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(54) PROTECTIVE SHEATH FOR TRANSVAGINAL ANCHOR IMPLANTATION DEVICE

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Related U.S. Application Data

(60) Division of application No. 09/238,654, filed on Jan. 26, 1999, which is a continuation-in-part of application No. 08/744,438, filed on Nov. 8, 1996, now Pat. No. 6,052,380 and which is a non-provisional of provisional application No. 60/072,641, filed on Jan. 27, 1998.

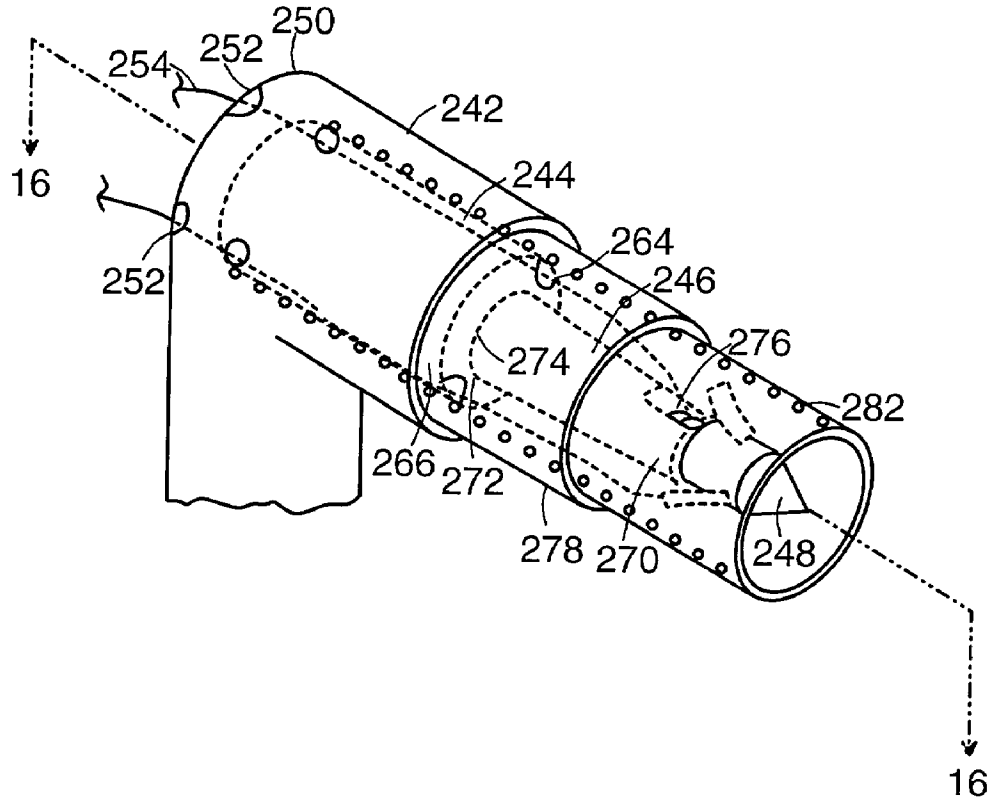
Publication Classification

(51) **Int. Cl.**[7] **A61B 17/00**

(52) **U.S. Cl.** **606/232**

(57) **ABSTRACT**

Bone anchor implantation devices and methods for their use are disclosed. The bone anchor implantation devices and methods find particular application in maintaining or improving urinary continence by suspending or stabilizing the bladder neck. Protective sheaths for covering a bone anchor on a bone anchor implantation device are disclosed. The protective sheaths protect the bone anchor from contacting tissue during insertion and prevent contamination of the bone anchor.



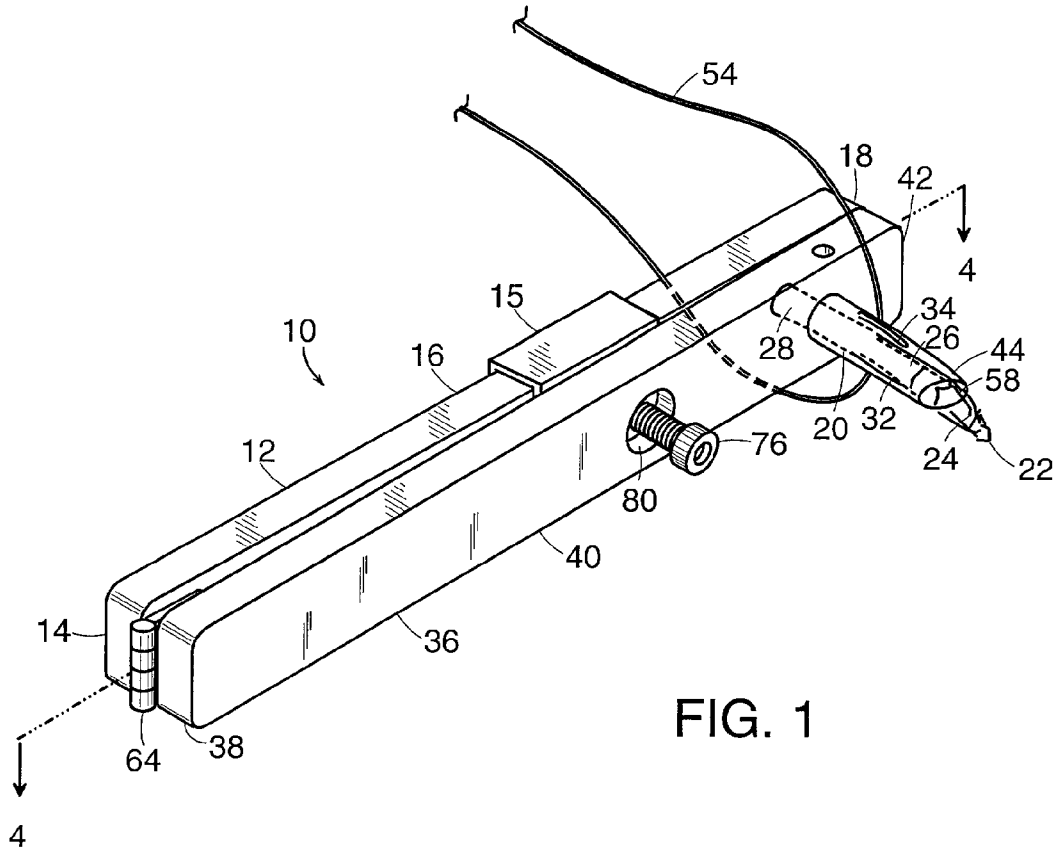


FIG. 1

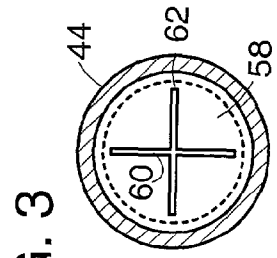

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FIG. 3

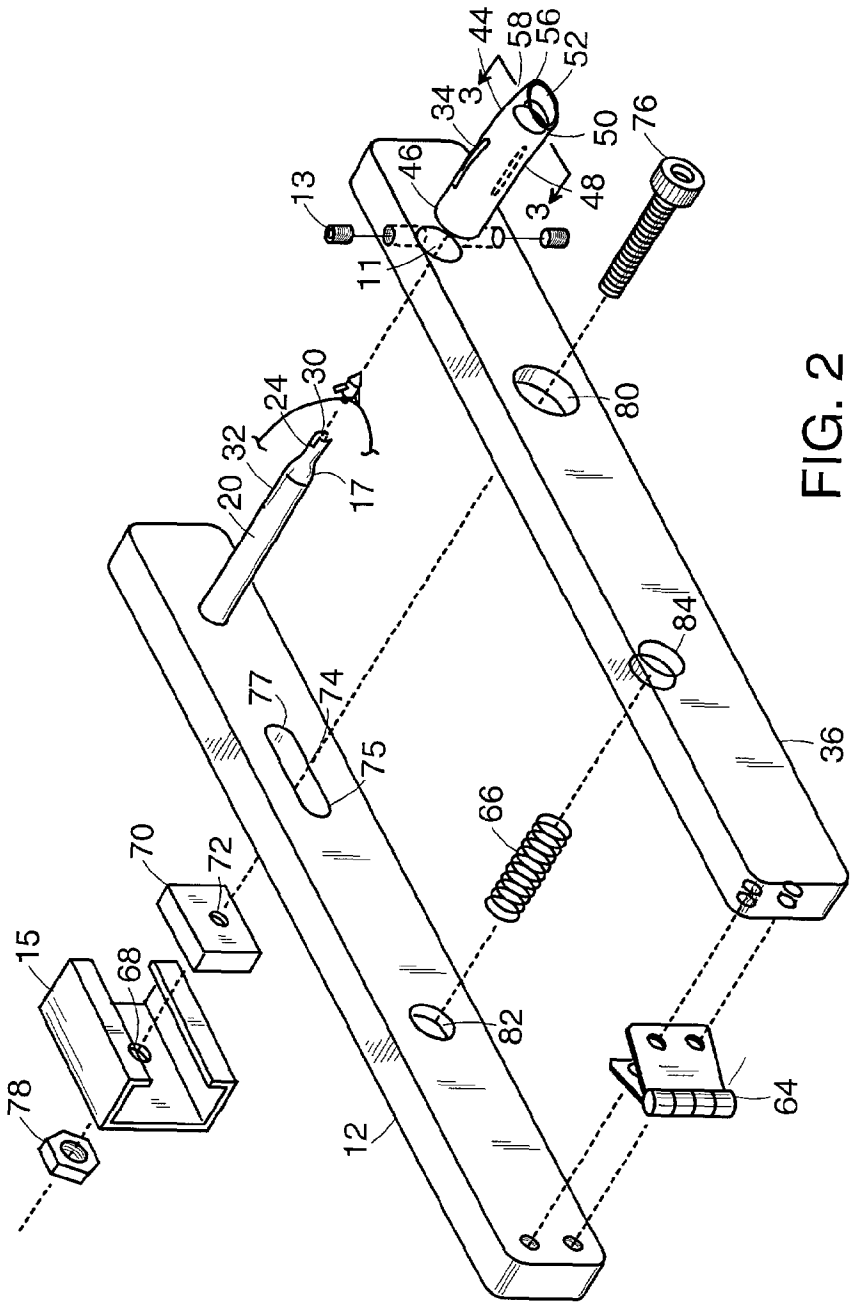
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FIG. 2

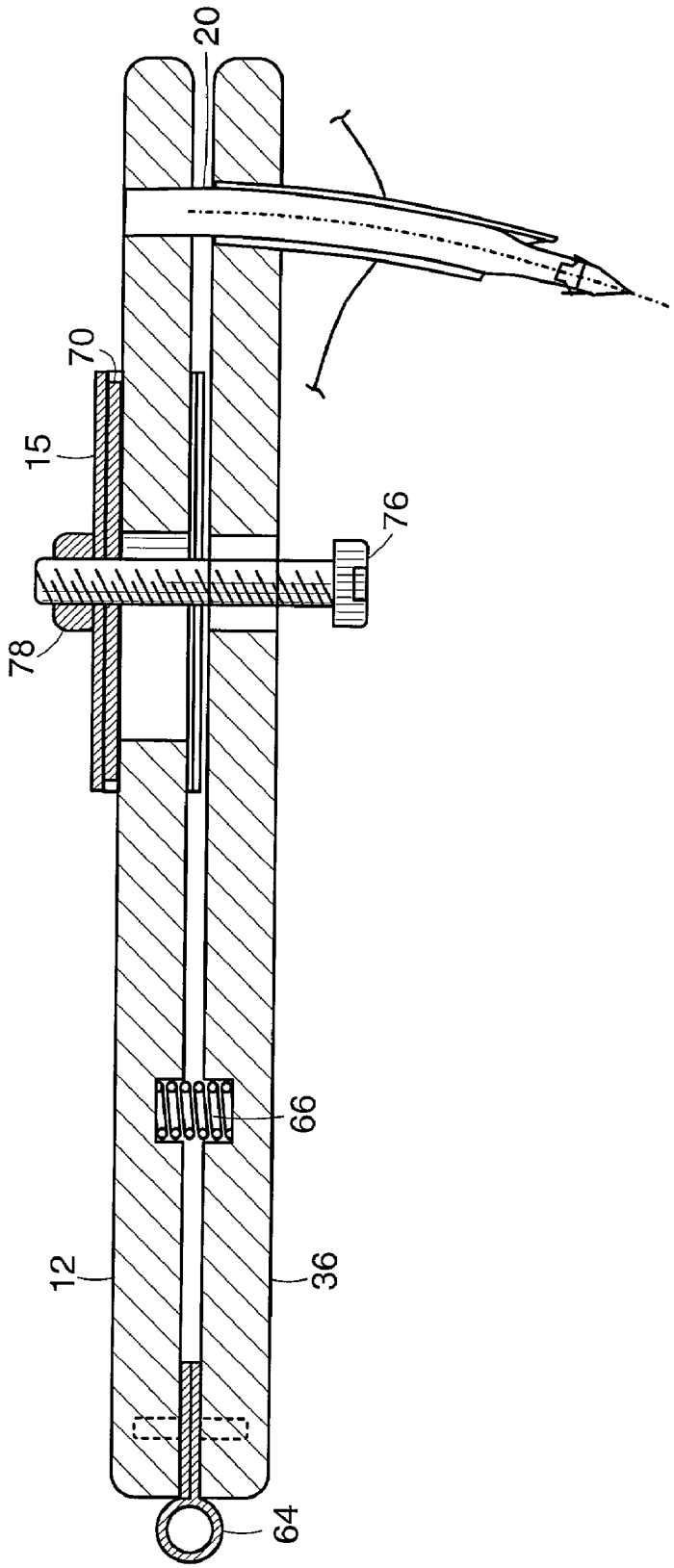


FIG. 4

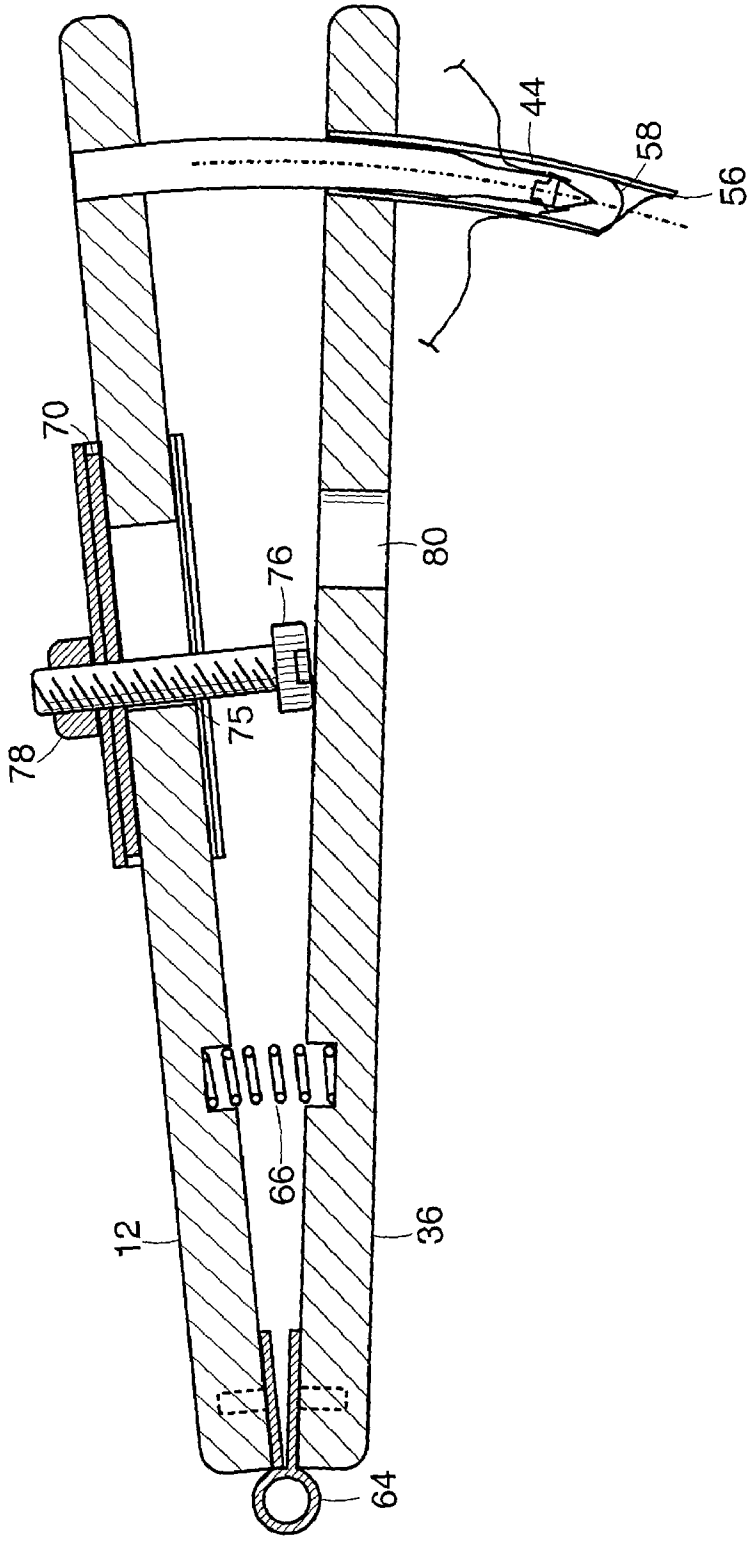


FIG. 5

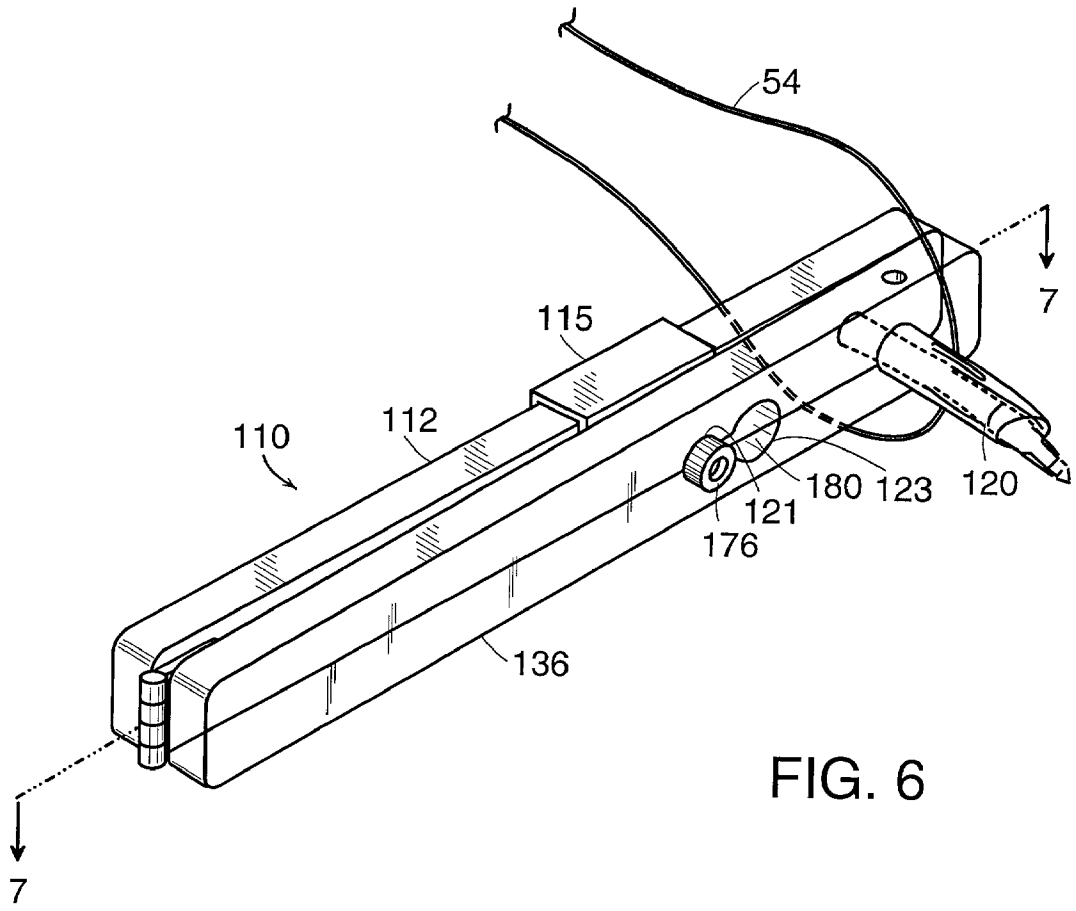
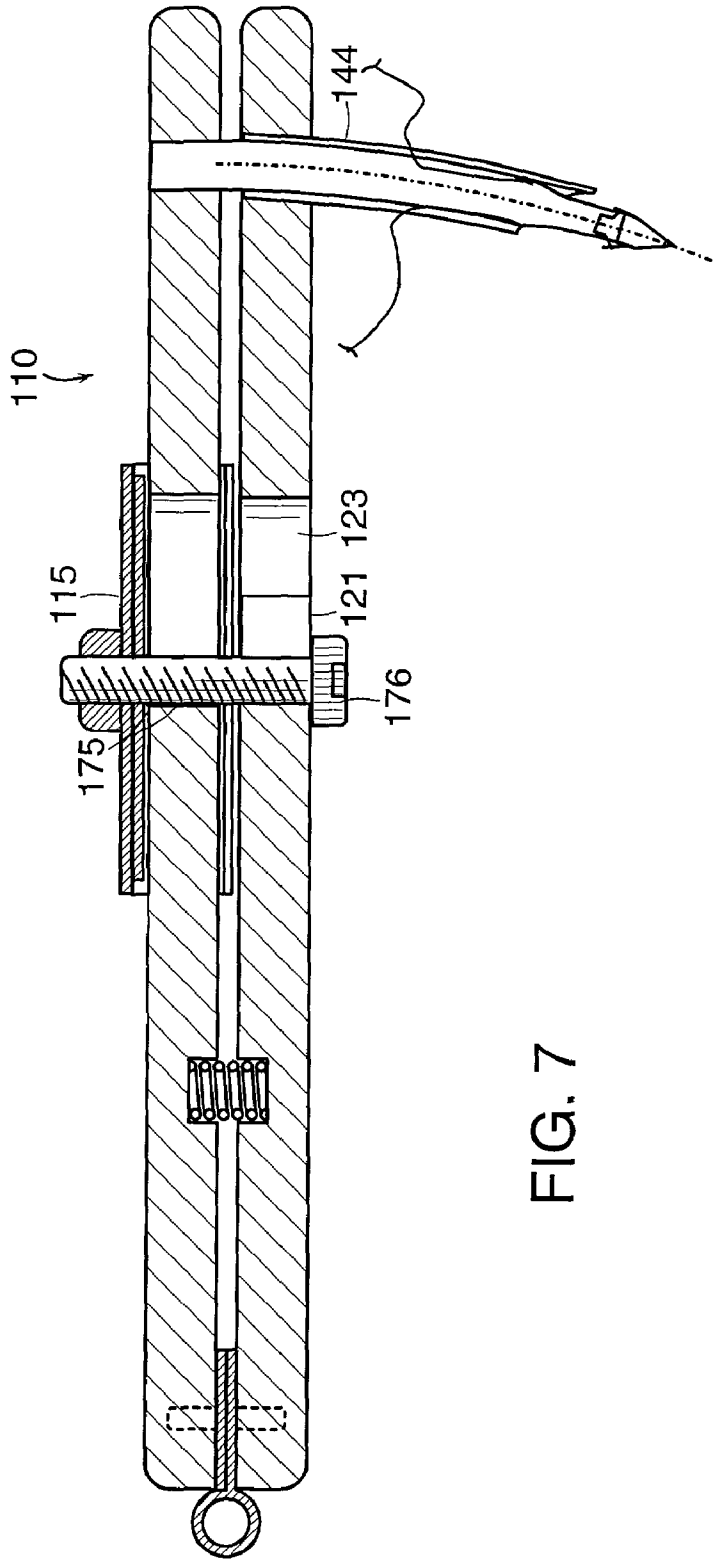


FIG. 6



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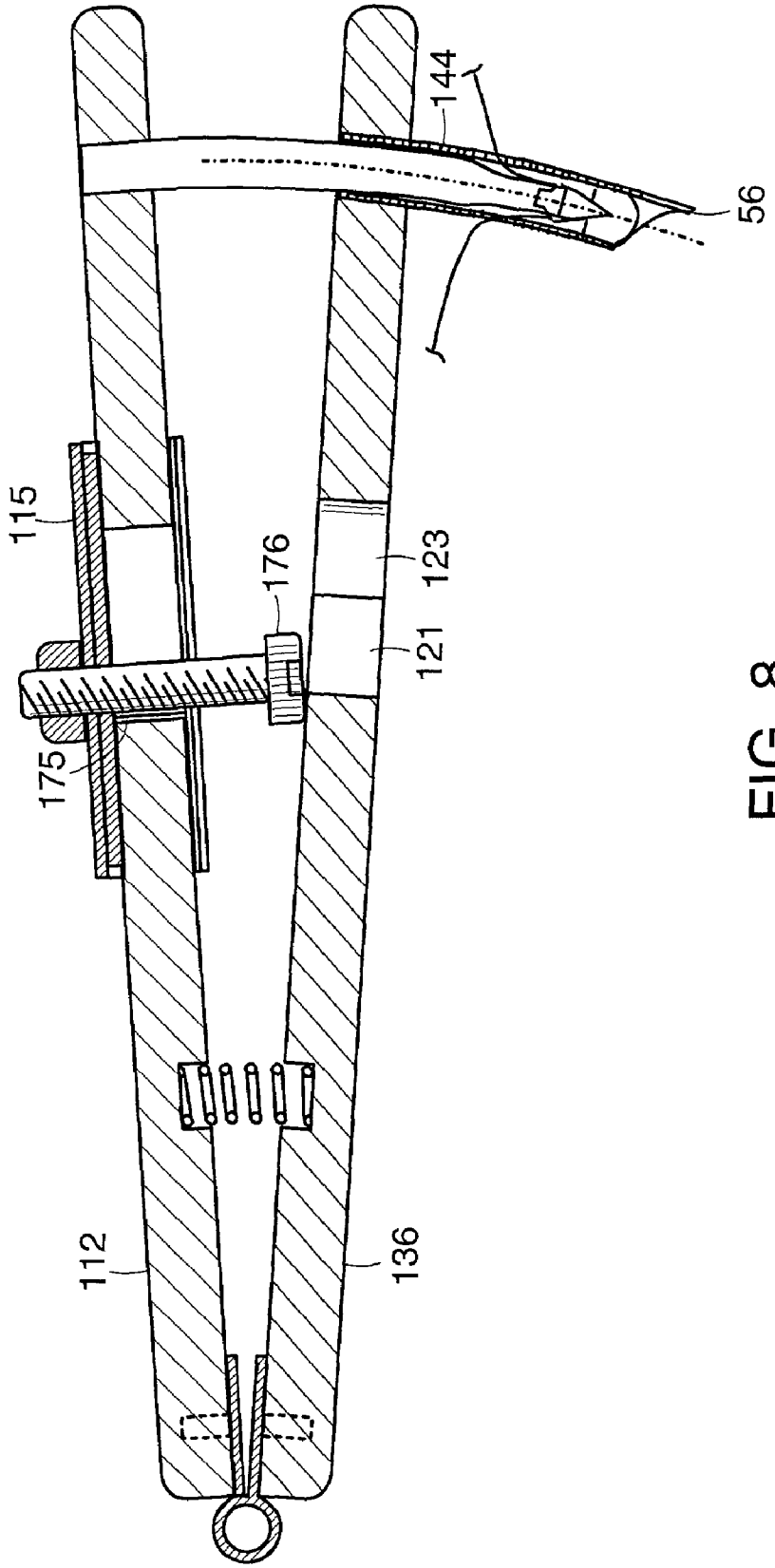

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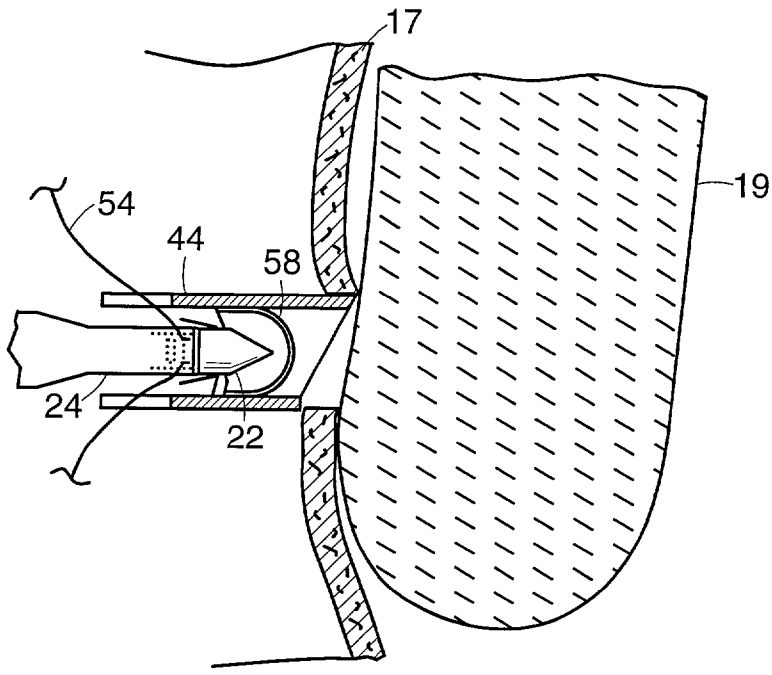

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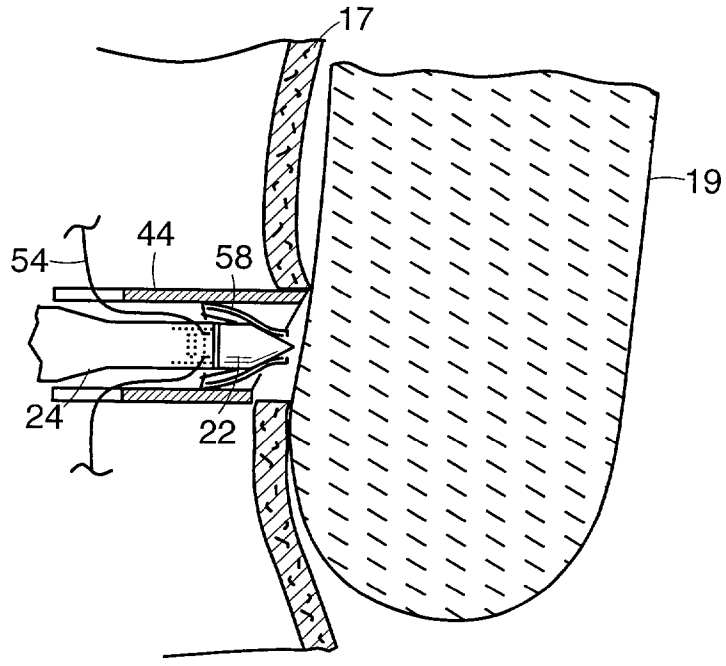

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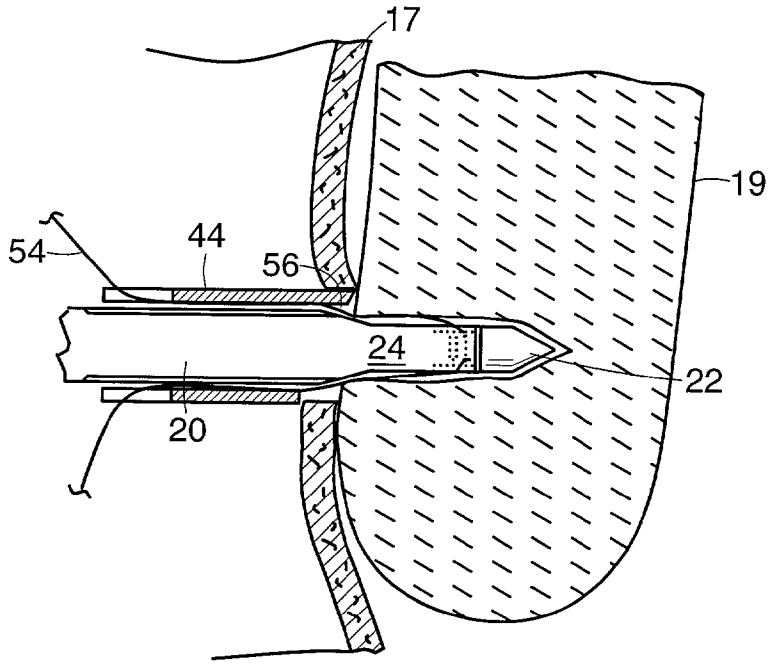

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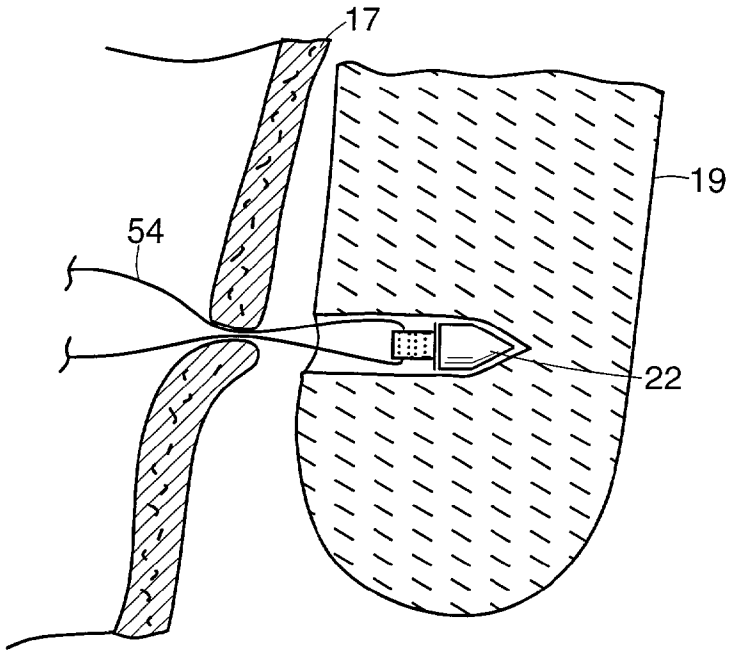

FIG. 12

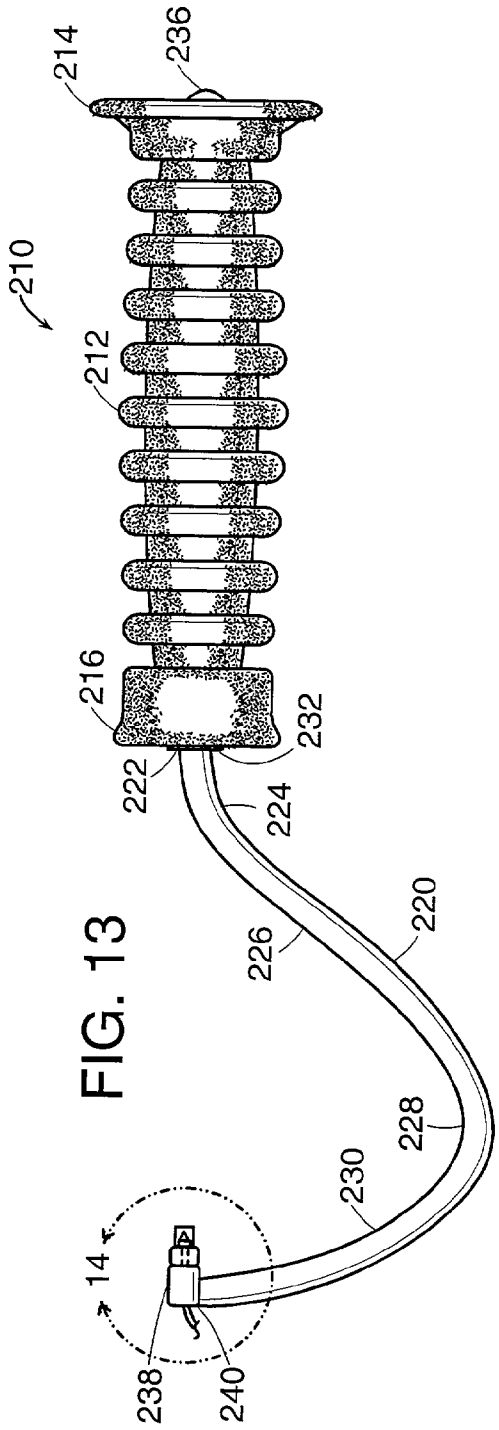
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FIG. 13

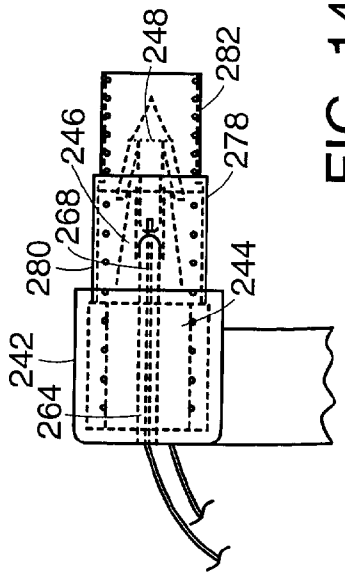
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FIG. 14

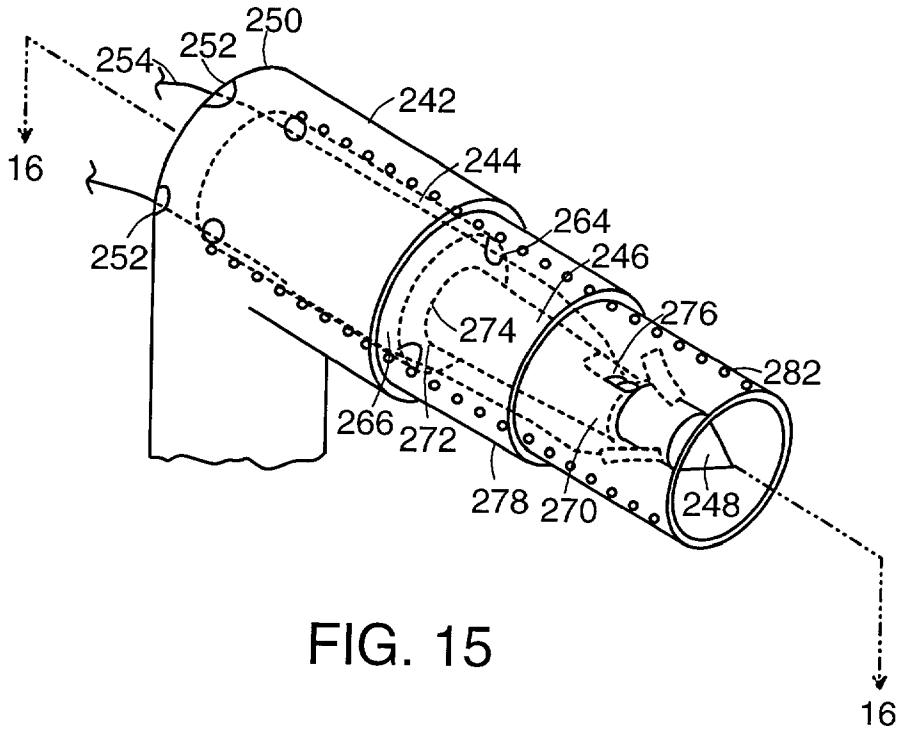
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FIG. 15

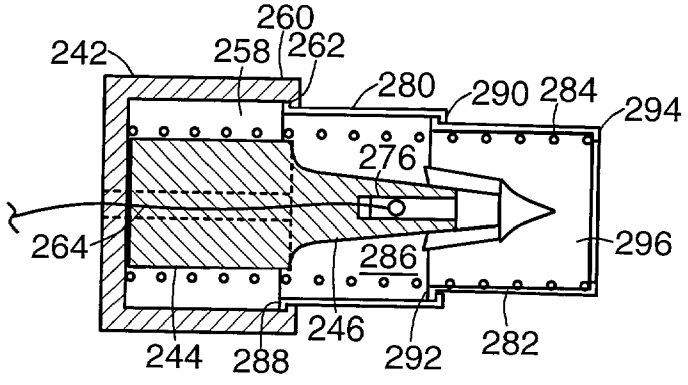
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FIG. 16

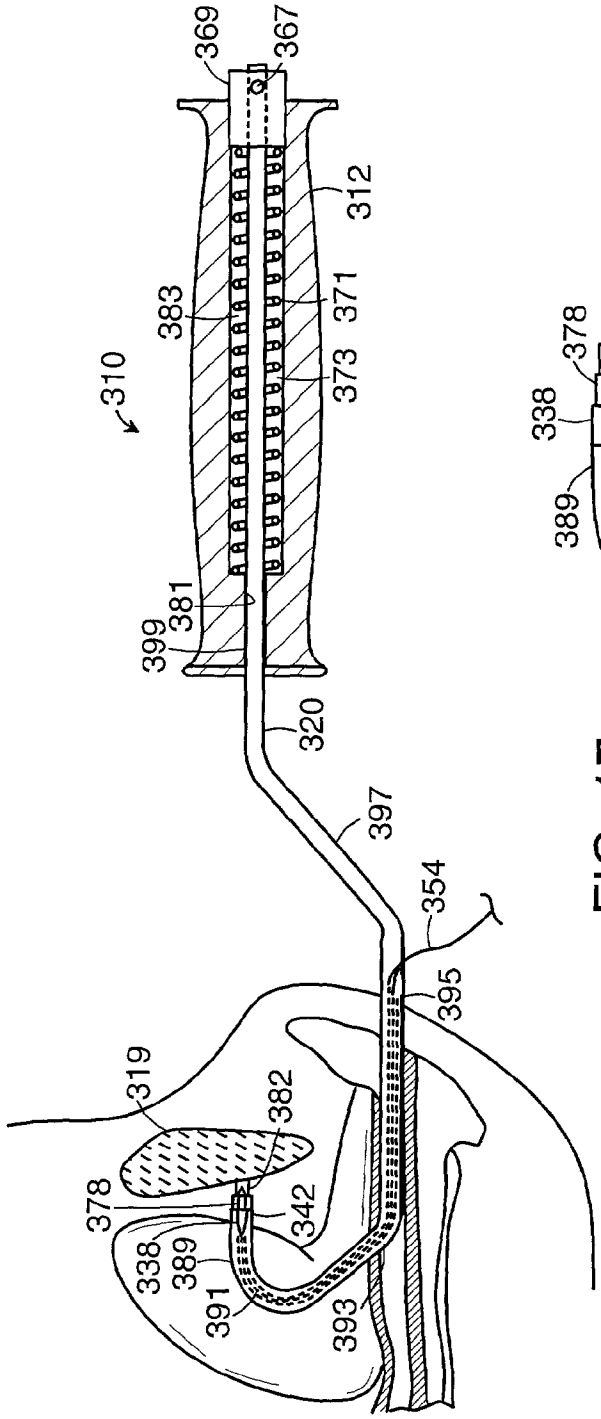
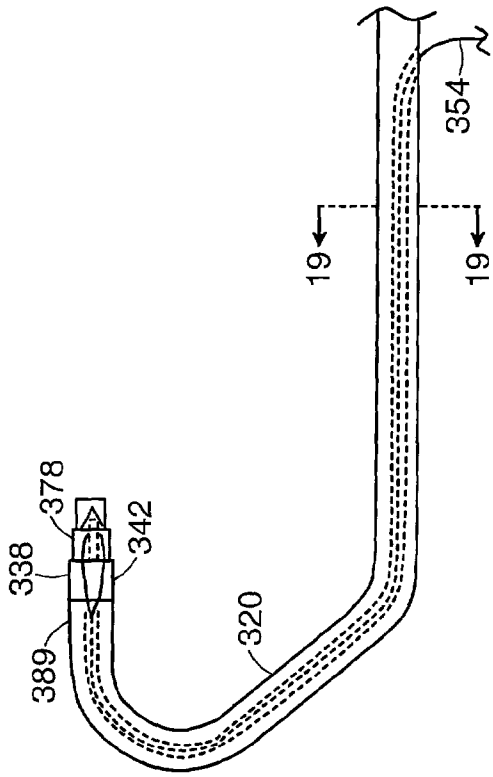


FIG. 17



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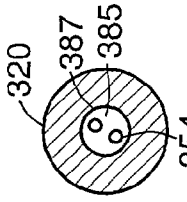

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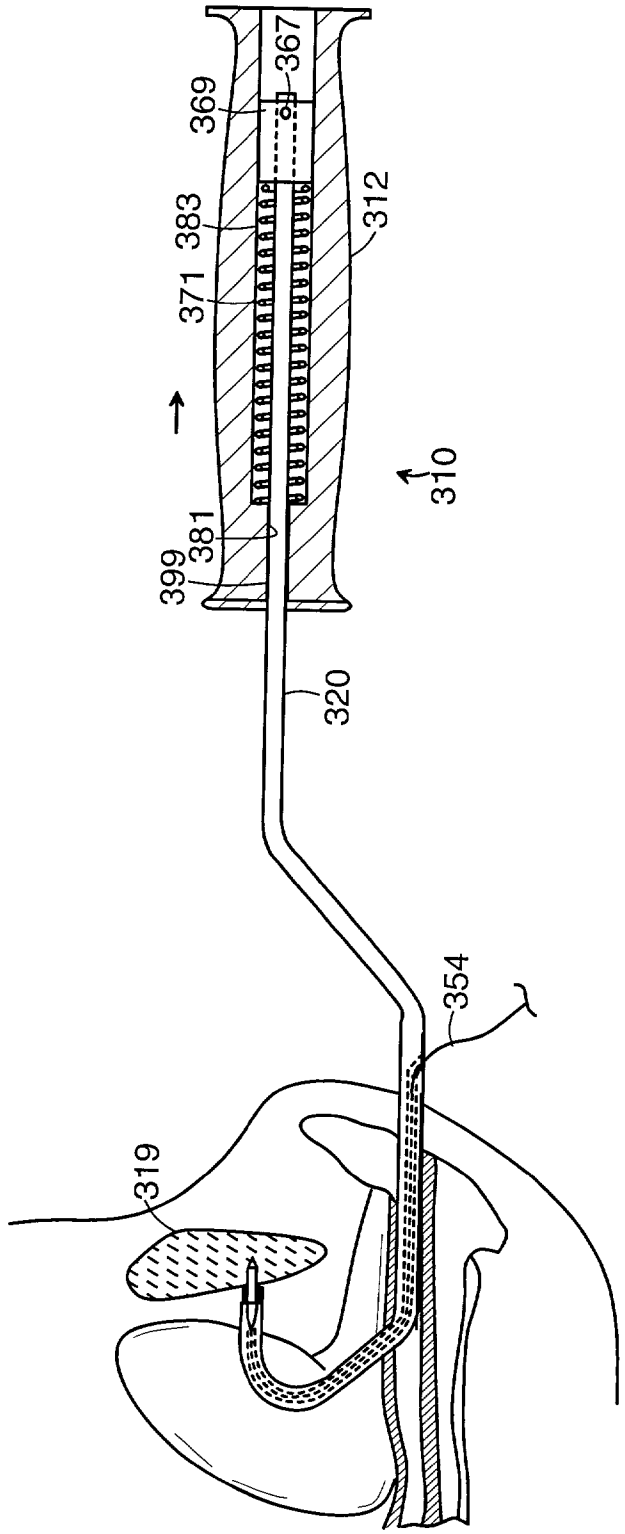

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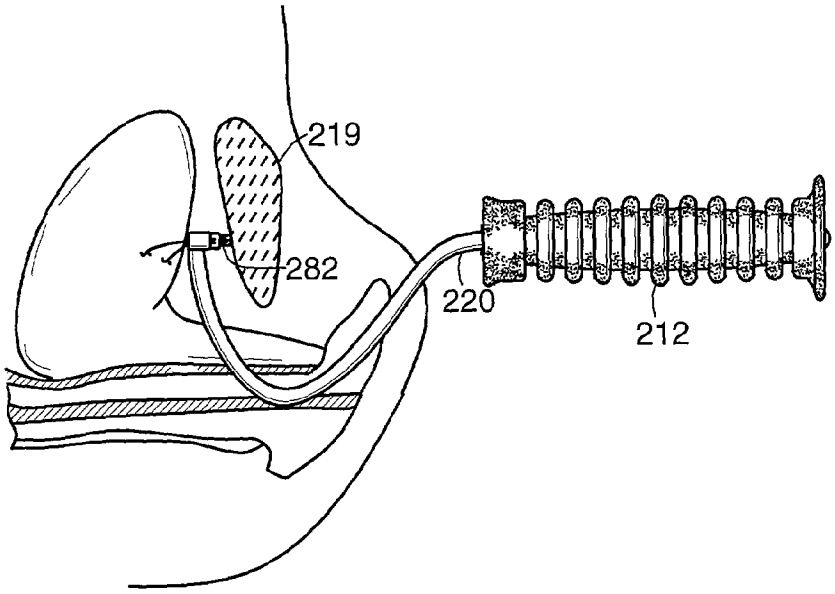

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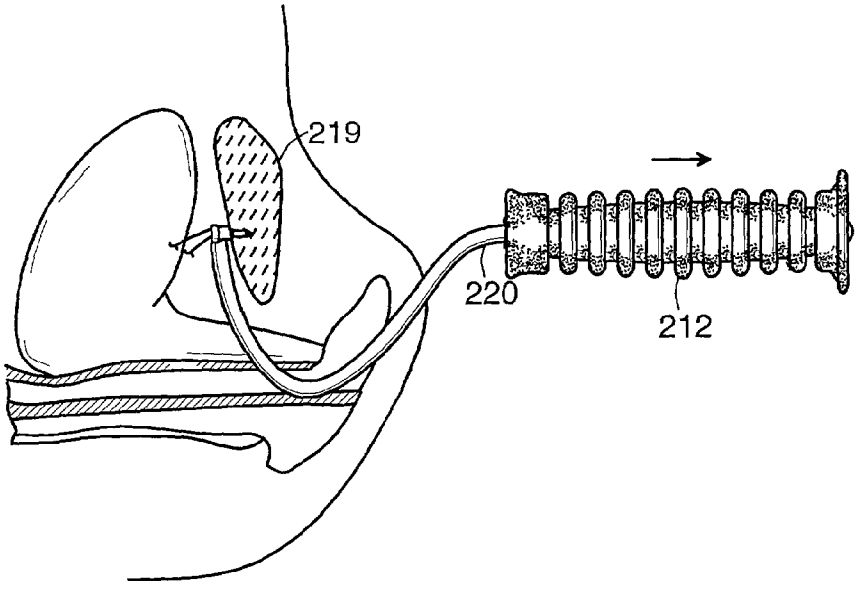
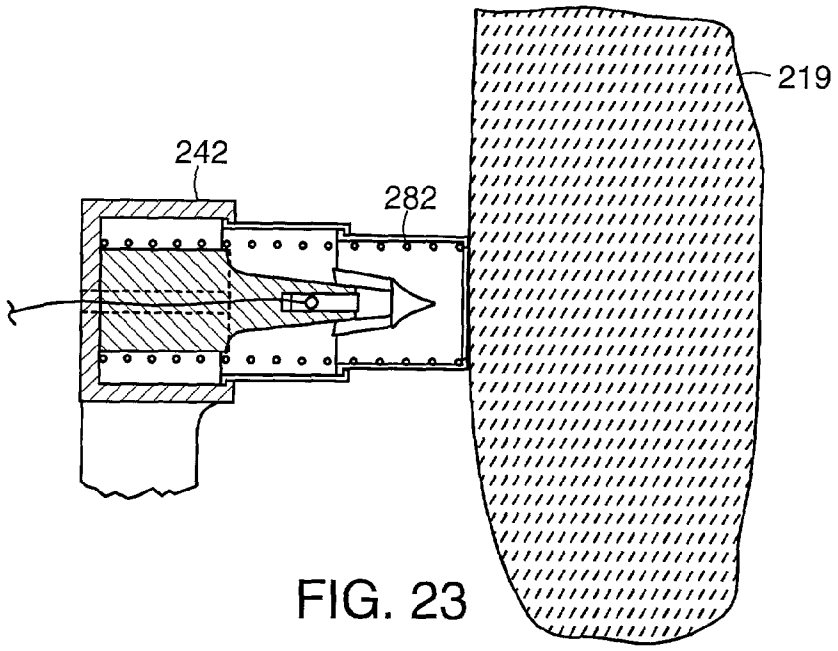


FIG. 22



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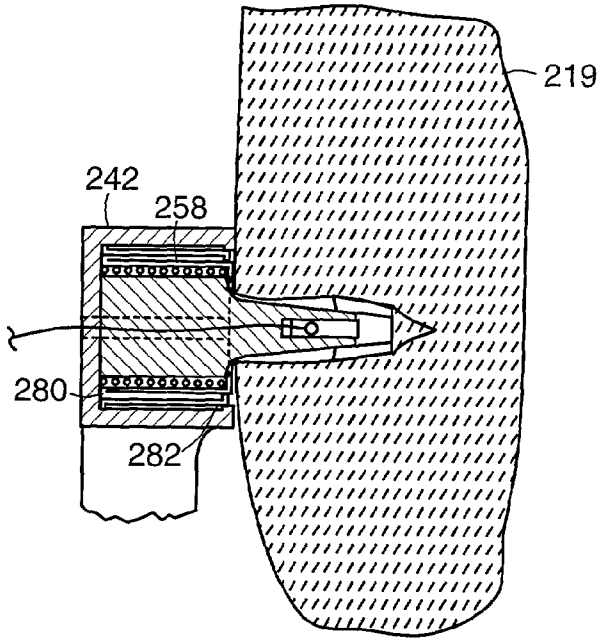

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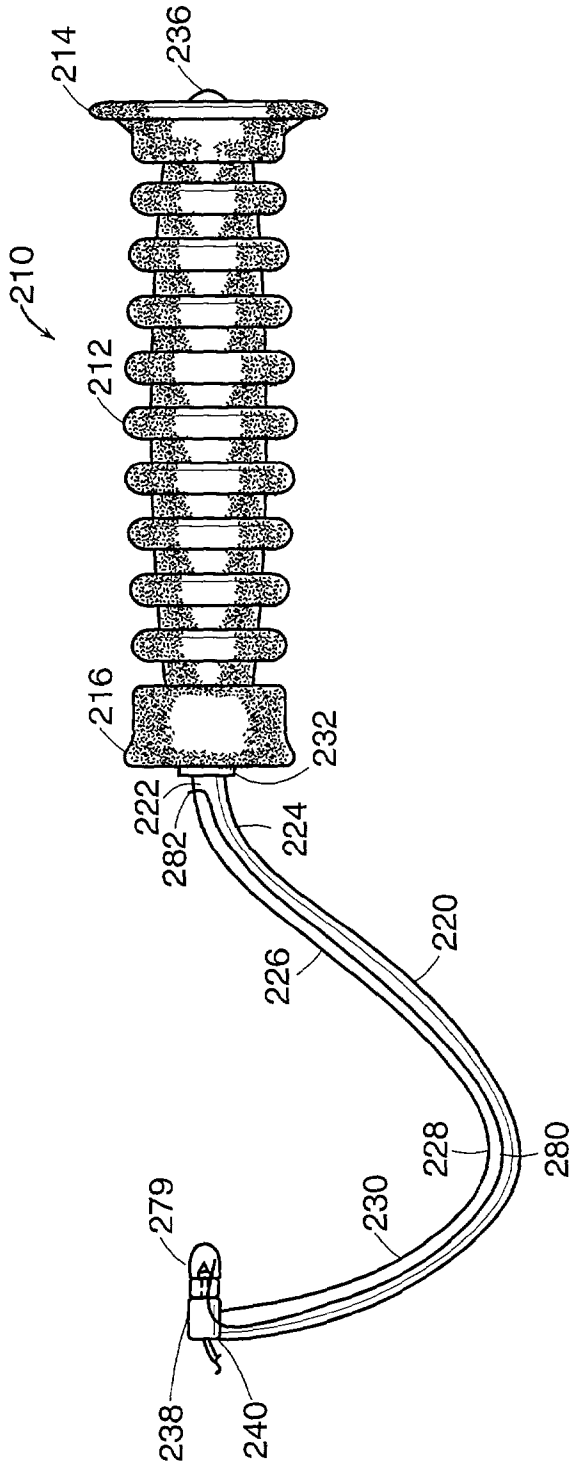
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FIG. 25

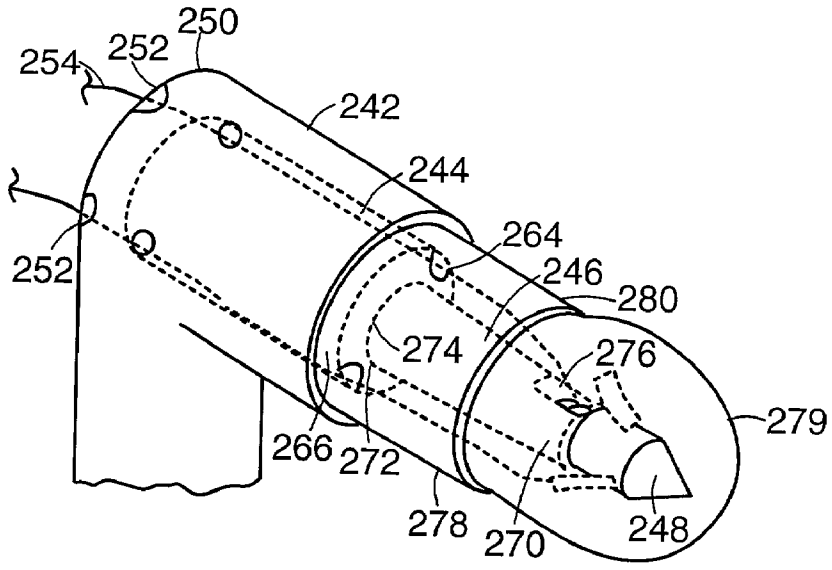

FIG. 26a

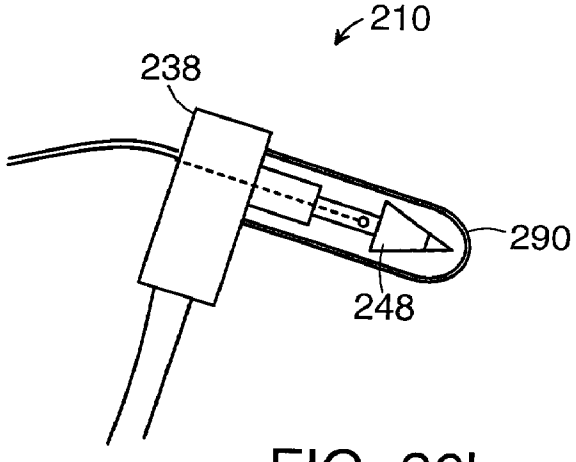

FIG. 26b

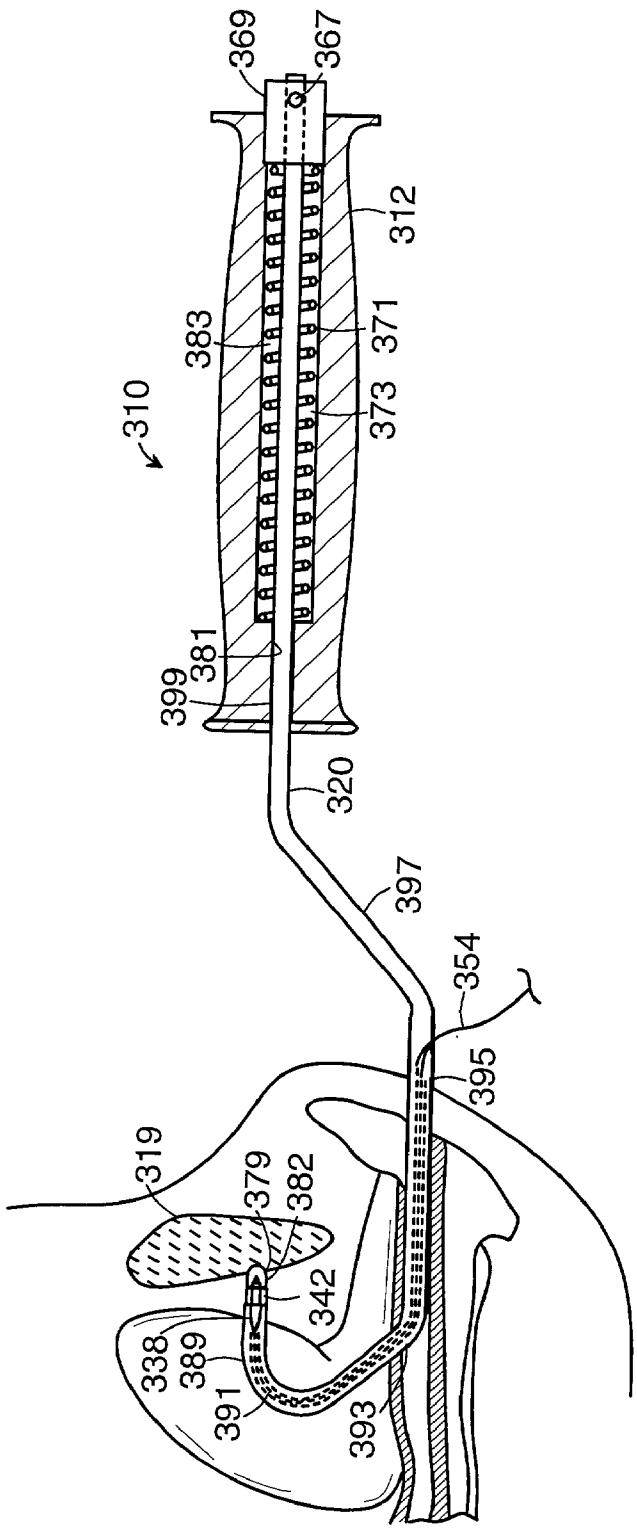
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FIG. 27

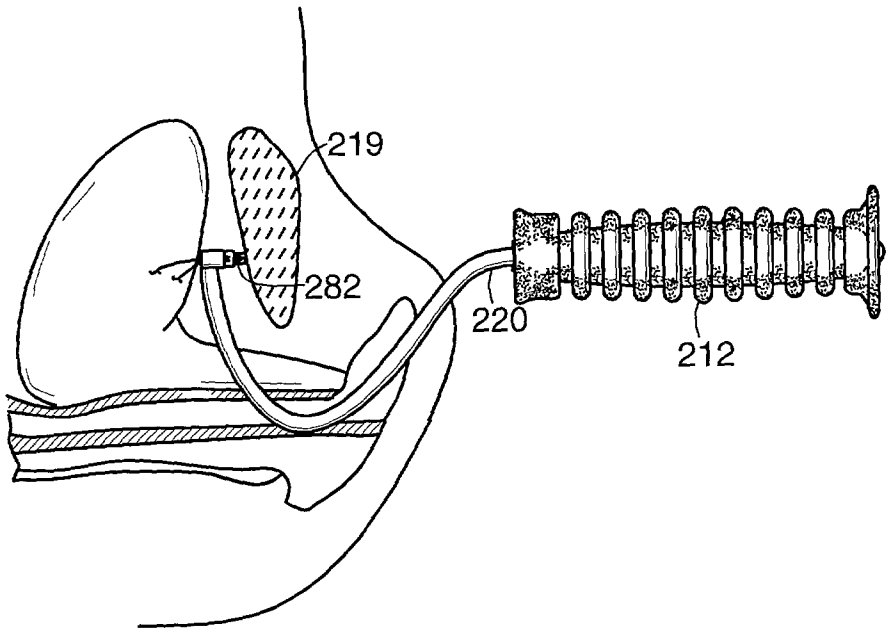
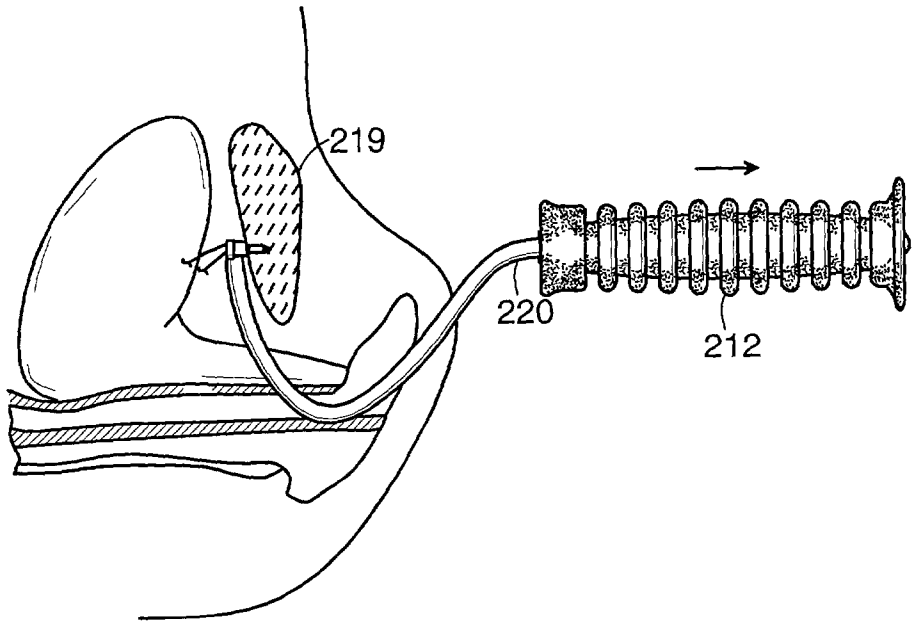


FIG. 28



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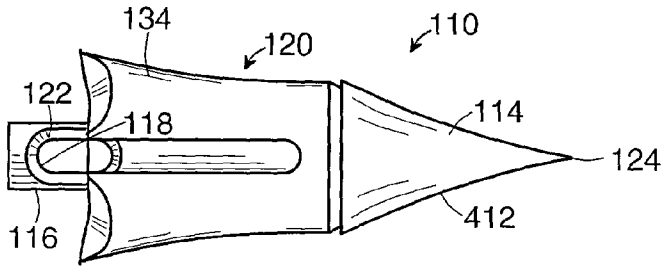
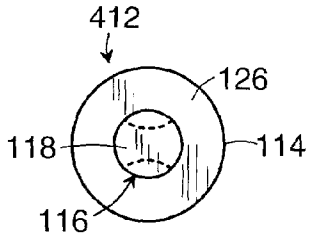


FIG. 30



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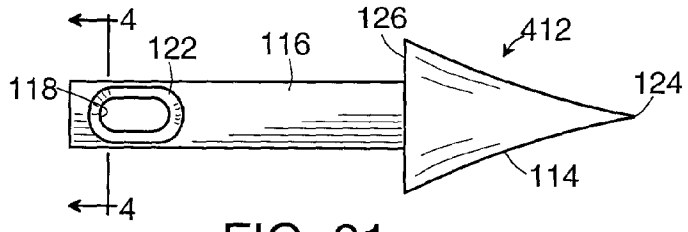

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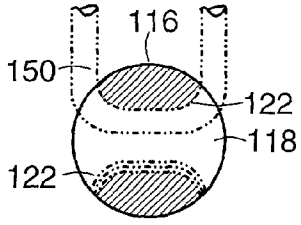


FIG. 33

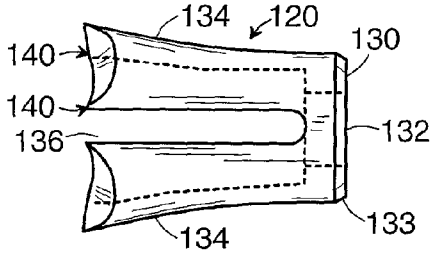


FIG. 34

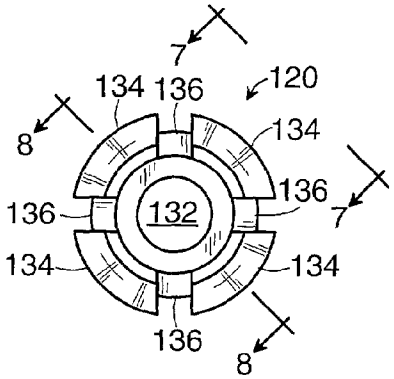
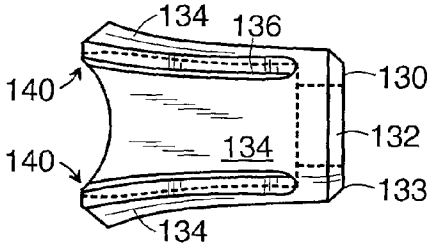


FIG. 35



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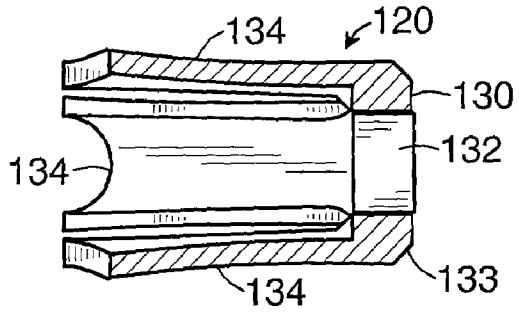

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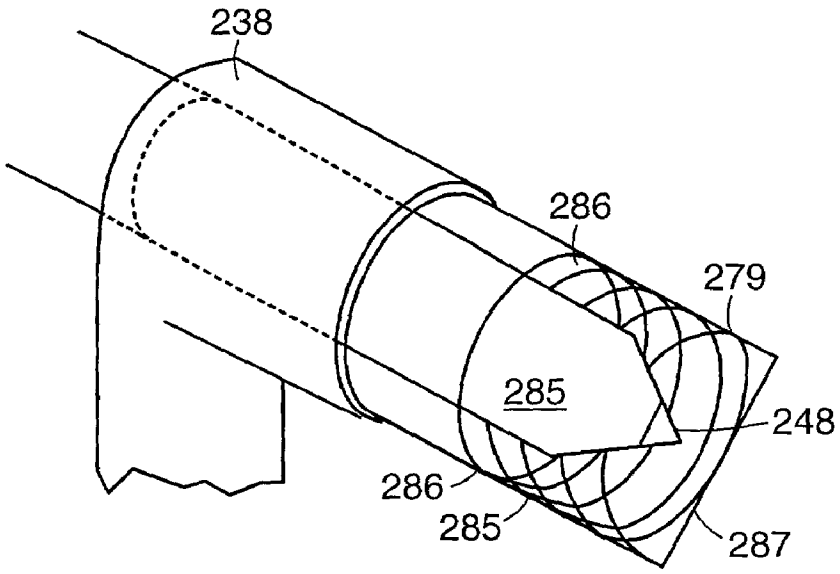

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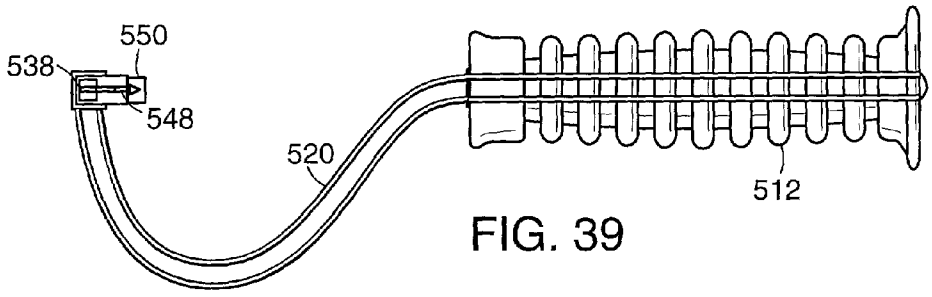

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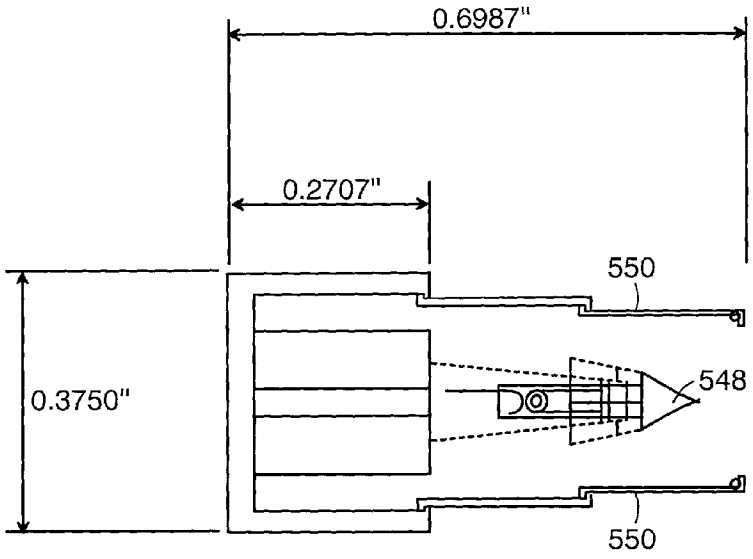

FIG. 40a

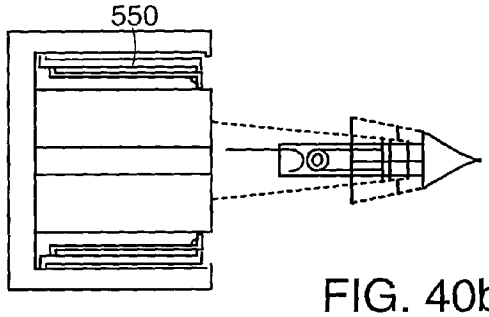

FIG. 40b

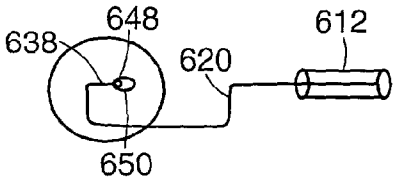

FIG. 41A

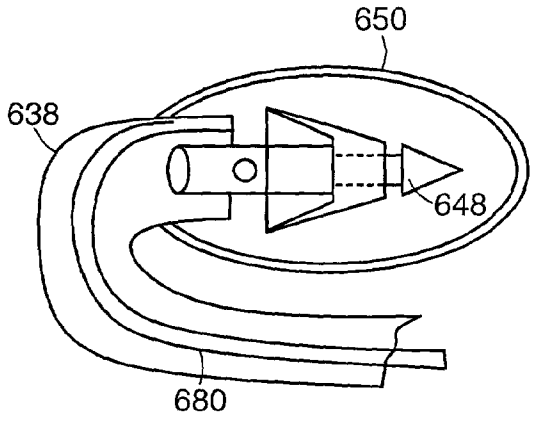

FIG. 41B

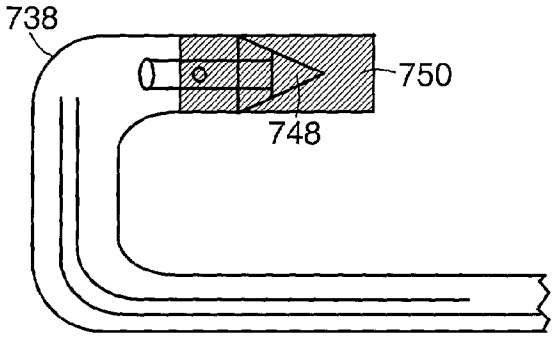

FIG. 42A

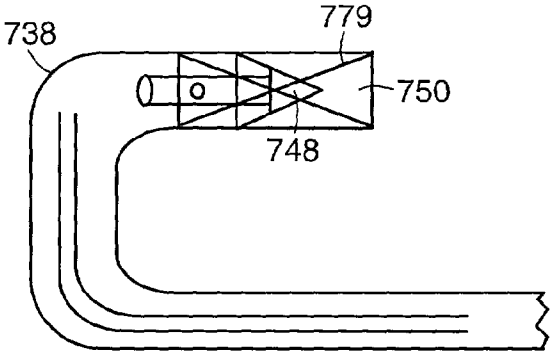

FIG. 42B

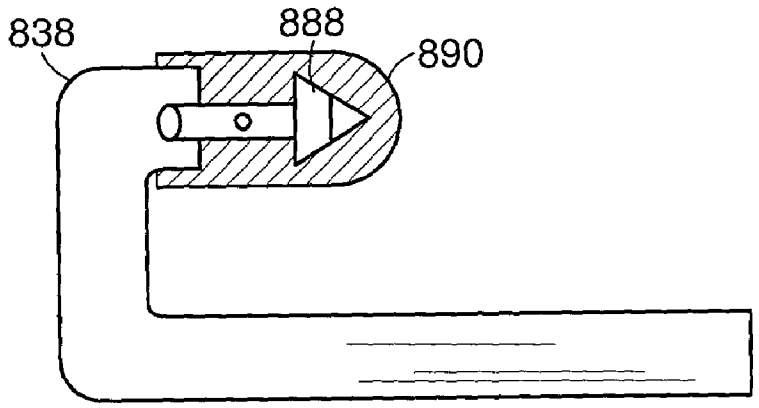

FIG. 43

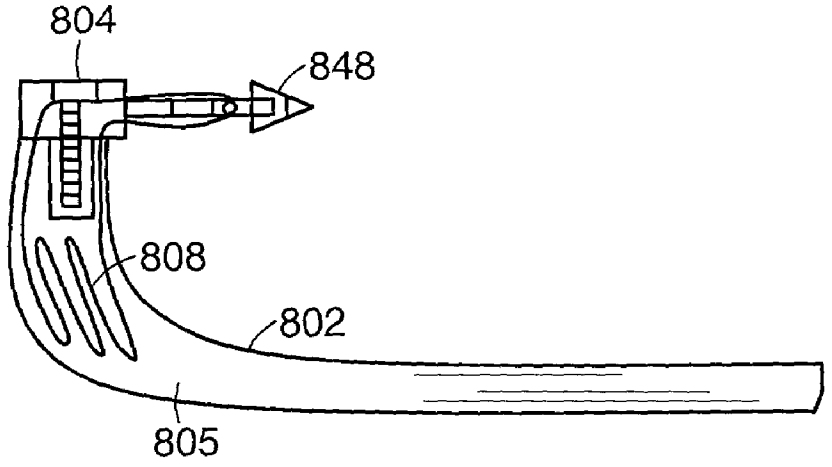

FIG. 44

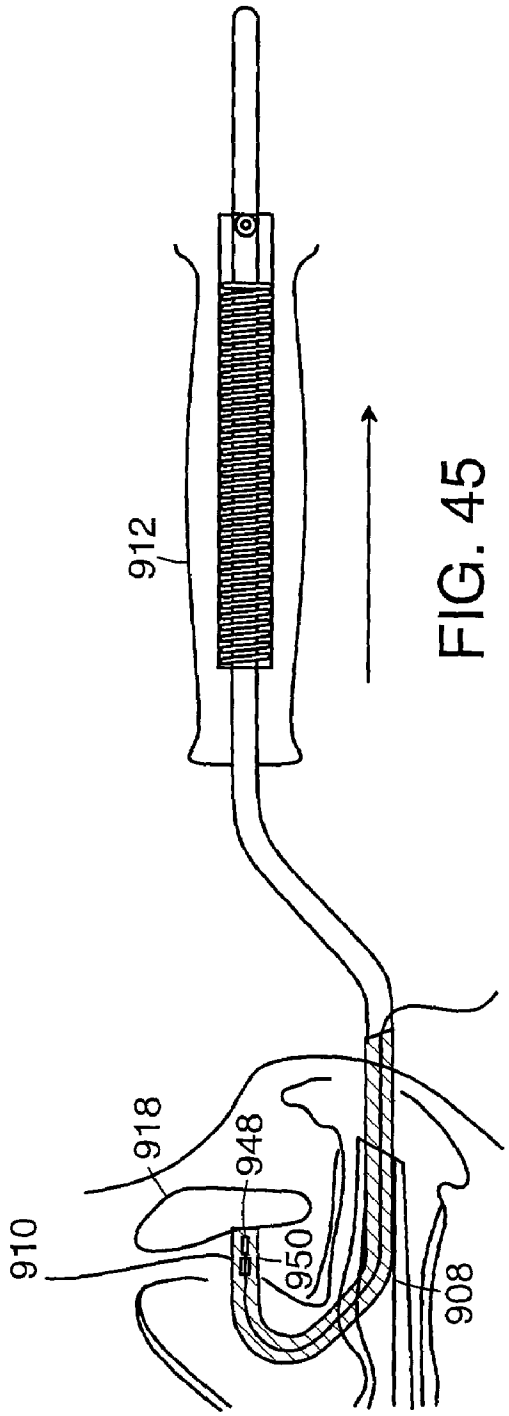

FIG. 45

PROTECTIVE SHEATH FOR TRANSVAGINAL ANCHOR IMPLANTATION DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This is a continuation-in-part of U.S. patent application Ser. No. 08/744,438 filed Nov. 8, 1996. This also is based on and claims priority to and the benefit of U.S. Provisional Patent Application Ser. No. 60/072,641 filed Jan. 27, 1998. The entirety of these two priority documents are hereby incorporated herein by reference.

TECHNICAL FIELD

[0002] This invention relates to a protective sheath or cap for a bone anchor implantation device. The bone anchor implantation device is used in maintaining or improving urinary continence.

BACKGROUND INFORMATION

[0003] Urinary incontinence, the inability to control urination from the bladder, is a widespread problem in the United States and throughout the world. Urinary incontinence affects people of all ages and can severely impact a patient both physiologically and psychologically.

[0004] In approximately 30% of the women suffering from urinary incontinence, incontinence is caused by intrinsic sphincter deficiency (ISD), a condition in which the valves of the urethral sphincter do not properly coapt. In approximately another 30% of incontinent women, incontinence is caused by hypermobility, a condition in which the muscles around the bladder relax, causing the bladder neck and proximal urethra to rotate and descend in response to increases in intraabdominal pressure. Hypermobility may be the result of child delivery or other conditions which weaken, stretch or tear the muscles. In an additional group of women with urinary incontinence, the condition is caused by a combination of ISD and hypermobility.

[0005] In males, urinary incontinence may be the consequence of post radical prostatectomy, which can destroy the valves of the urethral sphincter.

[0006] In addition to the conditions described above, urinary incontinence has a number of other causes, including birth defects, disease, injury, aging, and urinary tract infection.

[0007] Numerous approaches for treating urinary incontinence are available. In one procedure, referred to as bladder neck stabilization (BNS), sutures are placed around the muscles on either side of the urethra and affixed to the rectus fascia or pubic bone and tensioned to treat hypermobility. Other procedures which treat both hypermobility and intrinsic sphincter deficiency (ISD) involve the placement of a sling under the urethra/bladder which compresses the sphincter while simultaneously acting as a stabilizer of the bladderneck (preventing excessive downward mobility). The bone anchors which support the sling sutures may be inserted into rectus fascia or various locations on the pubis bone to provide a non-moveable anchoring method.

SUMMARY OF THE INVENTION

[0008] The present invention generally relates to devices and methods for inserting anchors, such as bone anchors, into a bone or tissue and more particularly to a protective sheath or cap for isolating the bone anchor to prevent both accidents with the sharp bone anchor before it is inserted into a target site and contamination of the target site by insertion of the bone anchor therethrough.

[0009] Bone anchors are often attached into bones in order to provide support for a "sling" useful in improving or maintaining a patient's urinary incontinence. In one procedure, a suture-carrying anchor is driven through the vaginal wall and into the posterior portion of the pubic bone or symphysis pubic, and the suture(s) attached to the bone anchor(s) extend through the vaginal wall and may be attached to the endopelvic fascia, the vaginal wall, a sling, or other material to stabilize and/or slightly compress the urethra thereby improving the patient's urinary incontinence. The present invention effectively addresses concerns in affixing an anchor to bone or tissue.

[0010] The present invention is directed to a protective sheath for the bone anchor. The protective sheath prevents accidents with the sharp bone anchor tip before insertion into the target site, and it prevents infection of the pubic bone. The protective sheath prevents exposure and accidental puncture of the surgeon's gloves as well as premature insertion into unintended tissue in the patient. It also provides a sterile barrier around the bone anchor. The protective sheath shields the bone anchor from contacting microorganisms in the vagina and area surrounding the implantation site during insertion. The protective sheath of the present invention ensures that the bone anchor implants into the bone implantation site free from contamination and thus prevents the occurrence of biological complications.

[0011] One aspect of the present invention is a bone anchor implantation device comprising an elongated member having a first end and a second end, and a related method. A bone anchor is releasably engaged to the elongated member in the vicinity of the first end. A protective sheath is mounted over the bone anchor. The protective sheath can be axially movable relative to the bone anchor such that the bone anchor is exposed from the sheath as the bone anchor is pressed into a bone by the elongated member. Alternatively, the protective sheath can be a balloon, gelatin structure, or other covering that encapsulates or covers the bone anchor prior to implantation. The balloon or thin film can be hermetically sealed around the bone anchor, but in any case the balloon isolates the bone anchor from contact with tissue and prevents contamination prior to implantation of the bone anchor. The balloon is perforated by the bone anchor as the bone anchor is pressed into the bone by the elongated member or shaft. The balloon may be made of a variety of materials such as plastic, thermoplastic, elastromers, PET, PETG, rubber, vinyl, latex, or silicone. In one preferred embodiment, the balloon is made of latex. The balloon can also be made of a biodegradable material. In another preferred embodiment, the balloon comprises a polymer such as a synthetic polymer. Nonlimiting examples of useful polymers include the following: polyglycolic acid (PGA), polyactic acid(PLA), poly (dioxanone)(PDO), poly (l-lactide) (LPLA), poly (dl-lactide)(DLPLA), poly (glycolide-co-trimethylene carbonate)(PGA-TMC), poly (l-lac-

tide-co-glycolide)(PGA-LPLA), poly (dl-lactide-co-glycolide) (PGA-DLPLA), poly(l-lactide-co-dl-lactide)(LPLA-DLPLA), poly(glycolide-co-trimethylene carbonate-co-dioxanone)(PDO-PGA-TMC), poly(ϵ-caprolactone), poly(dioxanone)(a polyether-ester), poly(lactide-co-glycotide), poly(SA-HDA anhydride), poly(orthoester), and polyglyconate. The protective sheath can also take the form of a gelatin structure (similar to a pill capsule).

[0012] In some embodiments, the protective sheath (e.g. balloon or gelatin structure) can contain an antibiotic which is released when the sheath is perforated by the bone anchor. The antibiotic prevents infection at the site where the bone anchor is pressed into the bone. Nonlimiting examples of antibiotics which can be used include the following: nafcillin, aminogylcoside, ciprofloxin, clindamcin, piperacillin/tazobactum, ampicillin/sulbactum, aminoglcoside, vancomycin, cephalosporin, TMP/SMX, ampicillin, gentaminicin, tobramycin, and ciprofloxacin. Those skilled in the art will appreciate that there are numerous ways to insert the antibiotic into the balloon or the gelatin structure. In one embodiment, the bone anchor implantation device has a port which extends from the first end to the second end of the shaft into the balloon or gelatin structure. Antibiotics can be inserted into the protective sheath through a port.

[0013] In general, in another aspect, the invention features a bone anchor implantation device which has a spring attached to the sheath within the balloon which retracts when the sheath is pressed against the bone by the shaft, thereby causing the bone anchor to perforate the balloon and implant into the bone. The spring element may be an open-coiled helical spring which surrounds the bone anchor. The spring element retracts when pressure is applied to the sheath causing the bone anchor to puncture the balloon.

[0014] In some embodiments, the shaft of the bone anchor implantation device can have a hollow section which accommodates one or more sutures coupled to the releasably engaged bone anchor. Also, the shaft preferably is hook shaped.

[0015] A method for inserting such a bone anchor that is releasably engaged to such a bone anchor implantation device can include the steps of locating a bone anchor implantation site on the bone and applying a retrograde force to the bone anchor to implant the bone anchor into the bone or to retract the spring to cause the bone anchor to perforate the sheath and implant into the bone.

[0016] The foregoing and other objects, aspects, features, and advantages of the invention will become more apparent from the following description and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] In the drawings, like reference characters generally refer to the same parts throughout the different views. Also, the drawings are not necessarily to scale, emphasis instead generally being placed upon illustrating the principles of the invention.

[0018] **FIG. 1** is a plan view of the bone anchor implantation device.

[0019] **FIG. 2** is an exploded view of the anchor implantation device.

[0020] **FIG. 3** is a cross-sectional view of the distal end of the cannula showing the protective cap therein taken along line **3-3** of **FIG. 2**.

[0021] **FIG. 4** is a cross-sectional view of the bone anchor implantation device of **FIG. 1** taken along line **4-4** of **FIG. 1**.

[0022] **FIG. 5** is a cross-sectional view of the bone anchor implantation in its locked configuration.

[0023] **FIG. 6** is a plan view of an alternate embodiment of the bone anchor implantation device having a keyhole-shaped bore in the second handle.

[0024] **FIG. 7** is a cross-sectional view taken along line **7-7** of the alternate embodiment shown in **FIG. 6** locked in the position in which the inserter shaft is fully extended from the cannula.

[0025] **FIG. 8** is a cross-sectional view of the alternate embodiment of **FIG. 6** locked in the position in which the inserter shaft is fully retracted within the cannula.

[0026] **FIG. 9** is a cross-sectional view of the distal end of the inserter shaft in the cannula showing location of the bone anchor implantation site by sliding the cannula along the endopelvic fascia.

[0027] **FIG. 10** is a cross-sectional view of the distal end of the inserter shaft and the cannula showing the inserter shaft penetrating the protective cap near the distal end of the cannula.

[0028] **FIG. 11** is a cross-sectional view of the distal ends of the inserter shaft in the cannula showing the bone anchor being drive into the bone.

[0029] **FIG. 12** shows the bone anchor with sutures extending therefrom after implantation into the bone.

[0030] **FIG. 13** is a side view of a bone anchor implantation device having a hooked shaft.

[0031] **FIG. 14** is an enlarged side view of a distal portion of the bone anchor implantation device taken along line **14-14** of **FIG. 13** showing the internal structure of the bone anchor mount.

[0032] **FIG. 15** is a perspective view of the bone anchor mount.

[0033] **FIG. 16** is a cross sectional view of the bone anchor mount of **FIG. 15** taken along line **16-16**.

[0034] **FIG. 17** is a schematic view showing the interior structure of the handle an alternate embodiment of the bone anchor implantation device inserted into the vagina with the proximal end of the second telescoping cylinder contacting the pubic bone.

[0035] **FIG. 18** is an enlarged view of the shaft of the alternate embodiment of the bone anchor implantation device illustrated in **FIG. 17**.

[0036] **FIG. 19** is a cross sectional view of the shaft of the bone anchor implantation device shown in **FIG. 18** taken along line **19-19** of **FIG. 18**.

[0037] **FIG. 20** is a schematic view showing the interior structure of the handle of an alternate embodiment of the bone anchor implantation device illustrated in **FIG. 17**

inserted into the vagina showing the implantation of a bone anchor into the pubic bone and the compression of the spring.

[0038] **FIG. 21** is a side view of the bone anchor implantation device of **FIG. 13** showing a protective sheath contacting the pubic bone.

[0039] **FIG. 22** is a side view of the bone anchor implantation device of **FIG. 13** showing the bone anchor implanted into the pubic bone.

[0040] **FIG. 23** is a cross sectional view of the bone anchor mount and protective sheath when the protective sheath is containing the pubic bone.

[0041] **FIG. 24** is a cross sectional view of the bone anchor mount and the protective sheath when the bone anchor is being implanted into the pubic bone.

[0042] **FIG. 25** is a side view of a bone anchor implantation device having a hooked-shaped shaft and a balloon.

[0043] **FIG. 26***a* is a perspective view of the bone anchor and a balloon.

[0044] **FIG. 26***b* is a perspective view of a bone anchor and a gelatin structure.

[0045] **FIG. 27** is a schematic view showing the interior structure of the handle of an alternate embodiment of the bone anchor implantation device with balloon inserted into the vagina with the proximal end of the second telescoping cylinder contacting the pubic bone.

[0046] **FIG. 28** is a side view of the bone anchor implantation device of **FIG. 25** showing a balloon contacting the pubic bone.

[0047] **FIG. 29** is a side view of the bone anchor implantation device of **FIG. 25** showing the bone anchor implanted into the pubic bone.

[0048] **FIG. 30** is a side elevational view of a bone anchor.

[0049] **FIG. 31** is a side elevational view of the spear member of bone anchor shown in **FIG. 30**.

[0050] **FIG. 32** is a rear elevational view of the spear member of the bone anchor shown in **FIG. 30**.

[0051] **FIG. 33** is an enlarged sectional view of a shaft of the spear member of the bone anchor taken along the lines **4-4** of **FIG. 31**.

[0052] **FIG. 34** is a side elevational view of a collar member of the bone anchor shown in **FIG. 30**.

[0053] **FIG. 35** is a rear elevational view of the collar member of the bone anchor shown in **FIG. 30**.

[0054] **FIG. 36** is a side elevational view of the collar member of the bone anchor taken along the direction of the lines **7-7** of **FIG. 35**.

[0055] **FIG. 37** is a sectional view of the collar member of the bone anchor taken along the lines **8-8** of **FIG. 35**.

[0056] **FIG. 38** is a perspective view of the bone anchor tip on a bone anchor implantation device having a balloon with a spring element.

[0057] **FIG. 39** is a side view of a bone anchor implantation device with a telescoping sheath.

[0058] **FIG. 40***a* is an enlarged view of the telescoping sheath of **FIG. 39** with the telescoping sheath in an expanded position.

[0059] **FIG. 40***b* is an enlarged view of the telescoping sheath of **FIG. 39** with the telescoping sheath in a retracted position.

[0060] **FIG. 41 a** is a view of a bone anchor implantation device with a balloon sheath.

[0061] **FIG. 41***b* is an enlarged view of the balloon sheath on bone anchor implantation device of **FIG. 41***a*.

[0062] **FIG. 42***a* is a view of a bone anchor implantation device with a latex sheath and a spring element.

[0063] **FIG. 42***b* is another view of the bone anchor implantation with a latex sheath and a spring element.

[0064] **FIG. 43** is a view of a bone anchor implantation device with a caplet sheath.

[0065] **FIG. 44** is a view of a bone anchor implantation device that has a lumen that can hold one or more sutures.

[0066] **FIG. 45** is a view of a bone anchor implantation device of **FIG. 39** inserted into the vagina showing the implantation of a bone anchor into the pubic bone.

DESCRIPTION

[0067] The present invention relates to a device for affixing a bone anchor to a bone. More particularly, the invention relates to a protective sheath for protecting the bone anchor from contacting tissue during implantation and thereby preventing contamination of the bone anchor. It also relates to methods for improving or maintaining a patient's urinary continence in which bone anchors are inserted transvaginally into the posterior portion of the pubic bone or symphysis pubis and devices for use in such methods. As used herein, the terms "transvaginally" or "transvaginal access" refer to access through the vaginal introitus or from within the vagina, as opposed to access from the patient's abdominal side.

[0068] As will be described in more detail below, the methods and devices of the present invention drive a bone anchor through the vaginal wall and into the posterior portion of the pubic bone or symphysis pubis. The public bone may also be accessed through a suprapublic bone incision. Preferably, at least one bone anchor is driven into the pubic bone on either side of the urethra. However, one of skill in the art will appreciate that a single bone anchor may also be used. The sutures attached to the bone anchors extend through the vaginal wall and may then be attached to the endopelvic fascia, the vaginal wall, a sling, or other material to stabilize and/or slightly compress the urethra, thereby improving or maintaining the patient's urinary continence.

[0069] Two Handle Bone Anchor Implantation Device

[0070] In one embodiment, the anchor implantation device has a first handle having an inserter shaft attached thereto. The inserter shaft is adapted to releasably engage or attach to a bone anchor. A second handle is hingedly attached to the first handle and has a cannula attached thereto. The cannula has a central bore extending therethrough. The cannula is aligned with the inserter shaft such that the inserter shaft is

inside the central bore of the cannula and is extendible from and retractable in the cannula. Preferably, a biasing member is disposed between the first handle and the second and biases the first handle and the second handle apart.

[0071] **FIGS. 1 and 2** provide a plan view and an exploded view of an anchor implantation device **10** for introducing a bone anchor **22** transvaginally and driving it into the pubic bone or symphysis pubis. The device comprises a first handle **12** having a proximal end **14**, a central region **16**, and a distal end **18**. The first handle **12** may be made of any relatively firm material, including plastic or metal. Preferably, the first handle **12** is made of plastic, aluminum, stainless steel, or titanium. However, those skilled in the art will appreciate that a wide range of other material may also be employed.

[0072] The first handle **12** may be configured in any of a variety of shapes compatible with vaginal insertion. Preferably, the first handle **12** is rectangular. However, those skilled in the art will appreciate that a variety of configurations may be employed, such as a handle which tapers towards the distal end, and the present invention contemplates the use of any handle configuration compatible with vaginal insertion.

[0073] The dimensions of the first handle **12** are also compatible with vaginal insertion. The first handle **12** may be from about 4 inches to about 8 inches in length, about 0.25 inches to about 1.25 inches in width, and about 0.05 inches to about 0.5 inches in height. Preferably, the first handle **12** is about 5 inches to about 7 inches in length, about 0.5 inches to about 1 inch in width, and about 0.1 inches to about 0.3 inches in height. More preferably, the first handle **12** is has a length of 6 inches, a width of 0.75 inches and a height of 0.2 inches.

[0074] An inserter shaft **20** adapted for releasably engaging a bone anchor **22** is located near the distal end **18** of the first handle **12**. A variety of bone anchors **22** can be used. In a preferred embodiment, illustrated in **FIG. 30** the bone anchor comprises a spear member **112** which is able to pierce and securely engage the bone. The spear member **112** has a generally cone shaped head portion **114** which is used to pierce the bone to which the and a shaft portion **116** with an oval eyelet **118** therethrough for receiving and holding a suture strand(s). To provide means for retaining the spear member **112** within the bone, the bone anchor **122** further comprises a collar member **120**. The collar member is used for retaining the bone anchor **122** in place, once it has been driven into the bone, by lodging within the bone in a manner to resist removal of the bone anchor **122**. The bone anchor **122** and its component parts are more fully described below.

[0075] The spear member **112** of the bone anchor **122** will now be described with additional reference to FIGS. **31-33**. The shaft portion **116** of the spear member **112** is generally cylindrical in shape and has the eyelet **118**, or bore, formed radially therethrough proximate one of its ends. The eyelet **118** may be oval, round or other suitable shapes and is of a sufficient size to permit suture strand or strands to pass therethrough. The circumference of each outer end of the eyelet **118** is chamfered or grounded to provide a bevel portion **122**. It should be appreciated that the bevel portion **122** provides a generally smooth surface for contacting suture strand which has been passed through the eyelet **118**. The eyelet **118** is located on the shaft portion **116** of the spear member **112** such that the transverse axis of the eyelet **118** intersect the longitudinal axis of the spear member **112**.

[0076] The generally cone-shaped head portion **114** of the spear member **112** is located at an end of the shaft portion **116** opposite the end having the eyelet **118**. As best shown in **FIGS. 30 and 31**, the apex of the cone-shaped head portion is a point **124** which is suitable for piercing and being driven into bone. The diameter of the cone-shaped head portion **114** increases, when viewed along a longitudinal direction rearwardly from the point **124** towards the shaft portion **116**. The cone angle along this region is preferably about **30** degrees. The diameter of the cone-shaped head portion **114** increases at a greater rate along approximately the rearward half thereof, when viewed along the same longitudinal direction. Thus, the rearward half of the cone-shaped head portion **114** arcs outwardly from the central longitudinal axis of the spear member **112**. As show in **FIGS. 31 and 32**, the base **126** of the cone-shaped head portion **114** is a ring-shaped planar surface which is oriented substantially perpendicular to the longitudinal axis of the shaft portion **116**.

[0077] Preferably, the cone-shaped head portion **114** is formed integrally with the shaft portion **116** of the spear member **112**. Alternatively, the cone-shaped head portion **114** and the shaft portion **116** may initially be formed separately and then subsequently attached to one another by any suitable means.

[0078] The collar member **120** of the bone anchor **122** will now be described with particular reference to **FIG. 30** and FIGS. **34-37**. The collar member **120** is provided with a ring-shaped generally planar forward surface **130** which is adapted to bear against, and mate with the base **126** of the cone-shaped head portion **114** of the spear member **112**. A circular bore **132** is located centrally through the planar forward surface **130** and is adapted to receive the shaft portion **116** of the spear member **112** therethrough. The circumference of the planar forward surface **130** may be, but is not necessarily, chamfered to formed a beveled outer rim portion **133**.

[0079] Four separate flanges **134** extend rearwardly from the planar forward surface **130** of the collar member **120** as shown in FIGS. **34-39**. The flanges **134** are separated from one another by longitudinally extending slots **136**. The portions of the flanges **134** which are proximate to the planar forward surface **130** run generally parallel to the central longitudinal axis of the collar member **120**. Each of the flanges **134** arcs generally outward from the central longitudinal axis as the flange **134** extends in a direction away from the planar forward surface **130**. The lateral width of each of the flanges **134** increases as the flange **134** extends in a direction away from the planar forward surface **130**. The extreme rearward end of each of the flanges **134** curves away from the planar forward surface **130** in the form a shallow C-shape, thereby providing two trailing tips **140** for each flange **134**.

[0080] As set forth above, the collar member **120** is rotatably fitted over the shaft portion **116** of the spear member **112** to form the assembled bone anchor **122** as shown in **FIG. 1**. While there is no need to permanently secure the collar member **120** to the spear member **112**, the planar forward surface **130** may nevertheless be securely attached to the base **126** of the cone-shaped head member

114 of the spear member **112** by any suitable means. It will be appreciated, however, that by permitting the spear member **112** to freely rotate with respect to collar member **120**, the suture strand **150** can be rotated by the surgeon after implantation to a position where the forces acting on the suture strand **150** by the bone anchor **122** are more evenly distributed around the region of the shaft portion **116** adjacent to the eyelet **118**. Such a position of the suture strand **150** is shown in **FIG. 33**.

[**0081**] In addition, it should also be appreciated that the two-piece construction of the bone anchor **122**, affords machining advantages over a single-piece bone anchor. That is, it is easier to machine each of these components separately and to subsequently assemble them together, as opposed to machining the same basic structural features from a single piece of material. Any known materials suitable for orthopedic anchor devices may be employed to construct the bone anchor **122** of the present invention. Preferably, the bone anchor **122** is formed from a metallic material possessing sufficient strength to penetrate the bone. Such materials include titanium 316 LVM stainless steel, CoCrMo alloy, Nitinol alloy, or other suitable materials. Preferably, the bone anchor is made of titanium.

[**0082**] Referring now back to **FIGS. 1 and 2**, the inserter shaft **20** has a distal end **24**, a central region **26**, and a proximal end **28**. Preferably, the inserter shaft extends at an angle of about 90° from the first handle **12**.

[**0083**] The inserter shaft **20** may be made of any of a variety of materials, including steel, stainless steel, aluminum, titanium, and plastic, but is preferably made of stainless steel. Additionally, the inserter shaft **20** may have a variety of cross sectional shapes including rectangular, hexagonal, or triangular but preferably the inserter shaft **20** has a circular cross section.

[**0084**] The inserter shaft **20** maybe located from about 0.05 inches to about 0.5 inches from the distal end **18** of the first handle **12**. preferably, the inserter shaft **20** is located from about 0.1 inches to about 0.3 inches from the distal end **18**. More preferably, the inserter shaft **20** is located 0.2 inches from the distal end **18** of the handle.

[**0085**] The length of the inserter shaft **20** is consistent with transvaginal delivery of the releasable bone anchor **22**. Thus, the inserter shaft **20** maybe from about 0.5 inches to about 1.5 inches long. Preferably, the inserter shaft **20** is from about 0.75 inches to about 1.25 inches in length. More preferably, the inserter shaft **20** is 1 inch in length.

[**0086**] Preferably, the proximal end **28** and the central region **26** of the inserter shaft **20** have an equal cross sectional area, which is larger than the cross sectional area of the bone anchor **22** and distal end **24**. Thus, a shoulder **17** is formed at the junction between the central region **25** of the inserter shaft and the distal region of the inserter shaft. The shoulder **17** acts as a stop which will not penetrate the cortical shell of the bone.

[**0087**] The diameter of the inserter shaft is dependent upon the size of the bone anchor. In embodiments in which the inserter shaft **20** is cylindrical, the diameter of the proximal end **28** and central region **26** of the inserter shaft is from about 0.1 inches to about 0.3 inches, and that of the distal end **24** is from about 0.04 inches to about 0.2 inches. Preferably, the diameter of the proximal end **28** and central region **26** of the inserter shaft is from about 0.15 inches to about 0.25 inches, and that of the distal end **24** is from about 0.07 inches to about 0.11 inches. More preferably, the diameter of the proximal end **28** and central region **26** of the inserter shaft is 0.2 inches and that of the distal end **24** is 0.09 inches.

[**0088**] Preferably, the inserter shaft **20** is curved as shown in **FIGS. 1 and 2**. As will be appreciated by those of skill in the art, the inserter shaft **20** may also be straight. In those embodiments in which the inserter shaft **20** is curved, the radius of curvature of the inserter shaft **20** is the distance between the pivot point of the hinge and the center of the inserter shaft. The radius of curvature of the inserter shaft **20** may be from about 3.5 inches to about 7.9 inches. Preferably, the radius of curvature of the inserter shaft **20** is from about 4.7 inches to about 6.9 inches. More preferably, the radius of curvature of the inserter shaft **20** is 5.8 inches.

[**0089**] The distal end **24** of the inserter shaft **20** is adapted to releasably engage a bone anchor **22**. In one embodiment, the bone anchor **22** is housed within a notch **30** at the distal end **24** of the inserter shaft, and frictionally engages the inner wall of the distal end **24** of the inserter shaft. However, it will be appreciated by those of skill in the art that the inserter shaft **20** may releasably engage the bone anchor **22** through a variety of means other than that described above, and such means are specifically contemplated by the present invention.

[**0090**] The distal end **24** of the inserter shaft maybe hollow or solid and has a complementary shape to the proximal end of the bone anchor **22** to permit the bone anchor **22** to frictionally engage the distal end **24** of the inserter shaft. For example, the distal end **24** of the inserter shaft and the proximal end of the bone anchor may be square, rectangular, pentagonal, triangular or hexagonal in cross section. Preferably, the distal end **24** of the inserter shaft and the proximal end of the bone anchor are cylindrical. However, those skilled in the art will appreciate that numerous shapes may be employed, and the present invention specifically contemplates any such shape.

[**0091**] The central region **26** of the inserter shaft has a pair of grooves **32** therein for receiving a suture **54** attached to the bone anchor as illustrated in **FIGS. 1 and 2**. Preferably, the grooves **32** in the inserter shaft are coextensive with slots **34** in the outer cannula and are aligned with the slots **34**.

[**0092**] The device also comprises a second handle **36** hingedly connected to the first handle **12** and having a proximal end **38**, a central region **40**, and a distal end **42**. The second handle **36** may be fabricated from any of the materials discussed above with regard to the first handle **12**. Additionally, the second handle **36** may have any of the dimensions and shapes discussed above with regard to the first handle **12**. The preferred materials, dimensions, and shapes for the second handle **36** are the same as those discussed above with regard to the first handle **12**.

[**0093**] The second handle **36** has a cannula **44** positioned near its distal end **42** and fixed within a bore **11** in the second handle by screws **13**. The cannula **44** has a proximal end **46**, a central region **48**, and a distal end **50**, with a central bore **52** running through its entire length. Preferably, the cannula **44** extends at an angle of about 90° from the second handle **36**.

[0094] The cannula **44** may be fabricated from any of the materials described above with regard to the inserter shaft **20**. Preferably, the cannula **44** is made of stainless steel.

[0095] The cannula **44** may have any of the shapes discussed above with regard to the inserter shaft **20**. Preferably, the shape of the cannula **44** is the same as that of the inserter shaft **20**.

[0096] The cannula **44** is located approximately the same distance from the distal end **42** of the second handle as the inserter shaft **20** is from the distal end **18** of the first handle and the central bore **52** of the cannula has an inner diameter larger than the outer diameter of the inserter shaft **20**. In this way, the inserter shaft **20** extends into the central bore in the cannula as depicted in **FIG. 1**. The inserter shaft **20** is extendible and retractable relative to the cannula **44**.

[0097] Preferably, the cannula **44** has two oppositely disposed slots **34** therein through which the suture **54** attached to the bone anchor passes. These slots reduce the possibility of the suture **54** becoming tangled. Preferably, the slots **34** in the cannula are aligned with and coextensive with the grooves **32** in the inserter shaft.

[0098] Alternatively, the sutures can be contained within the cannula and extend out another portion of the device such as the first handle **12**.

[0099] Preferably, the distal end **50** of the cannula has a sharp tip **56** to facilitate its use in piercing tissue.

[0100] As illustrated in **FIGS. 1 and 2**, in the embodiments in which the inserter shaft **20** is curved, the cannula **44** is preferably also curved in the same arc as the inserter shaft **20**. By curving the cannula **44**, the diameter of the cannula **44** can be reduced in comparison with embodiments in which the inserter shaft and the cannula are not curved. Thus, in the embodiments in which the inserter shaft **20** and cannula **44** are curved, the inner diameter of the cannula **44** is from about 0.1 inches to about 0.25 inches and the outer diameter of the cannula **44** is from about 0.14 inches to about 0.31 inches. Preferably the inner diameter of the cannula **44** is from about 0.15 inches to about 0.2 inches. In a highly preferred embodiment, the inner diameter of the cannula is 0.170 inches, the wall is about 0.02 inches, and the outer diameter is about 0.210 inches. These dimensions also apply to the devices in **FIGS. 5 and 6** in which the inserter shaft and the cannula are also curved.

[0101] In a preferred embodiment, the cannula **44** has a protective cap **58** inside the central bore **52** and located at the distal end **50** of the cannula, as shown in **FIGS. 2, 3** and **5**. The protective cap **58** may be made of a variety of materials, such as plastic, thermoplastic elastomers, PET, PETG, rubber material, vinyl, gelatin, latex, thermoset rubbers and silicone. Preferably, the protective cap **58** is made of silicone or plastic.

[0102] The internal protective cap **58** acts to shield the bone anchor **22** from contamination, e.g., from contact with microorganisms in the vagina which could cause infection if introduced into the pubic bone during implantation of the bone anchor. In one embodiment, the protective cap **58** has a vertical slit **60** and a horizontal slit **62** therein which intersect to form a cross. Alternatively, the protective cap **58** has slits three slits which intersect to form a Y.

[0103] In one embodiment, the slits **60** and **62** penetrate entirely through the material of the protective cap **58**, thereby dividing the protective cap into discrete segments. Preferably, the slits **60** and **62** are scored in the material of the protective cap **58** but do not extend entirely therethrough.

[0104] The slits **60** and **62** permit the bone anchor **22** to move through the protective cap **58** during implantation. In embodiments in which the slits **60** and **62** penetrate entirely through the material of the protective cap **58**, the bone anchor **22** forces the segments of the protective cap **58** to separate as the bone anchor **22** is extended through the protective cap **58**. The protective cap **58** remains in contact with the external surface of the bone anchor **22** as it is inserted into the bone, thereby shielding the bone anchor from contact with potentially infectious microorganisms in the vaginal wall.

[0105] The operation of the protective cap **58** in embodiments in which the slits **60** and **62** are scored in the protective cap is identical to that described above. However, in such embodiments, the tip of the bone anchor **22** pierces the material of the protective cap **58** as the bone anchor **22** is extended, thereby causing the protective cap **58** to separate into segments along the scores.

[0106] The proximal ends of the first and second handles, **14** and **38** respectively, are hingedly connected to permit them to move towards and away from one another. Any suitable type of hinge can be used, for example, this can be accomplished using a hinge **64** similar to that commonly found on doors as shown in **FIGS. 1 and 2**. Alternatively, a piece of rubber may be interposed between the first and second handles at their proximal ends **14** and **38** and secured thereto by bolts extending into holes in each of the handles. Those skilled in the art will appreciate that other means of hingedly connecting the first and second handles may be employed, and the present invention specifically contemplates embodiments in which such other hinging mechanisms are employed.

[0107] The first handle **12** and the second handle **36** are biased apart. In one embodiment, the biasing force is provided by a spring **66**, as discussed below. The spring **66** can be metal, resilient polymer, pneumatically driven, or of any other suitable design. However, those skilled in the art will appreciate that a number of other structures can be employed to achieve the same biasing effect. The present invention specifically contemplates such other means of biasing the handles apart.

[0108] When sufficient force is applied to the distal ends of the first and second handles (**18** and **42**) to overcome the resistance of the spring, the distal ends (**18** and **42**) of the first and second handles move closer together. In the position in which the distal ends of the first and second handles are maximally separated, the inserter shaft **20** and bone anchor **22** thereon are fully retracted inside the cannula **44**. As increasing force is applied to the handles and the distal ends approach one another, the inserter shaft **20** and bone anchor **22** thereon emerge from the distal end **50** of the cannula. At the point where the distal ends (**18** and **42**) of the first and second handles are touching, the inserter shaft **20** and bone anchor **22** thereon are maximally extended from the distal end **50** of the cannula.

[0109] At the point of maximum extension, the length of the inserter shaft **20** extending from the cannula **44** is from

about 0.05 inches to about 0.8 inches. Preferably, at the position of maximum extension, the length of the inserter shaft **20** extending from the cannula **44** is about 0.1 inches to about 0.5 inches. More preferably, the length of the inserter shaft **20** extending from the cannula **44** at the position of maximum extension is 0.2 inches.

[**0110**] In the above embodiment, the bone anchor **22** is inserted in the bone by manually moving the inserter shaft **20** axially through the bore **52** in the cannula until the inserter shaft and bone anchor **22** thereon extend from the cannula **44**. However, the those skilled in the art will appreciate that approaches other than manually moving the inserter shaft may also be used to implant the bone anchor into the bone. For example, the bone anchor **22** can be forced into the bone by applying sufficient pneumatic pressure through the inserter shaft to eject the bone anchor from the inserter shaft with sufficient force to implant the bone anchor in the bone. Alternatively, the bone anchor may be driven into the bone by a spring mechanism.

[**0111**] Preferably, the device further comprises a locking mechanism for locking the device in the position in which the inserter shaft is fully retracted within the cannula in order to avoid accidental insertion of the bone anchor into tissue. As those skilled in the art will appreciate, a variety of locking structures may be used to achieve such locking.

[**0112**] One exemplary locking mechanism is shown in **FIG. 2**. The locking mechanism comprises a locking plate **15** slidably mounted over the first handle **12** and having a bore **68** therein. The locking plate **15** is separated from the first handle **12** by a spacer **70** having an internally threaded bore **72** therein which is aligned with the bore **68** in the locking plate. The first handle **12** has an elongate hole **74** herein having a proximal end **75** and a distal end **77**. A locking screw **76** extends through the elongate hole **74** in the first handle and the bores **72**.**68** in the spacer **70** and locking plate **15**. The locking screw **76** is secured to the locking plate **15** by a nut **78**.

[**0113**] The second handle **36** has a bore **80** therethrough having a diameter larger than that of the head of the locking screw **76**. In the unlocked position, the bore **80** can be aligned with the locking screw **76** as shown in **FIG. 4** thereby permitting the first handle **12** and the second handle **36** to be squeezed together such that the inserter shaft **20** extends from the cannula **44**.

[**0114**] As illustrated in **FIG. 5**, in the locked position, the locking plate **15** is positioned at the proximal end **75** of the elongate hold **74** in the first handle. In this position, the locking screw **76** is disposed between the first and second handles such that the head of the screw abuts the inner side of the second handle **36**, thereby preventing the first handle **12** and the second handle **36** form being squeezed together.

[**0115**] In an alternate embodiment, the bone anchor implantation device **110** may have a dual position lock permitting the device to be locked in a position in which the inserter shaft **120** is fully retracted within the cannula **144** or in a position in which the inserter shaft **120** is fully extended from the cannula **144**. In this embodiment, illustrated in **FIG. 6** the bore **180** of the second handle **136** is keyhole shaped. The narrower part **121** of the keyhole shaped bore is sufficiently narrow to prevent the head of the locking screw **176** from passing therethrough. As illustrated in **FIG. 7**, when the locking plate **115** is positioned at the proximal end **175** of the elongate bore in the first handle, the head of the locking screw **176** is over the narrow part **121** of the keyhole shaped aperture **180**. As shown in **FIG. 7**, in this position the inner side of the head of locking screw **176** contacts the outer side of the second handle. The device is locked in the position in which the inserter shaft and bone anchor thereon are fully extended.

[**0116**] When the locking plate **115** is positioned at the distal end **177** of the elongate bore in the first handle, the head of locking screw **176** is aligned with the wide portion **123** of the keyhole shaped bore. The locking plate **115** can then be returned to the proximal end **175** of the elongate hole, such that the head of the locking screw **176** is disposed between the first handle **112** and the second handle **136** and the head of the locking screw **176** abuts the inner side of the second handle **136**, as shown in **FIG. 8**. In this position the inserter shaft **120** is fully retracted and the first handle **112** and the second handle **136** cannot be squeezed together.

[**0117**] The above locking mechanisms may be used in the embodiments where the inserter shaft and cannula are straight. As those skilled in the art will appreciate, a variety of other locking structures may be used to achieve such dual position locking. Such other locking mechanisms are specifically contemplated by the present invention.

[**0118**] In the embodiments described above, the force biasing the two handles apart is preferably provided by a spring **66** disposed between two depressions **82** and **84** in the first handle **12** and the second handle **36**. In the embodiments described above, the spring **66** is located in the central regions **16** and **40** of the first and second handles. However, those skilled in the art will appreciate that the location of the spring is not critical to the operation of the present invention. Additionally, it will be appreciated that biasing members other than a spring may be employed to bias the handles apart.

[**0119**] Using the present bone anchor implantation device, the bone anchor is transvaginally introduced into the pubic bone as follows.

[**0120**] After making an incision in the anterior vaginal wall, the endopelvic fascia is accessed using techniques well known to those of skill in the art, such as with a conventional retractor. A Foley catheter may be introduced to assist in locating the bladder neck. The bone anchor implantation device is inserted into the vaginal introitus and the first desired site for bone anchor implantation is located by digital palpation of the urethra, pubic symphysis or other anatomical landmark or other techniques known to those of ordinary skill in the art. The device is locked in the position in which the inserter shaft is fully retracted during this procedure.

[**0121**] Once the desired site for bone anchor implantation is located, the sharp tip **56** on the distal end of the cannula is driven through the endopelvic fascia **17**. The pointed end of the cannula can also be employed to locate the desired implantation site by inserting the device into the vaginal introitus and through the incision, piercing the endopelvic fascia, and moving the cannula along the pubic bone **19** to the desired implantation site, as shown in **FIG. 9**.

[**0122**] The device is then unlocked from the position in which the inserter shaft **20** is fully retracted. In the embodi-

ment having a single position lock, the first and second handles (**12** and **36**) are pressed together with enough pressure to extend the inserter shaft **20** out of the cannula **44** and drive the bone anchor **22** into the posterior portion of the bone **19**. Alternatively, in the embodiment having a dual position lock, the device is locked in the position in which the inserter shaft **120** is fully extended from the cannula **144** and the manual pressure is applied to drive the bone anchor **122** into the posterior portion of the pubic bone **19**.

[**0123**] As shown in **FIG. 10**, when the first and second handles are squeezed towards one another, the inserter shaft moves towards the bone **19**. The bone anchor **22** pierces the protective cap **58** which separates as the bone anchor **22** passes therethrough. The protective cap **58** shields the bone anchor **22** from contact with the vaginal tissue.

[**0124**] As shown in **FIG. 11**, when the inserter shaft **20** is extended beyond the distal tip of the cannula **56**, the bone anchor contacts the bone **19** and is driven therein.

[**0125**] The inserter shaft **20** is then retracted into the cannula **44**, leaving the bone anchor **22** implanted in the bone **19** with the attached suture **54** extending through the wound in the vaginal wall and the endopelvic fascia as shown in **FIG. 12**.

[**0126**] The above site location and bone anchor implantation procedure is repeated to implant a second bone anchor on the opposite side of the urethra from the first bone anchor.

[**0127**] In one embodiment, the sutures are attached to a needle, looped back through the vaginal wall, and attached to tissue such as the endopelvic fascia or the vaginal wall so as to bias the tissue surrounding the urethra towards the urethra. The biasing force compresses or stabilizes the bladder neck thereby maintaining or improving urinary continence.

[**0128**] Alternatively, the sutures attached to the bone anchors can be attached to a sling which compresses or stabilizes the bladder neck. In such procedures, an incision is made midline to the urethra. An opening or pocket for receiving the sling is created in the tissue between the urethra and the upper vaginal wall. The bone anchor implantation device is inserted through the incision, into the pocket, and through the endopelvic fascia to contact the pubic bone. At least one bone anchor is inserted into the pubic bone on each side of the urethra. The sling is introduced into the opening or pocket and attached to the sutures. The tension on the sling provided by the sutures is adjusted to provide the appropriate biasing force to the urethra.

[**0129**] Example 1 describes one method of using the present bone anchor implantation device to compress or stabilize the bladder neck with sutures. it will be appreciated that the bone anchor implantation device can be used with other methods in which sutures compress or stabilize the bladder neck.

EXAMPLE 1

[**0130**] Compression or Stabilization of the Bladder Neck with Sutures

[**0131**] The bone anchor implantation device can be used in incontinence treatments in which the bladder neck is compressed or stabilized with sutures. A Foley catheter is inserted into the urethra to indicate its location. An incision is then made through the anterior vaginal wall, preferably approximately 1 cm lateral to midline and adjacent to the bladder neck. The vaginal wall is retracted to allow access to the endopelvic fascia. The bone anchor implantation device, having a bone anchor with sutures attached thereto releasably engaged with the inserter shaft, is introduced through the opening in the vaginal wall with the device locked in the position in which the inserter shaft is fully retracted within the cannula, and the sharp point is pressed through the fascia to contact the posterior pubic bone. Preferably, the anchor implantation site is located lateral to the symphysis pubis and cephalad to the inferior edge of the pubic bone. The anchor implantation site is located by palpating the inferior rim of the pubic bone and the symphysis pubis, moving laterally until the lower border of the obturator foramen is located. Preferably, the anchor is located from about 0.5 to 4 cm lateral to the symphysis pubis and from about 0.5 to 3 cm cephalad to the inferior edge. More preferably, the anchor implantation site is located approximately 1 cm lateral to the symphysis pubis and 1 cm cephalad to the inferior edge of the pubic bone. In addition, the anchor implantation site can be located on the pubic ramus.

[**0132**] The locking mechanism of the bone anchor implantation device is then placed in the unlocked position, and the two handles are squeezed together such that the inserter shaft is in the extended position. Alternatively, for devices having a dual position locking mechanism, the bone anchor may be exposed by locking the device in the position in which the inserter shaft is fully extended from the cannula. In either case, the anchor is driven into the pubic bone using manual pressure and opposing thumb pressure on the external pubic section if necessary.

[**0133**] The bone anchor implantation device is withdrawn, leaving the two free ends of the anchored suture exiting the endopelvic fascia **17**. A device such as a Mayo needle is then attached to one free end of the anchored suture and a "bite of fascia" is taken adjacent to the bladder neck. Preferably, the entry and exit points of the suture are adjacent to the bladder neck approximately 0.5 cm lateral to the urethra. This step is then repeated with the other free end of the suture, and the two ends are tied together. The vaginal wall incision is then closed.

[**0134**] Alternatively, the entry and exit points of the suture can be made as illustrated in **FIG. 13*a*** of U.S. Pat. No. 5,611,515 to Benderev, the disclosure of which is incorporated herein by reference.

[**0135**] The above procedure is then repeated on the opposite side of the urethra to complete the bladder neck suspension. The sutures are then appropriately tensioned. Appropriate tension is confirmed using well known means such as cystoscopy or a standard Q tip test.

EXAMPLE 2

[**0136**] Example 2 describes use of the bone anchor implantation device in a procedure in which the bladder neck is compressed or stabilized with a sling. However, it will be appreciated that the bone anchor implantation device can be used with other methods in which the bladder neck is compressed or stabilized with a sling.

[0137] Double Anchor Placement: For Sling or Bolster Procedure

[0138] The bone anchor implantation device can also be used in incontinence treatments in which the bladder neck is compressed or stabilized using a sling. Preferably, in such procedures two bone anchors are placed on either side of the urethra. However, one of ordinary skill in the art will appreciate that one or more than two bone anchors per side can be used. The procedure is performed as follows.

[0139] A Foley catheter is inserted into the urethra to indicate its location. Starting adjacent to the bladder neck on either side of the urethra, a 1 cm incision is made through the anterior vaginal wall approximately 1 cm lateral to and parallel to the midline of the urethra. The vaginal wall is retracted to allow access to the endopelvic fascia **17**. Blunt dissection is used to tunnel under the urethra and form a pocket for the sling.

[0140] The bone anchor implantation device is introduced through the opening in the vaginal wall with the device locked in position in which the inserter shaft is fully retracted within the cannula, and the sharp point of the cannula is pressed through the fascia **17** near the distal end of the vaginal wall incision closer to the bladder neck, to contact the posterior aspect of the pubic bone. Preferably, the first anchor implant site is located lateral to the symphysis pubis and cephalad to the inferior edge of the pubic bone. More preferably, the first anchor implant site is located approximately 1 cm lateral to the symphysis pubis and 1 cm cephalad to the inferior edge of the pubic bone.

[0141] The locking mechanism of the bone anchor implantation device is then placed in the unlocked position, and the two handles are squeezed together to expose the anchor. Alternatively, for devices having a dual position locking mechanism, the bone anchor may be exposed by locking the device in the position in which the inserter shaft is fully extended from the cannula. The anchor is driven into the pubic bone using manual pressure and opposing thumb pressure on the external pubic region if necessary.

[0142] The bone anchor implantation device is withdrawn leaving the two free ends of suture exiting the endopelvic fascia.

[0143] The above bone anchor implantation procedure is repeated to introduce a second anchor on the same side of the urethra as the first anchor. The second anchor implant site is located by palpating the obturator foramen in the pelvis just cephalad to the ramus. For implantation of the second anchor, the fascial tissue near the proximal end of the vaginal wall incision farther from the bladder neck is pierced. The second anchor is implanted on the superior (cephalad) aspect of the ramus.

[0144] The bone anchor implantation device is removed as before trailing the two free ends of each suture from the vaginal wall incision.

[0145] The above procedures for implantation of the first and second anchors are repeated on the opposite side of the urethra.

[0146] The sling is then positioned in the pocket under the urethra. The free ends of suture from the two anchors on each side of the urethra are then tied to the corresponding corners of the sling. The sutures are then tied off with the appropriate amount of tension to suspend or stabilize the bladder neck. The vaginal wall incisions are then closed on each side.

[0147] Alternatively, the above procedure can also be utilized in techniques in which only a single bone anchor is inserted on either side of the urethra. Preferably, in such procedures the anchor implantation site is located approximately 1 cm lateral to the symphysis pubis and 1 cm cephalad to the inferior edge of the pubic bone. More preferably, the anchor implantation site is located approximately 1 cm lateral to the symphysis pubis and 1 cm cephalad to the inferior edge of the pubic bone.

[0148] Bone Anchor Implantation Device with Hooked Shaft

[0149] In another embodiment, the anchor implantation device of the present invention has a hooked shaft with a bone anchor mount for releasably engaging a bone anchor on the distal end of the shaft. This embodiment reduces the amount of force required to drive the bone anchor into the bone by utilizing the patient's body weight to provide an opposing force.

[0150] In this embodiment, the anchor implantation device comprises a handle, a hooked shaft secured to the handle and a bone anchor mount adapted to releasably engage a bone anchor attached to the distal end of the shaft. The bone anchor mount generally points toward the handle, such that the user can drive the bone anchor into the bone by simply pulling back on the handle and using the patient's body weight to provide an opposing force. Preferably, the longitudinal axis of the bone anchor mount is aligned with the longitudinal axis of the handle. Preferably, a protective sheath is attached to the bone anchor mount such that the bone anchor releasably engaged to the bone anchor mount is enclosed within the protective sheath and isolated from tissue contact during placement of the device. More preferably, the protective sheath is a telescoping sheath or a balloon.

[0151] A representative anchor implantation device having a hooked shaft is shown in **FIG. 13**. As illustrated in **FIG. 13**, the anchor implantation device **210** has a handle **212** having a proximal end **214** and a distal end **216**. The handle **212** may be made of a variety of materials, such as plastic or metal.

[0152] The shaft **220** may be made of a variety of materials such as stainless steel engineering plastics, fiber-bearing components, or other materials. Preferably, the shaft is made of stainless steel.

[0153] In the embodiment of the bone anchor implantation device shown in **FIG. 13**, shaft **220** comprises a straight proximal section **222**, a first generally curved section **224** distal to the straight proximal section, a second generally curved section **226** distal to the first curved section, a third generally curved section **228** distal to the second curved section, and a fourth generally curved section **230** distal to the third curved section. However, one skill in the art would appreciate that the shaft could also comprise a series of straight segments angled relative to one another to form a hook.

[0154] The straight proximal section **222** of the shaft **220** has an annular shoulder **232** which abuts the distal end **216**

of the handle. The straight proximal section **222** passes through a lumen (not shown) extending through the handle. The proximal end of the straight proximal section **222** has a threaded bore which is adapted to receive a screw **236** which secures the shaft **220** to the handle. If desired, a washer (not shown) may be placed between the proximal end **214** of the handle and the screw **236**.

[**0155**] While one means of securing the shaft **220** to the handle **212** was described above, those skilled in the art will appreciate that a variety of other means may be employed. For example, a plastic handle may be formed over the shaft such that the shaft is integral with the handle.

[**0156**] The straight proximal section **222** of the shaft **220** may be from about 3 inches to about 6 inches in length. Preferably, the straight proximal section **222** is from about 4 inches to about 5 inches in length. More preferably, the straight proximal section **222** is about 4.5 inches in length.

[**0157**] The handle **212** defines an axis at the proximal end of the anchor implantation device **210**, and ten moving distally from the handle **212** the shaft **220** first curves away from the axis of the handle and then back toward the axis of the handle **212**. The distal end of the shaft **220** preferably is located in the vicinity of the axis of the handle **212**. In some preferred embodiments, the shaft **220** at the distal end can be generally perpendicular to the axis of the handle or can actually be curving back toward the handle **212**. Preferably the distance from the distal end of the handle **212** to the tip of the tapered bone anchor receptacle **246** measured along the longitudinal axis of the handle **212** is about 3⅜inches. Preferably, the distance from the distal end of the handle **212** to the distal end of the bone anchor mount **238** is about 4 inches. Preferably, the distance of a line perpendicular to the longitudinal axis of the handle **212** extending from the bottom of the third curved section **228** is about 2 inches.

[**0158**] Referring to FIGS. **13-16**, a bone anchor mount **238** is attached to the distal end **240** of the fourth curved section **230** of the shaft **220**. The bone anchor mount **238** may be oriented at an angle from about 60° to about 120° relative to the distal end **240** of the fourth curved section. Preferably, the bone anchor mount **238** is oriented at an angle from about 80° to about 100° relative to the distal end **240** of the fourth curved section. More preferably, the bone anchor mount **238** is oriented at an angle of approximately 90° relative to the distal end **240** of the fourth curved section, as illustrated in **FIG. 13**.

[**0159**] The bone anchor mount comprises an outer cylinder **242**, an inner cylinder **244**, and a tapered bone anchor receptacle **246** for releasably engaging a bone anchor **248**. As was the case with the two handle bone anchor implantation device discussed above, a variety of bone anchors can also be used with the bone anchor implantation device having a hooked shaft. Preferably, the bone anchor used with the hooked shaft device is the bone anchor discussed above with respect to the two handle bone anchor implantation device.

[**0160**] In any event, it is preferred that the bone anchor mount **238** and the bone anchor receptacle **246** are oriented so that the bone anchor **248** is pointed in the general direction of the handle **212**. In one preferred embodiment, the axis of the bone anchor **248** is generally aligned with the axis of the handle **212**, with the bone anchor pointed toward the handle **212**.

[**0161**] The bone anchor mount **238** may be fabricated from the same materials as the shaft **220** and may be attached to the shaft **220** by a variety of methods known to those skilled in the art, such as brazing. As best shown in **FIG. 15** the distal end **250** of the outer cylinder **242** has a pair of holes **252** therein sized to accommodate a suture **254**.

[**0162**] The outer cylinder **242** may have a diameter from about 0.18 inches to about 0.6 inches. Preferably, the outer cylinder **242** has a diameter from about 0.25 inches to about 0.5 inches. More preferably, the outer cylinder **242** has a diameter of about 0.375 inches.

[**0163**] As best shown in the cross section of **FIG. 16**, the outer cylinder **242** has a cavity **258** formed therein, creating a cup in the proximal region of the outer cylinder **242**. The proximal end **260** of the outer cylinder **242** has an annular shoulder **262** thereon.

[**0164**] The inner cylinder **244** is connected to the outer cylinder **242** and extends into the cavity **258** as best shown in **FIG. 16**. The inner cylinder **244** may be connected to the outer cylinder **242** in a variety of ways known to those skilled in the art. For example, the inner cylinder **244** may be fused to the outer cylinder **242**. As best shown in **FIG. 15**, the inner cylinder **244** has grooves **264** therein adapted to accommodate the suture **254**.

[**0165**] A tapered bone anchor receptacle **246** extends from the proximal end **266** of the inner cylinder **244**. The tapered bone anchor receptacle **246** has grooves **268** therein adapted to accommodate the suture **254**.

[**0166**] The tapered bone anchor receptacle **246** may extend from the proximal end **266** of the inner cylinder **244** by a distance of from about 0.3 inches to about 0.7 inches. Preferably, the tapered bone anchor receptacle **246** extends from the proximal end **266** of the inner cylinder **244** by a distance of from about 0.4 inches to about 0.6 inches. More preferably, the tapered bone anchor receptacle **246** extends from the proximal end **266** of the inner cylinder **244** by a distance of about 0.5 inches.

[**0167**] The distal end **270** of the tapered bone anchor receptacle **246** preferably has a width smaller than that of the proximal end **266** of the inner cylinder **244**. This configuration produces a shoulder **272** which may serve as a depth stop to ensure that the bone anchor **248** is driven into the bone to the desired depth.

[**0168**] The distal end **270** of the tapered bone anchor receptacle **246** may be from about 0.08 inches to about 0.12 inches in width. Preferably, the distal end **270** of the tapered bone anchor receptacle **246** is from about 0.09 inches to about 0.110 inches in width. More preferably, the distal end of the tapered bone anchor receptacle **246** is 0.1 inches in width.

[**0169**] The proximal end **274** of the tapered bone anchor receptacle **246** may be from about 0.110 inches to about 0.15 inches in width. Preferably, the proximal end **274** of the tapered bone anchor receptacle **246** is from about 0.12 inches to about 0.14 inches in width. More preferably, the proximal end **274** of the tapered bone anchor receptacle **246** is 0.13 inches in width.

[**0170**] The proximal end **274** of the tapered bone anchor receptacle **246** may have a variety of cross sectional shapes adapted to releasably engage the bone anchor **248**. For

example, the proximal end **274** of the tapered bone anchor receptacle **246** may be square, rectangular, pentagonal, triangular or hexagonal in cross section.

[**0171**] As depicted in FIGS. **14-16**, the tapered bone anchor receptacle **246** may have a notch **276** therein in which the bone anchor **248** is releasably seated.

[**0172**] Alternatively, the outer cylinder, inner cylinder, and tapered bone anchor receptacle may be a single integral component.

[**0173**] Preferably, the bone anchor implantation device has a protective sheath connected to the bone anchor mount which protects the point of the bone anchor from tissue contact during placement of the device and also protects the bone anchor from contacting potentially infectious micro-organisms.

[**0174**] One embodiment of the protective sheath **278** is shown in FIGS. **13-16**. In this embodiment, the protective sheath **278** comprises a first telescoping cylinder **280** and a second telescoping cylinder **282**. A spring **284** biases the first telescoping cylinder **280** and the second telescoping cylinder **282** to a position in which they extend from the outer cylinder **242** and cover the bone anchor **248**.

[**0175**] The first and second telescoping cylinders **280**, **282** may be made of a variety of materials such as stainless steel or plastic. Preferably, the first and second telescoping cylinders **280**, **282** are made of stainless steel.

[**0176**] The first telescoping cylinder **280** has a lumen **286** extending therethrough.

[**0177**] The first telescoping **280** cylinder has a first shoulder **288** which engages shoulder **262** on the outer cylinder **242** and a second shoulder **290** which engages a first shoulder **292** on the second telescoping cylinder **282**.

[**0178**] The second telescoping cylinder **282** has a first shoulder **292** which engages the second shoulder **290** on the first telescoping cylinder **280** as described above. A second shoulder **294** is located at the proximal end of the second telescoping cylinder **282** and engages the spring **284**. The second telescoping cylinder **282** also has a lumen **296** extending therethrough which is in fluid communication with the lumen **286** of the first telescoping cylinder **280** and the cavity **258** in the outer cylinder **242**.

[**0179**] The inner diameter of the first telescoping cylinder **280** is slightly larger than the outer diameter of the second telescoping cylinder **282** such that the second telescoping cylinder **282** can retract inside the first telescoping cylinder **280**. The first telescoping cylinder **280** and the second telescoping **282** can retract inside the cavity **258** of the outer cylinder **242**.

[**0180**] The first telescoping cylinder **280** may be from about 0.2 inches to about 0.3 inches in length, with an inner diameter of from about 0.27 inches to about 0.33 inches and an outer diameter of about 0.3 inches to about 0.36 inches. Preferably, the first telescoping cylinder **280** is from about 0.23 inches to about 0.27 inches in length, with an inner diameter of from about 0.29 inches to about 0.31 inches and an outer diameter of about 0.32 inches to about 0.34 inches. More preferably, the first telescoping cylinder **280** is about 0.25 inches in length, with an inner diameter of about 0.3 inches and an outer diameter of about 0.33 inches.

[**0181**] The second telescoping cylinder **282** may be from about 0.2 inches to about 0.3 inches in length, with an inner diameter of from about 0.22 inches to about 0.31 inches and an outer diameter of about 0.25 inches to about 0.35 inches. Preferably, the second telescoping cylinder **282** is from about 0.23 inches to about 0.27 inches in length, with an inner diameter of from about 0.24 inches to about 0.29 inches and an outer diameter of about 0.27 inches to about 0.33 inches. More preferably, the second telescoping cylinder **282** is about 0.25 inches in length, with an inner diameter of about 0.27 inches and an outer diameter of about 0.3 inches.

[**0182**] As illustrated in FIGS. **13-16**, a spring **284** biases the first and second telescoping cylinders **280** and **282** towards a position in which the first telescoping cylinder **280** and the second telescoping cylinder **282** are extended from the outer cylinder **242**.

[**0183**] Another embodiment of the protective sheath is depicted in **FIGS. 25 and 26***a*. The bone anchor implantation device as described above with respect to FIGS. **14-17** has a balloon which encapsulates the bone anchor. The bone anchor implantation device **210** has a balloon **279** which is coupled to the bone anchor mount **238** and which covers the bone anchor **279**. The balloon **279** protects the bone anchor from contacting potentially infections microorganisms prior to implantation.

[**0184**] The balloon **279** may be made of any material which exhibits a strength that allows it to be punctured by the bone anchor. Examples of suitable materials include plastic, thermoplastic, elastromers, PET, PETG, rubber, vinyl, latex, gelatin or silicone. In a preferred embodiment, the balloon is made of latex.

[**0185**] Alternatively, the balloon **279** can be made of a biodegradable material. A suitable biodegradable material dissolves within the patient after a predetermined period of time. Following implantation of the bone anchor the punctured sheath remains are simply metabolized by natural biological processes.

[**0186**] In a preferred embodiment, the balloon comprises a biodegradable polymer.

[**0187**] The polymer may be either natural or synthetic. Synthetic polymers offer greater advantages that natural materials in that they can be tailored to give a wider range of properties and are more uniform than materials from natural sources. Synthetic polymers also offer a more reliable source of raw materials which reduce the risks of invoking an immunogenic response.

[**0188**] Biodegradable polymers are synthesized from chemical functional groups such as, for example, esters, anhydrides, orthoesters and amides, which have hydrolytically unstable linkages in the backbone. Preferably, the balloon is made of a biodegradable materials such as polyglycotic acid (PGA), polylactic acid (PLA), poly (dioxanone)(PDO), poly (l-lactide)(LPLA), poly (dl-lactide)(DLPLA), poly (glycolide-co-trimethylene carbonate) (PGA-TMC), poly (l-lactide-co-glycolide) (PGA-LPLA), poly (dl-lactide-co-glycolide) (PGA-DLPLA), poly (l-lactide-co-dl-lactide) (LPLA-DLPLA), poly(glycolide-co-trimethylene carbonate-co-dioxanone) (PDO-PGA-TMC), poly(ϵ-caprolactone), poly(dioxanone)(a polyether-ester), poly (lactide-co-glycotide), poly(SA-HDA anhydride), poly(orthoester), polyglyconate.

[0189] The balloon or structure can be filled with air, water, antibiotic or any substance which inflates the balloon so as to prevent the bone anchor from puncturing the balloon prior to implantation. Alternatively, as illustrated in **FIG. 38** and discussed below, the device may further include a spring which is attached to the shaft within the balloon to maintains the shape of the balloon and prevent the bone anchor from puncturing the balloon prematurely. In a preferred embodiment, the balloon **278** contains an antibiotic that is released when the sheath is perforated by the bone anchor during implantation. The balloon may contain several antibiotics that have complementary activity. The antibiotic prevents infection at the site where the bone anchor is pressed into the bone. Non-limiting examples of suitable antibiotics for use in the invention include nafcillin, aminogylcoside, ciprofloxin, clindamcin, piperacillin/tazobactum, ampicillin/sulbactum, aminoglcoside, vancomycin, cephalosporin, TMP/SMX, ampicillin, gentaminicin, tobramycin and ciprofloxacin.

[0190] There are numerous ways to insert an antibiotic or other desired substance into the balloon. In one embodiment, the bone anchor implantation device further comprises an port **280** which allows antibiotics to be inserted into the balloon. As shown in **FIG. 25**, the port **280** extends from the balloon **279** into a lumen which extends from one end of the shaft to the other. The port **280** has an opening **282** at the distal end of the shaft. Antibiotics inserted into the opening **282** travel through the port **280** into the balloon **279**. In an alternate embodiment (not shown), the port extends from the balloon into a lumen which extends from one end of the shaft to the other end and through the handle to an opening. Those skilled in the art will appreciate other ways of inserting the antibiotic into the balloon.

[0191] In general, in another aspect illustrated in **FIG. 38**, the invention features a bone anchor implantation **210** device that has a spring element attached to the shaft within the balloon which retracts when the balloon contacts the bone anchor implantation site causing the bone anchor to perforate the balloon and implant in the bone. The spring element reduces the amount of force required to perforate the sheath and implant the bone anchor in the bone. The spring element **285** can be any type of spring which is elastically or plastically deformable. The spring element **285** has a first end **286** which is attached or grounded to the bone anchor mount **238** and a second floating end **287** which contacts the balloon. Preferably, the spring is a compression spring which is normally in an open position. A compression spring retracts when pressure is applied causing the point to puncture the balloon. As illustrated in **FIG. 38**, the spring element **285** can be an open-coiled helical spring which surrounds the bone anchor **248**. The spring mechanism **285** must have some minimum deflection strength so as to prevent the bone anchor from puncturing the balloon prematurely during insertion but must have enough deflection strength to puncture the balloon when force is applied to the bone anchor implantation device at the desired location. The balloon **279** which covers the spring and the bone anchor has the same attributes as the balloon discussed above with respect to FIGS. **25-26***a*.

[0192] Another embodiment of the protective sheath is illustrated in **FIG. 26***b*. The bone anchor implantation device **210** as described above with respect to FIGS. **14-17** has a gelatin structure **290** which covers the bone anchor. The bone anchor implantation device **210** has a gelatin structure or caplet which is coupled to the bone anchor mount **238** and which encapsulates the bone anchor **248**. The gelatin structure **290** protects the bone anchor **248** from contamination. As discussed above with reference to FIGS. **25-26***a*, the gelatin structure may be filled with an antibiotic. The device may also include a port for inserting antibiotic into the gelatin structure.

[0193] An alternative embodiment of the bone anchor implantation device **310** is shown in FIGS. **17-20** and **FIG. 27**.

[0194] As illustrated in **FIGS. 17 and 18**, the shaft **320** has a generally straight proximal section **399**, a first generally bent section **397**, a generally straight median section **395**, a second bent section **393**, a generally curved section **391**, and a distal generally straight section **389**.

[0195] The straight proximal section **399** may be from about 3.0 inches to about 6.0 inches in length. Preferably, the straight proximal section **399** is from about 4.0 inches to about 5.0 inches in length. More preferably, the straight proximal section **399** is about 4.5 inches in length.

[0196] The first bent section **397** may be from about 1.0 inches to about 3.0 inches in length. Preferably, the first bent section **397** is from about 1.5 inches to about 2.5 inches in length. More preferably, the first bent section **397** is about 2 inches in length.

[0197] The first bent section **397** may bend at an angle of from about 35° to about 55° relative to the straight proximal section **399**. Preferably, the first bent section **397** bends at an angle of from about 40° to about 50° relative to the straight proximal section **399**. More preferably, the first bent section **397** bends at an angle of about 45° relative to the straight proximal section **399**.

[0198] The straight median section **395** may be from about 2 inches to about 4 inches in length. Preferably, the straight median section **395** is from about 2.5 inches to about 3.5 inches in length. More preferably, the straight median section **395** is about 3 inches in length.

[0199] The second bent section **393** may be from about 0.5 inches to about 2.5 inches in length. Preferably, the second bent section **393** is from about 1.0 inches to about 2.0 inches in length. More preferably, the second bent section **393** is about 1.5 inches in length.

[0200] The second bent section **393** may bend at an angle of from about 125° to about 145° relative to the straight median section **395**. Preferably, the second bent section **393** bends at an angle of from about 130° to about 140° relative to the straight median section **395**. More preferably, the second bent section **393** bends at an angle of about 135° relative to the straight median section **395**.

[0201] The curved section **391** may curve through an arc of from about **700** to about 110° with a radius from about 0.2 inches to about 0.6 inches. Preferably, the curved section curves **391** through an arc of from about 80° to about 100° with a radius from about 0.3 inches to about 0.5 inches. More preferably, the curved section **391** curves through an arc of about 90° with a radius of 0.4 inches.

[0202] The distal straight section **389** may be from about 0.5 inches to about 0.9 inches in length. Preferably, the distal

straight section **389** is from about 0.6 inches to about 0.8 inches in length. More preferably, the distal straight section **389** is about 0.7 inches in length.

[**0203**] The shaft **320** has a lumen extending therethrough. The lumen may have a diameter from about 0.03 inches to about 0.07 inches and the shaft **320** may have an outer diameter from about 0.2 inches to about 0.3 inches. Preferably, the lumen has a diameter from about 0.04 inches to about 0.06 inches and the shaft **320** has an outer diameter from about 0.24 inches to about 0.26 inches. More preferably, the lumen has a diameter of about 0.05 inches and the shaft **320** has an outer diameter of about 0.250 inches.

[**0204**] Preferably, the shaft **320** has an insert **387** therein with a lumen **385** extending therethrough as best illustrated in the cross section of **FIG. 19**. The insert **387** may be made of a variety of materials such as stainless steel or plastic.

[**0205**] The insert **387** has an outer diameter approximately that of the diameter of the lumen in the shaft such that the insert **387** fits snugly within the lumen of the shaft. The insert **387** may have an outer diameter from about 0.2 inches to about 0.3 inches. Preferably, the insert **387** has an outer diameter from about 0.21 inches to about 0.27 inches. More preferably, the insert **387** has an outer diameter of about 0.23 inches.

[**0206**] The insert **387** has a lumen **385** extending therethrough having a diameter large enough to accommodate a suture **354**. The diameter of the lumen **385** may be from about **0.02 inches to about** 0.100 inches. Preferably, the diameter of the lumen **385** is from about 0.04 inches to about 0.08 inches. More preferably, the diameter of the lumen **385** is about 0.06 inches.

[**0207**] As illustrated in **FIGS. 17, 18** and **20**, the shaft **320** has a bore therein which is large enough to permit the suture **354** to exit from the shaft **320**. In the embodiment shown in **FIGS. 17, 18** and **20**, the bore is located in the straight median section **395** at a position in which it is located outside of the patient's body when the bone anchor **348** has been inserted into the patient's bone. However, those skilled in the art will appreciate that the bore may be located in other locations such as the first bent section **397**.

[**0208**] As illustrated in **FIGS. 17 and 20**, the shaft **320** extends through a lumen **383** in the handle **312**. The lumen **383** has a narrow distal section **381** having a diameter slightly larger than the outer diameter of the shaft **320** and a wide proximal section **373** adapted to receive a spring **371**.

[**0209**] The shaft **320** passes through the interior of the spring **371** as depicted in **FIGS. 17 and 20**. The distal end of the spring **371** contacts the distal end of the wider proximal section **373** of the lumen. The proximal end of the spring contacts a plug **369**. The plug **369** has a lumen through which the shaft **320** passes and a bore adapted to receive a screw **367**. The screw **367** passes through the bore in the plug **369** and a bore in the shaft **320** which is aligned with the bore in the plug, thereby securing the shaft **320** to the plug **369**.

[**0210**] The resistance of the spring **371** is selected to be equal to the force with which the bone anchor **348** is to be driven into the bone. For example, where the bone anchor **348** is to be driven into the bone by applying 20 pounds of force, the spring **371** is a 20 pound spring. The spring indicates when the desired amount of force has been applied because the user can sense when the spring has been completely compressed.

[**0211**] The spring **371** may have a resistance of from about 5 to about 35 pounds. Preferably, the spring **371** has a resistance from about 15 to 25 pounds. More preferably, the spring **371** has a resistance of 20 pounds.

[**0212**] Those skilled in the art will appreciate that the anchor implantation device shown in FIGS. **13-16** may also be adapted to include a force indicating spring in the handle.

[**0213**] As illustrated in **FIGS. 17, 18** and **20**, a bone anchor mount **338** and a protective sheath **378** as described above with respect to the embodiment of FIGS. **13-16** are attached to the end of the distal straight section **389**.

[**0214**] In an alternate embodiment, illustrated in **FIG. 27**, the protective sheath on the bone anchor implantation device **310** is a balloon **279** as described above with respect to the embodiments of **FIGS. 25 and 26***a*. The balloon is attached to the distal straight section **389** of the bone anchor implantation device **310** as described above with respect to the embodiment of **FIGS. 24 and 25**. The device may further comprise a spring element as discussed above with respect to **FIG. 38**.

[**0215**] The hooked bone anchor implantation devices **210**, **310** are used as follows. An incision in the anterior vaginal wall is made as described above. The site for bone anchor implantation is located by palpation as described above.

[**0216**] The hooked bone anchor implantation device **210**, **310** is inserted into the vagina as shown in **FIGS. 17 and 21** with the patient in the lithotomy position and the surgeon located between the patient's legs. The shaft **220**, **320** is inserted through the incision and the protective sheath **278**, **378** is positioned such that the proximal end of the second telescoping cylinder **282**, **382** contacts the pubic bone **219**, **319** as shown in **FIGS. 17, 21** and **23**. At this time, the first and second telescoping cylinders **280**, **380**, **282**, **382** are biased to a position in which they extend from the outer cylinder **242**, **342** to cover the bone anchor. The bone anchor is inserted into the bone by applying a retrograde force to the bone anchor. The retrograde force can be applied in a number of ways as will be apparent to one of skill in the art. Preferably, the bone anchor is implanted by pulling the handle. For example, the handle may be pulled in a retrograde direction (toward the user) to implant the anchor as shown in **FIGS. 20 and 22**. As the device is pulled in a retrograde motion, the first and second telescoping cylinders **280**, **282**, **380**, **382** retract inside the cavity **258**, **358** of the outer cylinder as shown in **FIGS. 20, 22** and **24** and the bone anchor **248**, **348** is driven into the pubic bone **219**, **319**. Because the patient's body weight provides an opposing force, the user need only apply a small amount of force, such as 10-20 pounds, in order to drive the bone anchor **248**,**348** into the bone **219**,**319**. The device **210**,**310** is then pushed away from the implanted anchor to disengage the device from the anchor. The device is then removed from the vagina, leaving the bone anchor **248**,**319** in the bone **219**, **319** with the suture extending therefrom. The bladder neck is then compressed, suspended or stabilized using the suture(s) extending from the bone anchor(s) as described above.

[**0217**] As shown in **FIG. 20**, in the device **310** having a spring **371** inside the handle **312**, the spring **371** is com-

pressed when the handle is pulled in a retrograde direction to drive the bone anchor into the bone. In this embodiment, the user can detect when the spring **371** has been completely compressed, or compressed by a predetermined amount, indicating that the desired amount of force for driving the bone anchor into the bone has been applied.

[**0218**] The hooked bone anchor implantation device with balloon illustrated in FIGS. **25-27** is used as follows. An incision in the anterior vaginal wall is made as described above. The site for bone anchor implantation is located by palpation of the urethra, pubic symphsis or other anatomical landmark or other techniques known by those skilled in the art.

[**0219**] The hooked bone anchor implantation device with a balloon or gelatin structure **210, 310** is inserted into the vagina as shown in **FIGS. 27 and 28** with the patient in the lithotomy position and the surgeon located between the patient's legs. The shaft **220, 320** is inserted through the incision and the balloon or gelatin structure **279, 379** is positioned such that the balloon or gelatin structure **279** contacts the pubic bone **219, 319** as shown in **FIGS. 27 and 28**. The bone anchor is inserted into the bone by applying a retrograde force to the bone anchor **238,348**. The force is transmitted through the bone anchor implantation device **210, 310** to the bone anchor **279, 379** and causes the balloon or gelatin structure **279, 379** to press against the pubic bone **279, 379**. The application of additional force causes the bone anchor point to puncture the balloon or gelatin structure **279, 379** and drives the bone anchor **248, 348** into the pubic bone **219, 319**. Because the patient's body weight provides an opposing force, the user need only apply a small amount of force, such as 10-20 pounds, in order to drive the bone anchor **248, 348** into the bone **219, 319**. In one embodiment (not shown), the retrograde force retracts a spring element attached to the shaft within the balloon which causes the bone anchor to perforate the sheath and implant into the bone. In a preferred embodiment, an antibiotic is inserted into the balloon or gelatin structure and is released when the sheath is punctured. The antibiotic may be inserted into the balloon or gelatin structure via a port which extends from one end of the shaft to the other end of the shaft into the balloon. The device **210, 310** is then pushed away from the implanted anchor to disengage the device from the anchor. The device is then removed from the vagina, leaving the bone anchor **248, 319** in the bone **219, 319** with the suture extending therefrom. The bladder neck is then compressed, suspended or stabilized using the suture(s) extending from the bone anchor(s) as described above.

[**0220**] Other embodiments of the invention, particularly various types of protective sheaths which prevent premature insertion, are illustrated in FIGS. **39-45**.

[**0221**] FIGS. **39-40***b* illustrate a bone anchor implantation device with a telescoping sheath which retracts upon insertion. As discussed above with reference to FIGS. **13-16**, the bone anchor implantation device with telescoping sheath comprises a handle **512**, a hooked shaped shaft **520** secured to the handle **212**, a bone anchor mount **538** adapted to releasably engage a bone anchor **548** and attached at the distal end of the shaft **520**, and a telescoping sheath **550** which attaches to the bone anchor mount **538** and covers the bone anchor **548**. **FIG. 40***a* depicts the telescoping sheath **550** in an extended or open position covering the bone anchor **548**. **FIG. 40B** illustrates the telescoping sheath **550** in a retracted position. Details regarding the telescoping sheath are discussed above with reference to FIGS. **13-16**. A spring biases the telescoping sheath **550** between extended and retracted positions.

[**0222**] As illustrated in **FIG. 45** the bone anchor implantation device with telescoping sheath shown in **FIG. 39** is inserted into the vagina **908** and positioned so that the telescoping sheath **950** contacts the pubic bone **918**. The bone anchor **948** is then inserted by applying a retrograde force to the bone anchor **948** by pulling the handle **912** of the device in a retrograde direction. There is an annular shoulder **910** on the bone anchor **948** which acts as a depth stop to ensure adequate penetration. Further details regarding the method of inserting the bone anchor are described above with reference to **FIGS. 17 and 21**.

[**0223**] **FIGS. 41***a* and **41***b* illustrate a hooked-shaped bone anchor implantation device which a balloon **650** covering the bone anchor **648**. The device comprises a handle **612**, a hooked-shaped shaft secured to the handle **612**, a bone anchor mount **638** attached to the distal end of the shaft and adapted to releasably engage a bone anchor **648**, and a balloon **650** which covers the bone anchor **648**. Features of the balloon sheath are discussed above with reference to **FIGS. 25 and 26***a*. The balloon **650** may be filled with one or more antibiotics to combat infection at he implantation site. The device may also comprise a port **680** for inserting antibiotics into the balloon. The balloon is perfed away upon implantation.

[**0224**] **FIGS. 42***a* and **42***b* illustrate a bone anchor implantation device having a latex sheath **750** with a spring element **779** which covers the bone anchor **748**. As described above with reference to **FIG. 38**, the spring element can be any type of spring which is elastically or plastically deformable. Preferably the spring is a compression spring such as a coiled helical spring which surrounds the bone anchor and which retracts when pressure is applied. The latex sheath can be hermetically sealed to the bone anchor implantation device. The sheath may also be filled with one or more antibiotics to prevent infection at the implantation site. The latex sheath perfs away upon implantation.

[**0225**] **FIG. 43** illustrates a bone anchor implantation device with gelatin structure or a capsule **890** that covers the bone anchor **888** The capsule **890** can be coupled to the bone anchor mount **838**. The capsule **890** can be made of biodegradable materials such as those described above with reference to the balloon sheath illustrated in **FIGS. 25 and 26***a*. Preferably the caplet is made of gelatin. The bone anchor **888** perfs the capsule **890** and any remaining capsule particles are absorbed or metabolized.

[**0226**] **FIG. 44** illustrates a bone anchor implantation device that has a sheath **802** with a lumen **805** that a diameter large enough to accommodate one or more sutures **808** which are preattached to the bone anchor **848**. The sheath **802** protect the sutures **808** from contamination. Further details regarding a shaft with a lumen that accommodates one or more sutures are discussed above with respect to FIGS. **17-20**. The bone anchor **848** with attached sutures **808** has a screw or locking device **804** which secures the bone anchor **848** to the bone anchor implantation device. The locking mechanism **804** prevents accidental insertion of the bone anchor **848** into tissue.

[0227] Although this invention has been described in terms of certain preferred embodiments, other embodiments which will be apparent to those of ordinary skills in the art in view of the disclosure herein are also within the scope of this invention. Accordingly, the scope of the invention is intended to be defined only by reference to the appended claims.

What is claimed is:

1. A bone anchor implantation device, comprising:

a hook-shaped shaft having a first end and a second end;

a bone anchor releasably engaged to one end of the shaft; and

a protective sheath for encapsulating the bone anchor prior to implantation.

2. The device of claim 1, wherein said protective sheath comprises:

at least one telescoping cylinder

a first telescoping cylinder having a proximal end, a distal end and a lumen extending therethrough, a first shoulder at said distal end of said first telescoping cylinder and a second shoulder at said proximal end of said first telescoping cylinder.

a second telescoping cylinder having a proximal end, a distal end and a lumen extending therethrough, a first shoulder at said distal end of said second telescoping cylinder and a second shoulder at said proximal end of said second telescoping cylinder; and

a spring, wherein said first shoulder of said first telescoping cylinder engages said shoulder of said outer cylinder, said second shoulder of said first telescoping cylinder engaged said first shoulder of said second telescoping cylinder, and said spring is disposed between said second shoulder of said second telescoping cylinder and said outer cylinder, whereby said first and second telescoping cylinders are movable between a first position in which they are extended from said outer cylinder to cover said bone anchor and a second position in which they are retracted in said cavity of said outer cylinder to expose said bone anchor.

3. The device of claim 1 wherein the protective sheath comprises a balloon.

4. The device of claim 1 wherein the protective sheath comprises a gelatin structure.

5. The device of claim 3 wherein said balloon is perforatable by the bone anchor as the bone anchor is pressed into a bone.

6. The device of claim 3 wherein said balloon is hermetically sealed around the bone anchor.

7. The device of claim 3 wherein said balloon comprises a material selected from the group consisting of plastic, thermoplastic, elastromers, PET, PETG, rubber, vinyl, latex, and silicone.

8. The device of claim 3 wherein said balloon comprises latex.

9. The device of claim 3 wherein said balloon comprises a biodegradable material.

10. The device of claim 9 wherein said biodegradable material comprises a polymer.

11. The device of claim 10 wherein said polymer comprises a synthetic polymer.

12. The device of claim 9 wherein said polymer is selected from the group consisting of polyglycolic acid (PGA), polylactic acid (PLA), poly (dioxanone) (PDO), poly (l-lactide) (LPLA), poly (dl-lactide) (DLPLA), poly (glycolide-co-trimethylene carbonate) (PGA-TMC), poly (l-lactide-co-glycolide) (PGA-LPLA), poly (dl-lactide-co-glycolide) (PGA-DLPLA), poly (l-lactide-co-dl-lactide) (LPLA-DL-PLA), poly(glycolide-co-trimethylene carbonate-co-dioxanone) (PDO-PGA-TMC), poly(ϵ-caprolactone), poly(dioxanone)(a polyether-ester), poly (lactide-co-glycotide), poly(SA-HDA anhydride), poly(orthoester), polyglyconate.

13. The device of claim 3 wherein said balloon contains an antibiotic.

14. The device of claim 4 wherein said gelatin structure contains an antibiotic.

15. The device of claim 3 further comprising a port which extends from the first end to the second end of said shaft into the balloon.

16. The device of claim 4 further comprising a port which extends from the first end to the second end of said shaft into the gelatin structure.

17. The device of claim 13 wherein said antibiotic is released when the balloon is perforated.

18. The device of claim 14 wherein said antibiotic is release when the gelatin structure is perforated.

19. The device of claim 13 or 14 wherein said antibiotic is selected from the group consisting of nafcillin, aminogylcoside, ciprofloxin, clindamcin, piperacillin/tazobactum, ampicillin/sulbactum, aminoglcoside, vancomycin, cephalosporin, TMP/SMX, ampicillin, gentaminicin, tobramycin and ciprofloxacin.

20. The device of claim 3 further comprising a spring element attached to the shaft within to the balloon which retracts when the balloon is pressed against the bone by the shaft causing the bone anchor to perforate the sheath.

21. The device of claim 20 wherein the spring element comprises an open-coiled helical spring which surrounds the bone anchor.

22. The device of claim 1 wherein one or more sutures are coupled to the bone anchor and wherein the shaft includes a hollow section in which the sutures are disposed.

23. A method of inserting into a bone a bone anchor that is releasably engaged to a bone anchor implantation device and covered by a sheath, comprising:

(1) locating a bone anchor implantation site on the bone,

(2) applying a retrograde force to said bone anchor to perforate said sheath and implant said bone anchor into said bone.

24. The method of claim 23 wherein said sheath comprises a balloon and step (2) includes perforating the balloon.

25. The method of claim 24 further comprising the step of inserting an antibiotic into the balloon which is released when the sheath is perforated.

26. The method of claim 24 wherein said bone anchor implantation device further comprises a spring element attached to the end of the shaft within the balloon and step (2) further comprises retracting the spring element.

* * * * *