

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

(19) World Intellectual Property Organization

International Bureau

(43) International Publication Date

22 April 2021 (22.04.2021)



(10) International Publication Number

WO 2021/076820 A1

(51) International Patent Classification:

A61B 17/04 (2006.01) *A61B 17/10* (2006.01)
A61B 17/08 (2006.01)

(72) Inventors; and

(71) Applicants: **WHITMAN, Michael, P.** [US/US]; 1544 River Road, New Hope, PA 18938 (US). **DATCUK, Peter** [US/US]; 1665 Kumry Road, Quakertown, PA 18951 (US).

(21) International Application Number:

PCT/US2020/055861

(74) Agent: **KOUEH, Won-Joon** et al.; Duane Morris LLP, 30 S. 17 Street, Philadelphia, PA 19103 (US).

(22) International Filing Date:

15 October 2020 (15.10.2020)

(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, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, IT, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

(54) Title: SYSTEMS AND METHODS FOR MINIMALLY INVASIVE ANNULOPLASTY

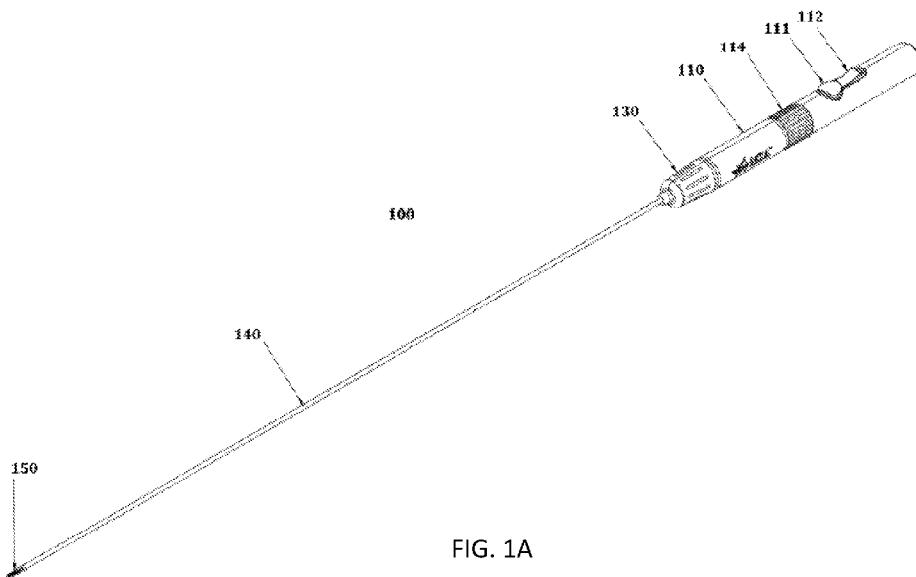


FIG. 1A

(57) **Abstract:** An apparatus for deploying a tissue anchor is disclosed. The apparatus includes a catheter tube having a proximal end and a distal end defining the catheter's length, where the distal end has an anchor housing configured to hold a tissue anchor before deployment; and a pusher wire positioned within the catheter tube and extending through the length of the catheter tube. The apparatus is configured to provide a pushing force on the pusher wire from the proximal end of the catheter tube, thus displacing the pusher wire in a distal direction to the pusher wire's fully extended anchor deployment position which in turn deploys the tissue anchor from the anchor housing in the distal direction by pushing the tissue anchor in the distal direction.



(84) **Designated States** (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, 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, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

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

5 SYSTEMS AND METHODS FOR MINIMALLY INVASIVE ANNULOPLASTY

FIELD OF THE INVENTION

[1] The present invention relates to systems and devices for percutaneously carrying out minimally-invasive surgical intervention.

BACKGROUND

10 [2] The treatment of tricuspid and mitral valves is well documented. Surgical procedures have been in existence for over 70 years and are well documented in textbooks such as Carpentier's Reconstructive Valve Surgery, Sanders 1957. While these treatments are effective in reducing regurgitation, they are generally very invasive procedures requiring anesthesia and surgical intervention. Advances in percutaneous structural heart disease 15 treatments such as transcatheter aortic valve implantation (TAVI) have greatly advanced the standard of care for these diseases. TAVI is rapidly becoming the standard of care as this percutaneous procedure has obviated the need for surgical intervention. Interventional percutaneous approaches have the benefit of accessing the heart through the circulatory system, eliminating the need for surgical incisions, general anesthesia and the comorbidities 20 associated with such. Specifically, tricuspid and mitral diseases generally fall into one of two categories: functional disease and degenerative disease. No effective percutaneous interventional procedures currently exist to address these disease states. For instance, the treatment of tricuspid and mitral valve disease requires that the patient be under general anesthesia, have a sternotomy or other access to the heart, catheters placed in the heart, the 25 heart placed on bypass, and direct visualization gained through surgical access. There are a number of comorbidities associated with this access and recovery from bypass. There is a need for a percutaneous approach to the treatment of diseases as the improvement of patient recovery and long-term efficacy are well documented.

SUMMARY

30 [3] In accordance with example embodiments of the present invention, systems for transcatheter tricuspid and mitral valve interventions are provided.

[4] Example embodiments of the present invention include a percutaneous device that delivers low mass anchors to the annulus of either the tricuspid and/or mitral valve forming a fixation point, allowing for the reconfiguration of the annulus (i.e., annuloplasty). The 35 anchors are connected by a suture or other material that allows for the anchors to be drawn into apposition and secured utilizing a lock. Once the anchors are drawn into a position such

5 that the structure will enable reduced regurgitation and restructuring of the valve, the lock is applied to fix the anchors in position.

[5] Provided is an apparatus for deploying a tissue anchor comprising: a catheter tube having a proximal end and a distal end defining the catheter's length, wherein the distal end comprising an anchor housing configured to hold a tissue anchor before deployment; and a 10 pusher wire positioned within the catheter tube and extending through the length of the catheter tube, wherein the pusher wire has a proximal end and a distal end corresponding with the proximal end and the distal end of the catheter tube, wherein the apparatus is configured to provide a pushing force on the pusher wire from the proximal end of the catheter tube, thus displacing the pusher wire in a distal direction to the pusher wire's fully extended anchor 15 deployment position which in turn deploys the tissue anchor from the anchor housing in the distal direction by pushing the tissue anchor in the distal direction..

BRIEF DESCRIPTION OF THE DRAWINGS

[6] Further features and aspects of example embodiments of the present invention are described in more detail below with reference to the appended figures. All figures are 20 schematic and not intended to show actual dimensions.

[7] FIG. 1A shows an anchor deployment mechanism in accordance with an example embodiment of the present invention.

[8] FIG. 1B shows a cross-sectional view of the anchor deployment mechanism of FIG. 1A in accordance with an example embodiment of the present invention.

25 [9] FIG. 1C shows an overhead view of anchors according to an exemplary embodiment of the present invention.

[10] FIG. 1D shows an overhead view of the anchors and suture lock according to an exemplary embodiment of the present invention.

30 [11] FIG. 1E shows an overhead view of the anchors according to an exemplary embodiment of the present invention.

[12] FIG. 1F shows an overhead view of the anchors and suture lock according to an exemplary embodiment of the present invention.

[13] FIGS. 2A-2C show a configuration of a distal anchor housing of the anchor deployment mechanism in FIG. 1A in accordance with an example embodiment of the 35 present invention.

[14] FIGS. 2D-2F show another configuration of a distal anchor housing of the anchor deployment mechanism in FIG. 1A in accordance with an example embodiment of the present invention.

5 [15] FIGS. 2G-2H show the stabilization pins of FIG. 2A prior to contact with tissue in accordance with an example embodiment of the present invention.

[16] FIGS. 2I-2J show the stabilization pins of FIG. 2A after contact with tissue in accordance with an example embodiment of the present invention.

[17] FIGS. 3A-3C show an anchor for use in the anchor deployment mechanism of FIG. 10 FIG. 1A in accordance with an example embodiment of the present invention.

[18] FIGS. 4A-4C show another anchor for use in the anchor deployment mechanism of FIG. 1A in accordance with an example embodiment of the present invention.

[19] FIG. 4D shows another anchor for use in the anchor deployment mechanism of FIG. 1A in accordance with an example embodiment of the present invention.

15 [20] FIG. 4E shows another anchor for use in the anchor deployment mechanism of FIG. 1A in accordance with an example embodiment of the present invention.

[21] FIGS. 4F-4G show another anchor for use in the anchor deployment mechanism of FIG. 1A in accordance with an example embodiment of the present invention.

[22] FIGS. 5A-5B show another anchor for use in the anchor deployment mechanism of FIG. 20 FIG. 1A in accordance with an example embodiment of the present invention.

[23] FIGS. 5C-5E show the anchor in FIG. 5A in accordance with another example embodiment of the present invention.

[24] FIGS. 6A-6C show a distal anchor housing of the anchor deployment mechanism in FIG. 1A in accordance with an example embodiment of the present invention.

25 [25] FIG. 6D shows an anchor and suture for use with the anchor deployment mechanism in FIG. 1A in accordance with an example embodiment of the present invention.

[26] FIGS. 7A-7B show an anchor deployment mechanism in accordance with an example embodiment of the present invention.

[27] FIGS. 7C-7D show another configuration of the anchor deployment mechanism in FIG. 30 FIG. 7A in accordance with an example embodiment of the present invention.

[28] FIGS. 7E-7F show another configuration of the anchor deployment mechanism in FIG. 7A in accordance with an example embodiment of the present invention.

[29] FIGS. 8A-8B show a suture lock deployment mechanism in accordance with an example embodiment of the present invention.

35 [30] FIGS. 8C-8D show another configuration of the suture lock deployment mechanism in FIG. 8A in accordance with an example embodiment of the present invention.

[31] FIGS. 8E-8F show another configuration of the suture lock deployment mechanism in FIG. 8A in accordance with an example embodiment of the present invention.

5 [32] FIGS. 8G-8H show another configuration of the suture lock deployment mechanism in FIG. 8A in accordance with an example embodiment of the present invention.

[33] FIGS. 8I-8J show another configuration of the suture lock deployment mechanism in FIG. 8A in accordance with an example embodiment of the present invention.

[34] FIGS. 8K-8L show another configuration of the suture lock deployment mechanism in 10 FIG. 8A in accordance with an example embodiment of the present invention.

[35] FIGS. 8M-8N show another configuration of the suture lock deployment mechanism in FIG. 8A in accordance with an example embodiment of the present invention.

[36] FIGS. 9A-9B show an suture lock deployment mechanism in accordance with an example embodiment of the present invention.

15 [37] FIGS. 9C-9D show another configuration of the suture lock deployment mechanism in FIG. 9A in accordance with an example embodiment of the present invention.

[38] FIGS. 9E-9F show another configuration of the suture lock deployment mechanism in FIG. 9A in accordance with an example embodiment of the present invention.

[39] FIGS. 9G-9H show another configuration of the suture lock deployment mechanism in 20 FIG. 9A in accordance with an example embodiment of the present invention.

[40] FIGS. 9I-9J show another configuration of the suture lock deployment mechanism in FIG. 9A in accordance with an example embodiment of the present invention.

[41] FIGS. 9K-9L show another configuration of the suture lock deployment mechanism in FIG. 9A in accordance with an example embodiment of the present invention.

25 [42] FIG. 10A shows another configuration of an suture cutting mechanism in accordance with an example embodiment of the present invention.

[43] FIG. 10B shows a distal anchor housing of the suture cutting mechanism of FIG. 10A.

[44] FIG. 10C shows an exploded view of the suture cutting mechanism of FIG. 10A.

[45] FIGS. 10D-10E show a cross sectional view of the suture cutting mechanism of FIG. 30 10A.

[46] FIGS. 10F-10G show a cross sectional view of the suture cutting mechanism of FIG. 10A.

[47] FIG. 11A shows an exploded view of an anchor deployment mechanism in accordance with an example embodiment of the present invention.

35 [48] FIG. 11B shows a cross sectional view of the anchor deployment mechanism of FIG. 11A.

[49] FIG. 12A shows an exploded view of an anchor deployment mechanism in accordance with an example embodiment of the present invention.

5 [50] FIG. 12B shows a cross sectional view of the anchor deployment mechanism of FIG. 11A.

[51] FIG. 13A shows an exploded view of an anchor deployment mechanism in accordance with an example embodiment of the present invention.

10 [52] FIG. 13B shows a cross sectional view of the anchor deployment mechanism of FIG. 11A.

[53] FIG. 14A shows a suture tensioner according to an exemplary embodiment of the present invention.

[54] FIG. 14B shows an exploded view of the suture tensioner of FIG. 14A.

15 [55] FIG. 14C shows a suture tensioner according to an exemplary embodiment of the present invention.

[56] FIG. 14D shows a suture tensioner according to an exemplary embodiment of the present invention.

[57] FIG. 14E shows a cross sectional view of the suture tensioner of FIG. 14A.

[58] FIG. 14F shows a cross sectional view of the suture tensioner of FIG. 14A.

20 [59] FIG. 15 shows an exploded view of an anchor deployment mechanism in accordance with an example embodiment of the present invention.

[60] FIG. 16A shows a cross sectional view of the anchor deployment mechanism in accordance with an example embodiment of the present invention.

25 [61] FIG. 16B shows a cross sectional view of the anchor deployment mechanism in accordance with an example embodiment of the present invention.

[62] FIG. 16C shows a cross sectional view of the anchor deployment mechanism in accordance with an example embodiment of the present invention.

[63] FIG. 17A shows a cross sectional view of the anchor deployment mechanism in accordance with an example embodiment of the present invention.

30 [64] FIG. 17B shows a cross sectional view of the anchor deployment mechanism in accordance with an example embodiment of the present invention.

[65] FIG. 17C shows a cross sectional view of the anchor deployment mechanism in accordance with an example embodiment of the present invention.

[66] FIG. 17D shows a cross sectional view of the anchor deployment mechanism in accordance with an example embodiment of the present invention.

35 [67] FIG. 17E shows a cross sectional view of the anchor deployment mechanism in accordance with an example embodiment of the present invention.

5 [68] FIG. 17F shows a cross sectional view of the anchor deployment mechanism in accordance with an example embodiment of the present invention.

[69] FIG. 18A shows a cross sectional view of the anchor deployment mechanism in accordance with an example embodiment of the present invention.

10 [70] FIG. 18B shows a cross sectional view of the anchor deployment mechanism in accordance with an example embodiment of the present invention.

[71] FIG. 18C shows a cross sectional view of the anchor deployment mechanism in accordance with an example embodiment of the present invention.

[72] FIG. 19A shows a cross sectional view of the anchor deployment mechanism in accordance with an example embodiment of the present invention.

15 [73] FIG. 19B shows a cross sectional view of the anchor deployment mechanism in accordance with an example embodiment of the present invention.

[74] FIG. 20A shows a distal housing of the anchor deployment mechanism in accordance with an example embodiment of the present invention.

20 [75] FIG. 20B shows a distal housing of the anchor deployment mechanism in accordance with an example embodiment of the present invention.

[76] FIG. 20C shows a distal housing of the anchor deployment mechanism in accordance with an example embodiment of the present invention.

[77] FIG. 20D shows a distal housing of the anchor deployment mechanism in accordance with an example embodiment of the present invention.

25 [78] FIG. 20E shows a distal housing of the anchor deployment mechanism in accordance with an example embodiment of the present invention.

[79] FIG. 20F shows a distal housing of the anchor deployment mechanism in accordance with an example embodiment of the present invention.

[80] FIG. 20G shows a distal housing of the suture locking mechanism in accordance with an example embodiment of the present invention.

30 [81] FIG. 20H shows a distal housing of the suture locking mechanism in accordance with an example embodiment of the present invention.

[82] FIG. 20I shows a suture lock of the anchor deployment mechanism in accordance with an example embodiment of the present invention.

35 **DETAILED DESCRIPTION**

[83] As set forth in greater detail below, example embodiments of the present invention allow for the reliable and effective percutaneous intervention in heart tissue that limits the

5 possibility of human error, e.g., by quickly and reliably deploying surgical anchors by simple user operation. In some examples, two or more surgical anchors are driven into tissue in succession, with the possibility of being connected to each other by one or more sutures. The anchors are driven in succession to permit the anchors to be driven into the tissue at different locations while remaining connected by one or more sutures, and then drawn together to
10 bring the affected tissue into apposition. As applied to, for example, a failing heart valve experiencing heart valve regurgitation, drawing together the heart valve tissue can repair the heart valve to proper healthy operation.

[84] FIG. 1A shows an anchor deployment mechanism 100 in accordance with an example embodiment of the present invention. As depicted in FIG. 1A, anchor deployment mechanism 15
100 can include a handle 110, a release button 111, a safety button 112, stabilization pin control knob 114, deflection knob 130, a catheter tube 140, and a distal anchor housing 150.

[85] FIG. 1B is a cross-sectional view of the anchor deployment mechanism of FIG. 1A. As depicted in FIG. 1B, the anchor deployment mechanism may also include a pawl spring 101, a ratchet 102, a pawl 103, ratchet housing 106, a pusher wire 107, a compression spring 20 121 and a pusher 122. In an example embodiment, the elements within the handle 110 are configured to impart a pushing force on anchors located in the distal anchor housing 150. For example, if the safety button 112 is maintained in an “off” position, a user can selectively initiate the transfer of a pushing force from the compression spring 121 in a compressed state to the anchors by engaging the release button 111. Specifically, when the release button 111

25 is engaged (e.g., pressed), the release button disengages from a slot in the pusher 122, allowing the compressed spring 121 to decompress and exert a pushing force in the distal direction. In an example embodiment, the pushing force from the decompression of the compressed spring 121 is transmitted to the anchors via guide and pusher wire 107 in the handle 110. In another example embodiment, the pushing force exerted on the anchors may 30 be imparted by other electrical, mechanical, pneumatic, or hydraulic operation. For example, an electrical operation can be applied to create an electrical pushing force, via an electrical linear actuator. As a further example, a mechanical operation can be applied to create a mechanical pushing force, via a motorized or geared actuator. As a further example, a pneumatic or hydraulic operation can be applied via a compressed carbon dioxide (or a 35 similar gas) cartridge housed in the handle of the device, or a fluid, and selectively opening the cartridge to expel the gas or fluid into a cylindrical chamber to drive the pusher wire.

[86] FIG. 1B further illustrates a stabilization pin control knob 114 for deploying stabilization pins 151 (see FIGS. 2C-2F) from the distal end of the device. Stabilization pin

5 control knob **114** may be coupled to a stabilization pin control screw **115**, such that turning of the stabilization pin control knob **114** imparts a force on the stabilization pin control screw **115** to drive the screw in proximal or distal directions. By moving the stabilization pin control screw **115** in the distal direction, stabilization pins **151** may be pushed to extend beyond the distal end of the device, as shown in FIGS. 2D-2F.

10 [87] FIG. 1C shows an array of anchors connected via a tensioning element, the suture **20**, in accordance with an example embodiment. In an example embodiment, the array comprises a primary anchor **30** and a plurality of secondary anchors **31**. The primary anchor **30** is the first one in the array that gets placed or anchored into the target tissue in the patient and is attached to the terminal end of the suture **20**. The secondary anchors **31** are the anchors that 15 get anchored into the target tissue in the patient subsequently. Each of the anchors **30** and **31** includes a distal end **30d** and **31d**, respectively, and a stem **30s** and **31s**, respectively, extending proximally from the distal end. Further, the proximal ends of the stems of the secondary anchors **31** include an eyelet **31e**. The suture **20** whose terminal end is connected to the primary anchor **30** is threaded through the eyelets **31e** of the secondary anchors **31** thus 20 connecting the secondary anchors **31** in series behind the primary anchor **30**.

[88] In an example embodiment, each of the primary and secondary anchors **30** and **31** can also include a plurality of corrugated wings or barbs **30b** and **31b**, respectively, that extend proximally and radially outward from the distal ends **30d**, **31d** of the respective anchors, and, in an example embodiment, are radially flexible with respect to the distal ends, so that the 25 wings or barbs **30b**, **31b** can be compressed towards the stems or extended radially outward. Further, in the illustrated examples shown in FIGS. 1C and 1D, the distal ends **30d**, **31d** of each of the primary and secondary anchors **30** and **31** are hollow.

[89] Further, as depicted in the figure, the suture **20** can be attached to the primary anchor **30** and connected to a plurality of secondary anchors **31** via the respective eyelets **30e**, **31e**. In 30 an example embodiment, the eyelets **30e**, **31e** allow the secondary anchors **31** to slide along the suture **20**. Accordingly, as depicted in FIG. 1D, once the primary anchor **30** and the secondary anchors **31** are driven/anchored into the target tissue, the anchors, and hence the tissue, can be drawn closer together by pulling on the suture **20** tight. The resulting arrangement of the anchors, **30**, **31** and the tissue anchored thereto can be held in place with a 35 suture lock **21** that is clamped onto the suture **20**. The structure and operation of the suture lock **21** is described in more detail below with reference to FIGS. 8A-9L.

[90] In an example embodiment, these anchors **30** and **31** can be implanted around a heart valve annulus, such as the tricuspid or mitral valve annulus, or other tissue that needs to be

5 drawn together. Accordingly, after the anchors **30** and **31** are anchored in place at appropriate locations about the valve annulus, the valve annulus tissue can be restructured by drawing the suture **20** to move the anchors **30** and **31** together. This addresses the heart valve regurgitation that may occur as valve leaflets lose the ability to properly coapt as a result of the annulus prolapsing over time, limiting the leaflet effectiveness. By bringing the annulus 10 back to a tighter configuration and allowing the valve leaflets to properly coapt, the valve structure is optimized and regurgitation is minimized. This procedure supports various repair and closure procedures, including tricuspid valve repair, mitral valve repair, chordae repair, patent foramen ovale closure, atrial septal defect closure, arterial closure, arterial access site closure, among others.

15 [91] FIGS. 1E and 1F show another embodiment of an array of anchors connected via a suture **20**. In this example embodiment, the primary anchor **32** and the plurality of secondary anchors **33** are similar to the configuration of anchors **30** and **31**, respectively, depicted in FIGS. 1C and 1D, except that the distal ends **32d** and **33d** of the anchors **32** and **33** are tapered to a pointed tip, and are not hollow. The anchors **32** and **33** also comprise a plurality 20 of corrugated wings or barbs **32b** and **33b**, respectively, that extend proximally and radially outward from the distal ends **32d**, **33d** of the respective anchors, and, in an example embodiment, are radially flexible with respect to the distal ends, so that the wings or barbs **32b**, **33b** can be compressed towards the stems or extended radially outward. Each of the anchors **32** and **33** includes a distal end **32d** and **33d**, respectively, and a stem **32s** and **33s**, 25 respectively, extending proximally from the distal end. Further, the proximal ends of the stems of the secondary anchors **33** include an eyelet **33e**. The purpose of the eyelet **33e** is the same as that of the eyelet **31e** on the secondary anchors **31** described above.

[92] FIGS. 2A-2C show a configuration of a distal anchor housing **150** of the anchor deployment mechanism in FIG. 1A in accordance with an example embodiment of the 30 present invention. As depicted in the longitudinal cross-sectional view in FIG. 2C, the distal anchor housing **150** in this embodiment includes one or more stabilization pins **151**. In these illustrations, a secondary anchor **33** is loaded into the distal anchor housing **150** for deployment. In the deployment position loaded in the distal anchor housing **150**, the corrugated barbs **33b** are in their compressed position against the stem **33e** of the anchor **33**.

35 [93] In FIGS. 2A-2C, the stabilization pins **151** are in their retracted position within the distal anchor housing **150**. As shown in FIGS. 2D-2F, the anchor deployment device **100** is configured to extend the stabilization pins **151** out of the distal anchor housing **150** in the distal direction. By placing the distal end of the distal anchor housing **150** against the surface

5 of the target tissue location and deploying the stabilization pins **151** into the tissue, the anchor deployment mechanism **100** can be more securely held against the surface of the target tissue before deploying a tissue anchor **30**, **31**, **32**, or **33**. Secure positioning of the anchor deployment mechanism **100** can aid in accurately and properly deploying the anchors into the tissue. Further, in an example embodiment, the stabilization pins **151** can be made with a tip
10 sharp enough to pierce the native annulus of the heart. Further, the stabilization pins **151** may be configured to extend from the distal anchor housing **150** at an angle α denoted in FIG. 2F. The angle α can be a perpendicular angle, acute angle, or obtuse angle to the surface of the tissue. In some embodiments, α can be about 5° - 20° , and preferably about 13° for applications such as annuloplasty. In an example embodiment, the stabilization pins **151** can
15 enter the tissue to a maximum, set depth regardless of a deflection of catheter tube **140**. This is necessary because the catheter length changes as the distal end is deflected. As in the pusher wire, the set depth is achieved by building in an “over travel” length of the stabilization pins, which is longer than the set depth. This “over travel” length allows for sufficient length of the stabilization pins (or, similarly, the pusher wire), regardless of the
20 angle of deflection of the distal end of the device.

[94] Referring to FIG. 2F, a stabilization pin stop **152** is provided on each of the stabilization pins **151** at a fixed distance **D** from the tip of the stabilization pin **151**. The stabilization pin stop **152** can be provided as a bump or a thicker portion that has a larger diameter than the rest of the stabilization pin **151**. The stabilization pins **151** can freely travel
25 in the distal direction until the stabilization pin stop **152** contacts a mating geometry at the proximal face **150f** of the anchor housing **150** that prevents the stabilization pin **151** from traveling or extending beyond a preset distance in the distal direction by interfering with the proximal end of the anchor housing. At this point, the distal projection of the stabilization pin **151** is at its maximum. The over travel described above is necessary because the catheter tube
30 **140** is deflected at a variety of angles when stabilization pins are being extended. Building in more length than is required and including the stabilization pin stop **152** ensures that they always travel the desired distance regardless of the catheter tube deflection.

[95] FIGS. 2G and 2H show the stabilization pins **151** prior to contact with the target tissue in accordance with an example embodiment. In particular, the stabilization pins **151** are
35 shown extending partially from the distal anchor housing **150** but the distal anchor housing **150** has not yet in contact with the tissue.

[96] FIGS. 2I and 2J shows after the distal anchor housing **150** has made a contact with the tissue at the desired location and the stabilization pins **151** have been fully deployed into the

5 tissue securing the placement of the distal anchor housing **150** in accordance with an example embodiment. In particular, the sectional view in FIG. 2J shows the stabilization pins **151** embedded within the tissue.

[97] In an example embodiment, the stabilization pins **151** can be used as a sensor to determine when the anchor deployment mechanism is in the proper position against the target 10 tissue site to deploy the anchors. As an example, with the stabilization pins **151** partially extending from the distal anchor housing **150** as shown in FIGS. 2G and 2H, the stabilization pins **151** can be electrically biased, so that the current passes between the stabilization pins **151** through the tissue when the distal end of the distal anchor housing **150** is pressed against or into the tissue. When the stabilization pins **151** are in contact with the tissue, a closed 15 circuit will be achieved between the stabilization pins **151** through the tissue. Once the circuit is closed, one can determine that the distal anchor housing **150** is in contact with the tissue by measuring the impedance between the stabilization pins **151**. After contact is detected, the anchor **33** can then be deployed into the tissue.

[98] In some example embodiments, the stabilization pins **151** can be used to detect 20 various levels of impedance, to differentiate between the types of tissue or fluid that may be encountered, such as blood, tissue, the right coronary artery, previously ablated or damaged tissue, other arteries, or other structures that would not be conducive to proper anchor deployment or patient outcomes. For example, the stabilization pins **151** may be configured to detect the electrical impedance of the tissue or fluid encountered by the stabilization pins. 25 The existence of a tissue or fluid between the stabilization pins can create a form of a circuit, a voltage can be applied to the pins, and the opposition of that circuit to the applied voltage can be measured in an electrical feedback system. If the impedance levels are detected to be consistent which predetermined levels corresponding to, e.g., healthy tissue depth, and not levels known to correspond to blood or inadequate tissue depth, then it can be assumed that 30 the stabilization pins have made adequate tissue contact. The detected impedance levels can be presented on a user interface or other display integrated into, or in communication with, the surgical device, including an indication that the stabilization pins have reached a sufficient tissue depth. For example, the display may indicate "sufficient tissue depth," "insufficient tissue depth," "tissue contact," "no tissue contact," "damaged tissue," "artery 35 detected at deployment site," or other information determined by the detected impedance. To enable the electrical features of the stabilization pins **151**, the anchor deployment mechanism **100** would be operably connected to one or more appropriate electrical equipment that would be known to those skilled in the art.

5 [99] Moreover, in an example embodiment, the stabilization pins **151** may be radiopaque, thereby allowing the stabilization pins **151** to be easily identifiable under fluoroscopy. The stabilization pins **151** are positioned near the distal end of the surgical device, and so the visibility of the stabilization pins under fluoroscopy is useful in determining the location of the distal end as the surgical device is being manipulated towards a site for deploying
10 anchors. In this manner, it is helpful to avoid impacting any significant structure or tissue that should not be engaged by the surgical device.

15 [100] FIGS. 3A-3C show the primary anchor **32** for use in the anchor deployment mechanism **100** of FIG. 1A in accordance with an example embodiment. In an example embodiment, the primary anchor **32** includes a distal end **32d** and a stem **32s** extending proximally from the distal end. Further, the anchor **32** also includes a plurality of corrugated wings or barbs **32b** that extend proximally and radially outward from the distal end of the anchor **32**, and, in an example embodiment, are radially flexible with respect to the distal end **32d**, so that the wings or barbs **32b** may be compressed towards the stem **32s** or extended radially outward. Further, in an example embodiment, the anchor **32** can include an anchor cup **32c**, a mesh **32m**, and an anchor crimp band **20c**.
20

25 [101] In an example embodiment, the anchor cup **32c** is closed at its distal end and open at its proximal end, and may be positioned within the distal end **32d** of the anchor **32**. Further, the anchor cup **32c** is configured to receive the pusher wire **107** of the deployment mechanism **100** via its open proximal end. The anchor cup **32c** is provided to protect the anchor **32** from being damaged by the pusher wire **107** during deployment of the anchor. The anchor cup **32c** is preferably made of strong material such as stainless steel for that purpose. A tissue anchor **30**, **31**, **32**, or **33** are deployed into the tissue using the anchor deployment mechanism **100** by triggering the pusher wire **107** to quickly push or jab the anchor into the tissue. The pusher wire **107** can be made of stainless steel and the anchors are usually made of a plastic or polymer material. Therefore, the pusher wire **107** can damage the anchor **32** during deployment. The anchor cup **32c** also prevents the pusher wire **107** from being embedded in the anchor **32** and possibly pull the anchor out from the tissue during the retraction of the pusher wire **107** after anchor deployment. In an example embodiment, the anchor cup **32c** being provided in a metallic form adds another combined beneficial feature 30 because metal is radiopaque, thereby allowing the anchor **32** to be easily identifiable under fluoroscopy.
35

[102] In an example embodiment, the mesh **32m** can be placed between the wings or barbs **32b** of the anchor **32**, to occupy the distal portion of the space between the barbs **32b** to

5 maintain hemostasis. In particular, the mesh **32m** minimizes blood flow through the hole in the tissue potentially created by the deployment of the anchor **32**. In addition, the mesh **32m** can promote coagulation and decrease adverse risk if the anchor **32** is deployed in a manner that breaches a tissue wall. In an example embodiment, the mesh **32m** can be comprised of 17 grams per square meter (gsm) polypropylene.

10 [103] In an example embodiment, the anchor crimp band **20c** is located at a proximal end of the anchor stem **32s**. The anchor **32** is an example of a primary anchor according to the present disclosure so the anchor is non-slidably affixed to the distal end of the suture **20**. The distal end of a suture **20** may be securely affixed to the stem **32s** of the anchor **32** by the crimp band **20c** which may be closed tightly around the distal end of the suture **20**.

15 [104] FIGS. 4A-4C show another example of a tissue anchor **70** for use in conjunction with the anchor deployment mechanism **100** of FIG. 1A in accordance with an example embodiment. The tissue anchor **70** is an example of a secondary anchor. FIG. 4A is a perspective view of the anchor **70**. FIG. 4B is a side view of the anchor **70**. FIG. 4C is a top view of the anchor **70**. In an example embodiment, the anchor **70** includes a distal end **70d** and a stem **70s** extending proximally from the distal end. Further, the anchor **70** also includes a plurality of corrugated wings or barbs **70b** that extend proximally and radially outward from the distal end of the anchor **70**, and, in an example embodiment, are radially flexible with respect to the distal end **70d**, so that the wings or barbs **70b** may be compressed towards the stem or extended radially outward.

20 [105] In an example embodiment, the anchor **70** can be comprised of a soft, compliant material such as polypropylene. Further, in an example embodiment, the anchor **70** can also include a stem insert **71**. The stem insert **71** includes an anchor cup portion **70c** at its distal end and a plurality of fenestrations **72** at its proximal end. In an example embodiment, the purpose of the anchor cup **70c** is the same as the anchor cup **32c** discussed above in reference to the tissue anchor **32**. The anchor cup **70c** is configured to receive a pusher wire such as the pusher wire **107** of the anchor deployment mechanism **100** via its open proximal end.

25 [106] The stem insert **71** including the anchor cup portion **70c** is preferably made of strong material such as stainless steel. The stem insert **71** can be overmolded by the polypropylene that forms the rest of the anchor **70**.

30 [107] Further, in an example embodiment, the fenestrations **72** can facilitate tissue ingrowth after implantation, thereby enhancing the durability of the anchor **70**. At least one of the fenestrations such as the one denoted as **72e** can be used to feed the suture **20** through like the eyelets **31e** and **33e** in the anchor embodiments **31** and **33**. In some embodiments, some of

5 the fenestrations **72** in the stem insert can be overmolded with the anchor body material (e.g. polypropylene). Depending on the particular shape of the stem insert **71**, overmolding more portions of the stem insert **71** could help prevent any unwanted separation of the stem insert **71** from the anchor body while still maintaining their ability to facilitate tissue ingrowth. For example, in the example shown in FIG. 4C, the fenestrations **72** other than the one denoted as
10 **72e** are overmolded with polypropylene.

[108] FIG. 4D illustrates an alternative exemplary embodiment of the anchor **70**, without the fenestrations **72** as part of stem insert **71**. Further, as illustrated in FIG. 4E, the whole of anchor **70**, or some portion thereof, can be jacketed in Fibrin or other biologic coating **73** to promote tissue ingrowth.

15 [109] FIGS. 4F-4G show another alternative embodiment of the anchor **70**, without the fenestrations **72** as part of stem insert **71**, and including an alternative embodiment of the anchor cup **70c**. In this embodiment, the anchor cup portion of stem insert **71** is comprised of tabs **74** aligned with the wings or barbs of the anchor **70**. As mentioned previously, the stem insert **71** is made of a metal such as stainless steel. In FIG. 4G, the body of the anchor **70**
20 formed of polypropylene is rendered to be translucent to show the tabs **74**.

[110] In addition, in any of the embodiments of the anchor, the stem insert **71** can be comprised of a metal, thereby providing some metallic rigidity to the anchor **70**. Further, the stem insert **71** can also be radiopaque, thereby allowing the stem insert **71** to be easily identifiable under fluoroscopy.

25 [111] FIGS. 5A-5B show another anchor **80** for use in the anchor deployment mechanism **100** of FIG. 1A in accordance with an example embodiment of the present invention. FIGS. 5A and 5B are illustrations of the anchor **80** at a point in time during the deployment procedure where the anchor **80** has partially penetrated into the tissue. FIG. 5A shows a view from the proximal end of the anchor **80** and FIG. 5B is a longitudinal sectional view taken along the section line **E-E** in FIG. 5A. In both views, the flexible corrugated barbs **80b** have collapsed radially inward toward the stem **80s** as the anchor advances into the tissue. The circle around the anchor **80** in FIG. 5A denotes the tissue region surrounding the anchor. In an example embodiment, the anchor **80** includes a distal end **80d** and a stem **80s** extending proximally from the distal end **80d**. In an example embodiment, the anchor **80** also includes a plurality of corrugated wings or barbs **80b** that extend proximally and radially outward from the distal end **80d** of the anchor **80**, and, in an example embodiment, are radially flexible with respect to the distal end, so that the wings or barbs **80b** may be compressed towards the stem **80s** or extended radially outward (similar to the canopy of an umbrella). In an example
30
35

5 embodiment, the distal end **80d** of the anchor **80** is hollow. Further, in an example embodiment, the stem **80s** is flexible with respect to the distal end **80d** of the anchor **80** and the wings or barbs **80b** of the anchor **80**. The stem **80s** can also include a concave profile as viewed from the proximal end of the stem which allows the pusher wire to slip into the concave portion and be guided toward the anchor cup **80c** during the deployment of the
10 anchor. This concave profile can be better seen in the anchor embodiment **32** in FIG. 3C. The anchor **32** has a stem **32s**. The stem **32s** is generally a tubular shaped structure but is open along its length as shown. Thus, the stem **32s** forms a trough like structure that is being referred to herein as concave profile. Further, as the anchor **80** is an example of a secondary anchor, the proximal end of the stem also includes an eyelet **80e** through which the suture **20**
15 can be threaded.

[112] In an example embodiment, the anchor **80** includes three wings or barbs **80b** that are configured to collapse upon entering the tissue as depicted in the figure. In particular, the three wings or barbs **80b** can be at an equal distance away from each other, thereby providing radial symmetry between the wings or barbs. The radial symmetry enables the anchor **80** to
20 advance into the tissue in a straight path. Although not shown in FIG. 5B, if the anchor deployment mechanism **100** is being used to deploy the anchor **80** into the tissue, the pusher wire **107** would be positioned in the anchor cup **80c** and pushing the anchor **80** in the distal direction.

[113] FIGS. 5C-5E show the anchor **80** of FIGS. 5A-5B in accordance with another
25 example embodiment. FIG. 5C is a side view of the fully deployed anchor **80**. FIG. 5D is a view of the fully deployed anchor **80** from the proximal end. FIG. 5E is a longitudinal sectional view of the fully deployed anchor **80** taken along the section line A-A in FIG. 5D. In particular, FIGS. 5C-5E show the anchor **80** after it is fully embedded into the tissue. In an example embodiment, after the anchor **80** has entered the tissue into its fully seated position,
30 when a tension is applied to the suture **20** (not shown in FIGS. 5A-5E) to pull the array of anchors (i.e. one primary anchor and subsequently deployed plurality of secondary anchors **80**) together by the suture **20**, the suture **20** would apply some amount of pulling force in proximal direction. This proximal pulling action causes the three wings or barbs **80b** to open up in response and captures a roughly cone shaped volume of tissue **80'** in the proximal
35 direction from the barbs **80b** as shown in FIGS. 5C-5E. This results in maximizing the volume of the tissue that resists pullout of the anchor **80**. Thus, stress may be distributed over a greater mass of tissue.

5 [114] FIGS. 6A-6C show a distal anchor housing **150** of the anchor deployment mechanism **100** in FIG. 1A in accordance with an example embodiment of the present invention. After a primary anchor is deployed at the surgical site, before a secondary anchor, such as **31**, **33**, or **80** can be deployed at the surgical site, such secondary anchor need to be first loaded into the distal anchor housing **150** and the free end of the suture **20**, which is attached to the already
10 deployed primary anchor, is threaded through the eyelet **31e**, **33e**, or **80e** of the secondary anchor **31**, **33**, **80**, respectively. Then, the free end of the suture **20** needs to be threaded through the length of the catheter tube **140** of the anchor deployment mechanism **100** up to or close to the handle **110**. However, because the suture **20** is floppy like a thread, this threading task can be difficult if not impossible. According to an embodiment of the present disclosure,
15 the anchor deployment mechanism **100** can be configured with a snare **170** to recapture the suture **20** and thread it through the catheter tube **140**.

[115] For example, according to the surgical procedure of the present disclosure, after a primary anchor **30** or **32** has been deployed in the tissue of the surgical site, the suture **20** remains connected to that primary anchor and a secondary anchor **31**, **33**, or **80** can be
20 applied to the same surgical site by loading a secondary anchor to the distal anchor housing **150** of the anchor deployment mechanism **100**, threading the free end of the suture **20** through the eyelet **31e**, **33e**, or **80e** of the secondary anchor, and then threading the free end of the suture **20** through a loop of snare **170** as shown in FIGS. 6A-6C.

[116] Next, the distal anchor housing **150** end of the anchor deployment mechanism **100** is
25 percutaneously inserted to the surgical site by sliding the loaded secondary anchor along the suture **20**. As can be seen in the longitudinal cross-section view of the distal anchor housing **150** in FIG. 6C, the snare **170** is positioned adjacent to the eyelet **31e**, **33e**, or **80e** of the secondary anchor **31**, **33**, or **80**. The snare **170** is positioned within a lumen L that extends from the distal anchor housing **150** through the catheter tube **140** to the handle **110**.

30 Therefore, the suture **20** which is now captured by the loop of snare **170** can be threaded through the length of the catheter tube **140** by pulling of the snare **170** through the lumen L to draw the suture **20** in the proximal direction of the device, via a snare grip (not shown), located in the handle of the device. Once the suture **20** has been drawn back to the proximal handle, the secondary anchor **31**, **33**, or **80** can be deployed in a similar manner to the
35 primary anchor. Similarly, additional secondary anchors can be deployed by repeating this process.

[117] Additionally, a suture locking device and the suture cutting device described below can also be deployed to the same surgical site by similar procedural steps: (1) passing the free

5 end of the suture **20** through the suture locking device or the suture cutting device; (2) attaching the suture locking device or the suture cutting device to the distal end of the catheter tube **140**; (3) passing the free end of the suture **20** through the snare **170**; (4) recapturing the suture **20** through the catheter tube **140** by pulling the snare **170** through the lumen **L**; then (5) deploying the suture locking device or the suture cutting device to the 10 surgical site by advancing the catheter tube **140** percutaneously to the surgical site. In some embodiments, the above-recited steps (2) and (3) may be performed in reverse order. In particular, this loading of the suture **20** within the catheter tube **140** allows for increased friction control and precise suture management when applying a secondary anchor to the same suture that is attached to a primary anchor. Further, the snare **170** may be composed of 15 a nitinol wire for improved strength and precision.

[118] Alternatively, according to an exemplary embodiment, instead of using the snare **170**, a wire **180** attached to the free end of the suture **20** can be used to facilitate the reloading of the suture **20** through the catheter tube **140** during the secondary anchor loading procedure, suture locking device loading procedure, or the suture cutting device loading procedure. FIG. 20 6D shows a suture **20** connected to a primary anchor **31**. As in FIG. 3A, the distal end of the suture **20** may be securely attached to the anchor **31** by a crimp band **20c**. In this embodiment, the free end of the suture **20** may be connected to a wire **180**. The wire **180** may be made from any material that is stiffer than the suture **20**, including nitinol or stainless steel. The wire **180** may be crimped or otherwise attached to the suture **20**, such as by a wire- 25 suture crimp band **190**. In this exemplary embodiment, after the primary anchor **31** has been deployed into the surgical site, instead of passing the free end of the suture **20** through both the eyelet **32e** of a secondary anchor **32** and the snare **170**, the wire **180**, connected to the free end of the suture **20**, may be passed through the anchor eyelet **32e** and then passed into the lumen **L**, shown in FIG. 6C, provided in the distal anchor housing **150** at the distal end of the catheter. Alternatively, the catheter tube **140** may include a hole in the side of the catheter, 30 located at a position proximal to the distal end. The stiffness of the wire **180** allows for the wire to be passed into the distal end of the catheter tube **140** with ease through at least some portion of the length of the catheter, and out through the side hole. The wire **180** may be manipulated to draw the suture **20** through the anchor eyelet, into the distal end of the catheter, such that the free end of the suture **20** can be drawn through the hole in the catheter. The hole in the catheter may be located at a position proximal to the distal end, far enough 35 from the distal end such that, when the distal end of the catheter is returned to the surgical site, the free end of the suture **20** remains sufficiently outside of the surgical site that it may

5 be manipulated during the surgical procedure. In an exemplary embodiment, the hole is located 20 centimeters from the distal end. In this manner, a secondary anchor can be deployed on the same suture as the primary anchor. In particular, this exemplary embodiment permits the securing of the suture **20** without drawing the suture all the way to the proximal handle, allowing for a shorter suture, and limiting the concern that the suture will experience
10 unnecessary proximal force that may cause the deployed anchors to damage tissue.

15 [119] FIGS. 7A-7B show an anchor deployment mechanism **200** in accordance with an example embodiment of the present invention. FIG. 7B shows the detailed view of the distal end of the anchor deployment mechanism **200** denoted as area B in FIG. 7A. The structure of the mechanism in the handle portion of the anchor deployment mechanism **200** is similar to those of the anchor deployment mechanism **100** discussed above. As depicted in the figure, an anchor deployment device **200** can include a compression spring **221** a pusher carriage **201**, a safety button **202**, a pin retractor **203**, a pin retractor spring **204**, a pawl **205**, a release button **206**, pusher wire **207**, a catheter tube **210**, and a distal anchor housing **220**. In an example embodiment, the pusher wire **207** can include a stop **207a**. Further, the distal anchor housing **220** can include an anchor support tube **221** and the anchor **80**. In an example embodiment, the elements within the anchor deployment device **200** are configured to impart a pushing force on the anchor **80** located in the distal anchor housing **220**. For example, if the safety button **202** is maintained in an “off” position, a user can selectively transfer a pushing force from the pusher carriage **201**, via the pusher wire **207**, to the anchor **80** by engaging the release button **206**. However, as depicted in the figure, the safety button **202** is maintained in an “on” position, thereby preventing the user from engaging the release button and, thus, the deployment of the anchor **80**. Further, the anchor deployment device **200** can be configured to retract the pusher wire **207** back into the anchor deployment device **200**, e.g. immediately after anchor deployment, with the pin retractor **203** and the corresponding pin retractor spring **204**. In particular, the pin retractor **203** can retract the pusher wire **207** after the pawl **205**, which maintains the position of the pin retractor **203**, is tripped. As such, if the pawl **205** is not tripped, then the pin retractor **203** will remain in connection with the pawl **205** and, therefore, will not cause the pusher wire **207** to retract.

30 35 [120] In an example embodiment, the catheter tube **210** is steerable such that the catheter tube **210** may be articulated or bent to suit the needs of the application. When the catheter tube **210** is in its bent form, a pusher wire (e.g., wire **207**) may not meet the distal end of the catheter in the same relative position as it would in a straight, unbent catheter. Accordingly, there is a need to provide a uniform distance for the pusher wire **207** to drive the anchors

5 from the distal end of the catheter, independent of the form or shape of the steerable catheter. To solve this problem, a collar or flange, i.e., the stop **207a**, may be added to the pusher wire **207** at a predetermined distance from the distal end of the pusher wire **207**. In an example embodiment, the collar extends radially from the pusher wire, creating a diameter large enough to abut a mating geometry at the proximal face of distal anchor housing **220** and stop
10 the distal movement of the pusher wire **207**, to keep the pusher wire **207** from extending beyond the distal end of the anchor housing **220** at more than a predetermined distance. In an example embodiment, the pusher wire **207**, independent of the positioning of the steerable catheter tube **210**, will be pushed to this predetermined distance.

15 [121] For example, if the pusher carriage **201** travels 23 mm and the anchor **80** is allowed to travel no more than 16 mm, then the pusher wire **207** is set back 6 mm from contact with the anchor **80** (i.e. contact with the anchor cup **80c** of the anchor **80**) when the catheter tube **210** is straight. As the catheter tube **210** is deflected up to 90 degrees, the overall length of the catheter tube **210** will be shortened by approximately 6 mm, which is compensated for by the gap between the distal tip of the pusher wire **207** and the anchor **80** when the catheter tube
20 is straight. In an example embodiment, the stop **207a** on the pusher wire **207** contacts the proximal surface of the distal anchor housing **220** after the anchor **80** travels 16 mm.

25 [122] FIGS. 7C-7D show another configuration of the anchor deployment mechanism **200** shown in FIG. 7A in accordance with an example embodiment. In particular, FIG. 7C shows the anchor deployment device **200** with the safety button **202** in an “off” position, thereby allowing the user to engage the release button **206** to transfer a pushing force from the pusher carriage **201** to the anchor **80**. Specifically, when the release button **206** is engaged (e.g., pressed), the release button **206** disengages from a notch in the pusher carriage **201**, thereby allowing the compression spring **221** to push the pusher carriage **201** in the distal direction which, in turn, exerts a pushing force on the anchor **80** in the distal direction. In an example embodiment, the pushing force from the pusher carriage **201** is transmitted to the anchor **80** via the pusher wire **207**. In another example embodiment, the pushing force exerted on the anchor may be imparted by other electrical, mechanical, pneumatic, or hydraulic operation. Further, as depicted in FIG. 7D, the anchor **80** is pushed in the distal direction until the stop **207a** on the pusher wire **207** contacts the proximal surface of the distal anchor housing **220**.
30 In addition, after deployment of the anchor **80**, the pawl **205** may contact a pin **208**. This is an intermediate stage, as the pusher carriage **201** depicted in this figure has not reached full travel.

5 [123] FIGS. 7E-7F shows another configuration of the anchor deployment mechanism in FIG. 7A in accordance with an example embodiment of the present invention. In particular, FIG. 7E shows the anchor deployment device **200** after full travel of pusher carriage **201**, and the pawl **205** tripped by the pin **208**. In an example embodiment, the pin **208** can cause the pawl **205** to trip after a retract button (not shown) is engaged (e.g., pressed). Further, as
10 depicted in the figure, after the pawl **205** is tripped, the pin retractor **203** is released from the pawl **205**'s grip, which causes the corresponding pin retractor spring **204** to extend in the proximal direction. In an example embodiment, the extension of the pin retractor spring **204** in the proximal direction causes the pin retractor **203** to also move in the proximal direction. Further, because the proximal end of the pusher wire **207** is attached to the proximal end of
15 the pin retractor **203**, the pusher wire **207** is pulled (i.e., retracted) in the proximal direction. In an example embodiment, the pusher wire **207** can be retracted immediately after the anchor **80** is deployed into tissue. As such, the pusher wire **207** is retracted without the anchor **80**.

[124] FIGS. 8A-8B show a suture locking mechanism in accordance with an example embodiment of the present invention. As depicted in the figure, a suture locking device **300** can include a release shaft **301**, a deployment spring **302**, a spring sleeve **303**, a stepped washer **304**, a safety button **305**, a pusher **306**, a release button **307**, a pusher tube **308**, a suture **309**, a catheter tube **310**, a distal housing **320**, a suture locking housing **330**, and a suture locking tab **331**. In an example embodiment, the distal housing **320** can include a drive shaft **321**. In an example embodiment, the suture locking housing **330** and the suture locking tab **331** can be detached from the distal housing **320**. Further, in an example embodiment, the suture **309** may pass through the suture locking housing **330** at a particular angle (e.g., 20° to 35°). Further, the suture locking tab **331** can also be inserted into the suture locking housing **330**. In an example embodiment, after the suture locking tab **331** is inserted into the suture locking housing **330**, the geometry inside of the suture locking housing **330** forces the suture **309** to make a series of tight bends. In an example embodiment, the linear motion of the suture locking tab **331** generates the tight bends in the suture **309**, which requires low force to lock the lock but generates high slip force thus preventing the suture **309** from slipping out of the locked assembly of the suture locking housing **330** and the suture locking tab **331**. In
25 addition to the compression fit described above, corresponding mechanical features of the suture locking tab and suture locking housing secure the components together (see FIGS. 8K-
30 8L).

5 [125] In an example embodiment, the suture locking tab **331** can be attached to the suture locking housing **330** after the pusher tube **308** is released in the distal direction, e.g., during deployment of the suture lock. In an example embodiment, a suture lock can be deployed via the interaction of the deployment spring **302**, the spring sleeve **303**, the stepped washer **304**, the safety button **305**, the pusher **306**, the release button **307**, the pusher tube **308**, and the catheter tube **310** in the suture lock deployment device **300**. For example, assuming the safety button **305** is maintained in an “off” position, a user can selectively transfer a pushing force from the deployment spring **302** to the suture locking tab **331** by engaging the release button **307**. Specifically, after the release button **307** is engaged (e.g., pressed), the deployment spring **302**, which is a compression spring, decompresses and, therefore, exerts a pushing force in the distal direction. In an example embodiment, the pushing force from the decompression of the deployment spring **302** is transmitted to the suture lock via the pusher tube **308** through the catheter tube **310**. Further, as depicted in the figure, after the suture lock is deployed, the suture locking tab **331** can be attached to the suture locking housing **330** to begin the crimping of the suture **309**.

10 [126] FIGS. 8C-8D show another configuration of the anchor deployment mechanism in FIGS. 8A-8B in accordance with an example embodiment of the present invention. In particular, FIG. 8C shows the suture lock deployment device **300** as the suture **309** is being crimped by the attachment of the suture locking tab **331** to the suture locking housing **330**.

15 [127] FIGS. 8E-8F show another configuration of the suture lock deployment mechanism in FIGS. 8A-8B in accordance with an example embodiment of the present invention. In particular, FIGS. 8E-8F show the suture lock housing **330** and the suture locking tab **331** being detached from the distal housing **320**. In an example embodiment, the suture lock housing **330** and the suture locking tab **331** can be detached from the distal housing **320** by rotating the release shaft **301** from the proximal end of the handle of the suture lock deployment device **300** as depicted in FIGS. 8G, 8H, 8I and 8J. In an example embodiment, FIGS. 8G-8H show the suture lock housing **330** and the suture locking tab **331** assembly before the release shaft **301** is rotated. FIGS. 8I-8J shows the suture lock housing **330** and the suture locking tab **331** assembly after the release shaft **301** is rotated in the direction noted by the arrow R. In an example embodiment, the suture lock housing **330** the suture locking tab **331** assembly may be detached from the distal housing **320** after the suture lock housing **330** and the suture locking tab **331** are rotated 45°. In an example embodiment, the release shaft **301** can be rotated in a counter-clockwise rotation as depicted in FIGS. 8G, 8H, 8I and 8J. FIGS. 8G and I are end view seen from the distal end of the suture lock deployment device

5 **300.** FIGS. 8H and 8J are end view seen from the proximal end of the suture lock deployment device **300**.

[128] FIGS. 8K, 8L, 8M, and 8N illustrate perspective and side views of the suture lock housing **330** and the suture locking tab **331**, with FIGS. 8K-8L illustrating the suture lock housing **330** and the suture locking tab **331** in an un-locked state corresponding to FIGS. 8A-

10 8B, and FIGS. 8M-8N illustrating the suture lock housing **330** and the suture locking tab **331** in a locked state corresponding to FIGS. 8C, 8D, 8E, and 8F. In an exemplary embodiment, the suture lock housing **330** and the suture locking tab **331** are held together with the aid of a receptacle **332** and a retention feature **333**. The retention feature **333** may be a tab or other extension from the suture locking tab **331**, which may be compressed as the suture locking

15 tab **331** is inserted into the suture lock housing **330**, and which may expand when the retention feature reaches the receptacle **332**, to resist separation of the suture lock housing **330** and suture locking tab **331**. Alternatively, the retention feature **333** may be situated on the suture lock housing **330**, and the receptacle **332** on the suture locking tab **331**. To release or separate the suture locking tab **331** from the suture lock housing **330**, the retention feature 20 may be compressed to slide from receptacle **332**.

[129] FIGS. 9A-9B shows a suture locking mechanism in accordance with an example embodiment of the present invention. As depicted in the FIG., suture locking mechanism **400** can include a safety button **401**, a pin retractor **402**, a pusher **403**, a pin retractor spring **404**, a pawl **405**, a release button **406**, a pusher wire **407**, a suture **409**, a catheter tube **410**, a distal housing **420**, a suture locking housing **430**, a suture locking tab **431**, and an actuator **432**. In an example embodiment, the distal housing **420** includes a support tube **421**, a cutting block **422**, a suture cutting control wire **423**, a suture lock control wire **424**, and a suture cutting blade **425**.

[130] In an example embodiment, the elements within the suture locking mechanism **400**

30 are configured to lock and hold a suture after deployment of an anchor (not shown) into tissue. For example, if the safety button **401** is maintained in an “off” position, a user can selectively transfer a pushing force from the pusher **403**, via the pusher wire **407**, to the suture locking tab **431** by engaging the release button **406**. However, as depicted in the figure, the safety button **401** is maintained in an “on” position, thereby preventing the user 35 from engaging the release button **406** and, thus, the deployment of the suture locking tab **431**. Further, in an example embodiment, the pusher wire **407** may be retracted back into the suture locking mechanism **400** with the pin retractor **402** and the corresponding pin retractor spring **404**. In particular, the pin retractor **402** can retract the pusher wire **407** after the pawl

5 **405**, which maintains the position of the pin retractor **402**, is tripped. As such, if the pawl **405** is not tripped, then the pin retractor **402** will remain in connection with the pawl **405** and, therefore, not cause the pusher wire **407** to retract.

10 **[131]** Further, in an example embodiment, the suture locking housing **430** and the suture locking tab **431** can be detached from the distal housing **420**. In an example embodiment, the suture **409** may pass through the suture locking housing **430** at a particular angle (e.g., 20° to 35°). Further, the suture locking tab **431** can also be inserted into the suture locking housing **430**. In an example embodiment, after the suture locking tab **431** is inserted into the suture locking housing **430**, a geometry inside of the suture locking housing **430** forces the suture **409** into a series of tight bends. In an example embodiment, the linear motion of the suture locking housing **430** generates the tight bends in the suture **409**, which requires low force to lock but generates high slip force.

15 **[132]** FIGS. 9C-9D show another configuration of the suture locking mechanism in FIGS. 9A-9B in accordance with an example embodiment of the present invention. In particular, FIGS. 9C-9D show the suture locking mechanism **400** with the safety button **401** in an “off” position, thereby allowing the user to engage the release button **406** to transfer a pushing force from the pusher **403** to a suture locking tab **431**. Specifically, after the release button **406** is engaged (e.g., pressed), the release button **406** disengages from a notch in the pusher **403**, thereby allowing the pusher **403** to exert a pushing force in the distal direction. In an example embodiment, the pushing force from the pusher **403** is transmitted to the anchors via the pusher wire **407**. In another example embodiment, the pushing force exerted on the suture locking tab **431** may be imparted by other electrical, mechanical, or hydraulic operation. Further, after deployment of the suture locking tab **431**, the pawl **405** may contact a pin **408**. Further, as depicted in the figures, after the suture locking tab **431** is deployed, the suture lock housing **430** can begin crimping the suture **409**. This figure illustrates an intermediate stage, as the pusher **403** depicted in this figure has not reached full travel.

20 **[133]** FIGS. 9E-9F show another configuration of the suture locking mechanism in FIGS. 9A-9B in accordance with an example embodiment of the present invention. In particular, FIGS. 9E-9F show the suture locking mechanism **400** after the pawl **405** is tripped by the pin **408**, and the pusher **403** has reached full travel. As depicted in the figures, after the pawl **405** is tripped, the pin retractor **402** is released from the pawl **405**’s grip, which causes the corresponding pin retractor spring **404** to extend in the proximal direction. In an example embodiment, the extension of the pin retractor spring **404** in the proximal direction causes the pin retractor **402** to also move in the proximal direction. Further, because the proximal end of

5 the pusher wire **407** is attached to the proximal end of the pin retractor **402**, the pusher wire **407** is pulled (i.e., retracted) in the proximal direction.

[134] FIGS. 9G, 9H, 9I, 9J, 9K, and 9L show additional configurations of the suture locking mechanism in FIGS. 9A-9B in accordance with an example embodiment of the present invention. In particular, once the suture has been locked into suture locking housing **430**,

10 FIGS. 9G, 9H, 9I, 9J, 9K, and 9L illustrate control knobs for releasing the suture lock from the distal housing, and for cutting the suture. The control knob for releasing the suture lock may be situated adjacent to the control knob for cutting the suture, so that the release of the suture lock and the cutting of the suture can be easily achieved in simple, similar motions.

[135] FIGS. 9G-9H show the suture locking mechanism **400** before the suture lock housing

15 **430** and the suture locking tab **431** is detached from the distal housing **420**. FIGS. 9G-9H also depicts a cross section of a suture lock control knob **426**, which includes the suture cutting control wire **423** and a suture lock release wire **429**. Suture lock control knob **426a** includes suture lock threading **4261**, which interacts with suture lock screw **4262**, such that a turning of the suture lock control knob **426a** translates the suture lock screw **4262** in the proximal or 20 distal directions. By drawing the suture lock screw in the proximal direction, suture lock release wire **429** is drawn in the proximal direction, pulling the actuator **432** from around the suture lock to release the suture lock from the distal housing.

[136] FIGS. 9I-9J shows the suture locking mechanism **400** after the suture lock housing **430** and the suture locking tab **431** is detached from the distal housing **420**. The suture lock

25 control knob **426a** has been turned, translating suture lock screw **4262** in the proximal direction, drawing on suture lock release wire **429** to release the suture lock housing **430**. In an example embodiment, the suture lock housing **430** and the suture locking tab **431** can be detached from the distal housing **420** after the actuator **432** is moved in the proximal direction. In particular, detachment may occur after the actuator **432** is no longer underneath 30 the suture lock housing **430** and the suture locking tab **431**. In FIGS. 9I-9J, the suture cutting control knob **426b** has not yet been turned, so that suture cutting screw **4264** and remains in the distal position. The suture cutting control knob **426b** includes suture cutting threading **4263**, which interacts with suture cutting screw **4264**, such that a turning of the suture cutting control knob **426b** translates the suture cutting screw **4264** in the proximal or distal

35 directions. By drawing the suture cutting screw in the proximal direction, suture cutting control wire **423** is drawn in the proximal direction, as is the suture cutting blade **425**. When suture cutting blade **425** is drawn sufficiently in the proximal direction, the blade **425** meets suture **409** and cutting block **422**, and presses against suture **409** with sufficient force to cut

5 the suture. The suture lock control knob and the suture cutting control knob may instead be combined into one control knob, which first turns to release the suture lock, and then turns again to cut the suture.

10 [137] FIGS. 9K-9L shows the suture locking mechanism **400** after the suture **409** is cut by the suture cutting blade **425**. The entire implant, including the anchors, the suture, and the suture lock, is now free of the surgical device, and may remain at the surgical site.

15 [138] A further embodiment of the suture cutting mechanism is illustrated in FIGS. 10A, 10B, 10C, 10D, 10E, 10F, and 10G. FIG.s 10A, 10B, and 10C illustrate a surgical device **450** including the handle **460**, catheter **470**, and distal housing **480**. Handle **460** includes the spring **461**, suture cutting control knob **462**, suture cutting screw **463**, suture cutting wire mount **464**, suture cutting wire clamp **465**, safety **466**, adapter **467**, and cap **468**. Distal housing **480** includes a suture cutting blade **481**, suture cutting wire **482**, and blade holder **483**. FIGS. 10D-10E illustrate the handle **460** and the distal housing **480** in position to cut the suture **409**. As illustrated in FIGS. 10D-10E, suture cutting screw **463** fits into the suture cutting threading **469**, and is in a distal position within handle **460**. Suture cutting wire mount **464** and suture cutting wire clamp **465** hold suture cutting wire **482** to the suture cutting screw **463**. In the distal housing **480**, suture cutting wire **482** is attached to blade **481**, in position to cut suture **409**. As illustrated in FIGS. 10F-10G, suture cutting control knob **462** has been turned, translating suture cutting screw **463** in the proximal direction, drawing suture cutting wire **482**, and therefore blade **481**, in the proximal direction into suture **409**, cutting the suture.

20 [139] FIG. 11A shows an exploded view of an anchor deployment mechanism in accordance with an example embodiment of the present invention. As depicted in FIG. 11A, anchor deployment mechanism **500** includes an outer handle **510**, a compressed gas tank **515**, a trigger handle **520**, a deployment button **521**, a cap **530**, a steering knob **540**, a catheter **550**, a retaining block **501**, an actuation cylinder **502**, a piston **503**, and a return spring **504**. Further, in an example embodiment, a distal end of the catheter **550** may be connected to a distal anchor housing (e.g., distal anchor housing **150** or **220**) including one or more anchors.

30 [140] FIG. 11B is a cross-sectional view of the anchor deployment mechanism of FIG. 11A. As depicted in FIG. 11B, the anchor deployment mechanism **500** also includes a pusher wire **505**. In an example embodiment, the elements within the anchor deployment mechanism **500** are configured to impart a pushing force on the anchor(s) in the connected distal anchor housing (not shown). Specifically, a pushing force is imparted onto the anchor(s) by the deployment of compressed gas from the compressed gas tank **515**. For example, after the

5 deployment button **521** is engaged (e.g., pressed), gas escaping from the compressed gas tank **515** and into a second closed system, e.g. a cylinder, exerts a pushing force in the distal direction. In an example embodiment, the pushing force from the released gas is transmitted to the anchors via the pusher wire **505**. In an example embodiment, engaging the deployment button **521** releases gas sufficient to drive a single anchor into tissue. In another example 10 embodiment, engaging the deployment button **521** releases gas sufficient to drive a plurality of anchors into tissue. Further, in an example embodiment, after the anchor is driven into tissue, the return spring **504** exerts a pulling force on the pusher wire **505** in the proximal direction. Accordingly, the pusher wire **504** is brought back to its original position and, therefore, the anchor deployment mechanism **500** can be utilized to drive additional anchors 15 into tissue. In an example embodiment, the compressed gas tank **515** is disposable and replaceable. Further, in another example embodiment, carbon dioxide or a similar gas may be used to exert the pushing force on the anchors.

[141] FIG. 12A shows an exploded view of an anchor deployment mechanism in accordance with an example embodiment of the present invention. As depicted in FIG. 12A, 20 anchor deployment mechanism **600** includes an outer handle **610**, a motor **615**, a deployment button **621**, a cap **630**, an actuation shaft **602**, and a pusher wire clamp **603**. Further, in an example embodiment, a distal end of a catheter **650** may be connected to a distal anchor housing (e.g., distal anchor housing **150** or **220**) including one or more anchors.

[142] FIG. 12B is a cross-sectional view of the anchor deployment mechanism of FIG. 12A. 25 As depicted in FIG. 12B, the anchor deployment mechanism **600** also includes a pusher wire **605**. In an example embodiment, the elements within the anchor deployment mechanism **600** are configured to impart a pushing force on the anchor(s) in the connected distal anchor housing (not shown). Specifically, a pushing force is imparted onto the anchor(s) by the actuation of a motor **615**. For example, after the deployment button **621** is engaged (e.g., pressed), motor **615** turns its rotor, and actuation shaft **602** is in a screw-threaded communication, such that the turning of the rotor translates to a pushing force on the actuation shaft in the distal direction. In an example embodiment, engaging the deployment button **621** presents sufficient force to drive a single anchor into tissue. In another example embodiment, engaging the deployment button **621** presents sufficient force to drive a 30 plurality of anchors into tissue. Further, in an example embodiment, after the anchor is driven into tissue, the motor may be run in reverse, to exert a pulling force on the pusher wire **605** in the proximal direction. Accordingly, the pusher wire **605** is brought back to its original 35

5 position and, therefore, the anchor deployment mechanism **600** can be utilized to drive additional anchors into tissue.

[143] FIG. 13A shows an exploded view of an anchor deployment mechanism in accordance with an example embodiment of the present invention. As depicted in FIG. 13A, anchor deployment mechanism **700** includes an outer handle **710**, a cylinder **715** housing an actuation shaft or plunger **702**, a deployment button **721**, a cap **730**, and a set screw **703**.
10 Further, in an example embodiment, a distal end of a catheter **750** may be connected to a distal anchor housing (e.g., distal anchor housing **150** or **220**) including one or more anchors.

[144] FIG. 13B is a cross-sectional view of the anchor deployment mechanism of FIG. 13A. As depicted in FIG. 13B, the anchor deployment mechanism **700** also includes a pusher wire **705**.
15 In an example embodiment, the elements within the anchor deployment mechanism **700** are configured to impart a pushing force on the anchor(s) in the connected distal anchor housing (not shown). Specifically, a pushing force is imparted onto the anchor(s) by the actuation of an actuation shaft or plunger **702**. For example, after the deployment button **721** is engaged (e.g., pressed), cylinder **715** is flooded with a hydraulic fluid, exerting a force on actuation shaft **702** in the distal direction. In an example embodiment, engaging the deployment button **721** presents sufficient force to drive a single anchor into tissue. In another example embodiment, engaging the deployment button **721** presents sufficient force to drive a plurality of anchors into tissue. Further, in an example embodiment, after the anchor is driven into tissue, the hydraulic fluid may be withdrawn from the cylinder, to exert
20 a pulling force on the pusher wire **705** in the proximal direction. Accordingly, the pusher wire **705** is brought back to its original position and, therefore, the anchor deployment mechanism **700** can be utilized to drive additional anchors into tissue.

[145] To ensure that the amount of force applied to an anchor already deployed in tissue during a percutaneous procedure is not too great, so as to damage the tissue, or too small, so
30 as to allow for excess of suture in the surgical site that may become knotted or looped, a suture tensioner may be used to hold the suture. The suture tensioner **800**, illustrated in FIG. 14A, can hold the suture during the surgical procedure, maintaining a constant force on the suture.

[146] An exploded view of the suture tensioner **800** is illustrated in FIG. 14B. Suture
35 tensioner **800** includes tensioner housing **810**, spring pulley **811**, suture pulley **812**, screw(s) **813**, dowel pin(s) **814**, monofilament **815**, constant force spring **816**, tensioner cover **817**, suture grip spring retainer **820**, release button spring **821**, suture grip base **822**, and suture grip slide **823**.

5 [147] FIG. 14C illustrates the suture tensioner **800** in an exemplary embodiment of the present invention. The suture tensioner **800**, including spring pulley **811** and suture pulley **812**, is in its initial state, with no force applied. Constant force spring **816** is wrapped around the spring pulley **811**. In FIG. 14D, the suture tensioner **800** is in its extended state, subject to an applied force. In this extended state, constant force spring **816** is extended from its

10 wrapping around spring pulley **811**, as monofilament **815** is drawn in the direction of suture grip slide **823** and suture grip base **822**. The unwrapping of the constant force spring **816** from the spring pulley **811** provides a constant tension on the monofilament **815**, which in turn provides the same constant tension on the clamped suture, as described below.

15 [148] Clamping of the suture in the suture grip of the suture tensioner is illustrated in FIGS. 14E and 14F. In FIG. 14E, the suture clamp is open. The suture grip slide **823** has been drawn away from the suture grip base **822**, compressing the release button spring **821**. This slide operation may be achieved by hand during the surgical procedure. Suture **824** is then placed between the suture grip slide **823** and the suture grip base **822**. In FIG. 14F, the suture grip slide **823** has been released, release button spring **821** has decompressed, pushing suture grip 20 slide **823** into apposition with suture grip base **822**. By this movement of the suture grip slide **823** to suture grip base **822**, the suture clamp has been closed, and suture **824** has been clamped therein. By holding suture tensioner **800** by the tensioner housing **810**, the tensioner **800** can be used to hold or manipulate suture **824**, and only a constant force will be applied to the suture **824**.

25 [149] According to an exemplary embodiment of the present invention, the surgical device described herein may include a detachable reload anchor housing, to provide more rapid deployment of secondary anchors following the deployment of a primary anchor. FIG. 15 shows an exploded view of the distal end, including secondary anchor **80**, anchor cup insert **81**, eyelet **82**, pusher wire guide tube **83**, catheter **140**, catheter crimp band **141**, delivery 30 device seal **142**. The detachable reload anchor housing **90** may include reload base **91** and reload cap **92**, and is formed to attach to, or detach from, the distal end of the surgical device, specifically with reload socket base **93**, and reload socket cap **94**.

[150] FIGS. 16A, 16B, and 16C show the mechanisms for installing a detachable reload anchor housing, for example, for preparing and deploying a secondary anchor. Anchor **80** is situated within the reload anchor housing **90**. To attach the reload anchor housing **90** to the distal end of the surgical device, reload anchor housing is brought into apposition with reload socket base **93** and reload socket cap **94**. Reload anchor housing **90** includes a notch **95**. As the proximal end of reload anchor housing **90** is pressed against the distal end of reload

5 socket base **93** and reload socket cap **94**, reload catch **96** is compressed until the catch **96** passes in the notch **95**. The catch **96** expands into the notch **95**, and holds the reload anchor housing in place against the reload socket base **93** and reload socket cap **94**. The reloaded device is now ready for a suture to be passed through the eyelet of the secondary anchor **80**, to prepare for deployment.

10 [151] FIG.s 17A-17F illustrates the distal end of the surgical device through deployment of a primary anchor, and then deployment of a secondary anchor, according to an exemplary embodiment. FIG. 17A shows primary anchor **50**, situated within reload anchor housing **90**, connected to suture **160**, with pusher wire **104** prepared to deploy the anchor. FIG. 17B shows pusher wire **104** extended beyond the distal end of the surgical device, to deploy the

15 primary anchor **50** and the distal end of suture **160** into tissue (not shown). In FIG. 17C, anchor **50** has been deployed, and pusher wire **104** has been retracted. At this stage, the surgical device may be removed from the surgical site, and reload anchor housing **90** may be released from the distal end of the surgical device, by compressing reload catch **96** within notch **95**. As described in the above FIGS. 16A, 16B, and 16C, another reload anchor housing

20 **90** may be installed, including a secondary anchor **80**. As described in the above FIGS. 6A or 6B, suture **160** may be passed through the anchor eyelet **82** and into the catheter. Then, as shown in FIG. 17D, the secondary anchor **80** is ready for deployment. FIG. 17E shows pusher wire **104** extended beyond the distal end of the surgical device, to deploy the secondary anchor **80** and the associated portion of suture **160** into tissue (not shown). In FIG.

25 17F, secondary anchor **80** has been deployed, and pusher wire **104** has been retracted. The device is now ready for an additional component, for example, an additional secondary anchor, or a cutting and locking mechanism as described herein, to be attached to the deployed suture and used to complete the surgical procedure.

[152] In an exemplary embodiment of the present invention, to deploy a secondary anchor after the deployment of a primary anchor, the driving mechanism must be re-armed, or otherwise re-set to a pre-firing position. FIGS. 18A, 18B, and 18C illustrate this re-arming in an exemplary embodiment of the present invention, for a spring-based driving mechanism. FIG. 18A shows a handle for an anchor deployment mechanism, similar to the anchor deployment mechanism shown in FIG. 1B. As in FIG. 1B, the handle **110** of FIG. 18A includes elements configured to impart a pushing force on anchors located in the distal anchor housing (not shown), including release button **111**, pawl **103**, tensioned spring **121**, pawl spring **101**, pin retractor spring **204**, and pin retractor **203**. In FIG. 18A, the tension of spring **121** has already been released, having exerted its pushing force. To re-arm the handle

5 **110**, crank **123** may be introduced, including a threaded shaft **124**. Handle **110** may include a threaded pusher cap **125**, situated between, and attached to, the pusher **122** and the spring **121**. As shown in FIGS. 18B and 18C, shaft **124** of crank **123** may be inserted into the proximal end of handle **110**, to be threaded into pusher cap **125**. As the crank **123** is rotated, pusher cap **125** is drawn in the proximal direction, compressing the spring **121**. As the spring **121** is compressed, and the pusher is moved in the proximal direction, the release button **111** is reset into a notch in the pusher **122** from pressure exerted by the release button spring **821**.
10 The safety button **112** may be reset manually. The spring **121** is now re-tensioned, and the device is re-armed for the next deployment. It should be noted that pin retractor **203** is held axially stationary by the end of the threaded shaft **124**. When the pusher **122** is drawn fully proximal, the pin retraction spring **204** is compressed, and the pawl **103** re-engages with the groove in the pin retractor **203**, resetting the pin retraction mechanism.
15

[153] FIGS. 19A and 19B illustrate the retraction of the stabilization pins more fully described above in connection with FIGS. 2A-2D. In the context of a detachable reload anchor housing, FIGS. 19A and 19B show that the stabilization pins **151** may be sufficiently retracted to a position proximal to the reload anchor housing (as shown in FIG. 19B), so that the stabilization pins do not interfere with the detachment of the reload anchor housing.
20

[154] According to exemplary embodiments of the present invention, the surgical device described herein may be used to deploy a series of anchors along a suture, and draw the suture to bring the anchors into apposition around a valve. FIG. 20A illustrates a damaged valve, as a catheter sheath **311** is moved into position around the surgical site, the catheter sheath **311** containing catheter **310** or **410**. A distal housing **320** or **420** is extended beyond the catheter sheath **311**. In FIG. 20B, the distal housing **320** or **420** has been positioned against the tissue, in preparation for deploying an anchor into the tissue. The stabilization pins described herein may be used in this regard, to ensure that the distal housing **320** or **420** is in proper position with respect to the tissue before deployment of anchors. In FIG. 20C, a primary anchor has already been deployed into tissue, and a secondary anchor is being deployed in another tissue site, with a suture **309** or **409** connecting the two anchors. In FIG. 20D, a series of secondary anchors has been deployed along the suture **309** or **409**. In FIG. 20E, the distal housing **320** or **420** is retracted as the anchor deployment mechanisms are switched for the locking and cutting mechanisms. In FIGS. 20F, 20G, and 20H, the suture **309** or **409** is drawn proximally into the catheter, pulling on the primary anchor and drawing the series of anchors into apposition, and in turn tightening the tissue surrounding the valve. Further, in FIG. 20H, the locking and cutting procedure is applied as discussed herein, to
25
30
35

5 close the suture locking housing **330** or **430** on the suture **309** or **409**, to cut the suture **309** or **409**, and to separate the cut portion of the suture from the portion of the suture contained in the catheter. In FIG. 20I, the entire implant, including the anchors, suture, and suture locking housing remains, to maintain the position of the suture and the anchors in holding the tissue, the valve now being restructured to allow the leaflets to properly coapt.

10 [155] Modern manufacturing processes allow for highly precise component features at previously unattainable scale. The anchors **30**, **40**, **50**, **70**, and **80** may have a diameter of, e.g., one millimeter, or approximately one millimeter, and a length that is in a range from, e.g., 5 millimeters to 10 millimeters. According to some example embodiments, the diameter is less than one millimeter. According to some example embodiments, the diameter is in a

15 range from 0.8 millimeters to 1.2 millimeters. It should be understood, however, that other dimensions may be provided.

[156] Further, the anchors **30**, **40**, **50**, **70** and **80** are driven at an optimal speed, such that the anchor has sufficient velocity to overcome the surface tension of the tissue and penetrate the tissue, without displacing it. Sufficient deployment speeds allow the anchor to maintain a

20 necessary rigidity to pierce tissue during deployment. In exemplary embodiments, such speeds may be up to 300 meters per second. However, it should be understood that the anchors may be driven at any suitable speed sufficient for the anchors to puncture tissue.

[157] Further, the anchors **30**, **40**, **50**, **70**, and **80** may be driven into a single layer or multiple layers of tissue and that the speed may be selected based on the structural properties,

25 dimensions, and relative locations of the one or more tissues into which the anchors are driven.

[158] To accurately penetrate soft tissues that are not held or secured on a distal side, a rapid penetration of each layer of tissue may be required to effect penetration of the tissue layer or layers. If an anchor is applied slowly, the tissue or tissues may be pushed distally away by the anchor without adequate penetration. Thus, some example delivery mechanisms eject each anchor at a relatively high speed, as set forth above. Although the deployment mechanisms **100**, **200**, **300**, **400**, **450**, and **500** may utilize a spring-loaded mechanical driving mechanism, it should be understood that other drivers may be provided. In some examples, saline is used to pressurize a channel within a catheter, needle, or other tube at such a rate that

30 a plunger will eject the anchor at the precise speed. Further example embodiments push the anchors **30**, **40**, **50**, **70**, and **80** using long push rods which run the length of a catheter or other tube. The ejection modality may be computer-controlled and/or operator-controlled. For

5 example, as with the spring loaded mechanical system of the illustrated examples, an ejection force may be predetermined and repeatable by an operator's actuation of a trigger.

[159] Moreover, the driver may be configured to drive the anchors **30, 40, 50, 70, and 80** to a predetermined depth. In an example embodiment, the precision of the depth may be accomplished by a precise hydraulic driving force, engagement with other stops, or a suture 10 that tautens to limit the depth. Further, the depth may be monitored using fluoroscopy, echocardiography, intravascular ultrasound or any other appropriate imaging mechanism. The driving mechanism may include pressurized saline or other hydraulic fluid that is pressurized through the thoracoscopic catheter shaft. Thus, very precise control may be accomplished.

[160] The piercing of the tissue may provide access to the opposed side of the tissue (e.g., 15 the interior of a viscus such as the heart, etc.) by thoracoscopic or other surgical and interventional instruments including guide wires and catheters.

[161] Further, in an example embodiment, any of the anchors **30, 40, 50, 70, and 80** could be utilized with any of deployment mechanisms **100, 200, 300, 400, 450, and 500** of the present invention.

20 [162] Further, the anchors **30, 40, 50, 70, and 80** may be driven after forming the aperture. Similarly, it is feasible to drive the anchors **30, 40, 50, 70, and 80** prior to dilating the hole.

[163] Further, it should be understood that the deployment mechanisms **100, 200, 300, 400, 450, and 500** may be provided in connection with any appropriate surgical device, e.g., a catheter or flexible thoracoscopic shaft. Moreover, any appropriate driving mechanism for 25 driving the anchors **30, 40, 50, 70, and 80** may be provided.

[164] Further, although the sutures **60, 160, 309, and 409** are each formed as a single monolithic piece, it should be understood that any suture described herein may be comprised of multiple component pieces.

[165] Moreover, although the examples described herein are described as firing a plurality 30 of anchors that are each identical to each other, it should be understood that a driven set of anchors may include one or more anchors that differ from the other anchors of the set. For example, situations with non-uniform tissue properties and/or dimensions may be addressed by firing, e.g., simultaneously, different types of anchors at different locations. In this regard, the deployment mechanisms **100, 200, 300, 400, 450, and 500** may be adapted to receive 35 different types of anchors in the same slot and/or have interchangeable housing portions to receive the various anchors.

[166] Further, any of the implantable elements described herein, e.g., anchors **30, 40, 50, 70, and 80** and/or sutures **60, 160, 309, and 409** may be formed wholly or partly of a material

5 absorbable into the patient's body, or of a non-absorbable material, depending on, e.g., the specific application. For example, these elements may be formed of polyglycolic acid (PGA), or a PGA copolymer. These elements may also, or alternatively, be formed of copolymers of polyester and/or nylon and/or other polymer(s). Moreover, these elements may contain one or more shape-memory alloys, e.g., nitinol, spring-loaded steel, or other alloy or material with
10 appropriate properties. Additionally, biologics, e.g. Fibrin, may be utilized to enable tissue ingrowth.

15 [167] Absorbable materials may be advantageous where there is a potential for misfiring or improper locating of the various implants. For example, in a situation where the driver drives an anchor **30, 40, 50, 70, and 80** at an unintended location, or where the tissue does not properly receive the implant, the implant even where not needed, would be relatively harmless, as it would eventually absorb into the patient's body.

20 [168] Although particular example surgical applications have been described above, the deployment mechanisms **100, 200, 300, 400, 450, and 500** are in no way limited to these examples.

[169] Although the present invention has been described with reference to particular examples and exemplary embodiments, it should be understood that the foregoing description is in no manner limiting. Moreover, the features described herein may be used in any combination.

5 What is claimed is:

1. An apparatus for deploying a tissue anchor comprising:
a catheter tube having a proximal end and a distal end defining the catheter's length,
wherein the distal end comprising an anchor housing configured to hold a tissue anchor
before deployment; and

10 a pusher wire positioned within the catheter tube and extending through the length of
the catheter tube, wherein the pusher wire has a proximal end and a distal end corresponding
with the proximal end and the distal end of the catheter tube,

wherein the apparatus is configured to provide a pushing force on the pusher wire
from the proximal end of the catheter tube, thus displacing the pusher wire in a distal

15 direction to the pusher wire's fully extended anchor deployment position which in turn
deploys the tissue anchor from the anchor housing in the distal direction by pushing the tissue
anchor in the distal direction.

2. The apparatus of claim 1, wherein the pushing force is an impulse force that pushes
the tissue anchor out of the anchor housing with sufficient speed for the tissue anchor to
penetrate a target tissue surface.

3. The apparatus of claim 2, further comprising a compression spring for delivering the
pushing force.

4. The apparatus of claim 2, further comprising a compressed gas cartridge for
delivering the pushing force by a pneumatic operation.

25 5. The apparatus of claim 2, further comprising a motorized or geared actuator for
delivering the pushing force.

6. The apparatus of claim 1, further comprising a handle provided at the proximal end of
the catheter tube that is configured to deliver the pushing force, and wherein the pusher wire
extends from the handle to the anchor housing.

30 7. The apparatus of claim 6, wherein the handle comprises a compression spring for
delivering the pushing force.

8. The apparatus of claim 6, wherein the handle comprises a compressed gas cartridge
for delivering the pushing force by a pneumatic operation.

35 9. The apparatus of claim 6, wherein the handle comprises a motorized or geared
actuator for delivering the pushing force.

5 10. The apparatus of claim 6, wherein the handle further comprises:
a pusher carriage attached to the proximal end of the pusher wire and configured to travel linearly within the handle between a first position and a second position,
wherein, in the first position, the pusher wire is in its retracted position, and in the second position, the pusher wire is in its extended position,

10 wherein the pushing force operates on the pusher carriage thereby displacing the pusher wire to its extended position.

11. The apparatus of claim 6, wherein the pusher wire has a distal end and a proximal end, and the pusher wire comprising a stop provided at a fixed distance from the distal end of the pusher wire, wherein the stop prevents the pusher wire from extending beyond the proximal end of the anchor housing.

15 12. The apparatus of claim 10, wherein the handle further comprises:
a pin retractor provided within the pusher carriage and attached to the proximal end of the pusher wire,
wherein the pin retractor is configured to travel linearly within the pusher carriage between a first position and a second position,

20 wherein, in the first position, the pin retractor is in its locked position with respect to the pusher carriage which is most-distal position within the pusher carriage, and in the second position, the pin retractor is in its unlocked position with respect to the pusher carriage which is most-proximal position within the pusher carriage; and

25 13. The apparatus of claim 10, wherein the handle further comprises:
a pin retractor spring positioned within the pusher carriage and arranged to provide a force constantly urging the pin retractor toward the pin retractor's second position,
wherein when the pusher carriage is in its first position, the pin retractor is in its first position and the pusher wire is in its retracted position, and when the pusher carriage reaches the pusher carriage's second position which corresponds to the pusher wire's fully extended anchor deployment position, the pin retractor transitions into its second position whereby retracting the pusher wire from the fully extended anchor deployment position to a retracted position.

30 14. An apparatus for deploying a tissue anchor comprising:
a catheter tube having a proximal end and a distal end defining the catheter's length,
35 wherein the distal end comprising an anchor housing configured to hold a tissue anchor before deployment;

5 a pusher wire positioned within the catheter tube and extending through the length of the catheter tube, wherein the pusher wire has a proximal end and a distal end corresponding with the proximal end and the distal end of the catheter tube,

10 wherein the apparatus is configured to provide a pushing force on the pusher wire from the proximal end of the catheter tube, thus displacing the pusher wire in a distal direction to the pusher wire's fully extended anchor deployment position which in turn deploys the tissue anchor from the anchor housing in the distal direction by pushing the tissue anchor in the distal direction; and

15 one or more stabilization pins extending through the length of the catheter and through corresponding passageways provided in the anchor housing, wherein the stabilization pins are configured to be manipulated from the proximal end of the catheter tube to be moved between a retracted position in which the stabilization pins do not extend out of the anchor housing, and an extended position in which the stabilization pins are in their extended position.

14. The apparatus of claim 13, wherein the stabilization pins are configured to extend 20 distally from the center line of the anchor housing at an angle of 5° - 20°.

15. The apparatus of claim 12, wherein the stabilization pins are configured to extend distally from the center line of the anchor housing at an angle of 11°.

16. The apparatus of claim 13, wherein each of the stabilization pins has a distal end and a proximal end, and each of the stabilization pins comprising a stabilization pin stop provided 25 at a fixed distance from the distal end of the stabilization pin, wherein the stabilization pin stop prevents the stabilization pin from extending beyond a preset distance by interfering with the proximal end of the anchor housing.

17. An apparatus for deploying a tissue anchor comprising:

30 a catheter tube having a proximal end and a distal end defining the catheter's length, wherein the distal end comprises an anchor housing, such anchor housing configured to hold a tissue anchor in a relaxed state prior to deployment, and compress the anchor during deployment.

18. An apparatus for deploying a tissue anchor comprising:

35 a catheter tube having a proximal end and a distal end defining the catheter's length, wherein the distal end comprising an anchor housing configured to hold a tissue anchor

5 before deployment; and

a pusher wire positioned within the catheter tube and extending through the length of the catheter tube, wherein the pusher wire has a proximal end and a distal end corresponding with the proximal end and the distal end of the catheter tube,

wherein the apparatus is configured to provide linear forces on the pusher wire from the proximal end of the catheter tube, whereby the provision of the linear forces displace the pusher wire in the distal direction deploying the tissue anchor into tissue by a first linear force and displaced in the proximal direction by a second linear force.

19. The apparatus of claim 18, further comprising:

a pusher carriage attached to the proximal end of the pusher wire and configured to travel linearly within the handle between a first position and a second position, a pin retractor provided within the pusher carriage and attached to the proximal end of the pusher wire,

wherein the pin retractor is configured to travel linearly within the pusher carriage between a first position and a second position,

wherein, in the first position, the pin retractor is in its locked position with respect to the pusher carriage which is most-distal position within the pusher carriage, and in the second position, the pin retractor is in its unlocked position with respect to the pusher carriage which is most-proximal position within the pusher carriage; and

a pin retractor spring positioned within the pusher carriage and arranged to provide a force constantly urging the pin retractor toward the pin retractor's second position,

25 wherein when the pusher carriage is in its first position, the pin retractor is in its first position and the pusher wire is in its retracted position, and when the pusher carriage reaches the pusher carriage's second position which corresponds to the pusher wire's fully extended anchor deployment position, the pin retractor transitions into its second position whereby retracting the pusher wire from the fully extended anchor deployment position to a 30 retracted position.

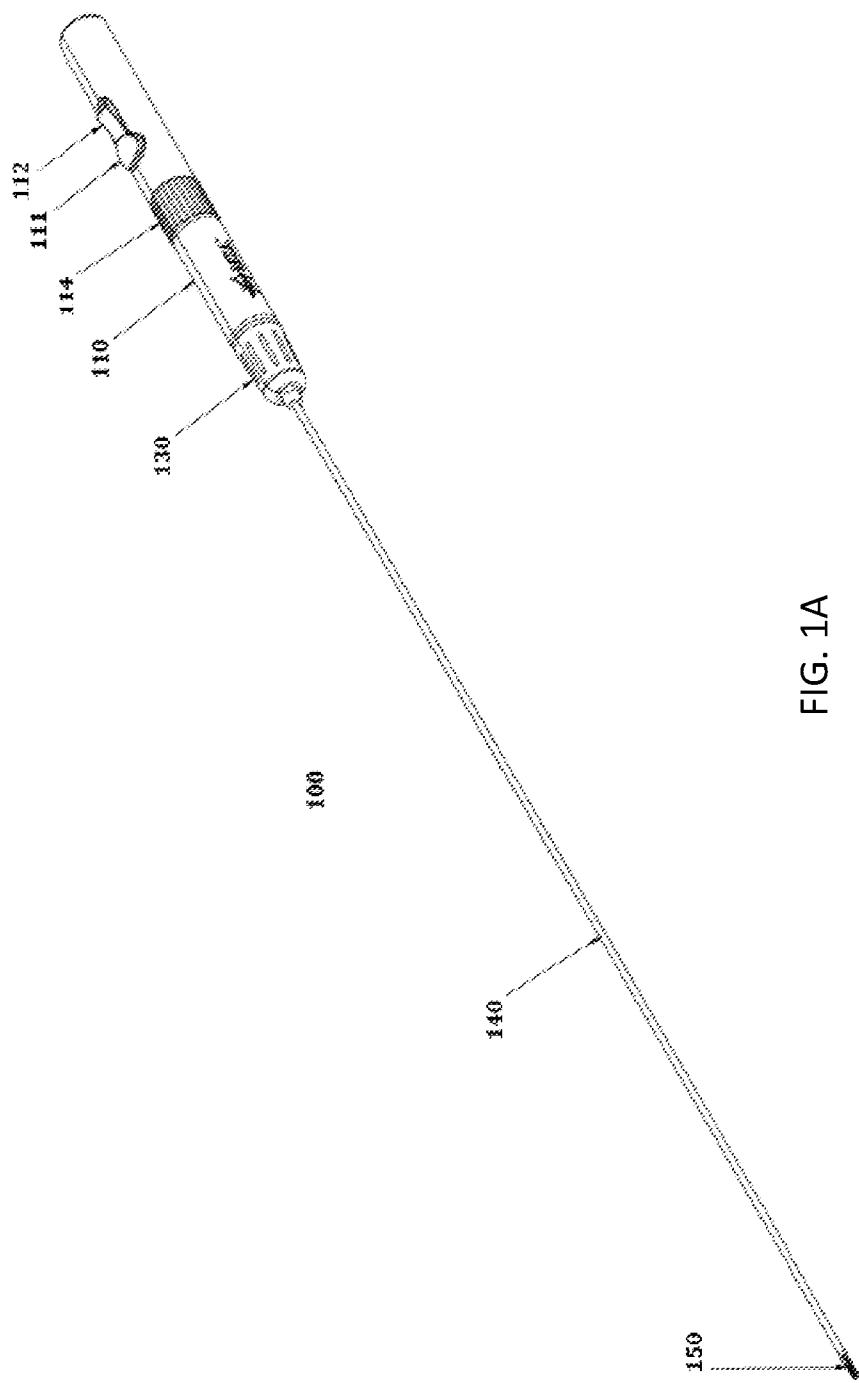


FIG. 1A

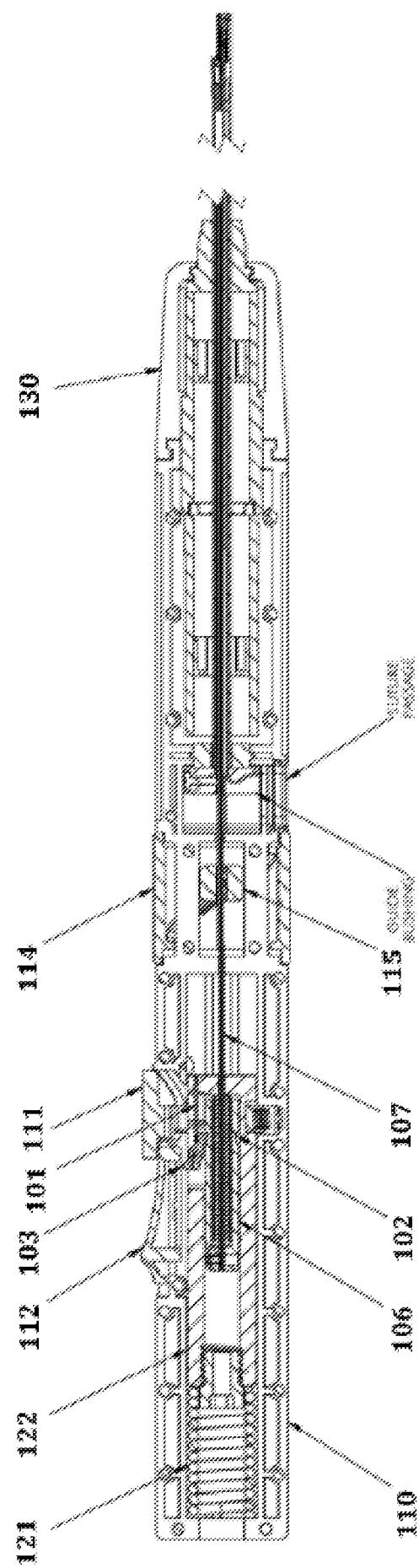


FIG. 1B



FIG. 1C

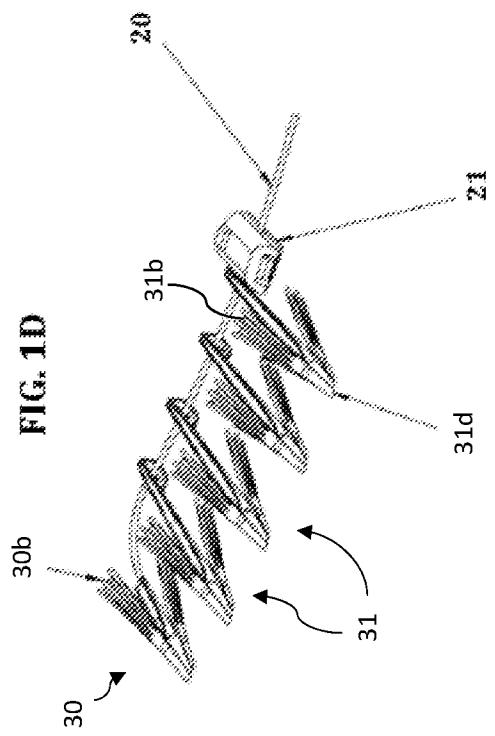


FIG. 1D



FIG. 1E

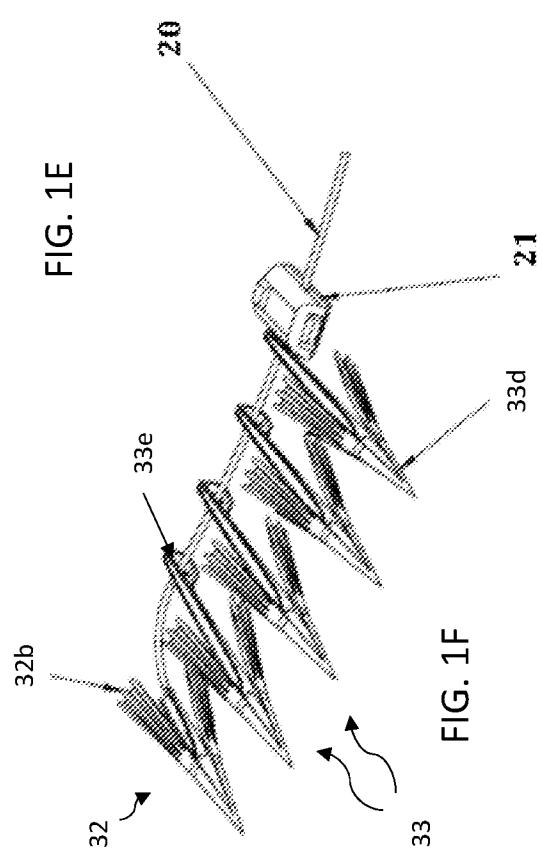


FIG. 1F



FIG. 2A

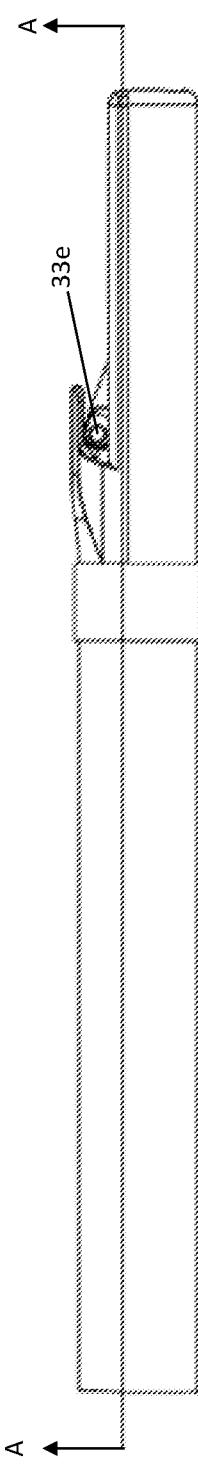


FIG. 2B

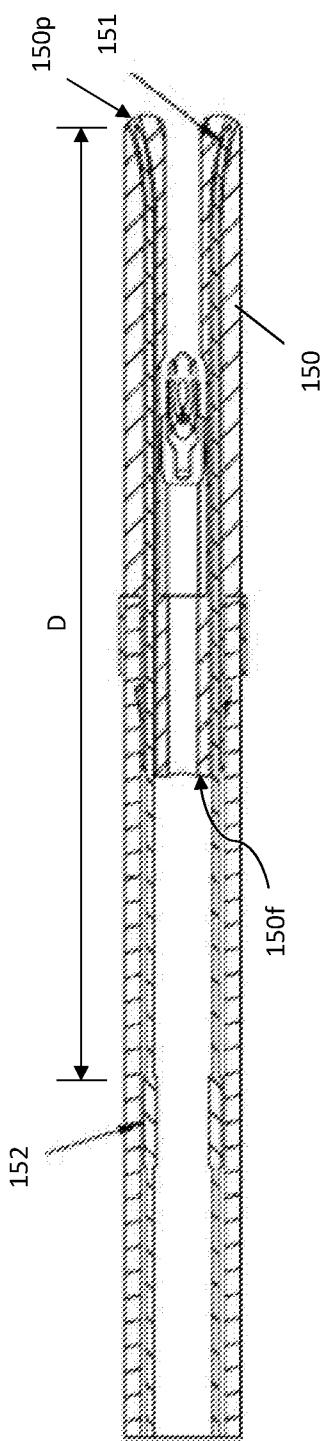


FIG. 2C

SECTION A-A

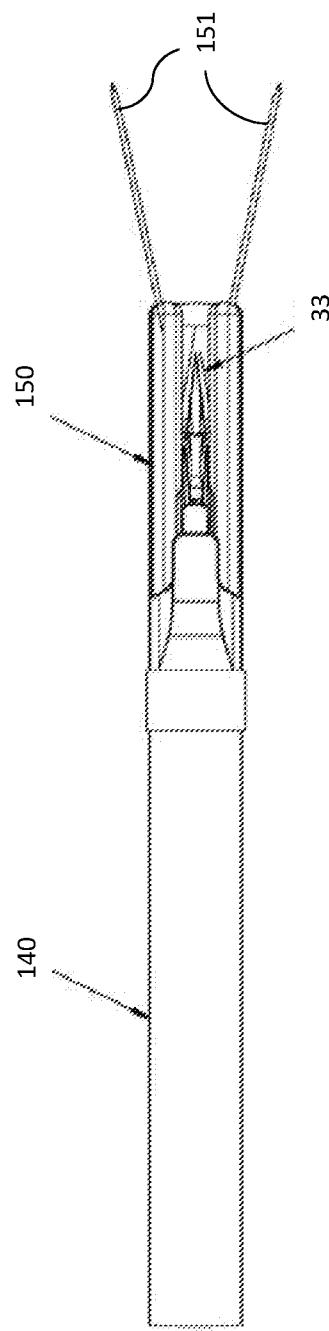


FIG. 2D

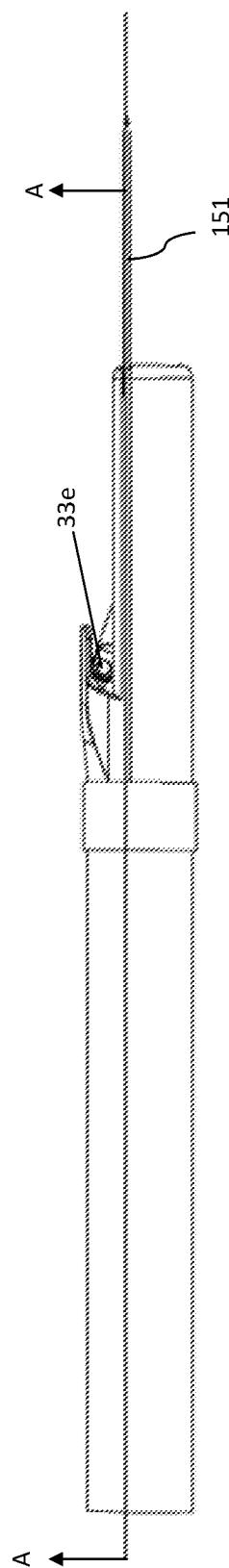


FIG. 2E

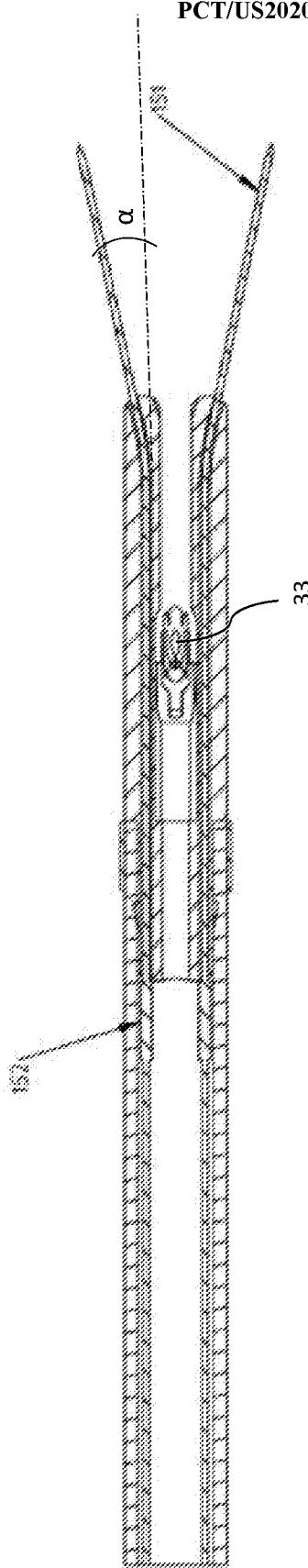


FIG. 2F

SECTION A-A

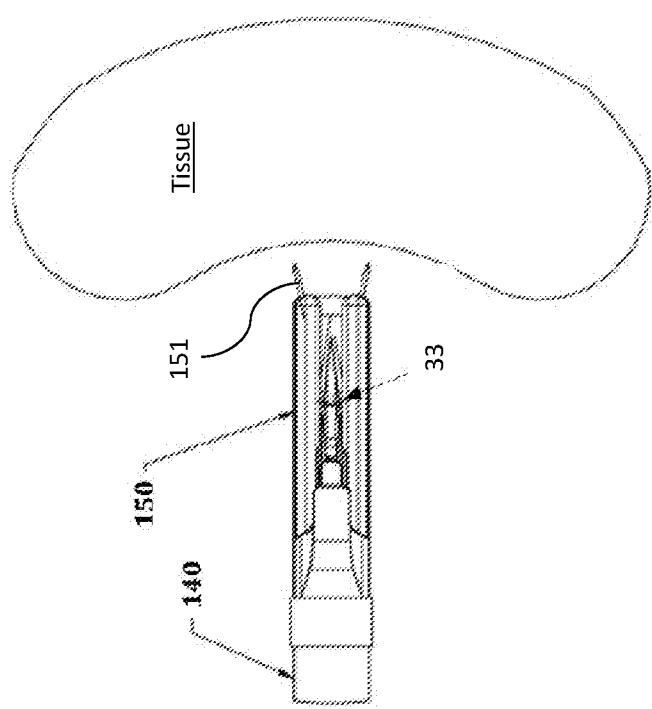
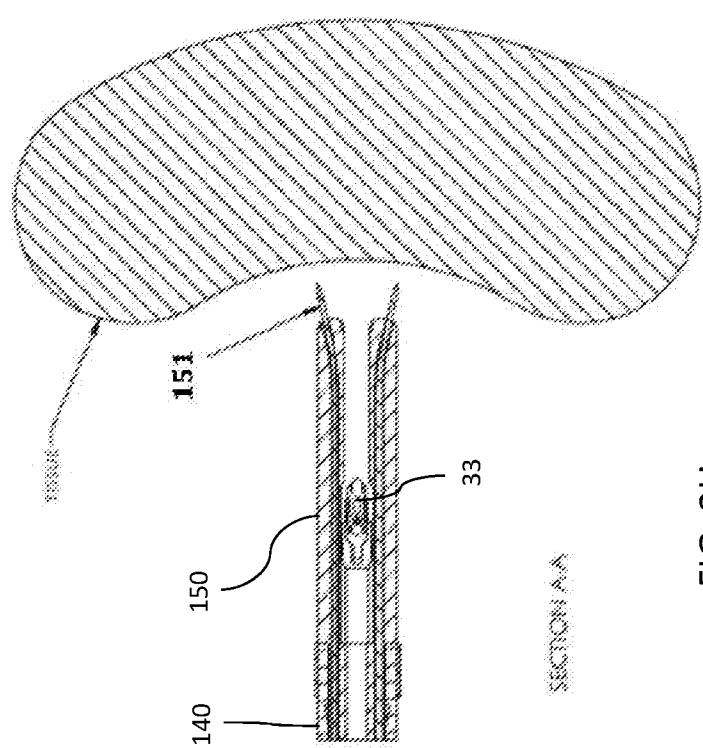


FIG. 2G

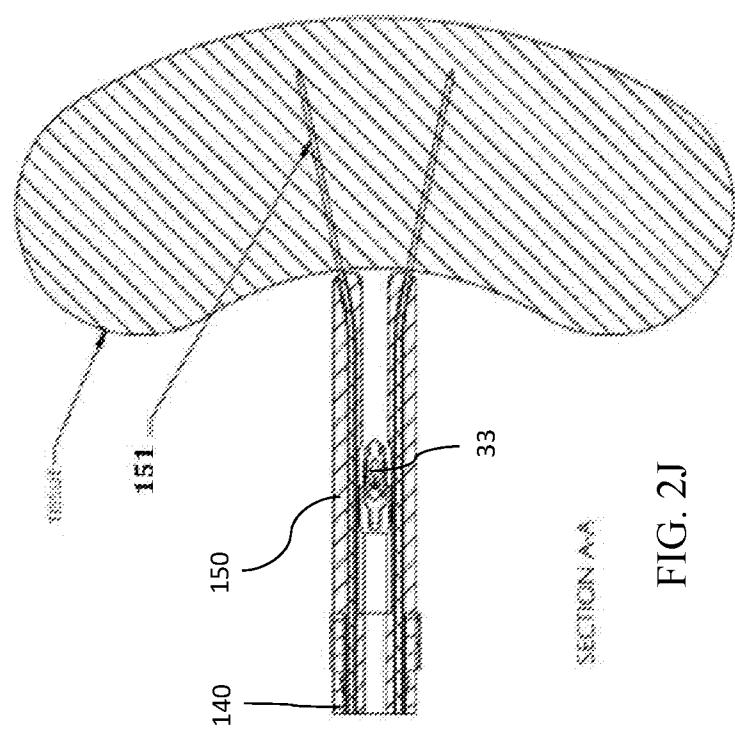


FIG. 2J

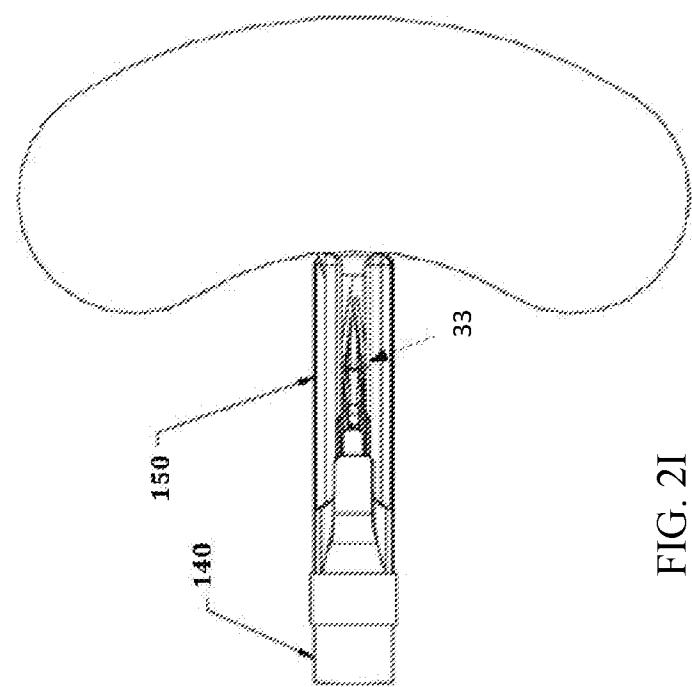


FIG. 2I

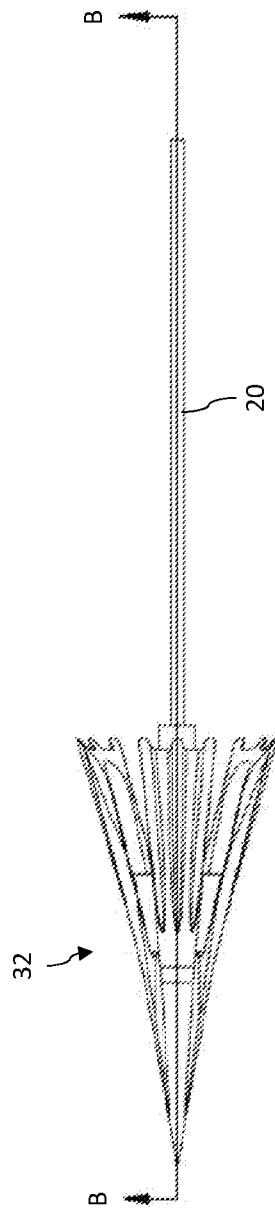
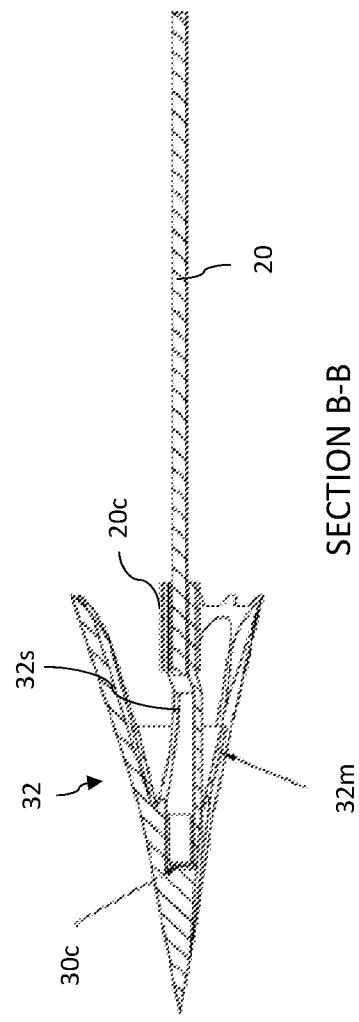
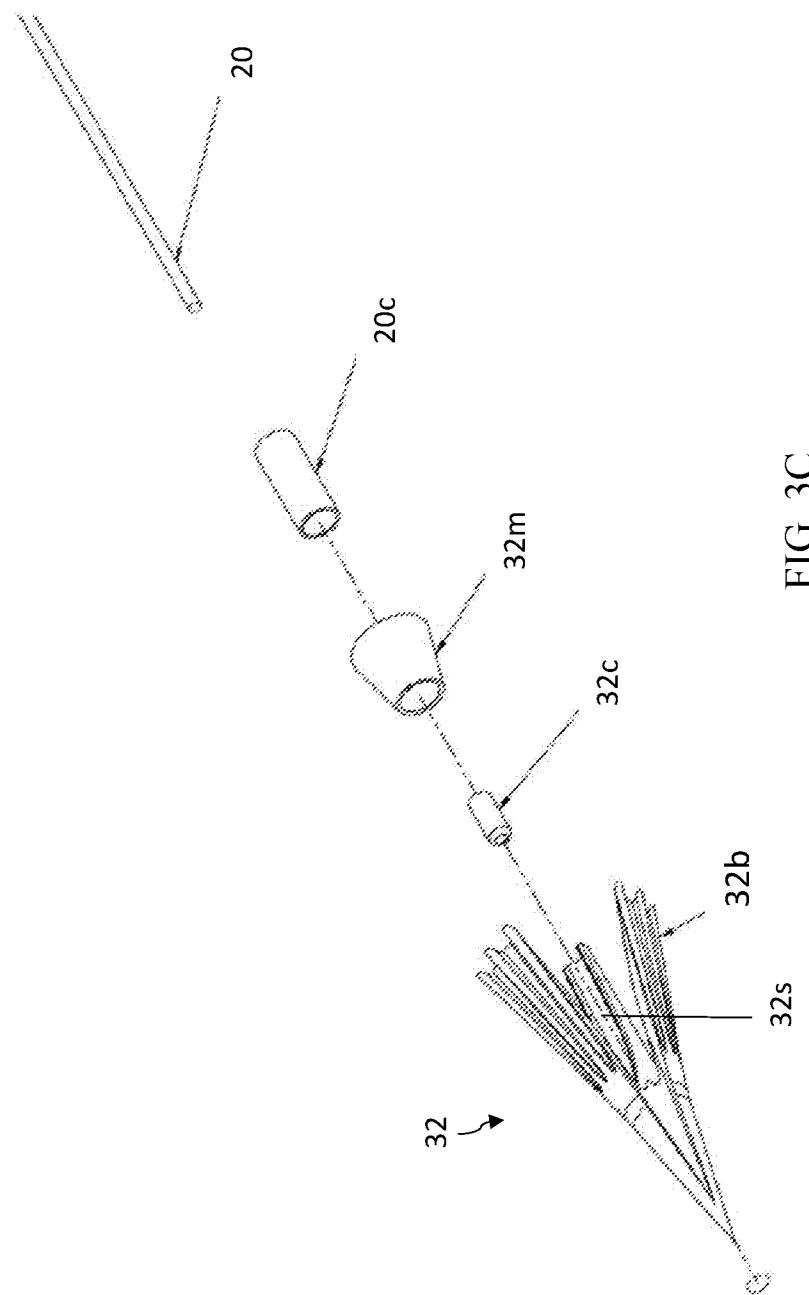


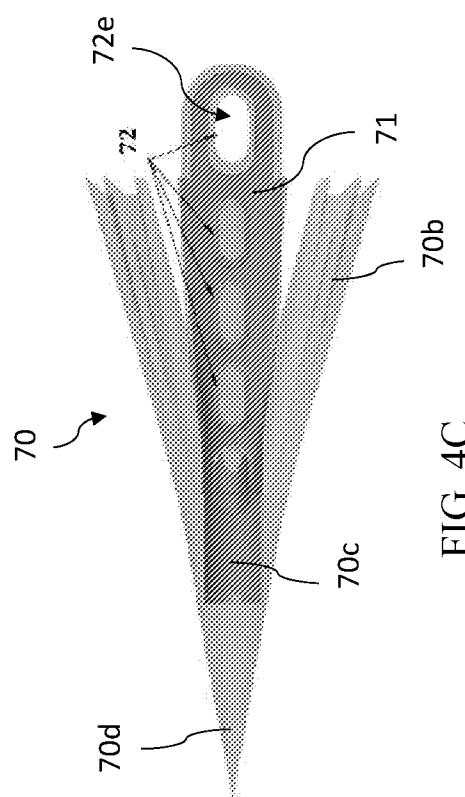
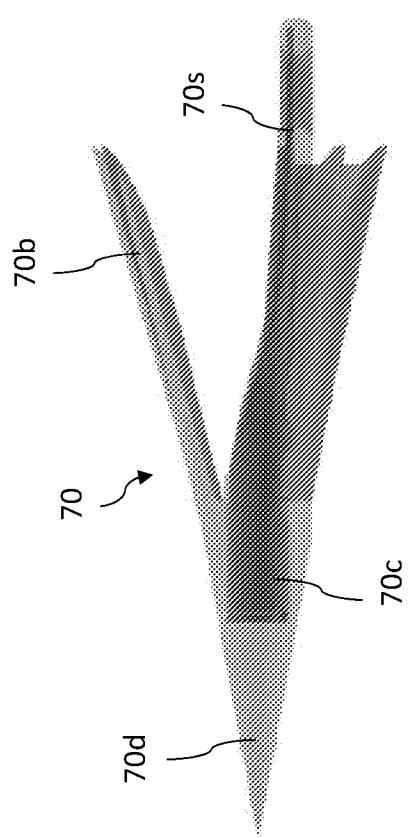
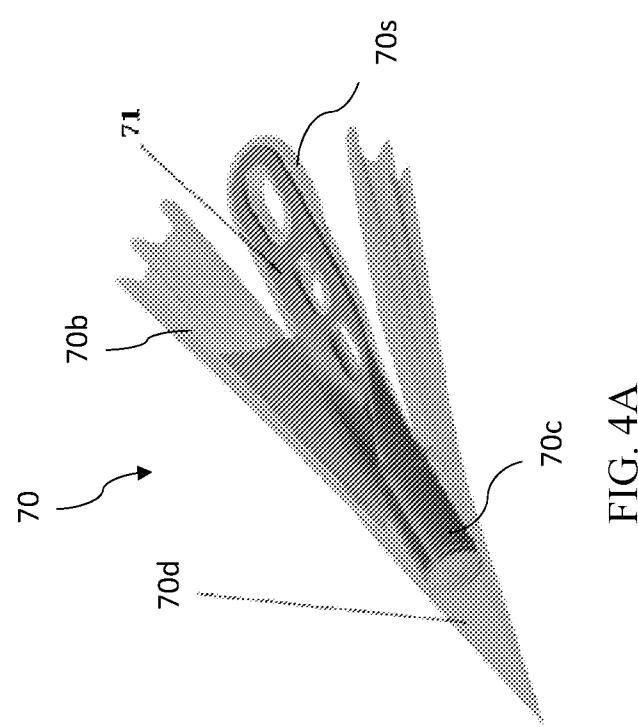
FIG. 3A



SECTION B-B

FIG. 3B





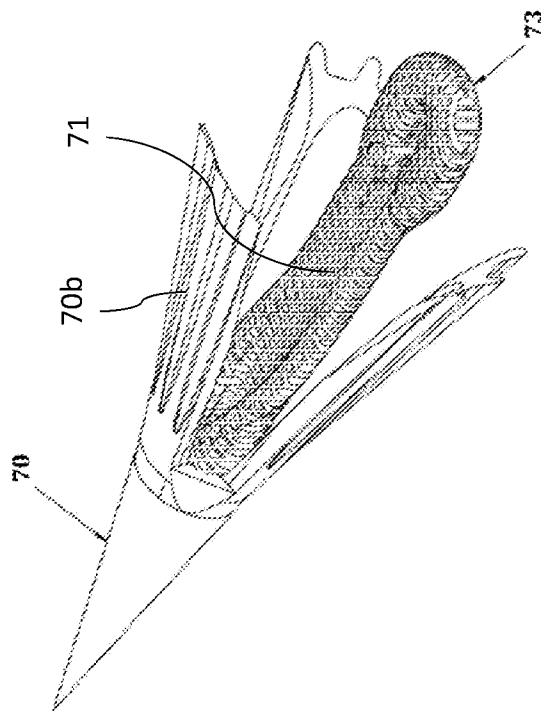


FIG. 4E

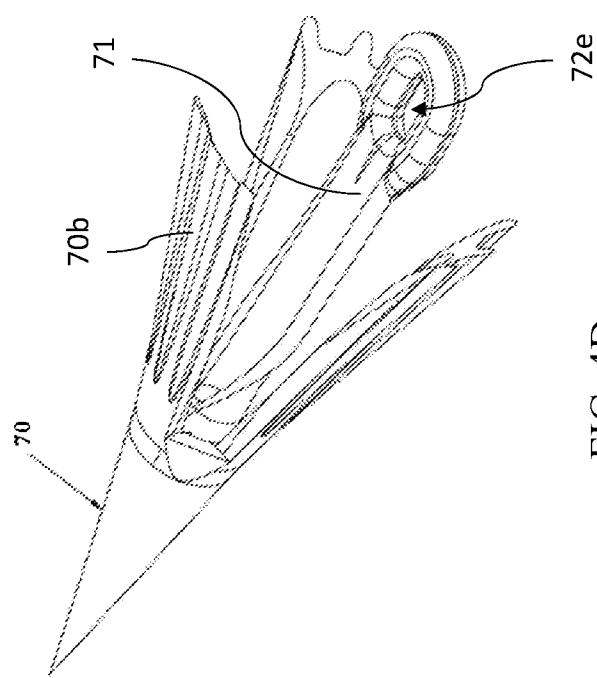


FIG. 4D

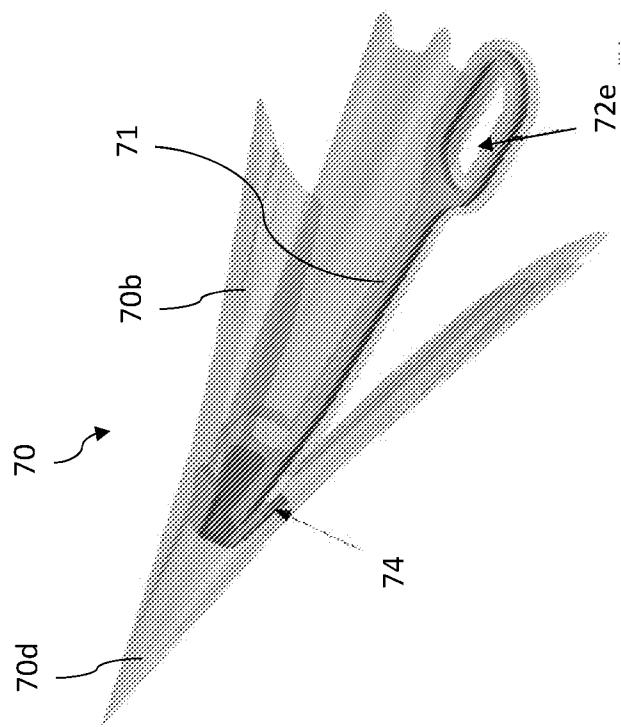


FIG. 4G

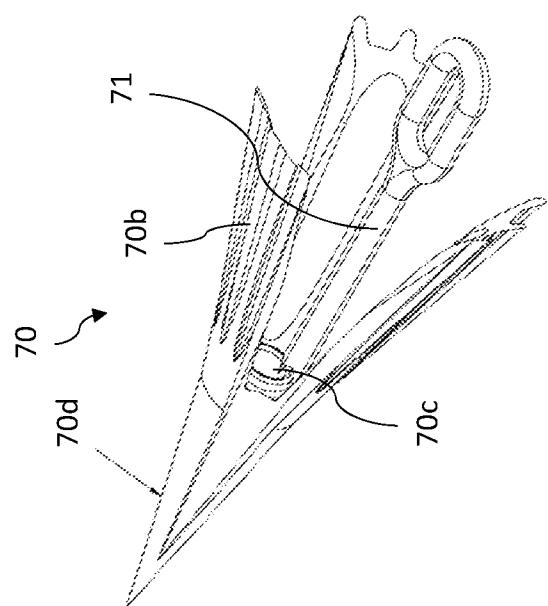


FIG. 4F

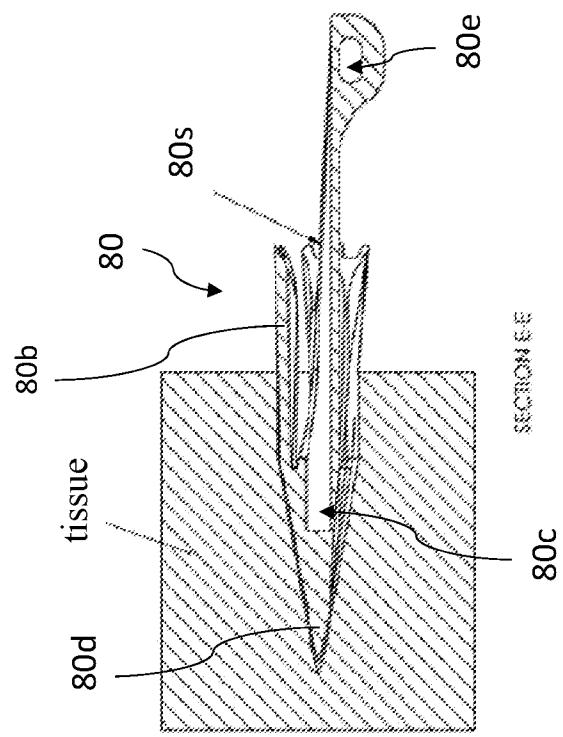


FIG. 5B

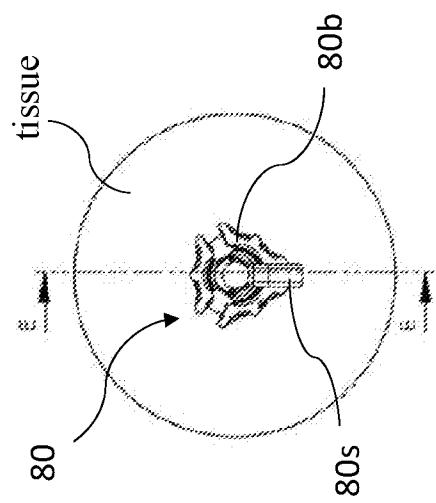


FIG. 5A

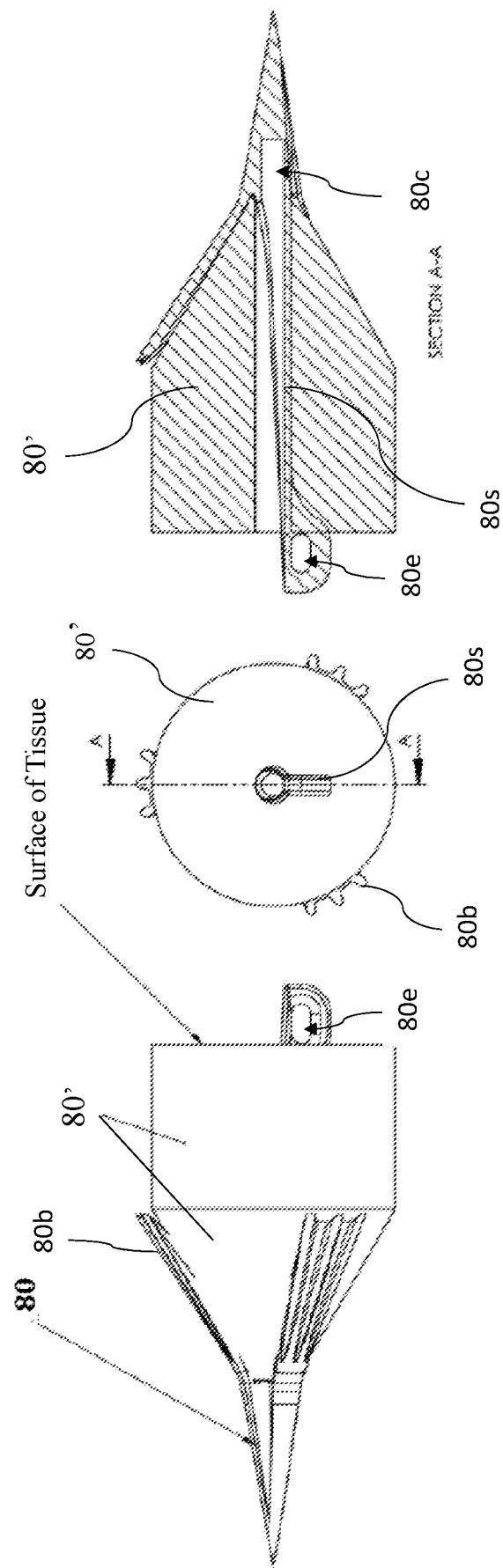


FIG. 5C

FIG. 5D

FIG. 5E

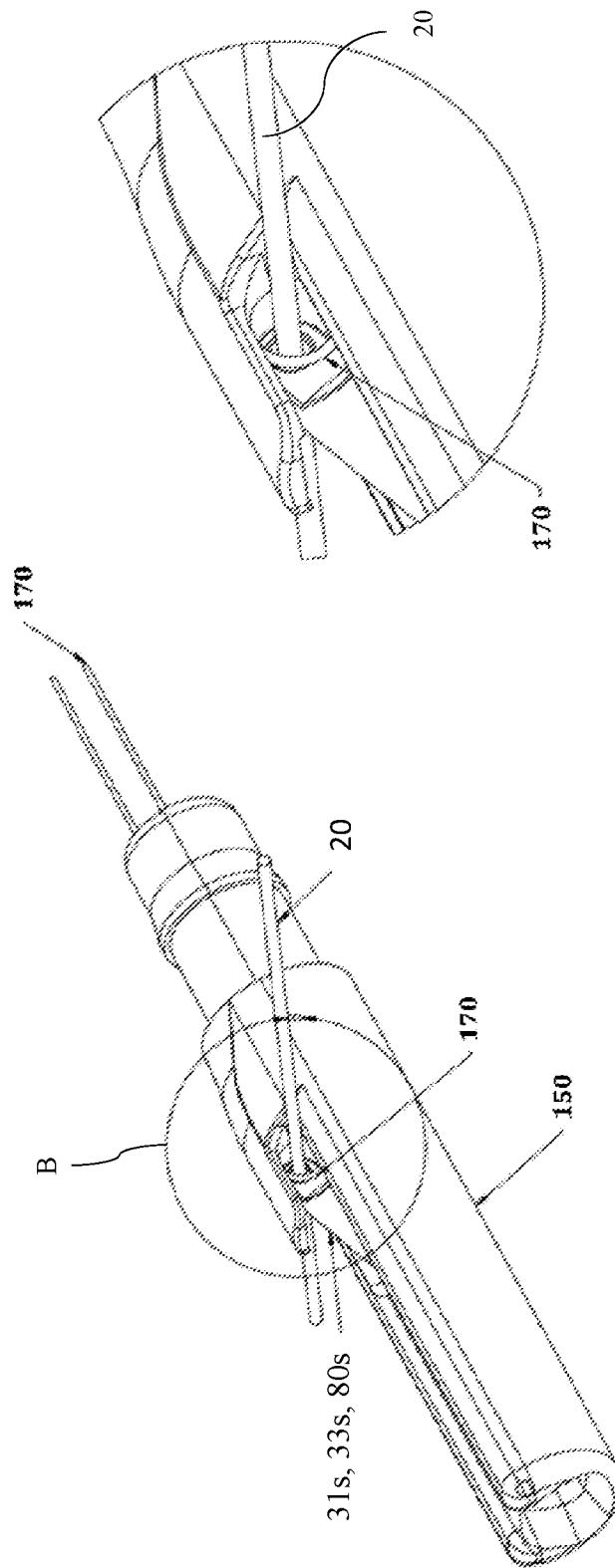
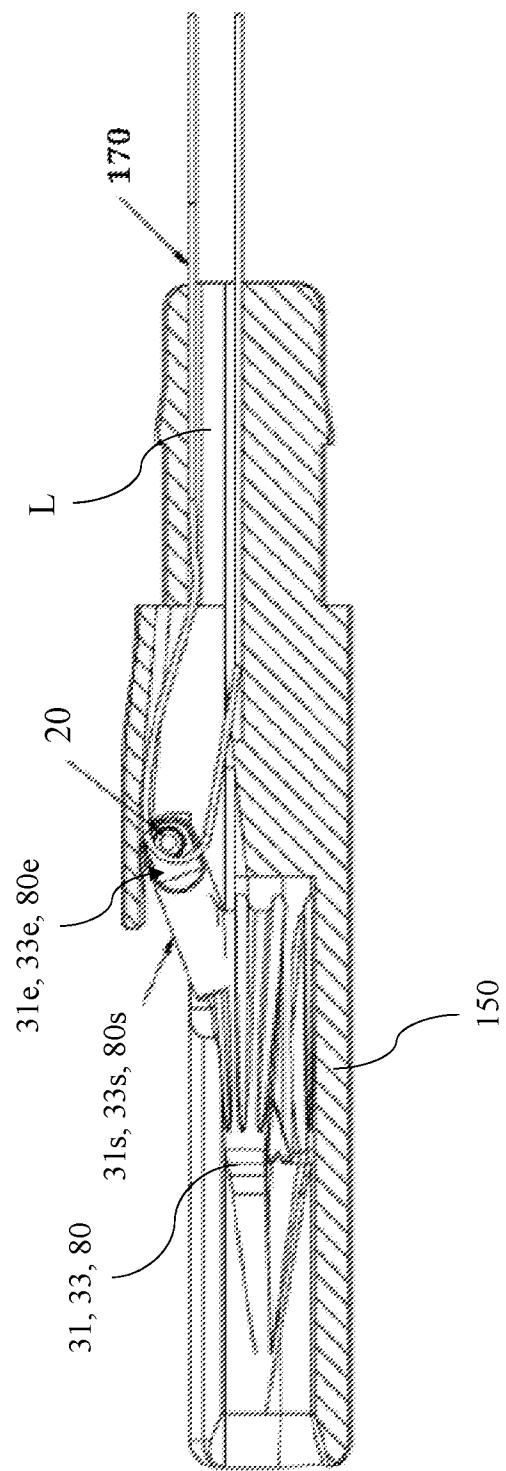


FIG. 6A

FIG. 6B

Detail B



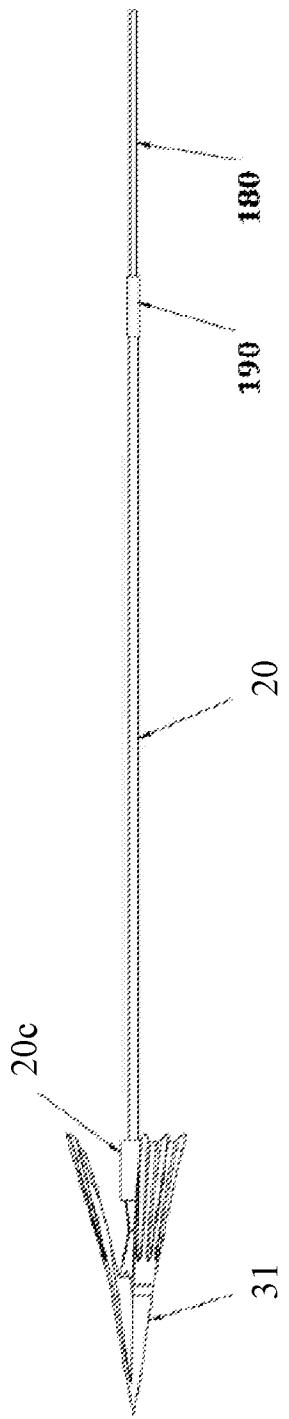


FIG. 6D

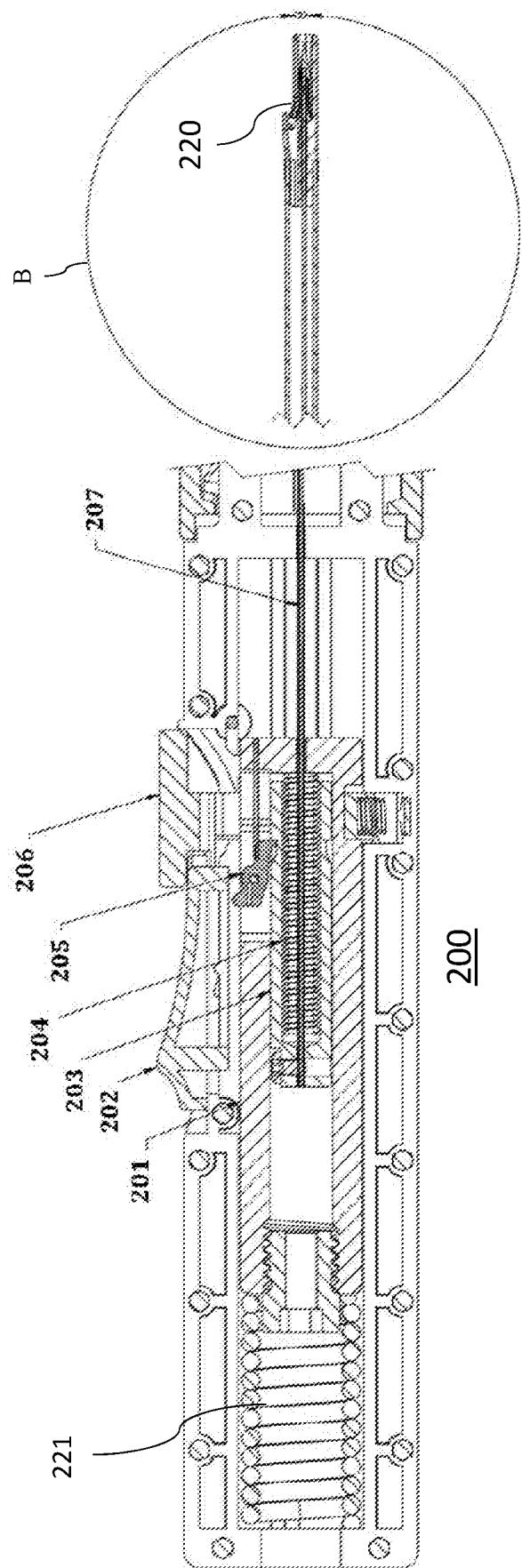


FIG. 7A

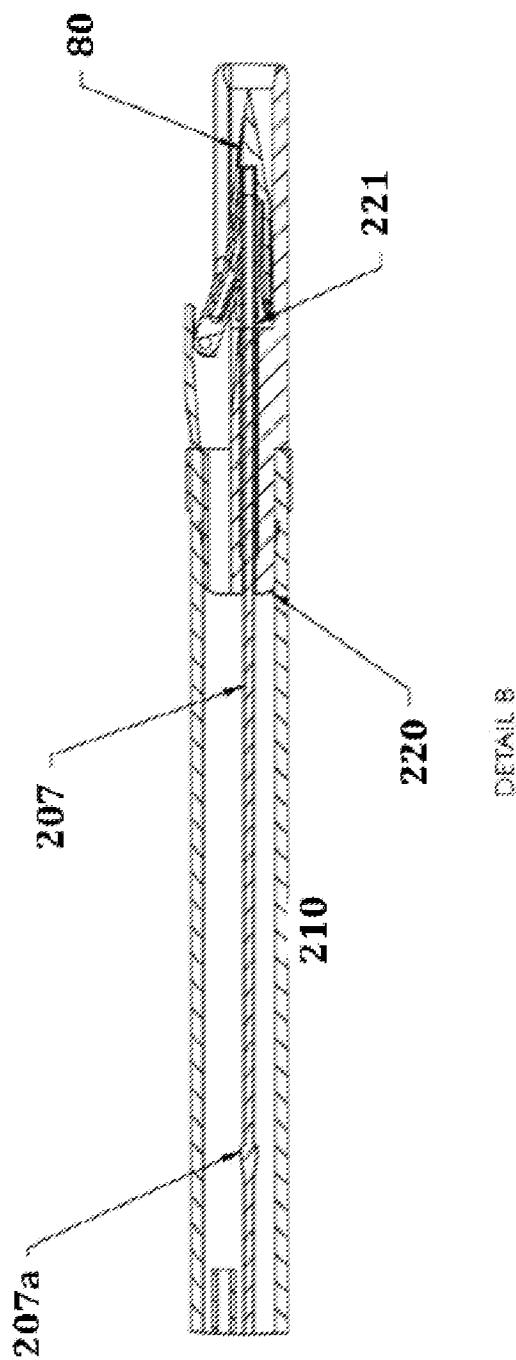


FIG. 7B

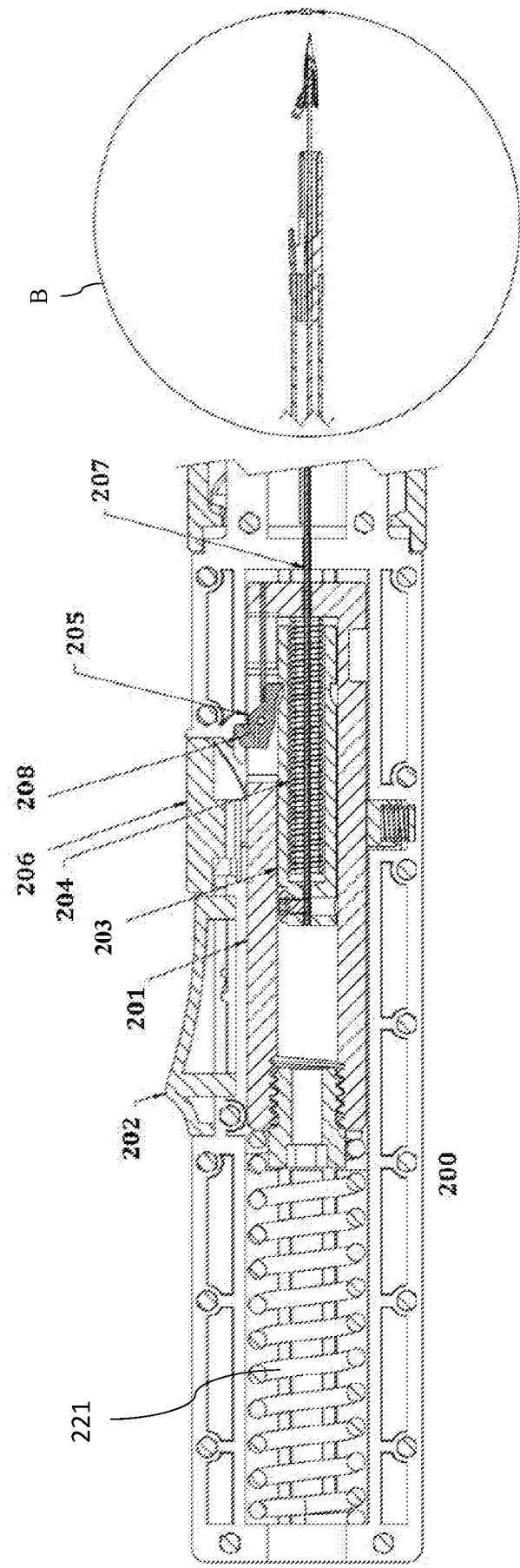


FIG. 7C

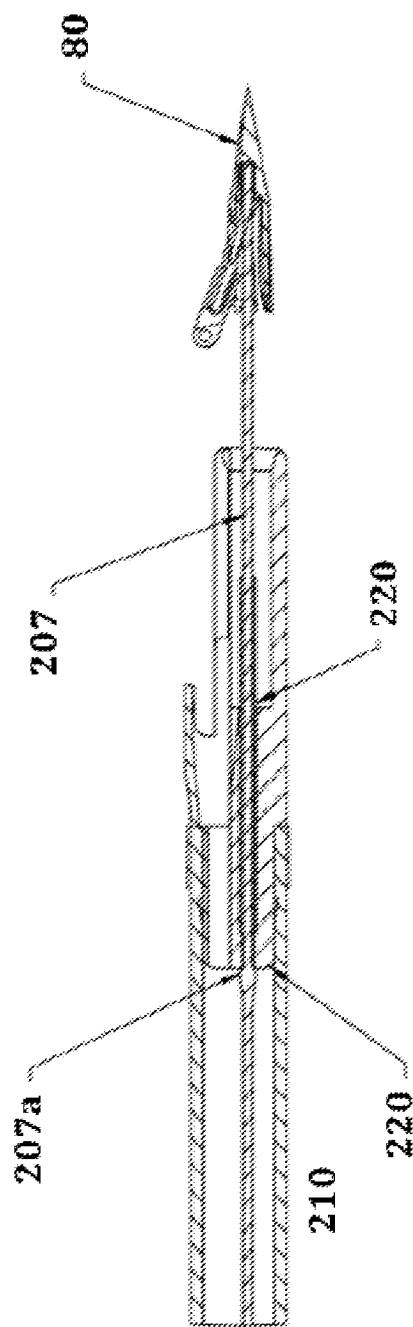


FIG. 7D

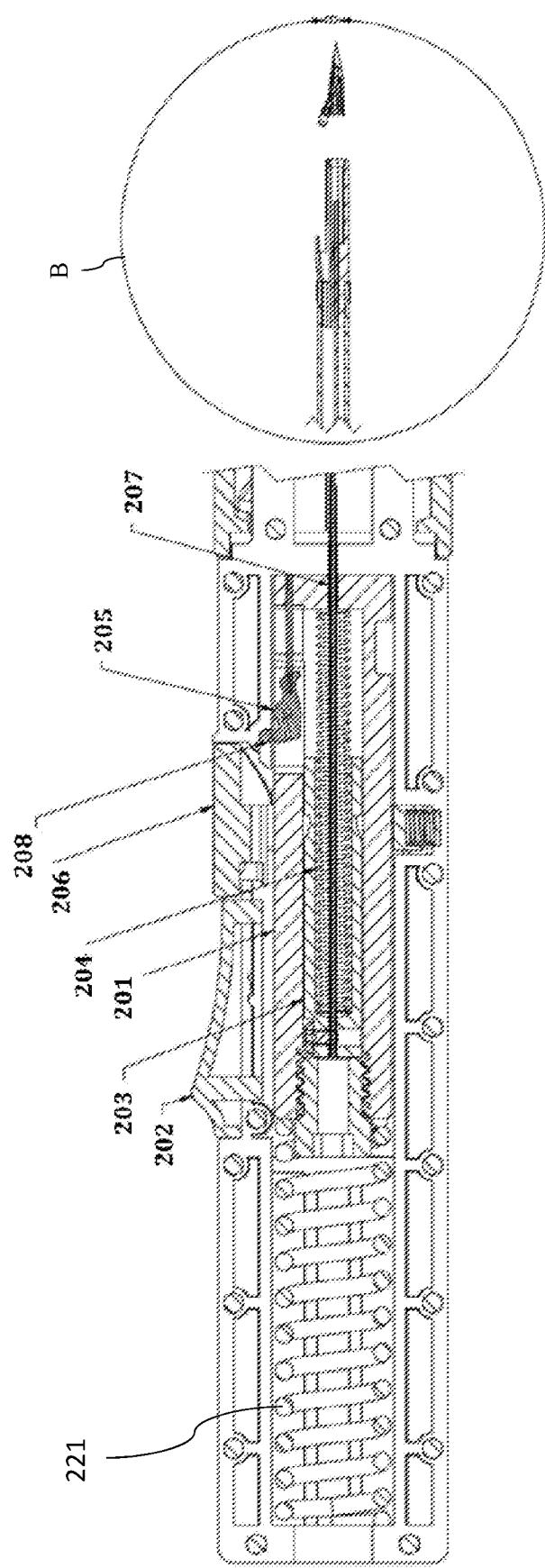


FIG. 7E

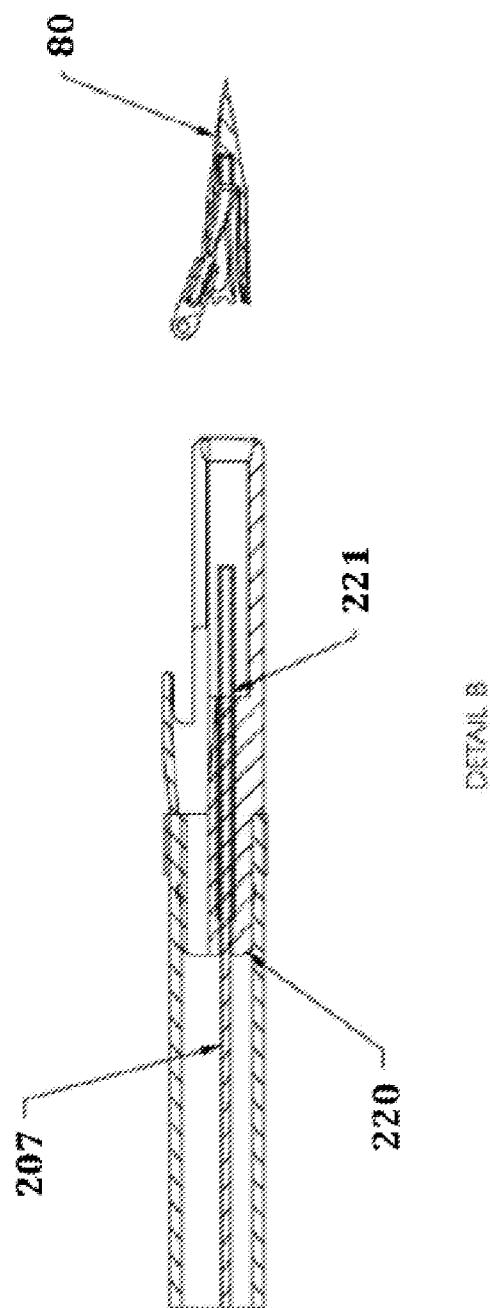


FIG. 7F

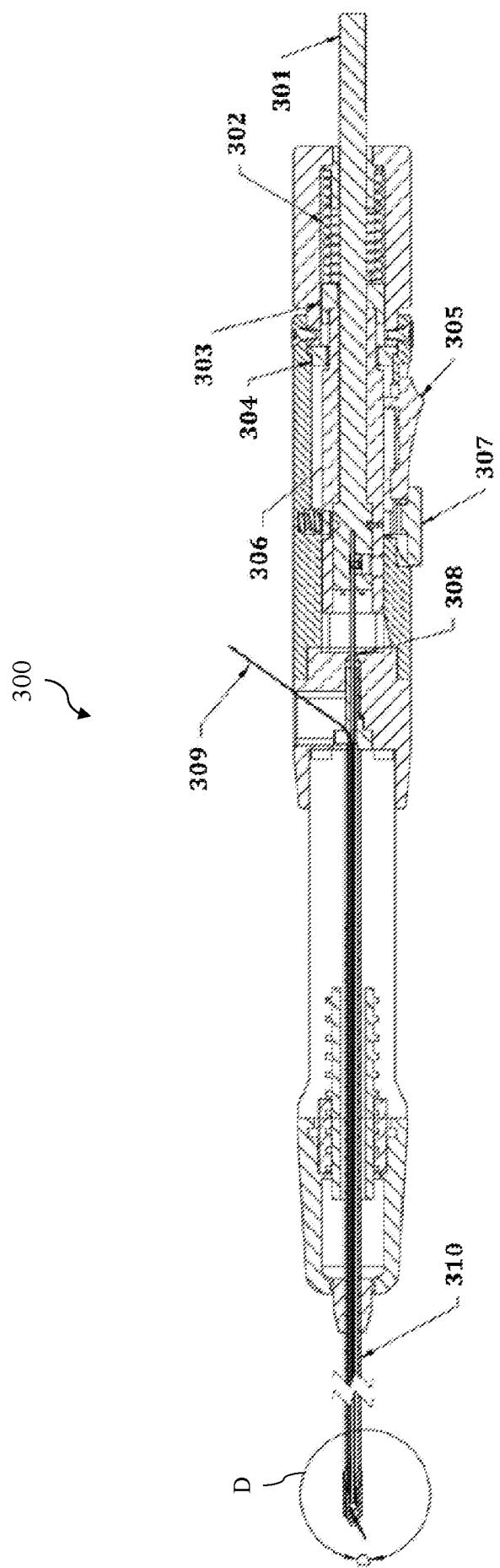


FIG. 8A

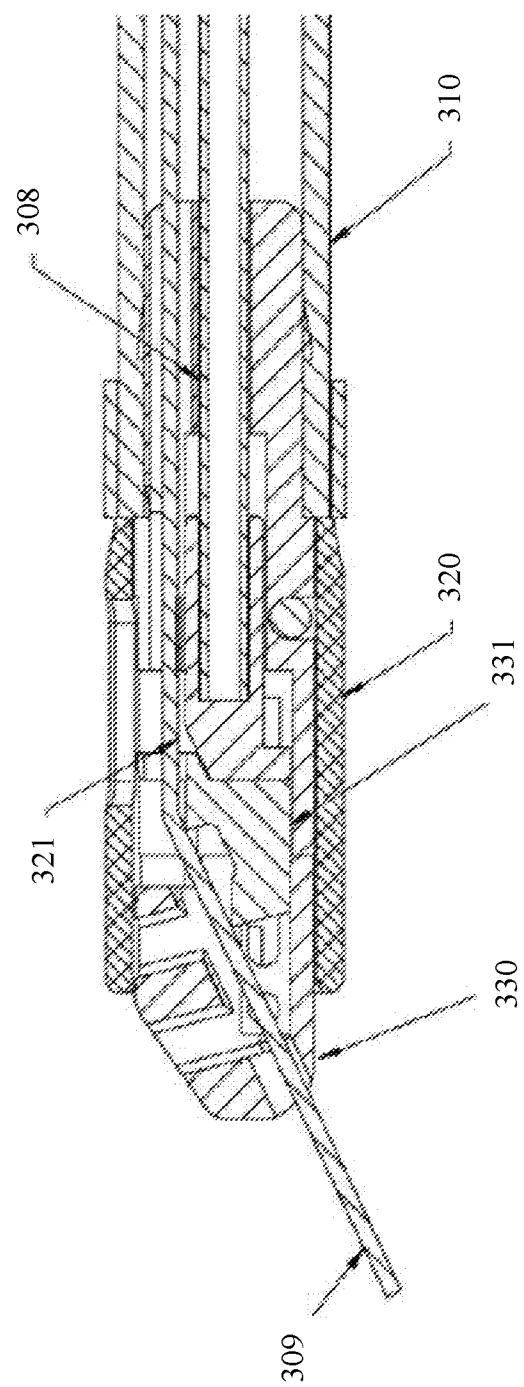


FIG. 8B

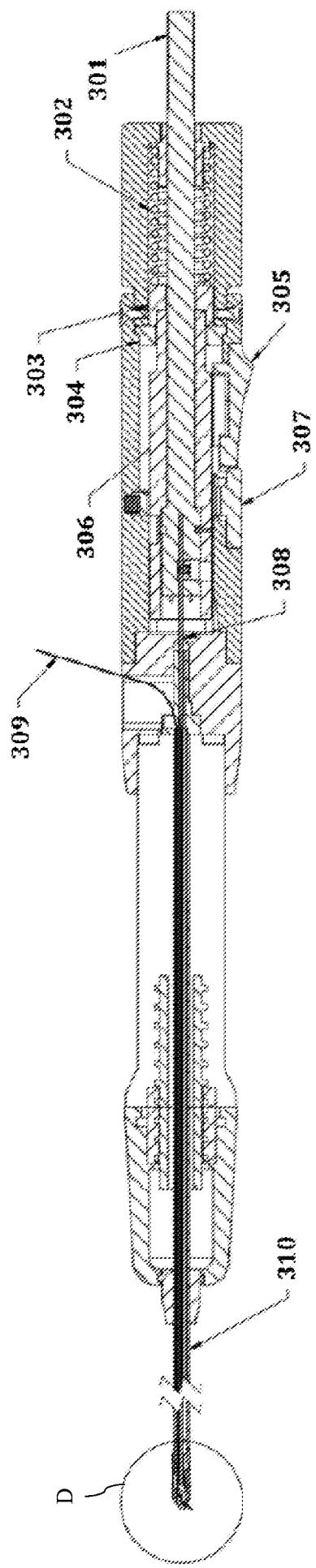


FIG. 8C

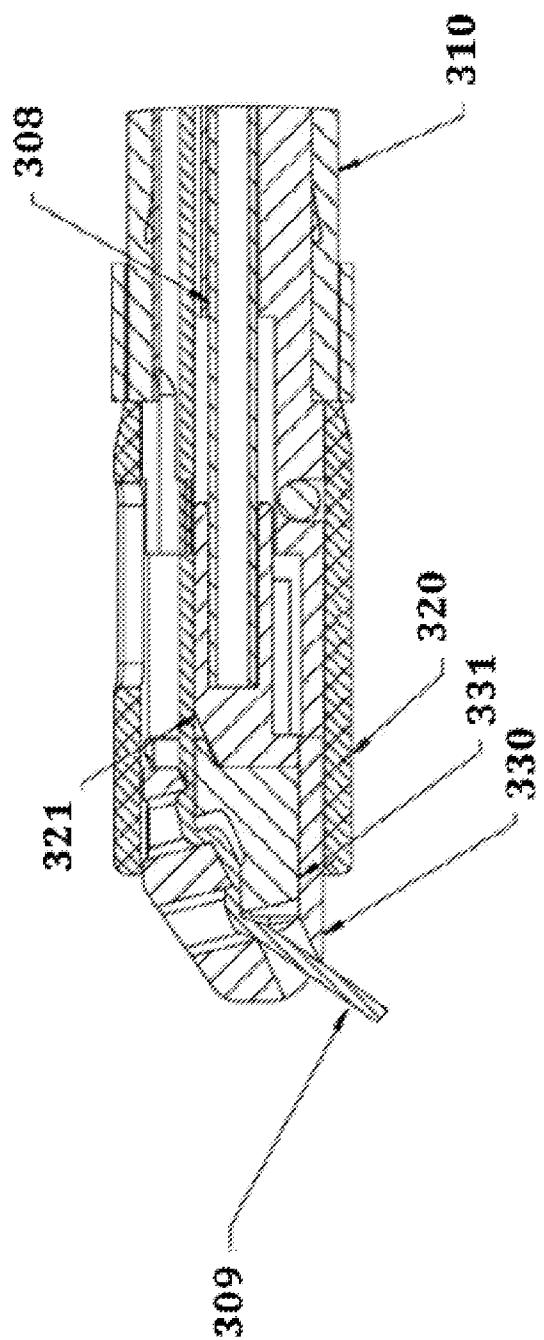


FIG. 8D

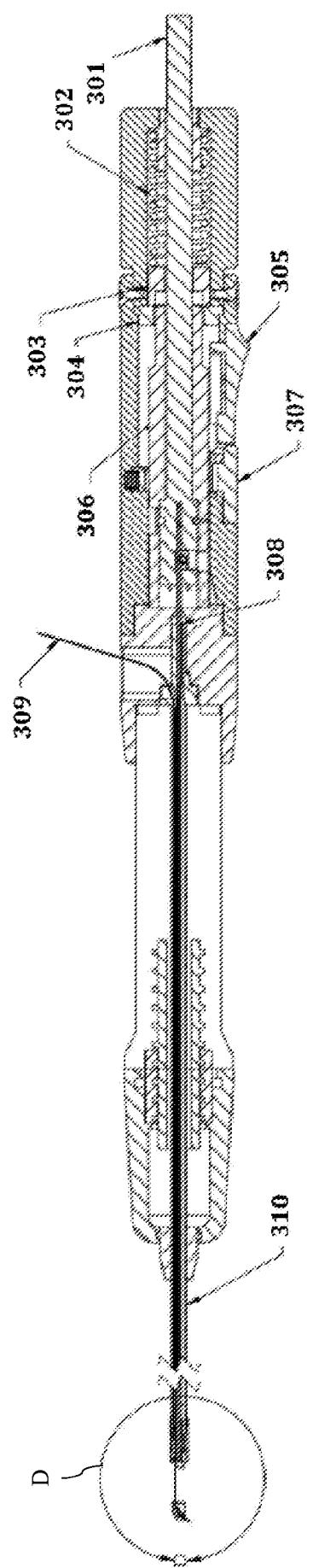


FIG. 8E

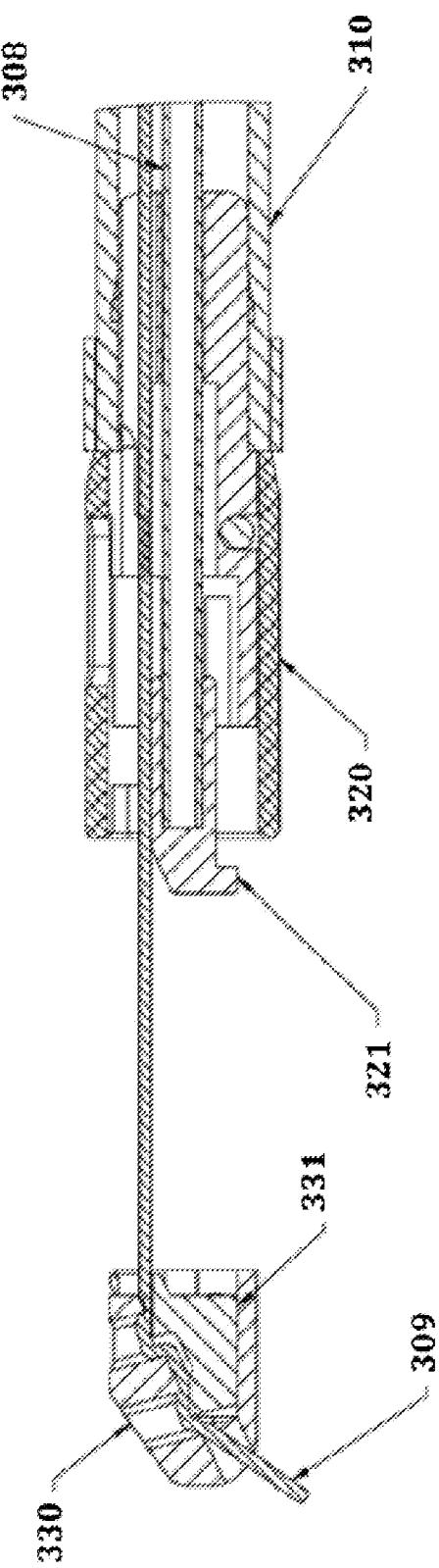


FIG. 8F

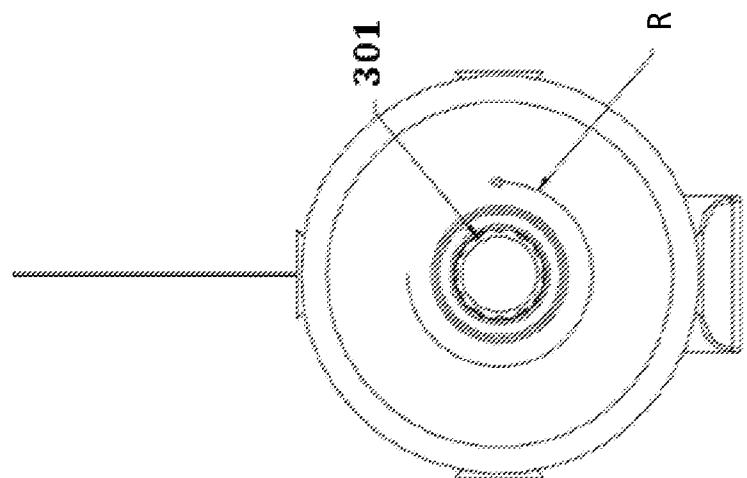


FIG. 8H

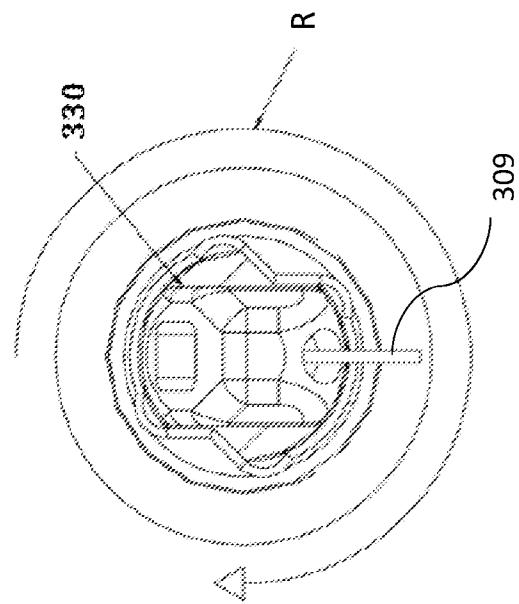


FIG. 8G

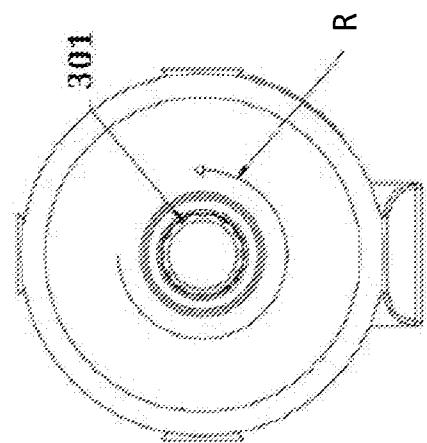


FIG. 8J

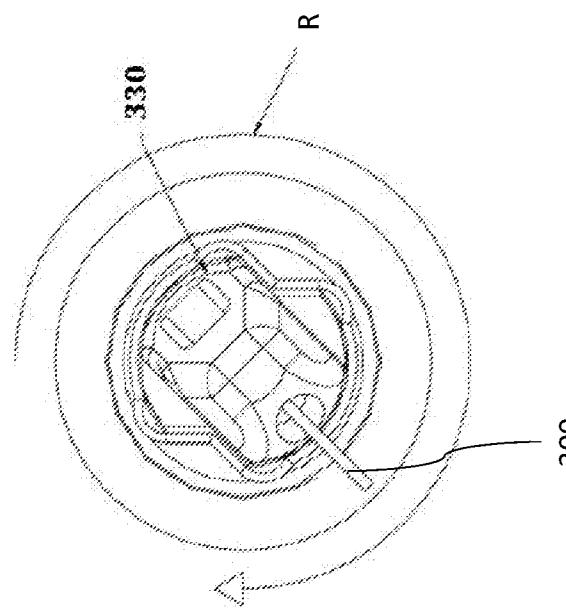


FIG. 8I

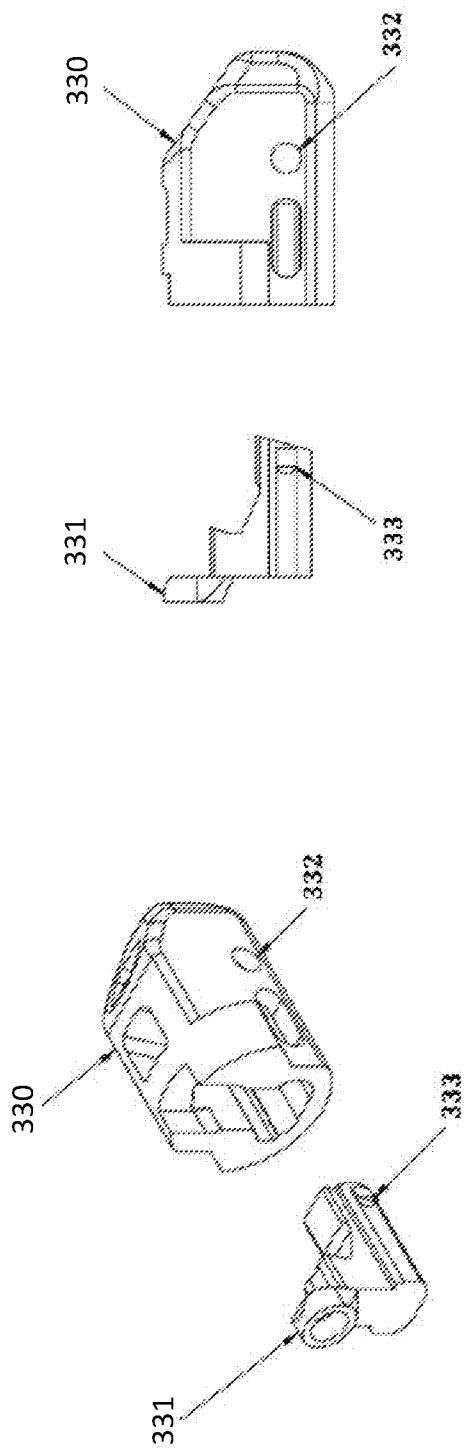


FIG. 8K



FIG. 8L

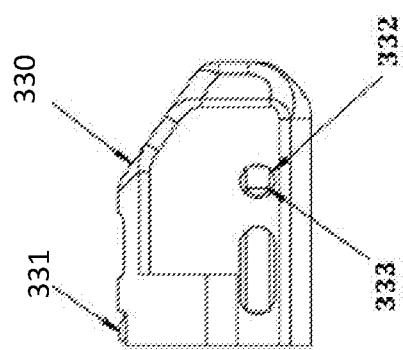


FIG. 8M

FIG. 8N

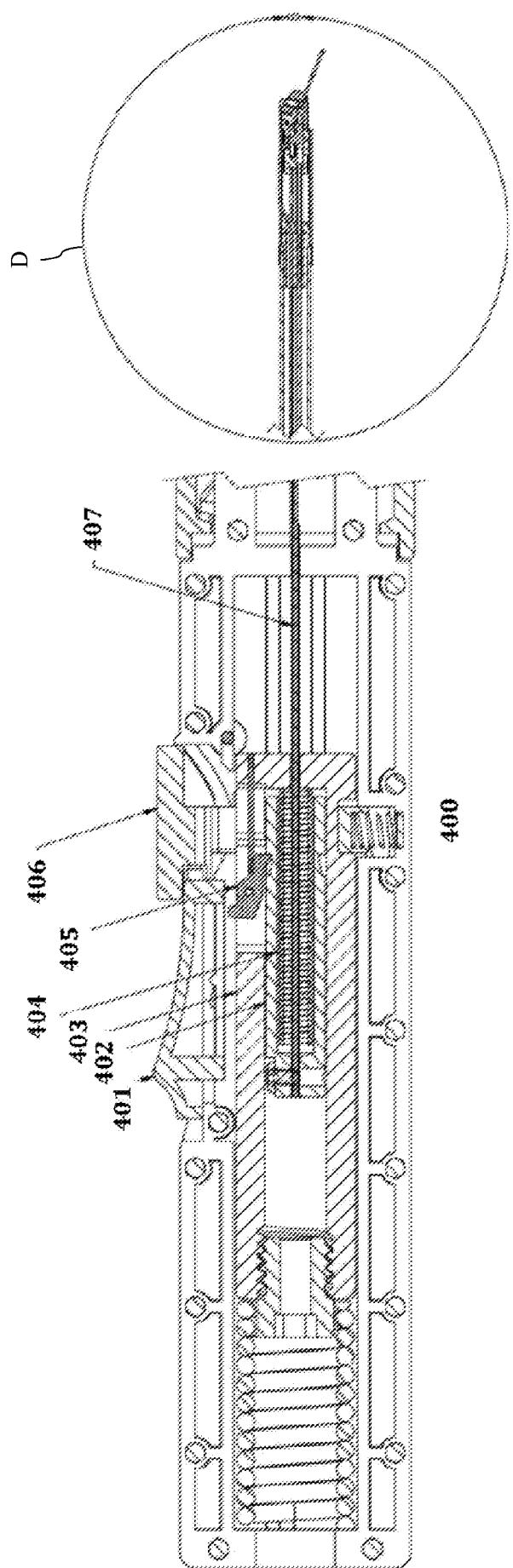


FIG. 9A

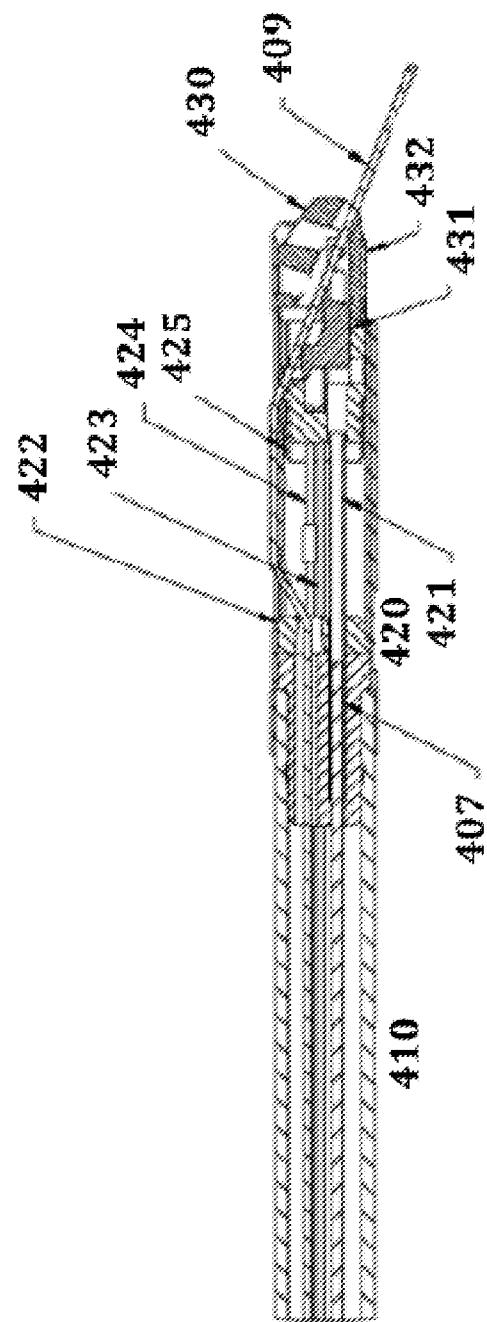


FIG. 9B

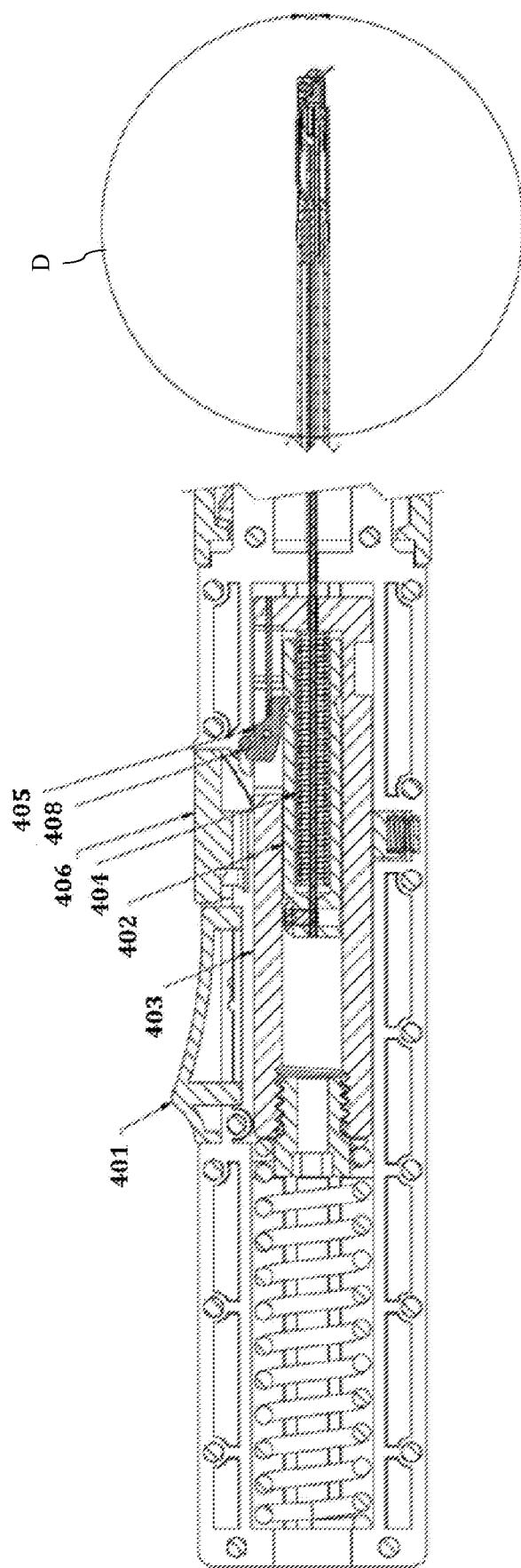


FIG. 9C

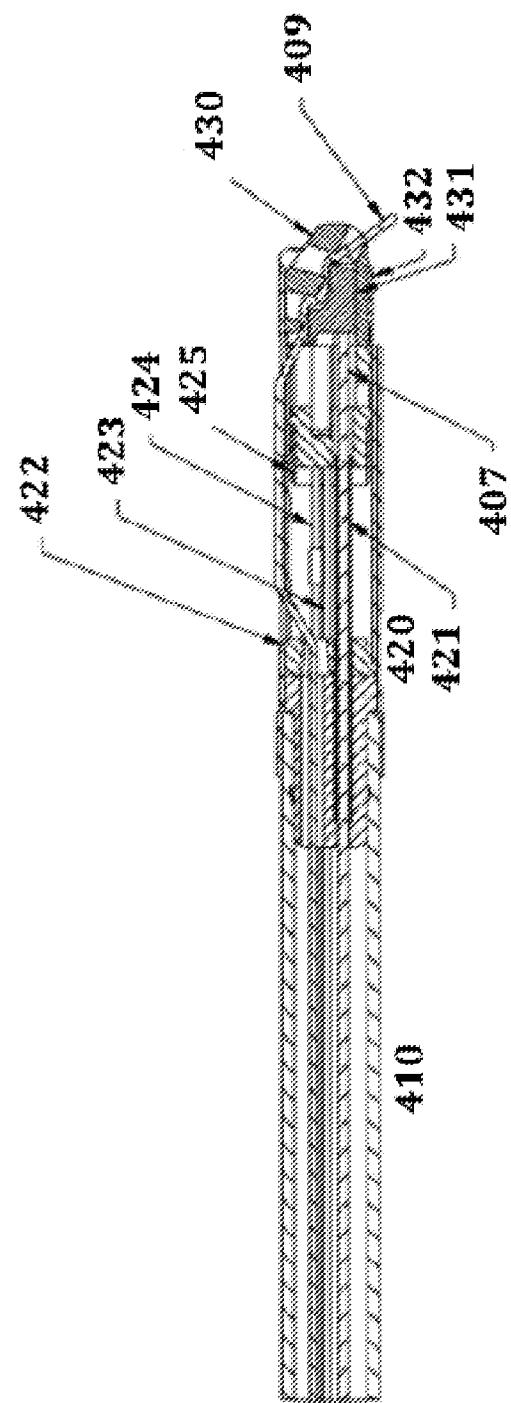
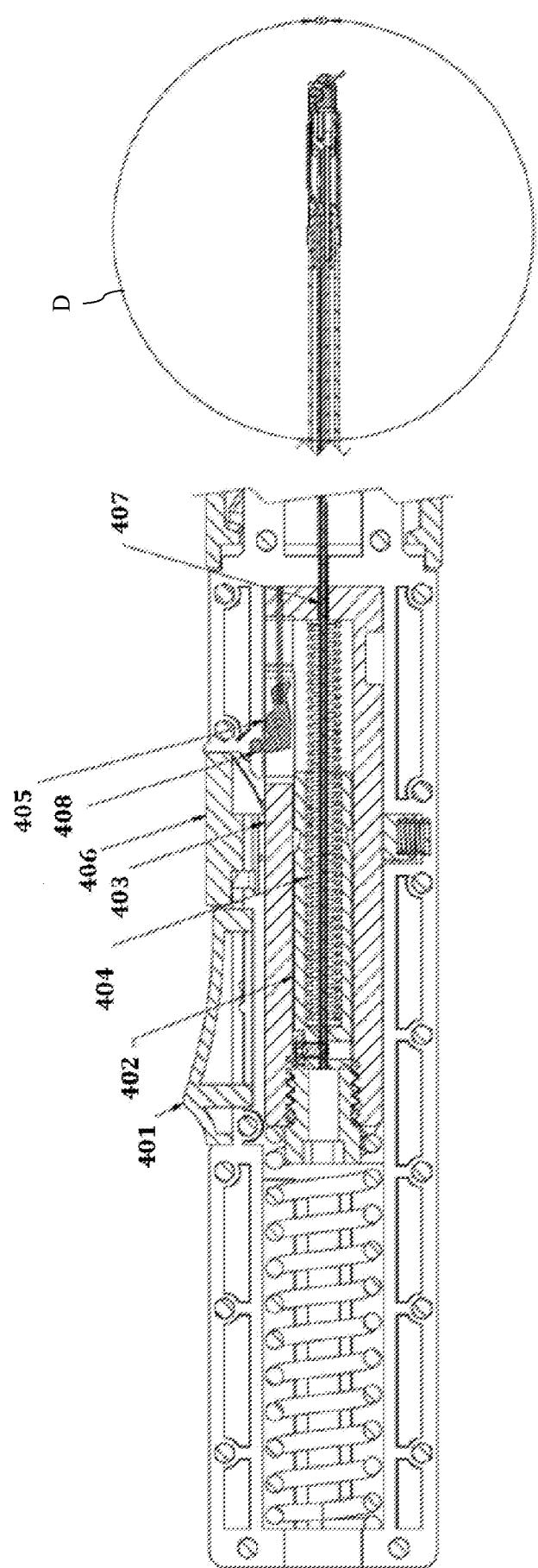


FIG. 9D



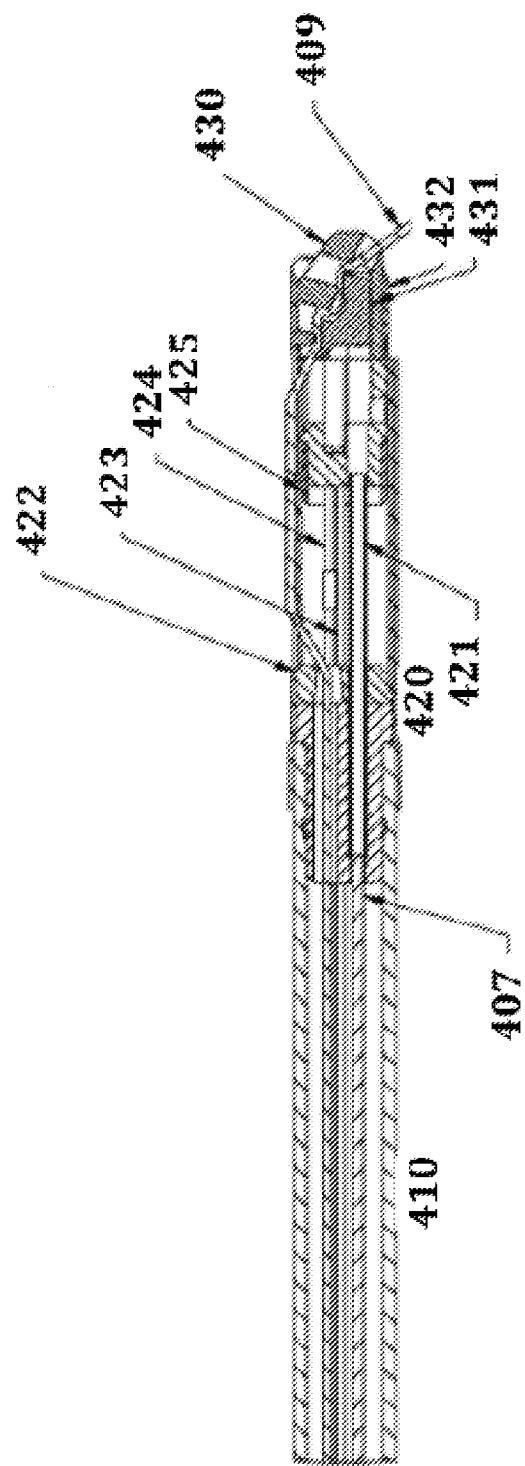


FIG. 9F

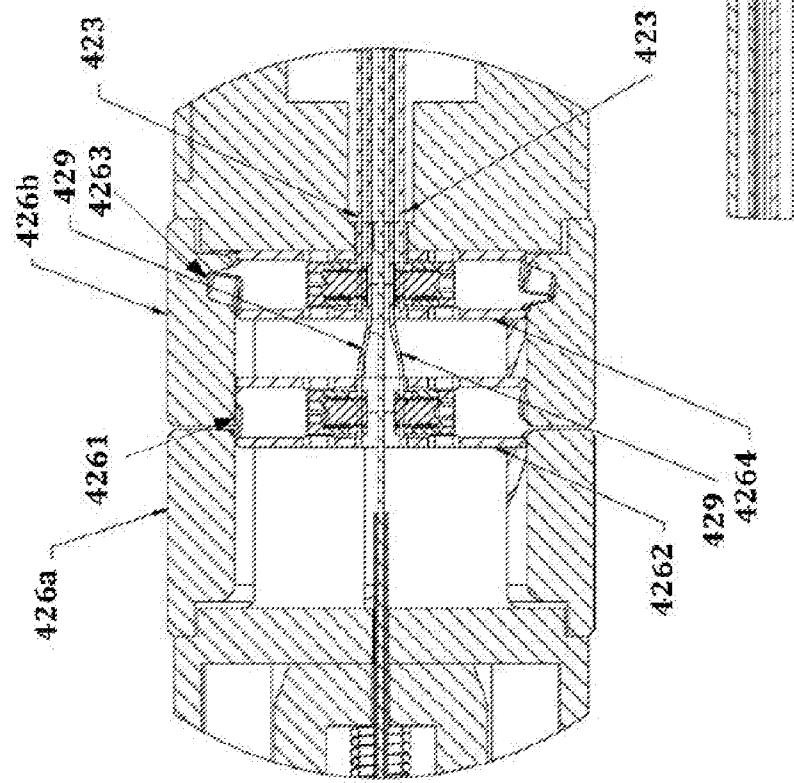


FIG. 9G

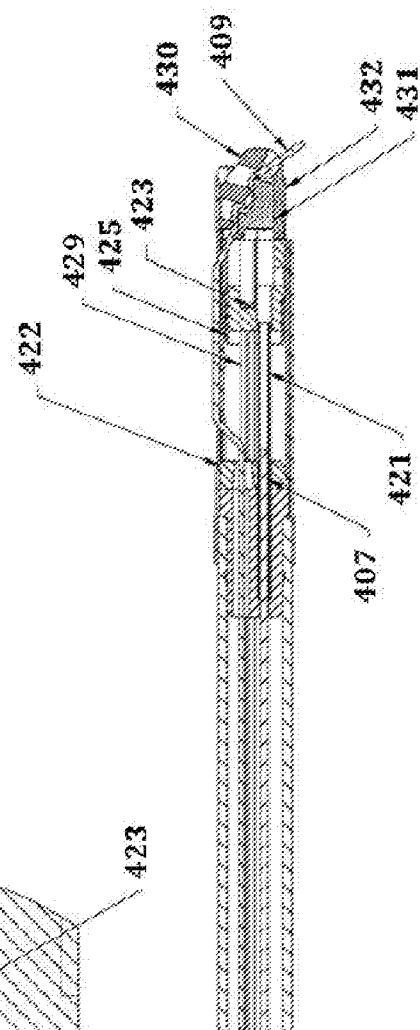


FIG. 9H

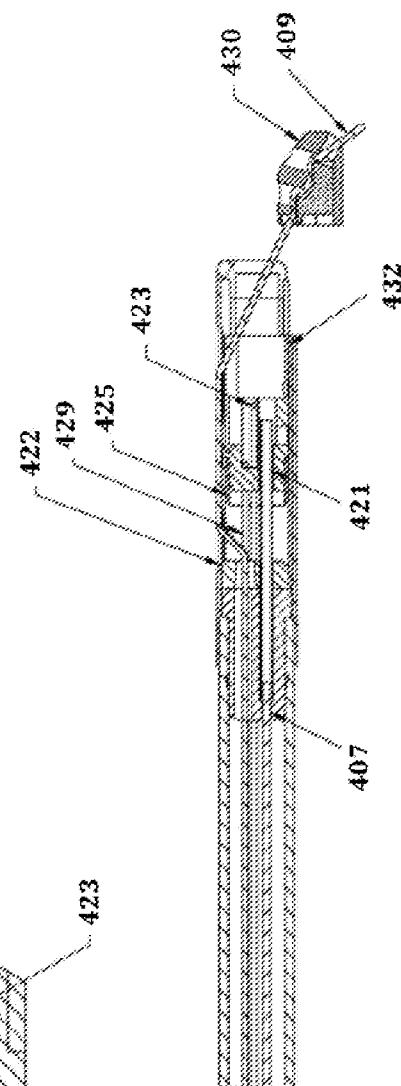
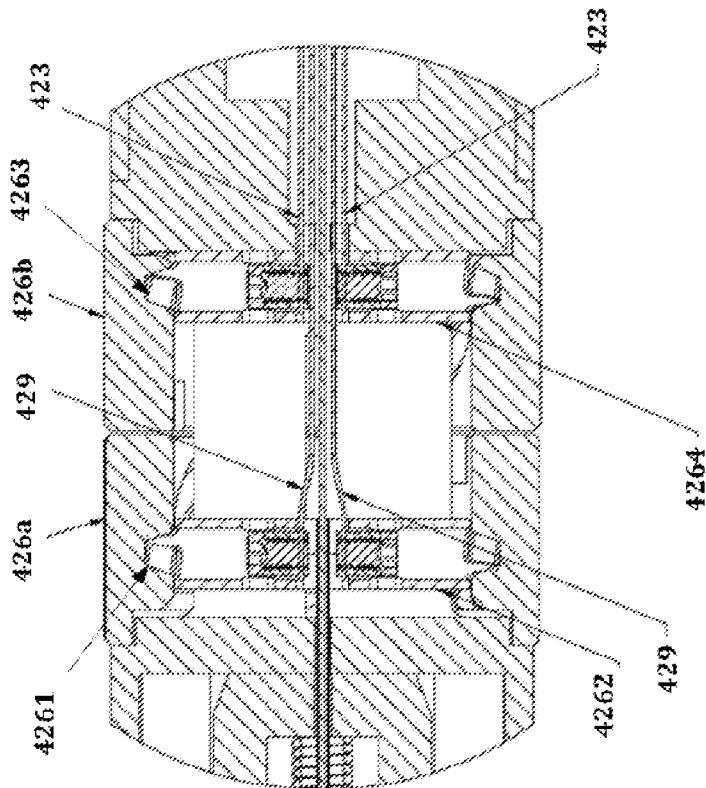


FIG. 9K

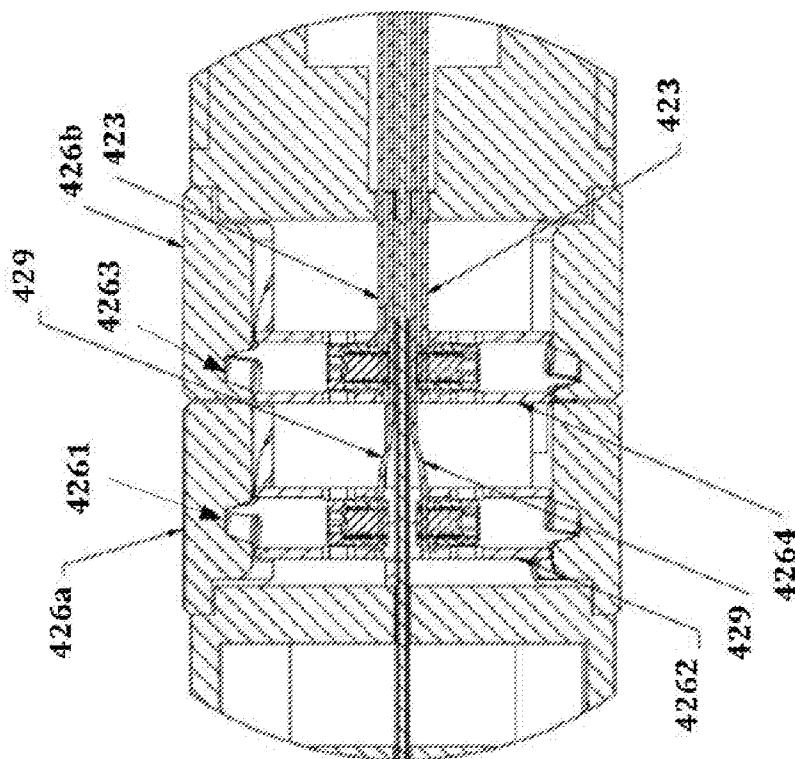
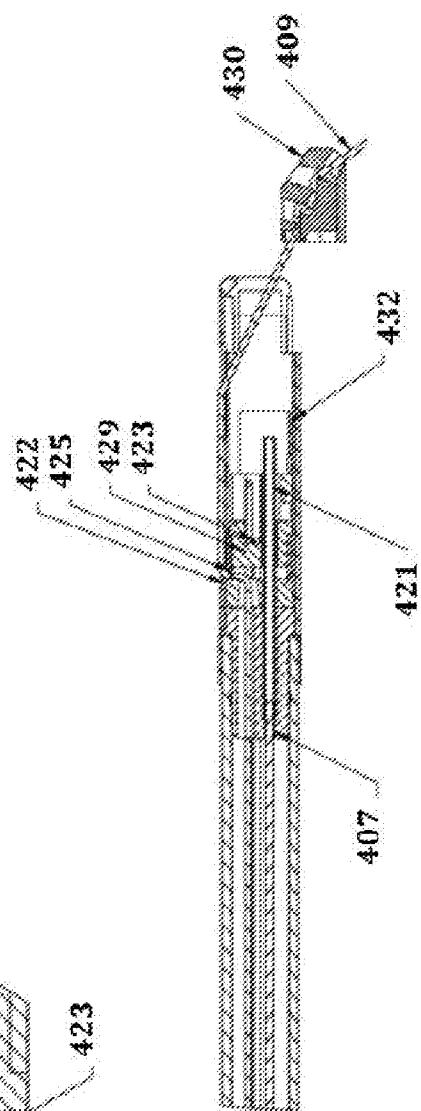
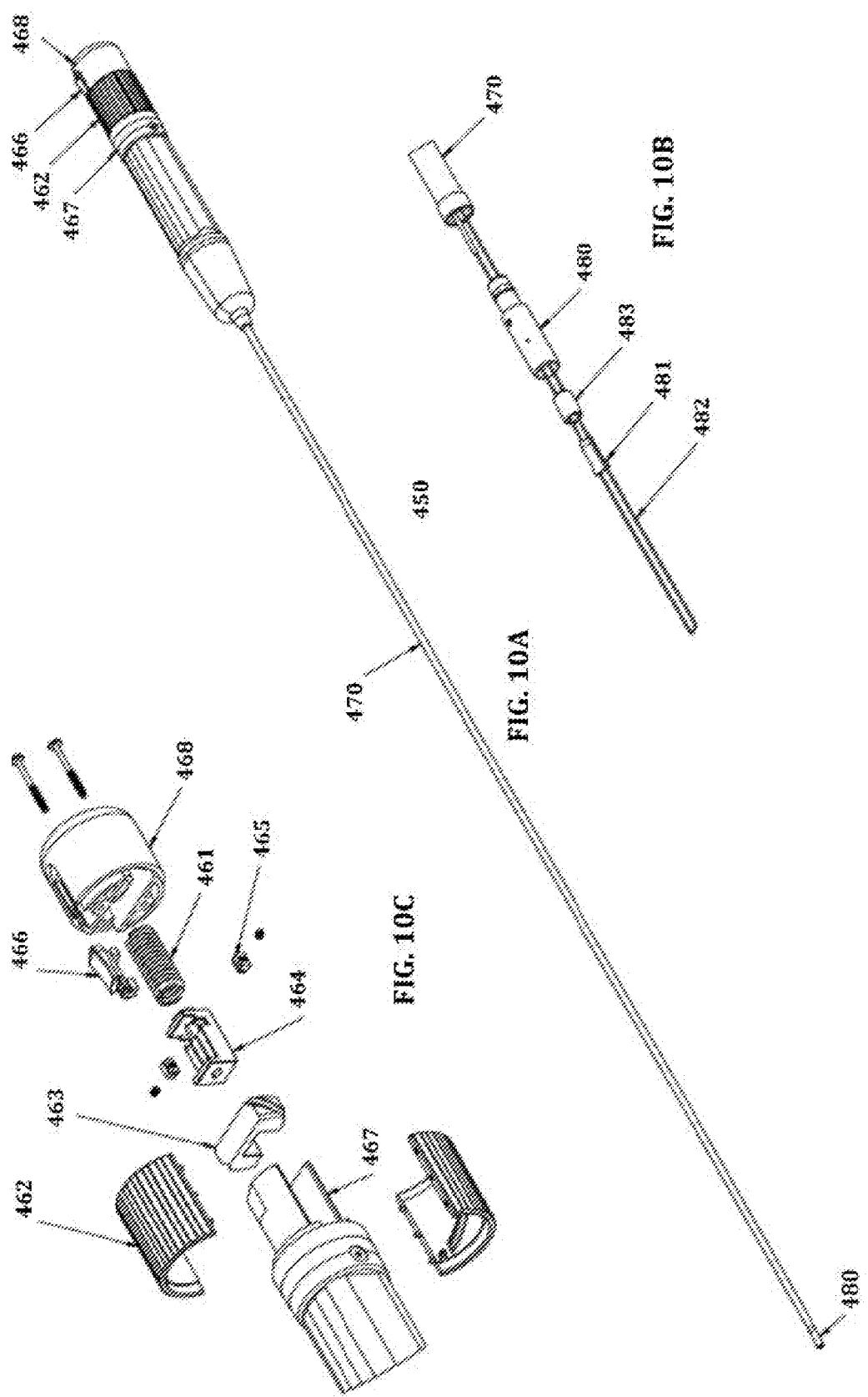


FIG. 9L





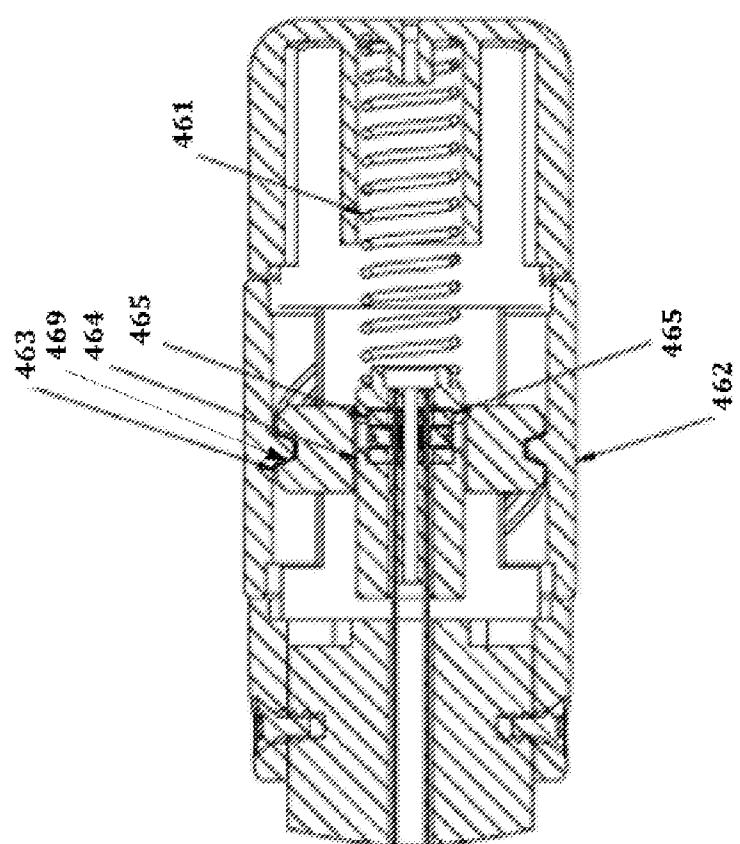


FIG. 10E

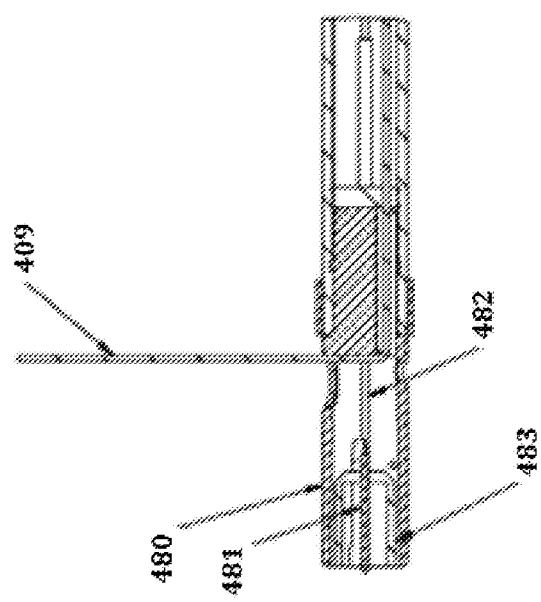


FIG. 10D

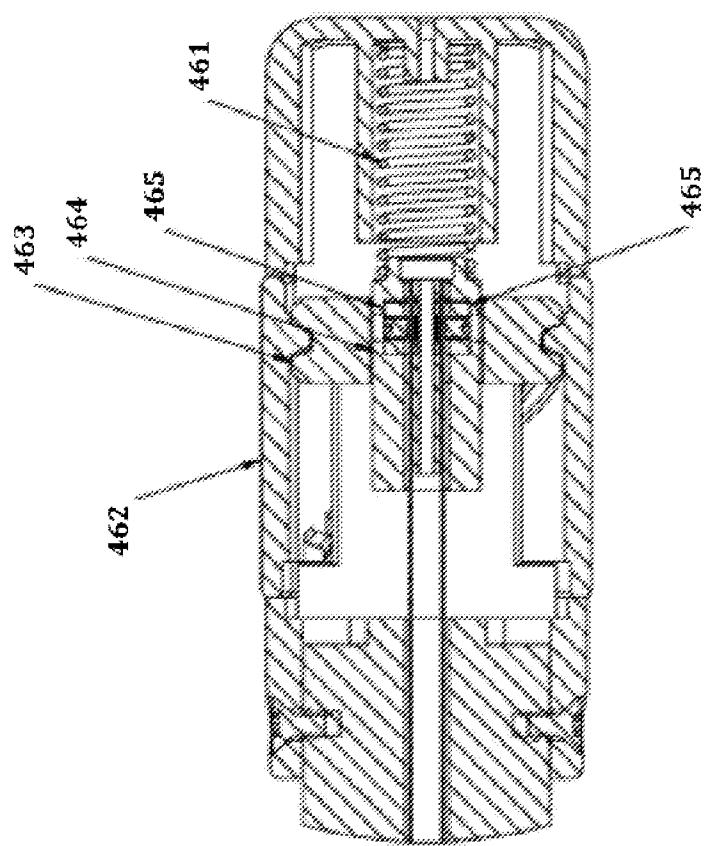


FIG. 10G

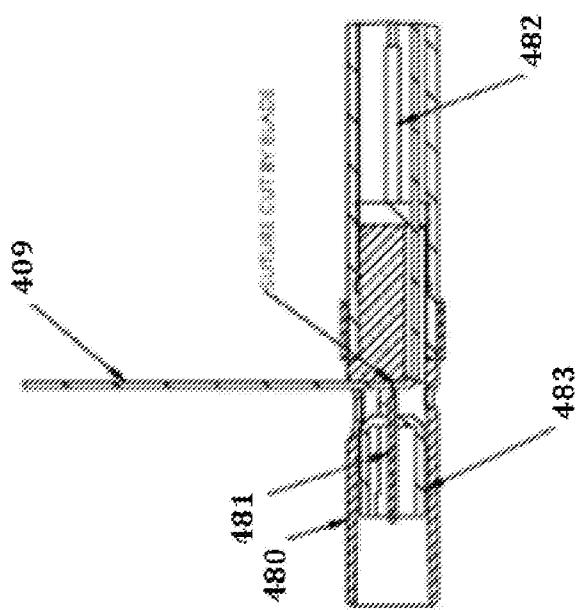


FIG. 10F

FIG. 11A

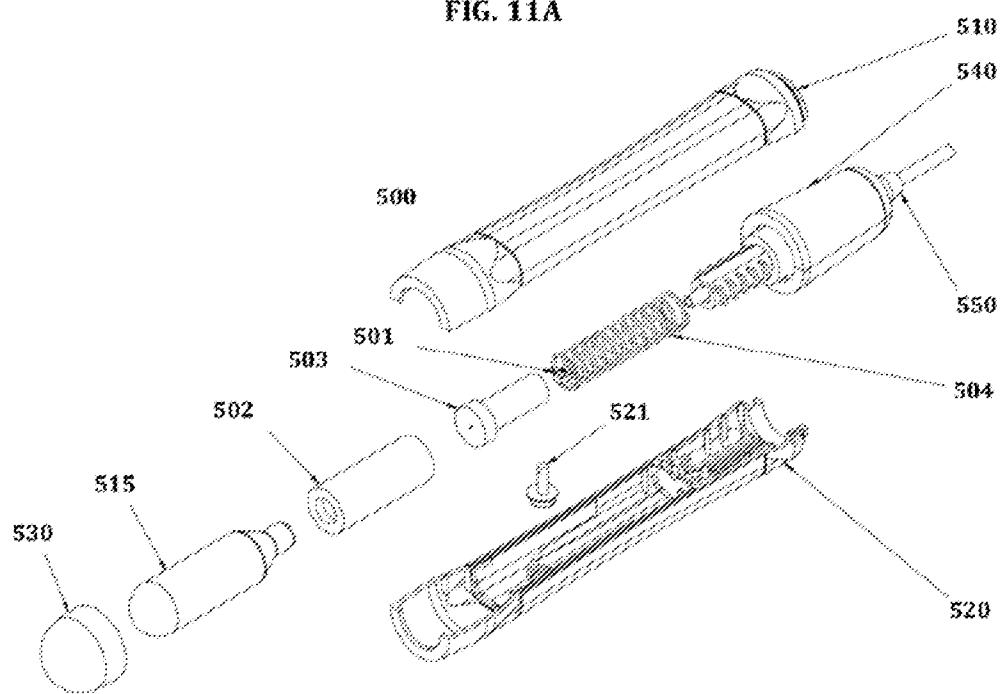


FIG. 11B

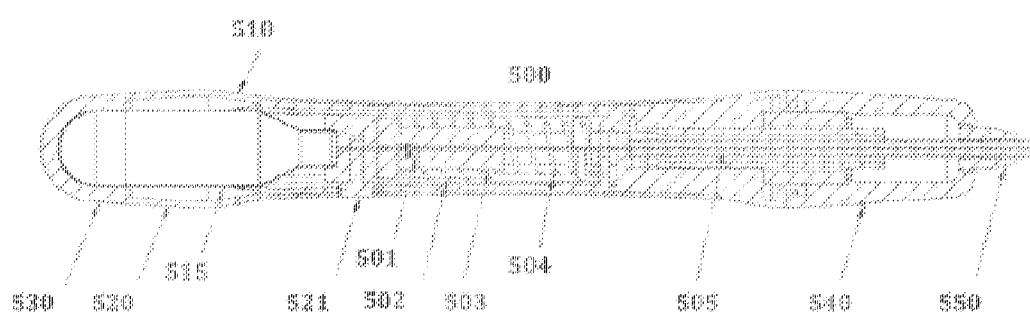


FIG. 12A

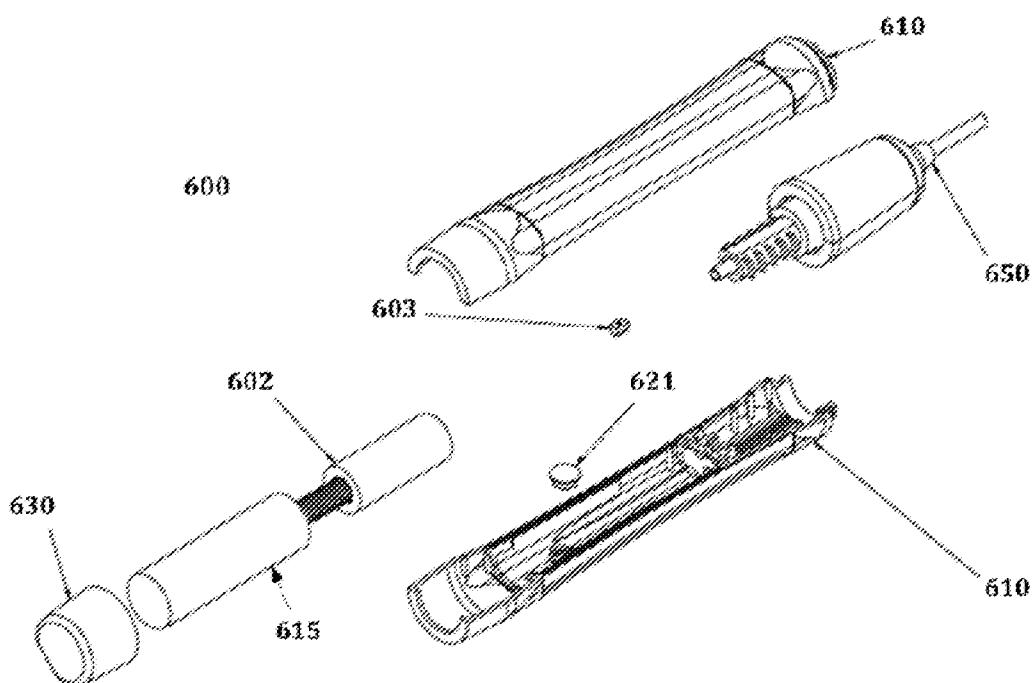


FIG. 12B

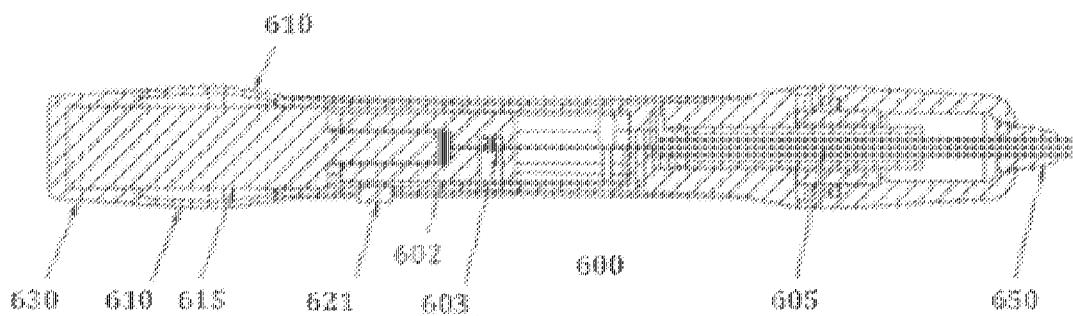


FIG. 13A

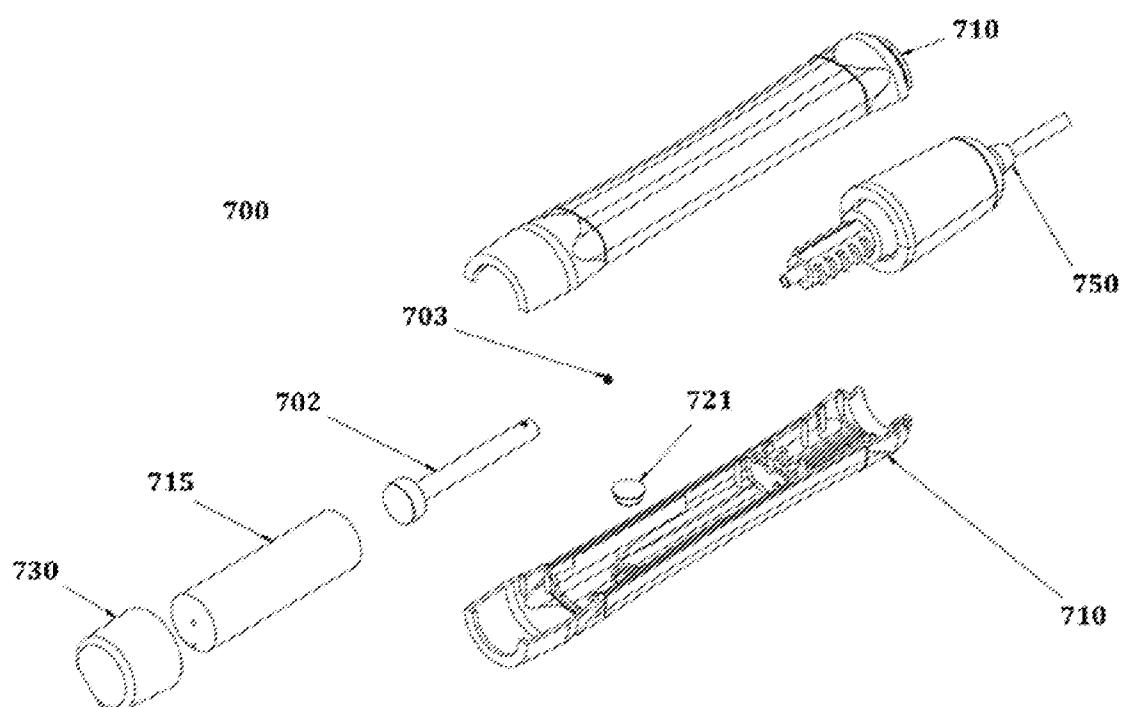


FIG. 133

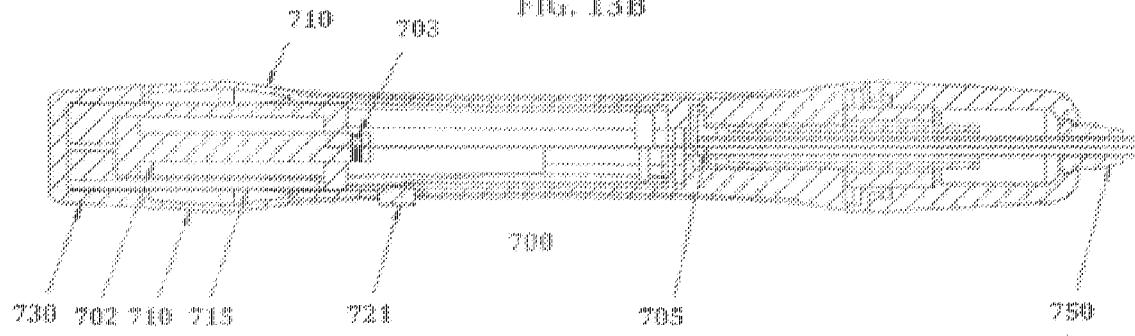


FIG. 14A

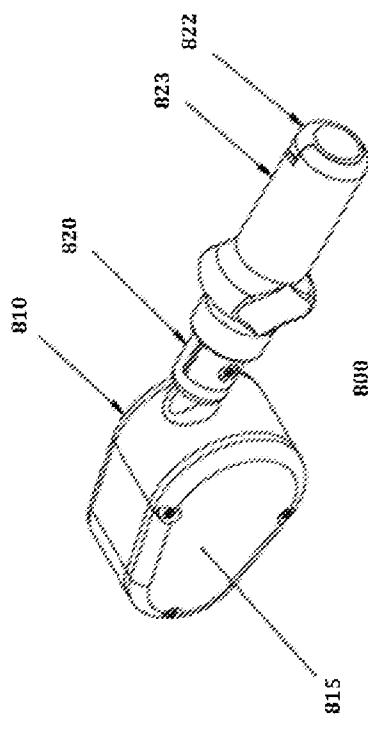


FIG. 14B

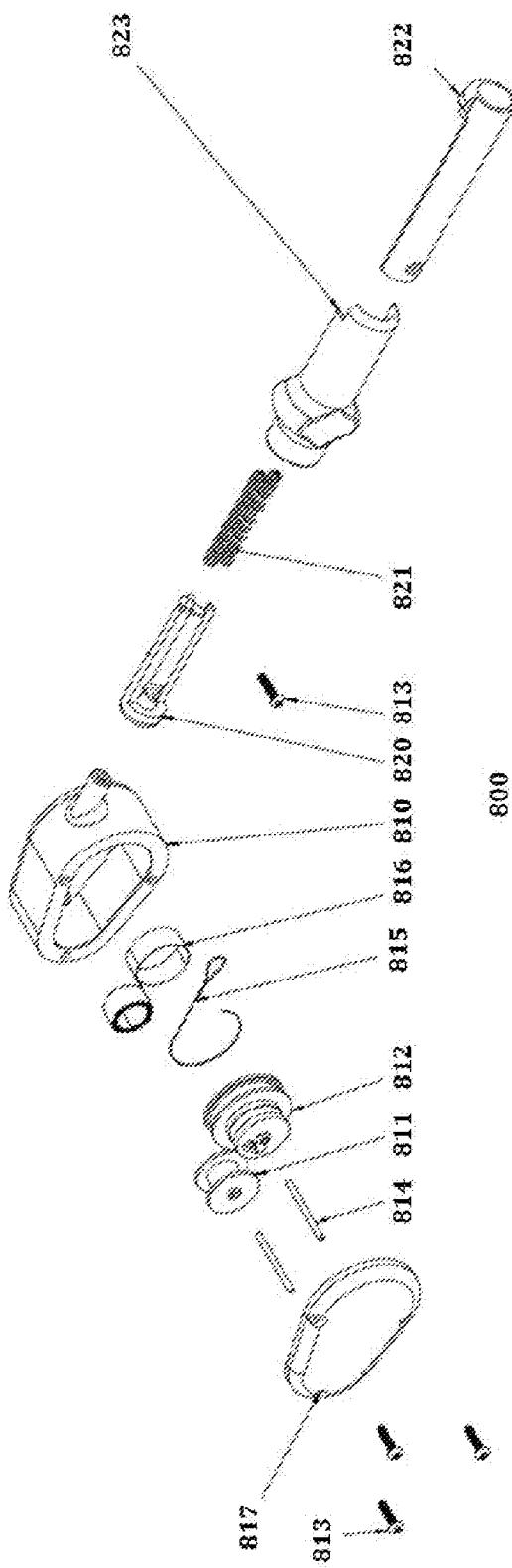


FIG. 14C

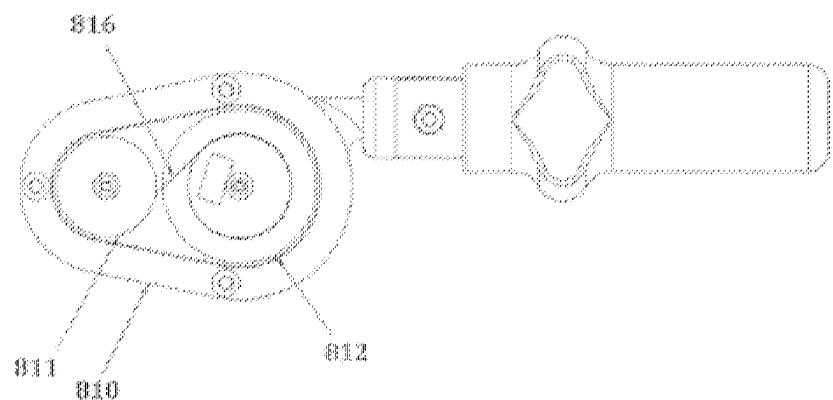


FIG. 14D

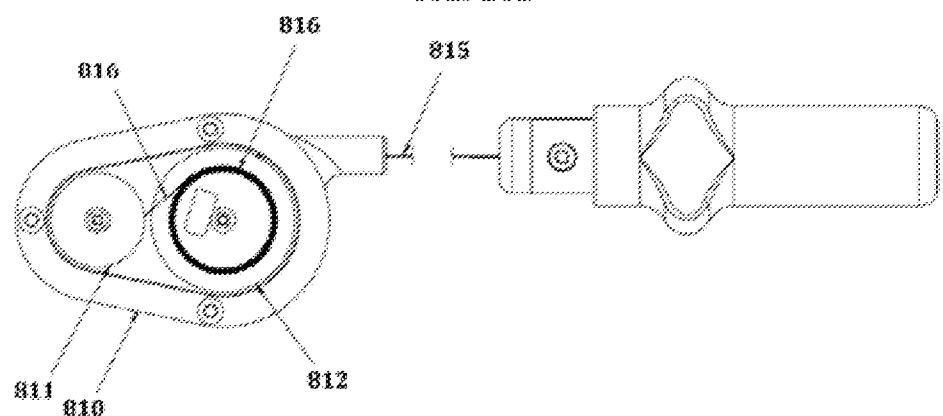


FIG. 14E

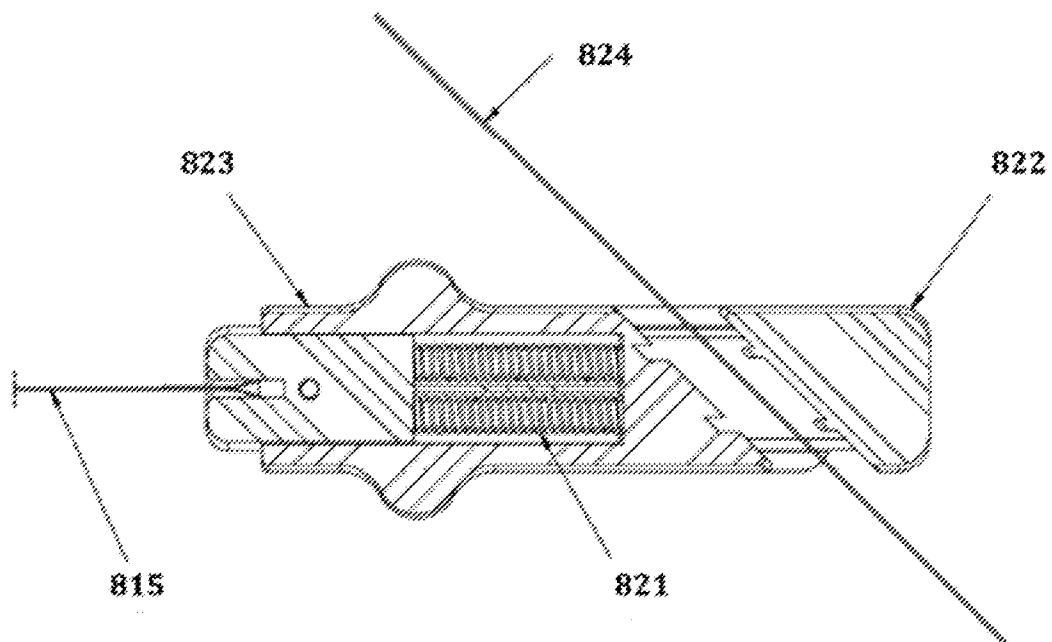
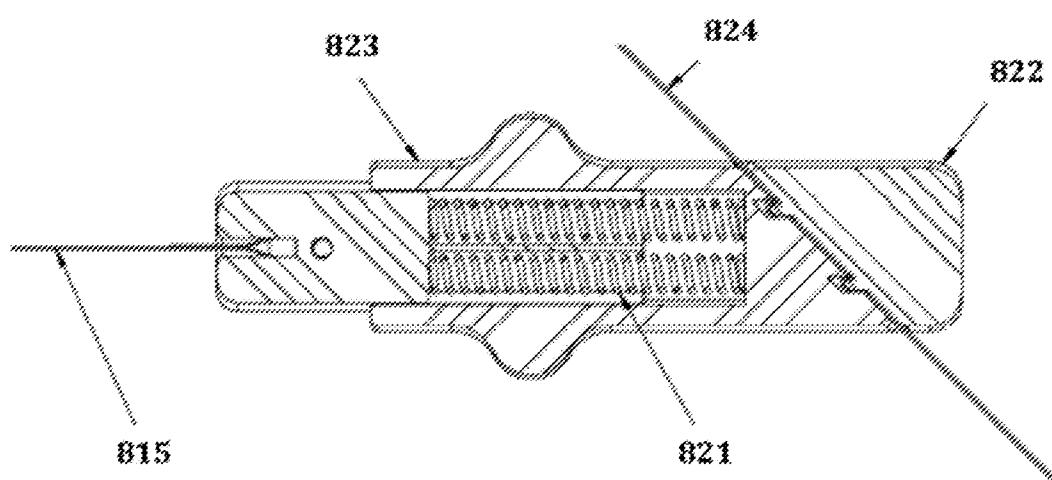
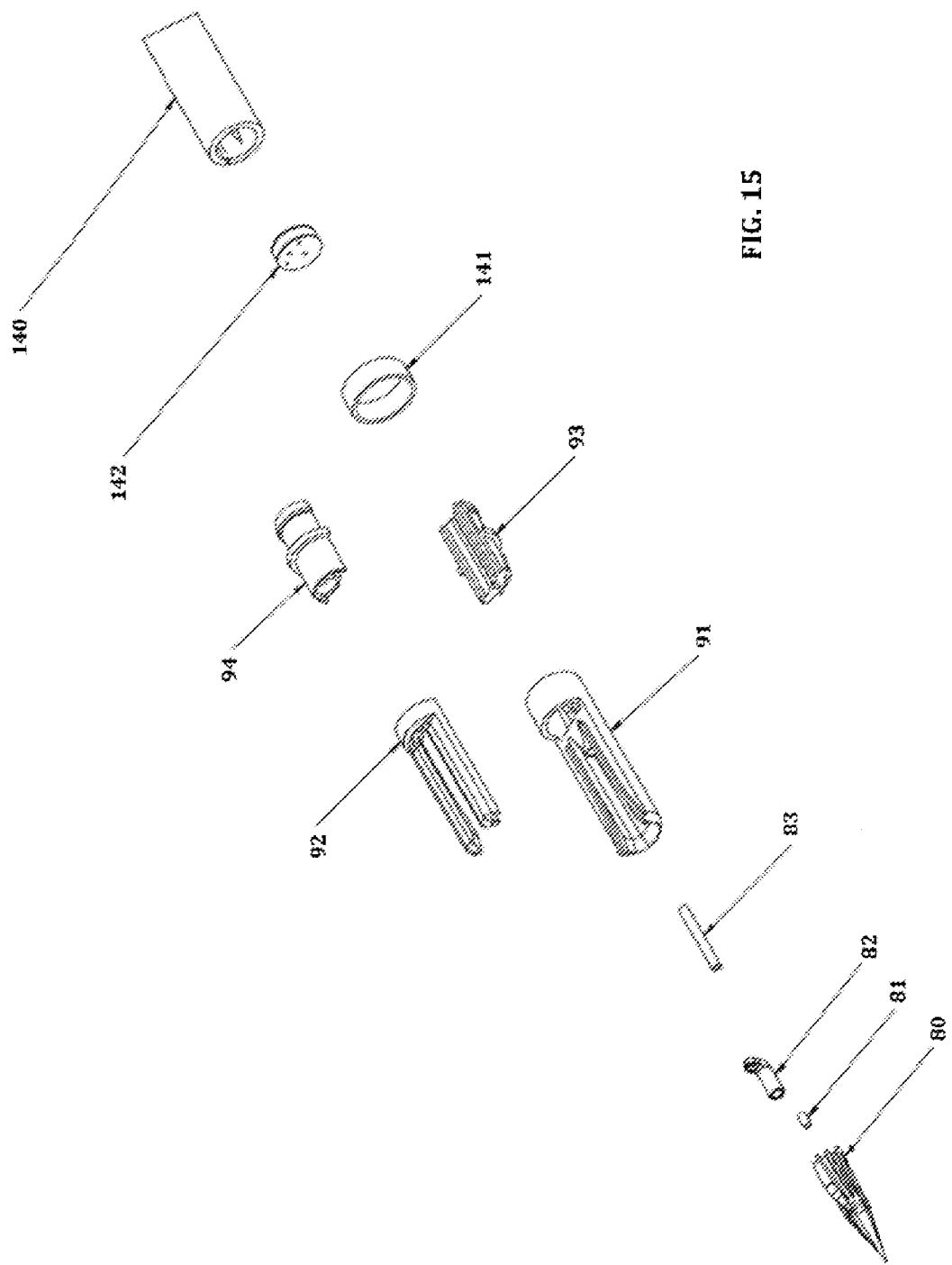


FIG. 14F





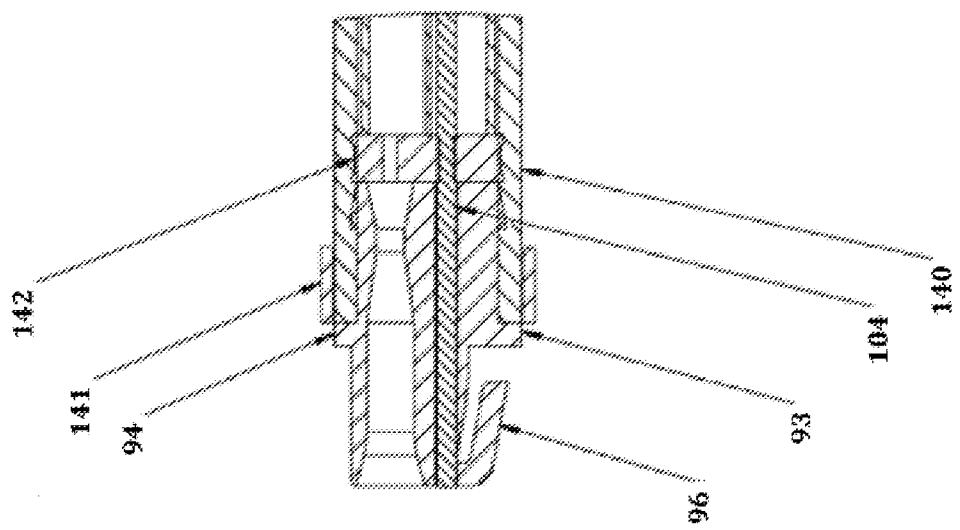
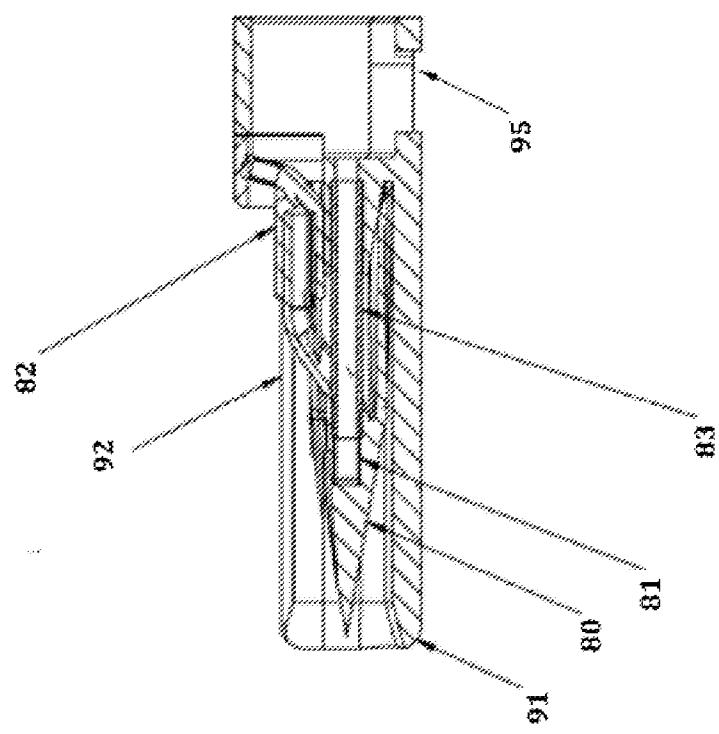
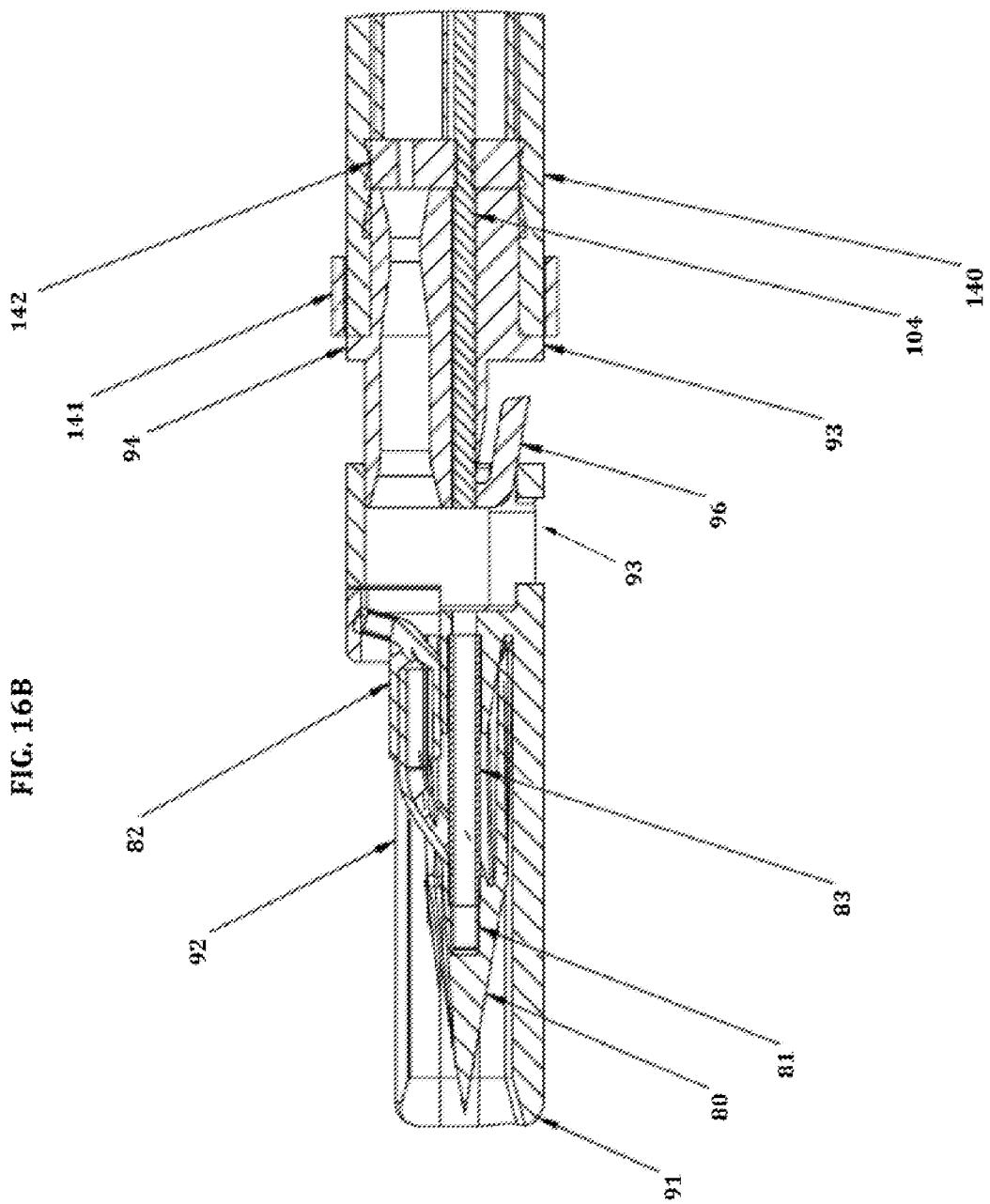
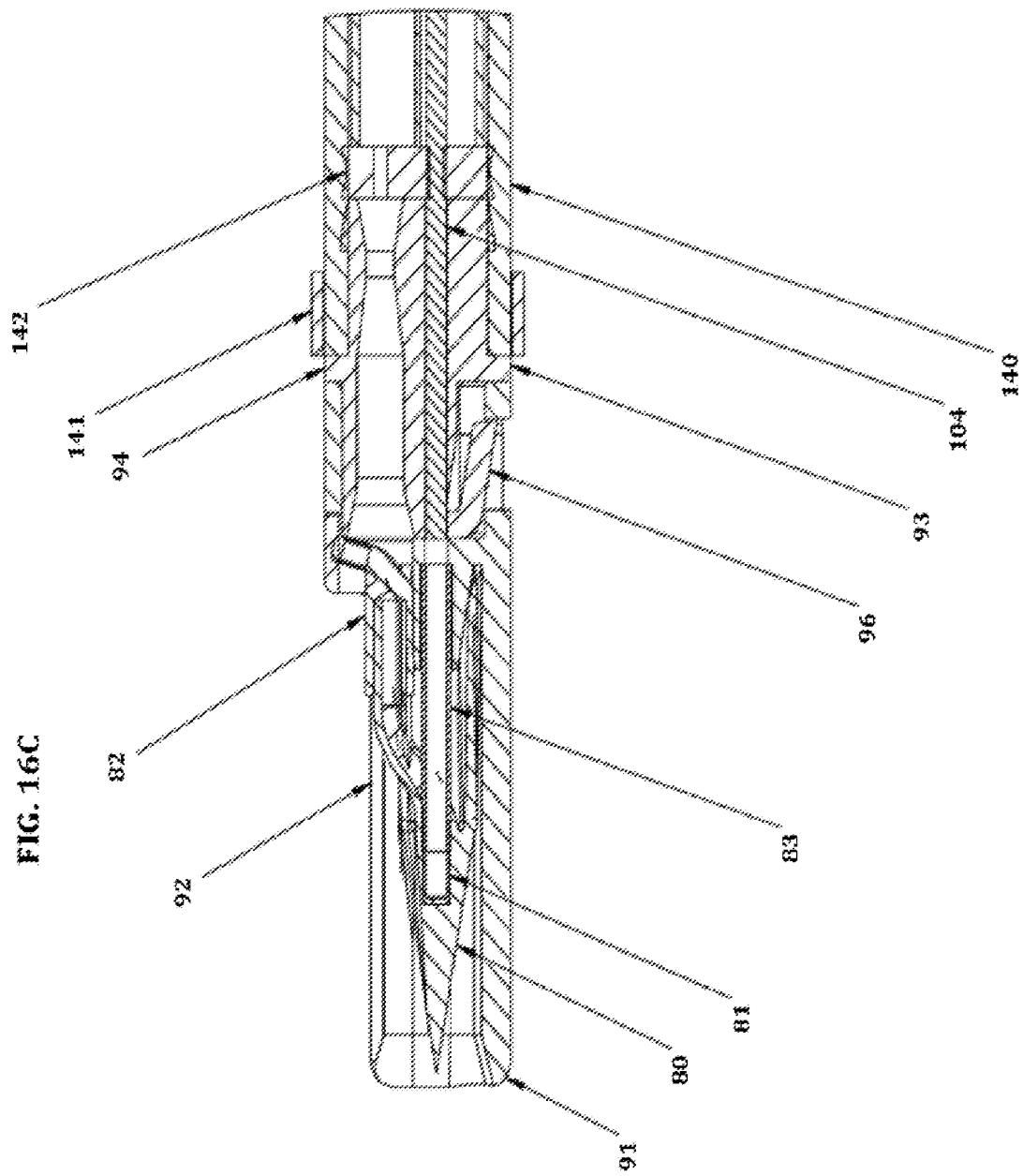


FIG. 16A







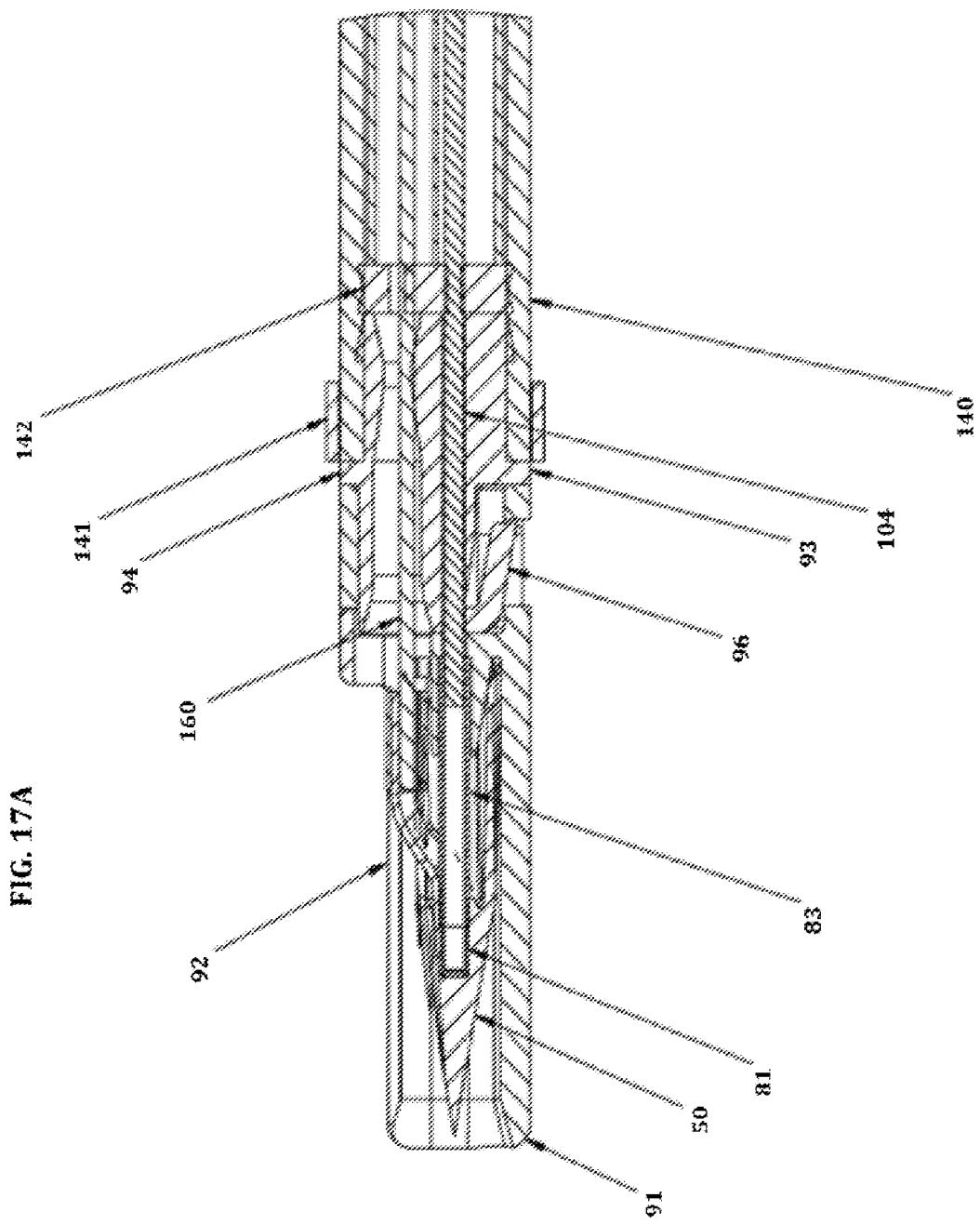


FIG. 17B

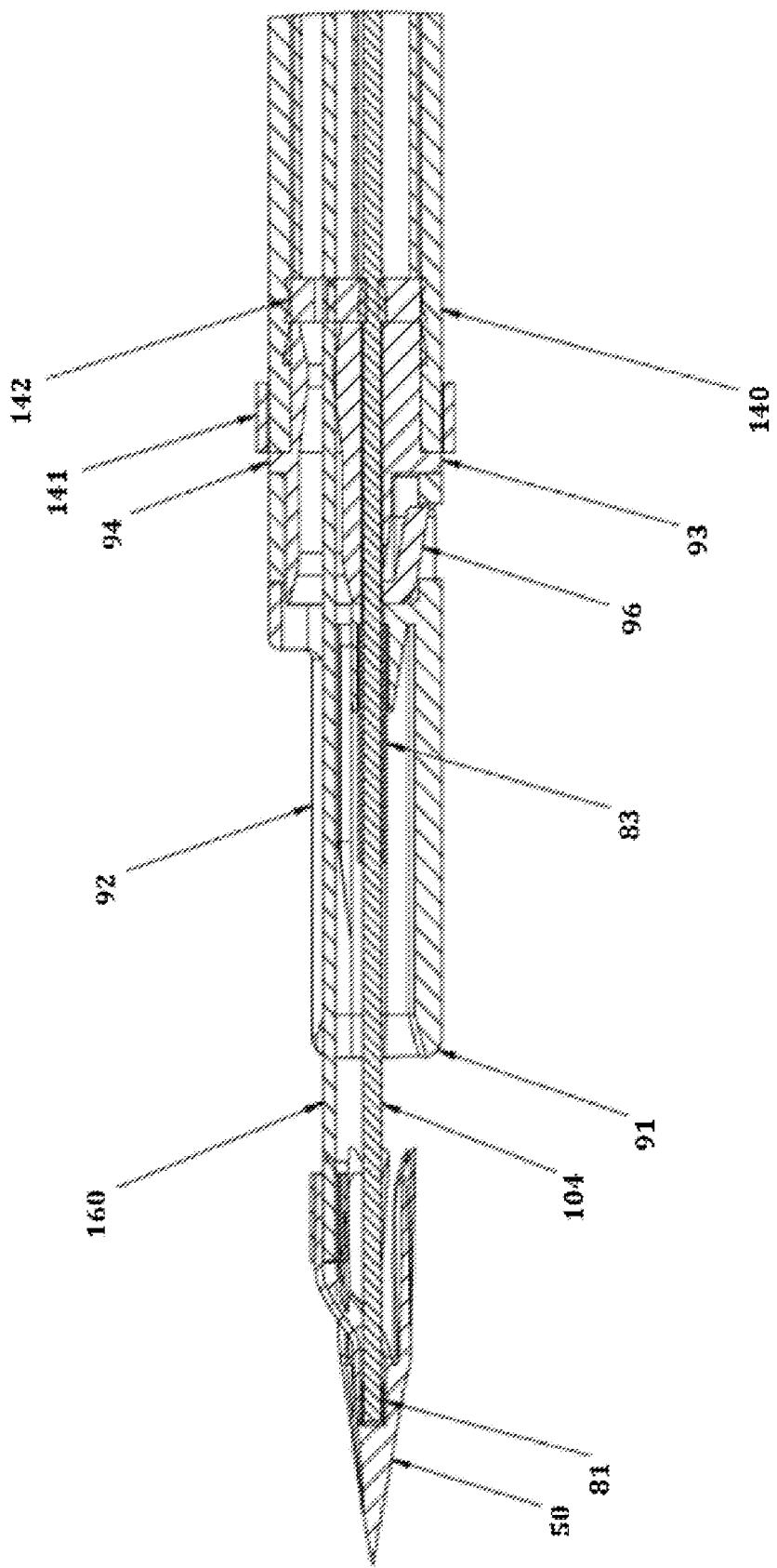


FIG. 17C

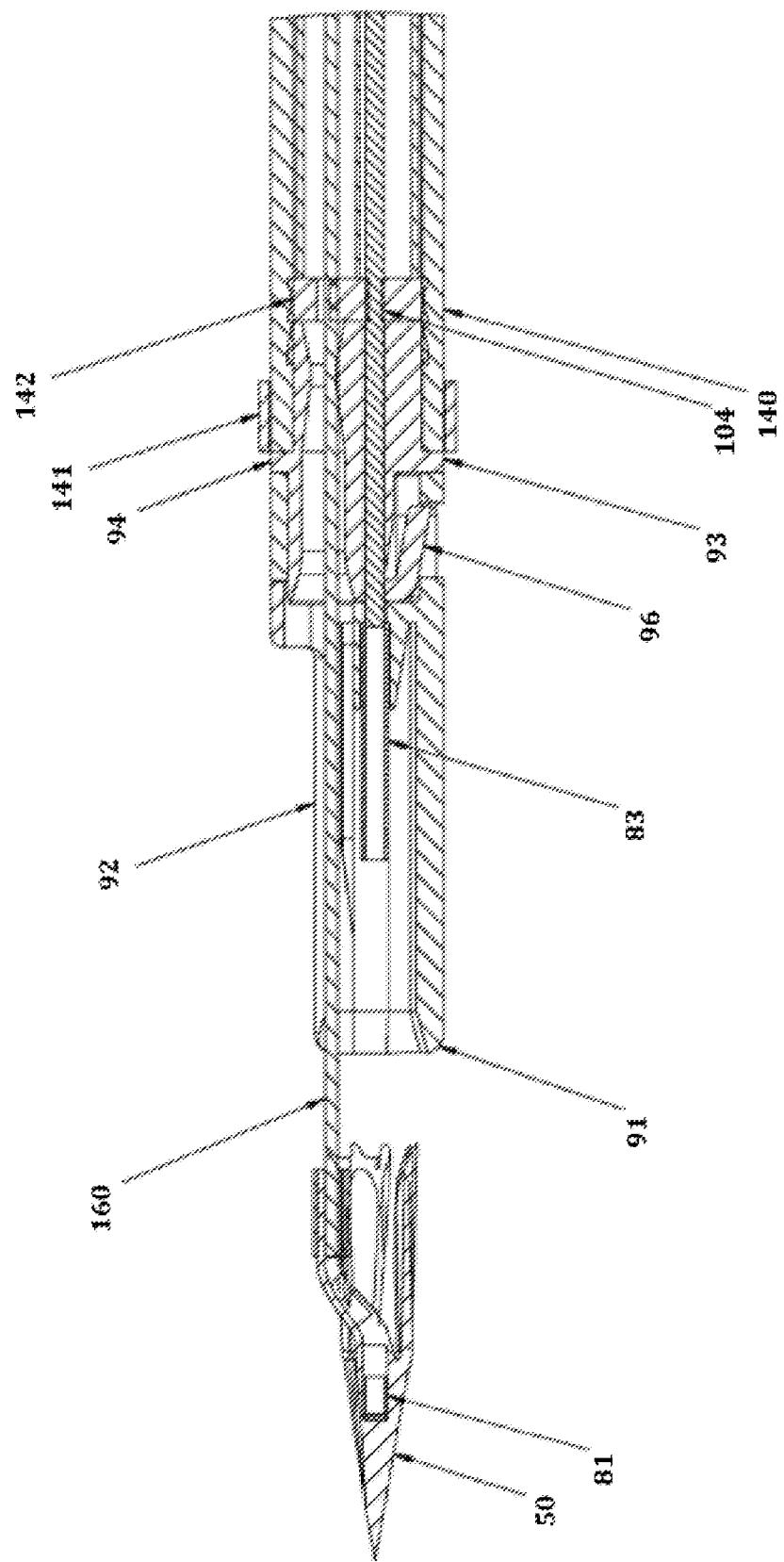


FIG. 17D

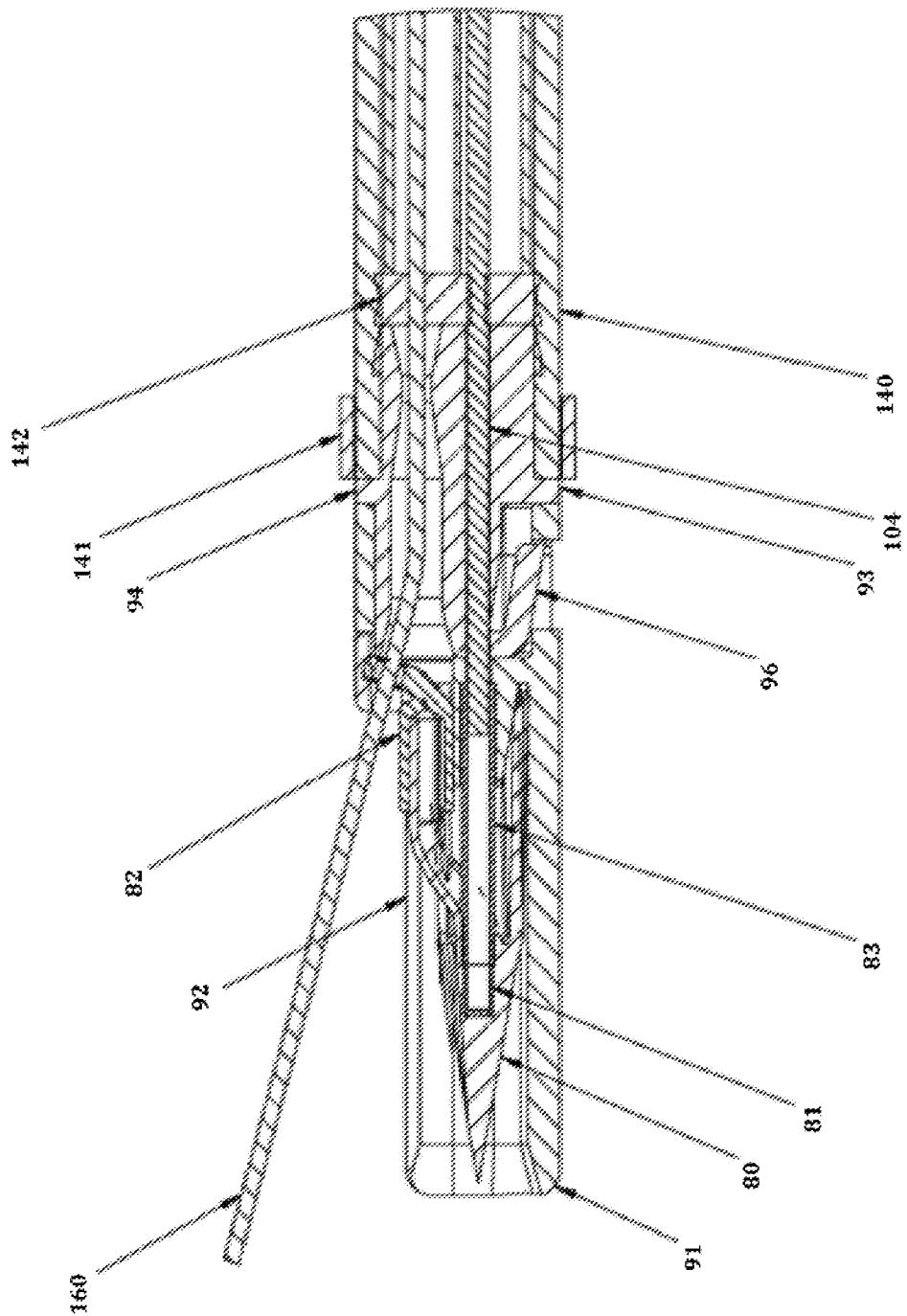


FIG. 17E

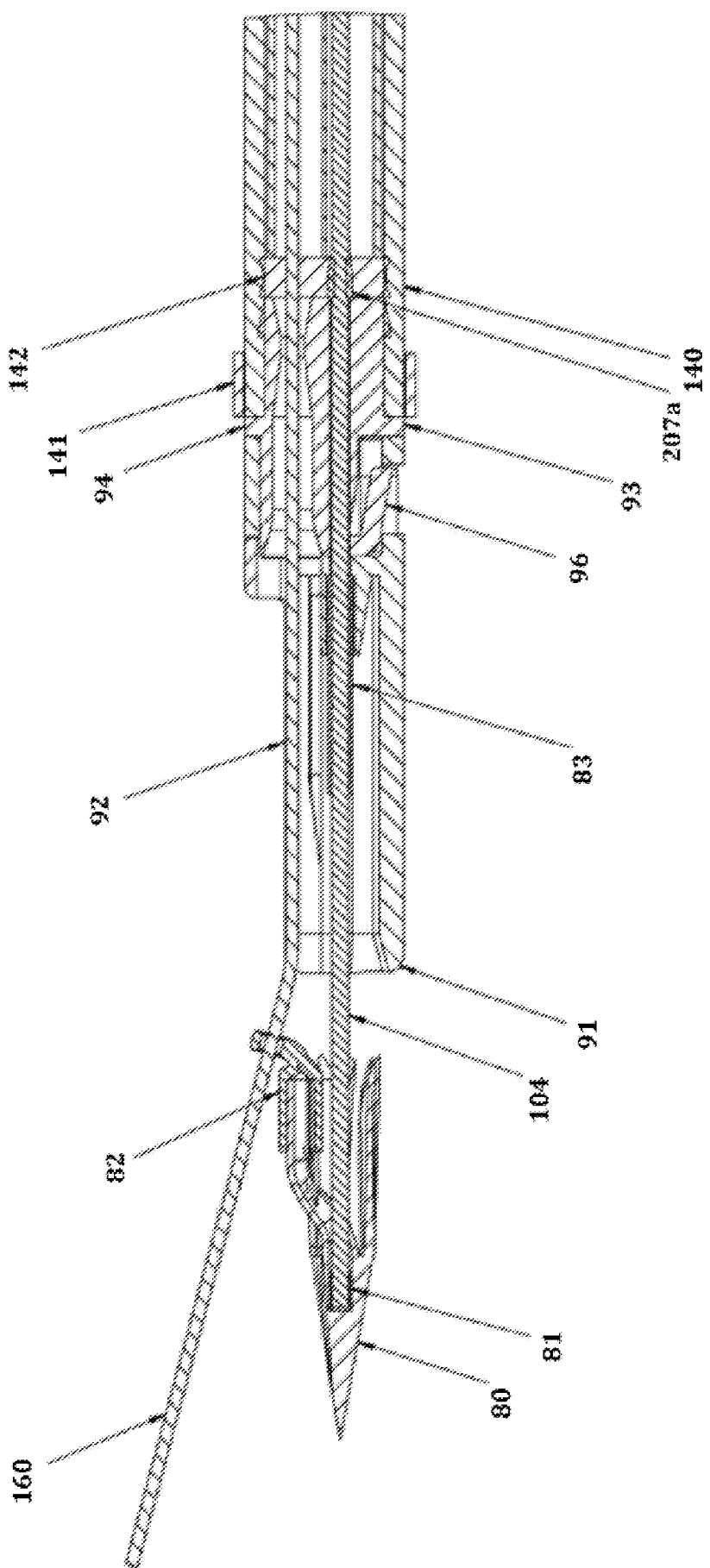


FIG. 17F

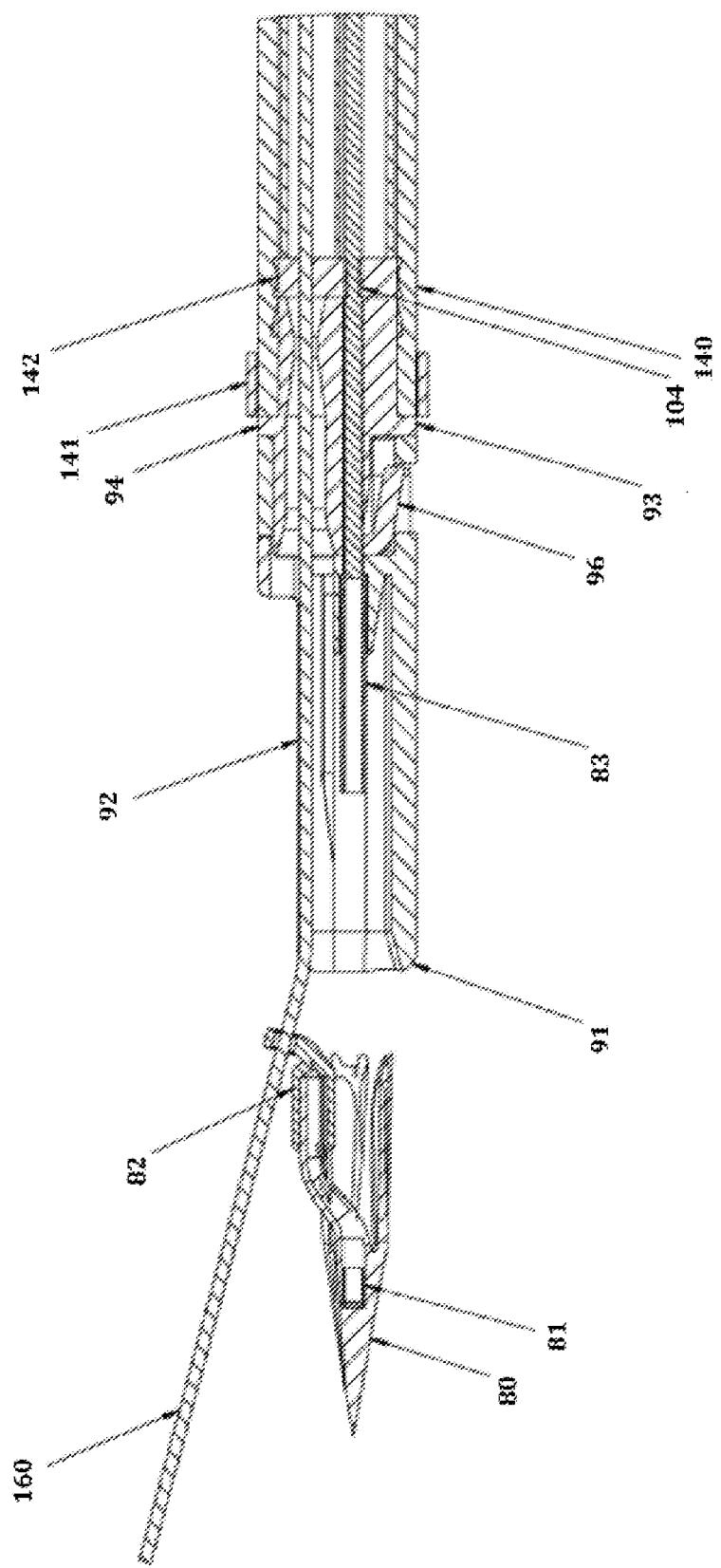
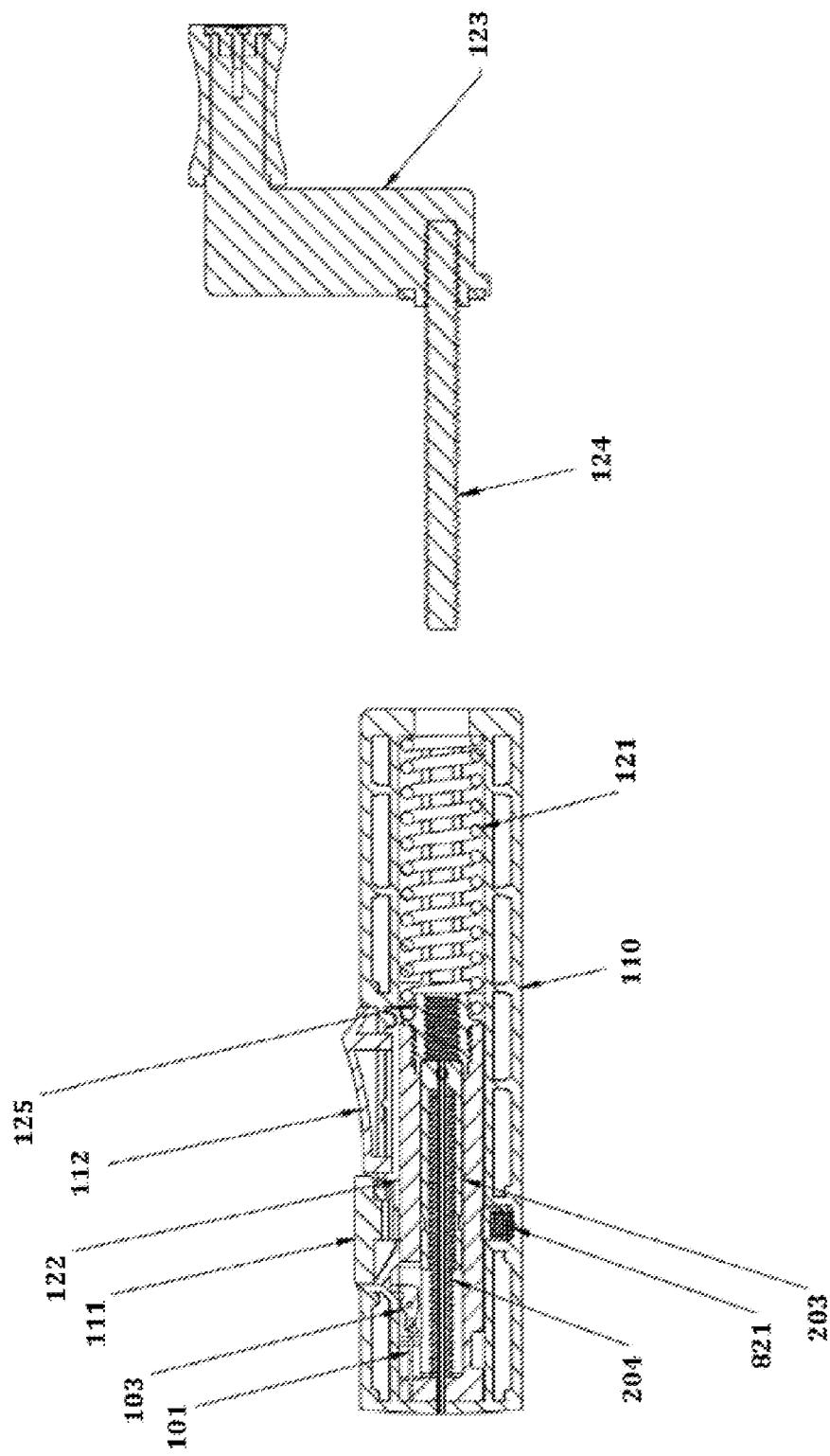


FIG. 18A



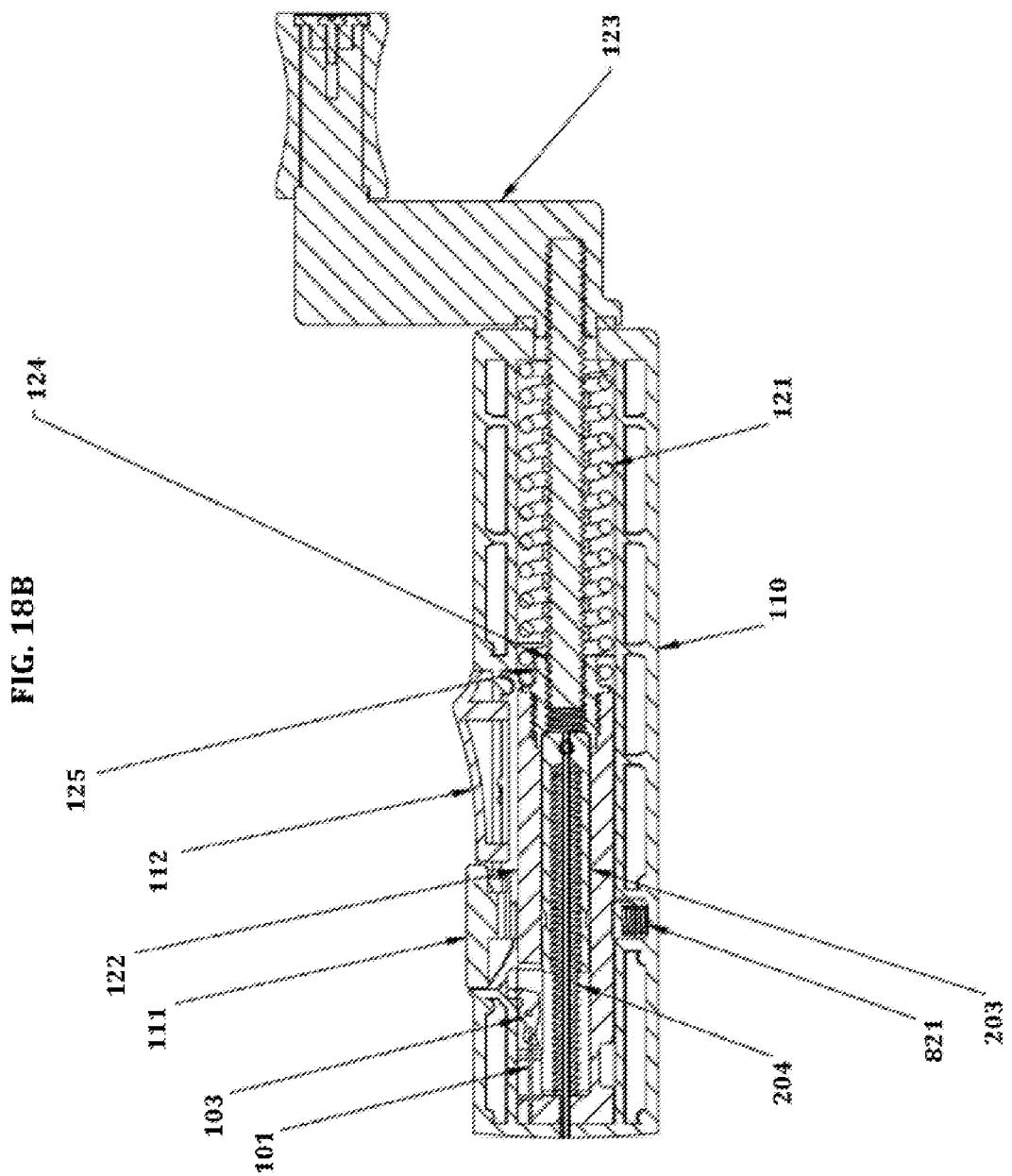


FIG. 18C

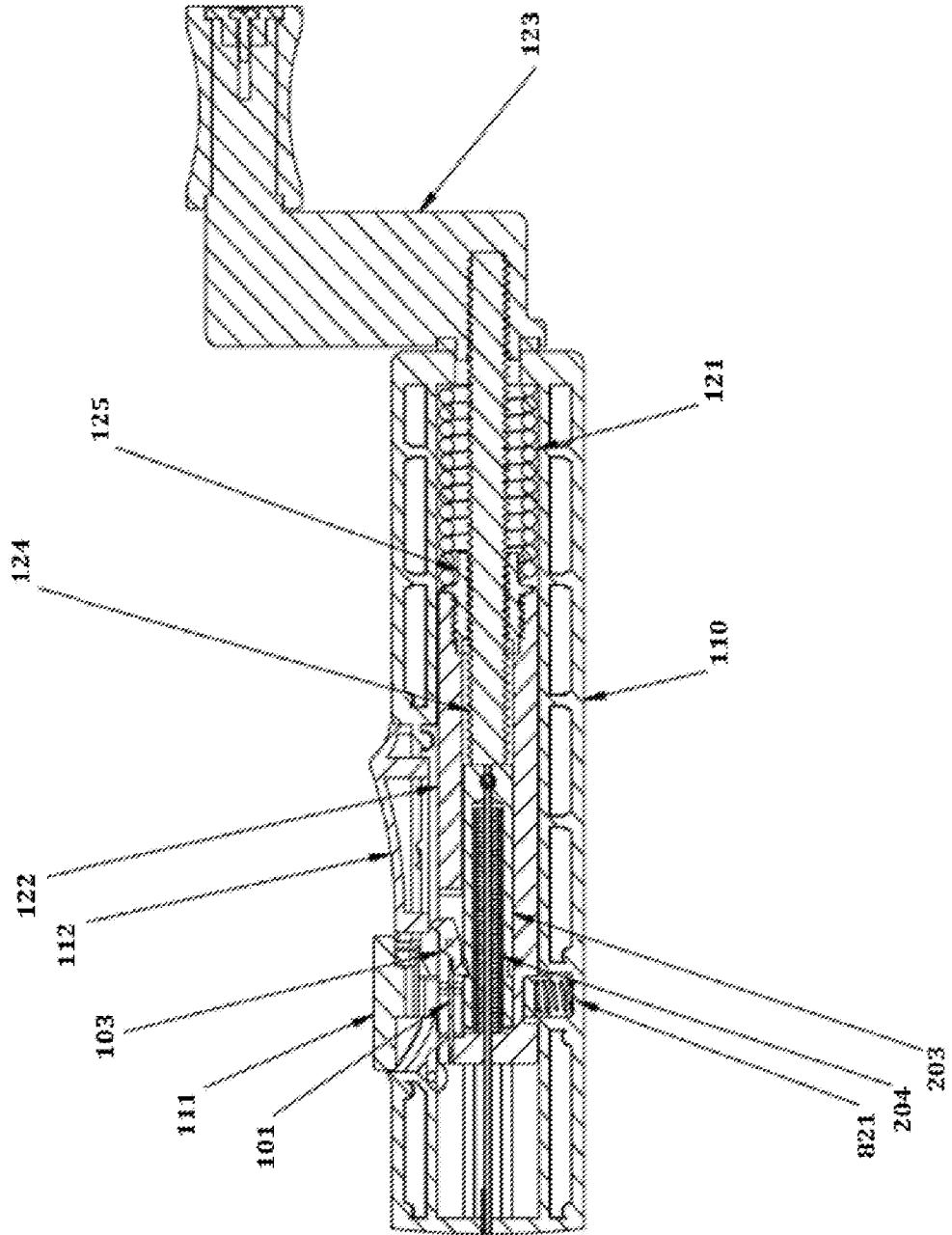


FIG. 19A

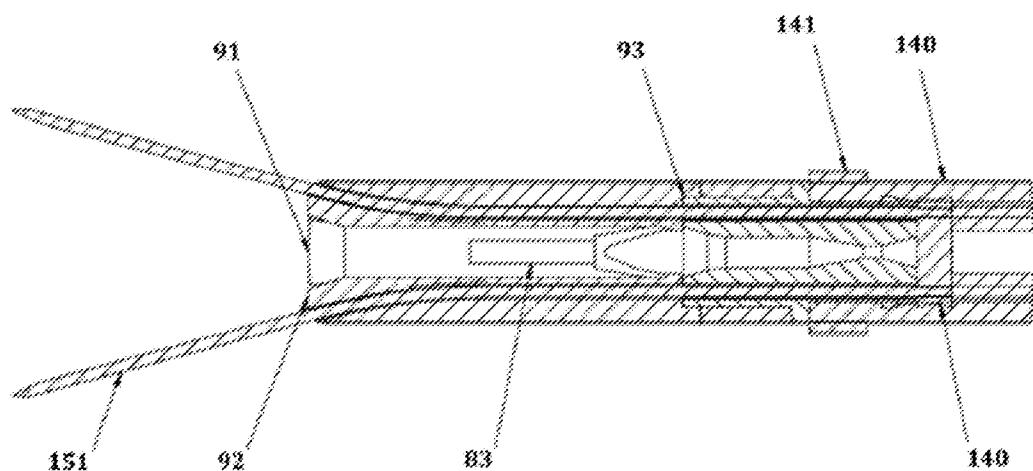


FIG. 19B

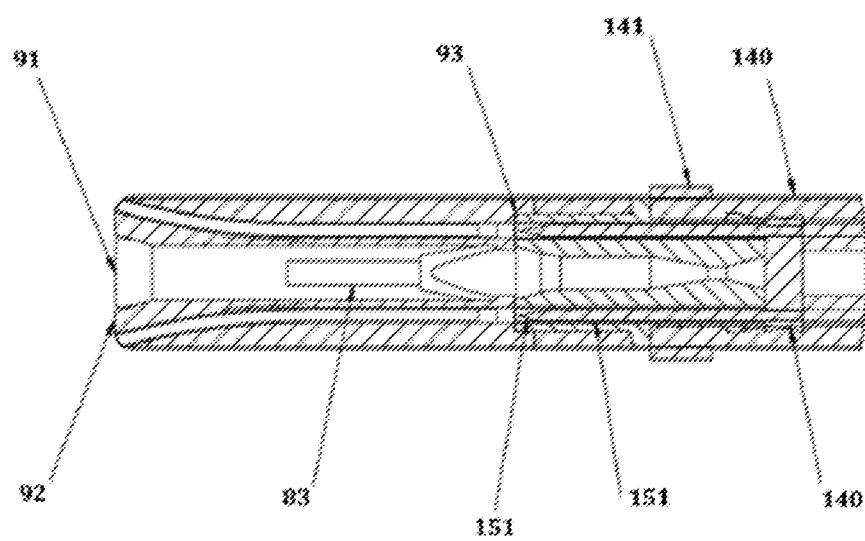


FIG. 20A

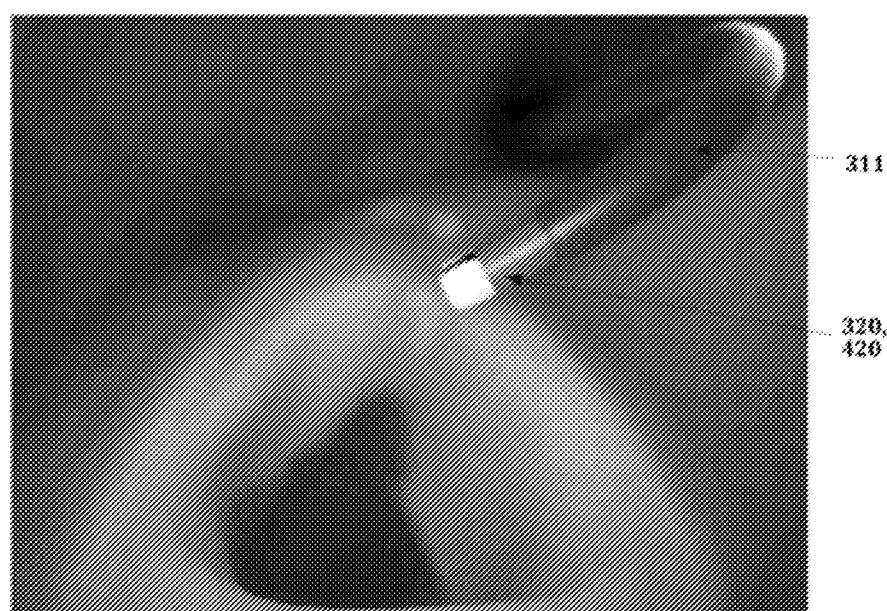


FIG. 20B

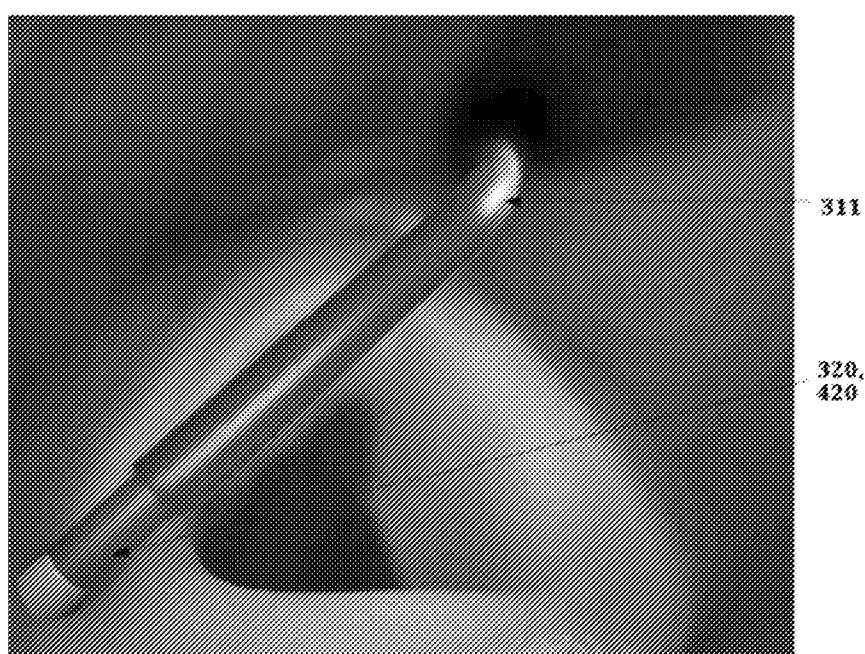


FIG. 20C

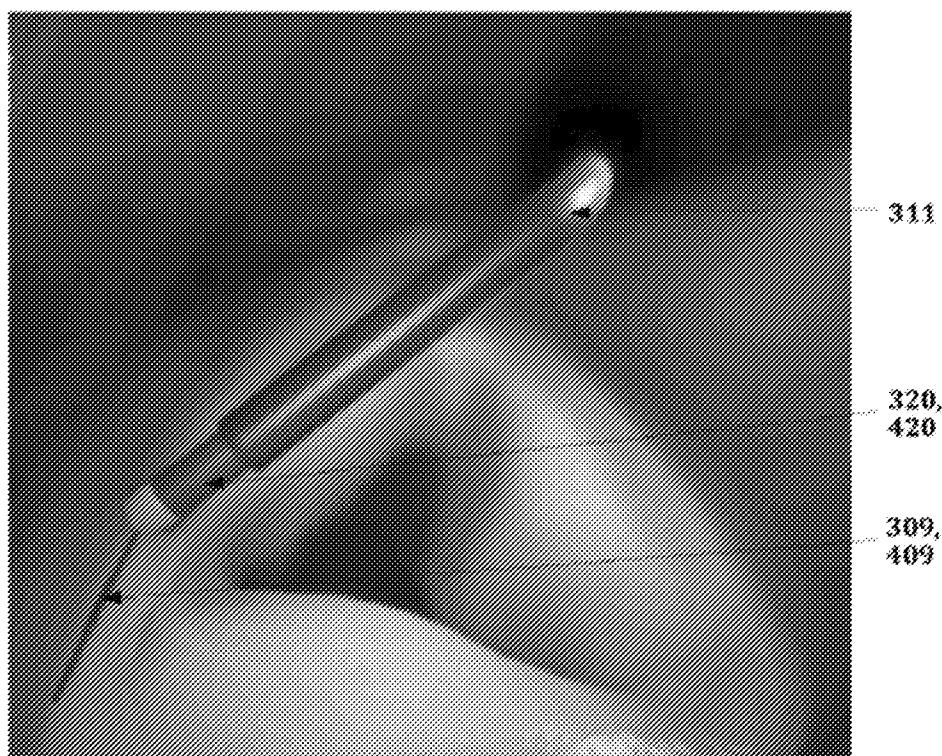


FIG. 20D

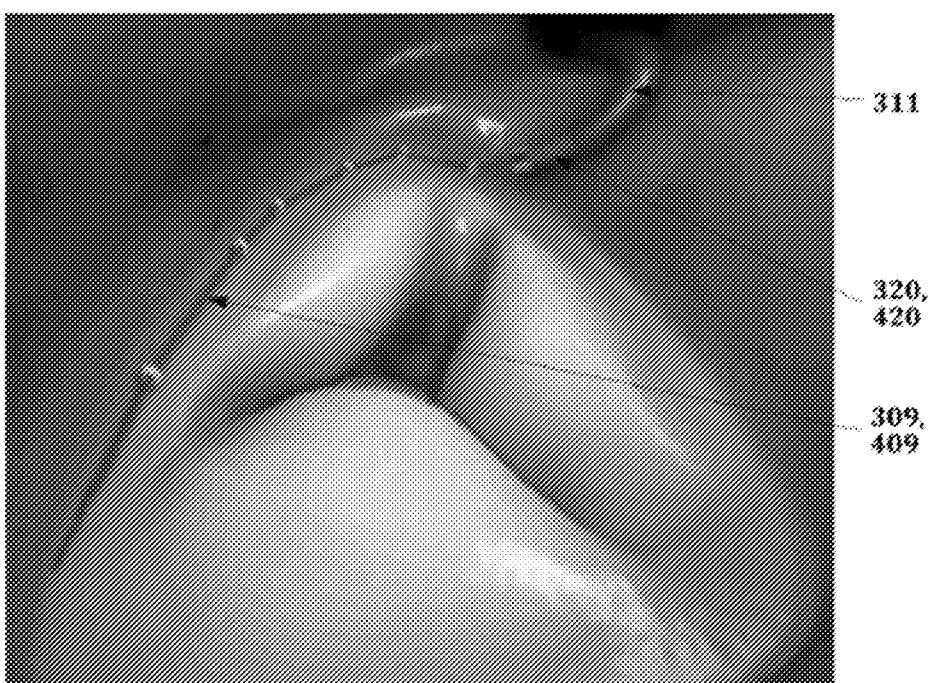


FIG. 20E

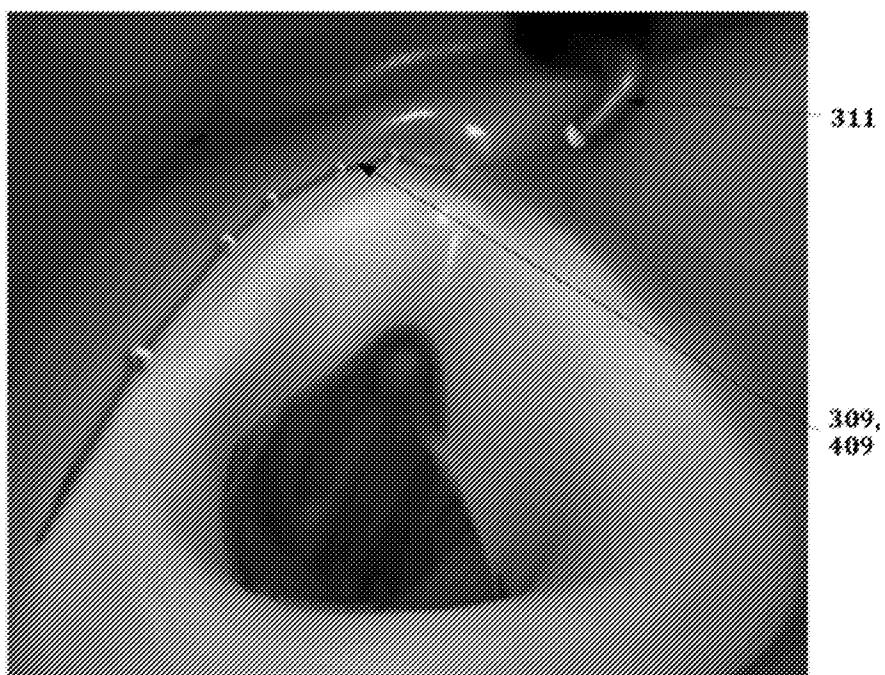


FIG. 20F

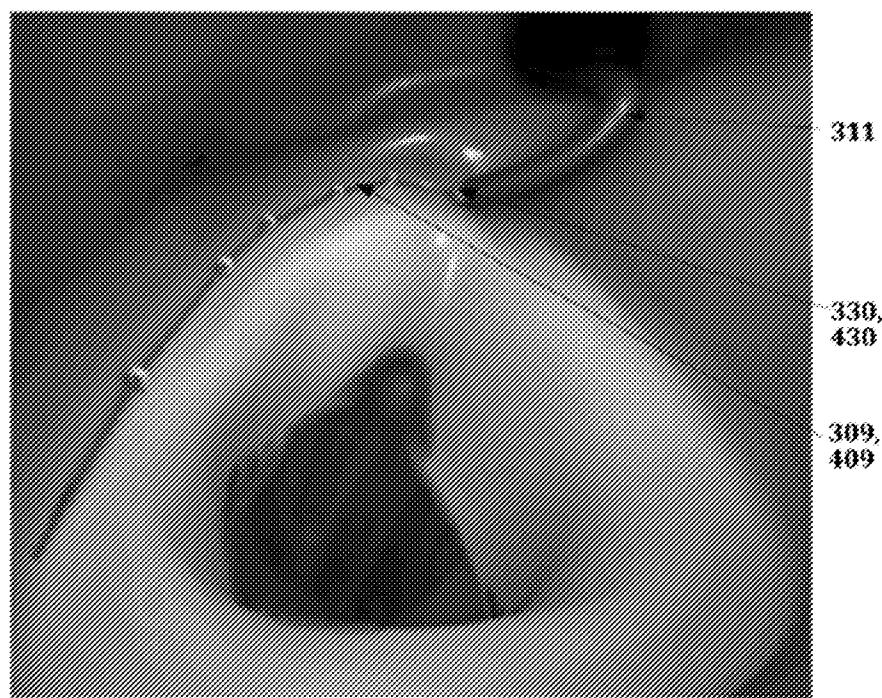


FIG. 20G

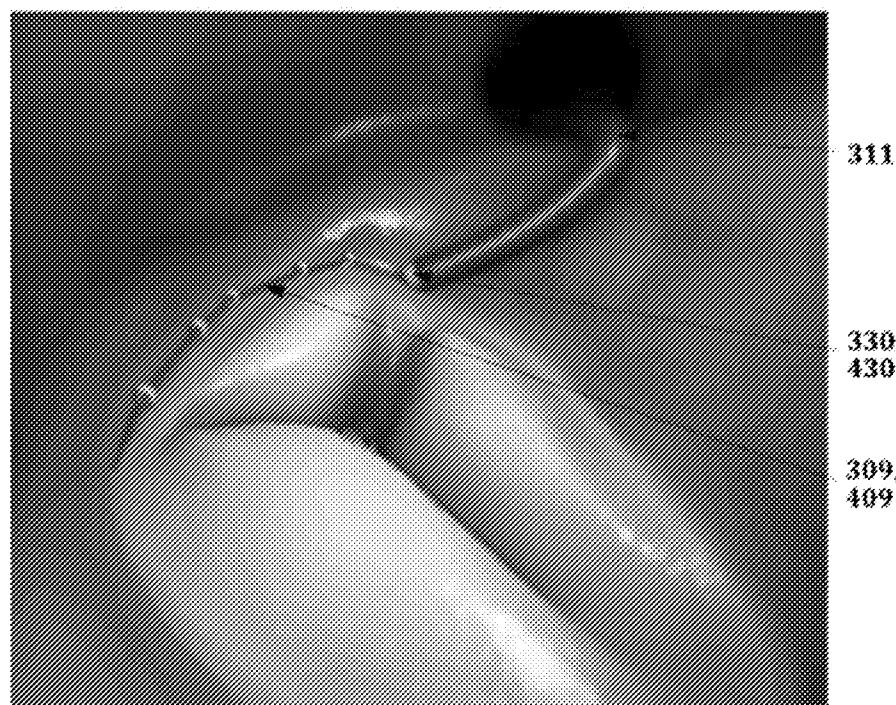


FIG. 20H

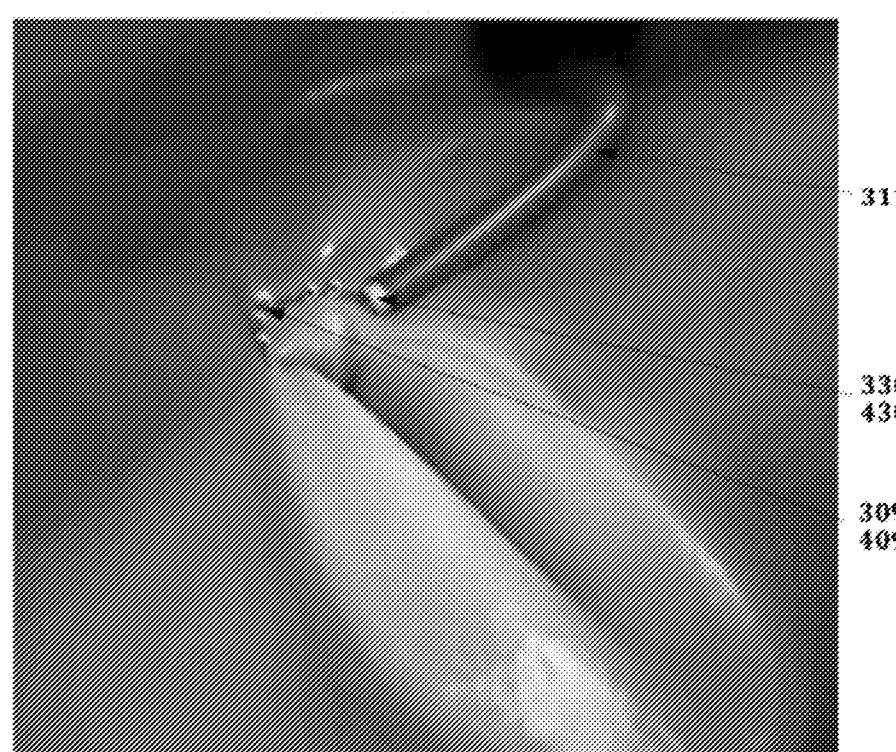
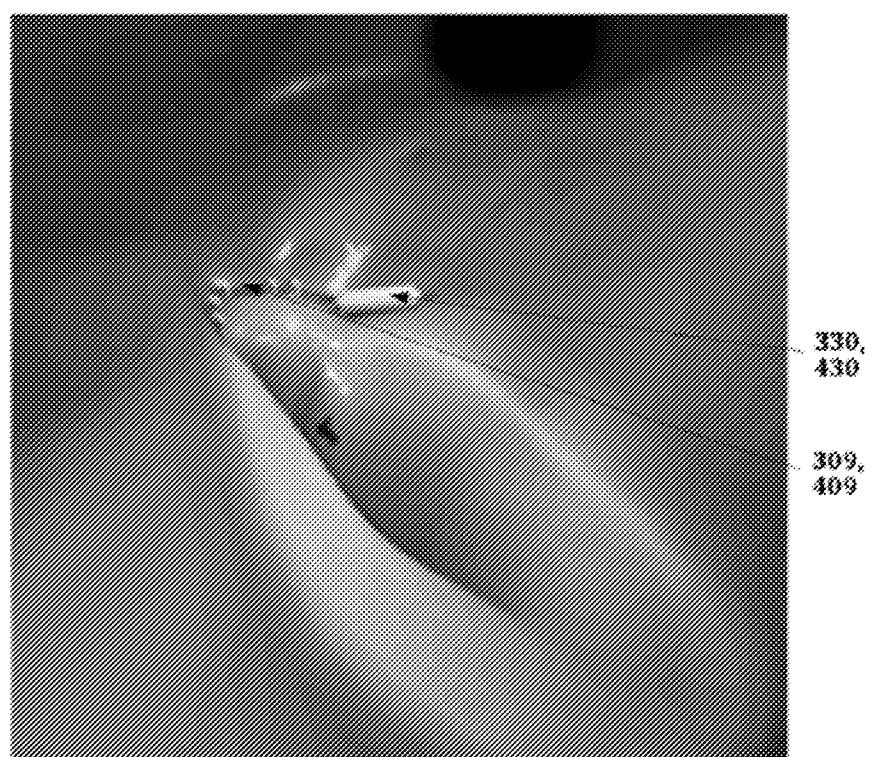


FIG. 201



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2020/055861

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/04; A61B 17/08; A61B 17/10 (2020.01)

CPC - A61B 17/0401; A61B 2017/0409; A61B 2017/0464 (2020.08)

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)

see Search History document

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

see Search History document

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

see Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2012/0253392 A1 (BENTLEY et al) 04 October 2012 (04.10.2012) entire document	1, 2, 6
---		---
Y		3-5, 7-10, 13-15
X	US 2014/0316458 A1 (MICRO INTERVENTIONAL DEVICES, INC.) 23 October 2014 (23.10.2014) entire document	17
---		---
Y		3, 7
X	US 2015/0320413 A1 (THE FOUNDRY LLC) 12 November 2015 (12.11.2015) entire document	18
---		---
Y		4, 8, 10
Y	US 2018/0153550 A1 (ETHICON, INC.) 07 June 2018 (07.06.2018) entire document	5, 9
Y	US 2017/0189061 A1 (GORDIAN SURGICAL LTD.) 06 July 2017 (06.07.2017) entire document	13-15
A	US 2000/0271074 A1 (EWERB et al) 30 November 2006 (30.11.2006) entire document	1-19
A	US 2019/0008504 A1 (NEOTRACT, INC.) 10 January 2019 (10.01.2019) entire document	1-19
A	US 2005/0251175 A1 (WEISENBURGH II et al) 10 November 2005 (10.11.2005) entire document	1-19

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "D" document cited by the applicant in the international application
- "E" earlier application or patent but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

09 December 2020

Date of mailing of the international search report

14 JAN 2021

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, VA 22313-1450

Faxsimile No. 571-273-8300

Authorized officer

Blaine R. Copenheaver

Telephone No. PCT Helpdesk: 571-272-4300