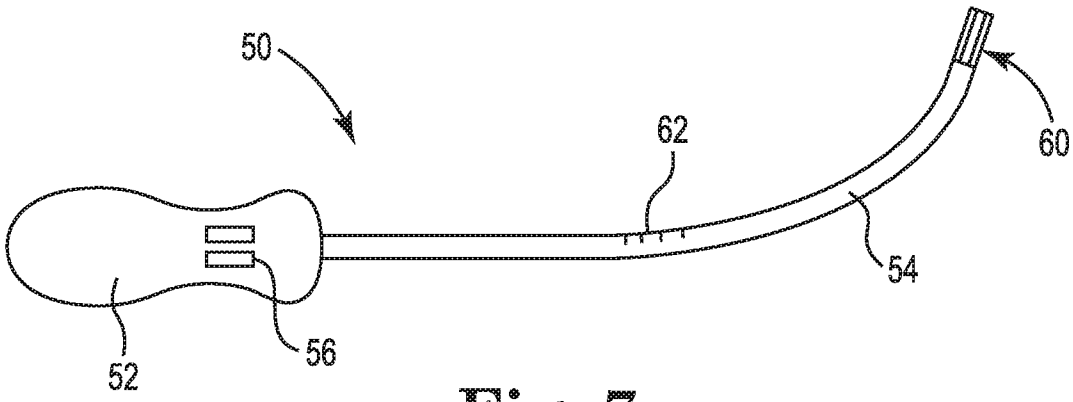

Fig. 7

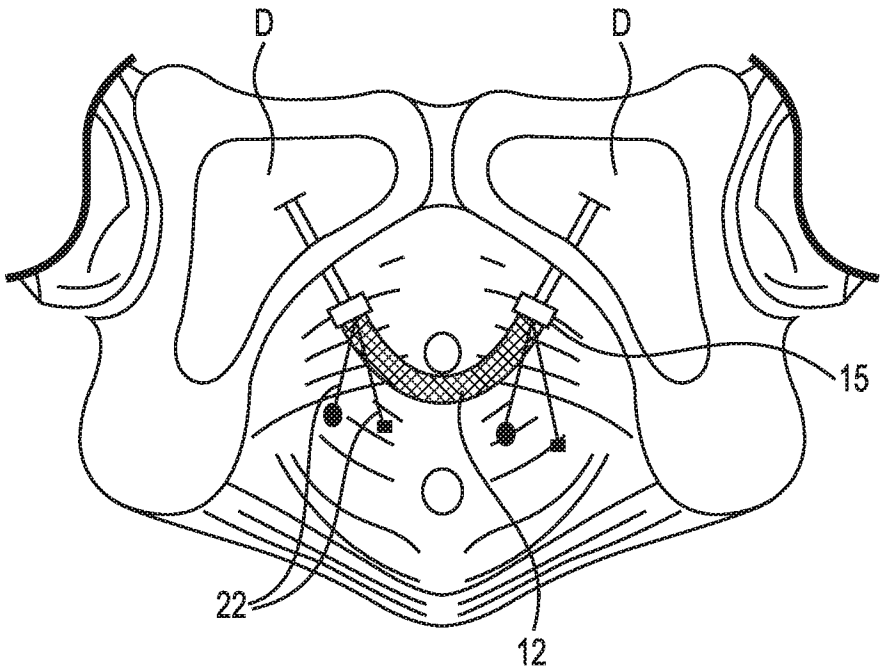

Fig. 8

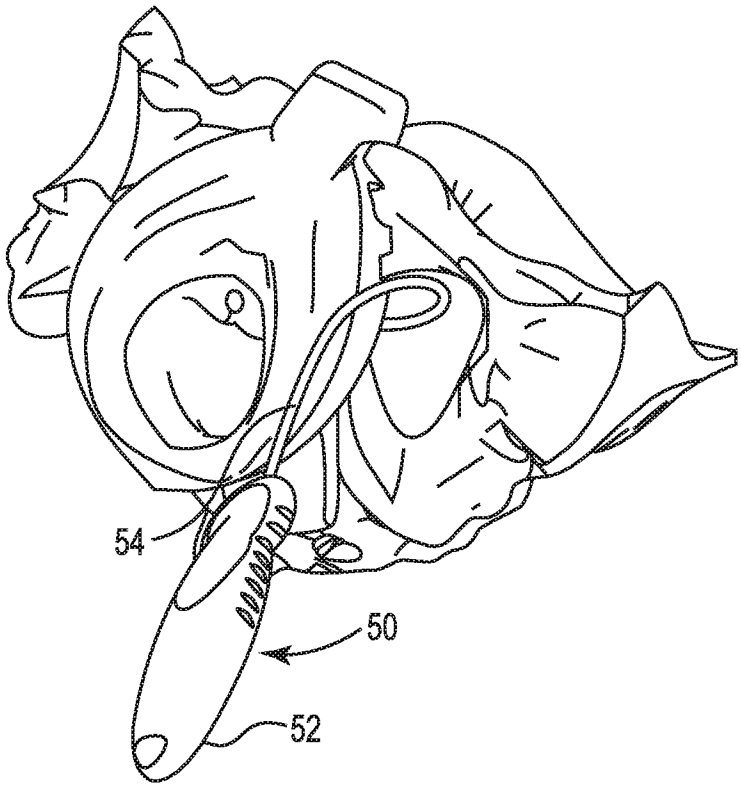

Fig. 9

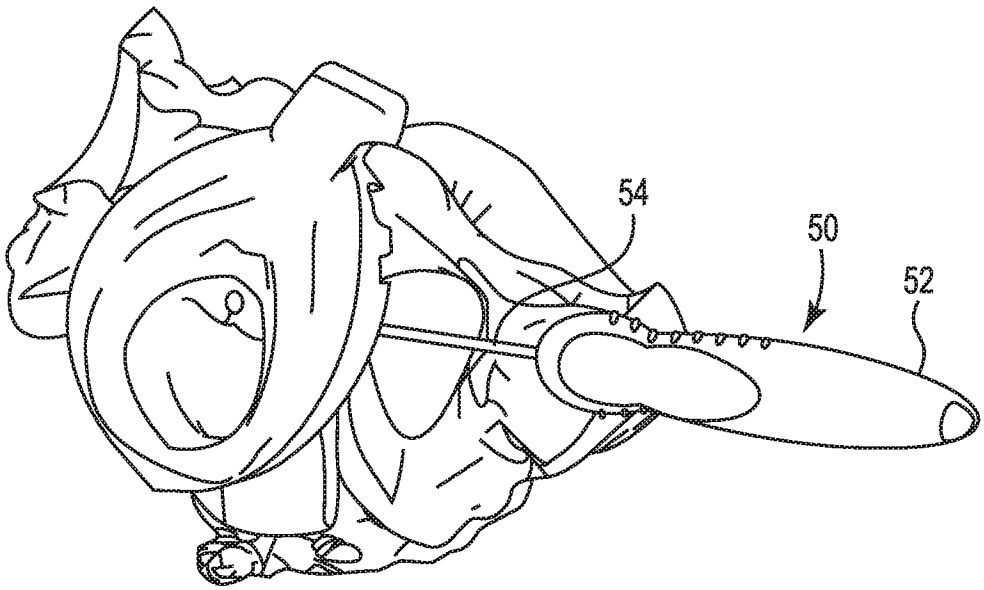

Fig. 10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 16/41902

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/02 (2016.01)
CPC - A61F 2/0045, 2/005
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 2/02 (2016.01)
CPC : A61F 2/0045, 2/005

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
IPC(8) : A61F 2/00 (2016.01)
CPC: A61F 2/00, 2/0004, 2/0031, 2/0036, 2/0063, 2002/0072

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Patbase, Google Patent, Google Scholar: mesh, sling, support, vagina, intravaginal, transvaginal, incontinence, urethral, pelvic, pelvis, adjust, anchor, loop, coupling, element, member, fasten, fixate, pull, draw, tab, tag, handle, suture, grommet, eyelet, toggle, pulley

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 2009/0221868 A1 (EVANS) 3 September 2009 (03.09.2009) see especially para [0039]-[0042], [0052], [0064], [0069], [0075], fig 1A-B, 2, 4A-C	1, 6-7, 14-17, 20 --- 2-5, 12-13, 18-19
X --- Y	US 2012/0203060 A1 (ROLL et al) 9 August 2012 (09.08.2012) see especially para [0052], [0056], [0068]-[0070], fig 5, 10, 33-35	8-11 --- 12-13
Y	US 2014/0073847 A1 (MUJWID et al) 13 March 2014 (13.03.2014) see especially para [0061], fig 1	2-4
Y	WO 2014/146023 A2 (AMS RESEARCH CORPORATION) 18 September 2014 (18.09.2014) see especially pg 13, ln 1-5, pg 14, ln 5-20, fig 4-5, 8	5
Y	US 2009/0259092 A1 (OGDAHL et al) 15 October 2009 (15.10.2009) see especially para [0096], fig 10	18-19
A	US 2014/0088344 A1 (MUJWID et al) 27 March 2014 (27.03.2014) see whole document	1-20
A	US 2011/0288368 A1 (VANDEWEGHE et al) 24 November 2011 (24.11.2011) see whole document	1-20
A	US 2011/0230708 A1 (BROWNING) 22 September 2011 (22.09.2011) see whole document	1-20
A	US 2009/0137861 A1 (GOLDBERG et al) 28 May 2009 (28.05.2009) see whole document	1-20
A	US 2006/0089525 A1 (MAMO et al) 27 April 2006 (27.04.2006) see whole document	1-20

☐ 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
26 August 2016	03 OCT 2016
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. 571-273-8300	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (January 2015)