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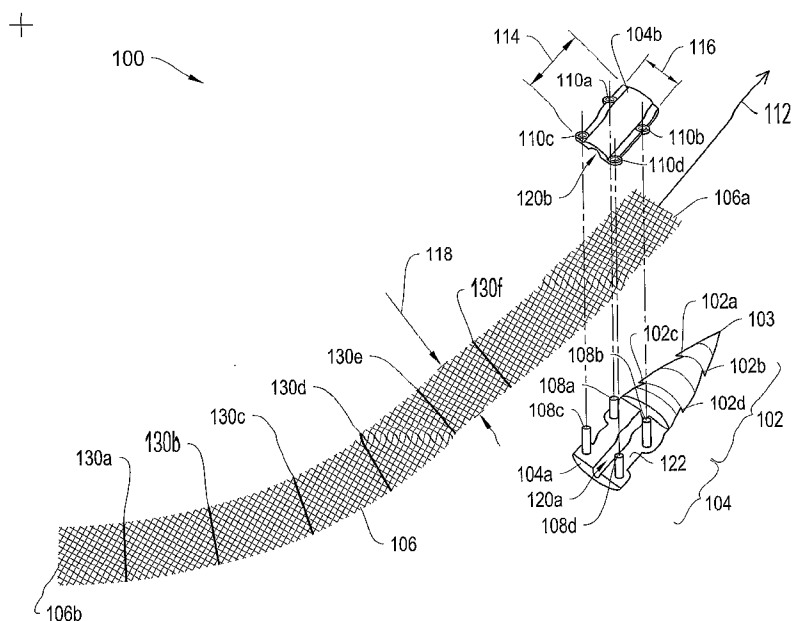
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(54) Title: **SNAP FIT SLING ANCHOR SYSTEM AND RELATED METHODS**



(57) Abstract: The invention provides, in various embodiments, systems, devices and methods relating to employing soft tissue anchors in combination with an implantable sling to treat urinary incontinence.

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## SNAP FIT SLING ANCHOR SYSTEM AND RELATED METHODS

### Field of the Invention

The invention generally relates to systems and methods for delivering a supportive sling to an anatomical location in a patient. More particularly, in various  
5 embodiments, the invention relates to an anchor system for attaching to an end of a sling or sling assembly for affixing the sling in place.

### Background of the Invention

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

A popular treatment of SUI uses a surgical sling placed under the bladder  
20 neck or the mid-urethra to provide a urethral platform. Placement of the sling limits the endopelvis fascia drop. The sling is traditionally affixed using a bone anchoring method. Recent advances in surgical techniques have demonstrated the effectiveness of anchorless approaches toward mid-urethra sling stabilization. However, conventional anchorless techniques suffer from some deficiencies. For example,  
25 many do not provide an easily used mechanism for anchoring a sling in place, at least temporarily. Others do not provide an easily used mechanism for adjusting the length of the sling based, for example, on application and patient size.

Accordingly, there is a need for an improved approach to sling placement that simplifies the procedure and reduces trauma to the patient.

### **Summary of the Invention**

The systems and methods described herein are generally directed to the treatment of stress urinary incontinence. More particularly, in various embodiments, the invention provides systems and methods relating to delivering a supportive sling to the periurethral tissue of a patient, without the need for abdominal or ishiopubic incisions. According to further embodiments, the invention makes it easier for a medical operator to accurately place the supportive sling at a desired anatomical location. In other embodiments, the invention makes it easier for a medical operator to disassociate a sling from a delivery device and/or a remaining portion of a sling assembly. According to additional embodiments, the invention makes it easier to attach an anchor to an end of the sling and to adjust the length of the sling by varying the placement of the anchor.

In one aspect, the invention provides a tissue anchor including a fixation portion and a body portion. The fixation portion may have any shape suitable for affixing the anchor within an anatomical membrane, muscle, ligament, soft tissue, bone or other anatomical site. By way of example, the fixation portion may have edges, tapers, barbs or other protrusions for anchoring the fixation portion in place. The body portion attaches to the sling. According to one embodiment, the body portion is separable into first and second sections, between which a sling end may be interfitted to attach the sling end to the tissue anchor. In one implementation, the first and second body sections are two separate and distinct parts sized and shaped to fit together. According to another implementation, the first and second body sections are hinged such that they remain connected to each other when separated/opened to introduce a sling end. In either case, the body sections may be interfitted together, for example, by way of snap fitting, heat staking, press fitting, gluing or other suitable mechanism.

According to one configuration, the first body section includes one or more apertures (which, optionally, may be through apertures), and the second body section includes one or more protuberances for extending into and interfitting with the apertures of the first body section to fit the first and second body sections together, for example, by way of a snap fitting, press fitting, heat staking, gluing, or other

suitable mechanism. The one or more protuberances of the second body section may also fit through holes in a sling prior to interfitting into the one or more apertures of the first body section. Such holes include, without limitation, mesh openings or particularly created (and optionally reinforced) anchor engaging openings in the sling  
5 end. According to one feature, the sling includes holes along its length and the first and second body portions fit together through any of a plurality of the holes to adjust a functional length of the sling.

According to another configuration, the first body section includes a latch structure along an axially extending edge, the latch structure having an indent or  
10 through aperture, and the second body section includes a protuberance along a corresponding axial edge for snap fitting into the through aperture of the first body section to secure the first and second body sections together. An advantage to this configuration is that it enables a medical operator to easily remove the anchor from the sling if it needs to be moved to a different location along the sling. In this  
15 configuration, the body sections may also include the previously mentioned one or more apertures and protuberances for engaging with the sling openings, but they need not be sized and shaped for snap fitting together.

According to one embodiment, the body portion is elongated having a length that extends axially along the length of a sling (when attached) that is greater than a  
20 width that extends transversely across at least a portion of the width of the sling (when attached). According to an alternative embodiment, the body portion has a length and a width that are substantially equal. The body portion may have any suitable shape for attaching to the sling. By way of example, without limitation, it may be generally rectangular in nature, or alternatively may have rounded sides and  
25 be cylindrical in nature.

According to another embodiment, inner sling contacting surfaces of the first and second body sections may be ridged or otherwise textured to further engage with the sling to facilitate attachment to the sling end. According to a further embodiment, at least one of the first and second body sections include an axially  
30 extending slot/channel for slidably interfitting over a distal end of a shaft of a delivery device for implanting and positioning the anchor at an anatomical site.

According to another aspect, the fixation portion and the body portion of the tissue anchor are formed integrally with each other, and the anchor is separable into first and second sections, with each section including a body portion and a fixation portion. In one embodiment, the tissue anchor is elongated and is separable along a plane that extends axially through the tissue anchor. This aspect of the invention may include any of the features described above with respect to the separate body and fixation portion configuration.

In a further aspect, the invention is directed to a sling delivery system for delivering a sling assembly including a snap fit tissue anchor of the invention.

According to one embodiment, the delivery system includes a shaft and a handle attached to a proximal end of the shaft. The shaft may be substantially straight or may include one or more curved sections. Additionally, the shaft may lie substantially in one plane or may be shaped to lie in multiple planes. The shaft may be of substantially constant outside diameter or may include portions of differing outside diameters. In various embodiments, the shaft may include hooked and/or helical portions.

According to one embodiment, the shaft includes a narrowed distal end for fitting into an axially extending slot/channel in the body of the tissue anchor. In one embodiment, the distal end of the shaft includes a shoulder extending radially outward. In one configuration, the shoulder extends around the entire circumference of the shaft. In other configurations, the shoulder extends around only a portion of the circumference. In both cases, the shoulder extends far enough to impede the tissue anchor from sliding proximally along the length of the shaft past the shoulder.

In a further embodiment, the sling delivery system includes a pusher assembly slidably interfitted over the shaft and slidably actuatable in a distal direction by a medical operator to push an end of a sling assembly off the distal end of the shaft. In one configuration of this embodiment, a distal end of the pusher assembly forms the shoulder, which contacts a proximal end of the body of the tissue anchor.

According to another aspect, the invention provides an implantable sling, either alone or as part of a sling delivery system. According to one configuration, the

sling or a sling assembly including the sling includes features for indicating length measurements for aiding in positioning of the sling. According to one configuration, the sling and/or sling assembly also includes a feature for indicating a center location along the length of the sling, also for aiding in accurate sling placement. Preferably, the center feature, and the length measurement and/or position-indicating features are distinguishable from each other. By way of example, the length measurement and/or position-indicating features, and center features may be differently colored and/or of different widths.

In one configuration, protuberances of the tissue anchor extend through and engage with a double layer of sling material formed from folding the sling end lengthwise along the length indicating feature and toward the center indicating feature. In another configuration, the sling assembly includes preformed, structurally reinforced through apertures at its ends for engaging and interfitting the tissue anchor protuberances.

According to another aspect, the invention provides a method for delivering a sling to an anatomical location in a patient including the steps of snap fitting a tissue anchor onto a sling at a desired location, engaging a distal end of a delivery device with the tissue anchor, introducing the distal end of the delivery device with the tissue anchor so engaged into the body of the patient, and removing the distal end of the delivery device from the tissue anchor and the body of the patient to deliver the sling to the anatomical location in the patient. According to one embodiment, the step of snap fitting includes snap fitting the tissue anchor onto the sling assembly at a length indicating feature. According to a further embodiment, the method includes the step of folding an end of a sling included in the sling assembly lengthwise at a length indicating feature to adjust the length of the sling, and the step of snap fitting includes snap fitting the tissue anchor over two layers of sling material near the length indicating feature. In another embodiment, the removing step includes actuating a pusher assembly to slide the tissue anchor off of the distal end of the delivery device.

According to a feature of the invention, the sling delivery systems and devices of the invention may be particularly sized and shaped for transvaginal /

prepubic procedures. Such procedures, according to one approach, involve a single midline incision in the vaginal wall, through which both ends of the sling assembly are delivered. The tissue anchors at each end of the sling assembly may be positioned, for example, near or through an obturator membrane, in the periurethral  
5 tissues, in a prepubic space and/or in a retropubic space. According to another embodiment, the tissue anchors of the invention are formed from a biodegradable / bioabsorbable material. Preferably, the material is selected such that the tissue anchors dissolve at a rate that provides enough time for tissue to grow into the sling to hold the sling in place when the tissue anchors are gone.

10 Other aspects and advantages are described below.

### **Brief Description of the Drawings**

The following figures depict certain illustrative embodiments of the invention in which like reference numerals refer to like elements. These depicted embodiments may not be drawn to scale and are to be understood as illustrative of the invention  
15 and not as limiting in any way.

Figure 1A is an exploded perspective view of a tissue anchor for affixing a sling end at an anatomical site according to an illustrative embodiment of the invention.

Figure 1B is a front perspective view of a tissue anchor for affixing a sling  
20 end at an anatomical site according to an alternative illustrative embodiment of the invention.

Figure 2 is an exploded perspective view of a tissue anchor for affixing a sling end at an anatomical site according to another illustrative embodiment of the invention.

25 Figure 3 shows a sling assembly of the invention interfitted over a distal end of a shaft of a delivery device.

Figure 4 shows a sling assembly of the invention interfitted over a distal end of a delivery device employing a pusher assembly according to an illustrative embodiment of the invention.

Figure 5 shows a delivery device according to an illustrative embodiment of the invention.

Figures 6A-6C show delivery devices according to illustrative embodiments of the invention.

5        Figures 7A-7B are conceptual diagrams showing affixation of a sling end to an obturator membrane using a tissue anchor according to an illustrative embodiment of the invention.

10        Figures 8A-8B are conceptual diagrams showing affixation of a sling end to an obturator membrane using a tissue anchor according to an illustrative embodiment of the invention.

Figures 9A-9B are conceptual diagrams illustrating deficiencies in prior art sling assembly configurations.

Figures 10A-10B show a tissue anchor for affixing a sling end at an anatomical site according to an illustrative embodiment of the invention.

15        **Illustrative Description**

In general, the invention is directed to systems, methods and devices for treating urinary incontinence. As described below in more detail, in various illustrative embodiments, the invention provides systems, methods and devices employing an improved soft tissue anchor for anchoring a sling end in place, at least temporarily. According to one advantage, the tissue anchor of the invention facilitates delivery of a supportive sling to the periurethral tissue of a patient, without the need for abdominal or ishiopubic incisions. According to other advantages, the invention makes it easier for a medical operator to accurately place the supportive sling at a desired anatomical location. According to further advantages, the tissue anchor of the invention makes it easier for a medical operator to adjust the effective length of a sling, and also facilitates improved affixation of the sling ends to surrounding tissue.

Without limitation, examples of slings, sling assemblies, sling delivery devices and approaches, sling assembly-to-delivery device association mechanisms, and sling anchoring configurations with which the invention may be employed are

disclosed in U.S. Patent No. 6,042,534, entitled "Stabilization Sling for Use in Minimally Invasive Pelvic Surgery," U.S. Patent No. 6,755,781, entitled "Medical Slings," U.S. Patent No. 6,666,817, entitled "Expandable Surgical Implants and Methods of Using Them," U.S. Patent No. 6,042,592, entitled "Thin Soft Tissue Surgical Support Mesh," U.S. Patent No. 6,375,662, entitled "Thin Soft Tissue Surgical Support Mesh," U.S. Patent No. 6,669,706, entitled "Thin Soft Tissue Surgical Support Mesh," U.S. Patent No. 6,752,814, entitled "Devices For Minimally Invasive Pelvic Surgery," U.S. Patent Application Serial No. 10/918,123, entitled "Surgical Slings," U.S. Patent Application Serial No. 10/641,376, entitled "Spacer for Sling Delivery System," U.S. Patent Application Serial No. 10/641,192, entitled "Medical Slings," U.S. Patent Application Serial No. 10/641,170, entitled "Medical Slings," U.S. Patent Application Serial No. 10/640,838, entitled "Medical Implant," U.S. Patent Application Serial No. 10/460,112, entitled "Medical Slings," U.S. Patent Application Serial No. 10/631,364, entitled "Bioabsorbable Casing for Surgical Sling Assembly," U.S. Patent Application Serial No. 10/092,872, entitled "Medical Slings," U.S. Patent Application Serial No. 10/939,191, entitled "Devices for Minimally Invasive Pelvic Surgery," U.S. Patent Application Serial No. 10/774,842, entitled "Devices for Minimally Invasive Pelvic Surgery," U.S. Patent Application Serial No. 10/774,826, entitled "Devices for Minimally Invasive Pelvic Surgery," U.S. Patent Application Serial No. 10/015,114, entitled "Devices for Minimally Invasive Pelvic Surgery," U.S. Patent Application Serial No. 10/973,010, entitled "Systems and Methods for Sling Delivery and Placement," U.S. Patent Application Serial No. 10/957,926, entitled "Systems and Methods for Delivering a Medical Implant to an Anatomical Location in a Patient," U.S. Patent Application Serial No. 10/939,191, entitled "Devices for Minimally Invasive Pelvic Surgery," U.S. Patent Application Serial No. 10/918,123, entitled "Surgical Slings," U.S. Patent Application Serial No. 10/832,653, entitled "Systems and Methods for Sling Delivery and Placement," U.S. Patent Application Serial No. 10/642,397, entitled "Systems, Methods and Devices Relating to Delivery of Medical Implants," U.S. Patent Application Serial No. 10/642,395, entitled "Systems, Methods and Devices Relating to Delivery of Medical Implants," U.S. Patent Application Serial No. 10/642,365, entitled "Systems, Methods and Devices Relating to Delivery of Medical Implants,"

U.S. Patent Application Serial No. 10/641,487, entitled "Systems, Methods and Devices Relating to Delivery of Medical Implants," U.S. Patent Application Serial No. 10/094,352, entitled "System for Implanting an Implant and Method Thereof," U.S. Patent Application Serial No. 10/093,498, entitled "System for Implanting an  
5 Implant and Method Thereof," U.S. Patent Application Serial No. 10/093,450, entitled "System for Implanting an Implant and Method Thereof," U.S. Patent Application Serial No. 10/093,424, entitled "System for Implanting an Implant and Method Thereof," U.S. Patent Application Serial No. 10/093,398, entitled "System for Implanting an Implant and Method Thereof," and U.S. Patent Application Serial  
10 No. 10/093,371, entitled "System for Implanting an Implant and Method Thereof," the entire contents of all of which are incorporated herein by reference.

Figure 1A is an exploded perspective view of a tissue anchor 100 for affixing a sling end at an anatomical site according to an illustrative embodiment of the invention. As shown, the tissue anchor 100 includes a fixation portion 102 and a  
15 body portion 104. The fixation portion 102 may have any shape suitable for affixing the anchor within an anatomical membrane, muscle, ligament, soft tissue, bone or other anatomical site. By way of example, the fixation portion 102 may have edges, tapers, barbs or other protrusions for anchoring the fixation portion in place. According to the illustrative embodiment of Figure 1A, the fixation portion 102  
20 includes radially extending barbs 102a-102d. The barbs 102a-102d are tapered to narrow toward a distal tip 103 of the anchor 100 to facilitate the anchor 100 passing into tissue and resist it being pulled out of the tissue.

The body portion 104 is sized and shaped to attach to a sling, such as the sling 106. According to the illustrative embodiment of Figure 1A, the body portion 104 is  
25 separable into first 104a and second 104b sections, between which the sling 106 may be interfitted to attach the sling 106 to the tissue anchor 100. In the illustrative embodiment of Figure 1A, the first 104a and second 104b body sections are two separate and distinct parts sized and shaped to fit together. More particularly, one body portion, such as the first body portion 104a, includes one or more protuberances  
30 108a-108d, and the other body portion, such as the second body portion 104b, includes one or more apertures 110a-110d (which, optionally, may be through apertures) with which the protuberances 108a-108d interfit and engage to fit the first

104a and second 104b body portions together, for example, by way of a snap fitting, press fitting, heat staking, gluing, or other suitable mechanism. As shown, the protuberances 108a-108d of the second body section fit through holes in the mesh material of the sling 106 prior to interfitting into the apertures 110a-110d to secure  
5 the sling 106 between the first 104a and second 104b body sections. According to other illustrative embodiments, the holes in the sling 106 may include, without limitation, particularly created (and optionally reinforced) anchor engaging openings.

According to one feature, the sling 106 has an initial length as measured from one terminal end 106a to another terminal end 106b, and includes holes (such as the  
10 mesh openings) along its length. The first 104a and second 104b body portions may be fit together through any of the plurality of the holes along the length of the sling 106 to adjust a functional length of the sling, as measured between a first tissue anchor, such as the tissue anchor 100 and a second tissue anchor, not shown. The sling 106 may include markings, such as the transverse markings 130a-130f, for  
15 indicating length measurements of the sling. A marking, such as the marking 130d, may be included to indicate a middle location along the length of the sling 106.

According to the depicted embodiment of Figure 1A, the tissue anchor 100 is elongated in nature, with the tissue engaging portion 102 extending axially from the body portion 104. In the illustrative embodiment of Figure 1A, the tissue engaging  
20 portion 102 also extends substantially axially from the sling 106, as opposed to extending along an axis substantially offset from a sling axis 112. It should be noted that the sling axis 112 refers to an axis of the sling 106 taken along its length when it is extended in a substantially straight fashion.

The illustrative body portion 108 is also elongated and has a length 114 which  
25 extends axially along the length of the sling 106 (when attached) that is greater than a width 116 which extends transversely across at least a portion of the width 118 of the sling 106 (when attached). According to an alternative embodiment, the body portion 104 has a length 114 and a width 116 that are substantially equal. The body portion 104 may have any suitable shape for attaching to the sling 106. By way of  
30 example, without limitation, it may be generally rectangular in nature, or alternatively may have rounded sides and be cylindrical in nature.

According to the illustrative embodiment, inner sling contacting surfaces 122 of the first 104a and second 104b body sections may be ridged or otherwise textured to further engage with the sling 106 to facilitate attachment to the sling end.

According to another feature, the first body section 104a includes an axially  
5 extending channel 120a and the second body section 104b includes an axially  
extending channel 120b. With the first 104a and second 104b body sections attached  
together, the first 120a and second 120b channels come together to form an enclosed  
axially extending channel 120 in the body portion 104. As described below in further  
detail with regard to Figures 3 and 4, the axially extending channel 120 is sized and  
10 shaped for interfitting over a distal end of a delivery device shaft. As also described  
below, in other illustrative embodiments, the channel 120 is sized and shaped for  
fitting over the finger of a medical operator.

Figure 1B is a front perspective view of a soft tissue anchor 201 according to  
another illustrative embodiment of the invention. As in the case of the soft tissue  
15 anchor 100, the anchor 201 includes a tissue engaging portion 203 and a sling  
engaging body portion 205. Instead of having two separable sections, such as the  
sections 104a and 104b, of Figure 1A, the body portion 205 has two hinged sections  
205a and 205b, hinged along an axially extending edge 207. According to the  
illustrative embodiment, the hinged sections 205a and 205b are integrally formed  
20 together, with the axially extending edge 207 being thinned sufficiently to enable  
hinge like motion between the two sections 205a and 205b. The hinged section 205b  
also includes a latch 209 extending radially from an axially extending edge 211. The  
latch 209 includes an aperture 219 sized and shaped to snap fit with a protuberance  
213 located along an axially extending edge 213. The body portion 205 also includes  
25 an axially extending channel 217 sized and shaped for interfitting over a distal end of  
a delivery device shaft. In a similar fashion to the embodiment of Figure 1A, the two  
body sections 205a and 205b come together to sandwich and engage with a sling end  
there between.

Figure 2 is an exploded perspective view of a soft tissue anchor 200 for  
30 affixing an end 106a of a sling 106 at an anatomical site according to another  
illustrative embodiment of the invention. According to the illustrative embodiment of  
Figure 2, the fixation portion 202 and the body portion 204 of the tissue anchor 200

are formed integrally with each other. The anchor 200 is separable into first 200a and second 200b sections. The first section 200a includes a fixation portion 202a and a body portion 204a. Similarly, the second section 200b includes a fixation portion 202b and a body portion 204b.

5           The fixation portions 202a and 202b come together to have any shape suitable for affixing the anchor 200 within an anatomical membrane, muscle, ligament, soft tissue, bone or other anatomical site. By way of example, the fixation portions 202a and 202b may have edges, tapers, barbs or other protrusions for anchoring the fixation portion in place. According to the illustrative embodiment of Figure 2, the  
10          fixation portions 202a and 202b include radially extending barbs 203a-203d of the type depicted in Figure 1A at 102a-102d.

          The body portion 204 is sized and shaped to attach to a sling, such as the sling 106. According to the illustrative embodiment of Figure 2, the first 204a and second 204b sections of the body portion 204 come together to sandwich and affix to the  
15          sling 106. In the illustrative embodiment of Figure 2, the first 204a and second 204b body sections are two separate and distinct parts sized and shaped to fit together. More particularly, one body portion, such as the first body portion 204a, includes one or more protuberances 208a-208d, and the other body portion, such as the second body portion 204b, includes one or more apertures 210a-210d (which, optionally,  
20          may be through apertures) with which the protuberances 208a-208d interfit and engage to fit the first 200a and second 200b anchor portions together, for example, by way of a snap fitting, press fitting, heat staking, gluing, or other suitable mechanism. As shown, the protuberances 208a-208d of the second body section fit through reinforced holes 107a-107d in the mesh material of the sling 106 prior to  
25          interfitting into the apertures 210a-210d to secure the sling 106 between the first 204a and second 204b body sections.

          As in the case of the illustrative embodiment of Figure 1A, the tissue anchor 200 is elongated in nature, with the tissue engaging portion 202 extending axially from the body portion 204. The tissue engaging portion 202 also extends  
30          substantially axially from the sling 106, as opposed to extending along an axis substantially offset from a sling axis 112. The illustrative body portion 208 is also

elongated and has a length which extends axially along the length of the sling 106 (when attached) that is greater than a width which extends transversely across at least a portion of the width 118 of the sling 106 (when attached). According to an alternative embodiment, the body portion 204 has a length and a width that are substantially equal. The body portion 204 may have any suitable shape for attaching to the sling 106. By way of example, without limitation, it may be generally rectangular in nature, or alternatively may have rounded sides and be cylindrical in nature.

As in the case of the illustrative embodiment of Figure 1A, the inner sling contacting surfaces 222 of the first 204a and second 204b body sections may be ridged or otherwise textured to further engage with the sling 106 to facilitate attachment to the sling end 106a. According to another feature, the first anchor portion 200a includes an axially extending channel 220a and the second anchor portion 200b includes an axially extending channel 220b. With the first 200a and second 200b anchor portions attached together, the first 220a and second 220b channels come together to form an enclosed axially extending channel 220 in the anchor portion 200. As described below in further detail with regard to Figures 3 and 4, the axially extending channel 220 is sized and shaped for interfitting over a distal end of a delivery device shaft. As also described below, in other illustrative embodiments, the channel 220 is sized and shaped for fitting over the finger of a medical operator.

Although, Figures 1 and 2 depict the tissue anchors 100 and 200 as having separate and distinct body sections, 104a, 104b and 204a, 204b, respectively, this need not be the case. According to other illustrative configurations, one of the body sections, such as the first body section 104a/204a includes a latch structure along an axially extending edge. The latch structure may include, for example, an indent or through aperture. The other body section, such as the second body section 104b/204b, includes a mating protuberance along a corresponding axial edge for snap fitting into the through aperture of the first body section to secure the first and second body sections together. An advantage to this configuration is that it enables a medical operator to easily remove the anchor 100/200 from the sling 106 if the anchor 100/200 needs to be moved to a different location along the sling 106. In this

configuration, the body portions 104/204 may also include the previously mentioned one or more apertures and protuberances for engaging with the sling openings, but they need not be sized and shaped for snap fitting together, but instead only to secure the sling 106 in place between the body sections 104a, 104b or 204a, 204b.

- 5           In another illustrative embodiment, the sling 106 includes features for indicating length measurements for aiding in positioning of the anchors 100/200 along its length. According to one configuration, the sling also includes a feature for indicating a center location along its length. Preferably, the center feature, the length measurements, and the position-indicating features are distinguishable from each other. By way of example, the length measurement and/or position-indicating features, and center features may be differently colored and/or of different widths.

- According to various illustrative embodiments, the tissue anchors 100 and 200 may be made of any suitable biocompatible material. The tissue anchors 100 and 200 may be made, for example, of a synthetic material such as nylon,  
15   polyethylene, polyester, polypropylene, fluoropolymers or a co-polymer thereof. In some illustrative embodiments, they may be formed, at least in part, from a mammalian tissue material such as bovine, porcine, equine, human cadaveric or engineered tissue. In some illustrative embodiments, the material of the anchors 100 and 200 may include a combination of synthetic and mammalian tissue materials.

- 20           According to other illustrative embodiments, at least a portion of the anchors 100 and 200 is biodegradable and may also dissolve and/or be absorbed into the patient's tissues. Exemplary biodegradable materials that may be employed for at least a portion of the anchors 100 and 200 include, but are not limited to, polylactic acid, polyglycolic acid and copolymers and mixtures thereof, such as poly(L-lactide)  
25   (PLLA), poly(D,L-lactide) (PLA), polyglycolic acid [polyglycolide (PGA)], poly(L-lactide-co-D,L-lactide) (PLLA/PLA), poly(L-lactide-co-glycolide) (PLLA/PGA), poly(D,L-lactide-co-glycolide) (PLA/PGA), poly(glycolide-co-trimethylene carbonate) (PGA/PTMC), poly(D,L-lactide-co-caprolactone) (PLA/PCL), and poly(glycolide-co-caprolactone) (PGA/PCL); polyethylene oxide (PEO);  
30   polydioxanone (PDS); polypropylene fumarate; polydepsipeptides, poly(ethyl glutamate-co-glutamic acid), poly(tert-butyloxy-carbonylmethyl glutamate);

polycaprolactone (PCL), poly(hydroxy butyrate), polycaprolactone co-butylacrylate, polyhydroxybutyrate (PHBT) and copolymers of polyhydroxybutyrate; polyphosphazenes, poly(phosphate ester); maleic anhydride copolymers, polyiminocarbonates, poly[(97.5% dimethyl-trimethylene carbonate)-co-(2.5%  
5 trimethylene carbonate)], cyanoacrylate, hydroxypropylmethylcellulose; polysaccharides, such as hyaluronic acid, chitosan and regenerate cellulose; poly(amino acid) and proteins, such as gelatin and collagen; and mixtures and copolymers thereof.

According to another feature, the anchors 100 and 200 may be configured to  
10 dissolve within a particular time range. The anchors 100 and 200 may be configured, for example, to substantially absorb (or have a portion that substantially absorbs) into the patient's tissues within about 2, 4, 6 or 8 or more weeks from the time the sling is implanted. Preferably, the anchors 100 and 200 remain structurally in tact long enough for scar tissue and/or other neighboring cells or tissues to grow into the sling  
15 106 to effectively anchor it in place.

According to other illustrative embodiments, the sling 106 may be treated with one or more agents for release into the patient's tissues. One illustrative agent promotes, when applied to the patient's tissues in a pharmaceutically acceptable amount, well-organized collagenous tissue growth, such as scar tissue growth,  
20 preferably, in large quantities. According to one feature, the agent may or may not block or delay the dissolvability of the sling 106. This may be controlled by selecting differing methods for loading the agent onto the sling 106. The tissue growth factor may include natural and/or recombinant proteins for stimulating a tissue response so that collagenous tissue, such as scar tissue, growth is enhanced.  
25 The tissue growth factor may similarly include natural and/or recombinant proteins for stimulating a tissue response so that non-scar tissue growth is enhanced. Furthermore, the tissue growth factor may include non-protein, small molecule agents that mimic the effects of a natural and/or recombinant protein on scar or non-scar tissue growth. Exemplary growth factors that may be used include, but are not  
30 limited to, platelet-derived growth factor (PDGF), fibroblast growth factor (FGF), transforming growth factor-beta (TGF-beta), vascular endothelium growth factor

(VEGF), Activin/TGF and sex steroid, bone marrow growth factor, growth hormone, Insulin-like growth factor 1, and combinations thereof. Exemplary small molecule growth factors include, but are not limited to, small molecule agents that mimic the effects of one or more of the foregoing growth factors. The agent may also include a

5 hormone, including but not limited to estrogen, steroid hormones, and other hormones to promote growth of appropriate collagenous tissue such as scar tissue. The agent may also include stem cells or other suitable cells derived from the host patient or derived from a suitable donor. Suitable cells include, without limitation, embryonic stem cells, adult stem cells, and other suitable non-stem cells. Stem or

10 non-stem cells may be fibroblastic, mesenchymal, myoblastic, endothelial, and other cell types capable of maturing into appropriate tissues.

In various illustrative embodiments, the agent may include one or more therapeutic agents. The therapeutic agents may be, for example, anti-inflammatory agents, including steroidal and non-steroidal anti-inflammatory agents, analgesic

15 agents, including narcotic and non-narcotic analgesics, local anesthetic agents, antispasmodic agents, growth factors, gene-based therapeutic agents, and combinations thereof. Such therapeutic agents include protein and non-protein, small molecule agents.

Exemplary steroidal anti-inflammatory therapeutic agents (glucocorticoids)

20 include, but are not limited to, 21-acetoxyprefnenolone, aalclometasone, algestone, amcinonide, beclomethasone, betamethasone, budesonide, chloroprednisone, clobetasol, clobetasone, clocortolone, cloprednol, corticosterone, cortisone, cortivazol, deflazacort, desonide, desoximetasone, dexamethasone, diflorasone, diflucortolone, difluprednate, enoxolone, fluazacort, flucloronide, flumehtasone,

25 flunisolide, fluocinolone acetonide, fluocinonide, fluocortin butyl, fluocortolone, fluorometholone, fluperolone acetate, fluprednidene acetate, fluprednisolone, flurandrenolide, fluticasone propionate, formocortal, halcinonide, halobetasol priopionate, halometasone, halopredone acetate, hydrocortamate, hydrocortisone, loteprednol etabonate, mazipredone, medrysone, meprednisone,

30 methylprednisolone, mometasone furoate, paramethasone, prednicarbate, prednisolone, prednisolone 25-diethylaminoacetate, prednisone sodium phosphate, prednisone, prednival, prednylidene, rimexolone, tixocortal, triamcinolone,

triamcinolone acetonide, triamcinolone benetonide, triamcinolone hexacetonide, and pharmaceutically acceptable salts thereof.

Exemplary non-steroidal anti-inflammatory therapeutic agents include, but are not limited to, aminoarylcarboxylic acid derivatives such as enfenamic acid,  
 5 etofenamate, flufenamic acid, isonixin, meclofenamic acid, mefenamic acid, niflumic acid, talniflumate, terofenamate and tolfenamic acid; arylacetic acid derivatives such as acetmetacin, alclofenac, amfenac, bufexamac, cinmetacin, clopirac, diclofenac sodium, etodolac, felbinac, fenclofenac, fenclorac, fenclozic acid, fentiazac, glucametacin, ibufenac, indomethacin, isofezolac, isoxepac, lonazolac, metiazinic  
 10 acid, oxametacine, proglumetacin, sulindac, tiaramide, tolmetin and zomepirac; arylbutyric acid derivatives such as bumadizon, butibufen, fenbufen and xenbucin; arylcarboxylic acids such as clidanac, ketorolac and tinoridine; arylpropionic acid derivatives such as alminoprofen, benoxaprofen, bucloxic acid; carprofen, fenoprofen, flunoxaprofen, flurbiprofen, ibuprofen, ibuproxam, indoprofen,  
 15 ketoprofen, loxoprofen, mioprofen, naproxen, oxaprozin, piketoprofen, pirprofen, pranoprofen, protizinic acid, suprofen and tiaprofenic acid; pyrazoles such as difenamizole and epirizole; pyrazolones such as apazone, benzpiperylon, feprazone, mofebutazone, morazone, oxyphenbutazone, phenybutazone, pipebuzone, propyphenazone, ramifenazone, suxibuzone and thiazolinobutazone; salicylic acid  
 20 derivatives such as acetaminosalol, aspirin, benorylate, bromosaligenin, calcium acetylsalicylate, diflunisal, etersalate, fendosal, gentisic acid, glycol salicylate, imidazole salicylate, lysine acetylsalicylate, mesalamine, morpholine salicylate, 1-naphthyl salicylate, olsalazine, parsalimide, phenyl acetylsalicylate, phenyl salicylate, salacetamide, salicylamine o-acetic acid, salicylsulfuric acid, salsalate and  
 25 sulfasalazine; thiazinecarboxamides such as droxicam, isoxicam, piroxicam and tenoxicam; others such as  $\epsilon$ -acetamidocaproic acid, s-adenosylmethionine, 3-amino-4-hydroxybutyric acid, amixetrine, bendazac, benzydamine, bucolome, difenpiramide, ditazol, emorfazone, guaiazulene, nabumetone, nimesulide, orgotein, oxaceprol, paranyline, perisoxal, pifoxime, proquazone, proxazole and tenidap; and  
 30 pharmaceutically acceptable salts thereof.

Exemplary narcotic analgesic therapeutic agents include, but are not limited to, alfentanil, allylprodine, alphaprodine, anileridine, benzylmorphine, bezitramide,

buprenorphine, butorphanol, clonitazene, codeine, codeine methyl bromide, codeine phosphate, codeine sulfate, desomorphine, dextromoramide, dezocine, diampromide, dihydrocodeine, dihydrocodeinone enol acetate, dihydromorphine, dimenoxadol, dimepheptanol, dimethylthiambutene, dioxaphetyl butyrate, dipipanone, eptazocine,  
 5 ethoheptazine, ethylmethylthiambutene, ethylmorphine, etonitazene, fentanyl, hydrocodone, hydromorphone, hydroxypethidine, isomethadone, ketobemidone, levorphanol, lofentanil, meperidine, meptazinol, metazocine, methadone hydrochloride, metopon, morphine, myrophine, nalbuphine, narceine, nicomorphine, norlevorphanol, normethadone, normorphine, norpipanone, opium, oxycodone,  
 10 oxymorphone, papaveretum, pentazocine, phenadoxone, phenazocine, pheoperidine, piminodine, piritramide, proheptazine, promedol, properidine, propiram, propoxyphene, rumifentanil, sufentanil, tilidine, and pharmaceutically acceptable salts thereof.

Exemplary non-narcotic analgesic agents that may be combined with the sling  
 15 100 include, but are not limited to, aceclofenac, acetaminophen, acetaminosalol, acetanilide, acetylsalicylsalicylic acid, alclofenac, alminoprofen, aloxiprin, aluminum bis(acetylsalicylate), aminochlorthenoxazin, 2-amino-4-picoline, aminopropylon, aminopyrine, ammonium salicylate, amtolmetin guacil, antipyrine, antipyrine salicylate, antrafenine, apazone, aspirin, benorylate, benoxaprofen, benzpiperylon,  
 20 benzydamine, bermoprofen, brofenac, p-bromoacetanilide, 5-bromosalicylic acid acetate, buccetin, bufexamac, bumadizon, butacetin, calcium acetylsalicylate, carbamazepine, carbiphen, carsalam, chloralantipyrine, chlorthenoxazin(e), choline salicylate, cinchophen, cirmadol, clometacin, cropropamide, crotethamide, dexoadrol, difenamizole, diflunisal, dihydroxyaluminum acetylsalicylate,  
 25 dipyroctyl, dipyrone, emorfazone, enfenamic acid, epirizole, etersalate, ethenzamide, ethoxazene, etodolac, felbinac, fenoprofen, floctafenine, flufenamic acid, fluorenone, flupirtine, fluproquazone, flurbiprofen, fosfosol, gentisic acid, glafenine, ibufenac, imidazole salicylate, indomethacin, indoprofen, isofezolac, isoladol, isonixin, ketoprofen, ketorolac, p-lactophenetide, lefetamine, loxoprofen,  
 30 lysine acetylsalicylate, magnesium acetylsalicylate, methotrimeprazine, metofoline, miroprofen, morazone, morpholine salicylate, naproxen, nefopam, nifenazone, 5' nitro-2' propoxyacetanilide, parsalimide, perisoxal, phenacetin, phenazopyridine

hydrochloride, phenocoll, phenopyrazone, phenyl acetylsalicylate, phenyl salicylate, phenyramidol, pipebuzone, piperylone, prodilidine, propacetamol, propyphenazone, proxazole, quinine salicylate, ramifenazone, rimazolium metilsulfate, salacetamide, salicin, salicylamide, salicylamide o-acetic acid, salicylsulfuric acid, salsalte, 5 salverine, simetride, sodium salicylate, sulfamipyrine, suprofen, talniflumate, tenoxicam, terofenamate, tetradrine, tinoridine, tolfenamic acid, tolpronine, tramadol, viminol, xenbucin, zomepirac, and pharmaceutically acceptable salts thereof.

Exemplary local anesthetic therapeutic agents include, but are not limited to, ambucaine, amolanone, amylocaine hydrochloride, benoxinate, benzocaine, 10 betoxycaine, biphenamine, bupivacaine, butacaine, butaben, butanilicaine, butethamine, butoxycaine, carticaine, chloroprocaine hydrochloride, cocaethylene, cocaine, cyclomethycaine, dibucaine hydrochloride, dimethisoquin, dimethocaine, diperadon hydrochloride, dyclonine, ecgonidine, ecgonine, ethyl chloride, beta-eucaine, euprocin, fenalcomine, fomocaine, hexylcaine hydrochloride, 15 hydroxytetracaine, isobutyl p-aminobenzoate, leucinocaine mesylate, levoadrol, lidocaine, mepivacaine, meprylcaine, metabutoxycaine, methyl chloride, myrtecaine, naepaine, octacaine, orthocaine, oxethazaine, parethoxycaine, phenacaine hydrochloride, phenol, piperocaine, piridocaine, polidocanol, pramoxine, prilocaine, procaine, propanocaine, proparacaine, propipocaine, propoxycaine hydrochloride, 20 pseudococaine, pyrrocaine, ropavacaine, salicyl alcohol, tetracaine hydrochloride, tolycaine, trimecaine, zolamine, and pharmaceutically acceptable salts thereof.

Exemplary antispasmodic therapeutic agents include, but are not limited to, alibendol, ambucetamide, aminopromazine, apotropine, bevonium methyl sulfate, bietamiverine, butaverine, butropium bromide, n-butylscopolammonium bromide, 25 caroverine, cimetroplum bromide, cinnamedrine, clebopride, coniine hydrobromide, coniine hydrochloride, cyclonium iodide, difemerine, diisopromine, dioxaphetyl butyrate, diponium bromide, drofenine, emepromium bromide, ethaverine, feclemine, fenalamide, fenoverine, fenpiprane, fempiverinium bromide, fentonium bromide, flavoxate, flopropione, gluconic acid, guaiactamine, hydramitrazine, hymecromone, 30 leiopyrrole, mebeverine, moxaverine, nafiverine, octamylamine, octaverine, oxybutynin chloride, pentapiperide, phenamacide hydrochloride, phloroglucinol, pinaverium bromide, piperilate, pipoxolan hydrochloride, pramiverin, prifinium

bromide, properidine, propivane, propyromazine, prozapine, racefemine, rociverine, spasmolytol, stilonium iodide, sultroponium, tiemonium iodide, tiquizium bromide, tiopramide, trepibutone, tricromyl, trifolium, trimebutine, n-ltrimethyl, 3-diphenyl-propylamine, tropenzile, trospium chloride, xenytropium bromide, and

5 pharmaceutically acceptable salts thereof.

As mentioned above with regard to Figures 1 and 2, the soft tissue anchors of the invention may be employed with any suitable delivery device, or with no delivery device at all. Figure 3 shows a portion of a system 300 for implanting a sling 106 at an anatomical location in the body of a patient according to an illustrative  
10 embodiment of the invention. The system 300 includes a sling 106 having a soft tissue anchor 302 of the type described above with respect to Figures 1 and 2 affixed to one of its ends. The system 300 also includes a delivery device shaft 304 having a distal end 304a interfitted into an anchor channel, such as the anchor channels 120 and 220 described with respect to Figures 1 and 2, respectively, above. The shaft  
15 304 may be substantially straight, curved or include both curved and straight portions. The distal tip of the shaft 304 is illustratively conically shaped. However, any suitable tip shape may be employed.

Figure 4 shows a system 400 for implanting a sling 106 at an anatomical location in the body of a patient according to another illustrative embodiment of the  
20 invention. The sling 106 and anchor 410 are substantially the same as the anchors and sling of Figures 1-3. The delivery device 402 includes a handle 404 and a shaft 406 extending distally from the distal end of the handle 404. As in the case of the shaft 304, the shaft 406 may be substantially straight, curved or include both curved and straight portions. A pusher assembly 408 slidably interfits over the shaft 406.  
25 The pusher assembly 408 includes a shoulder 408a and an actuator 408b. A medical operator slides the pusher assembly 408 distally along the shaft 406 using the actuator 408b. The shoulder 408a abuts a proximal end of the anchor 410 to slide the anchor 410 distally off the distal end of the shaft 406 to place the anchor 410 at a desired location in the soft tissue of a patient.

30 Figure 5 shows another illustrative delivery device particularly sized and shaped for transobtural placement of an implantable sling 106 employing a soft tissue anchor, such as the anchors 100, 200, 302, and 410 described above. Figure 5

depicts a side view of the delivery device 500 according to an illustrative embodiment of the invention. The delivery device 500 includes a handle 512, a shaft 514, and a transitional portion 517 extending distally between a distal end 512a of the handle 512 and a proximal end of the shaft 514. The transitional portion 517

5 includes a first straight section 517a, a curved section 517b and a second straight section 517c, all lying substantially in a single plane, and may be formed as either part of the shaft 514 or as part of the handle 512. The shaft 514 includes a curved section 514a, a straight section 514b and a conical tip 514c, all lying substantially in the same plane as the transitional portion 517. In the illustrative embodiment, the

10 first straight section 517a of the transitional portion 617 attaches to the distal end 512a of the handle 512, extends distally along a first axis 511, and preferably has a substantially constant diameter. The curved section 517b of the transitional portion 517 extends from a distal end of the first straight section 517a, curves away from the first axis 511, and also preferably has a substantially constant diameter. The second

15 straight section 517c extends from a distal end of the curved section 517b along a second axis 513, and preferably has a diameter that decreases from its proximal end to its distal end to provide increased structural stability to the shaft 514. The curved section 514a, preferably, has a substantially constant diameter, smaller than the diameter of the curved section 517b of the transitional portion 517, and extends from

20 the distal end of the second straight section 517c of the transitional portion 517, curves back toward the first axis 511, and terminates at a distal end approximately at an intersection with the first axis 511. The straight section 514b, preferably, has a substantially constant diameter and extends from the distal end of the curved section 514a along a third axis 515, which crosses the first axis 511. In one configuration, a

25 conical tip 514c extends distally from the straight section 514b. In another configuration, the distal end 519 of the delivery device 510 may include a structure or feature for associating the delivery device 510 with a sling and/or sling assembly or an end of a sling and/or sling assembly. A distal portion 520 of the delivery device 510 may include, for example, a structure or feature, such as a tapered distal

30 portion as depicted in Figure 5, or a shoulder as depicted at 408a in Figure 4, for abutting a proximal end of a soft tissue anchor.

Figures 6A-6C show another illustrative delivery devices 600 also particularly sized and shaped for transobturator placement of an implantable sling, and employable with any of the illustrative embodiments of Figures 1-4. The delivery devices 600 includes a handle 602 with first 602a and second 602b substantially straight sections located substantially in a first plane and angled relative to each other, a transitional portion 605 extending out of a distal end 603 of the handle 602, and a shaft 604 extending from a distal end of the transitional portion 605. The shaft includes curved section 604a, a straight section 604b, and in one configuration, terminates in a conical tip 604c. In another configuration, the distal end 609 of the delivery device 600 may include a structure or feature for associating the delivery device 600 with a sling and/or sling assembly or an end of a sling and/or sling assembly. A distal portion 600 of the delivery device 600 may include, for example, a structure or feature, such as a tapered distal portion as depicted in Figure 5, or a shoulder as depicted in Figure 4, for abutting a proximal end of a soft tissue anchor.

The transitional portion 605 interfits and extends axially out of the distal end 603 of the second handle section 602c to affix the shaft 604 to the handle 602. As a result, the transitional portion 605 is substantially co-planer with the handle 602 in the first plane. The curved section 604a of the shaft 604 extends from a distal end of the transitional portion 605. The straight section 604b of the shaft 604 extends from a distal end of the curved section 604a. The curved section 604a and the straight section 604b are substantially coplanar in a second plane. According to the illustrative embodiment of Figures 6A-6C, the first and second planes are substantially orthogonal to each other. However, the first and second planes may be at any suitable angle (e.g., about 10, 20, 30, 45, 60, 70 or 80 degrees) to each other.

To provide structural reinforcement, sections 602b and 602c have a cross sectional diameter that tapers to be smaller at the distal end 603 of the handle 602. Additionally, rather than having the tapered section 607c of the transitional portion 607 being formed as part of the shaft 604, as shown in Figure 5, the tapered portions 602b and 602c of the embodiment of Figures 6A-6C are formed as part of the handle 602. According to one feature, this configuration reduces the length of the transitional portion 605 and thus, provides improved structural support for the curved section 604a. Preferably, in operation, neither the handle 602 nor the

intermediate/transitional portion 605 extends into the body of the patient, and provides a positive stop against this occurring.

According to other illustrative features, the invention is directed to various methods of implanting a sling 106 including a soft tissue anchor 100 at an anatomical location in the body of a patient. According to some methods, the sling is implanted via an initial transvaginal incision, and avoids the need for any abdominal or ishiopubic incisions.

Figures 7A and 7B depict one illustrative method of implanting the sling 106 in the periurethral tissue of a patient to form a platform under the urethra 700. As shown in Figure 7A, an incision 702 is made in the anterior vaginal wall and dissected bilaterally to the interior portion of the inferior pubic ramus. The soft tissue anchor 100 attached to an end of a sling 106 is interfitted over the distal end of a delivery device shaft 704. A medical operator grasps the delivery device handle 706 and passes the shaft 704 with the anchor 100 installed through the vaginal incision and upward into a desired anchoring location on a first side of the urethra 700, preferably, without piercing the abdomen. The anchoring location may be in any suitable abdominal soft tissue, such as without limitation, the retropubic space between the bladder and the abdomen, the space of Retzius, the Cooper's ligament. Additionally, the anchoring location may be in front of or behind the pubic bone. Once the anchor 100 is placed at the desired location, the delivery device shaft 704 is withdrawn leaving the anchor 100 in place. As shown in Figure 7B, the procedure is repeated on the contralateral side of the body, with the same or a second delivery device, to place the sling 106 under the urethra.

Figures 8A and 8B depict another illustrative embodiment in which the invention employs a delivery device such as depicted in Figure 5 or 6A-6C to position at least one of the first 106a and second 106b ends of the sling 106 near or through an obturator foramen (i.e., transobturally) and/or obturator membrane. The delivery device 500 is employed to describe this embodiment. However, the delivery device 600 may be employed in a similar fashion. As shown in Figure 8A, an incision 702 is once again made in the anterior vaginal wall and dissected bilaterally to the interior portion of the inferior pubic ramus. The soft tissue anchor 100

attached to an end of the a sling 106 is interfitted over the distal end of the delivery device shaft 514. A medical operator grasps the handle 512 and inserts the delivery device shaft 514 with the anchor 100 installed through the vaginal incision 702 in a lateral motion passing behind the ishiopubic ramius and piercing the obturator  
5 membrane 802. As shown in Figure 8A, the delivery device shaft 514 can then be withdrawn from the body leaving the anchor 100 implanted in or through the obturator membrane 802. This process is repeated with the same or a second delivery device and the second soft tissue anchor on the contralateral side of the body.

10 One advantage is that it enables an operator to accurately place a sling end with a soft tissue anchor attached. Another advantage is that the anchor and sling configuration facilitate placement of a sling end through the obturator membrane. Figures 9A and 9B depict one drawback of prior art anchoring approaches. As shown, according to some prior art approaches, the anchor 900 extended axially from  
15 a sling end, such as the sling end 902a of the sling 902, but did not also extend axially toward an opposite sling end. Consequently, if the anchor 900 were implanted within the obturator membrane 802 and a dissolvable anchor were employed, subsequent to the anchor 900 dissolving, the sling end 902a would no longer be anchored in the obturator membrane 802. Thus, anchor configurations are  
20 not suitable for bioabsorbable applications where the sling end is to be anchored in the obturator membrane.

In contrast to the deficiencies of the embodiment of Figures 9A and 9B, the soft tissue anchor 100 of the invention is particularly suited for anchoring in the obturator membrane, even when formed from a bioabsorbable material. More  
25 specifically, as shown in Figures 10A and 10B, the affixation portion 102 of the soft tissue anchor 100 extends axially from the sling end 106a while the body portion 104 extends axially along the sling toward the opposite sling end 106b. With this configuration, the sling end 106a is positioned through the obturator membrane 802. Thus, when the anchor 100 dissolves, the sling end 106a remains securely anchored  
30 in through obturator membrane 802.

Another advantage of the above described invention is that it enables a medical operator to place a supportive sling under the bladder neck or the mid-urethra to provide a urethral platform, without requiring any incision other than those made in a vaginal wall. More particularly, employing the devices, systems, methods  
5 and features of the invention, a medical operator can place an implantable sling without making any abdominal or ishiopubic incisions.

It should be understood that for the described procedures, and other procedures using the described devices and systems, the delivery devices and sling and/or sling assembly may be tailored, for example, in the dimensions of the devices,  
10 such as length, diameter, shape, and curvature; sling assembly, such as length and width of the sling or suture thread; and for a particular method of delivery or for placement to a specific anatomical site.

What is claimed is:

**Claims**

1. A soft tissue anchor comprising,  
a tissue engaging portion including a plurality of radially projecting features,  
and  
5 a sling engaging body portion formed integrally with the tissue engaging  
portion and located axially adjacent and proximal to the tissue engaging portion, the  
sling engaging body portion including first and second sections, each section  
including a sling contacting side, the sling contacting side of the first section  
including a plurality of apertures and the sling contacting side of the second section  
10 including a corresponding plurality of protuberances for passing through a sling and  
matingly interfitting with the plurality of apertures in the first section.
2. The soft tissue anchor of claim 1, wherein at least one of the contacting sides  
of the first and second sections is textured to engage with the sling.
3. The soft tissue anchor of claim 1, wherein the apertures are through apertures.
- 15 4. The soft tissue anchor of claim 1, wherein the apertures and the protuberances  
are sized and shape for snap fitting together.
5. The soft tissue anchor of claim 1, wherein the apertures and the protuberances  
are sized and shaped for reversibly and reusably interfitting together.
6. The soft tissue anchor of claim 1 formed at least in part from a bioabsorbable  
20 material.
7. A soft tissue anchor comprising,  
a tissue engaging portion including features sized and shaped for impeding  
removal of the soft tissue anchor from tissues of a patient, and  
a sling engaging body portion formed integrally with and extending axially  
25 from the tissue engaging portion in a proximal direction, the sling engaging body  
being split into first and second sections separated from each other along a plane  
extending axially through both the tissue engaging portion and the sling engaging  
body portion, the first section including a plurality of apertures and the second  
section including a corresponding plurality of protuberances for passing through a  
30 sling and matingly interfitting with the plurality of apertures in the first section to  
secure the sling between the first and second sections.

8. The soft tissue anchor of claim 7, wherein at least one of the contacting sides of the first and second sections is textured to engage with the sling.
9. The soft tissue anchor of claim 7, wherein the apertures are through apertures.
10. The soft tissue anchor of claim 7, wherein the apertures and the protuberances  
5 are sized and shape for snap fitting together.
11. The soft tissue anchor of claim 7, wherein the apertures and the protuberances are sized and shaped for reversibly and reusably interfitting together.
12. A soft tissue anchor comprising,  
a tissue engaging end including features sized and shaped for impeding  
10 removal of the anchor from tissues of a patient, and  
a sling engaging end formed integrally with and extending axially from the tissue engaging portion in a proximal direction,  
the soft tissue anchor being split into first and second sections along a plane extending axially through both the tissue engaging end and the sling engaging end,  
15 the first and second sections each including a portion of the tissue engaging end and a portion of the sling engaging end, the portions of the sling engaging end having cooperative sling contacting surfaces for cooperating to attach to a sling.
13. The soft tissue anchor of claim 12, wherein the first and second sections are connected via a hinge disposed along at least a portion of a first axially extending  
20 edge.
14. The soft tissue anchor of claim 13 including a latch having a first latch portion located on a second axially extending edge of the first section and a second latch portion sized and shaped for matingly interfitting with the first latch portion and located on a second axially extending edge of the second section.
- 25 15. The soft tissue anchor of claim 14, wherein the first and second latch portions are sized and shaped for reversibly and reusably interfitting together.
16. The soft tissue anchor of claim 12 formed from a biodegradable material.
17. The soft tissue anchor of claim 12, wherein at least one of the sling contacting surfaces is textured to engage with the sling.
- 30 18. A system for implanting a sling for treating urinary incontinence comprising,  
a sling assembly including an implantable sling sized and shaped for providing a urethral support, and

- a soft tissue anchor including,
- a tissue engaging end sized and shaped for impeding removal of the anchor from tissues of a patient,
- a sling engaging end formed integrally with the tissue engaging end and extending axially from in a proximal direction to the tissue engaging end, the sling engaging end including first and second sections, each of the first and second sections including a sling contacting side for interoperating to attach to a sling, and an axially extending channel, and
- a delivery device including a shaft having a distal end sized and shaped for fitting into the axially extending channel of the soft tissue anchor.
19. The soft tissue anchor of claim 18, wherein the first and second sections are connected via a hinge disposed along at least a portion of a first axially extending edge.
20. The soft tissue anchor of claim 19 including a latch having a first latch portion located on a second axially extending edge of the first section and a second latch portion sized and shaped for matingly interfitting with the first latch portion and located on a second axially extending edge of the second section.
21. The soft tissue anchor of claim 20, wherein the first and second latch portions are sized and shaped for reversibly and reusably interfitting together.
22. The soft tissue anchor of claim 18 formed from a biodissolvable material.
23. The soft tissue anchor of claim 18, wherein at least one of the sling contacting surfaces is textured to engage with the sling.
24. The soft tissue anchor of claim 18, wherein the first section includes a plurality of apertures and the second section includes a corresponding plurality of protuberances for passing through a sling and matingly interfitting with the plurality of apertures in the first section to secure the sling between the first and second sections.
25. The soft tissue anchor of claim 24, wherein the apertures are through apertures.
26. The soft tissue anchor of claim 24, wherein the apertures and the protuberances are sized and shape for snap fitting together.

27. The soft tissue anchor of claim 24, wherein the apertures and the protuberances are sized and shaped for reversibly and reusably interfitting together.
28. The soft tissue anchor of claim 18, wherein the sling includes length indicating markings.
- 5 29. A method for implanting a sling in the periurethral tissues of a patient comprising,
- attaching a first location on the sling to a first soft tissue anchor by sandwiching the first location between first and second sections of the first soft tissue anchor to extend a tissue engaging portion of the first soft tissue anchor along an axis
- 10 of the sling,
- interfitting a proximal end of the first soft tissue anchor over a distal end of a sling delivery device shaft, and
- inserting the distal end of the shaft with the first soft tissue anchor interfitted into the body of the patient to implant the sling in the periurethral tissues of the
- 15 patient.
30. The method of claim 29 comprising inserting the distal end of the shaft and the first soft tissue anchor into the body of the patient via an incision in the vaginal wall of the patient.
31. The method of claim 30 comprising delivering the first soft tissue anchor to
- 20 the space of Retzius.
32. The method of claim 30 comprising delivering the first soft tissue anchor at least partially through a first transobtural membrane.
33. The method of claim 30 comprising,
- attaching a second location on the sling to a second soft tissue anchor by
- 25 sandwiching the second location between first and second sections of the second soft tissue anchor to extend a tissue engaging portion of the second soft tissue anchor along an axis of the sling,
- interfitting a proximal end of the second soft tissue anchor over a distal end of the sling delivery device shaft, and
- 30 inserting the distal end of the shaft with the second soft tissue anchor interfitted into the body of the patient to implant the sling in the periurethral tissues of the patient.

34. The method of claim 33 comprising inserting the distal end of the shaft and the first soft tissue anchor into the body of the patient via an incision in the vaginal wall of the patient.

35. The method of claim 34 comprising delivering the second soft tissue anchor  
5 to the space of Retzius.

36. The method of claim 34 comprising delivering the second soft tissue anchor at least partially through a second transobtural membrane on a contralateral side of the body from the first transobtural membrane.

37. The method of claim 30 comprising,  
10 attaching a second location on the sling to a second soft tissue anchor by sandwiching the second location between first and second sections of the second soft tissue anchor to extend a tissue engaging portion of the second soft tissue anchor along an axis of the sling,  
interfitting a proximal end of the second soft tissue anchor over a distal end of  
15 a second sling delivery device shaft, and  
inserting the distal end of the second shaft with the second soft tissue anchor interfitted into the body of the patient to implant the sling in the periurethral tissues of the patient.

20

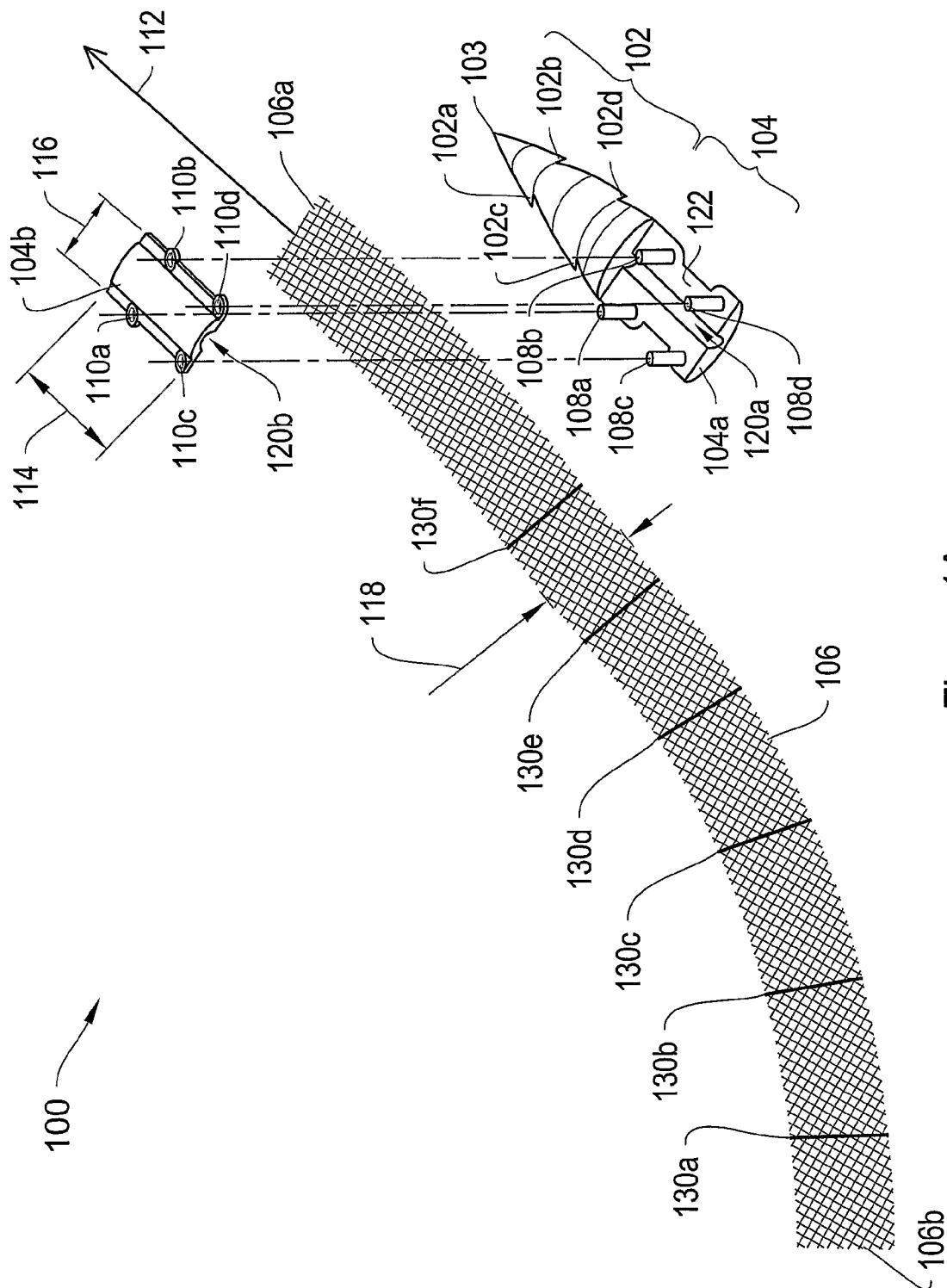


Figure 1A

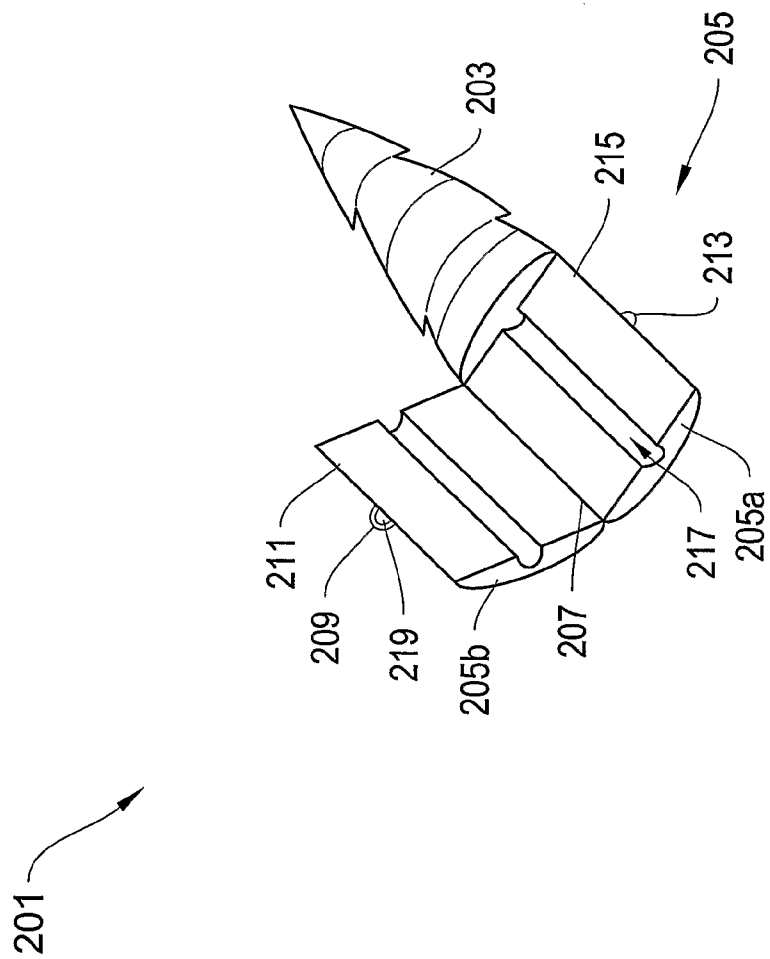


Figure 1B

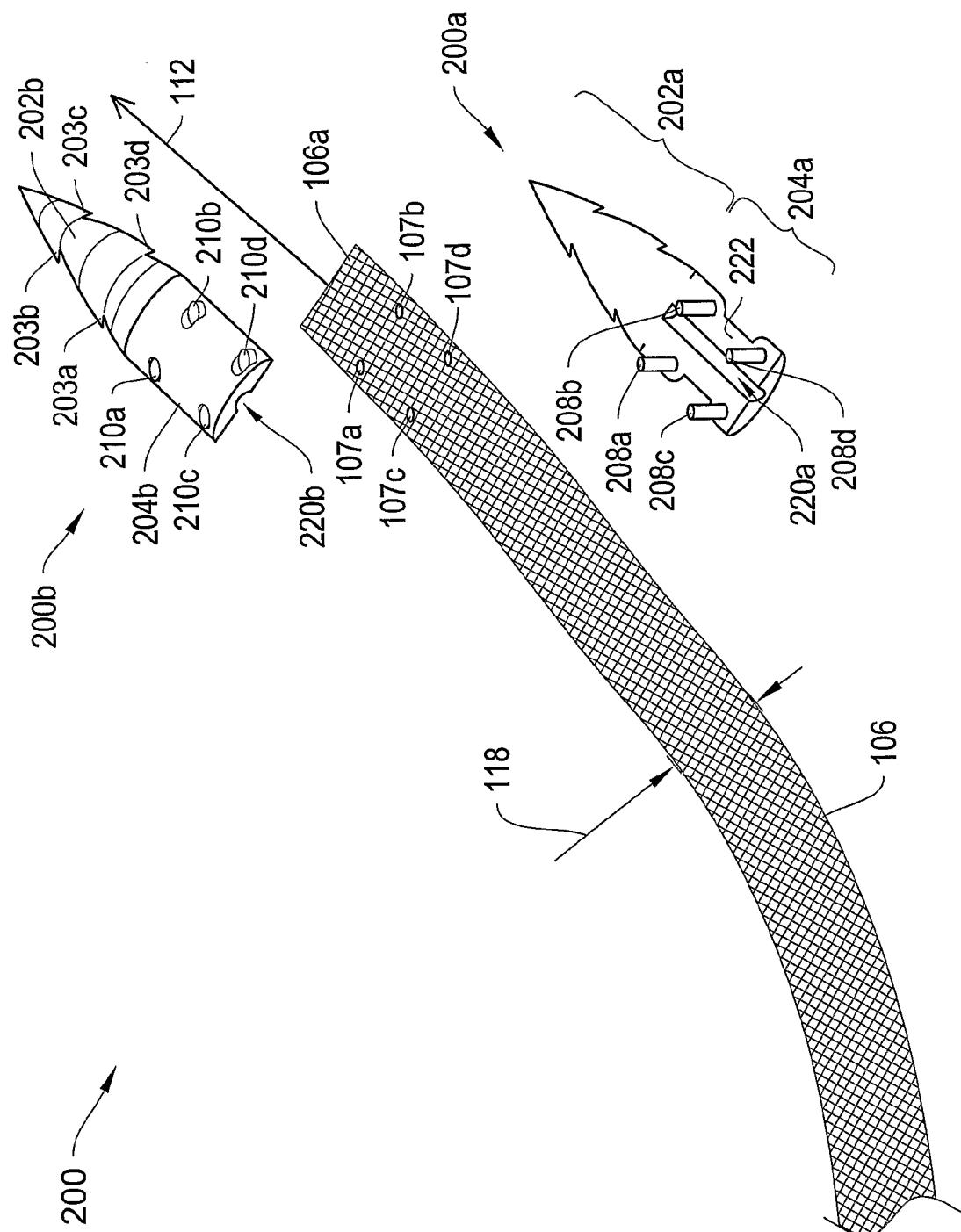


Figure 2

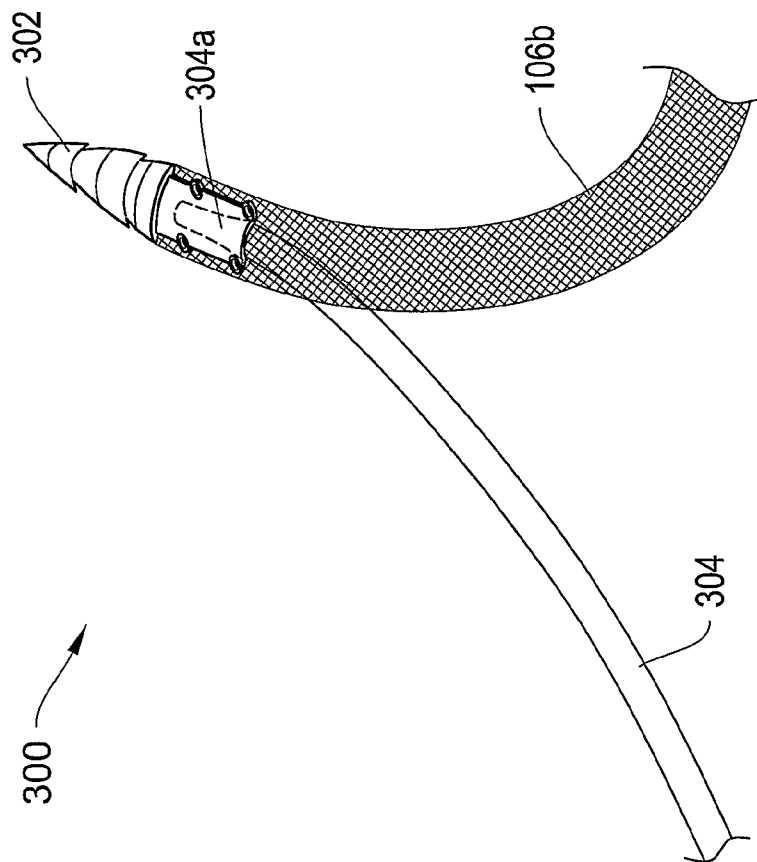


Figure 3

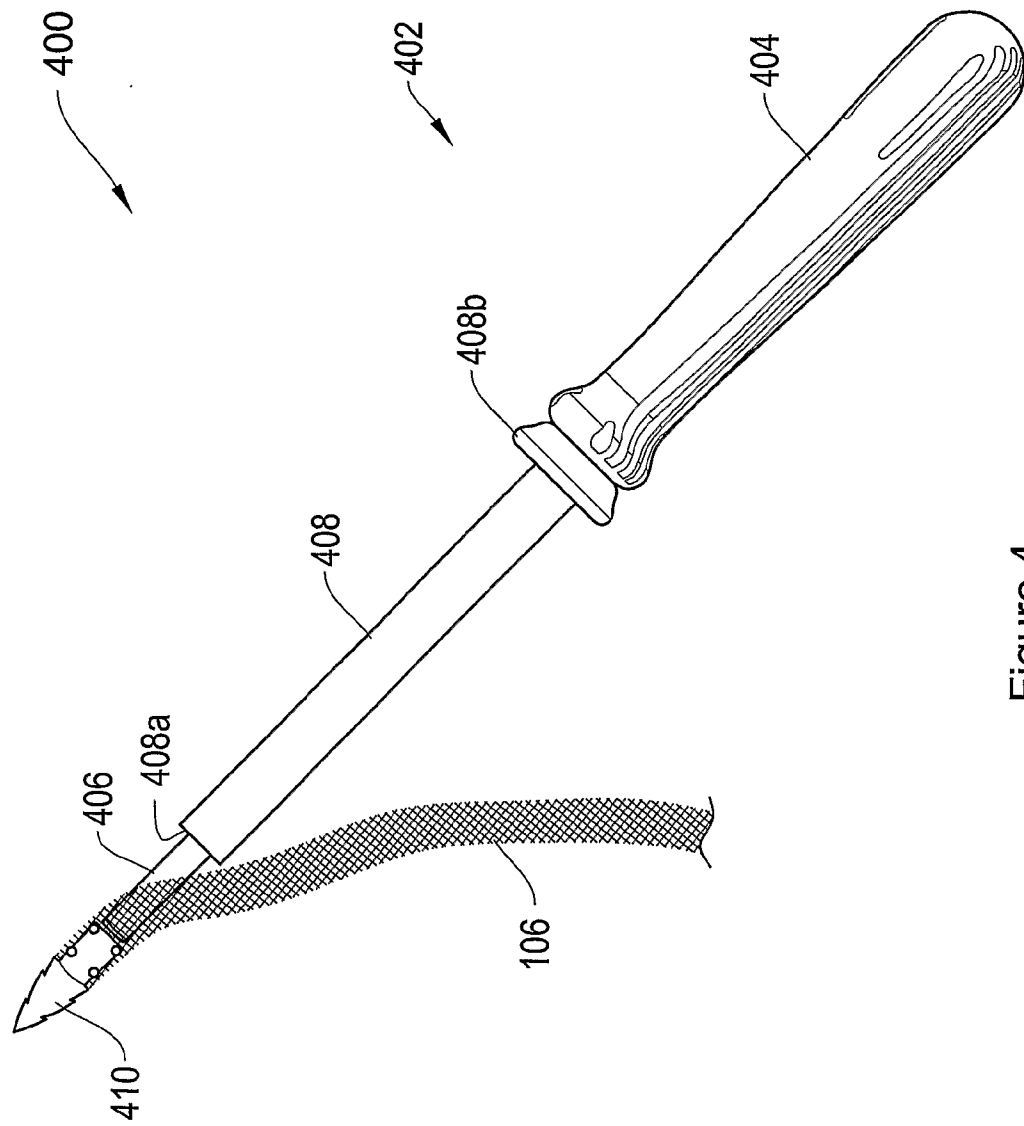


Figure 4

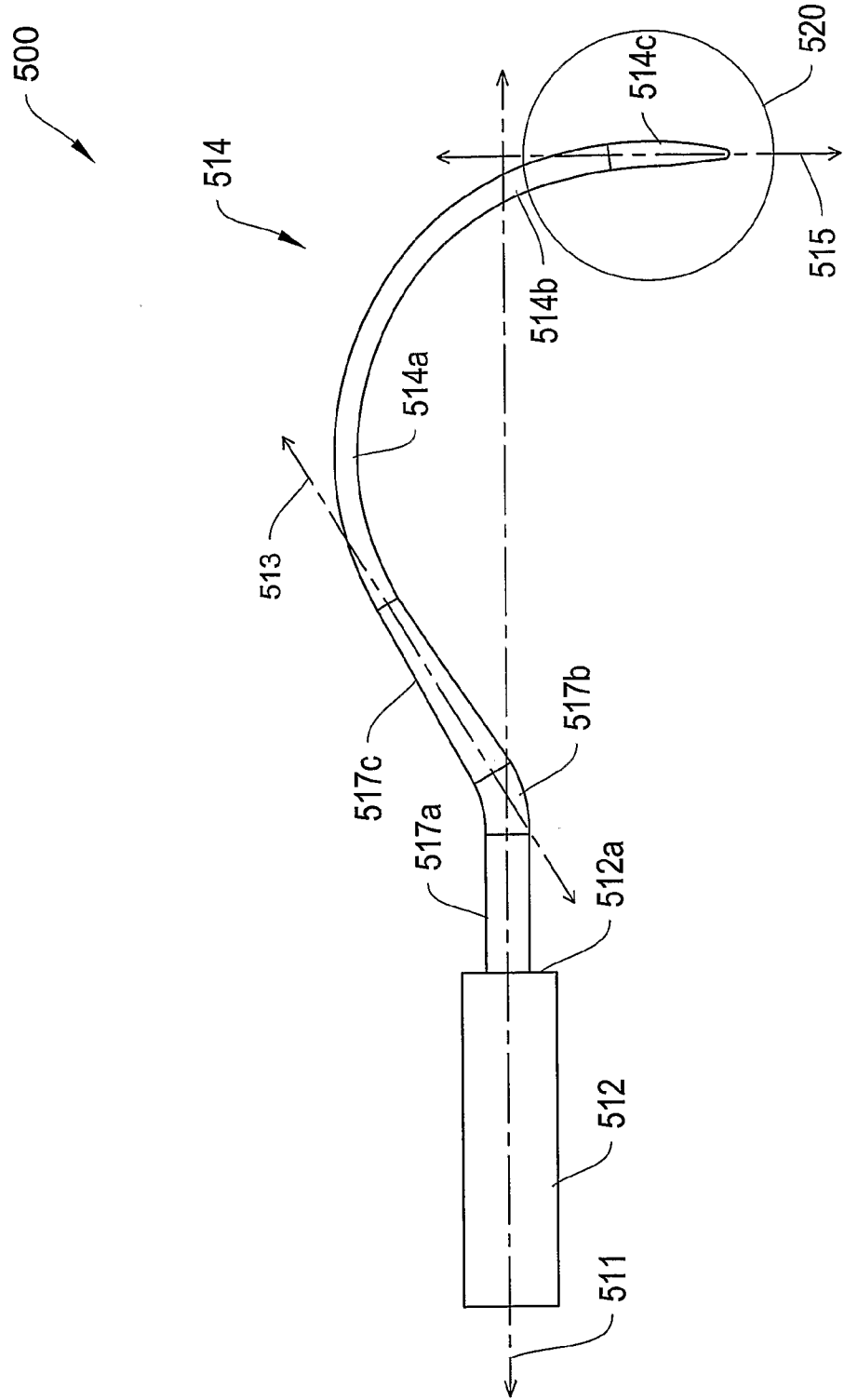
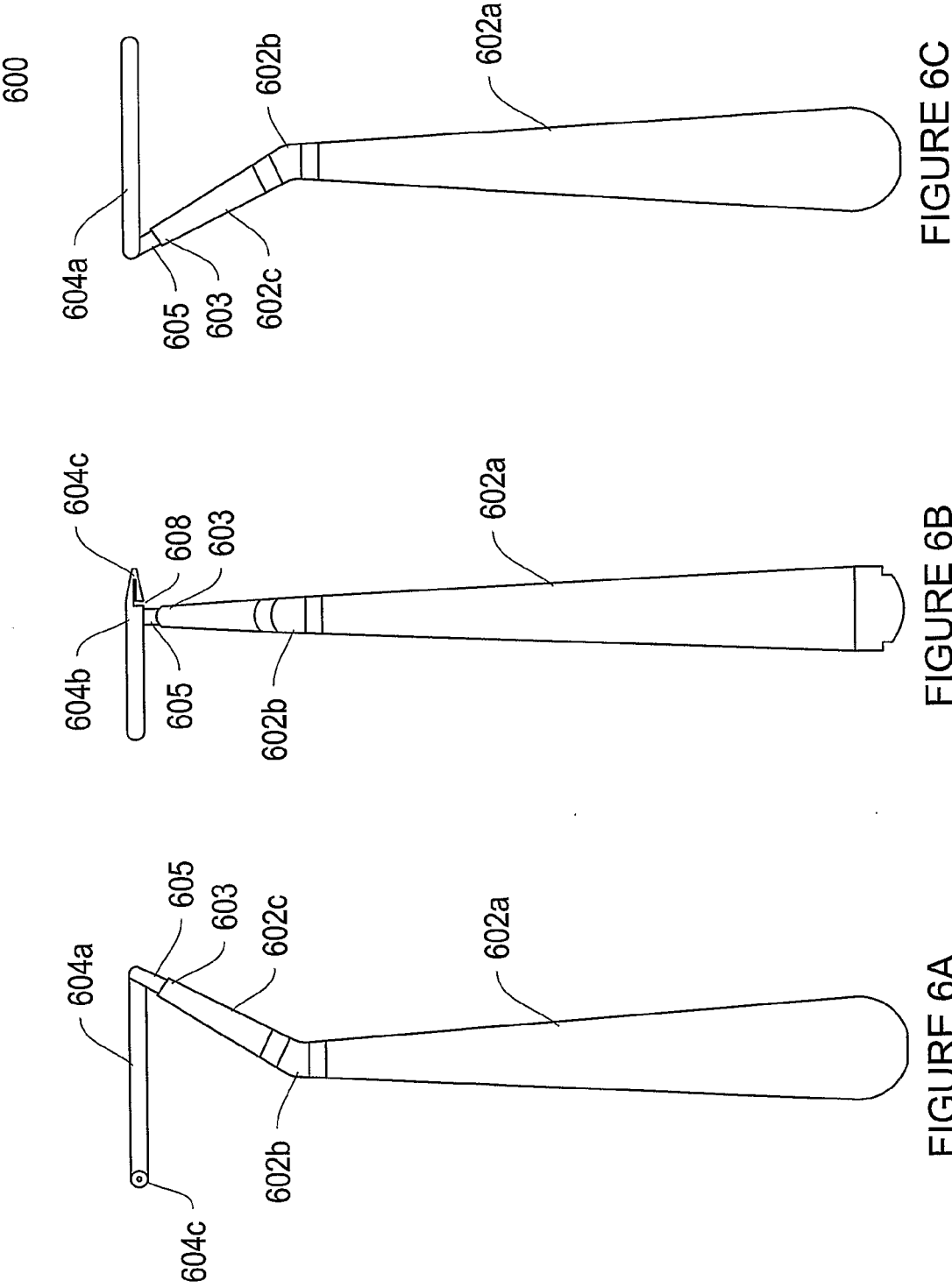


Figure 5



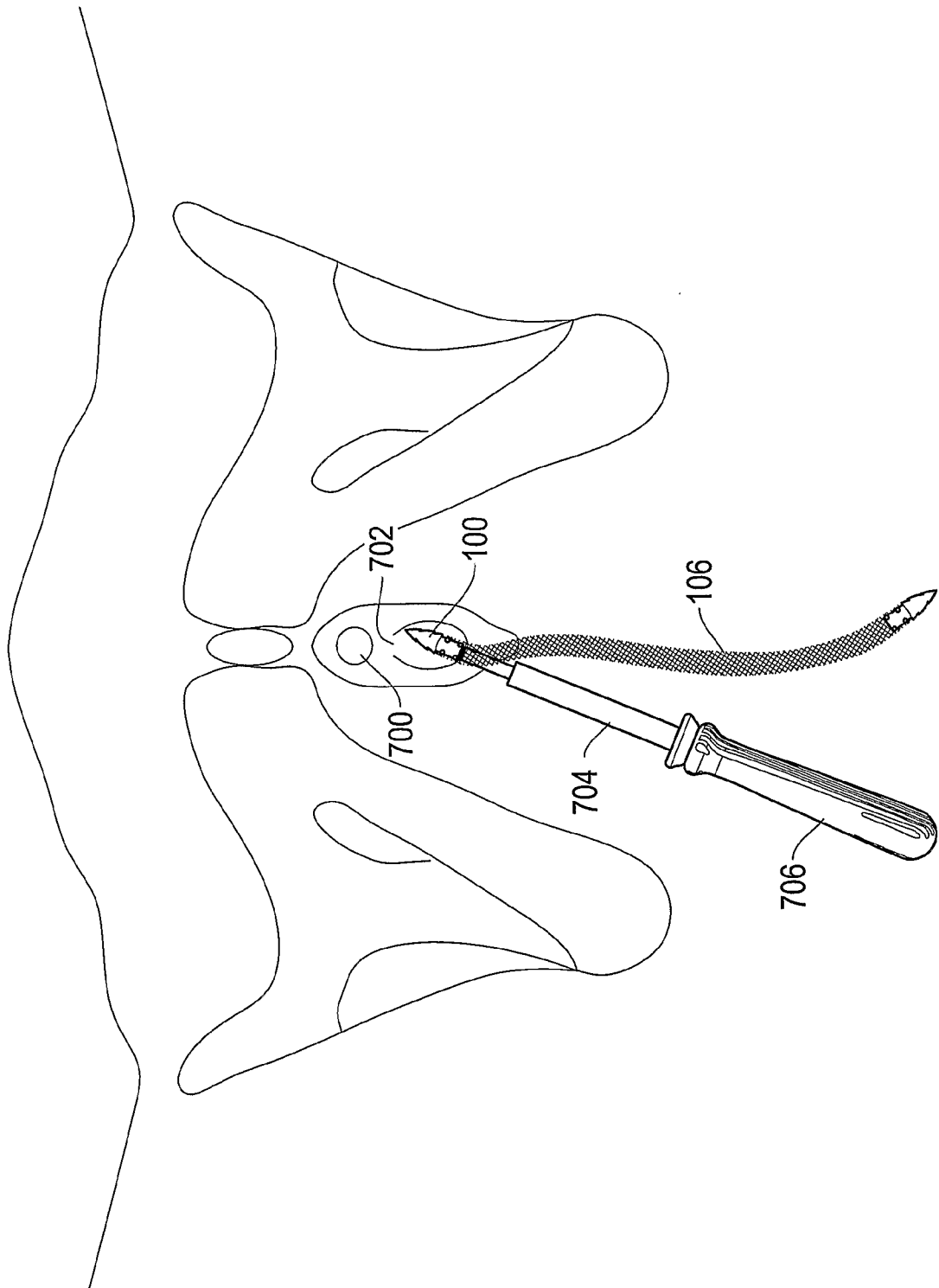


Figure 7A

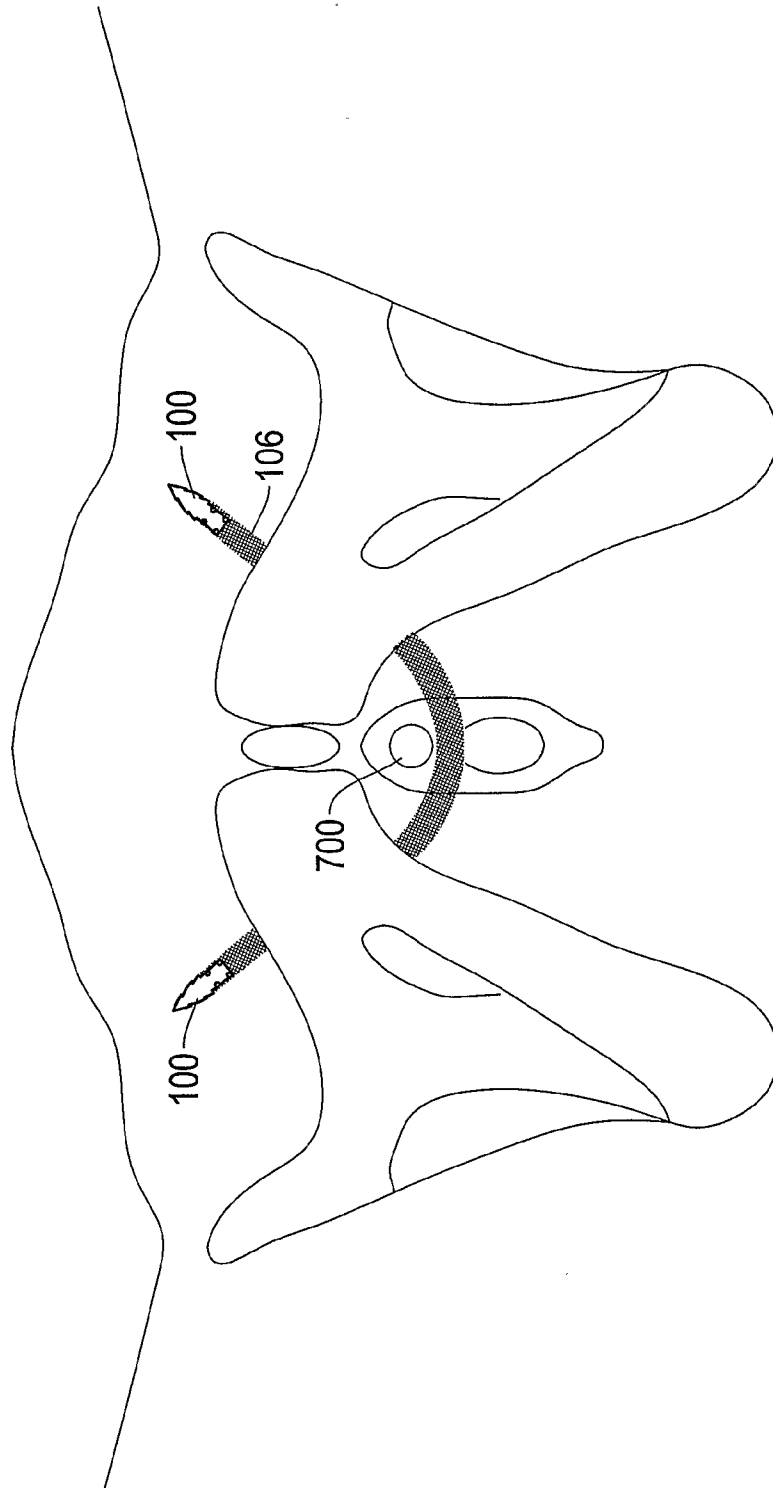


Figure 7B

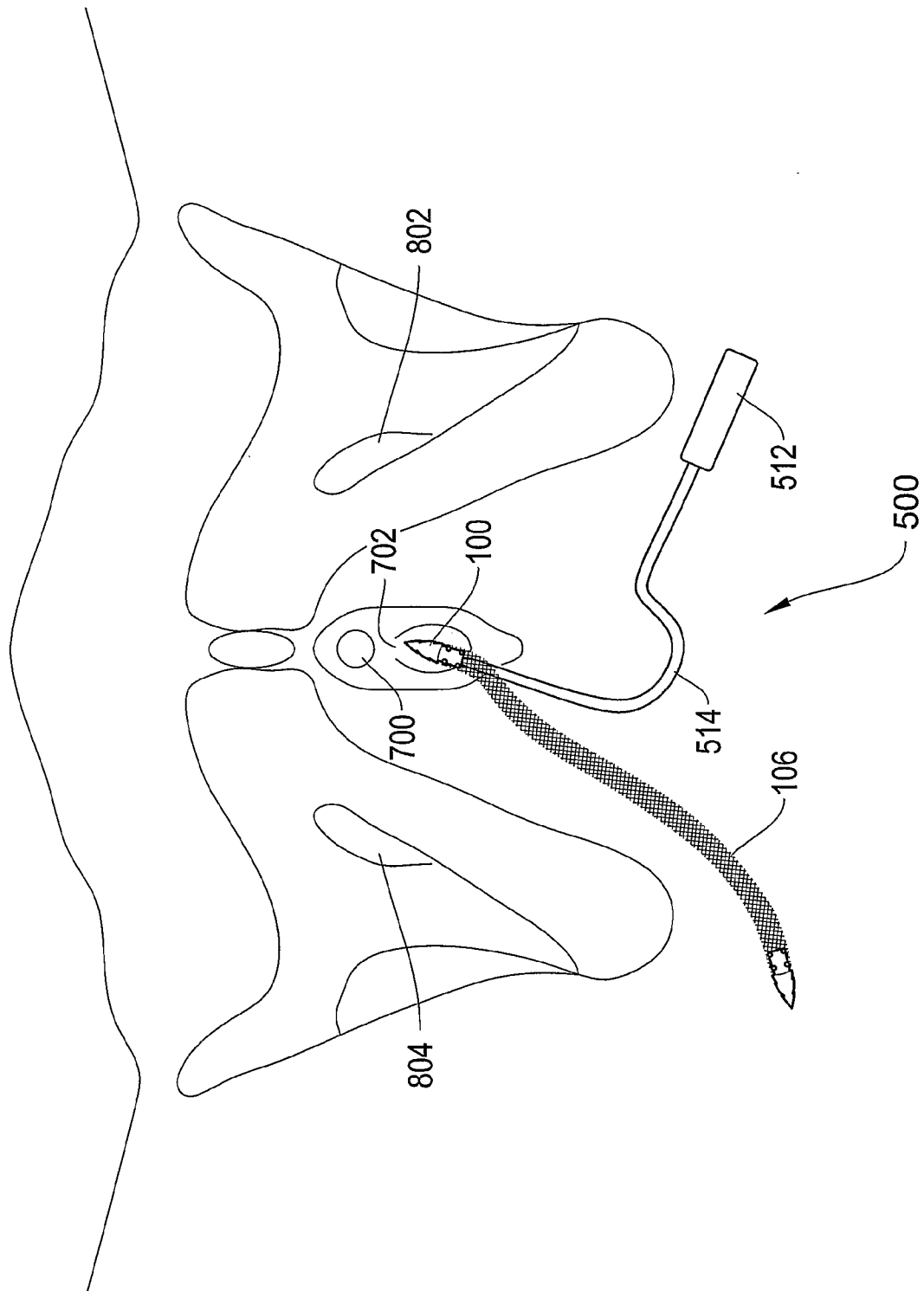


Figure 8A

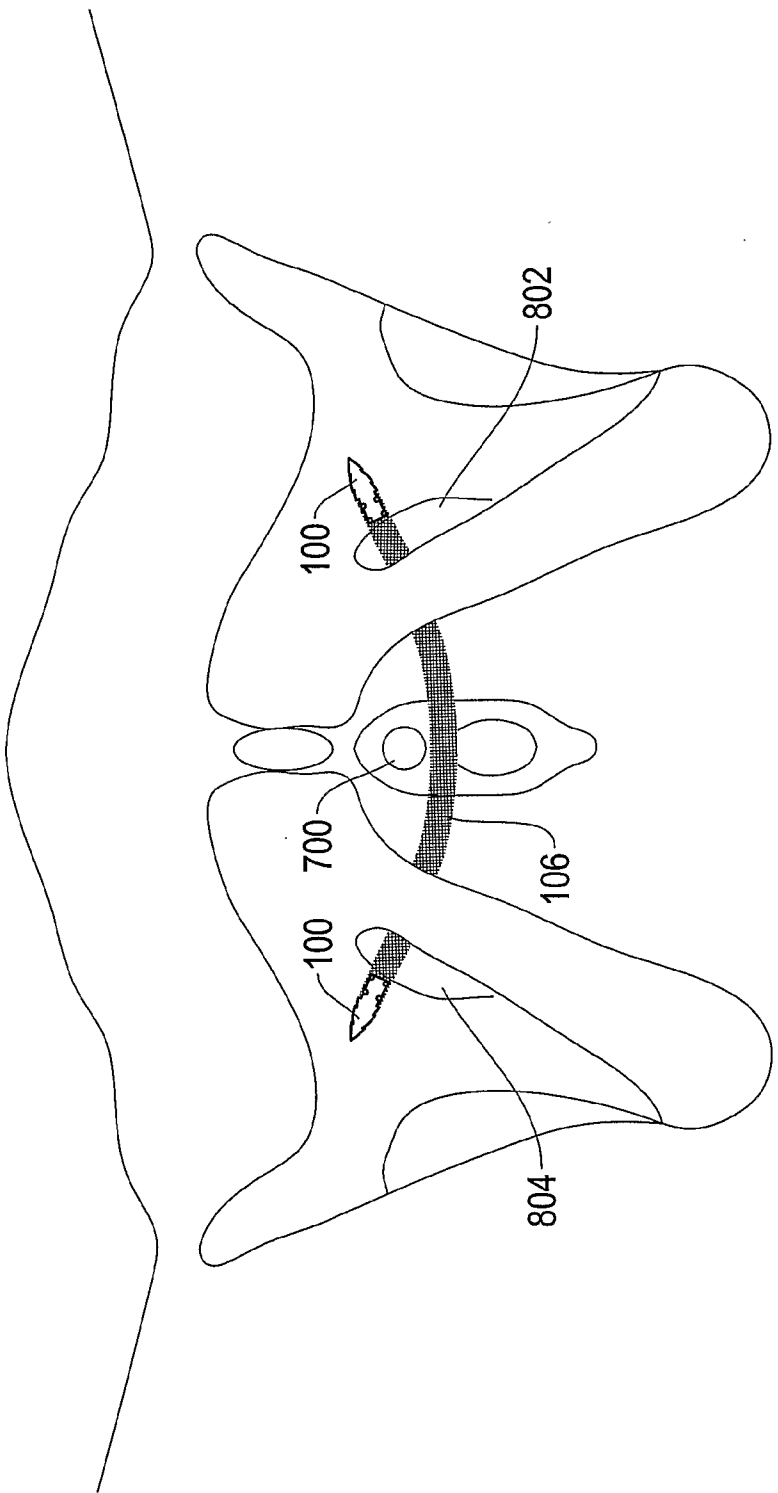


Figure 8B

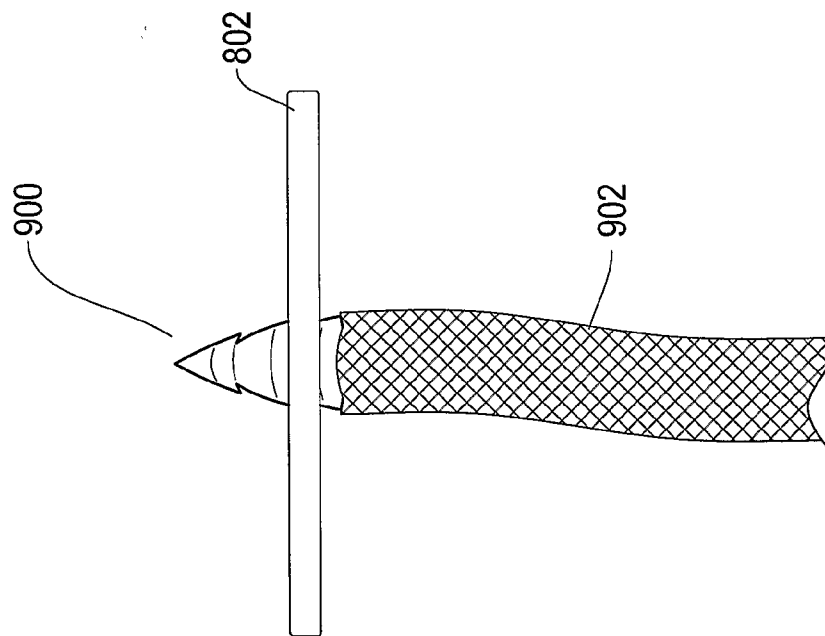


Figure 9A

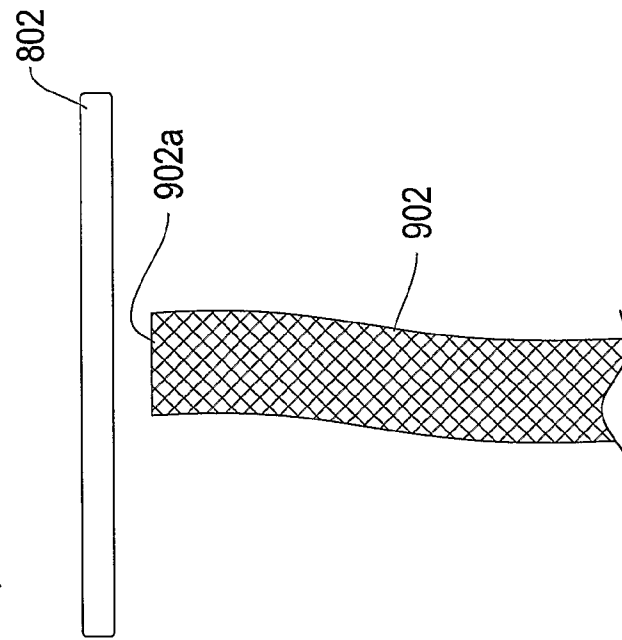


Figure 9B

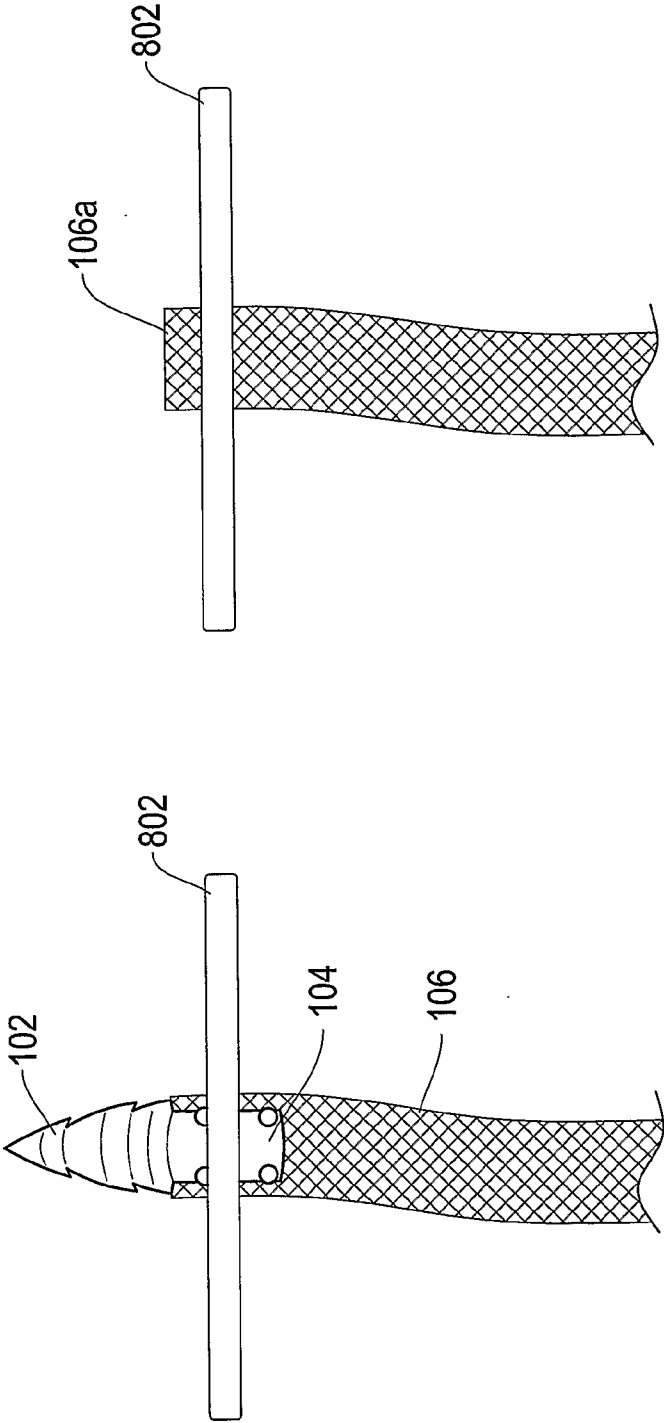


Figure 10B

Figure 10A

# INTERNATIONAL SEARCH REPORT

International application No

US2005/024835

## A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F2/00

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

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61F A61B

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages                                          | Relevant to claim No. |
|-----------|-----------------------------------------------------------------------------------------------------------------------------|-----------------------|
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| A         | WO 03/086205 A (GYNE IDEAS LIMITED;<br>BROWNING, JAMES)<br>23 October 2003 (2003-10-23)<br>claim 1<br>-----                 | 1-37                  |
| A         | US 6 582 443 B2 (CABAK JAMES E ET AL)<br>24 June 2003 (2003-06-24)<br>column 4, line 5 - line 35; figure 4<br>-----<br>-/-- | 1-37                  |

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

☒ See patent family annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

19 May 2006

Date of mailing of the international search report

30/05/2006

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# INTERNATIONAL SEARCH REPORT

International application No  
US2005/024835

| C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT |                                                                                         |                       |
|------------------------------------------------------|-----------------------------------------------------------------------------------------|-----------------------|
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| A                                                    | US 5 643 266 A (LI ET AL)<br>1 July 1997 (1997-07-01)<br>figures 2,4                    | 1-37                  |

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Information on patent family members

International application No

US2005/024835

| Patent document<br>cited in search report |    | Publication<br>date | Patent family<br>member(s) | Publication<br>date |
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