

(12) STANDARD PATENT
(19) AUSTRALIAN PATENT OFFICE

(11) Application No. **AU 2009322835 B2**

(54) Title
Insertion device and method for delivery of a tissue anchor

(51) International Patent Classification(s)
A61B 17/04 (2006.01) *A61B 17/00* (2006.01)
A61F 2/00 (2006.01)

(21) Application No: **2009322835** (22) Date of Filing: **2009.11.16**

(87) WIPO No: **WO10/065274**

(30) Priority Data

(31) Number	(32) Date	(33) Country
12/549,704	2009.08.28	US
61/120,105	2008.12.05	US

(43) Publication Date: **2010.06.10**

(44) Accepted Journal Date: **2015.04.09**

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(56) Related Art
WO 2005/122954
US 2002/0188301

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
10 June 2010 (10.06.2010)

PCT

(10) International Publication Number
WO 2010/065274 A1

(51) International Patent Classification:

A61B 17/04 (2006.01) A61B 17/00 (2006.01)
A61F 2/00 (2006.01)

(21) International Application Number:

PCT/US2009/064564

(22) International Filing Date:

16 November 2009 (16.11.2009)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

61/120,105 5 December 2008 (05.12.2008) US
12/549,704 28 August 2009 (28.08.2009) US

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

(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM,
ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ,
TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE,
ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV,
MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM,
TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW,
ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— as to applicant's entitlement to apply for and be granted
a patent (Rule 4.17(ii))

Published:

— with international search report (Art. 21(3))

(54) Title: INSERTION DEVICE AND METHOD FOR DELIVERY OF A MESH CARRIER

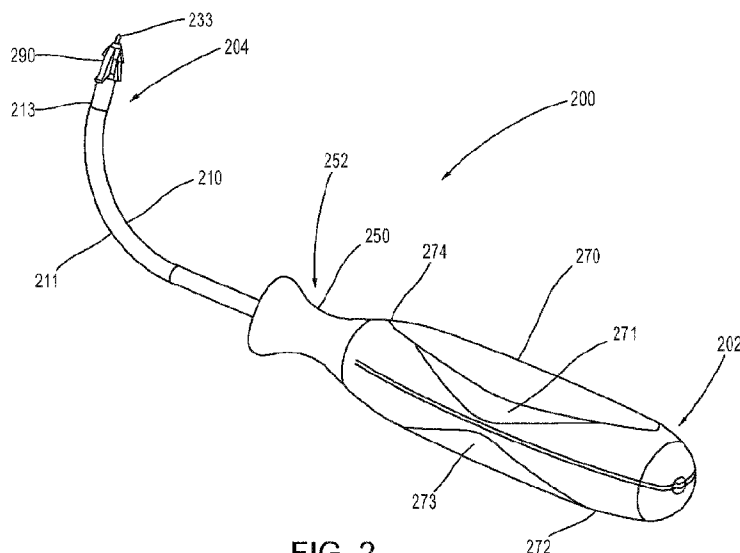


FIG. 2

(57) Abstract: An insertion device includes an elongate member and a stylet. The elongate member has a proximal end portion, a distal end portion, and defines a lumen therethrough. The stylet has a proximal end portion, a distal end portion, and is slidably coupled to the elongate member. The stylet is configured to move from a first position to a second position with respect to the elongate member. The proximal end portion of the stylet is configured to removably couple a mesh carrier thereto. A portion of the proximal end portion of the stylet is disposed outside of the lumen of the elongate member when the stylet is in its first position and is disposed within the lumen when the stylet is in its second position.

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INSERTION DEVICE AND METHOD FOR DELIVERY OF A TISSUE ANCHOR

[0001] The content of each of U.S. Patent Application Serial No. 12/549,704, filed August 28, 2009, and U.S. Provisional Patent Application Serial Number 61/120,105, filed December 5, 2008, is hereby incorporated by reference.

[0002] The disclosed embodiments relate generally to medical devices and more particularly to an insertion device for delivery of a mesh carrier into a body of a patient.

[0003] The disclosed embodiments are applicable to a wide variety of surgical procedures. For example, one such procedure is directed to urinary incontinence and includes fixing an implant to tissue within a body of a patient to provide support for the urethra. Another such procedure includes fixing an implant to bodily tissue of a patient to support a bladder of the patient.

[0004] Mesh carriers may be placed within a body of a patient to provide anchoring points for medical implants. In some procedures, it is necessary for a practitioner, such as a physician, to insert a mesh carrier into bodily tissue of the patient at a location not easily visible or accessible to the practitioner. For example, some locations are not visible or easily accessible due to internal obstructions, such as the pubic bone.

[0005] Known insertion devices can be used to position a mesh carrier at a first location within bodily tissue and to fix the mesh carrier to the tissue. However, in such procedures where the location is not easily visible or easily accessible, it may be difficult to manoeuvre the known insertion device around such obstructions and delivering the mesh carrier to a desired location in bodily tissue. Furthermore, the practitioner may require a larger incision at the incision site in order to allow ample room to rotate and/or pivot the known insertion device within the body in order to reach the desired location. In such an instance, the rotating and/or pivoting of the medical device may cause unintended stretching or tearing of tissue. Additionally, it may become necessary to remove the known insertion device from the body to better position it at the incision site. Unnecessary insertion, over-insertion, or excessive rotation could, therefore, induce trauma to the patient.

[0006] Thus, a need exists for an insertion device that has a configuration that

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facilitates insertion of an implant or a mesh carrier for an implant. For example, a need exists for an insertion device that facilitates insertion around or behind an internal obstruction, such as the pubic bone.

[0006A] According to a first aspect of the present invention, there is provided an insertion device comprising:

a handle member defining a cavity and a longitudinal axis;

an elongate member having a proximal end portion, a distal end portion, and defining a lumen therethrough, the lumen having a diameter of a first size, the elongate member including a curved portion between the proximal end portion and the distal end portion, the distal end portion configured to removably and frictionally couple a tissue anchor thereto such that a portion of the tissue anchor is disposed within the lumen defined by the elongate member and a portion of the tissue anchor having a diameter of a second size greater than the first size is disposed outside of the lumen defined by the elongate member, at least a portion of the elongate member being disposed within the cavity of the handle member, the elongate member being movably coupled to the handle member; and

a stylet having a proximal end portion, a distal end portion and being configured to move from a first position to a second position with respect to the elongate member, and when the stylet is in the first position, the distal end portion of the stylet defines a longitudinal axis that is offset from a longitudinal axis defined by the distal end portion of the elongate member, the stylet being configured to engage the tissue anchor to remove the tissue anchor from the elongate member such that a longitudinal axis defined by the tissue anchor is substantially orthogonal to the longitudinal axis defined by the handle, member the stylet being fixedly coupled to the handle member.

[0006B] According to a second aspect of the present invention, there is provided an insertion device comprising:

a handle member defining a cavity;

an elongate member having a proximal end portion, a distal end portion, and defining a lumen therethrough, wherein a longitudinal axis defined by the proximal end portion of the elongate member is substantially orthogonal to a longitudinal axis defined by the distal end portion of the elongate member, at least a portion of the elongate member being disposed within the cavity, the elongate member being movably coupled to the handle member; and

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a stylet having a proximal end portion and a distal end portion, at least a portion of the stylet disposed within the lumen of the elongate member, the stylet being slidably coupled to the elongate member such that the stylet is configured to move from a first position to a second position with respect to the elongate member, when the stylet is in the first position, the distal end portion of the stylet defines a longitudinal axis that is offset from the longitudinal axis defined by the distal end portion of the elongate member, the stylet being fixedly coupled to the handle member.

[0006C] According to a third aspect of the present invention, there is provided a method of inserting a tissue anchor into a body of a patient, comprising:

coupling the tissue anchor to a distal end portion of an elongate member of an insertion device such that a portion of the tissue anchor is disposed within a lumen defined by the elongate member and a portion of the tissue anchor is disposed outside of the lumen defined by the elongate member, a diameter of the portion of the tissue anchor disposed outside of the lumen being larger than a diameter of the lumen, the insertion device having an elongate member, a handle member, and a stylet, at least a portion of the elongate member being disposed within a cavity defined by the handle member, the elongate member being movably coupled to the handle member, the stylet being fixedly coupled to the handle member, the coupling of the tissue anchor includes extending a stylet through a filament coupled to the tissue anchor;

inserting the insertion device into the body;

decoupling the tissue anchor such that a longitudinal axis defined by the tissue anchor is substantially orthogonal to an axis defined by the proximal end portion of the elongate member; and

removing the insertion device from the body.

[0007] In some embodiments, the distal end portion is configured to removably couple a mesh carrier thereto and the stylet is configured to engage the mesh carrier to remove the mesh carrier from the elongate member such that a longitudinal axis defined by the mesh carrier is substantially orthogonal to the longitudinal axis defined by the handle.

[0008] The proximal end portion of the elongate member may define an axis substantially orthogonal to the axis defined by the distal end portion of the elongate member. At least a portion of the stylet may be disposed within the lumen of the elongate member. The

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stylet may be coupled to the elongate member such that the stylet is configured to move from the first position to the second position with respect to the elongate member.

[0008A] The present invention will now be described, by way of non-limiting example only, with reference to the accompanying drawings, in which:

[0008B] FIG. 1 is a schematic illustration of an insertion device according to one embodiment;

[0009] FIG. 2 is side perspective view of an insertion device coupled to a mesh carrier with a styler in a first position according to another embodiment;

[0010] FIG. 3 is a side perspective view of the insertion device of FIG. 2 with the stylet in a second position;

[0011] FIG. 4 is a side perspective view of the insertion device of FIG. 2 with the stylet removing the mesh carrier;

[0012] FIG. 5 is a partial cross-sectional view of the insertion device of FIG. 2;

[0013] FIG. 6 is a cross-sectional view of a distal end portion of the insertion device of FIG. 2;

[0014] FIG. 7 is a cross-sectional view of a distal end portion of the insertion device of FIG. 3;

[0015] FIG. 8 is a cross-sectional view of a distal end portion of the insertion device of FIG. 2 removing the mesh carrier;

[0016] FIG. 9 is a partial cross-sectional view of the insertion device of FIG. 2 with a first portion of a handle removed;

[0017] FIG. 10 is an exploded view of a portion of the insertion device of FIG. 2;

[0018] FIG. 11 is a side view of a portion of the insertion device of FIG. 2;

[0019] FIG. 12 is a cross-sectional view of the portion of the insertion device of FIG. 11 along line 12-12, with a stylet in a first position;

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[0020] FIG. 13 is a cross-sectional view of the portion of the insertion device of FIG. 11 along line 12-12, with a stylet in a second position;

[0021] FIG. 14 is a bottom, partial cross-sectional view of the insertion device of FIG. 2;

[0022] FIG. 15 is an end, partial cross-sectional view of the insertion device of FIG. 2;

[0023] FIG. 16 is a side view of a mesh carrier according to an embodiment;

[0024] FIG. 17 is a perspective view of the mesh carrier of FIG. 16;

[0025] FIG. 18 is a side view of a distal end portion of the insertion device of FIG. 2 and a filament;

[0026] FIG. 19 is a cross-sectional view of the insertion device and filament of FIG. 18;

[0027] FIG. 20 is a side view of an embodiment of an implant positioned within a body of a patient;

[0028] FIG. 21 is a side view of a distal end portion of the insertion device according to another embodiment;

[0029] FIG. 22 is a cross-sectional view of the insertion device of FIG. 21 along line 23-23 with a stylet in a first position;

[0030] FIG. 23 is a cross-sectional view of the insertion device of FIG. 21 along line 23-23, with a stylet in a second position;

[0031] FIG. 24 is a flowchart of a method according to an embodiment; and

[0032] FIGS. 25-27 illustrate locations within the female pelvic region in which an insertion device can be inserted.

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[0033] The insertion device and mesh carrier described herein can be inserted into a body of a patient, such as into bodily tissue. For example, the insertion device can be configured to deliver a first mesh carrier configured to selectively retain an implant (also referred to herein as a "filament", "tape", "implant", "mesh", "sling", or "strap") with respect to a bodily tissue. A plurality of such mesh carriers can be anchored within the body of a patient at spaced locations while retaining a filament between the plurality of mesh carriers to provide support for other portions of the body (e.g., organs or portions of organs).

[0034] The insertion device is configured to place, deposit, or otherwise insert. a mesh carrier into a bodily tissue of a patient. The filament is configured to suspend or support a bodily tissue or organ when the filament is retained within the patient by one mesh carrier. Thus, in one embodiment, the insertion device can place the mesh carrier into the obturator externus muscle for incontinence treatment. Specifically, first and second mesh carriers are each placed in opposing obturator externus muscles of a patient and the filament is extended

between the first and second mesh carriers to form a sling to provide support to the urethra or bladder neck of the patient. The insertion device can be a variety of different configurations and can have a variety of different components.

[0035] As used in this specification, the words “proximal” and “distal” refer to the direction closer to and further away from, respectively, an operator (e.g., surgeon, physician, nurse, technician, etc.) who would use an insertion device or a therapeutic device during a procedure. For example, the end of an insertion device first to contact the patient’s body would be the distal end, while the opposite end of the insertion device (e.g., the end of the insertion device being operated by the operator) would be the proximal end of the insertion device. Similarly, the end of a insertion device implanted the furthest within the patient’s body would be the distal end, while the opposite end of the insertion device (e.g., the end of the insertion device that is inserted the least amount within the body or the end of the insertion device that is disposed outside of the body) would be the proximal end.

[0036] FIG. 1 is a schematic illustration of an insertion device 100 according to an embodiment of the invention. The insertion device 100 can be inserted into a body of a patient, such as into bodily tissue.

[0037] The insertion device 100 has a proximal end portion 102 and a distal end portion 104. The insertion device 100 includes an elongate member 110, a stylet (not shown in FIG. 1), and a handle 170. At least a portion of the elongate member 110 and the stylet are configured to be inserted into a body of a patient. The elongate member 110 includes a proximal end portion 112 and a distal end portion 113. In some embodiments, the proximal end portion 112 of the elongate member 110 is configured to be slidably coupled to the handle 170. The distal end portion 113 of the elongate member 110 is configured to be coupled to a mesh carrier 190. In some embodiments, the elongate member 110 includes a curved portion 111 between the proximal end portion 112 and the distal end portion 113. The curved portion 111 is configured such that an axis XX-XX defined by the proximal end portion 112 of the elongate member 110 is substantially orthogonal to an axis YY-YY defined by the distal end portion 113 of the elongate member 110 and is substantially orthogonal to a longitudinal axis defined by the mesh carrier 190 when the mesh carrier 190 is delivered into bodily tissue. In such embodiments, the curved portion 111 facilitates insertion of the device 100 around or behind an internal obstruction, such as the pubic bone, and allows more control when delivering the mesh carrier 190 into bodily tissue.

Furthermore, curved portion 111 can define a radius of curvature of any suitable length. For example, the radius of curvature can be 1.0 inch, 1.1 inches, 1.5 inches, or 2 inches.

[0038] The handle 170 is slidably coupled to the proximal end portion 112 of the elongate member 110 and is fixedly coupled to the proximal end portion of the stylet. The handle 170 is configured to move the stylet relative to the elongate member 110.

[0039] Although a mesh carrier 190 is used with insertion device 100 as described in the above disclosed embodiment, it should be understood that in some embodiments, a tissue anchor can be used.

[0040] FIGS. 2-15, 18, and 19 illustrate one embodiment of an insertion device. Insertion device 200 includes a proximal end portion 202 and a distal end portion 204. The insertion device 200 includes an elongate member 210, a handle 270, and a stylet 230. The elongate member 210 and stylet 230 are configured to be at least partially inserted into a body of a patient.

[0041] The elongate member 210 includes a proximal end portion 212, a distal end portion 213, and defines a lumen 218 (shown, for example in FIGS. 5-10) extending therethrough. The lumen 218 is configured to receive at least a portion of the stylet 230.

[0042] As shown in FIGS 2-5 and 9-14, the proximal end portion 212 of the elongate member 210 is coupled to a coupling member 250 and defines a first axis A-A. The coupling member 250 includes a distal end portion 252, a proximal end portion 254 (shown, for example, in FIGS. 3, 9, 10, 12, and 13), and defines a lumen therethrough (shown in FIGS. 12 and 13) configured to fixedly receive at least a portion of the elongate member 210. Thus, the coupling member 250 is configured to be fixedly disposed about the portion of the elongate member 210 and is configured to be moved such that the coupling member 250 moves the elongate member 210 relative to the stylet 230.

[0043] The distal end portion 252 of the coupling member 250 includes a first end portion 251, and second end portion 253 (shown, for example in FIGS. 2-5, 9-14). The second end portion 253 is configured to be disposed proximate a distal end portion 274 of the handle 270 when the stylet 230 is in a first position (shown, for example in FIGS. 2, 4, 11, and 12) and is configured to be spaced apart from the distal end portion 274 of the handle 270 when the stylet 230 is in a second position (shown, for example, in FIGS. 3 and 13).

[0044] The proximal end portion 254 of the coupling member 250 defines a ribbed portion 256 including a first protrusion 256a and a second protrusion 256b (shown in FIGS. 10, 12, and 13). At least a portion of the proximal end portion 254 is configured to be slidably disposed within a cavity 276 defined by the handle 270. Specifically, the ribbed portion 256 is configured to engage a groove portion of the handle 270 such that the coupling member 250 is slidably coupled to the handle 270 (discussed in detail below).

[0045] Although the coupling member 250 is illustrated and described as being disposed about or fixedly coupled to the elongate member 210, other suitable coupling configurations can be used. For example, in some embodiments, the coupling member 250 and elongate member 210 can be monolithically constructed. In other embodiments, for example, the coupling member 250 can be insert-molded to the elongate member 210. Furthermore, the coupling member 250 can be constructed of any suitable material. In one embodiment, the coupling member 250 can be constructed of a polymer. For example, the coupling member 250 can be constructed of acrylonitrile butadiene styrene (ABS).

[0046] The distal end portion 213 of the elongate member 210 defines a second axis B-B, as shown, for example in FIG. 5. The distal end portion 213 of the elongate member 210 is configured to interact with a proximal end portion 294 of a mesh carrier 290. In the illustrated embodiment, the distal end portion 213 of the elongate member 210 is configured to be removably coupled to the mesh carrier 290. Specifically, as shown in FIGS. 6 and 7, the lumen 218 defined by the distal end portion 213 is configured to receive at least a portion of the proximal end portion 294 of the mesh carrier 290 such that an inner surface 219 of the elongate member 210 defining the lumen 218 is configured to provide an interference or slight frictional fit with the proximal end portion 294 of the mesh carrier 290 received in the lumen 218.

[0047] The elongate member 210 includes a curved portion 211 disposed between the proximal end portion 212 and the distal end portion 213. Specifically, in the illustrated embodiment, the curved portion 211 is configured such that the second axis B-B defined by the distal end portion 213 of the elongate member is substantially orthogonal to the first axis A-A defined by the proximal end portion 212 of the elongate member 210.

[0048] The elongate member 210 can be constructed of any material suitable for insertion into a body of a patient. For example, in some embodiments, the elongate member is

constructed of stainless steel. In other embodiments, the elongate member is constructed of a polymer.

[0049] The handle 270 has a proximal end portion 272 and a distal end portion 274, and is formed by a first portion (first half) 271, and a second portion (second half) 273. The handle defines a longitudinal axis B1-B (shown in FIG. 4) and is configured to rotate about the longitudinal axis B1-B in a first direction C and a second direction D as shown, for example, in FIG. 15. The handle 270 is configured to be slidably coupled to the elongate member 210. The distal end portion 274 of the handle 270 is slidably coupled to the proximal end portion 212 of the elongate member 210 and is fixedly coupled to the proximal end portion 234 of the stylet 230.

[0050] As shown in FIGS. 2-5, the first portion 271 of the handle 270 is fixedly coupled to the second portion 273 of the handle 270 (not illustrated separately). The first and second portions 271, 273 can be coupled by any suitable coupling mechanisms. For example, the first and second portions 271, 273 can be coupled by an ultrasonic weld. The first portion 271 and the second portion 273 collectively define a cavity 276 configured to receive the elongate member 210. Specifically, in the illustrated embodiment, the distal end portion 274 of the handle 270 defines an opening 278 in communication with the cavity 276 for receiving at least a portion of the proximal end portion 212 of the elongate member 210 and the proximal end portion 254 of the coupling member 250.

[0051] As shown in FIGS. 12 and 13, the first portion 271 of the handle 270 defines a first groove portion 276a, a first wall portion 277a, and a second wall portion 278a. The first groove portion 276a is configured to slidably receive the first projection 256a of the ribbed portion 256 of the coupling member 250. The second portion 273 of the handle 270 defines a second groove portion 276b, a first wall portion 277b, and a second wall portion 278b. The second groove portion 276b is configured to slidably receive the second projection 256b of the ribbed portion 256 of the coupling member 250. The first wall portions 277a, 277b are configured to contact the projections 256a, 256b when the stylet 230 is in its first position (shown in FIG. 12). The second wall portions 278a, 278b are configured to contact the projections 256a, 256b when the stylet 230 is in its second position (shown in FIG. 13) to prevent removal of the coupling member 250 from the handle 270.

[0052] The second portion 272 of the handle 270 defines an aperture 279. The aperture 279 is configured to fixedly receive a portion of a proximal end portion 234 of the stylet 230 such that movement of the handle 270 with respect to the elongate member 210, causes the stylet 230 to slidably advance or retract relative to the elongate member 210.

[0053] Although the handle 270 is illustrated as defining a contoured shape (shown in FIGS. 2-5, and 11-14), the handle 270 can define a variety of shapes, sizes, and configurations, such as cylindrical shape. The handle 270 can further be constructed of any suitable material. In some embodiments, the handle 270 can be constructed of at least one polymer. For example, the handle 270 can be constructed of acrylonitrile butadiene styrene (ABS). In other embodiments, the handle 270 can include a thermoplastic elastomer material (TPE) covering a portion its outer surface to provide a practitioner a comfortable or secure gripping area.

[0054] The stylet 230 includes a proximal end portion 234 and a distal end portion 233. The stylet 230 is slidably disposed within the lumen 218 defined by the elongate member 210. The proximal end portion 234 is fixedly coupled to the handle 270. As shown in FIGS. 10, 12, and 13, the proximal end portion 234 of the stylet 230 includes an L-shaped portion configured to be received within the aperture 279 defined by the handle 270. Thus, as discussed above, movement of the handle 270 with respect to the elongate member 210, causes the stylet 230 to slidably advance or retract relative to the elongate member 210.

[0055] The distal end portion 233 of the stylet 230 includes a tip 235. The tip 235 can be a variety of shapes. For example, in one embodiment, the stylet tip can be pointed. In another embodiment, the stylet tip can be blunt or tapered.

[0056] The stylet 230 has a first position, (i.e., an extended position) shown, for example, in FIGS. 6, 12, 18, and 19, a second position (i.e., a retracted position), shown, for example in FIGS. 3, 7, and 13. The stylet is biased to a substantially linear configuration. When the stylet 230 is in its first position, at least a portion of the distal end portion 233 of the stylet 230 extends out of the lumen 218 at the distal end portion 213 of the elongate member 210. The portion of the distal end portion 233 is configured to extend through the lumen 291 and out of an opening 291b defined by the mesh carrier (discussed in detail below). The portion of the distal end portion 233 is further configured to pierce and pass through a filament 205

received by the mesh carrier 290 (shown in FIGS. 18 and 19). Because the stylet 230 is biased to a substantially linear configuration, its engagement with mesh carrier 290 maintains its position within the center of the lumen 218 defined by the elongate member 210. Said another way, when the stylet 230 is in its first position, the interaction between the stylet 230 and the mesh carrier 290 results in the distal end portion 233 of the stylet 230 being disposed along the axis B-B defined by the distal end portion 213 of the elongate member 210 (shown, for example, in FIG. 5).

[0057] As the stylet 230 is moved proximally with respect to the elongate member 210 from its first position to its second position, the distal end portion 233 of the stylet is removed from the lumen 291 defined by the mesh carrier 290. When the stylet 230 is in its second position, the distal end portion 233 of stylet 230 is disposed within the lumen 218 of the elongate member 210. Because the stylet 230 is biased to a linear configuration, when it is in its second position and is no longer engaged with the mesh carrier 290, the distal end portion 233 of the stylet 230 is disposed substantially against the inner surface 219 of the elongate member 210 (shown, for example, in FIG. 7). Specifically, in the illustrated embodiment, when the stylet 230 is in its second position, the stylet 230 is disposed within the lumen 218 of the elongate member 210 such that the distal end portion 233 of the stylet 230 is offset from the axis B-B defined by the distal end portion 213 of the elongate member 210 (shown in FIG. 7).

[0058] In some embodiments, when the stylet 230 is moved from its first position to its second position (i.e., when the distal end 233 of the stylet 230 is removed from the lumen 291 of the mesh carrier 290 and contacts the inner surface 219 of the elongate member 210), a user can hear an audible click.

[0059] Once in its second position, the stylet 230 is configured to decouple or otherwise disengage the mesh carrier 290 from the elongate member 210. Because the distal end portion 233 of the stylet 230 is configured to contact the proximal end portion 294 of the mesh carrier 290, when the stylet 230 is moved in a distal direction, it can advance the mesh carrier 290 in a distal direction out of the lumen 218 of the elongate member 210, thereby disengaging or decoupling the mesh carrier 290 from elongate member 210 and fixing it into bodily tissue. Specifically, the distal end portion 233 of the stylet 230 is configured to engage the mesh carrier 290 such that an orientation of a longitudinal axis A1-A1 defined by

the mesh carrier 290 is substantially orthogonal to the longitudinal axis B1-B1 defined by the handle 270 coupled to the elongate member 210 (shown, for example, in FIG. 4).

[0060] The stylet 230 can be constructed of any material suitable for insertion into a body of a patient. For example, in some embodiment, the stylet can be constructed of stainless steel. In other embodiments, the stylet can be constructed of a polymer.

[0061] FIGS. 16 and 17 are side and perspective views, respectively, of a mesh carrier 290 that can be used with the insertion device 200 described above. The mesh carrier 290 has a proximal end portion 294, a distal end portion 293, defines a lumen 291 (shown in FIG. 19) extending between the proximal end portion 294 and the distal end portion 293, and defines an aperture 292. The proximal end portion 294 of the mesh carrier 290 is configured to engage or be removably coupled to at least a portion of the distal end portion 213 elongate member 210, shown, for example, in FIGS. 2-9, 18, and 19. In the illustrated embodiment, a portion of the proximal end portion 294 is configured to be disposed within the lumen 218 of the elongate member 210 (shown, for example, in FIGS. 18 and 19) such that the lumen 291 of the mesh carrier 290 is in communication with the lumen 218 of the elongate member 210. Said another way, the proximal end portion 294 of the mesh carrier 290 defines an opening 291a in communication with the lumen 291 of the mesh carrier 290. The opening 291a is in communication with the lumen 218 of the elongate member 210. Thus, the opening 291a, and thereby the lumen 291, are configured to receive the distal end portion 233 of the stylet 230 (shown in dashed lines in FIG. 16) from the elongate member 210.

[0062] Specifically, the mesh carrier 290 is coupled to the elongate member 210 by an interference or frictional fit. Although, the proximal end portion 294 of the mesh carrier 290 defines a substantially smooth outer surface, In other embodiments, the outer surface of the proximal end portion 294 can include a textured surface. For example, in some embodiments, the outer surface of the proximal end of the mesh carrier can include at least one rib or ridge (not shown) configured to help provide an interference or frictional fit with the lumen of the elongate member.

[0063] The proximal end portion 294 of the mesh carrier 290 includes protrusions 296, 297 disposed about a periphery of the mesh carrier 290 approximately 180 degrees apart (shown in FIGS. 16 and 17). In some embodiments, the protrusions 296, 297 are configured to contact the distal end portion 213 of the elongate member 210 when the mesh carrier 290

is coupled to the elongate member 210, as shown in FIGS. 18 and 19. Protrusions 296, 297 are further configured to help anchor at least a portion of the mesh carrier 290 in the body of the patient once the mesh carrier 290 is placed within the bodily tissue.

[0064] The proximal end portion 294 of the mesh carrier 290 further includes a first anchor portion 299 (shown, for example, in FIGS. 16 and 17) configured to help anchor the mesh carrier 290 in the bodily tissue of the patient once the mesh carrier 290 is placed within the bodily tissue. The first anchor portion 299 includes projections 299a and 299b disposed about the periphery of the proximal end portion 294 of the mesh carrier 290 approximately 180 degrees apart.

[0065] The distal end portion 293 of the mesh carrier 290 includes a second anchor portion 298 (shown, for example, in FIGS. 16 and 17) configured to help anchor at least a portion of the mesh carrier 290 in the body of the patient once the mesh carrier 290 is placed within the bodily tissue. The second anchor portion 298 includes projections 298a and 298b disposed about the periphery of the distal end portion 293 of the mesh carrier 290.

[0066] The first anchor portion 299 (i.e., projections 299a, 299b) and the second anchor portion 298 (i.e., projections 298a, 298b) are configured to help prevent the mesh carrier 290 from regressing through the bodily tissue in which it is placed. For example, in one application, the first anchor portion 299 and the second anchor portion 298 are configured to retain or anchor the mesh carrier 290 in one of the obturator internus or obturator externus muscles.

[0067] As illustrated in FIG. 19, the aperture 292 defined by the mesh carrier 290 is configured to receive at least a portion of the filament 205. The aperture 292 is configured to allow the filament 205 to be threaded or passed through the mesh carrier 290 via the aperture 292. The aperture 292 can be configured to allow movement or adjustment of at least a portion of the filament 205 through the aperture 292. For example, in some embodiments, the filament 205 can be movable through the aperture 292 in only a first direction (i.e. one way). In other embodiments, the filament 205 can be movable through the aperture 292 in the first direction and in a second direction that is different than the first direction. The aperture 292 can also be configured to provide little or no resistance to movement or adjustment of the filament 205. For example, the aperture 292 can have an opening greater in

size than the width or thickness of the filament 205. In such an embodiment, the filament 205 can readily be moved through the aperture 292, meeting minimal or no resistance.

[0068] In an one embodiment, the aperture 292 is configured to provide a frictional fit with the filament 205 passed through (or received within) the aperture 292. For example, the aperture 292 can be configured to be slightly smaller (or narrower) than the thickness of the filament 205. In such an embodiment, a force must be applied to move the filament 205 through the aperture 292. In yet another embodiment, the aperture 292 provides substantial resistance to movement or adjustment of the filament 205, such that the filament 205 is substantially fixed within the aperture 292.

[0069] The aperture 292 can have any suitable size or shape configured to receive the filament 205, for example the shape can be a U-shape (as illustrated in FIGS. 16 and 17), circle, square, rectangle star, triangle, trapezoid, or any other shape configured to receive a filament.

[0070] The mesh carrier 290 can be constructed of any material suitable for implantation into bodily tissue. For example, the mesh carrier 290 can be constructed of implantable grade polypropylene, implantable grade metal, a polymer, a biocompatible material, or any combination thereof. Suitable biocompatible materials include bioabsorbable, cadaveric, and bovine materials.

[0071] Although the mesh carrier 290 is illustrated and described as being received by the elongate member 210, it should be understood that other suitable configurations can be used. For example, the mesh carrier can be configured to receive a portion of the elongate member to couple the mesh carrier to the elongate member. Specifically, at least a portion of an outer surface of the elongate member can be configured to provide an interference or slight frictional fit with a mesh carrier when at least a portion of the elongate member is received in a lumen of the mesh carrier. Said another way, a portion of the mesh carrier can be configured to be disposed over a portion of the elongate member. In such an embodiment, the elongate member can include a sheath disposed about an outer surface of the elongate member for disengaging the mesh carrier (discussed in more detail below).

[0072] Although the mesh carrier 209 is illustrated and described above as defining a lumen 291 and an opening 291a configured to receive the distal end portion 233 of the stylet 230, other suitable configurations can be used. For example, the proximal end portion of the

mesh carrier can define a substantially solid surface configured to contact the distal end portion of the stylet. Specifically, in such embodiments, the stylet is moved in a distal direction, such that the distal end portion of the stylet moves distally within the lumen of the elongate member and contacts the proximal end portion of the mesh carrier to decouple or otherwise disengage the mesh carrier from the elongate member.

[0073] In some embodiments, the insertion device 200 described above, can be used to insert a plurality of mesh carriers within bodily tissue of a patient. As shown in FIG. 20, the insertion device 200 can be used to insert a first mesh carrier 290 and a second mesh carrier 390 into bodily tissue T of a patient. FIG. 20 illustrates an example of the first mesh carrier 290 and the second mesh carrier 390 anchored in bodily tissue T of the pelvic region of a patient. The filament 205 extends between the first mesh carrier 290 and the second mesh carrier 390 to provide support to the target tissue T or organ. In the illustrated embodiment, the filament 205 extends below the urethra and forms a sling to provide support to the urethra..

[0074] The filaments and implants as discussed above can be constructed of many different suitable materials and have many different suitable configurations. For example, in some embodiments, a polymer mesh implant is used, which can be used to support the urethra. In other embodiments, a polyform material can be used.

[0075] In some embodiments, a portion of the filament can be reinforced, such as with a reinforcing material. The reinforcing material, or reinforced portion of the filament, can be configured to assist in suspending or supporting the bodily tissue or organ. In one embodiment, the filament can be reinforced by a suture.

[0076] In some embodiments, at least a portion of the filament can include tangs or a tanged portion to grip or attach to a portion of bodily tissue. The terms “tanged” or “tangs” as used herein mean roughened or jagged edges or areas, such as can result from cutting a woven or knit mesh material or filament. The tangs enhance anchoring of the filament within bodily tissue, such as pubo-urethral tissue. In one embodiment, the filament includes tangs on an edge along an entire length of the filament. In another embodiment, tangs are only on the end portions of the filament.

[0077] In other embodiments, the filament is untanged or detanged, such as by heating the tangs on a polymer mesh so that they fuse and bead up to form a smooth finish.

[0078] In some embodiments, the filament includes a coating. For example, the filament can include a polymeric coating. In another example, the filament can include a therapeutic agent coating.

[0079] In yet other embodiments, the filament can be porous. A porous filament defines openings, or pores, in the filament or between threads of material forming the filament. For example, in one embodiment, the filament is a mesh. The filament can be a micro-porous mesh in which the openings, or pores, are small.

[0080] Although the stylet 230 as illustrated in FIGS. 2-15, 18, and 19 is slidably disposed within the lumen 218 of the elongate member 210, it should be understood that other configurations are possible. As shown in FIGS. 21-23, the stylet 330 can be fixedly retained within the elongate member 310. For example, the elongate member 310 and the stylet 330 can be formed as one component such that they do not move relative to one another. In such embodiments, the elongate member 310 is slidably disposed within a lumen 341 defined by a sheath 340. Said another way, the sheath 340 is slidably disposed about an outer surface 319 of the elongate member 310 for disengaging the mesh carrier 490 from the elongate member 310.

[0081] The proximal end portion 494 of the mesh carrier 490, in such embodiments, defines a cavity C configured to receive at least a portion the distal end portion 313 of the elongate member 310. Specifically, an inner surface 494a of the proximal end portion 494 of the mesh carrier 490, which defines the cavity C is configured to provide an interference or slight frictional fit with an outer surface 319 of the elongate member 310 received in the cavity C. In such embodiments, when the stylet 330 (and elongate member 310) is in its first configuration, the stylet 230 is configured such that a portion of the distal end portion 333 the stylet 330 extends through the lumen 491 of the mesh carrier 490 and out the opening 491b, as shown in FIG. 21 and 22. As the stylet 330 moves proximally with respect to the sheath 340 from its first position to its second position, the distal end portion 343 of the sheath 340 contacts a portion of the proximal end portion 494 of the mesh carrier 490 and prevents proximal movement of the mesh carrier 490. When the stylet 330 is in its second position, as illustrated, for example, in FIG. 23, the elongate member 310 and the distal end portion 333 of the stylet 330 is disposed within the lumen 341 of the sheath 340. Specifically, in the illustrated embodiment, when the stylet 330 is moved proximally from its first position, the distal end portion 343 of the sheath 340 contacts the proximal end portion 494 of the mesh

carrier 490 maintaining its location within bodily tissue. The mesh carrier 490 is thereby decoupled or removed from the distal end portion 313 of the elongate member 310 and is released in bodily tissue.

[0082] In some embodiments, an inner surface of the proximal end 494 of the mesh carrier 490 can include at least one rib or ridge configured to help provide the interference or frictional fit with the outer surface 319 of the elongate member 310.

[0083] Although the insertion devices are illustrated and described above as including an elongate member having a radius of curvature such that the proximal end portion of the elongate member defines an axis substantially orthogonal to an axis defined by the distal end portion of the elongate member, other suitable configurations can be used. For example, the axis defined by the proximal end portion of the elongate member and the axis defined by the distal end portion of the elongate member can define an angle greater than or less than 90 degrees relative to one another.

[0084] FIG. 24 is a flowchart of a method 500 for delivering a mesh carrier into bodily tissue of a patient using a insertion device according to an embodiment of the invention.

[0085] At 510, the mesh carrier is coupled to the stylet of the insertion device. For example, the proximal end portion of the mesh carrier is engaged with the distal end portion of the elongate member. For example, in some embodiments, a portion of the proximal end portion of the mesh carrier is received within the lumen defined by the distal end portion of the elongate member. In other embodiments, the portion of the proximal end portion of the mesh carrier is configured to receive a portion of the distal end portion of the elongate member

[0086] In some embodiments at least a portion of the filament is inserted into the aperture defined by the mesh carrier prior to the coupling of the mesh carrier to the elongate member. For example, at least a portion of the filament is inserted into the aperture such that at least a portion of the filament is substantially orthogonal to the lumen defined by the mesh carrier.

[0087] In some embodiments, the mesh carrier is coupled to or engaged with the elongate member when the stylet is in its first position. In such embodiments, the stylet passes through the filament inserted into the aperture defined by the mesh carrier and retains the filament within the aperture of the mesh carrier.

[0088] At 520, the insertion device is inserted into a body of a patient. For example, in one embodiment, the insertion device is inserted into the body of the patient through an incision made in bodily tissue. In a procedure for urinary incontinence, one approach for inserting the insertion device into the body of the patient includes making an incision in the vaginal wall and inserting a portion of the insertion device through the vaginal incision. The portion of the insertion device is then directed towards the desired bodily tissue. The curved elongate member is useful in navigating around certain bodily structures to reach the desired bodily tissue.

[0089] At 530, the mesh carrier is positioned proximate to a desired portion of bodily tissue, and the mesh carrier is inserted into the bodily tissue. For example, in a procedure for female urinary incontinence, the mesh carrier is inserted into one of the obturator internus or obturator externus muscles.

[0090] At 540, the mesh carrier is removed from the lumen at the distal end portion of the elongate member. Specifically, the stylet is moved from its first position to its second position, and then from its second position to its first position. For example, in one embodiment, as shown in FIG. 7, the stylet is moved in a proximal direction, from its first position to its second position, such that the distal end portion of the stylet is withdrawn from the lumen of the mesh carrier and the filament. By withdrawing the distal end portion of the stylet from the lumen of the mesh carrier and disposing it within the lumen of the elongate member, the distal end portion of the stylet becomes offset from an axis defined by the distal end portion of elongate member and contacts the inner wall of the elongate member. The distal end portion of the stylet is configured to contact a portion of the proximal end portion of the mesh carrier when in its second configuration. In one procedure, a practitioner concurrently pulls the handle in a proximal direction while holding the coupling member substantially stationary. In another procedure, the practitioner concurrently pushes the coupling member in a distal direction, thereby moving the elongate member in a distal direction, while holding the handle substantially stationary.

[0091] To remove the mesh carrier, the stylet is moved in a distal direction from its first position to its second position such that the distal end portion of the stylet concurrently moves the mesh carrier in a distal direction thereby removing the mesh carrier from the lumen at the distal end portion of the elongate member. Thus, the mesh carrier is decoupled

from the elongate member, and the mesh carrier and filament are fixed within the bodily tissue.

[0092] At 550, the filament is moved, or adjusted, through the aperture of the mesh carrier. In one embodiment, the filament is moved or adjusted through the aperture in a first direction. For example, the filament is moved in the first direction to increase tension in the filament. In another example, the filament is moved in the first direction to decrease the length of the filament, for example, to shorten the length of the filament that will support or suspend a target organ or tissue.

[0093] In some embodiments, the filament is moved, or adjusted, through the aperture in a second direction different than the first direction. For example, the filament is moved in the second direction to decrease the tension in the filament. In one embodiment, the filament is moved in the second direction to increase the length of the filament suspended between a first mesh carrier and a second mesh carrier. For example, the filament is moved in the second direction to alter the position of the organ or tissue being supported or suspended, such as by increasing the length of filament between a first mesh carrier and a second mesh carrier and lowering the organ or tissue to a more anatomically correct position.

[0094] In another example, the filament is moved in the second direction to create or increase a space between the filament and the organ or tissue to be supported or suspended. For example, in a treatment for urinary incontinence, the filament can be adjusted to leave a space between the filament and the urethra (the organ to be supported). The space exists between the filament and the urethra when the patient is in one position. When the patient moves to another position, such as an upright position, the urethra shifts to occupy the space and is then supported by the filament.

[0095] In one embodiment, the filament is manually moved by a practitioner. In another embodiment, the practitioner grips at least a portion of the filament with a medical instrument, such as forceps, to move the filament.

[0096] Adjustment of the filament through the aperture in the first direction or in the second direction different than the first direction can be repeated until the desired tension or length of filament is achieved. For example, a practitioner can alternatively move the filament in the first direction to increase tension and move the filament in the second direction to decrease tension until the desired tension is achieved.

[0097] In some embodiments, the filament can be trimmed to a preferred length once the desired tension is achieved or once the mesh carrier is disengaged from the elongate member and delivered into bodily tissue.

[0098] At 560, the insertion device is withdrawn from the body of the patient.

[0099] Although activities of a method of delivering a mesh carrier into bodily tissue have been illustrated and described in one order, each activity is not required for delivery of a mesh carrier into bodily tissue. For example, in some embodiments, the filament can be adjusted in only one direction through the aperture of the mesh carrier. In another example, the filament is not adjusted through the aperture of the mesh carrier at all.

[00100] A method for delivering a mesh carrier (and filament or implant) into bodily tissue of a patient can include delivering more than one mesh carrier for securing a filament to bodily tissue. For example, in one embodiment, as illustrated in FIG. 20 two mesh carriers are delivered into bodily tissue of the patient. Alternatively, three, four, or more mesh carriers are delivered into bodily tissue of the patient). In an embodiment with two or more mesh carriers, the first mesh carrier is delivered as described above. It is not necessary, however, to adjust the filament received within the aperture of the first mesh carrier. The length or tension of the filament can be adjusted with regard to any one or more of the second, third, fourth, or more mesh carriers. The length between fixed mesh carriers can be any suitable length. For example, the length between fixed mesh carriers can be about 8 centimeters, 10 centimeters, 12 centimeters, 14 centimeters, 16 centimeters, or longer or shorter. In an embodiment with two or more mesh carriers, each mesh carrier is delivered in a substantially similar manner as described above with respect to the first mesh carrier. For ease of operation, the filament can be inserted into the aperture of each mesh carrier before the first mesh carrier is delivered into bodily tissue.

[00101] FIGS. 25-27 illustrate locations within the female pelvic region in which an implant can be placed using the method of delivery as discussed above with respect to FIG. 24. In some embodiments, as illustrated in FIG. 25, an implant can be placed within the body through the obturator membrane and into the externus muscle as indicated by E_1 and E_2 . By inserting the insertion device through the obturator membrane and into the externus muscle, the insertion device can be directed in a lateral direction to form a hammock configuration. Specifically, by fixing the implant (i.e., mesh carriers, filament, etc.) in the E_1 location

(shown in FIG. 26) and the contra lateral side, the implant will form the hammock configuration. In some embodiments, the hammock configuration can be achieved by placing the mesh carriers in a muscle at a location I_1 . Alternatively, the insertion device can be moved in a direction toward a shoulder blade of a patient to provide a “U” shaped configuration. Specifically, by fixing the implant in the E_2 location (shown in FIG. 27) and the contra lateral side, the implant will form the “U” shaped configuration.

[00102] Although the “U” shaped implant is achieved when placed within the body through the obturator membrane and into the externus muscle, the “U” shaped implant configuration, however, can also be achieved via a retro-pubic approach by placing the mesh carriers at the locations marked R1 and R2.

[00103] When fixing the implant to tissue, an insertion device (for example, insertion device 200, including stylet 230 and mesh carrier 290, as discussed above with respect to FIGS. 2-19), is inserted through the vagina V and is advanced along and around the ischiopubic ramus IR, shown in FIG. 4, until the tip of the stylet is proximate the obturator membrane. The handle of the insertion device is rotated, in either the C direction or the D direction (shown in FIG. 15) such that the tip of the stylet 230 of the insertion device 200 is aimed at the desired tissue. The handle can also be pivoted in a direction H (shown in FIG. 26). Alternatively, the tip of the stylet 230 of the insertion device 200 can be aimed by pivoting the handle 270 to a location A, as shown in FIG. 4. The handle 270 is then pivoted such that the axis B1-B1 defined by the handle 270 (shown, for example, in FIG. 4) is parallel to the midline M of the patient (shown in FIG. 25). A force in a direction F (shown in FIGS. 4 and 27) is applied to the handle 270 such that the tip of the stylet 230 and the mesh carrier 290 is advanced through the obturator membrane OM and into the externus muscle, and such that the axis B1-B1 remains substantially parallel to the midline M of the patient. The elongate member 210 of the insertion device 200 contacts the ischiopubic ramus IR (shown in FIG. 4) such that it prevents further lateral movement of the stylet tip into the externus muscle.

[00104] In one embodiment, as shown in FIG. 26, the mesh carrier 290 is inserted in the E_1 location. In such an embodiment, a force of gravity G due to a weight of the handle 270 causes the handle 270 to rotate in a direction H such that inadvertent removal of the mesh carrier 290 due to the weight of the handle 270 is unlikely. In another embodiment, as shown in FIG. 27, the mesh carrier 290 is inserted in the E_2 location. In this instance, the force of

gravity G can cause the handle 270 to pivot such that the axis B1-B1 defined by the handle 270 is substantially offset from the midline M of the patient. The force of gravity G can also cause the handle 270 to rotate in a direction K about axis B-B defined by the distal end portion of the elongate member 210 of the insertion device 200. In such an embodiment, the force of gravity G due to the weight of the handle 270 can affect the holding strength of the mesh carrier 290. Therefore, in some embodiments, the possibility of inadvertent removal of the mesh carrier 290 can be reduced. For example, in such embodiments, the cavity defined by the handle 270, as discussed in detail above, can be defined such that the handle 270 has a minimal weight.

[00105] In one embodiment, an insertion device includes an elongate member having a proximal end portion, a distal end portion, and defining a lumen therethrough. The elongate member includes a curved portion between the proximal end portion and the distal end portion. The distal end portion is configured to be removably coupled to a mesh carrier. The proximal end portion includes a handle defining a longitudinal axis. The insertion device also includes a stylet that has a proximal end portion, a distal end portion and is configured to move from a first position to a second position with respect to the elongate member. The stylet is configured to engage the mesh carrier to remove the mesh carrier from the elongate member such that a longitudinal axis defined by the mesh carrier is substantially orthogonal to the longitudinal axis defined by the handle.

[00106] In one embodiment, the distal end portion of the stylet is configured to extend outside of the distal end portion of the elongate member when the stylet is in its first position. In another embodiment, the distal end portion of the stylet is configured to contact a proximal end portion of a mesh carrier when the stylet is moved from its second position to its first position.

[00107] In one embodiment, a longitudinal axis defined by the proximal end portion of the elongate member is substantially orthogonal to a longitudinal axis defined by the distal end portion of the elongate member. In another embodiment, the curved portion of the elongate member has a radius of curvature of approximately 1.1 inches.

[00108] In one embodiment, the lumen of distal end portion of elongate member is configured receive a portion of the mesh carrier and to provide an interference fit with the mesh carrier.

[00109] In one embodiment, the elongate member includes stainless steel. In another embodiment, the handle is slidably coupled to the proximal end portion of the elongate member and the handle has at least one groove. The proximal end of the elongate member includes a coupling member that has at least one protrusion configured to engage the at least one groove.

[00110] In one embodiment, the insertion device includes a coupling member coupled to the proximal end portion of the elongate member. The coupling portion defines at least one protrusion.

[00111] In another embodiment, the insertion device includes a coupling member coupled to the proximal end portion of the elongate member. The coupling member includes a coupling portion extending proximally therefrom. The coupling portion defining at least one protrusion. The handle is configured to engage the at least one protrusion of the coupling portion.

[00112] In another embodiment, an insertion device includes an elongate member having a proximal end portion, a distal end portion, and defining a lumen therethrough. An axis defined by the proximal end portion of the elongate member is substantially orthogonal to an axis defined by the distal end portion of the elongate member. The insertion device also includes a stylet having a proximal end portion and a distal end portion. At least a portion of the stylet is disposed within the lumen of the elongate member. The stylet is slidably coupled to the elongate member such that the stylet is configured to move from a first position to a second position with respect to the elongate member.

[00113] In one embodiment, the elongate member includes a curved portion that has a radius of curvature of 1.1 inches.

[00114] In another embodiment, the distal end portion of the elongate member is configured to be removably coupled to a mesh carrier. In yet another embodiment, the lumen defined by the elongate member is configured to receive a portion of a mesh carrier and to provide an interference fit with the mesh carrier.

[00115] In one embodiment, the stylet is biased to a linear configuration.

[00116] In another embodiment, the insertion device also includes a coupling member disposed about the proximal end portion of the elongate member. The coupling member has at least one protrusion. The handle has at least one groove to engage the at least one protrusion of the coupling member.

[00117] In one embodiment, the elongate member includes stainless steel.

[00118] In one embodiment, the distal end portion of the stylet is configured to pierce a filament received in a mesh carrier when the insertion device is in its first configuration. In another embodiment, the distal end portion of the stylet is configured to decouple a mesh carrier from the elongate member when the stylet is moved from its second position to its first position.

[00119] A method of inserting a mesh carrier into a body of a patient includes (1) coupling the mesh carrier to a distal end portion of an elongate member of an insertion device; (2) inserting the insertion device into the body; (3) decoupling the mesh carrier such that a longitudinal axis defined by the mesh carrier is substantially orthogonal to an axis defined by the proximal end portion of the elongate member; and (3) removing the insertion device from the body.

[00120] In one embodiment, the coupling of the mesh carrier includes moving the stylet to its first position such that a distal end portion of a stylet extends beyond the distal end portion of the elongate member. In another embodiment, the decoupling of the mesh carrier includes moving the stylet from its first position to a second position. In yet another embodiment, the moving of the stylet to its second position includes moving the stylet in a proximal direction.

[00121] In one embodiment, the method includes inserting a filament into an aperture defined by the mesh carrier prior to coupling the mesh carrier to the stylet. In another embodiment, the method includes inserting a filament into an aperture defined by the mesh carrier prior to coupling the mesh carrier to the stylet.

[00122] In one embodiment, the decoupling of the mesh carrier includes moving the stylet from its second position to its first position such that the distal end of the stylet contacts a proximal end portion of the mesh carrier. In another embodiment, the moving of the stylet to its first position includes moving the stylet in a distal direction.

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[00123] In one embodiment, the method includes coupling a second mesh carrier to the distal end portion of the elongate member when the stylet is in its first position and inserting the insertion device into the body of the patient. In another embodiment, the method includes moving the stylet from its second position to its first position to decouple the second mesh carrier at a second location, wherein an orientation of the second mesh carrier is orthogonal to the axis defined by the proximal end of the elongate member, and removing the insertion device from the body.

[00124] While various embodiments of the present invention have been described above, it should be understood that they have been presented by way of example only, and not by way of limitation. It will be apparent to a person skilled in the relevant art that various changes in form and detail can be made therein without departing from the spirit and scope of the invention. Thus, the present invention should not be limited by any of the above described exemplary embodiments. For example a delivery instrument can include various combinations and sub-combinations of the various embodiments described herein.

[00125] The reference in this specification to any prior publication (or information derived from it), or to any matter which is known, is not, and should not be taken as an acknowledgment or admission or any form of suggestion that that prior publication (or information derived from it) or known matter forms part of the common general knowledge in the field of endeavour to which this specification relates.

[00126] Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

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THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. An insertion device comprising:
a handle member defining a cavity and a longitudinal axis;
an elongate member having a proximal end portion, a distal end portion, and defining a lumen therethrough, the lumen having a diameter of a first size, the elongate member including a curved portion between the proximal end portion and the distal end portion, the distal end portion configured to removably and frictionally couple a tissue anchor thereto such that a portion of the tissue anchor is disposed within the lumen defined by the elongate member and a portion of the tissue anchor having a diameter of a second size greater than the first size is disposed outside of the lumen defined by the elongate member, at least a portion of the elongate member being disposed within the cavity of the handle member, the elongate member being movably coupled to the handle member; and
a stylet having a proximal end portion, a distal end portion and being configured to move from a first position to a second position with respect to the elongate member, and when the stylet is in the first position, the distal end portion of the stylet defines a longitudinal axis that is offset from a longitudinal axis defined by the distal end portion of the elongate member, the stylet being configured to engage the tissue anchor to remove the tissue anchor from the elongate member such that a longitudinal axis defined by the tissue anchor is substantially orthogonal to the longitudinal axis defined by the handle, member the stylet being fixedly coupled to the handle member.
2. The insertion device of claim 1, wherein the distal end portion of the stylet is configured to extend outside of the distal end portion of the elongate member when the stylet is in its first position.
3. The insertion device of claim 1 or 2, wherein the distal end portion of the stylet is configured to contact a proximal end portion of a tissue anchor when the stylet is moved from its second position to its first position.
4. The insertion device of any one of the preceding claims, wherein a longitudinal axis defined by the proximal end portion of the elongate member is substantially orthogonal to a longitudinal axis defined by the distal end portion of the elongate member.

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5. The insertion device of any one of the preceding claims, wherein the curved portion of the elongate member has a radius of curvature of approximately 1.1 inches.
6. The insertion device of any one of the preceding claims, wherein the handle member has at least one groove and the proximal end of the elongate member includes a coupling member having at least one protrusion configured to engage the at least one groove.
7. The insertion device of any one of the preceding claims, further comprising a coupling member coupled to the proximal end portion of the elongate member, the coupling member including a coupling portion extending proximally therefrom, the coupling portion defining at least one protrusion, wherein the handle member is configured to engage the at least one protrusion of the coupling portion.
8. An insertion device comprising:
 - a handle member defining a cavity;
 - an elongate member having a proximal end portion, a distal end portion, and defining a lumen therethrough, wherein a longitudinal axis defined by the proximal end portion of the elongate member is substantially orthogonal to a longitudinal axis defined by the distal end portion of the elongate member, at least a portion of the elongate member being disposed within the cavity, the elongate member being movably coupled to the handle member; and
 - a stylet having a proximal end portion and a distal end portion, at least a portion of the stylet disposed within the lumen of the elongate member, the stylet being slidably coupled to the elongate member such that the stylet is configured to move from a first position to a second position with respect to the elongate member, when the stylet is in the first position, the distal end portion of the stylet defines a longitudinal axis that is offset from the longitudinal axis defined by the distal end portion of the elongate member, the stylet being fixedly coupled to the handle member.
9. The insertion device of claim 8, wherein the distal end portion of the elongate member is configured to be removably coupled to a tissue anchor.
10. The insertion device of claim 8 or 9, wherein the stylet is biased to a linear configuration.

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11. The insertion device of any one of claims 8 to 10, further comprising a coupling member disposed about the proximal end portion of the elongate member, the coupling member having at least one protrusion, the handle having at least one groove to engage the at least one protrusion of the coupling member.

12. The insertion device of any one of claims 8 to 11, wherein the distal end portion of the stylet is configured to pierce a filament received in a tissue anchor when the insertion device is in its first configuration.

13. A method of inserting a tissue anchor into a body of a patient, comprising:
coupling the tissue anchor to a distal end portion of an elongate member of an insertion device such that a portion of the tissue anchor is disposed within a lumen defined by the elongate member and a portion of the tissue anchor is disposed outside of the lumen defined by the elongate member, a diameter of the portion of the tissue anchor disposed outside of the lumen being larger than a diameter of the lumen, the insertion device having an elongate member, a handle member, and a stylet, at least a portion of the elongate member being disposed within a cavity defined by the handle member, the elongate member being movably coupled to the handle member, the stylet being fixedly coupled to the handle member, the coupling of the tissue anchor includes extending a stylet through a filament coupled to the tissue anchor;

inserting the insertion device into the body;

decoupling the tissue anchor such that a longitudinal axis defined by the tissue anchor is substantially orthogonal to an axis defined by the proximal end portion of the elongate member; and

removing the insertion device from the body.

14. The method of claim 13, wherein the coupling of the tissue anchor includes moving the stylet to a first position such that a distal end portion of the stylet extends beyond the distal end portion of the elongate member.

15. The method of claim 13, wherein the decoupling of the tissue anchor includes moving the stylet from a first position to a second position.

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16. The method of any one of claims 13 to 15, further comprising inserting a filament into an aperture defined by the tissue anchor prior to coupling the tissue anchor to the stylet.
17. The method of claim 13, wherein the decoupling of the tissue anchor includes moving the stylet from a second position to a first position such that a distal end of the stylet contacts a proximal end portion of the tissue anchor.
18. The method of any claim 13, wherein the moving of the stylet to a first position includes moving the stylet in a distal direction.
19. The method of claim 13, further comprising:
 - coupling a second tissue anchor to the distal end portion of the elongate member when the stylet is in a first position; and
 - inserting the insertion device into the body of the patient.
20. The method of claim 13, further comprising:
 - moving the stylet from a second position to a first position to decouple the second tissue anchor at a second location, wherein an orientation of the second tissue anchor is orthogonal to the axis defined by the proximal end of the elongate member; and
 - removing the insertion device from the body.

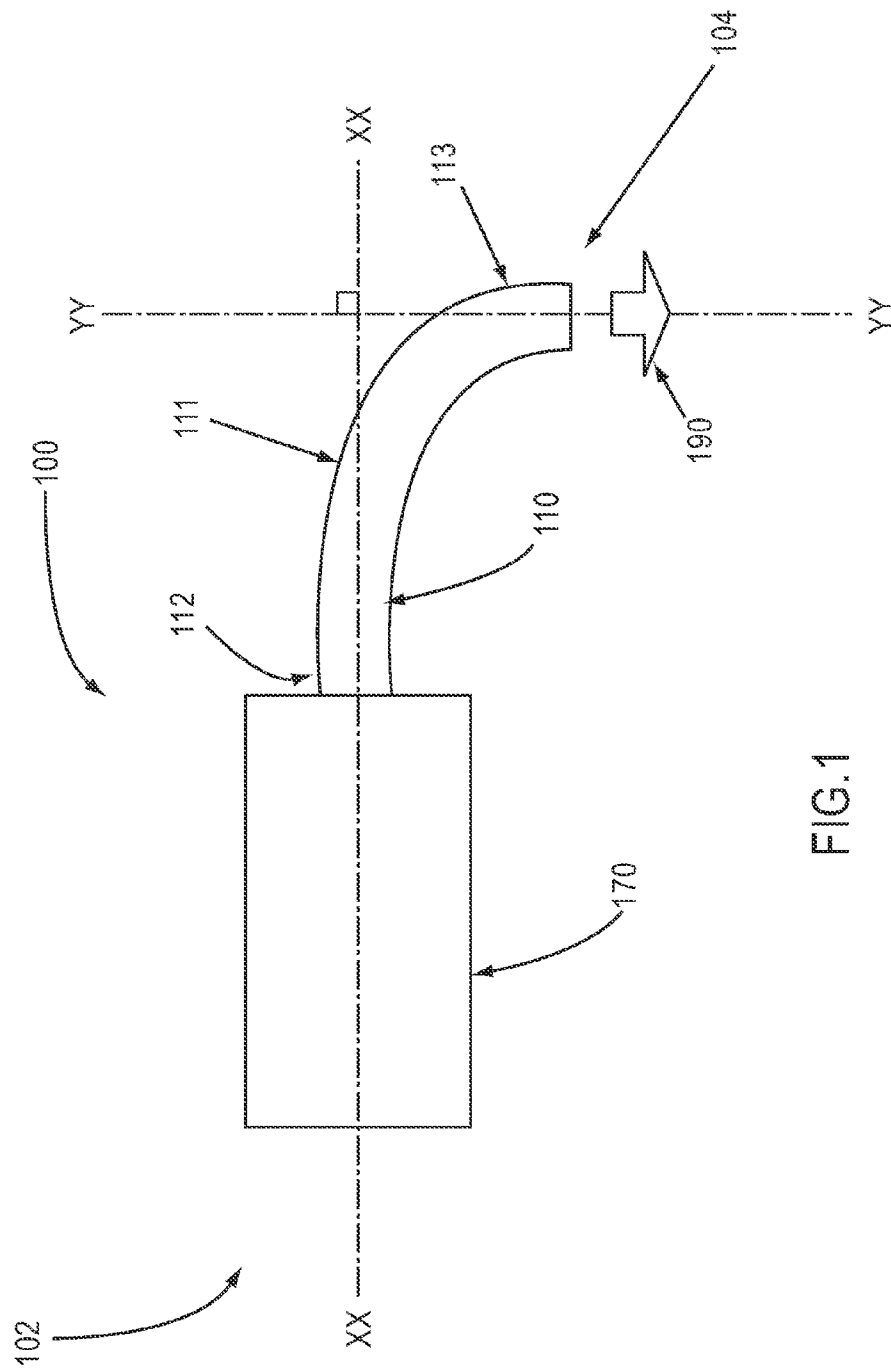


FIG.1

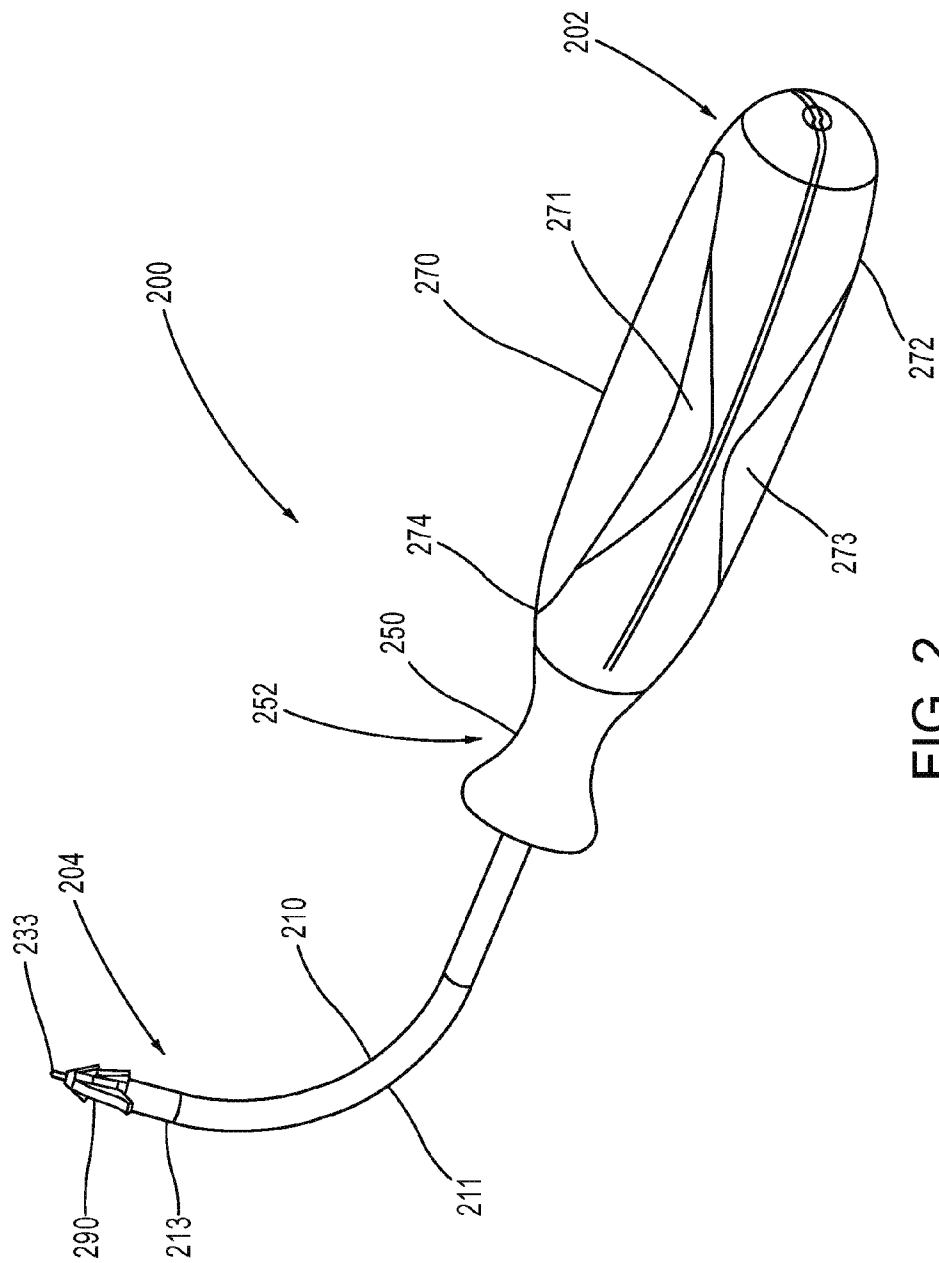


FIG. 2

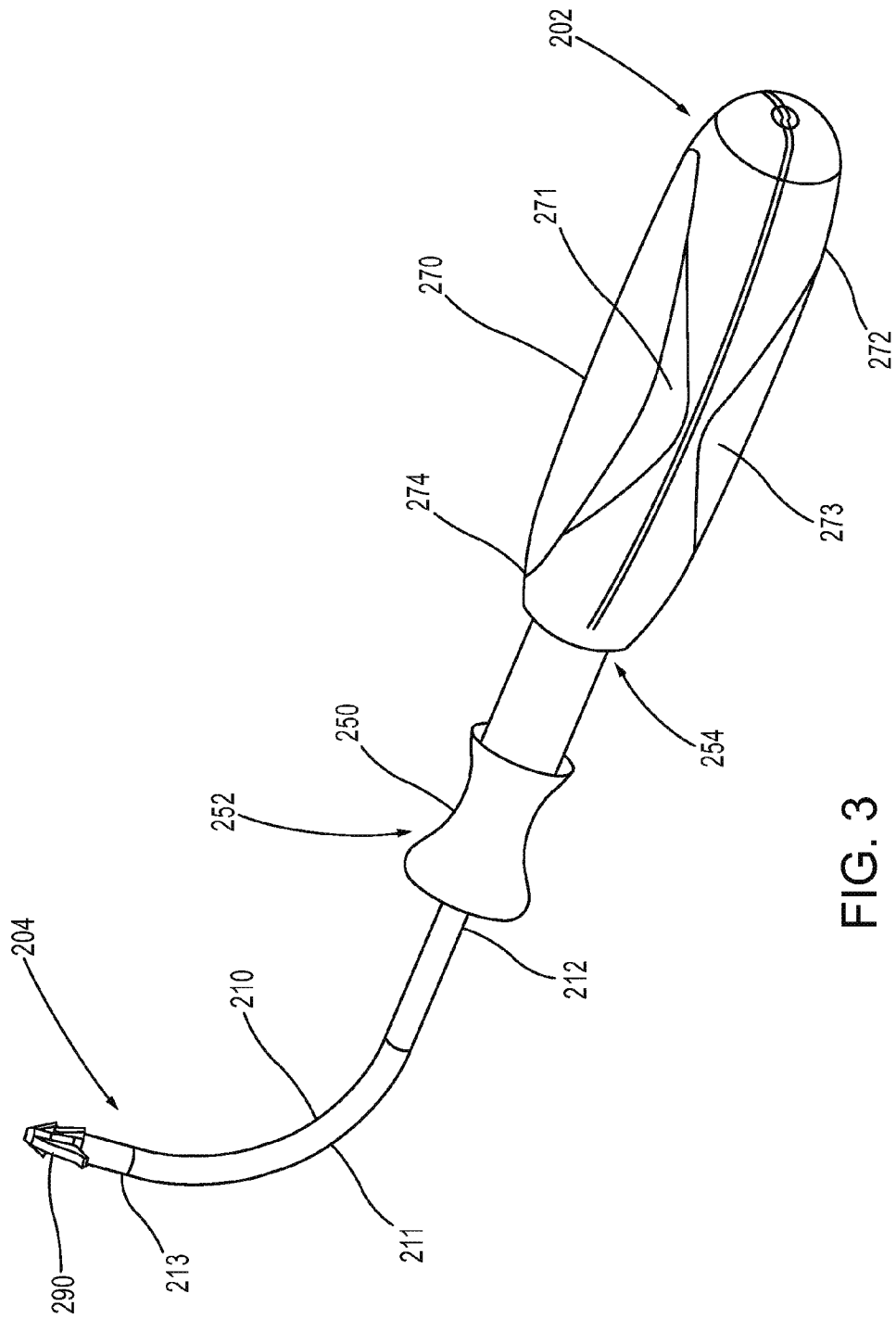
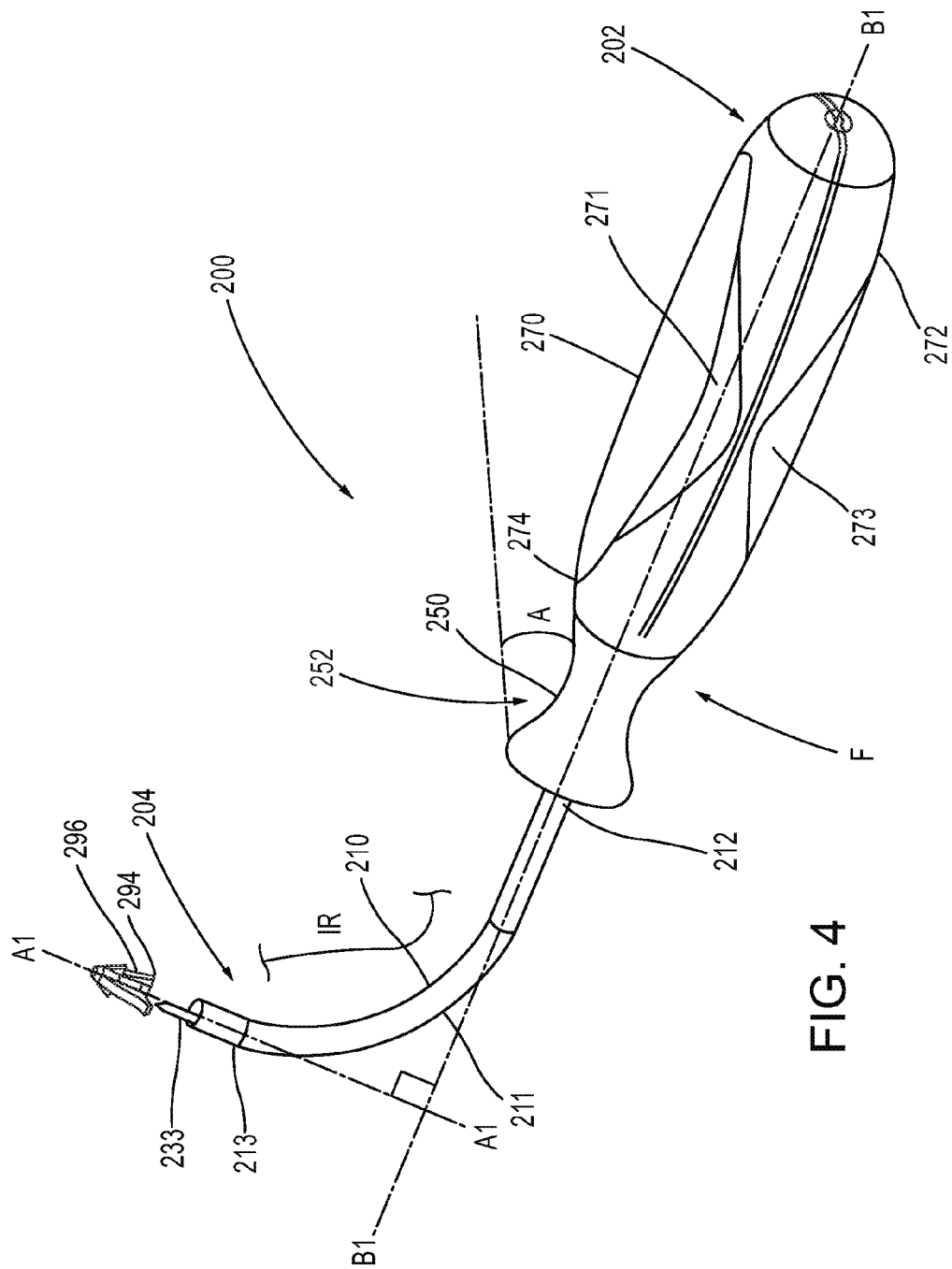


FIG. 3



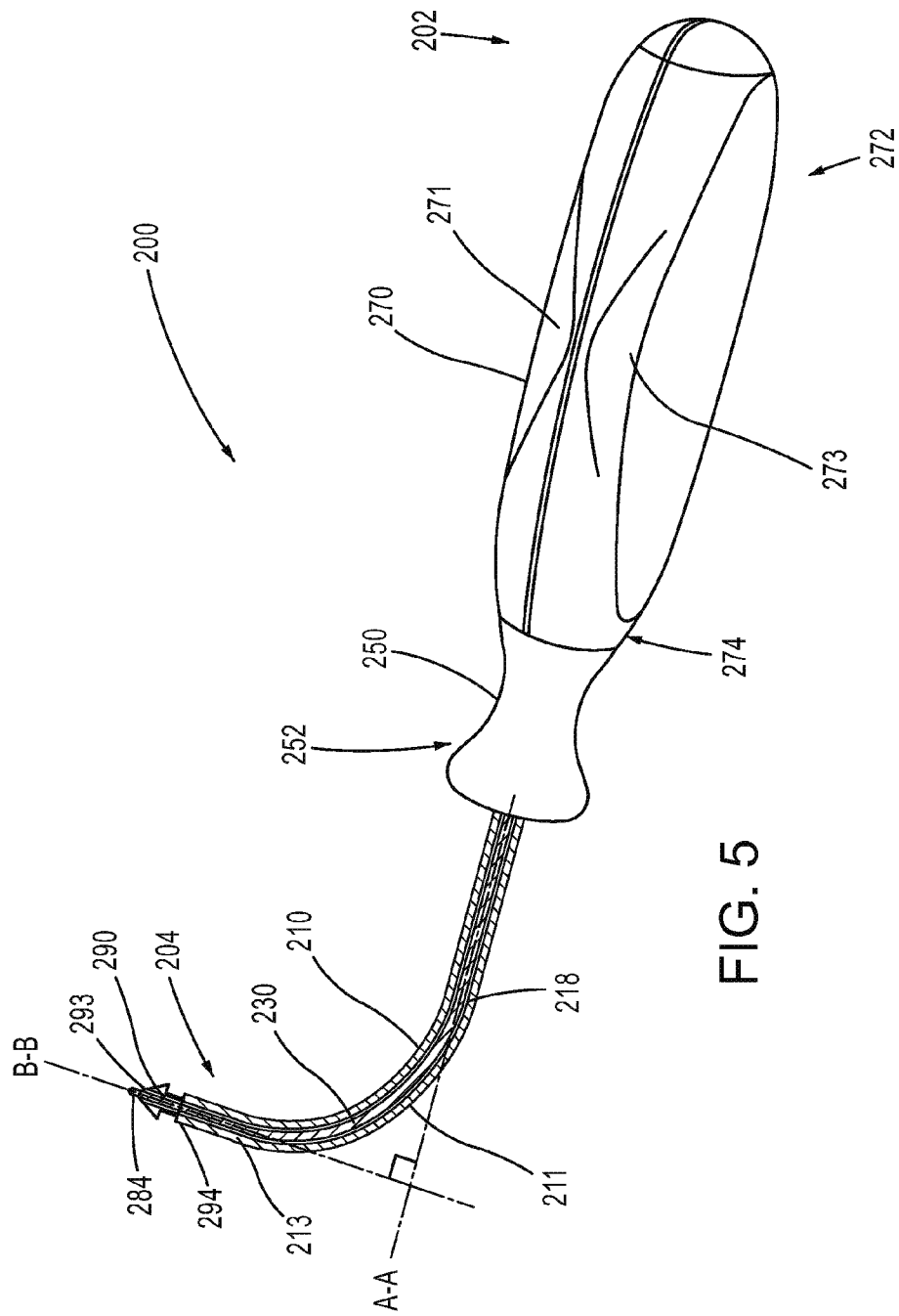


FIG. 5

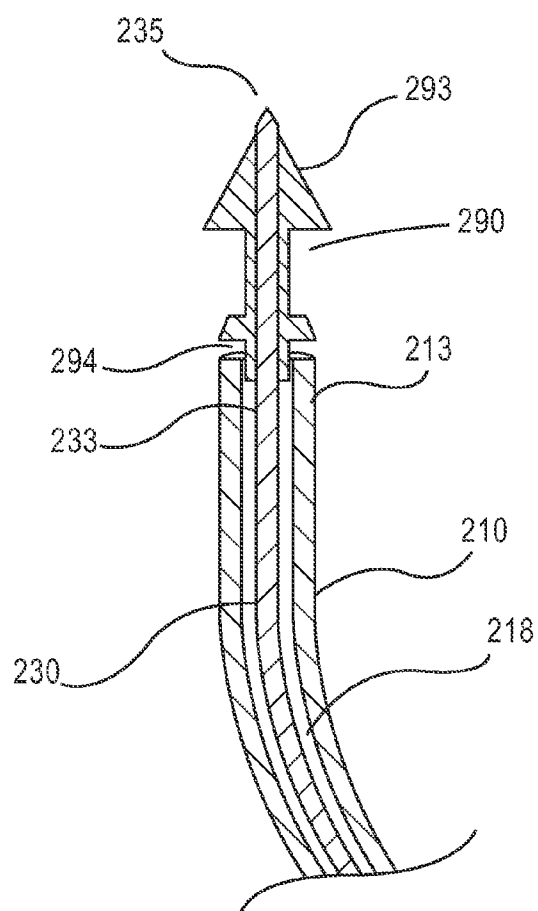


FIG. 6

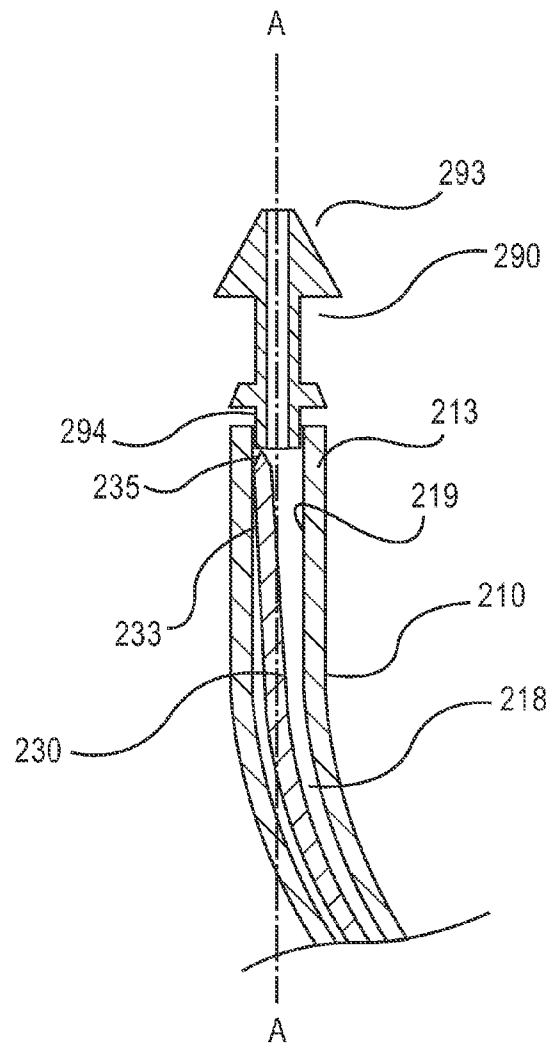
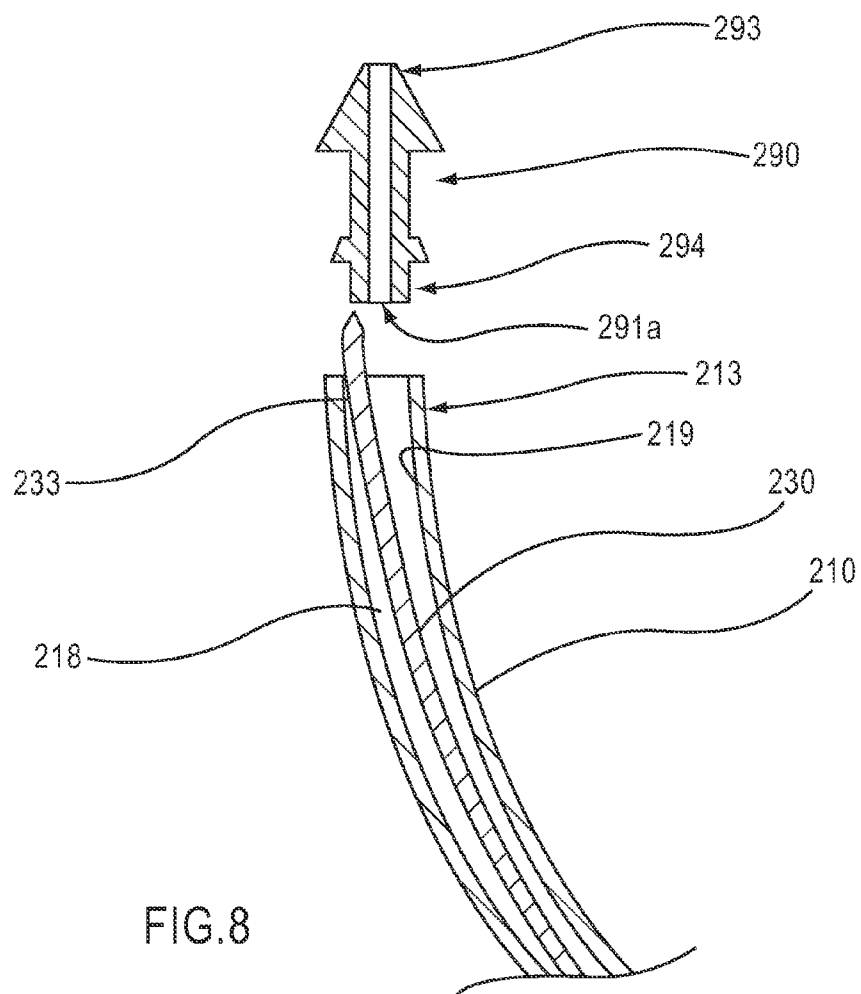


FIG. 7



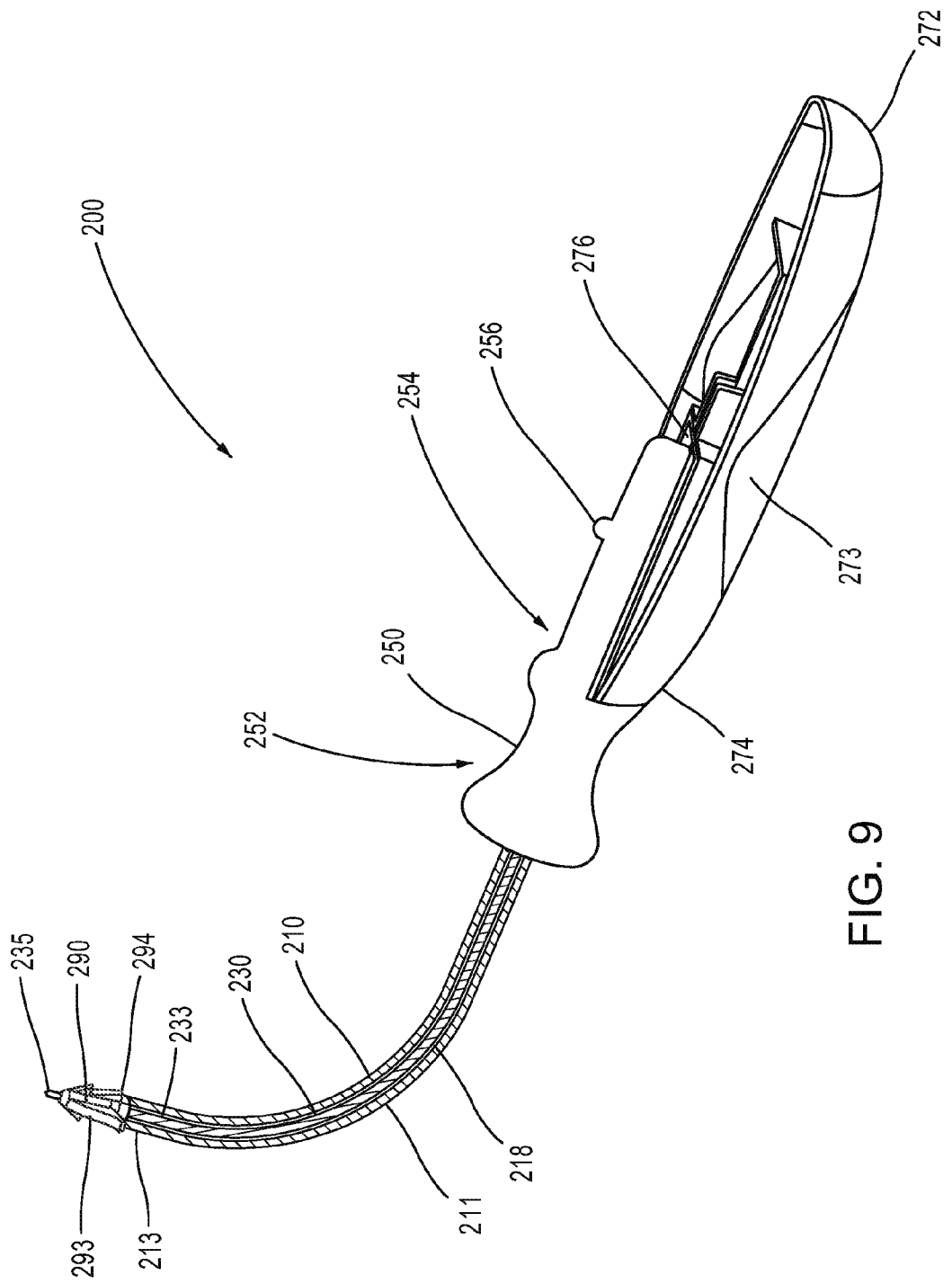


FIG. 9

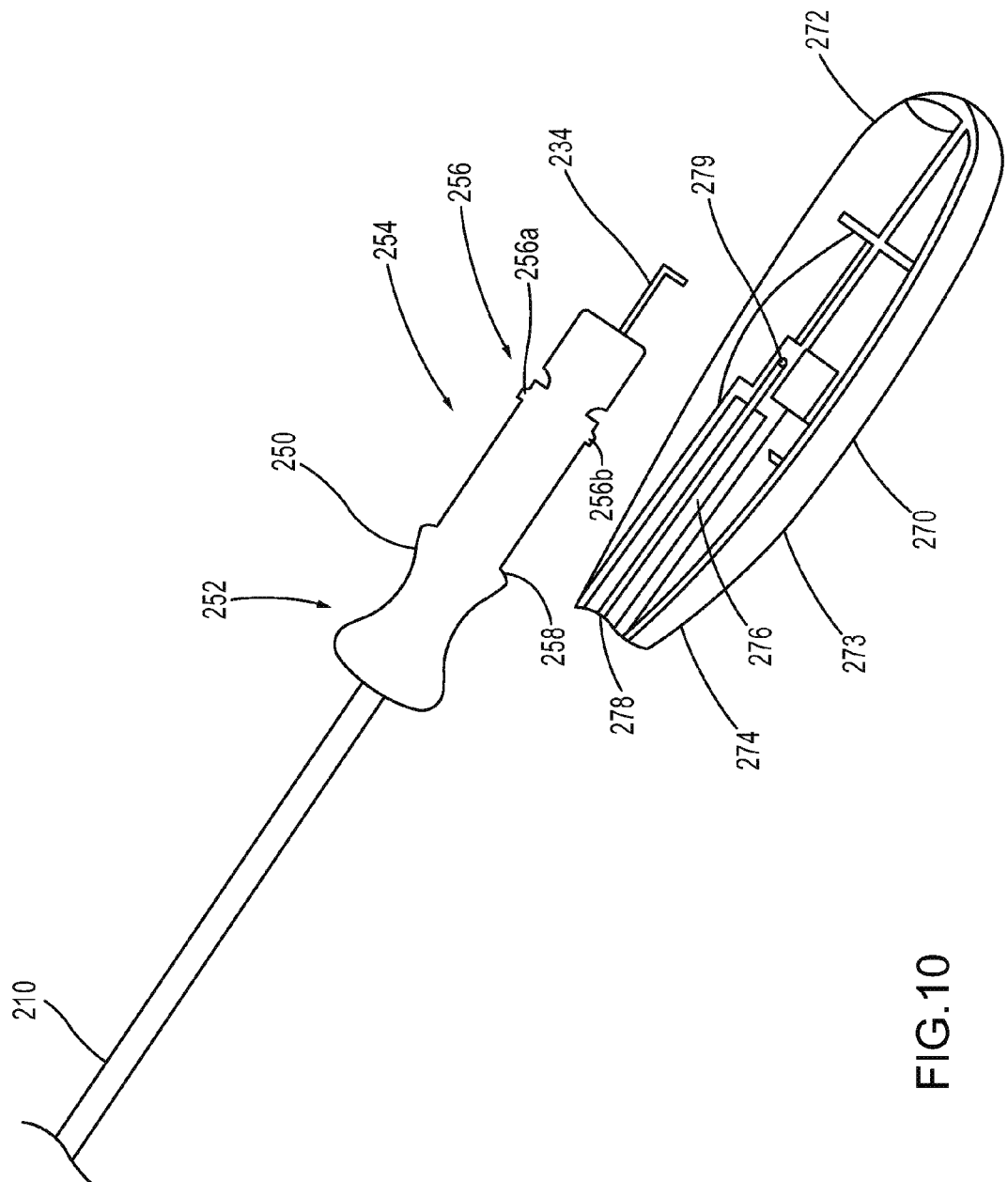


FIG. 10

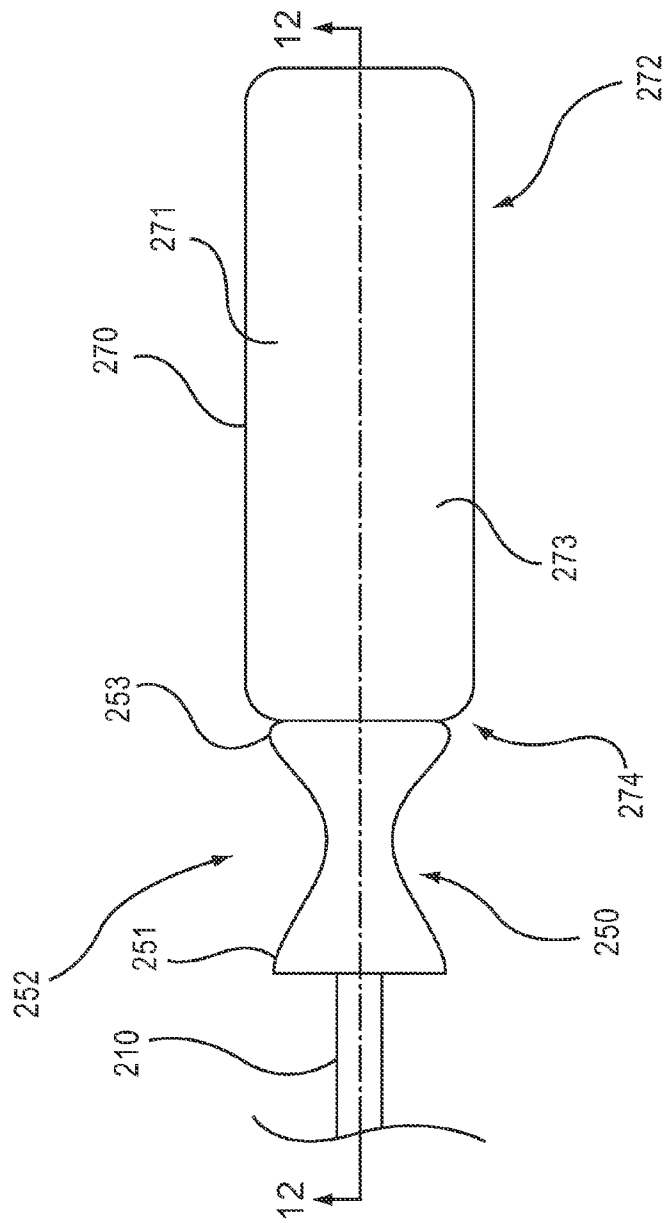


FIG.11

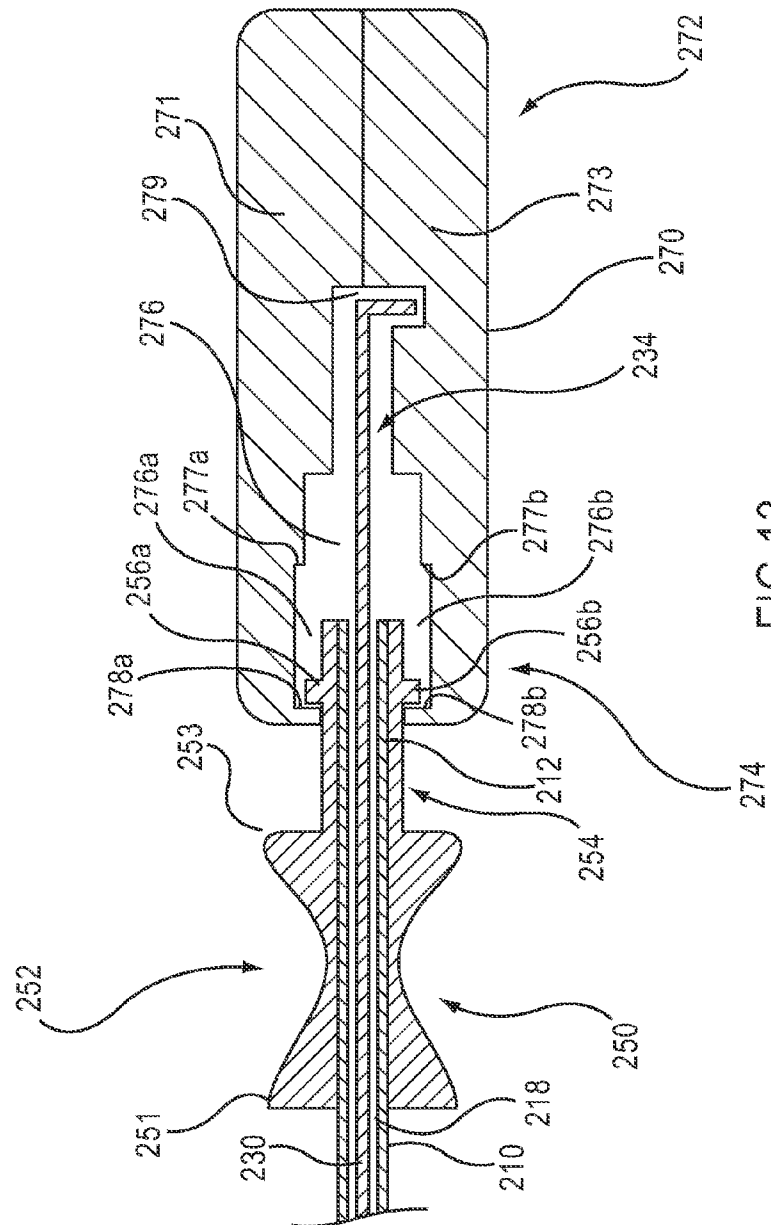
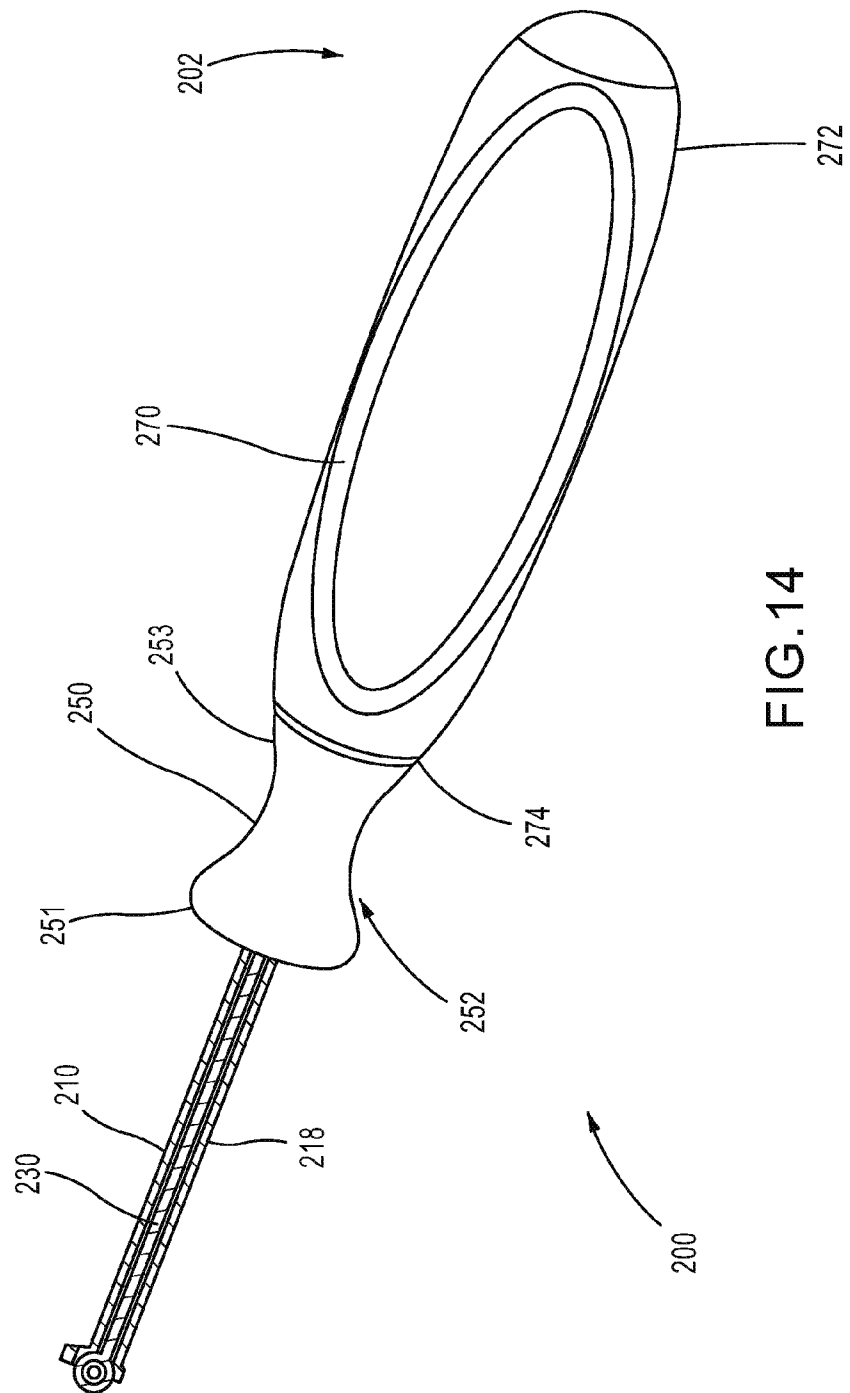


FIG.13



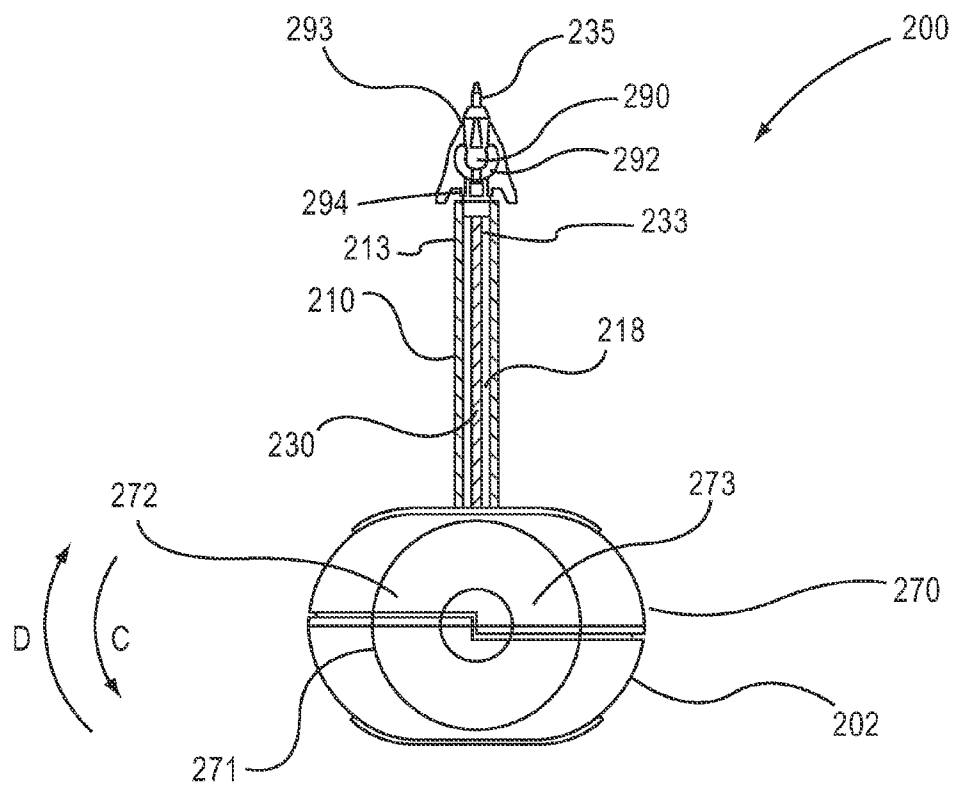


FIG. 15

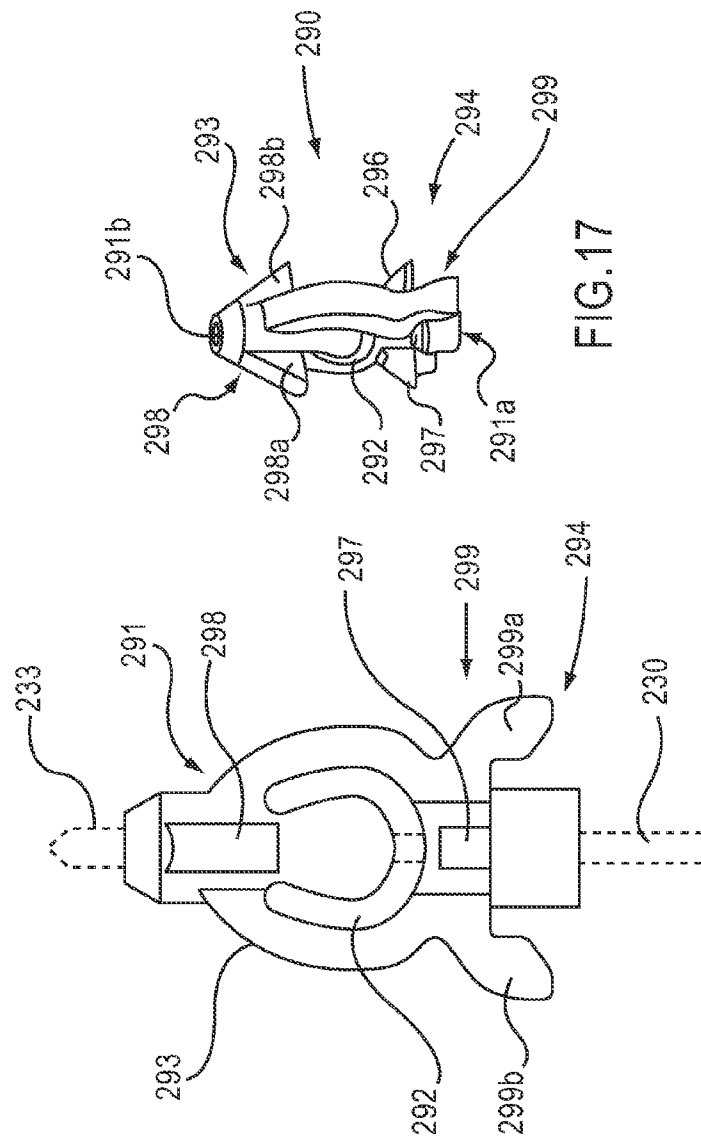


FIG.17

FIG.16

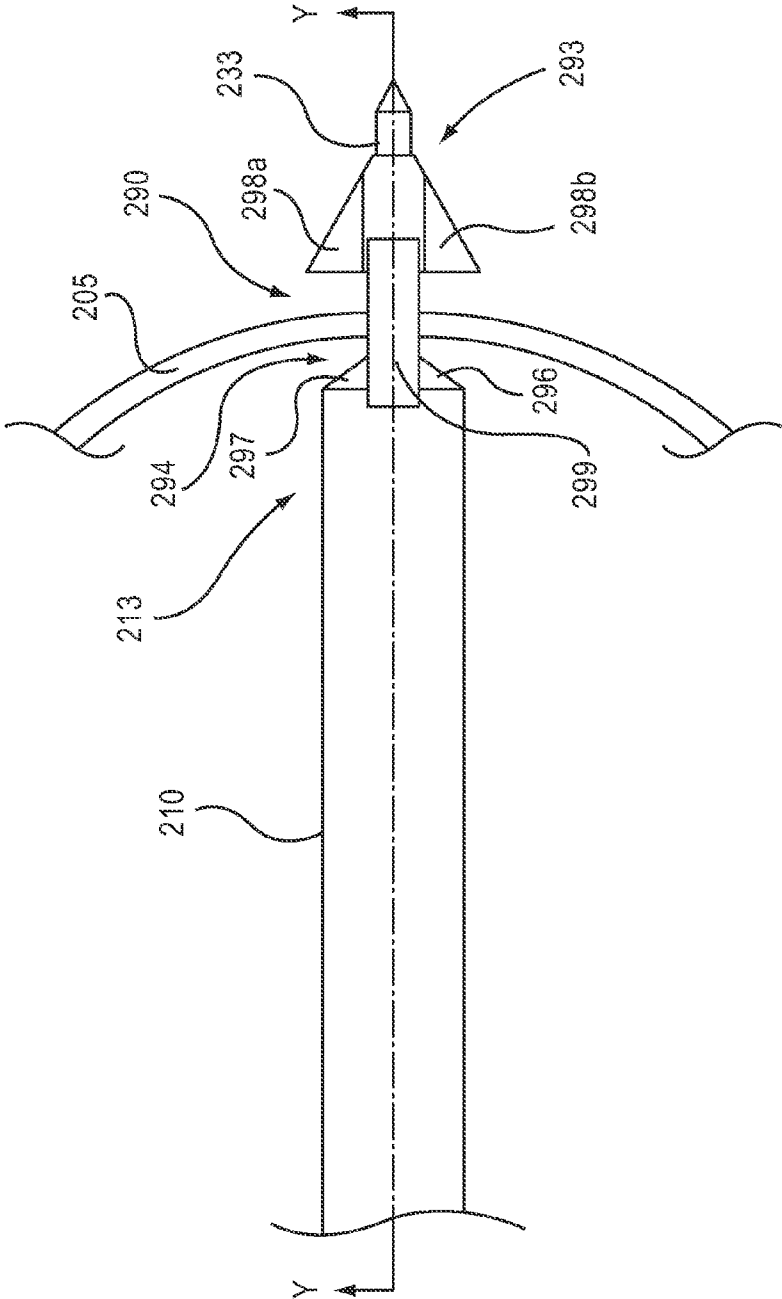


FIG.18

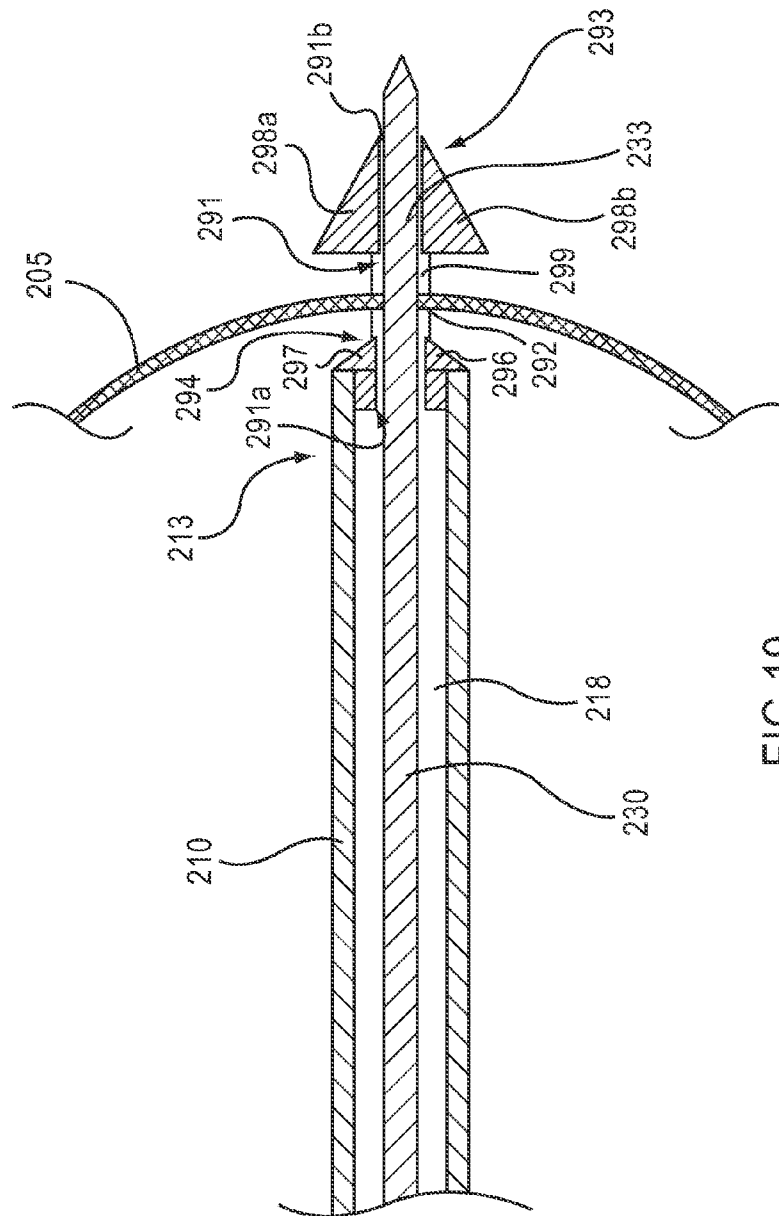


FIG.19

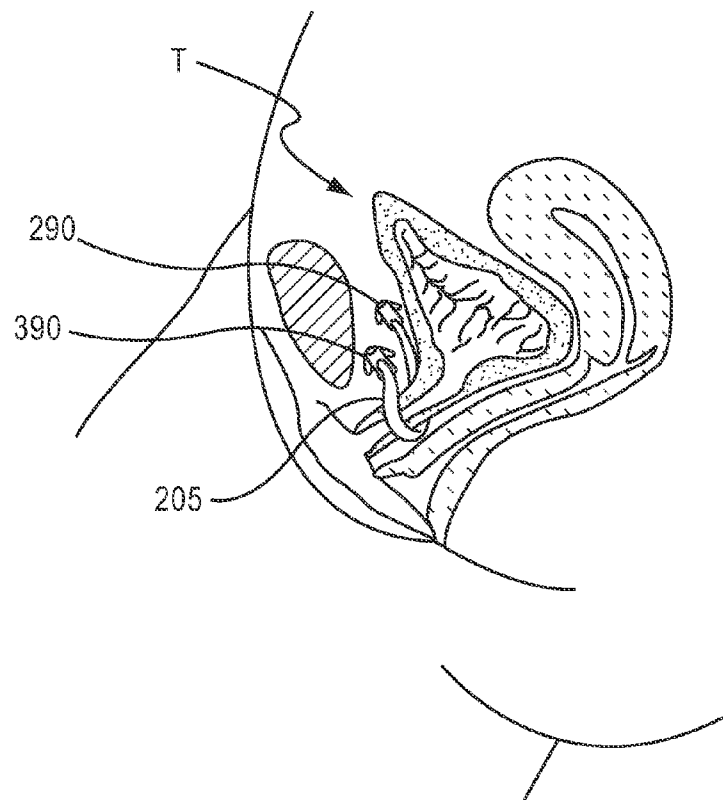


FIG. 20

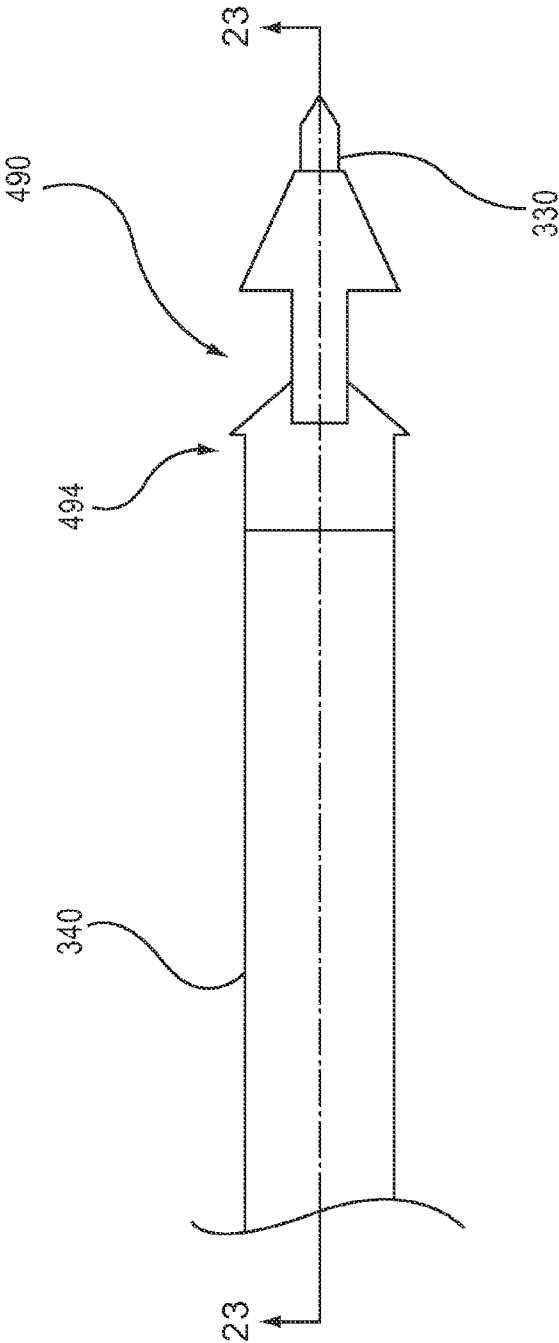


FIG. 21

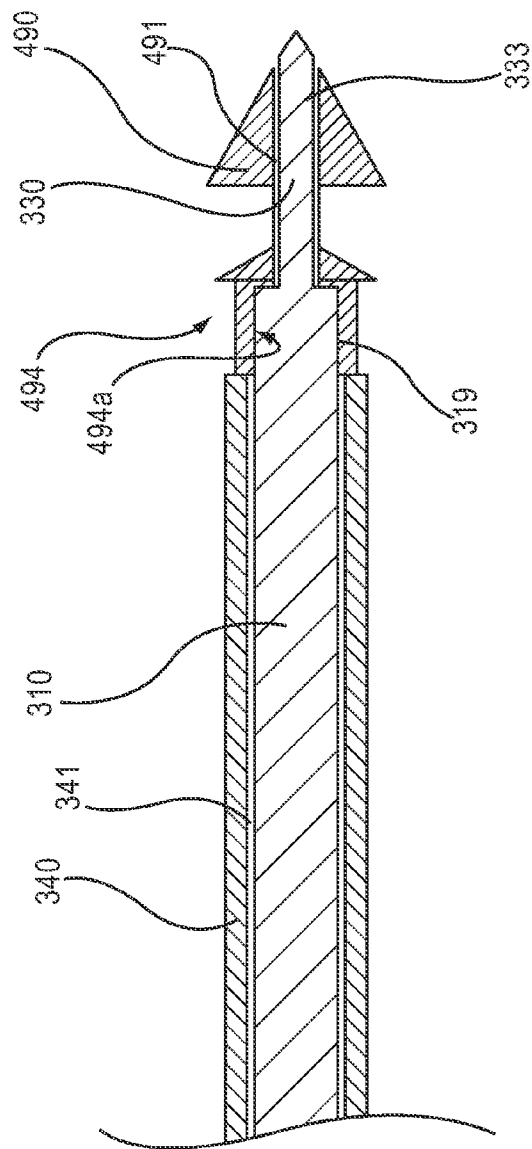
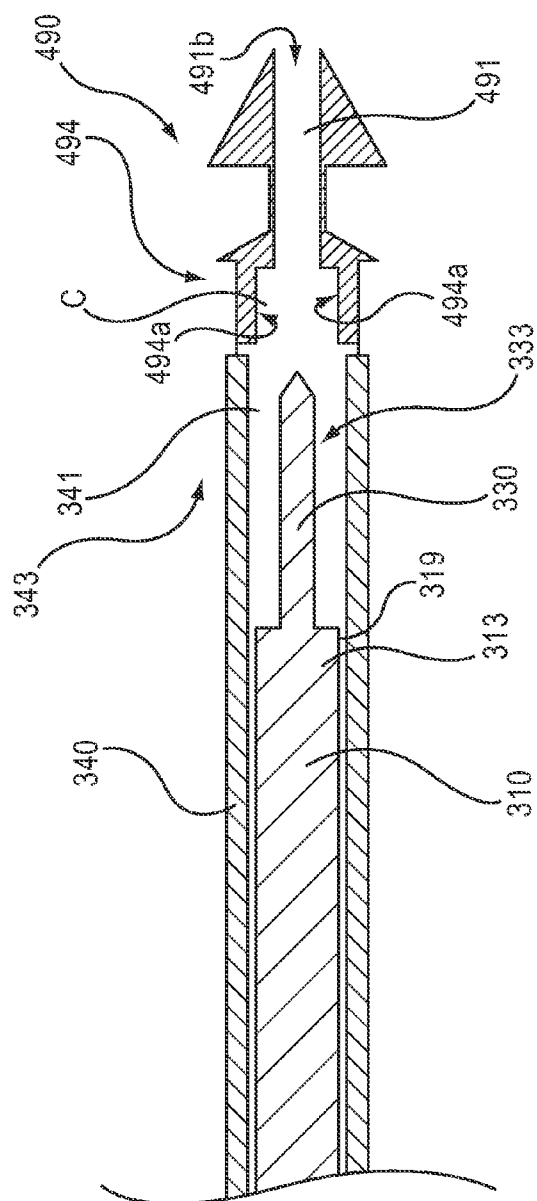


FIG.22



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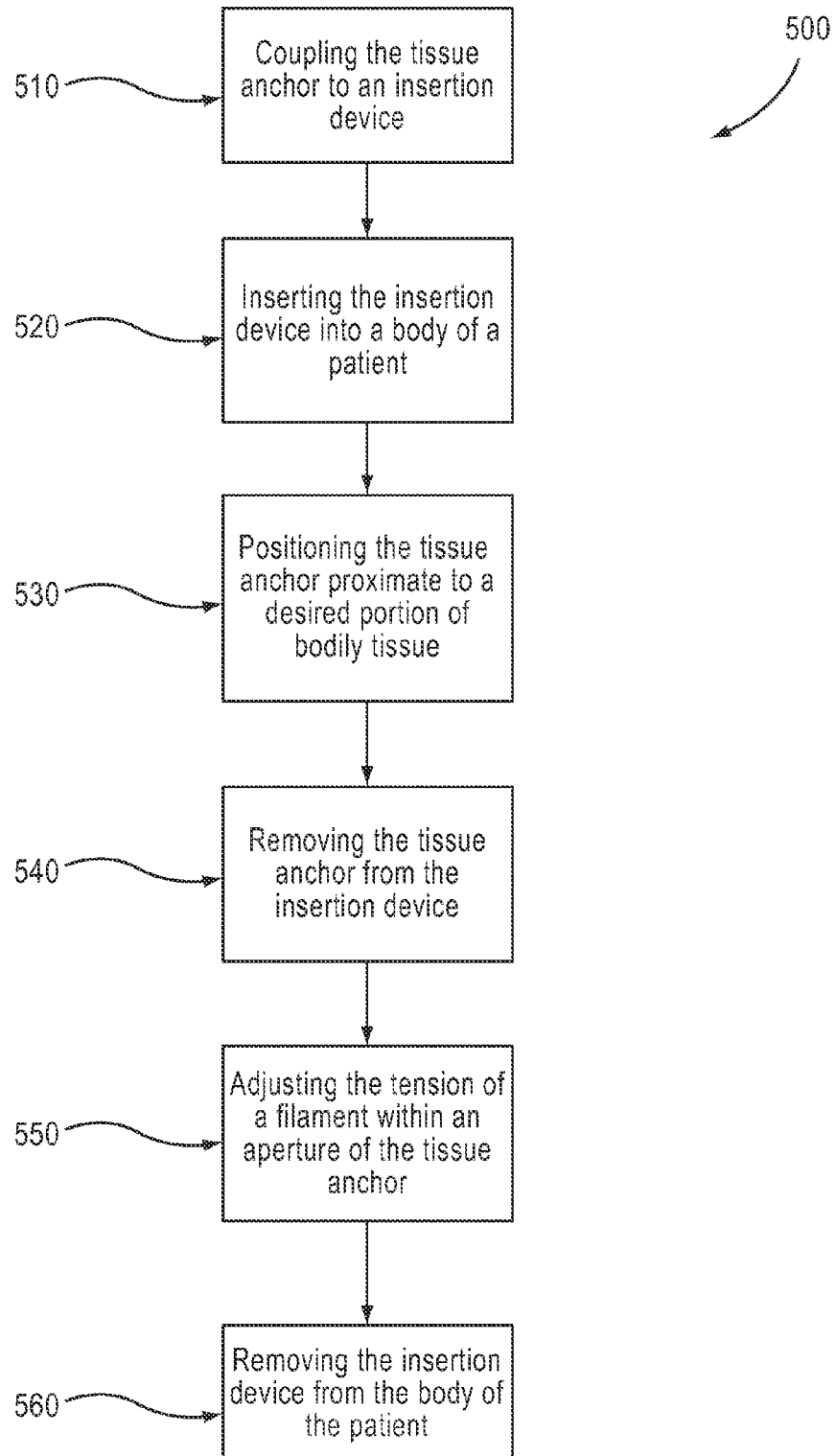


FIG.24

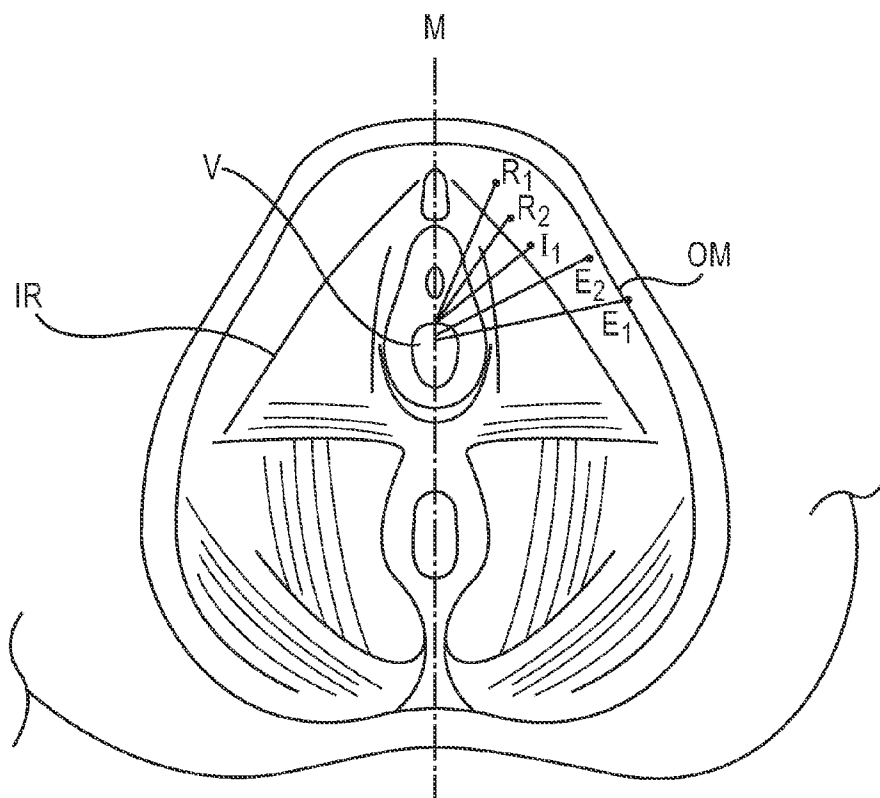


FIG.25

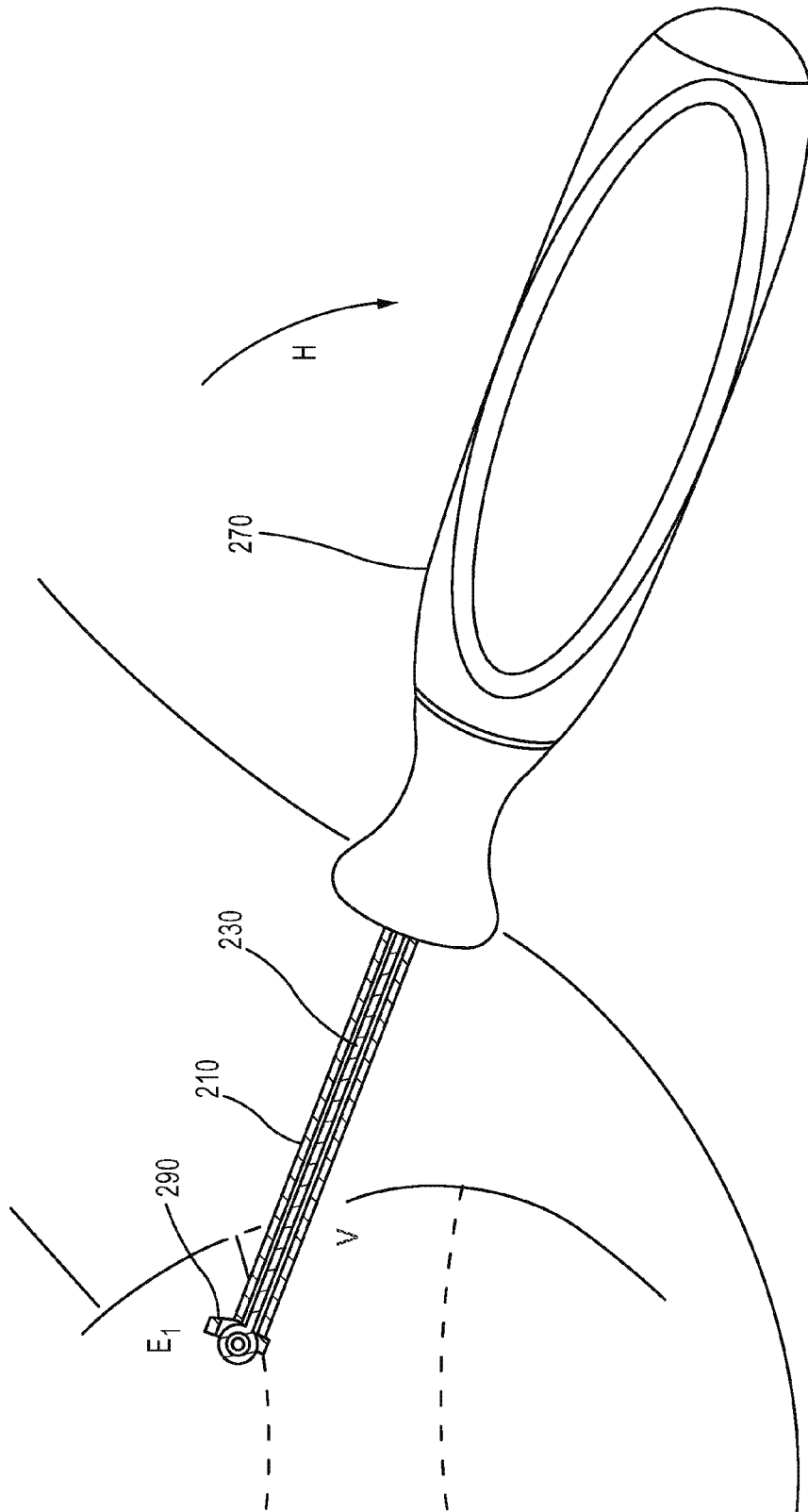


FIG. 26

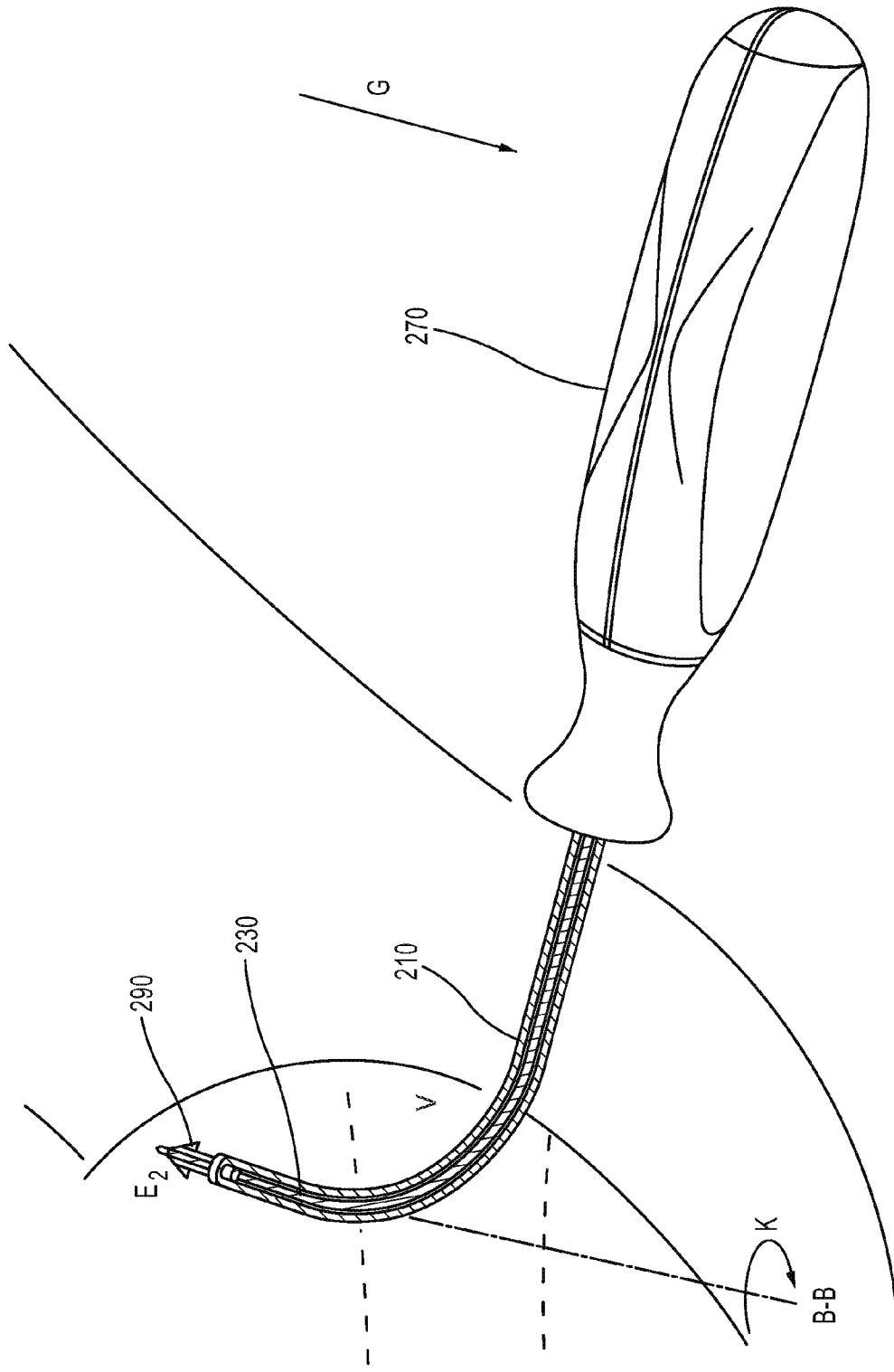


FIG. 27