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(54) Title: SYSTEMS AND METHODS FOR ENDOSCOPIC TISSUE SUTURING

(57) Abstract:



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SYSTEMS AND METHODS FOR ENDOSCOPIC TISSUE SUTURING**CROSSED-REFERENCED APPLICATIONS**

[0001] This application claims priority to and benefit of U.S. Provisional Application No. 63/518,208 filed August 8, 2023 and entitled “Systems and Methods for Endoscopic Tissue Suturing,” which is incorporated by reference herein in its entirety. This patent application is also related to U.S. Provisional Application No. 63/518,228, entitled “Systems and Methods for Endoscopic Tissue Suturing,” filed August 8, 2023, which is incorporated by reference herein in its entirety.

FIELD

[0002] Examples described herein relate to systems and methods for endoscopic suturing. More particularly, examples may relate to endoscopic suturing procedures that place full tissue thickness bites, create tension on suturing material, and terminate both ends of a suture material through an endoscopic system.

BACKGROUND

[0003] Minimally invasive medical techniques may generally be intended to reduce the amount of tissue that is damaged during medical procedures, thereby reducing patient recovery time, discomfort, and harmful side effects. Such minimally invasive techniques may be performed through natural orifices in a patient anatomy or through one or more surgical incisions. Through these natural orifices or incisions an operator may insert minimally invasive medical instruments such as therapeutic instruments, diagnostic instruments, imaging instruments, and surgical instruments. Some minimally invasive medical instruments may be used to perform endoscopic tissue apposition and suturing. Systems and methods are needed to provide effective tissue apposition and suturing.

SUMMARY

[0004] The following presents a simplified summary of various examples described herein and is not intended to identify key or critical elements or to delineate the scope of the claims.

[0005] In some examples, a method may comprise advancing an elongate device to a tissue at a procedure site. The elongate device includes a needle arm. The method also includes fixing a first termination member to a first portion of a suture strand. The method also includes driving the needle arm in a single direction from a staging position through the tissue and, continuing

in the single direction, back to the staging position to create an initial suture bite. The method also includes coupling a second termination member to a second portion of the suture strand, cinching the suture strand with the second termination member to create a tissue plication, and fixing the second termination member to the suture strand to secure the tissue plication.

[0006] In some examples, a method comprises advancing an elongate device to a tissue at a procedure site and coupling a first termination member to a needle arm. The needle arm has a free first end, a free second end, and a needle arm body between the first end and the second end. The first termination member is fixed to a first portion of a suture strand. The method also includes driving the first termination member, the first end of the needle arm, and the second end of the needle arm through the tissue to create an initial suture bite. The method also includes coupling a second termination member to a second portion of the suture strand, cinching the suture strand with the second termination member to create a tissue plication, and fixing the second termination member to the suture strand to secure the tissue plication.

[0007] It is to be understood that both the foregoing general description and the following detailed description are illustrative and explanatory in nature and are intended to provide an understanding of the present disclosure without limiting the scope of the present disclosure. In that regard, additional aspects, features, and advantages of the present disclosure will be apparent to one skilled in the art from the following detailed description.

BRIEF DESCRIPTIONS OF THE DRAWINGS

- [0008] FIGS. 1A and 1B illustrate a distal portion of an instrument system for creating a suture pattern, according to some examples.
- [0009] FIG. 2 is a flowchart illustrating a suturing procedure, according to some examples.
- [0010] FIG. 3 is a flowchart illustrating a forward cinch suturing procedure, according to some examples.
- [0011] FIGS. 4-6D illustrate processes of a forward cinch suturing procedure, according to some examples.
- [0012] FIGS. 7A-7H illustrate processes of a forward cinch suturing procedure, according to some examples.
- [0013] FIG. 8 is a flowchart illustrating a reverse cinch suturing procedure, according to some examples.
- [0014] FIGS. 9A-9F illustrate processes of a reverse cinch suturing procedure, according to some examples.
- [0015] FIGS. 10A-10G illustrate processes of a reverse cinch suturing procedure, according to some examples.
- [0016] FIG. 11 is a flowchart illustrating a suture cinch procedure, according to some examples.
- [0017] FIGS. 12A-12F illustrate processes of a suture cinch procedure, according to some examples.
- [0018] FIGS. 12G-12L illustrate a cinching tool, according to some examples.
- [0019] FIG. 13 is a flowchart illustrating a suture cinch procedure, according to some examples.
- [0020] FIGS. 14A-14C illustrate processes of a suture cinch procedure, according to some examples.
- [0021] FIG. 15 is a flowchart illustrating a suture cinch procedure, according to some examples.
- [0022] FIGS. 16A-16D illustrate processes of a suture cinch procedure, according to some examples.
- [0023] FIG. 17 is a flowchart illustrating a suture cinch procedure, according to some examples.
- [0024] FIGS. 18A-18D illustrate processes of a suture cinch procedure, according to some examples.
- [0025] FIG. 19 illustrates a capture device, according to some examples.

- [0026] FIG. 20 illustrates a tensioning tool, according to some examples.
- [0027] FIG. 21 is a simplified diagram of a patient anatomy, according to some examples.
- [0028] FIG. 22 is a robotically-assisted medical system, according to some examples.
- [0029] FIG. 23A is a simplified diagram of a medical instrument system according to some embodiments.
- [0030] FIG. 23B is a simplified diagram of a medical instrument system with an extended medical instrument according to some embodiments.
- [0031] FIG. 24 is a flowchart illustrating a suture anchoring procedure, according to some examples.
- [0032] FIGS. 25A-25J illustrate processes of a suture anchoring procedure, according to some examples.
- [0033] FIG. 26 is a flowchart illustrating a suture anchoring procedure, according to some examples.
- [0034] FIGS. 27A-27G illustrate partial cross-sectional and side views of an anchoring tool in processes of a suture anchoring procedure, according to some examples.
- [0035] Examples of the present disclosure and their advantages are best understood by referring to the detailed description that follows. It should be appreciated that like reference numerals are used to identify like elements illustrated in one or more of the figures, wherein showings therein are for purposes of illustrating examples of the present disclosure and not for purposes of limiting the same.

DETAILED DESCRIPTION

[0036] The technology described herein provides endoscopic techniques and treatment systems for tissue closure, apposition, and/or hemostasis. The techniques and treatment systems may be used, for example, in the upper or lower gastrointestinal track to perform procedures such as fistula closure, endoscopic submucosal dissections, endoscopic mucosal resections, peroral endoscopic myotomy, endoscopic sleeve gastropasty, and/or transoral outlet reduction endoscopy. The various techniques may be performed endoscopically and may involve creating full thickness suture bites, tensioning suture strands, and terminating both ends of a suture strand through an endoscopic device. In various examples, flexible instrument systems may include a suture apparatus that may fold, bend, pinch, or otherwise cause apposition of tissue such that two portions of tissue are brought close to each other or into contact with each other. The suture apparatus may then deliver a suture through the apposed tissue. Although the examples provided herein may be used for suturing of gastrointestinal

tissue, it is understood that the described technology may be used in performing procedures in artificially created lumens or any endoluminal passageway or cavity, including in a patient trachea, colon, intestines, stomach, liver, kidneys and kidney calices, brain, heart, circulatory system including vasculature, fistulas, and/or the like.

[0037] FIG. 1A illustrates a distal portion of an instrument system 100 including an elongate device 102 and a suture apparatus 104. In some examples, the instrument system 100 may be an endoscopic instrument system and the elongate device 102 may be a flexible, steerable endoscope. The device 102 may serve as a platform to drive motion of mechanisms in the suturing apparatus, deliver working components to the anatomic structures accessed by the instrument system 100, and capture image data of the anatomic structures. The device 102 may include a flexible body 106 through which extends one or more working channels 108. The working channel 108 may extend through the flexible body 106 to provide passage for removable instrument systems, suture material, and/or termination members and to allow instruments to be exchanged during a procedure. In some examples, a suture support tool 118 may be removably extendable within the working channel 108. In some examples, the working channel may be external to the flexible body 106. A suture support tool 118 may include, for example, a tissue apposition tool, a suture tensioning tool, a termination member transfer tool, a cinching tool, or other tool for use during a portion of a suturing procedure. The working channel 108 may also or alternatively allow fluid passage, deliver vacuum pressure, or otherwise provide access between proximal and distal portions of the elongate flexible device 102. Each working channel 108 may define an opening 110 in a distal end portion 112 of the device 102.

[0038] The suture apparatus 104 may include a suture needle 114 which may be coupled to a suture strand 116 or other type of natural or synthetic suture material. A suture strand may include, for example, a monofilament material, a multifilament material, or a braided material. In some examples, a barbed suture strand may be used to prevent movement of the suture strand within the tissue. Barbed suture material may be particularly useful with a forward cinch suturing technique described below. The suture strand 116 may be coupled to the suture needle 114 by crimp, tie, hook, clamp, clip, adhesive, woven through a tortuous/frictional path, or via connection to an anchoring termination member. The suture strand 116 may be coupled to the suture needle in any of various locations, including a leading end region of the needle, the middle region of the needle, or the trailing end region of the needle.

[0039] The suture needle 114 may be straight, arc-shaped, semi-circular, or another suitable shape for capturing a suture bite. The suture needle 114 may include a needle arm and at least

one end portion with a pointed tip configured to pierce tissue. In some examples, the suture needle may include an optional opposite second end portion with a pointed tip configured to pierce tissue. The suture apparatus 104 may also include a tissue apposition chamber 120 into which tissue may be drawn in a folded, bended, pinched, or otherwise apposite configuration. In some examples, a distal portion of the suture strand 116 may be coupled to the needle 114 and the suture strand 116 may extend through the working channel 108 with a proximal portion of the suture strand 116 extending proximally of the flexible body 106 and outside of the patient anatomy. In other examples, a distal portion of the suture strand 116 may be coupled to the needle 114 and the length of the suture strand, including a proximal portion may be housed within the instrument system, such as within the suture apparatus 104 or working channel 108. An example suture apparatus is described in U.S. Provisional Patent Application 63/421,029, filed October 31, 2022, which is incorporated by reference herein, in its entirety. In some examples, the suture needle 114 may move along a linear path. In some examples, the suture needle 114 may move from a staging position along an arcuate path in a single direction and return to the staging position. In some examples, the suture needle 114 may move in a bi-directional arcuate path.

[0040] The instrument system 100 may be used to perform a suturing procedure that places the suture strand 116 in tissue 124 through a series of suture bites 122A-122E. In some examples, a suture bite may be a full thickness suture throw through apposed tissue including all layers of the tissue. For example, in a stomach suturing procedure, the needle and suture strand may penetrate all four layers of the tissue including the submucosal, mucosal, muscle layers, and serosa. In some examples, the thickness of the tissue, including the four layers, may be between approximately 2 mm and 10 mm. In some examples, the tissue thickness may be approximately 5 mm. The sutures bites 122A-122E may form a suture pattern 135. In some examples, a single suture bite may form a suture pattern. In other examples, a suture pattern may have a plurality of sutures bites, as needed, to achieve a surgical result. A suture pattern may have an initial suture bite 122A, which may be the first suture created in the suture pattern, and may have final suture bite 122E, which may be the final suture in the suture pattern created by the instrument system 100. A pattern direction 134 indicates the order in which the suture needle moved to create the suture bites 122A-122E to form the suture pattern 135. A suture termination member 130 may be coupled to the suture strand 116 proximate to the initial suture bite 122A, and a termination member 132 may be coupled to the suture strand 116 proximate to the final suture bite 122E.

[0041] In various examples, as described below, the suture termination member 130 may be an anchoring termination member or a cinching termination member. An anchoring termination member or anchor may be a stopping mechanism attached to a suture strand that prevents the end of the suture from passing through the tissue, thus creating a reaction force between the suture and the tissue. The anchoring termination member may include any of a variety of fixation devices that may be deposited in an anatomy and may be formed of metal, plastic, ceramic, or another biocompatible material. The anchoring termination member may be fixedly coupled to (e.g., crimped, tied, fused, or otherwise fixed to) or near an end of the suture strand and may prevent or limit migration of the suture strand. For example, an anchoring termination member may include an aperture through which an end of the suture strand may be inserted before the end of the suture strand is knotted or otherwise terminated to fix the anchoring termination member to the suture strand. When the suture strand is cinched to create a tissue plication, an anchoring termination member may remain fixed to the suture strand. In some examples, an anchoring termination member may include all or a portion of the suture needle.

[0042] A cinching termination member may be, for example, an end suture cinching termination member or a mid-suture cinching termination member. An end suture cinching termination member may directly access an end of a suture strand. The free end of a suture strand may be fed into and passed through the end suture cinching termination member to allow the end suture cinching termination member to lock around the suture strand (e.g., after a desired amount of tension has been pulled onto the suture strand). A mid-suture cinching termination member may not require direct access to the end of a suture strand. The mid-suture cinching termination member may engage a suture strand anywhere along the suture's length, allowing the suture strand to slide through the mid-suture cinching termination member and be tensioned before locking into place. For some terminations, only one type of cinching termination may be suitable, but for other types of terminations, either of the two types of cinching termination member may be suitable. A cinching termination member may include any of a variety of fixation devices that may be deposited in an anatomy and may be formed of metal, plastic, ceramic, or another biocompatible material. During a process of pulling tension on the suture strand and creating tissue compression or plication, the suture strand is passed through a cinching termination member. The cinching termination member allows the suture strand to slide through the cinching termination member and be tensioned as the cinching termination member itself is forced against tissue. This countering movement allows the tissue to compress or tighten as the suture strand is pulled. The cinching termination member can then

be locked onto the suture strand (while the tension is applied to the suture strand) such that the suture strand no longer allows the suture to slide through the cinching termination member. Similarly to the anchoring termination member, the cinching termination member may prevent the suture strand end from passing back through the tissue. This allows the locked cinching termination member to maintain the compression in the tissue and the tension in the suture strand extending through the tissue. The cinching termination member may initially be movable along the suture strand as the suture strand is cinched and may then be fixedly coupled to (e.g., crimped, tied, fused, or otherwise fixed to) the suture strand to prevent or limit migration of the suture strand. For example, a cinching termination member may include a side opening through which the cinching termination member may be attached to a suture strand along the length of the strand, rather than from an end of the strand. In some examples, the cinching termination member may be a one-piece device that clamps to the suture strand. In some examples, the cinching termination member may be a two-piece device that clamps the suture strand between the two pieces. In some examples, the cinching termination member may include an aperture through which an end of the suture strand may be inserted before the end of the suture strand is knotted or otherwise terminated. In some examples, the cinching termination member may include a ratchet feature such that the cinch may only slide in a single direction along the suture and resists sliding in the opposite direction.

[0043] In various examples, a suturing procedure may be characterized as a forward cinch suturing procedure or a reverse cinch suturing procedure. The procedure type refers to the relative direction of suture strand movement with respect to tissue during two steps of the procedure, a needle passing process and a cinching process. During a needle passing process, as the needle is actuated and carries suture strand through tissue, the suture strand moves in the direction of needle movement or in a forward suture direction. During a cinching process, as the suture strand is pulled tight with respect to tissue in order to compress or plicate the tissue, suture strand can move in a direction either with or opposed to the forward suture direction. A forward cinch suturing process occurs when the suture strand moves in the same direction for tensioning and cinching with respect to tissue as during needle passing. A reverse cinch suturing process occurs when the suture strand moves in the opposite direction for tensioning and cinching with respect to tissue as during needle passing.

[0044] In some examples, a new length of suture strand (i.e., a per pattern suture strand) may be used for each suture pattern in a suturing procedure. For example after a tissue plication is formed, the suture strand may be severed to form a severed end of the suture strand extending from the elongate device. The severed end of the suture strand may be used to initiate a second

tissue plication. In some examples, a single long length of suture strand may be used for all suture patterns in a suturing procedure, with part of the suture strand forming the plication being cut from a distal end of the suture strand with each suture pattern. In some examples, the suture needle may be replaced after each suture pattern is created. In some examples, the same suture needle is used for all of the suture patterns in a suturing procedure.

[0045] FIG. 1A illustrates the suture pattern 135 prior to cinching the suture strand 166 and prior to plication or compression of the tissue 124. FIG. 1B illustrates the suture pattern 135 after cinching the suture strand 166 and after tissue compression or plication. As described in various examples below, the cinching of the suture strand 116 may be accomplished by pulling the strand in either the cinch direction D1 (e.g., away from the initial suture bite 122A as the termination member 130 is moved toward the suture bite 122A) or the cinch direction D2 (e.g., away from the final suture bite 122E as the termination member 132 is moved toward the suture bite 122E). In some examples, the plication may be accomplished by tensioning, at least partially, in both directions D1 and D2.

[0046] FIG. 2 is a flowchart illustrating a method 200 for suturing tissue during a medical procedure. The method 200 may be used in conjunction with any of the suture apparatuses disclosed herein. At a process 202, an elongate device may be advanced into a patient anatomy and into proximity with a patient tissue at a procedure site. For example, the elongate device 102 may be advanced into proximity with the tissue 124 at the procedure site. At a process 204, a first termination member may be fixed to a first portion of the suture strand. For example, an anchoring termination member may be attached to an end of a suture strand (e.g., suture strand 116), or a cinching termination member may be attached along a length of a suture strand. The first termination member may be an initial termination member (e.g., termination member 130) attached proximate to the initial suture of a suture pattern or may be a final termination member (e.g., termination member 132) attached proximate to the final suture of a suture pattern. In some examples, the first termination member may be coupled to, or may be a portion of, the suture needle (e.g. needle 114).

[0047] At a process 206, an apposition force may be applied to the patient tissue, or the patient tissue may otherwise be positioned within the path of the suture needle. For example, an apposition tool may extend from the working channel 108 and engage the patient tissue. The apposition tool and the engaged tissue may be retracted toward the elongate device 102 to create an apposed or folded tissue bite. In some examples, the apposition tool may engage a full thickness of the tissue (e.g., penetrate the four tissue layers). In some examples, an apposition tool may include a helical shaped component that extends from the working channel

toward the tissue surface. The helical shaped component may be pushed forward against the tissue while being rotated such that the helical shaped component drives into the tissue in a corkscrew movement. Once the helical shaped component has been driven into the tissue to a desired depth, the helical shaped component can be pulled back without twisting, bringing the tissue closer to the suturing apparatus and into the suturing needle path. In some examples, an apposition tool may include a tissue retracting component with an additional or alternative configuration than a helical shaped component, such as opposed jaws, clamps, or other configurations. In some examples, an apposition tool may create a vacuum pressure. Vacuum pressure may be pulled through the working channel of the elongate device, creating a negative pressure between the suturing apparatus and the tissue surface. This pressure may cause a portion of tissue to be pulled into the suture needle path. The apposition force may be a vacuum force through the working channel 108 or another channel of the device 102 that draws the tissue toward the device. In some examples, the apposition force may draw the apposed tissue into the tissue apposition chamber 120. In some examples, an apposition force applied to tissue may be via a combination of use of a tissue retracting component (e.g., a helical shaped component) and vacuum pressure. In some examples, the elongate device 102 may be positioned or arranged such that the patient tissue extends within the path of the suture needle so that an apposition force is not required. For example, tissue may be presented to the suturing device by articulating the elongate device.

[0048] At a process 208, the apposed tissue may be engaged with the suture needle and the suture strand to create a suture bite. The suture bite may be a full thickness suture throw through apposed tissue including all layers of the tissue. In some examples, a full length of the suture needle, including a distal end and a proximal end may pass through the apposed tissue in a single direction motion to create the suture bite. In some examples, the suture needle may engage the full thickness of the tissue in a first direction and retract through the tissue in an opposite direction.

[0049] At a process 210, one or more suture bites may be created in the tissue to form a suture pattern in a pattern direction, between the initial suture and a final suture. The suture pattern may be linear or curved. The suture pattern may be achieved with a single length of suture material and may be bounded by termination members. In some examples, this process may be omitted.

[0050] At a process 212, a second termination member may be fixed to a second portion of the suture strand. For example, an anchoring termination member may be attached to an end of a suture strand, or a cinching termination member may be attached to an end or along a length

of a suture strand. The second termination member may be an initial termination member (e.g., termination member 130) attached proximate to the initial suture of a suture pattern or may be a final termination member (e.g., termination member 132) attached proximate to the final suture of a suture pattern. In some examples, the second termination member may be coupled to, or may be a portion of, the suture needle (e.g. needle 114).

[0051] At a process 214, the suture strand may be cinched to create a tissue plication. For example, tension may be applied to the suture strand 116 as the elongate device 102 or the second termination member (e.g., termination member 130, 132) is forced toward the tissue. A plication may result as the tissue forming the tissue bites and the tissue between the tissue bites is drawn together. In some examples, this process may be omitted.

[0052] At a process 216, the second termination member may be fixed to the suture strand to secure the tissue plication. For example, the second termination member may be clamped, clipped, crimped, tied, or otherwise secured to the second termination member after the tissue has been cinched to secure the tissue plication and limit or prevent migration of the suture strand from the tissue.

[0053] In various examples, a suturing procedure may be characterized as a forward cinch suturing procedure or a reverse cinch suturing procedure. A forward cinch suturing procedure may form a suture plication by cinching the suture strand in the same direction that the suture strand is routed through tissue during the suture pattern formation. For example, with reference to FIG. 1A, a forward cinch suturing procedure tensions the suture strand 116 in the direction D2, which is the same direction as the pattern direction 134. A reverse cinch suturing procedure may form a suture plication by cinching the suture strand in the opposite direction that the suture strand is routed through tissue during the suture pattern formation. For example, with reference to FIG. 1A, a reverse cinch suturing procedure tensions the suture strand 116 in the direction D1, which is opposite the pattern direction 134.

[0054] FIG. 3 is a flowchart illustrating a method 300 for suturing tissue with a forward cinch suturing procedure. The method 300 may be used in conjunction with any of the suture apparatuses disclosed herein. The description of method 300 is made with reference to examples in FIGS. 4-7H.

[0055] At a process 302, an elongate device may be advanced into a patient anatomy and into proximity with a patient tissue at a procedure site. For example, with reference to FIG. 4, an elongate device 352 (e.g., the elongate device 102) may be advanced into proximity with the tissue 374 (e.g. tissue 124).

[0056] At a process 304, an initial termination member may be fixed to a first portion of the suture strand. For example, with reference to FIG. 6A, an anchoring termination member 380 may be attached to a proximal end portion of a suture strand 356 (e.g., suture strand 116). A suture needle 364 may be attached to a distal end portion of the suture strand 356. In this example, the anchoring termination member 380 may become lodged proximate to the initial suture following plication, as described below. FIG. 7A illustrates another example of an initial termination member affixed to a first portion of a suture strand. An instrument system 400 (e.g., the instrument system 100) includes an elongate device 402 and a suture apparatus 404. A working channel 408 extends through the elongate device 402 and a portion of the suture apparatus 404. A tissue apposition tool 419 may be extendable from the working channel 408. In alternative embodiments, a tissue apposition tool 419 may be extendable thorough an exterior channel outside of an outer housing of the elongate device 402. The suture apparatus 404 includes an arcuate needle 414 including a needle arm 415, a first end portion 417, and a second end portion 418. The first and second end portion 417, 418 may be coupled at opposite ends of the needle arm 415 but otherwise may extend free from other components of the suture apparatus 404. A first end portion 421 of a suture strand 416 is coupled to the needle arm 415, and a second end 423 of the suture strand 416 may be coupled to an anchoring termination member 430 which may be an initial termination member. The suture strand 416 may extend through working channel 408 such that the second end 423 of the suture strand 416 is manipulatable outside of the elongate device 402.

[0057] With reference to FIG. 3, at a process 306, an apposition force may be applied to the patient tissue, or the patient tissue may otherwise be positioned within the path of the suture needle. For example, with reference to FIG. 5, an apposition tool 351 may extend from the elongate device 352 and grasp the tissue 374. As the apposition tool 351 is retracted relative to the elongate device 352, the grasped tissue 374 may begin to fold into an apposed configuration. FIG. 7A illustrates another example of applying an apposition force using an instrument system 400. In this example, the apposition tool 419 may include a helical extension 413 to threadedly engage the patient tissue 424. With the patient tissue 424 grasped by the helical extension 413, the apposition tool 419 may be retracted into the working channel 408, causing the tissue to tent and fold into an apposed configuration as shown in FIGS. 7A and 7B. In some examples, the elongate device 352 may be positioned or arranged such that the patient tissue extends within the path of the suture needle so that an apposition force is not required. For example, tissue may be presented to the suturing device by articulating the elongate device.

[0058] With reference to FIG. 3, at a process 308, the apposed tissue may be engaged with the suture needle and the suture strand to create a suture bite. The suture bite may be a full thickness suture throw through apposed tissue including all layers of the tissue. For example, with reference to FIG. 6A, the apposed tissue 374 is engaged with the suture needle 364 to create a suture bite 372A. With reference to the example of FIG. 7B, the suture needle 414 and the first end portion 421 of the suture strand 416 may pass through the apposed tissue 424. As shown in FIG. 7C, after the full length of the needle arm 415, including the first end portion 417 and the second end portion 418 passes through the apposed tissue 424, a suture bite 422A is created in the tissue 424. After the suture bite 422A is created, the apposition tool 419 may be released from the tissue 424 by reverse threading of the helical extension 413. In this example, the arcuate needle 414 may follow an arcuate or circular throw path in which the needle 414 travels approximately 360 degrees in a single motion direction to create the suture bite 422A. Along the path, the entire needle may pierce the tissue, pass through the tissue, exit the tissue and return to the original position. Motion of the arcuate needle 414 may originate from a staging position, and the needle may return to the staging position after creating the suture bite. Alternatively, the needle may engage the full thickness of the tissue in a first direction and retract through the tissue in an opposite direction.

[0059] With reference to FIG. 3, at a process 310, one or more suture bites may be created in the tissue to form a suture pattern in a pattern direction, between the initial suture and a final suture. For example, with reference to FIG. 6B, four suture bites 372A, 372B, 372C, 372D may be performed by repeating the processes 306 and 308 to form a suture pattern 355. Suture bite 372A may be the initial suture, and suture bite 372D may be the final suture. A single length of the suture strand 356 may be threaded through the tissue to form the suture pattern 355. With reference to FIG. 7C, the processes 306 and 308 may be repeated to create a plurality of suture bites 422A, 422B in the tissue 424. In some examples, this process 310 may be omitted.

[0060] With reference to FIG. 3, at a process 311, the initial termination member may be delivered into the patient anatomy. The delivery of the initial termination member into the anatomy may occur at various stages of the method 300. In some examples, the delivery of the initial termination member may occur after the final suture in the suture pattern is completed. In some examples, the initial termination member may be housed in the suture apparatus and may be delivered into the anatomy with the introduction of the elongate device. In some examples, the initial termination member may be delivered before or after the completion of the initial suture and prior to a second suture. With reference to FIG. 6B, anchoring termination member 380 may be delivered through the elongate device 352 and into the patient anatomy.

With reference to FIG. 7D, the anchoring termination member 430 and suture strand 416 may be delivered through the working channel 408 by a transfer tool 431.

[0061] With reference to FIG. 3, at a process 312 a final termination member may be fixed to a second portion of the suture strand proximate to the final suture. For example, with reference to FIG. 6B, a final termination member 382 may be delivered through or along the elongate device 352 by a transfer tool 383. In this example, the final termination member 382 may be a cinching termination member that includes a side slot that allows the termination member 382 to attach along the length of the suture strand 356. The cinching termination member 382 may be advanced in the direction D3, along the suture strand 356 toward the final suture bite 372D. A tensioning tool 385 may be operated through or along the elongate device 352 or distally of the elongate device to apply tension in the direction D4 to the suture strand 356 and/or move the suture strand into proximity of the cinching termination member 382 to attach the termination member to the suture strand. The tensioning tool 385 may engage with the suture strand 356 anywhere along the length of the suture strand and may allow the user to pull the suture proximally or into the working channel of the elongate device. The tensioning tool 385 may pull excess suture strand through the tissue as well as apply suture strand tension during cinching. In this example, the suture needle 364 may remain in the patient anatomy, coupled to a distal end of the suture strand 356, as the cinching termination member 382 is fixed to the suture strand. With reference to FIG. 7E, a final termination member 432 may be delivered through the working channel 408 by the transfer tool 431. In this example, the final termination member 432 may be a cinching termination member that includes a side slot that allows the termination member 432 to attach along the length of the suture strand 416 as shown in FIG. 7G.

[0062] With reference to FIG. 3, at a process 314, the suture strand may be cinched to create a tissue plication. For example, with reference to FIG. 6C, the cinching termination member 382 may be advanced along the suture strand 356 toward the anchoring termination member 380 (e.g., the initial termination member) as the suture strand is pulled in the direction D5, the direction in which the suture pattern was created. The tissue 374 may form a plication comprised of the tissue folded at the suture bites. As the tissue is pliated, the anchoring termination member 380 (e.g., the initial termination member) may be drawn toward the cinching termination member 382 (e.g., the final termination member), with the tensioning of the suture strand 356. With reference to FIG. 7G, the cinching termination member 432 (e.g., the final termination member) may be advanced along the suture strand 416 toward the final suture 422B as the suture strand is pulled in the direction D6, the direction in which the suture

pattern was created. The tissue 424 may form a plication comprised of the tissue folded at the suture bites. As the tissue is plicated, the anchoring termination member 430 (e.g., the initial termination member) may be drawn toward the final termination member 432, with the tensioning of the suture strand 416. In some examples, the process 314 may be omitted.

[0063] With reference to FIG. 3, at a process 316, the final termination member may be fixed to the suture strand to secure the tissue plication. For example, with reference to FIG. 6C, the cinching termination member 382 (e.g., the final termination member) may be crimped, clamped, clipped, tied, or otherwise fixed to the suture strand 356 to secure the plication and prevent migration of the suture strand 356 from the tissue 374. With reference to FIG. 7H, the cinching termination member 432 (e.g., the final termination member) may be fixed to the suture strand 416 to secure the plication and prevent migration of the suture strand 416 from the tissue 424. In some examples, the cinching termination member 432 may create a mid-cinch in a more extended suturing procedure that continues with a continuous length of the suture strand 416 and the suture needle 414.

[0064] Optionally, as shown in FIG. 6C, the suture strand 356 may be cut after the cinching termination member 382 is secured, and the suture needle 364 and the remnant suture strand 356 may be removed through the elongate device 352 using the tensioning tool 385 or another retrieval tool, as shown in FIG. 6D. In some examples, the suturing procedure may continue with a new suture strand and the same needle. Using a new suture strand for each plication may reduce or eliminate risks, such as tangling, associated with longer suture strands. In some examples, a new suture needle may be used with the new length of suture strand to reduce risks associated with needle dulling.

[0065] FIG. 8 is a flowchart illustrating a method 500 for suturing tissue with a reverse cinch suturing procedure. The method 500 may be used in conjunction with any of the suture apparatuses disclosed herein. The description of method 500 is made with reference to examples in FIGS. 9A-10G.

[0066] At a process 502, an elongate device may be advanced into a patient anatomy and into proximity with a patient tissue at a procedure site. For example, with reference to FIG. 9A, an elongate device 552 (e.g., the elongate device 102) may be advanced into proximity with the tissue 574 (e.g. tissue 124).

[0067] At a process 504, a final termination member may be fixed to a first portion of the suture strand. When the suture strand is finally secured to form a tissue plication (e.g. process 516), the final termination member may be located proximate to the final suture bite. For example, with reference to FIG. 9B, a final termination member may be an anchoring

termination member 582 attached to a distal end portion of a suture strand 556 (e.g., suture strand 116). A suture needle 564 may also be attached to a distal end portion of the suture strand 356. In some examples, the suture needle 564 may be coupled to the anchoring termination member 582. In some examples, the suture needle 564 may include the anchoring termination member 582. In this example, the anchoring termination member 582 may become lodged proximate to the final suture following plication, as described below. In some examples, the anchoring termination member 582 may be coupled to suture strand 556 outside of the patient anatomy and may be introduced through or along the elongate device 552 into the patient anatomy. In some examples, the anchoring termination member 582 may be coupled to the suture strand within the patient anatomy. In some examples, the anchoring termination member 582 may be coupled to the suture needle 564 outside of the patient anatomy and both may be introduced into the patient anatomy through or along the elongate device 552. In some examples, the anchoring termination member 582 may be coupled to the suture needle within the patient anatomy. FIG. 10A illustrates another example of a first termination member affixed to a first portion of a suture strand. An instrument system 600 (e.g. the instrument system 100) includes an elongate device 602 and a suture apparatus 604. A working channel 608 extends through the elongate device 602 and a portion of the suture apparatus 604. A first end portion 621 of a suture strand 616 is coupled to an anchoring termination member 632. A transfer tool 631 may be extendable through the working channel 608 to deliver the suture strand 616 and the anchoring termination member 632 into the patient anatomy. The suture strand 616 may extend through working channel 608 such that a second end portion of the suture strand 616 is manipulatable outside of the elongate device 602. The suture apparatus 604 includes an arcuate needle 614 including a needle arm 615, a first end portion 617, and a second end portion 618. The anchoring termination member 632 may be coupled to a second end portion 618 of the arcuate needle 614 as shown in FIG. 10B. For example, the second end portion 618 may include a projection insertable into a passage of the anchoring termination member 632. The anchoring termination member 632 may include an arcuate shape that may generally have a radius of curvature similar to the needle arm 615. In some examples, the anchoring termination member 632 may be a portion of the arcuate needle 614.

[0068] With reference to FIG. 8, at a process 506, an apposition force may be applied to the patient tissue, or the patient tissue may otherwise be positioned within the path of the suture needle. For example, with reference to FIG. 9B, an apposition tool 551 may extend from or along the elongate device 552 and grasp the tissue 574. As the apposition tool 551 is retracted relative to the elongate device 552, the grasped tissue 574 may begin to fold into an apposed

configuration. FIG. 10C illustrates another example of applying an apposition force using an instrument system 600. In this example, a tissue apposition tool 619 may be extendable from the working channel 608. The apposition tool 619 may include a helical extension 623 to threadedly engage the patient tissue 624. With the patient tissue 624 grasped by the helical extension 623, the apposition tool 619 may be retracted into the working channel 608, causing the tissue to tent and fold into an apposed configuration as shown in FIG 10C. In some examples, the elongate device 5522 may be positioned or arranged such that the patient tissue extends within the path of the suture needle so that an apposition force is not required. For example, tissue may be presented to the suturing device by articulating the elongate device.

[0069] With reference to FIG. 8, at a process 508, the apposed tissue may be engaged with the suture needle and the suture strand to create a suture bite. The suture bite may be a full thickness suture throw through apposed tissue including all layers of the tissue. For example, with reference to FIG. 9B, the apposed tissue 574 may be engaged with the suture needle 564, following a path 573 to create a suture bite 575. With reference to the example of FIG. 10C, the suture needle 614 and the first end portion 621 of the suture strand 616 may pass through the apposed tissue 624. After the full length of the needle arm 615, including the first end portion 617 and the second end portion 618 passes through the apposed tissue 624, a suture bite 622A is created in the tissue 624. After the suture bite 622A is created, the apposition tool 619 may be released from the tissue 624 by reverse threading of the helical extension 623. In this example, the arcuate needle 614 may follow a circular throw path in which the needle 614 travels approximately 360 degrees in a single motion direction to create the suture bite 622A. Alternatively, the needle may engage the full thickness of the tissue in a first direction and retract through the tissue in an opposite direction.

[0070] With reference to FIG. 8, at a process 510, one or more suture bites may be created in the tissue to form a suture pattern in a pattern direction, between the initial suture and a final suture. For example, with reference to FIG. 9D, four suture bites 572A, 572B, 572C, 572D may be performed by repeating the processes 506 and 508 to form a suture pattern 555. Suture bite 572A may be the initial suture, and suture bite 572D may be the final suture. A single length of the suture strand 556 may be threaded through the tissue to form the suture pattern 555. With reference to FIG. 7C, the processes 506 and 508 may be repeated to create a plurality of suture bites 522A, 522B in the tissue 524. In some examples process 510 may be omitted.

[0071] With reference to FIG. 8, at a process 511, the final termination member may be released from the needle. With reference to FIG. 9D, the anchoring termination member 582 may be released from the needle 564 and become lodged proximate to the final suture bite

572D. In some examples, the needle 564 may be removed from the patient anatomy through the elongate device 552 or may remain in the patient anatomy to create another suture pattern. In some examples, the needle 564 may optionally remain as part of the anchoring termination member 582 and not released. In some examples, the needle 564 may be withdrawn from the patient anatomy by withdrawing the elongate device 552 to which the needle is coupled. With reference to FIG. 10D, the anchoring termination member 632 may be released from the needle arm 615 to become lodged proximate to the final suture bite 622B.

[0072] With reference to FIG. 8, at a process 512 an initial termination member may be fixed to a second portion of the suture strand proximate to the initial suture. When the suture strand is finally secured to form a tissue plication (e.g. process 516), the initial termination member may be located proximate to the initial suture bite. For example, with reference to FIG. 9E, an initial termination member 580 may be delivered through or along the elongate device 552 by a transfer tool 583. In this example, the initial termination member 580 may be a cinching termination member that include a side slot that allows the termination member 580 to attach along the length of the suture strand 556. The cinching termination member 580 may be advanced along the suture strand 556 toward the final suture bite 572A. A tensioning tool (not shown) may be operated through or along the elongate device 552 or distally of the elongate device to apply tension to the suture strand 556 and/or move the suture strand into proximity of the cinching termination member 580 to attach the termination member to the suture strand. With reference to FIG. 10E, an initial termination member 630 may be delivered through the working channel 608 by the transfer tool 631. In this example, the initial termination member 630 may be a cinching termination member that includes a first portion 635 and a second portion 637 between which the suture strand 616 may be clamped. The first portion 635 of the cinching termination member 630 may be delivered through the transfer tool 631 along the suture strand 616. The second portion 637 of the cinching termination member 630 may be delivered through the transfer tool 631 along the suture strand 616.

[0073] With reference to FIG. 8, at a process 514, the suture strand may be cinched to create a tissue plication. For example, with reference to FIG. 9E, the cinching termination member 580 may be advanced along the suture strand 556 toward the anchoring termination member 582 (e.g., the final termination member) as the suture strand is pulled in the direction D7, the direction opposite that in which the suture pattern was created. The tissue 574 may form a plication comprised of the tissue folded at the suture bites. As the tissue is pliated, the anchoring termination member 582 (e.g., the final termination member) may be drawn toward the cinching termination member 580 (e.g., the initial termination member), with the tensioning

of the suture strand 556. With reference to FIG. 10F, the cinching termination member 630 (e.g., the initial termination member) may be advanced along the suture strand 616 toward the final suture 622A as the suture strand is pulled in the direction opposite that in which the suture pattern was created. The tissue 624 may form a plication comprised of the tissue folded at the suture bites. As the tissue is pliated, the anchoring termination member 632 (e.g., the final termination member) may be drawn toward the initial termination member 630, with the tensioning of the suture strand 616. In some examples, the process 514 may be omitted.

[0074] With reference to FIG. 8, at a process 516, the initial termination member may be fixed to the suture strand to secure the tissue plication. For example, with reference to FIG. 9F, the cinching termination member 580 (e.g., the initial termination member) may be crimped, clamped, clipped, tied, or otherwise fixed to the suture strand 556 to secure the plication and prevent migration of the suture strand 556 from the tissue 574. Optionally, the suture strand 556 may be cut after the cinching termination member 580 is secured, and the suture needle 564 and any remnant suture strand 556 may be removed through the elongate device 552. With reference to FIG. 10G, the cinching termination member 630 (e.g., the initial termination member) may be fixed to the suture strand 616 to secure the plication and prevent migration of the suture strand 616 from the tissue 624.

[0075] In some examples of a reverse cinch suturing procedure, the suturing procedure may continue with a new suture strand and a new anchoring termination member but the same suture needle. In some examples, the suturing procedure may continue with a new suture strand, a new anchoring termination member, and a new suture needle. In some examples, the anchoring termination member may include a portion of or the entire suture needle, and the suture needle (or portion thereof) for the first plication remains within the patient anatomy affixed to the suture. In this example, the suturing procedure may continue with a new suture strand and a new suture needle to serve as the anchoring termination member for a second plication.

[0076] Various systems and techniques may be used to perform a cinching process (e.g., processes 214, 314, 514) of a suturing procedure. In some examples, cinching tools may be used in a cinching process to tension the suture strand and apply a cinching termination member to the suture strand to secure a tissue plication. FIG. 11 is a flowchart illustrating a method 700 for cinching a suture strand and securing a tissue plication. The method 700 may be used in conjunction with any of the suture procedures disclosed herein. The description of method 700 is made with reference to examples in FIGS. 12A-12F.

[0077] At a process 702, a cinching tool may be extended from an elongate device. For example and with reference to FIG. 12A and 12B, an elongate device 750 (e.g., the elongate

device 102) may include a working channel 752. A cinching tool 754 may be slidable within and extendable from a distal end of the working channel 752. The cinching tool 754 may include a delivery tube 756 and outer portion 758 of a cinching termination member 760. The outer portion 758 may be coupled to a distal end of the delivery tube 756, for example by a press fit contact or a frictional slip fit between an inner surface 759 of the outer portion 758 and the delivery tube 756. In some examples, the outer portion 758 may have a tubular or partially tubular shape. The cinching tool 754 may also include a capture device 762 of a tensioning tool (e.g., a tensioning tool 385) sized to slide through a channel 764 of the delivery tube 756. The capture device 762 may include a control member 766 (or one or more control members 766) and a suture strand engagement portion 767 coupled to a distal end of the control member. The suture strand engagement portion 767 may include a hook, snare, or other structure to engage or catch the suture strand. The control member 766 may extend through the delivery tube 756. The control member 766 may include a wire, rod, or other structural member configured to advance, retract, and/or rotate the capture device 762. The cinching tool 754 may also include an inner portion or plug 768 of the cinching termination member 760. The inner portion 768 may be sized to pass through the channel 764 of the delivery tube 756 and extend within the outer portion 758 of the cinching termination member 760. In some examples, the inner portion 768 may have a tubular or partially tubular shape. The inner portion 768 may be removably coupled to a distal end of a control member 770 (or one or more control members 770) that extends through the delivery tube 756. The control member 770 may include a wire, rod, or other structural member configured to advance, retract, and/or rotate the inner portion 768. The control member 766 and the control member 770 may be independently controlled outside of the patient anatomy by, for example, manual operation or robotically-assisted control. The outer portion 758 of the cinching termination member 760 may include a slot 780 extending partially along the length of the outer portion 758 and a slot 782 extending partially along the length of the outer portion 758. The slot 780 may be shorter than the slot 782 and the slot 780 may be located approximately 180 degrees opposite the slot 782.

[0078] With reference to FIG. 11, at a process 704, a suture strand may be captured by a capture device of the cinching tool. For example and with reference to FIG. 12B, by manipulating the control member 766, the suture strand engagement portion 767 may be extended distally from delivery tube 756 and from the outer portion 758 of the cinching termination member 760 and may be rotated as needed to snare a suture strand 772 (e.g., the suture strand 116). In some examples, the cinching tool 754 and the suture strand 772 may be visualized with an imaging device 774 incorporated into the elongate device 750. The suture

strand engagement portion 767 may be extended between inner portion 768 and the outer portion 758 of the cinching termination member 760 so that capturing the suture strand 772 includes positioning the suture strand between the inner portion 768 and the outer portion 758 of the cinching termination member 760 as shown in FIG. 12B.

[0079] With reference to FIG. 11, at a process 706, the suture strand engagement portion and the inner portion of the cinching termination member may be retracted into the outer portion of the cinching termination member. For example and with reference to FIG. 12C, the capture device 762 and the inner portion 768 may be rotated relative to the outer portion 758 of the cinching termination member 760 to align the suture strand 772 within the slots 780, 782. Alternatively, the delivery tube 756 and the coupled outer portion 758 may be rotated to align the slots 780, 782 with the suture strand 772. The capture device 762, including the suture strand engagement portion 767 may be retracted in a direction D8 into the outer portion 758 and, optionally, into the delivery tube 756. In this position, the suture strand 772 is constrained by the outer portion 758 to prevent the suture strand from being removed from the capture device 762 but still allowing the suture strand to slide relative to the capture device. A portion 776 of the suture strand 772 may extend between the cinching tool 754 and patient tissue such as a suture bite. A portion 778 of the suture strand 772 may extend between the cinching tool 754 and a suturing needle.

[0080] With reference to FIG. 11, at a process 708, the suture strand engagement portion may be further retracted to tension the suture strand. For example and with further reference to FIG. 12C, the capture device 762 including the suture strand engagement portion 767 may be retracted further in the direction D8. The retraction of the capture device 762 may create tension in a direction D9 in the suture strand 772 captured by the suture strand engagement portion 767. Tension in the direction D9 may cause the suture strand 772 to tighten within the patient tissue and draw the suture bites closer together to create a tissue plication. Additionally, the cinching tool 754 may be advanced toward the tissue while tension is applied to the suture strand 772 so that the inner portion 768 and the outer portion 758 of the cinching termination member 760 are moved closer to the anchoring termination member, creating a tighter plication.

[0081] With reference to FIG. 11, at a process 710, the inner portion of the cinching termination member may be fixed to the outer portion of the cinching termination member to form a connected termination member. The suture strand may be clamped between the inner and outer portions to prevent or resist migration of the suture strand. For example and with reference to FIG. 12D, the inner portion 768 of the cinching termination member 760 may be

fixed to the outer portion 758 of the cinching termination member 760 to form a connected termination member 760. More specifically, the portion 776 of the suture strand 772 between the tissue and the cinching tool may be compressed or clamped between the outer surface of the inner portion 768 and the inner surface of the outer portion 758. The compression between the inner and outer portions of the cinching termination member 760 may create sufficient friction to prevent or restrict sliding of the suture strand 772 relative to the cinching termination member. Thus, the cinching termination member 760 may lock to the suture strand 772 and maintain the tissue plication with an applied amount of tension in the suture strand 772.

[0082] With reference to FIG. 11, at a process 712, the suture stand may be severed causing a portion of the suture strand to remain compressed within the cinching termination member and a proximal portion of the suture strand to become free from the cinching termination member. For example and with reference to FIG. 12E, the outer portion 758 may include a cutting surface 784 such as a pin or a sharpened edge. The inner portion 768 may be retracted relative to the outer termination member 760 to bring a cutting region 786 of the portion 776 of the suture strand 772 into contact with the cutting surface 784, causing the suture strand to become severed. With the suture strand 772 severed at the cutting region 786, the portion 776 of suture strand 772 remains compressed between the inner portion 768 and the outer portion 758 of the cinching termination member 760. The portion 778 of the suture strand 772 is disconnected from the connected termination member 760 and from the portion 776 of the suture strand 772.

[0083] With reference to FIG. 11, at a process 714 the outer portion of the cinching termination member may be separated from the delivery tube. For example and with reference to FIG. 12F, the outer portion 758 of the cinching termination member 760 may be separated from the delivery tube 756 and the control member 770 may be separated from the inner portion 768 of the cinching termination member 760. Thus separated from all supports of the cinching tool 754, the cinching termination member 760 (e.g., cinching termination member 630) may remain within the patient anatomy as a lock to maintain tension in the suture plication.

[0084] FIGS. 12G-12L depict an example cinching tool 754' that may be used to perform a cinching process according to the method 700 of FIG. 11. The cinching tool 754' is similar to the cinching tool 754 described with reference to FIGS. 12A-12F. To avoid repetition, differences between the cinching tool 754' and the cinching tool 754 will be primarily described.

[0085] As shown in FIGS. 12G-12L, the cinching tool 754' includes a delivery tube 756', a cinching termination member 760' having an outer portion 758' and an inner portion or plug

768', a capture device 762' of a tensioning tool (e.g., tensioning tool 385), an optional release member 765', and a control member 770'. The capture device 762' includes a control member 766' and a suture strand engagement portion 767' coupled to a distal end of the control member 766'. FIGS. 12G-12L further depict a suture strand 772' that is captured by the cinching tool 754'. The cinching tool 754' may be slidable within and extendable from a distal end of the working channel 752 of FIG 12A similarly as described above for the cinching tool 754.

[0086] Similarly as described for the cinching tool 754, the suture strand engagement portion 767' of the capture device 762' and the inner portion 768' of the cinching termination member 760' may be retracted relative to the outer portion 758' of the cinching termination member 760' to apply tension to a captured suture strand 772' and to lock the captured suture strand 772'. Different from the cinching tool 754, the cinching termination member 760' omits the slots 780, 782 of the outer portion 758 of the cinching termination member 760. By omitting the slots 780, 782, the inner portion 768' of the cinching termination member 760' may be retracted into engagement with the outer portion 758' and the suture strand 772' may be captured without a step of rotationally aligning the suture strand with the slots. That is, the user may retract the inner portion 768' of the cinching termination member 760' without consideration for how the inner portion 768' and how the suture strand 772' is rotationally oriented relative to the outer portion 758'. As such, the cinching termination member 760' may be rotationally agnostic. When cinching the captured suture strand 772', opposite portions of the suture strand 772' (e.g., portions 776', 778') may be locked when the cinching termination member 760' is locked. Similarly to the cinching termination member 760, the inner portion 768' of the cinching termination member 760' is removably coupled to a distal end of a control member 770'. The control member 770' may include a wire, rod, or other structural member configured to advance, retract, and/or rotate the inner portion 768'. The control member 770' may be centrally located relative to the inner portion 768' of the cinching termination member 760' (e.g., along a central longitudinal axis of the inner portion 768') to aid with distributing axial tensile forces.

[0087] The optional release member 765' may be provided at the distal end of the delivery tube 756'. The release member 765' may have a substantially hollow tubular body with a central opening configured to receive the inner portion 768' and the outer portion 758' of the cinching termination member 760'. The release member 765' may be used to releasably couple the outer portion 758' of the cinching termination member 760' to the delivery tube 756'. The delivery tube 756' is configured to be advanced distally to extend the outer portion 758' of the cinching termination member 760' from the elongate device 750. The release member 765'

may include one or more engagement members 777' that are configured to releasably engage with one or more complementary engagement members 779' of the outer portion 758' to hold the outer portion 758' in engagement with the delivery tube 756'. In some embodiments, the engagement members 777' of the release member 765' are in the form of protruding members (such as teeth or the like) and the engagement members 779' of the outer portion 758' may be in the form of one or more grooves to receive the protruding members of the release member 765'. In alternative embodiments, the release member 765' may have the one or more grooves and the outer portion 758' may have the one or more protruding members. In addition, the release member 765' may have one or more wedged-shaped indentations 781' on an inner diameter of the tubular body of the release member 765', and may have one or more axial slots 783'. The axial slots 783' allow the release member 765' to expand to release the cinching termination member 760' as described herein. The wedged-shaped indentations 781' may be arranged annularly on an inner diameter of the tubular body of the release member 765'. The wedged-shaped indentations 781' may have a tapered or sloping surface that extends inwardly towards a central longitudinal axis of the release member 765' in a distal to proximal direction of the release member 765'. A proximal end of the inner portion 768' of the cinching termination member 760' may have a tapered or sloping surface 785' that tapers inwardly towards the proximal end. In use, as the inner portion 768' of the cinching termination member 760' is retracted into engagement with the outer portion 758' to lock a suture strand 772', the tapered surface 785' of the inner portion 768' comes in contact with the wedged-shaped indentations 781' of the release member 765'. Further retraction of the inner portion 768' causes the release member 765' to expand outwardly and release the cinching termination member 760'. The inner portion 768' and the outer portion 758' of the cinching termination member 760' are sized such that the cinching termination member 760' will be released once inner portion 768' has been seated to a fully engaged position with the outer portion 758'. That is, the release member 765' will not expand and disengage the outer portion 758' until the inner member 768' is sufficiently retracted to lock the suture strand 772' and causes the release member 765' to expand. In so doing, the release member 765' helps to prevent inadvertent premature release of the cinching termination member 760'. It should be appreciated that the release member 765' may be omitted in some embodiments, and the outer portion 758' of the cinching termination member 760' may be coupled to the distal end of the delivery tube 756', for example, by a frictional slip fit contact between an inner surface of the outer portion 758' and the delivery tube 756'.

[0088] The capture device 762' includes an axial slot 787' to accommodate the control member 770' used to move the inner portion 768' of the cinching termination member 760'. The axial slot 787' may run along a central longitudinal axis of the capture device 762' to allow the control member 770' to extend through the capture device 762'. The capture device 762' further includes the control member 766' to advance, retract, and/or rotate the suture strand engagement portion 767'. The control member 766' may be in the form of a tubular member (e.g., torque tube or coil pipe) and a distal end of the control member 766' may be rigidly affixed to a proximal end of the suture strand engagement portion 767'.

[0089] FIG. 13 is a flowchart illustrating an alternative method 800 for cinching a suture strand and securing a tissue plication. The method 800 may be used in conjunction with any of the suture procedures disclosed herein. The description of method 800 is made with reference to examples in FIGS. 14A-14C.

[0090] At a process 802, a cinching tool may be extended from an elongate device. For example and with reference to FIG. 14A, a cinching tool 850 may be slidable within and extendable from a distal end of a working channel of an elongate device (e.g., elongate device 102). The cinching tool 850 may include an elongate shaft 851. The cinching tool 850 may include a cinching termination member 852 including an outer portion 854 and an inner portion 856. In this example, the outer portion 854 may include a coil and the inner portion 856 may include a suture strand engagement portion 858 and a plug portion 860. The suture strand engagement portion 858 may include a hook, snare, or other structure to engage or catch the suture strand. The coiled outer portion 854 may be sized to extend coaxially around the inner portion 856. The coiled outer portion 854 may include a region 862 in which the spacing or pitch between the coil wraps is expanded to allow passage of a suture strand 870. The inner portion 856 may be sized to pass within the coil of the outer portion 854 and may be coupled to the elongate shaft 851. Motion of the inner portion 856 and the outer portion 854 may be controlled by manipulation of control members or other mechanisms or structures of the suture apparatus. The inner portion 856 may be inserted into the outer portion 854 by manipulation of one or both portions within the patient anatomy, or the inner portion 856 may be inserted into the outer portion 854 prior to insertion into the patient anatomy.

[0091] With reference to FIG. 13, at a process 804, a suture strand may be captured by a suture strand engagement portion of the cinching termination member. For example and with further reference to FIG. 14A, the spaced region 862 of the outer portion 854 may be aligned with the suture strand engagement portion 858 of the inner portion 856. By manipulating the suture strand 870, the outer portion 854, and/or the inner portion 856, the suture strand 870

may be snared within the spaced region 862 and the suture strand engagement portion 858. In some examples, the cinching tool 850 and the suture strand 870 may be visualized with an imaging device.

[0092] With reference to FIG. 13, at a process 806, the outer portion of the cinching termination member may be retracted longitudinally to secure the suture strand within the capture device. For example and with reference to FIG. 14B, the outer portion 854 may be moved proximally relative to the inner portion 856 so that the coil wraps of the outer portion 854 cover the opening of the suture strand engagement portion 858. With the suture strand engagement portion 858 covered, the suture strand 870 may be loosely captured within the suture strand engagement portion by the outer portion 854.

[0093] With reference to FIG. 13, at a process 808, the suture strand may be tensioned to create a tissue plication. For example and with reference to FIG. 14B, the suture strand 870 may be tensioned in the direction D10. The tensioning force on the suture strand 870 may be provided by, for example, manual manipulation or robotically-assisted manipulation of a proximal end portion of the suture strand 870. Tension in the direction D10 may cause the suture strand 870 to tighten within the patient tissue and draw the suture bites of sutured tissue closer together to create a tissue plication. Additionally, the cinching termination member 852 may be advanced toward the tissue while applying tension to the suture strand 870 so that the inner portion 856 and the outer portion 854 of the cinching termination member 852 are moved closer to the anchoring termination member, creating a tighter plication.

[0094] With reference to FIG. 13, at a process 810, the outer portion of the cinching termination member may be retracted relative to and further along the inner portion of the cinching termination member to compress the suture strand between the outer portion and the inner portion. For example and with further reference to FIG. 14B, outer portion 854 may be further retracted relative to and along the inner portion 856, after the suture strand 870 has been tensioned, to compress the suture strand 870 between the outer portion 854 and the inner portion 856. The compression between the inner and outer portions of the cinching termination member 852 may prevent or restrict sliding of the suture strand 870 relative to the cinching termination member 852. Thus, the cinching termination member 852 may lock to the suture strand 870 and maintain the tissue plication.

[0095] With reference to FIG. 13, at a process 812, the suture stand may be severed causing a portion of the suture strand to remain compressed within the cinching termination member and a proximal portion of the suture strand to become free from the cinching termination member. For example and with reference to FIG. 14C, the suture strand 870 may be severed.

The suture strand 870 may be cut, for example, by engaging the suture strand 870 with a cutting tool extended through or along the elongate device into the patient anatomy or otherwise positioned near the cinching termination member 852 within the patient anatomy. With the suture strand 870 severed, a portion 872 of the suture strand 870 remains compressed between the inner portion 856 and the outer portion 854.

[0096] With reference to FIG. 13, at a process 814 the cinching termination member may be separated from the delivery tube. For example and with further reference to FIG. 14C, the cinching termination member 852 may be separated from all supports of the cinching tool 850, and the cinching termination member 852 (e.g., cinching termination member 630) may remain within the patient anatomy as a lock to maintain tension in the suture plication.

[0097] FIG. 15 is a flowchart illustrating an alternative method 900 for cinching a suture strand and securing a tissue plication. The method 900 may be used in conjunction with any of the suture procedures disclosed herein. The description of method 900 is made with reference to examples in FIGS. 16A-16D.

[0098] At a process 902, a cinching tool may be extended from an elongate device. For example and with reference to FIG. 16A and 16B, an elongate device 950 (e.g., the elongate device 102), may be used to create a suture pattern 951 through tissue 953 with a suture strand 972 using any of the suturing procedures previously described. The elongate device 950 may include a working channel 952. In this example, which may follow a forward cinch suturing procedure, a cinching termination member may be applied to the suture strand 972 after a final suture 955B. In this example, an anchoring termination member 957 may be advanced over a proximal portion 959 of the suture strand 972 and through the working channel 952 to be fixed to the suture strand 972 proximate to an initial suture 955A. Alternatively, the anchoring termination member 957 may be affixed to the suture strand proximally of the elongate device 950, and the proximal portion 959 of the suture strand with the affixed anchoring termination member 957 may be delivered through the working channel 952 and deposited in the patient anatomy.

[0099] A cinching tool 954 may be slidable within and extendable from a distal end of the working channel 952. The cinching tool 954 may include a delivery tube 956 and outer portion 958 of a cinching termination member 960. The outer portion 958 may be coupled to a distal end of the delivery tube 956. In some examples, the outer portion 958 may have a tubular or partially tubular shape. The cinching tool 954 may also include a capture device 962 sized to slide through a channel 964 of the delivery tube 956. The capture device 962 may include a suture strand engagement portion 967 coupled to a distal portion of a control member 966. The

suture strand engagement portion 767 may include a snare or other structure to engage or catch the suture strand. The suture strand engagement portion 967 may include a bounded aperture or channel 961 extending generally perpendicular to a long axis of the capture device 962 and sized to receive passage of a suture needle 963. The suture needle 963 may be similar to the arcuate suture needle 414 or 614 and may be a component of a suture apparatus similar to suture apparatus 404 or 604. A suture strand 972 may be coupled to the suture needle 963. The control member 966 may extend through the delivery tube 956. The control member 966 may include a wire, rod, or other structural member configured to advance, retract, and/or rotate the capture device 962. The cinching tool 954 may also include an inner portion or plug 968 of the cinching termination member 960. The inner portion 968 may be sized to pass through the channel 964 of the delivery tube 956 and extend within the outer portion 958 of the cinching termination member 960. In some examples, the inner portion 968 may have a tubular or partially tubular shape. The inner portion 968 may be removably coupled to a distal end of a control member 970 that extends through the delivery tube 956. The control member 970 may include a wire, rod, or other structural member configured to advance, retract, and/or rotate the inner portion 968. The control member 966 and the control member 970 may be independently controlled outside of the patient anatomy by, for example, manual operation or robotically-assisted control. Apertures 980 may extend through opposite sides of the outer portion 958.

[0100] With reference to FIG. 15, at a process 904, a suture needle and suture strand may be extended through the capture device. For example and with reference to FIG. 16B, the cinching tool 954 may be extended into the path of the suture needle 963 with apertures 980, 961 positioned proximate the path of the suture needle 963. The suture needle 963 may be moved along an arcuate path through the apertures 980 of the outer portion 958 of the cinching termination member 960 and through the aperture 961 of the suture strand engagement portion 967. As the suture needle 963 passes through the apertures 980, 961, the suture strand 972 is also pulled through the apertures 980, 961, thus threading the suture strand through the suture strand engagement portion 967. The entire length of the arcuate needle 963 may pass through the apertures 980, 961. In some examples, the cinching tool 954 and the suture strand 972 may be visualized with an imaging device 974 incorporated into the elongate device 950.

[0101] With reference to FIG. 15, at a process 906, the capture device including the suture strand engagement portion may be retracted to tension the suture strand and create a tissue plication. For example and with reference to FIG. 16C, capture device 962 may be retracted within the outer portion 958 and optionally into the delivery tube 956 to tension the suture strand 972 and create a plication in the tissue 953. The suture strand 972 may slide within the

apertures 980 as the capture device 962 is moved and the suture strand is tensioned. As the capture device 962 is retracted to create the tension, the inner portion 968 of the cinching termination member 960 may be positioned distally of the apertures 980. Additionally, the cinching tool 954 may be advanced toward the final suture 955B while the capture device 962 is retracted so that the inner portion 968 and the outer portion 958 of the cinching termination member 960 are moved closer to the anchoring termination member 957, creating a tighten plication.

[0102] With reference to FIG. 15, at a process 908, the inner portion may be fixed to the outer portion to form a connected termination member. The suture strand may be clamped between the inner and outer portions of the cinching termination member to prevent or resist migration of the suture strand. For example and with reference to FIG. 16D, the inner portion 968 may be fixed to the outer portion 958 to form a connected termination member 960. More specifically, the suture strand 972 may be compressed or clamped between the outer surface of the inner portion 968 and the inner surface of the outer portion 958. The compression between the inner and outer portion of the cinching termination member 960 may create sufficient friction to prevent or restrict sliding of the suture strand 972 relative to the cinching termination member. Thus, the cinching termination member 960 may lock to the suture strand 972 and maintain the tissue plication.

[0103] With reference to FIG. 15, at a process 910, the suture stand may be severed causing a portion of the suture strand to remain compressed within the cinching termination member and a proximal portion of the suture strand to become free from the cinching termination member. With the suture strand 972 severed, a portion 976 of the suture strand 972 remains compressed between the inner portion 968 and the outer portion 958.

[0104] With reference to FIG. 15, at a process 912 the outer portion of the cinching termination member may be separated from the delivery tube. For example, the outer portion 958 of the cinching termination member 960 may be separated from the delivery tube 956 and the control member 970 may be separated from the inner portion 968. Thus separated from all supports of the cinching tool 954, the cinching termination member 960 may remain within the patient anatomy as a lock to maintain tension in the suture plication. The use of the cinching procedure and system as described in FIGS. 15-16D in which actuation of the suture needle captures the suture strand within the cinching termination member may be more efficient than procedures and systems that require careful tool manipulation and visualization to snare the suture strand within the cinching termination member.

[0105] FIG. 17 is a flowchart illustrating an alternative method 1000 for cinching a suture strand and securing a tissue plication. The method 1000 may be used in conjunction with any of the suture procedures disclosed herein. The description of method 1000 is made with reference to examples in FIGS. 18A-18D. In this example, the elongate device 950 may be used to deliver a cinching tool 1054. The preceding description of the structure and function of the elongate device 950 and the arcuate needle 963 will also be referenced for this example.

[0106] At a process 1002, a cinching tool may be extended from an elongate device. For example and with reference to FIG. 18A, a cinching tool 1054 may be slidable within and extendable from a distal end of the working channel 952 of the elongate device 950. The cinching tool 1054 may include a delivery tube 1056 and outer portion 1058 of a cinching termination member 1060. The outer portion 1058 may be coupled to a distal end of the delivery tube 1056. In some examples, the outer portion 1058 may have a tubular or partially tubular shape. The cinching tool 1054 may also include a suture strand engagement portion 1062 that has a compressed configuration (FIG. 18A) and an expanded configuration (FIG. 18B). The suture strand engagement portion 1062 may include a snare or other structure to engage or catch the suture strand. The suture strand engagement portion 1062 may be formed from an elastic shape-memory material that allows the capture device to transition from the compressed configuration when constrained (e.g., when within a working channel) to an expanded configuration when unconstrained (e.g., when released from a working channel). The suture strand engagement portion 1062 may be formed of a continuous wire. The suture strand engagement portion 1062 includes an opening 1061 sized to receive passage of the suture needle 963 when in the expanded configuration. In the compressed configuration, the suture strand engagement portion 1062 may be sized to slide through a channel 1064 of the delivery tube 1056 and the outer portion 1058 of the cinching termination member 1060. The suture strand engagement portion 1062 may be removably coupled to a distal end of a control member 1066 that extends through or along the delivery tube 1056. The control member 1066 may include a wire, rod, or other structural member configured to advance, retract, and/or rotate the suture strand engagement portion 1062. The cinching tool 1054 may also include an inner portion or plug 1068 of the cinching termination member 1060. The inner portion 1068 may extend distally of the outer portion 1058 as the cinching tool 1054 is advanced through the working channel 952 of the elongate device 950. In some examples, the inner portion 1068 may have a partially cylindrical or tubular shape. The inner portion 1068 may include a region 1069 with a diameter sized to fit within the outer portion 1058 and a region 1071 with a diameter larger than an inner diameter of the outer portion. The inner portion 1068 may be

removably coupled to a distal end of a control member 1070 that extends through the delivery tube 1056. The control member 1070 may include a wire, rod, or other structural member configured to advance, retract, and/or rotate the inner portion 1068. The control member 1066 and the control member 1070 may be independently controlled outside of the patient anatomy by, for example, manual operation or robotically-assisted control.

[0107] With reference to FIG. 17, at a process 1004, a suture needle and suture strand may be extended through the capture device. For example and with reference to FIG. 18B, the cinching tool 1054 may be extended into the path of the suture needle 963, and the suture strand engagement portion 1062 may be advanced from the outer portion 1058 of the cinching termination member 1060 and into the expanded configuration. When advanced, the suture strand engagement portion 1062 may be positioned such that an opening 1061 of the suture strand engagement portion 1062 is proximate the path of the suture needle 963. The suture needle 963 may then be moved along an arcuate path through the opening 1061 of the suture strand engagement portion 1062. As the suture needle 963 passes through the opening 1601, the suture strand 972 is also pulled through the opening, thus threading the suture strand through the suture strand engagement portion 1062. The entire length of the arcuate needle 963 may pass through the opening 1061. In some examples, the cinching tool 1054 and the suture strand 972 may be visualized with the imaging device 974 incorporated into the elongate device 950.

[0108] With reference to FIG. 17, at a process 1006, the capture device may be retracted to tension the suture strand and create a tissue plication. For example and with reference to FIG. 18C, the suture strand engagement portion 1062 may be retracted and compressed within the outer portion 1058 and optionally within the delivery tube 1056 to tension the suture strand 972 and create a plication in the tissue. As the suture strand engagement portion 1062 is retracted to create the tension, the inner portion 1068 of the cinching termination member 1060 may remain spaced distally of the outer portion 1058. The cinching tool 1054 may be advanced toward the final suture (e.g., final suture 955B) while retracting the suture strand engagement portion 1062 to apply tension to the suture strand 972 so that the inner portion 1068 and the outer portion 1058 of the cinching termination member 1060 are moved closer to the anchoring termination member (e.g., anchoring termination member 957), creating a tighten plication.

[0109] With reference to FIG. 17, at a process 1008, the inner portion of the cinching termination member may be fixed to the outer portion of the cinching termination member to form a connected termination member. The suture strand may be clamped between the inner and outer portions to prevent or resist migration of the suture strand. For example and with

reference to FIG. 18D, the inner portion 1068 may be press fit into or otherwise fixed to the outer portion 1058 to form a connected termination member 1060. More specifically, the suture strand 972 may be compressed or clamped between the outer surface of the inner portion 1068 and the inner surface of the outer portion 1058. The compression between the inner and outer portion of the cinching termination member 1060 may create sufficient friction to prevent or restrict sliding of the suture strand 972 relative to the cinching termination member. Thus, the cinching termination member 1060 may lock to the suture strand 972 and maintain the tissue plication.

[0110] With reference to FIG. 17, at a process 1010, the suture stand may be severed causing a portion of the suture strand to remain compressed within the cinching termination member and a proximal portion of the suture strand to become free from the cinching termination member. With the suture strand 972 severed, a portion 1076 of the suture strand 972 remains compressed between the inner portion 1068 and the outer portion 1058.

[0111] With reference to FIG. 17, at a process 1012 the outer portion of the cinching termination member may be separated from the delivery tube. For example, the outer portion 1058 of the cinching termination member 1060 may be separated from the delivery tube 1056 and the control member 1070 may be separated from the inner portion 1068. Thus separated from all supports of the cinching tool 1054, the cinching termination member 1060 may remain within the patient anatomy as a lock to maintain tension in the suture plication. The use of the cinching procedure and system as described in FIGS. 17-18D may be similar to the examples of FIGS. 15-16D using a hook-shaped capture device, but the use of the collapsible snare member of FIGS. 17-18D may provide a significantly larger opening for needle passage and thus may require less precision in the positioning of the cinching tool relative to the suture needle.

[0112] FIG. 19 illustrates a capture device 1080 which may be used in place of the suture strand engagement portion 1062. The capture device 1080 including compressible ribs 1082 coupled to bounding rings 1084 which form a basket-like structure. In this example, the capture device 1080 includes four ribs 1082 but more or fewer ribs may be used. The capture device may have a compressed configuration within the delivery tube and an expanded configuration as shown in FIG. 19. In the expanded configuration, the ribs 1082 may expand an opening 1086 through which the suture needle and the suture strand may extend.

[0113] FIG. 20 illustrates a tensioning tool 1100 (e.g., tensioning tool 385) that may be used as any of the tensioning tools described herein. The tensioning tool 1100 may include a control member 1102 coupled to a tensioning device 1104. The tensioning device may include a body

1106 including a slot 1108 withing the body 1106. A pulley 1110 extends within the slot 1108 and couples to the body 1106. In use, the tensioning device may capture a suture strand 1112 anywhere along the length of the suture strand. The suture strand 1112 may extend over the pulley 1110. As the tensioning tool 1100 is retracted, the suture strand 1112 is pulled with the tensioning tool, and the suture strand may slide along the pulley 1110. The pulley 1110 may allow one side of the suture to be tensioned while the other side is fixed elsewhere.

[0114] FIG. 21 illustrates an endoscopic instrument system 1200 (e.g., the instrument system 100) extending within anatomic passageways 1202 of an anatomical structure 1204. In some examples the anatomic structure 1204 may be a stomach. The anatomical structure 1204 has an anatomical frame of reference (X_A , Y_A , Z_A). A distal end portion 1206 of the endoscopic instrument system 1200 may be advanced into an anatomic opening (e.g., a patient mouth) and through the anatomic passageways 1202 to perform a medical procedure, such as a suturing procedure, at or near target tissue located in a region 1208 of the anatomical structure 1204 using any of the methods or systems described herein.

[0115] FIG. 22 illustrates a robotically-assisted medical system, according to some examples. In some examples, the systems and methods disclosed herein may be used in a suturing procedure performed with a robotically-assisted medical system as described in further detail below. As shown in FIG. 22, a robotically-assisted medical system 1300 may include a manipulator assembly 1302 for operating a medical instrument 1304 (e.g., instrument system 100 or any of the instruments described herein) in performing various procedures on a patient P positioned on a table T in a surgical environment 1301. For example, the manipulator assembly 1302 may drive needle motion in the suture apparatus or manipulate control members. The manipulator assembly 1302 may be teleoperated, non-teleoperated, or a hybrid teleoperated and non-teleoperated assembly with select degrees of freedom of motion that may be motorized and/or teleoperated and select degrees of freedom of motion that may be non-motorized and/or non-teleoperated. A master assembly 1306, which may be inside or outside of the surgical environment 1301, generally includes one or more control devices for controlling manipulator assembly 1302. Manipulator assembly 1302 supports medical instrument 1304 and may optionally include a plurality of actuators or motors that drive inputs on medical instrument 1304 in response to commands from a control system 1312. The actuators may optionally include drive systems that when coupled to medical instrument 1304 may advance medical instrument 1304 into a naturally or surgically created anatomic orifice. Other drive systems may move the distal end of medical instrument in multiple degrees of freedom, which may include three degrees of linear motion (e.g., linear motion along the X, Y,

Z Cartesian axes) and in three degrees of rotational motion (e.g., rotation about the X, Y, Z Cartesian axes). The manipulator assembly 1302 may support various other systems for irrigation, treatment, or other purposes. Such systems may include fluid systems (including, for example, reservoirs, heating/cooling elements, pumps, and valves), generators, lasers, interrogators, and ablation components.

[0116] Robotically-assisted medical system 1300 also includes a display system 1310 for displaying an image or representation of the surgical site and medical instrument 1304 generated by an imaging system 1309 which may include an endoscopic imaging system. Display system 1310 and master assembly 1306 may be oriented so an operator O can control medical instrument 1304 and master assembly 1306 with the perception of telepresence. Any of the previously described graphical user interfaces may be displayable on a display system 1310 and/or a display system of an independent planning workstation.

[0117] In some examples, the endoscopic imaging system components of the imaging system 1309 may be integrally or removably coupled to medical instrument system 1304. However, in some examples, a separate endoscope, attached to a separate manipulator assembly may be used with medical instrument system 1304 to image the surgical site. The endoscopic imaging system 1309 may be implemented as hardware, firmware, software, or a combination thereof which interact with or are otherwise executed by one or more computer processors, which may include the processors of the control system 1312.

[0118] The sensor system 1308 may include a position/location sensor system (e.g., an actuator encoder or an electromagnetic (EM) sensor system) and/or a shape sensor system (e.g., an optical fiber shape sensor) for determining the position, orientation, speed, velocity, pose, and/or shape of the medical instrument 1304. The sensor system 1308 may also include temperature, pressure, force, or contact sensors or the like.

[0119] Robotically-assisted medical system 1300 may also include control system 1312. Control system 1312 includes at least one memory 1316 and at least one computer processor 1314 for effecting control between medical instrument 1304, master assembly 1306, sensor system 1308, and display system 1310. Control system 1312 also includes programmed instructions (e.g., a non-transitory machine-readable medium storing the instructions) to implement a suturing procedure using the robotically-assisted medical system including for navigation, steering, imaging, engagement feature deployment or retraction, and driving the needle.

[0120] Control system 1312 may optionally further include a virtual visualization system to provide navigation assistance to operator O when controlling medical instrument 1304 during an image-guided surgical procedure. Virtual navigation using the virtual visualization system may be based upon reference to an acquired pre-operative or intra-operative dataset of anatomic passageways. The virtual visualization system processes images of the surgical site imaged using imaging technology such as computerized tomography (CT), magnetic resonance imaging (MRI), fluoroscopy, thermography, ultrasound, optical coherence tomography (OCT), thermal imaging, impedance imaging, laser imaging, nanotube X-ray imaging, and/or the like. The control system 1312 may use a pre-operative image to locate the target tissue (using vision imaging techniques and/or by receiving user input) and create a pre-operative plan, including an optimal first location for performing bronchial passageway and vasculature occlusion. The pre-operative plan may include, for example, a planned size to expand the expandable device, a treatment duration, a treatment temperature, and/or multiple deployment locations.

[0121] FIG. 23A is a simplified diagram of a medical instrument system 1400 according to some embodiments. In some embodiments, medical instrument system 1400 may be used as the instrument systems 100, 1300 (or any of the instruments described herein) in an image-guided medical procedure. In some examples, medical instrument system 1400 may be used for non-teleoperational exploratory procedures or in procedures involving traditional manually operated medical instruments, such as endoscopy.

[0122] Medical instrument system 1400 includes elongate flexible device 1402 (an example of elongate device 102), such as a flexible catheter or endoscope, coupled to a drive unit 1404. Elongate device 1402 includes a flexible body 1416 having proximal end 1417 and distal end, or tip portion, 1418. In some embodiments, flexible body 1416 has an approximately 14-20 mm outer diameter. Other flexible body outer diameters may be larger or smaller.

[0123] Medical instrument system 1400 optionally includes a tracking system 1430 for determining the position, orientation, speed, velocity, pose, and/or shape of distal end 1418 and/or of one or more segments 1424 along flexible body 1416 using one or more sensors and/or imaging devices. The entire length of flexible body 1416, between distal end 1418 and proximal end 1417, may be effectively divided into segments 1424. Tracking system 1430 may optionally be implemented as hardware, firmware, software or a combination thereof which interact with or are otherwise executed by one or more computer processors, which may include the processors of control system 1312 in FIG. 22.

[0124] Tracking system 1430 may optionally track distal end 1418 and/or one or more of the segments 1424 using a shape sensor 1422. In some embodiments, tracking system 1430 may optionally and/or additionally track distal end 1418 using a position sensor system 1420, such as an electromagnetic (EM) sensor system. In some examples, position sensor system 1420 may be configured and positioned to measure six degrees of freedom, e.g., three position coordinates X, Y, Z and three orientation angles indicating pitch, yaw, and roll of a base point or five degrees of freedom, e.g., three position coordinates X, Y, Z and two orientation angles indicating pitch and yaw of a base point.

[0125] Flexible body 1416 includes one or more channels 1421 sized and shaped to receive one or more medical instruments 1426 (or suture tools described herein). In some embodiments, flexible body 1416 includes two channels 1421 for separate instruments 1426, however, a different number of channels 1421 may be provided. FIG. 18B is a simplified diagram of flexible body 1416 with medical instrument 1426 extended according to some embodiments. In some embodiments, medical instrument 1426 may be used for procedures such as surgery, biopsy, ablation, illumination, irrigation, or suction. Medical instrument 1426 can be deployed through channel 1421 of flexible body 1416 and used at a target location within the anatomy. Medical instrument 1426 may include, for example, image capture probes, biopsy instruments, laser ablation fibers, and/or other surgical, diagnostic, or therapeutic tools. Medical tools may include end effectors having a single working member such as a scalpel, a blunt blade, an optical fiber, an electrode, and/or the like. Other end effectors may include, for example, forceps, graspers, scissors, clip appliers, and/or the like. Other end effectors may further include electrically activated end effectors such as electrosurgical electrodes, transducers, sensors, and/or the like. Medical instrument 1426 may be advanced from the opening of channel 1421 to perform the procedure and then retracted back into the channel when the procedure is complete. Medical instrument 1426 may be removed from proximal end 1417 of flexible body 1416 or from another optional instrument port (not shown) along flexible body 1416.

[0126] Medical instrument 1426 may additionally house cables, linkages, or other actuation controls (not shown) that extend between its proximal and distal ends to controllably bend distal end of medical instrument 1426. Flexible body 1416 may also house cables, linkages, or other steering controls (not shown) that extend between drive unit 1404 and distal end 1418 to controllably bend distal end 1418 as shown, for example, by broken dashed line depictions 1419 of distal end 1418. In some examples, at least four cables are used to provide independent “up-down” steering to control a pitch of distal end 1418 and “left-right” steering

to control a yaw of distal end 1418. In embodiments in which medical instrument system 1400 is actuated by a robotically-assisted assembly, drive unit 1404 may include drive inputs that removably couple to and receive power from drive elements, such as actuators, of the teleoperational assembly. In some embodiments, medical instrument system 1400 may include gripping features, manual actuators, or other components for manually controlling the motion of medical instrument system 1400. The information from tracking system 1430 may be sent to a navigation system 1432 where it is combined with information from visualization system 1431 and/or the preoperatively obtained models to provide the physician or other operator with real-time position information.

[0127] Various systems and techniques may be used to perform a suture anchoring process of a suturing procedure. In some examples, an anchoring tool may be used to apply an anchoring termination member to the suture strand to provide a backstop for tissue during suture tensioning with a suture cinch. The suture anchoring process may be used with a mid-suture anchoring termination member that allows applying the anchoring termination member to engage a suture strand anywhere along the suture strand's length. The mid-suture anchoring termination member may be particularly suited for use with an end suture cinching termination member wherein the end suture cinching termination member secures a free end of the suture strand (e.g., extending proximally to an initial suture bite). However, the mid-suture anchoring termination member may be used with either an end suture cinching termination member or a mid-suture cinching termination member (which applies a cinching termination member to a final suture bite). FIG. 24 is a flowchart illustrating a method 1500 for applying an anchoring termination member to a suture strand. The method 1500 may be used in conjunction with any of the suture cinching procedures disclosed herein. The description of method 1500 is made with reference to examples in FIGS. 25A-25E.

[0128] At a process 1502, an anchoring tool may be extended from an elongate device. For example and with reference to FIG. 25A, an elongate device 1550 (e.g., the elongate device 102) may include a working channel 1552. An anchoring tool 1554 may be slidable within and extendable from a distal end of the working channel 1552. The anchoring tool 1554 may include a delivery tube 1556, an anchoring termination member 1560 having an outer portion 1558 and an inner portion or plug 1568, a release member 1565, a control member 1570, and a handle 1530. The outer portion 1558 of the anchoring termination member 1560 may be coupled to a distal end of the delivery tube 1556. In some examples, the outer portion 1558 may have a tubular or partially tubular shape. The delivery tube 1556 may be a flexible member and may include a torque tube or coil pipe for advancing, retracting, and/or rotating the outer

portion 1558 of the anchoring termination member 1560. The delivery tube 1556 may include an interface member 1540 providing an abutting interface between the delivery tube 1556 and the outer portion 1558 of the anchoring termination member 1560. The release member 1565 may releasably couple the outer portion 1558 of the anchoring termination member 1560 to the delivery tube 1556 (e.g., to the interface member 1540 of the delivery tube 1556). The inner portion 1568 of the anchoring termination member 1560 may be coupled to the control member 1570 (or one or more control members 1570), with the control member 1570 extending through the delivery tube 1556. The control member 1570 may include a wire, rod, or other structural member configured to advance, retract, and/or rotate the inner portion 1568. The control member 1570 may include one or more guides 1571 to center the control member 1570 relative to the delivery tube 1556 and relative to the anchoring termination member 1560, and to prevent the control member 1570 from catching on the anchoring termination member 1560. A plurality of spaced apart guides 1571 (e.g., two, three, or more guides 1571) may be provided in some embodiments. The control member 1570 may be positioned within a central lumen 1520 of the inner portion 1568. To couple the control member 1570 to the inner portion 1568, the central lumen 1520 of the inner portion 1568 may have an enlarged diameter distal portion 1522 and a reduced diameter proximal portion 1524 forming a shoulder 1526 (see FIG. 25G). The control member 1570 may have an enlarged bulbous portion 1573 that is larger than the reduced diameter proximal portion 1524 and rests against the shoulder 1526 of the inner portion 1568.

[0129] With reference to FIG. 24, at a process 1504, a suture strand 1572 may be captured by the anchoring termination member 1560 (e.g., by being captured between the inner portion 1568 and the outer portion 1558 of the anchoring termination member 1560). For example and with reference to FIG. 25C, by manipulating the control member 1570, the inner portion 1568 may be extended distally from delivery tube 1556 and from the outer portion 1558 of the anchoring termination member 1560, and may be rotated as needed to snare a suture strand 1572 (e.g., the suture strand 116). To capture the suture strand 1572, a proximal portion of the inner portion 1568 may include a suture strand engagement portion 1569 (e.g., in the form of prongs or extending protrusions and/or a recess). The inner portion 1568 may be positioned by the control member 1570 to capture the suture strand 1572 (e.g., via the prongs of the suture strand engagement portion 1569). By capturing the suture strand 1572 with the suture strand engagement portion 1569, the suture strand 1572 becomes positioned between the inner member 1568 and the outer member 1558. In some examples, the anchoring tool 1554 and the

suture strand 1562 may be visualized with an imaging device 1574 incorporated into the elongate device 1550.

[0130] With reference to FIG. 24, at a process 1506, the suture strand engagement portion 1569 and the inner portion 1568 of the anchoring termination member 1560 may be retracted into the outer portion 1558 of the anchoring termination member 1560 to lock the suture strand. For example and with reference to FIGS. 25D-25E, the inner portion 1568 of the anchoring termination member 1560 and connected suture strand engagement portion 1569 may be retracted in a direction D11 into the outer portion 1558 and, optionally, into the delivery tube 1556. The inner portion 1568 may be retracted by retracting the control member 1570 to which the inner portion 1568 is coupled. In this position, the suture strand 1572 is locked into place by the outer portion 1558 and the inner portion 1568. The suture strand 1572 is locked (e.g., pinched) such that the suture strand 1572 can no longer slide through the anchoring termination member 1560. Once locked, a portion 1576 of the suture strand 1572 may extend between the anchoring termination member 1560 and patient tissue such as a suture bite (see FIG. 25F). A portion 1578 of the suture strand 1572 may extend between the anchoring tool 1554 and a suturing needle (see FIG. 25F).

[0131] With reference to FIG. 24, at a process 1508, the control member 1570 may be retracted further to release the anchoring termination member 1560 from the control member 1570. For example and with reference to FIG. 25H, further retraction of the control member 1570 causes the bulbous portion 1573 of the control member 1570 to break through the proximal portion of the inner portion 1568. The reduced diameter proximal portion 1524 of the lumen 1520 may plastically deform as the bulbous portion 1573 of the control member 1570 is forced proximally. As a result, the anchoring termination member 1560 is released from the control member 1570. At this time, the inner portion 1568 remains locked to the outer portion 1558 with the suture strand 1572 locked between the inner portion 1568 and the outer portion 1558 due to friction.

[0132] With reference to FIG. 24, at a process 1510, the anchoring termination member 1560 may be released from the delivery tube 1556. For example and with reference to FIG. 25I, the delivery tube 1556 may be retracted to release the outer portion 1558 of the anchoring termination member 1560 from the delivery tube 1556. The release member 1565 may engage outer portion 1558 with a frictional fit. The release member 1565 may be permanently affixed to delivery tube 1556. As delivery tube 1556 is retracted, the release member 1565 may move proximally with delivery tube 1556. The assembly of outer portion 1558 and inner portion 1568 may be held in place due to the attachment to suture. The opposition creates tension which

pulls outer portion 1558 out of engagement with the release member 1565. In other examples, a release component such as in FIG. 12J may facilitate the separation. Separated from all supports of the anchoring tool 1554, the anchoring termination member 1560 may remain within the patient anatomy as a lock for one end of a suture plication.

[0133] With reference to FIG. 24, at a process 1512, the portion 1578 of the suture strand 1572 extending between the anchoring tool 1554 and a suturing needle may be cut. For example and with reference to FIG. 25F, the portion 1578 of the suture strand 1572 may be cut by a cutting tool (or on a cutting surface of the device). With the portion 1578 severed, the anchoring termination member 1560 is now released from the suturing needle with the portion 1576 of the suture strand 1572 extending to the tissue plication. The anchoring termination member 1560 can then serve as a backstop for tissue during suture tensioning with a suture cinch attached to another end of the suture strand 1572 as described herein.

[0134] With reference to FIG. 25J, a proximal portion of the anchoring tool 1554 may optionally include a handle 1530 for actuating the anchoring tool 1554 and for operating the method 1500. For example, the handle 1530 may include a finger grasp portion 1532 coupled to the control member 1570. Moving the finger grasp portion 1532 relative to a body 1534 of the handle 1530 causes the control member 1570 to advance, retract, and/or rotate. For example, at the process 1506, retracting the finger grasp portion 1532 proximally can cause the control member 1570 to retract and the coupled inner portion 1568 to also retract and lock a suture strand. For example, at the process 1508, retracting the finger grasp portion 1532 further proximally can cause the control member 1570 to release from the anchoring termination member 1560. The body 1534 can be moved to advance, retract, and/or rotate the delivery tube 1556.

[0135] Various systems and techniques may be used to perform a suture anchoring process of a suturing procedure. In some examples, the suture anchoring process may be used with an end suture cinching termination member or an anchoring termination member. For example, a free end of a suture strand may be fed through the end-suture cinching termination member, and the end-suture cinching termination member may be locked around the suture strand (e.g., after a desired amount of tension has been pulled on the suture strand). FIG. 26 is a flowchart illustrating a method 1600 for applying a termination member to a suture strand. The method 1600 may be used in conjunction with any of the suture cinching or anchoring procedures disclosed herein. The description of method 1600 is made with reference to examples in FIGS. 27A-27G.

[0136] FIGS. 27A- 27G illustrate an anchoring tool 1654 including a delivery tool 1656 and a termination member 1660. The anchoring tool 1654 may be slidable within and extendable from a distal end of a working channel 1652 of an elongate device 1650 (e.g., the elongate device 102). In a delivery configuration (e.g. FIG. 27B), the termination member 1660 may be coupled to a distal end of the delivery tool 1656. In a terminated configuration (e.g. FIG. 27G), the termination member 1660 may be separated from the delivery tool 1656. The termination member 1660 may include an outer portion 1658 and an inner portion or plug 1668. The plug 1668 may include a distal section 1668a and a proximal section 1668b, with the distal section 1668a having a larger width or diameter than the proximal section 1668b. The proximal section 1668b may include a tapered proximal end. The proximal section 1668b may be sized to extend within the outer portion 1658. A channel 1668c may extend through at least a portion of the plug 1668 and may extend through an entire length of the plug 1668 in some embodiments. A first length of the channel 1668c, for example the length of the channel within the distal section 1668a, may be wider than a second length of the channel 1668c, for example the length of the channel within the proximal section 1668b. The termination member 1660 may be formed from any of a variety of materials including metals or polymers. In some examples, the inner and outer portions 1668, 1658 of the termination member 1660 may have a cylindrical or partially cylindrical shape.

[0137] The delivery tool 1656 may include a delivery tube 1657 and an interface member 1662 coupled to a distal end of the delivery tube 1657. The delivery tool 1656 may also include a control member 1670 extendable through and movable independently of the delivery tube 1657 and the interface member 1662. In the delivery configuration, the outer portion 1658 of the termination member 1660 may be coupled to a distal end of the interface member 1662. The delivery tube 1657 may be a flexible member and may include a torque tube or coil pipe for advancing, retracting, and/or rotating the outer portion 1658 of the termination member 1660.

[0138] The control member 1670 may include an elongate flexible shaft 1670a (e.g., a wire) and a distal bulbous portion 1670b having a greater width than the shaft 1670a. In the delivery configuration, a distal portion of the control member 1670 may extend within the channel 1668c of the plug 1668 so that movement of the control member 1670 may cause a corresponding movement of the distal motion of the plug 1668. The distal bulbous portion 1670b of the control member 1670 may extend within the wider, distal first length of the channel 1668c, and the narrower second length of the channel 1668c may provide resistance to proximal movement or retraction of the distal bulbous portion 1670b relative to the channel

1668c. As described below, with sufficient force, the resistance at the entry to the narrow second length of the channel 1668c may be overcome, and the bulbous portion 1670b may be pulled proximally through and out of the proximal end of the channel 1668c.

[0139] The outer portion 1658 of the termination member 1660 may be coupled to the outer distal end of the interface member 1662 by a retention clip 1665. The interface member 1662 may include a side opening 1664. As shown in FIG. 27B, the retention clip 1665 may include a pair of deflectable arms 1667 and a passage 1669 through which the shaft 1670a of the control member 1670 may slidably pass. The retention clip 1665 may be attached to a cutting member 1671 by the deflectable arms 1667 which may extend through slots 1671a in the cutting member 1671. The cutting member 1671 may be a generally cylindrical member and may be sized for a close, slidable fit within the inner diameter of the interface member 1662. The cutting member 1671 may include a sharpened surface sufficiently sharp to slice a suture strand extending through the side opening 1664 of the interface member 1662. In an uncompressed configuration (e.g., FIG. 27B), the arms 1667 of retention clip 1665 may couple to the termination member 1660 by extending through the cutting member 1671, into slots 1659 in the interface member 1662, and into slots 1673 in the outer portion 1658 of the termination member 1660. In a compressed configuration (e.g., FIG. 27E), the arms 1667 of the retention clip 1665 may deflect (e.g., inward towards each other) and withdraw from the slots 1673 in the outer portion 1658 of the termination member 1660 and the slots 1659 in the interface member.

[0140] With reference to method 1600 of FIG. 26, at a process 1602, a suturing procedure may be completed. For example and with reference to FIG. 27A, a reverse cinch suturing procedure may be performed on tissue 1640. An anchoring termination member 1642 may be attached to a distal end portion of a suture strand 1672 and may be lodged proximate to a final suture when the suture strand 1672 is tensioned and the tissue is plicated. In some examples the anchoring termination member 1642 may include a portion of or may be separated from a suture needle. In other examples, the anchoring termination member may be a separate anchoring element. With the suturing process completed, the suture strand 1672 may extend proximally through the working channel 1652 of the elongate device 1650. In an alternative example, the suturing procedure may be a forward cinch suturing procedure in which a termination member is attached to a proximal end portion of the suture strand and lodged proximate to the first suture when the suture strand is tensioned and the tissue is plicated. In this example, with the suturing process completed, a distal portion of the suture strand may be captured by a suture strand capture device and then extended proximally through the working

channel of the elongate device. Although the method 1600 and the FIGS. 27A-27G may generally illustrate a process for applying a termination member to a suture strand in a reverse cinch suturing procedure, the process may be entirely suitable for use in a forward cinch suturing procedure.

[0141] At a process 1604, a suture strand may be threaded through a termination member. For example, in a reverse cinch suturing procedure, the tail end of the suture strand 1672 may extend proximally from the elongate device 1650. Outside of the elongate device 1650 (e.g., proximal to the elongate device 1650), the suture strand 1672 may be threaded through a distal end of the outer portion 1658 of the 1660 and further through the side opening 1664 in the interface member 1662. In a forward cinch suturing procedure, a tensioning tool of a capture device (e.g., tensioning tool 385) may be extended through the side opening 1664 and distally through the outer portion 1658 to grab or hook the suture strand 1672. The tensioning tool may be pulled proximally and withdrawn through the outer portion 1658 to route the suture strand 1672 through the side opening 1664 in the interface member.

[0142] At a process 1606, the termination member may be extended through the elongate device. For example, the elongate device 1650 may be inserted into a patient anatomy, and (as shown in FIG. 27B) the anchoring tool 1654 may be advanced through the working channel 1652 of the elongate device 1650 so that the termination member 1660 extends into the patient anatomy distal of the distal opening of the working channel 1652.

[0143] At a process 1608, the tissue may be plicated by tensioning the suture strand while the termination member is advanced into contact with the tissue. For example, the termination member 1660, may be advanced along the suture strand 1672 and into contact with the tissue 1640. The suture strand 1672 may be extending through the side opening of the interface member 1662 and proximally out of the patient anatomy through the elongate device 1650. The distal end of the suture strand 1672 (e.g. a portion external to the patient anatomy) may be tensioned, for example, by a clinician's pull on the tail end of the suture strand as the plug 1668 and outer portion 1658 are advanced distally into contact with the tissue 1640. The tissue may be pulled against the termination member 1660 (e.g., the outer portion 1658) which may cause the tissue 1640 to fold or plicate.

[0144] At a process 1610, an inner portion of the termination member may be connected to the outer portion of the termination member. For example, as shown in FIG. 27C, the control member 1670 may be retracted in a proximal direction to pull the plug 1668 into the outer portion 1658 of the termination member 1660. Alternatively, the delivery tube 1657 may be advanced in a distal direction so that the outer portion 1658 is pushed over the proximal section

1668b of the plug 1668. Seating of the plug 1668 in the outer portion 1658 locks tension in the suture strand 1672 and the plicated tissue 1640. As the plug 1668 is seated within the outer portion 1658, the suture strand 1672 may become cinched, gripped, or otherwise confined between the plug and the outer portion, preventing movement of the suture strand relative to the termination member 1660. After the plug 1668 is seated in the outer portion 1658, sufficient force may be applied in a proximal direction to the control member 1670 to pull the bulbous portion 1670b through the narrowed portion of the channel 1668c of the plug 1668 and between the arms 1667 of the retention clip 1665, as shown in FIG. 27D and 27E. Further proximal motion of the control member 1670 may move the bulbous portion 1670b into contact with a proximal portion of the retention clip, causing the arms 1667 to deflect inward towards each other, out of the slots 1673 of the outer portion 1658 of the termination member 1660 and out of the slots 1659 of the interface member 1662.

[0145] At a process 1612, the suture strand may be cut. For example, and with reference to FIG. 27F, further proximal motion of the control member 1670 may cause the cutting member 1671 to retract in a proximal direction. More specifically, the arms 1667 of the retention clip 1665 engaged with the slots 1671a of the cutting member 1671 may cause the cutting member 1671 to move proximally as the bulbous portion 1670b, pulls the retention clip 1665 in a proximal direction. As the cutting member 1671 moves proximally within the interface member 1662, the suture strand 1672 may be severed by the cutting member 1671 and the edge of the side opening 1664. In some examples, the force on the control member 1670 needed to retract the cutting member 1671 may be less than the force needed to deflect the retention clip arms 1667 out of the slots 1673 of the outer portion 1658 and the slots 1659 of the interface member 1662.

[0146] At a process 1614, the termination member may be decoupled from the delivery tool. For example and with reference to FIG. 27G, the delivery tube 1657 and interface member 1662 may be withdrawn from the outer portion 1658, thus decoupling the termination member 1660 from the delivery tool 1656. With the delivery tool 1656 decoupled, the termination member 1660 and the anchoring termination member 1642 may remain within the patient anatomy to anchor the suture strand 1672 within the sutured tissue 1640. The severed tail end of the suture strand 1672 may be withdrawn through the working channel 1652 or may attached to a suture needle for a subsequent suturing procedure.

[0147] In the description, specific details have been set forth describing some examples. Numerous specific details are set forth to provide a thorough understanding of the examples. It will be apparent, however, to one skilled in the art that some examples may be practiced without

some or all these specific details. The specific examples disclosed herein are meant to be illustrative but not limiting. One skilled in the art may realize other elements that, although not specifically described here, are within the scope and the spirit of this disclosure.

[0148] Elements described in detail with reference to one example, implementation, or application optionally may be included, whenever practical, in other examples, implementations, or applications in which they are not specifically shown or described. For example, if an element is described in detail with reference to one example and is not described with reference to a second example, the element may nevertheless be claimed as included in the second example. Thus, to avoid unnecessary repetition in the description, one or more elements shown and described in association with one example, implementation, or application may be incorporated into other examples, implementations, or aspects unless specifically described otherwise, unless the one or more elements would make an example or implementation non-functional, or unless two or more of the elements provide conflicting functions. Not all the illustrated processes may be performed in all examples of the disclosed methods. Additionally, one or more processes that are not expressly illustrated in may be included before, after, in between, or as part of the illustrated processes. In some examples, one or more of the processes may be performed by a control system or may be implemented, at least in part, in the form of executable code stored on non-transitory, tangible, machine-readable media that when run by one or more processors may cause the one or more processors to perform one or more of the processes.

[0149] Any alterations and further modifications to the described devices, instruments, methods, and any further application of the principles of the present disclosure are fully contemplated as would normally occur to one skilled in the art to which the disclosure relates. In addition, dimensions provided herein are for specific examples and it is contemplated that different sizes, dimensions, and/or ratios may be utilized to implement the concepts of the present disclosure. To avoid needless descriptive repetition, one or more components or actions described in accordance with one illustrative example can be used or omitted as applicable from other illustrative examples. For the sake of brevity, the numerous iterations of these combinations will not be described separately. For simplicity, in some instances the same reference numbers are used throughout the drawings to refer to the same or like parts.

[0150] The systems and methods described herein may be suited for imaging and treatment, via natural or surgically created connected passageways, in any of a variety of anatomic systems, including the lung, colon, the intestines, the stomach, the liver, the kidneys and kidney

calices, the brain, the heart, the circulatory system including vasculature, and/or the like. While some examples are provided herein with respect to medical procedures, any reference to medical or surgical instruments and medical or surgical methods is non-limiting. For example, the instruments, systems, and methods described herein may be used for non-medical purposes including industrial uses, general robotic uses, and sensing or manipulating non-tissue work pieces. Other example applications involve cosmetic improvements, imaging of human or animal anatomy, gathering data from human or animal anatomy, and training medical or non-medical personnel. Additional example applications include use for procedures on tissue removed from human or animal anatomies (without return to a human or animal anatomy) and performing procedures on human or animal cadavers. Further, these techniques can also be used for surgical and nonsurgical medical treatment or diagnosis procedures.

[0151] The methods described herein may be illustrated as a set of operations or processes that may be performed in the same or in a different order than the order shown in the provided flowcharts. One or more of the illustrated processes may be omitted in some examples of the method. Additionally, one or more processes that are not expressly illustrated in the flowchart may be included before, after, in between, or as part of the illustrated processes. In some examples, one or more of the processes of a method may be implemented, at least in part, by a control system executing code stored on non-transitory, tangible, machine-readable media that when run by one or more processors (e.g., the processors of a control system) may cause the one or more processors to perform one or more of the processes.

[0152] One or more elements in examples of this disclosure may be implemented in software to execute on a processor of a computer system such as control processing system. When implemented in software, the elements of the examples of this disclosure may be code segments to perform various tasks. The program or code segments can be stored in a processor readable storage medium or device that may have been downloaded by way of a computer data signal embodied in a carrier wave over a transmission medium or a communication link. The processor readable storage device may include any medium that can store information including an optical medium, semiconductor medium, and/or magnetic medium. Processor readable storage device examples include an electronic circuit; a semiconductor device, a semiconductor memory device, a read only memory (ROM), a flash memory, an erasable programmable read only memory (EPROM); a floppy diskette, a CD-ROM, an optical disk, a hard disk, or other storage device. The code segments may be downloaded via computer networks such as the Internet, Intranet, etc. Any of a wide variety of centralized or distributed

data processing architectures may be employed. Programmed instructions may be implemented as a number of separate programs or subroutines, or they may be integrated into a number of other aspects of the systems described herein. In some examples, the control system may support wireless communication protocols such as Bluetooth, Infrared Data Association (IrDA), HomeRF, IEEE 802.11, Digital Enhanced Cordless Telecommunications (DECT), ultra-wideband (UWB), ZigBee, and Wireless Telemetry.

[0153] Note that the processes and displays presented might not inherently be related to any particular computer or other apparatus. Various general-purpose systems may be used with programs in accordance with the teachings herein, or it may prove convenient to construct a more specialized apparatus to perform the operations described. The required structure for a variety of these systems will appear as elements in the claims. In addition, the examples of the invention are not described with reference to any particular programming language. It will be appreciated that a variety of programming languages may be used to implement the teachings of the invention as described herein.

[0154] This disclosure describes various instruments, portions of instruments, and anatomic structures in terms of their state in three-dimensional space. As used herein, the term position refers to the location of an object or a portion of an object in a three-dimensional space (e.g., three degrees of translational freedom along Cartesian x-, y-, and z-coordinates). As used herein, the term orientation refers to the rotational placement of an object or a portion of an object (e.g., in one or more degrees of rotational freedom such as roll, pitch, and/or yaw). As used herein, the term pose refers to the position of an object or a portion of an object in at least one degree of translational freedom and to the orientation of that object or portion of the object in at least one degree of rotational freedom (e.g., up to six total degrees of freedom). As used herein, the term shape refers to a set of poses, positions, or orientations measured along an object.

[0155] While certain illustrative examples of the invention have been described and shown in the accompanying drawings, it is to be understood that such examples are merely illustrative of and not restrictive on the broad invention, and that the examples of the invention are not limited to the specific constructions and arrangements shown and described, since various other modifications may occur to those ordinarily skilled in the art.

CLAIMS

What is claimed is:

1. A method comprising:
 - advancing an elongate device to a tissue at a procedure site, the elongate device including a needle arm;
 - fixing a first termination member to a first portion of a suture strand;
 - driving the needle arm in a single direction from a staging position through the tissue and, continuing in the single direction, back to the staging position to create an initial suture bite;
 - coupling a second termination member to a second portion of the suture strand;
 - cinching the suture strand with the second termination member to create a tissue plication; and
 - fixing the second termination member to the suture strand to secure the tissue plication.
2. The method of claim 1, further comprising:
 - applying an apposition force to the tissue to create apposed tissue and wherein driving the needle arm through the tissue includes driving the needle arm through the apposed tissue.
3. The method of claim 1, wherein coupling the second termination member to the second portion of the suture strand occurs after the first termination member is fixed to the first portion of the suture strand.
4. The method of claim 1 further comprising:
 - creating a series of suture bites, wherein the series of suture bites includes the initial suture bite and a final suture bite.
5. The method of claim 4, wherein the secured tissue plication is configured with the first termination member is an initial termination member positioned proximate to the initial suture bite and the second termination member is a final termination member positioned proximate to the final suture bite.

6. The method of claim 4, wherein the secured tissue plication is configured with the first termination member is a final termination member positioned proximate to the final suture bite and the second termination member is an initial termination member positioned proximate to the initial suture bite.
7. The method of claim 1, wherein the suture strand includes a barbed suture strand material.
8. The method of claim 1, wherein cinching the suture strand includes applying tension to the suture strand and locking the suture strand while the tension is applied.
9. The method of claim 1, further comprising:
 - severing the suture strand to form a severed end of the suture strand extending from the elongate device and
 - initiating a second tissue plication with the severed end of the suture strand extending from the elongate device.
10. The method of claim 9, wherein severing includes moving a cutting member into contact with the suture strand after the second termination member is fixed to the suture strand.
11. The method of claim 1, wherein fixing the second termination member to the suture strand includes fixing the suture strand between an outer portion and an inner portion of the second termination member.
12. A method comprising:
 - advancing an elongate device to a tissue at a procedure site;
 - coupling a first termination member to a needle arm, the needle arm having a free first end, a free second end, and a needle arm body between the first end and the second end, the first termination member fixed to a first portion of a suture strand;
 - driving the first termination member, the first end of the needle arm, and the second end of the needle arm through the tissue to create an initial suture bite;
 - coupling a second termination member to a second portion of the suture strand;

cinching the suture strand with the second termination member to create a tissue plication; and

fixing the second termination member to the suture strand to secure the tissue plication.

13. The method of claim 12, further comprising:

applying an apposition force to the tissue to create apposed tissue and wherein driving the first and second ends of the needle arm through the tissue includes driving the first and second ends of the needle arm through the apposed tissue.

14. The method of claim 13, wherein applying the apposition force includes extending a helical member into the tissue and drawing the tissue toward the elongate device with the helical member.

15. The method of claim 13, wherein applying the apposition force includes applying a vacuum to the tissue to draw the tissue toward the elongate device.

16. The method of claim 13, wherein applying the apposition force includes applying a grasping tool to the tissue to draw the tissue toward the elongate device.

17. The method of claim 13, wherein applying the apposition force to the tissue causes the tissue to form a fold comprising two apposed tissue layers.

18. The method of claim 13, wherein driving the first termination member, the first end of the needle arm, and the second end of the needle includes driving in a single direction through the apposed tissue and, continuing in the single direction, back to a staging position to create an initial suture bite.

19. The method of claim 12, wherein coupling the second termination member to the second portion of the suture strand occurs after the first termination member is fixed to the first portion of the suture strand.

20. The method of claim 12 further comprising:
creating a series of suture bites, including the initial suture bite, wherein the series of suture bites includes an initial suture bite and a final suture bite.
21. The method of claim 20, wherein the secured tissue plication is configured with the first termination member is a final termination member positioned proximate to the final suture bite and the second termination member is an initial termination member positioned proximate to the initial suture bite.
22. The method of claim 12, wherein the first termination member is an anchoring termination member through which an end of the suture strand is threaded.
23. The method of claim 12, wherein the first termination member is an anchoring termination member to which an end of the suture strand is crimped.
24. The method of claim 12, wherein the first termination member includes a piercing end.
25. The method of claim 12, further comprising:
separating the needle arm from the first termination member before cinching the suture strand.
26. The method of claim 12, wherein the needle arm has an arcuate shape and driving the first termination member and the needle arm includes rotating the needle arm through a 360 degree path to create the initial suture bite.
27. The method of claim 12 further comprising:
delivering the first termination member and the first portion of the suture strand through the elongate device to the procedure site.
28. The method of claim 12 further comprising:
delivering the first termination member and the first portion of the suture strand through a working channel exterior of the elongate device.

29. The method of claim 12, wherein the second termination member is a cinching termination member.
30. The method of claim 29, wherein the cinching termination member is a single piece that clamps to the suture strand.
31. The method of claim 29, wherein the cinching termination member is a two-piece device that clamps the suture strand between the two pieces.
32. The method of claim 12, wherein coupling the second termination member includes delivering the second termination member through the elongate device to the procedure site.
33. The method of claim 12, wherein coupling the second termination member includes delivering the second termination member through a working channel exterior of the elongate device to the procedure site.
34. The method of claim 12, wherein cinching the suture strand includes applying tension to the suture strand and moving the second termination member toward the tissue.
35. The method of claim 34, wherein applying tension to the suture strand includes inserting a tensioning tool through the elongate device to engage and pull the suture strand.
36. The method of claim 34, wherein applying tension to the suture strand includes applying tension to a portion of the suture strand external of a patient anatomy.
37. The method of claim 12, wherein creating the tissue plication includes folding the tissue between the first and second termination members.
38. The method of claim 12, further comprising:
cutting the suture strand proximate to the second termination member.
39. The method of claim 12, wherein the suture strand includes a barbed suture strand material.

40. The method of claim 12, further comprising:
severing the suture strand to form a severed end of the suture strand extending from the elongate device and
initiating a second tissue plication with the severed end of the suture strand extending from the elongate device.
41. The method of claim 40, wherein severing includes moving a cutting member into contact with the suture strand after the second termination member is fixed to the suture strand.
42. The method of claim 12, wherein fixing the second termination member to the suture strand includes fixing the suture strand between an outer portion and an inner portion of the second termination member.

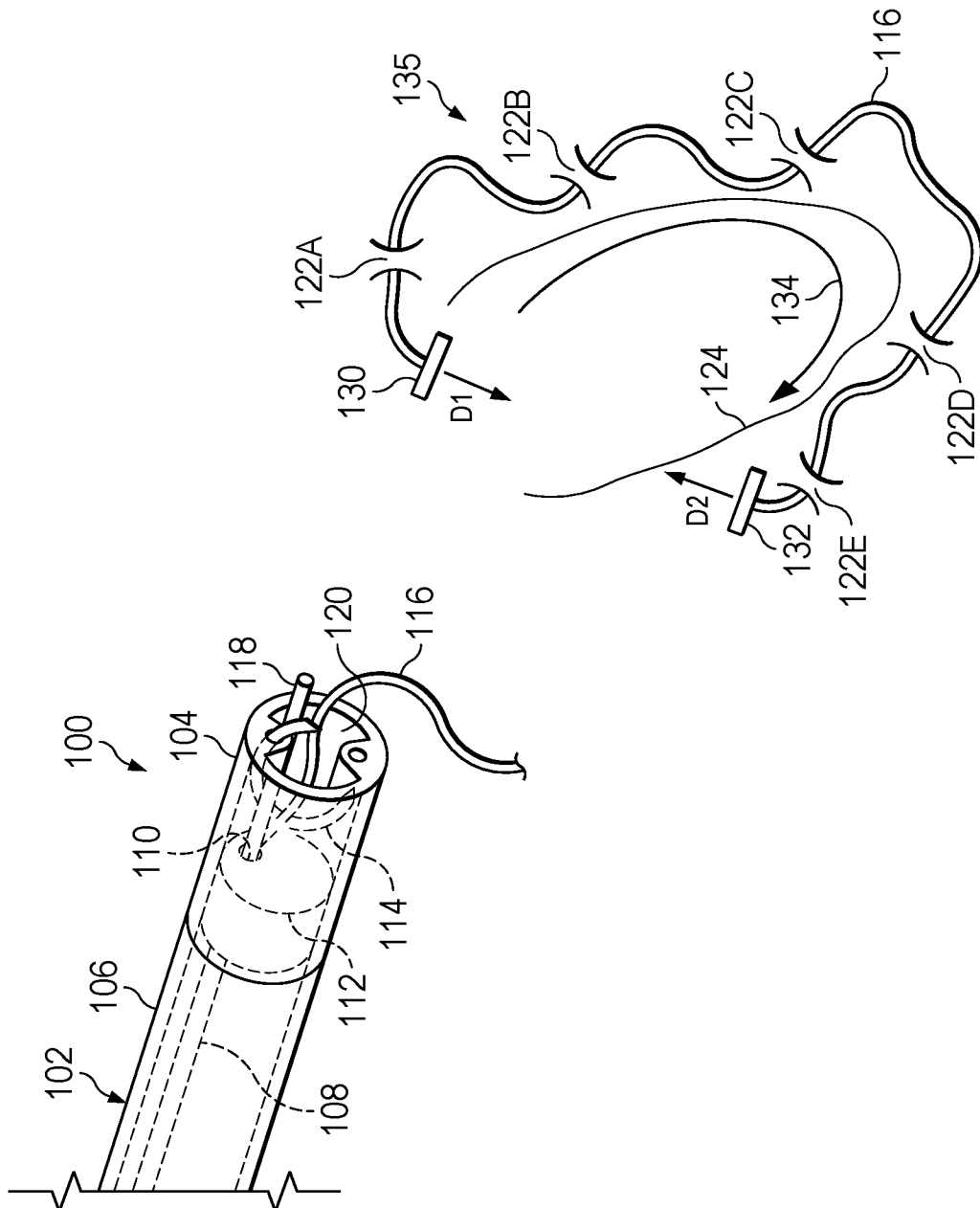


FIG. 1A

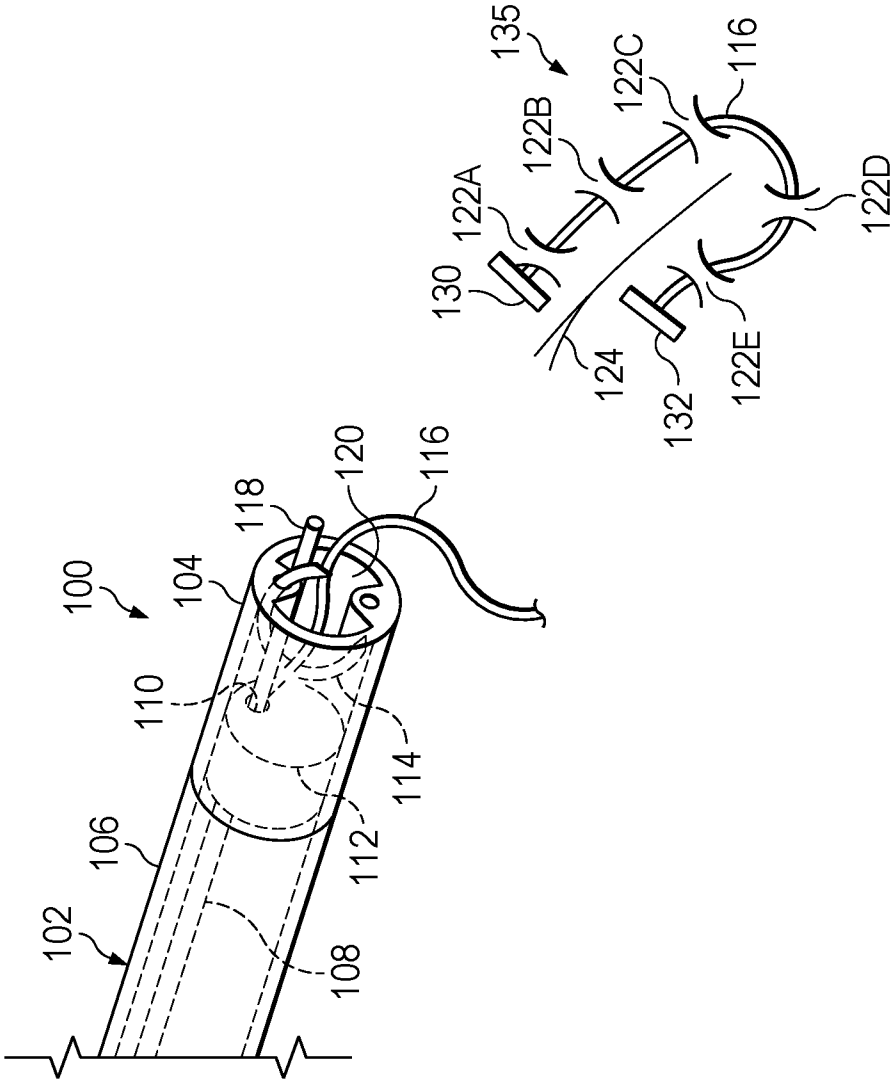


FIG. 1B

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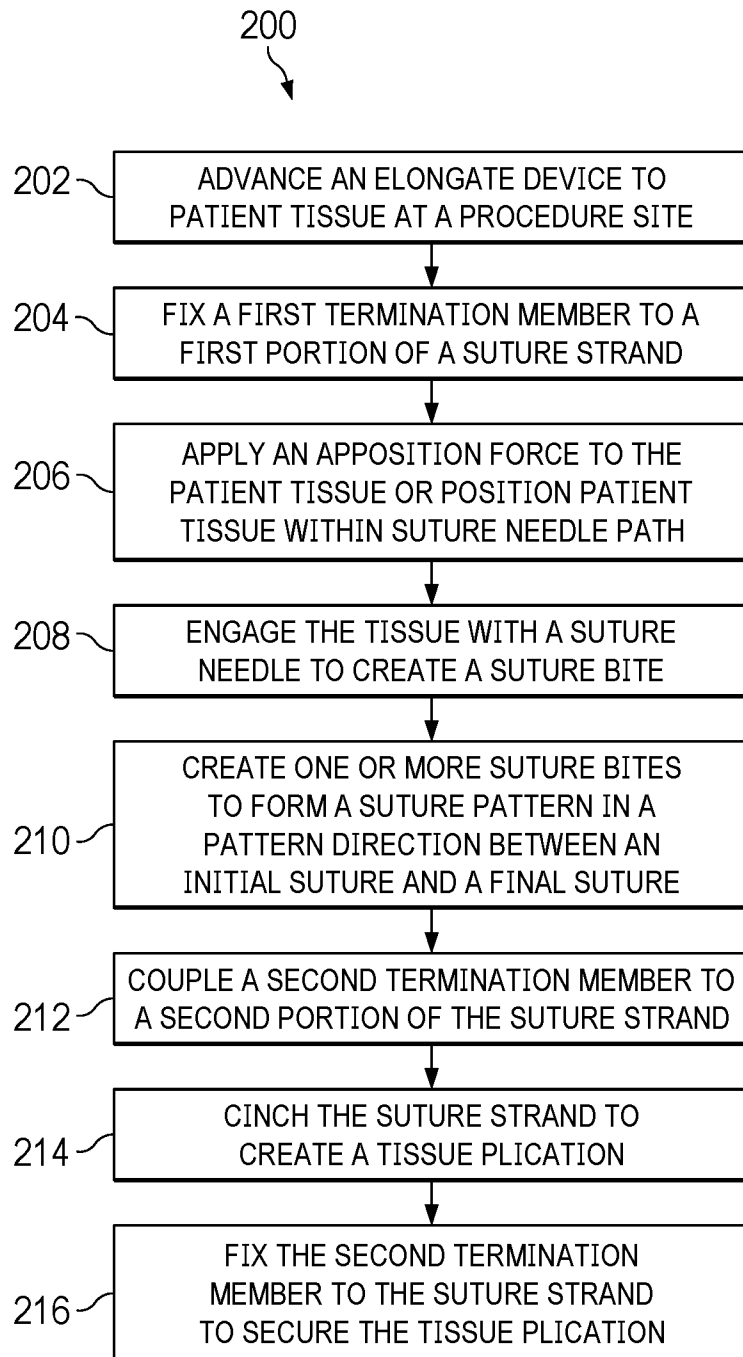


FIG. 2

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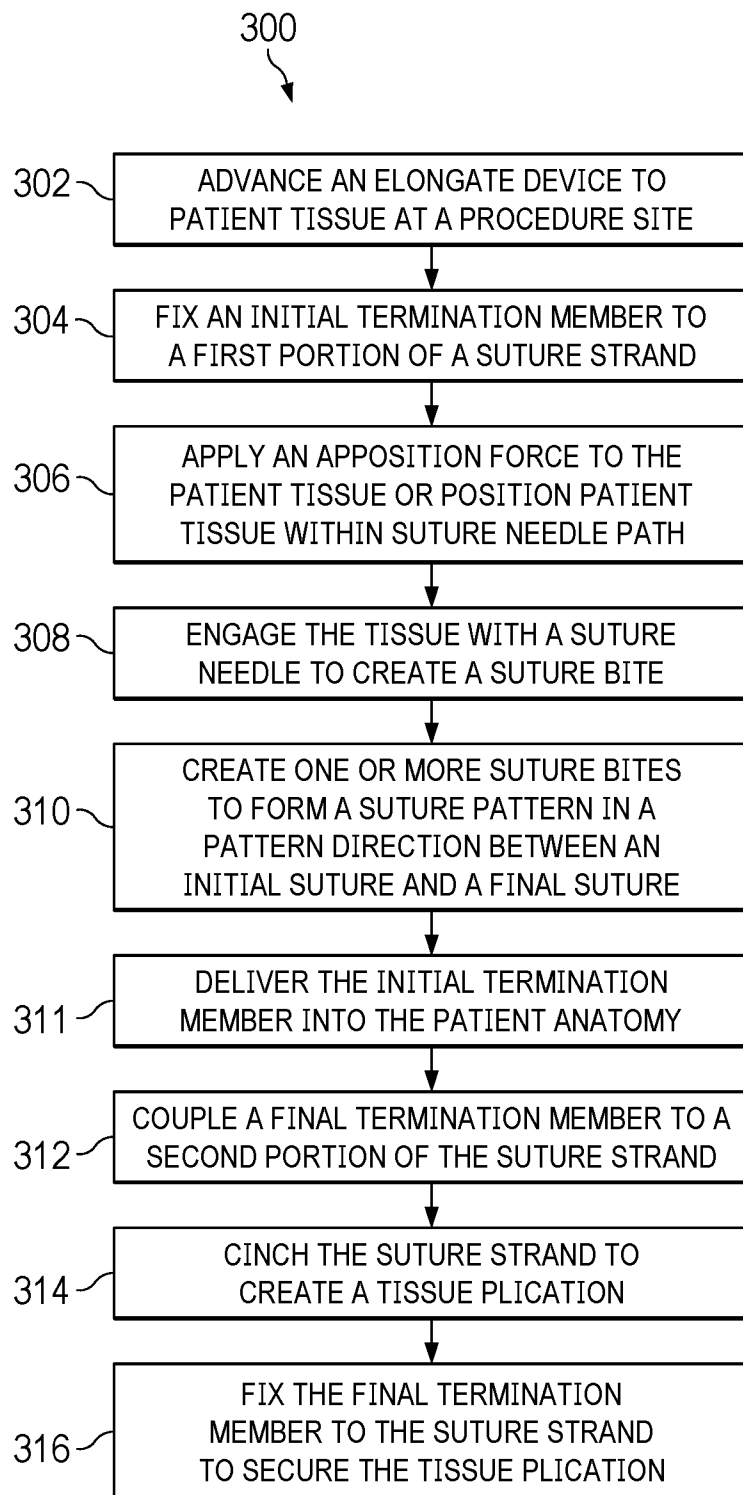


FIG. 3

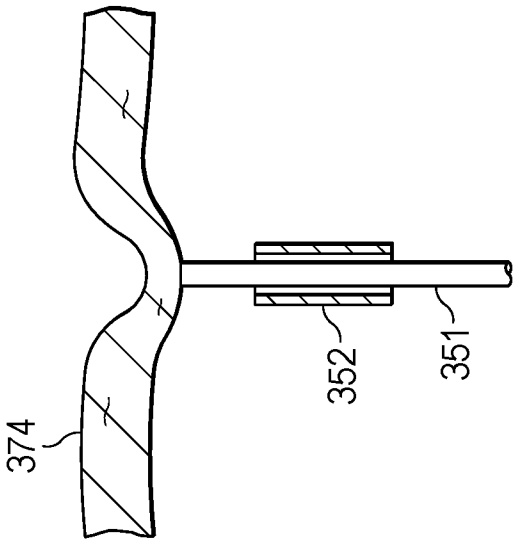


FIG. 5

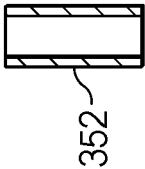


FIG. 4

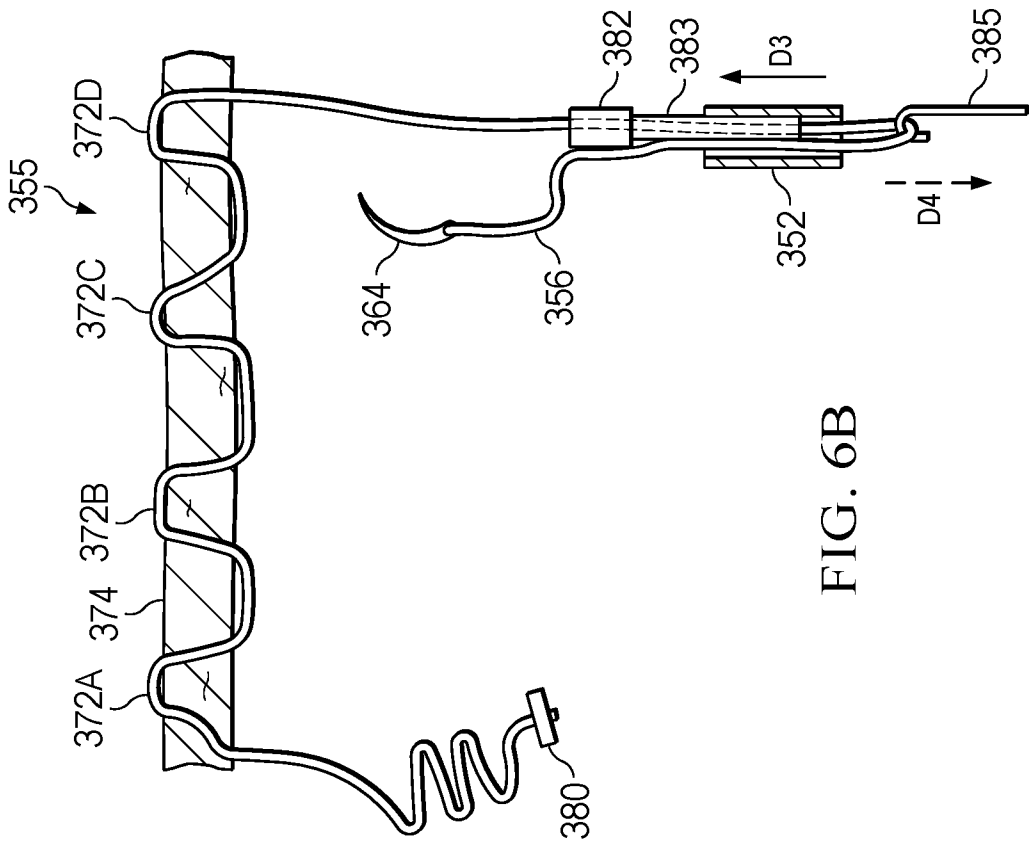


FIG. 6B

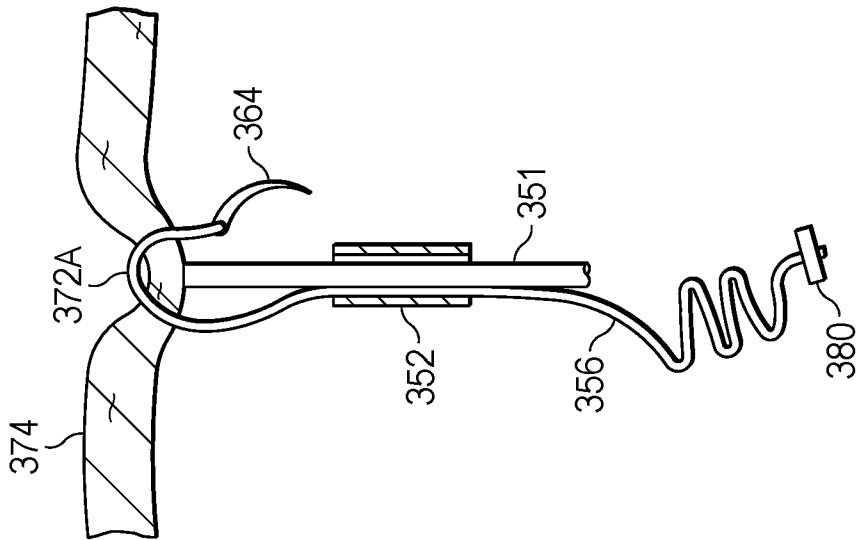


FIG. 6A

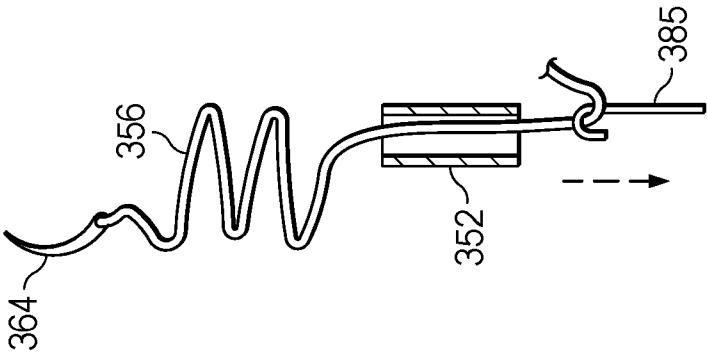


FIG. 6D

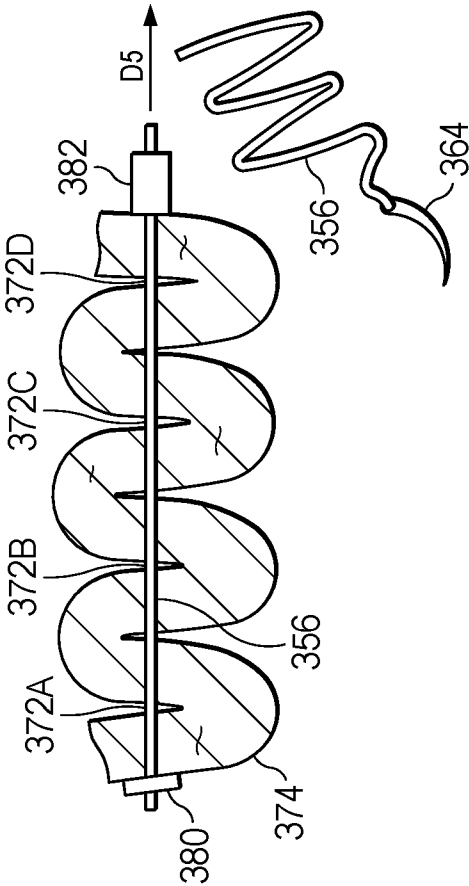


FIG. 6C

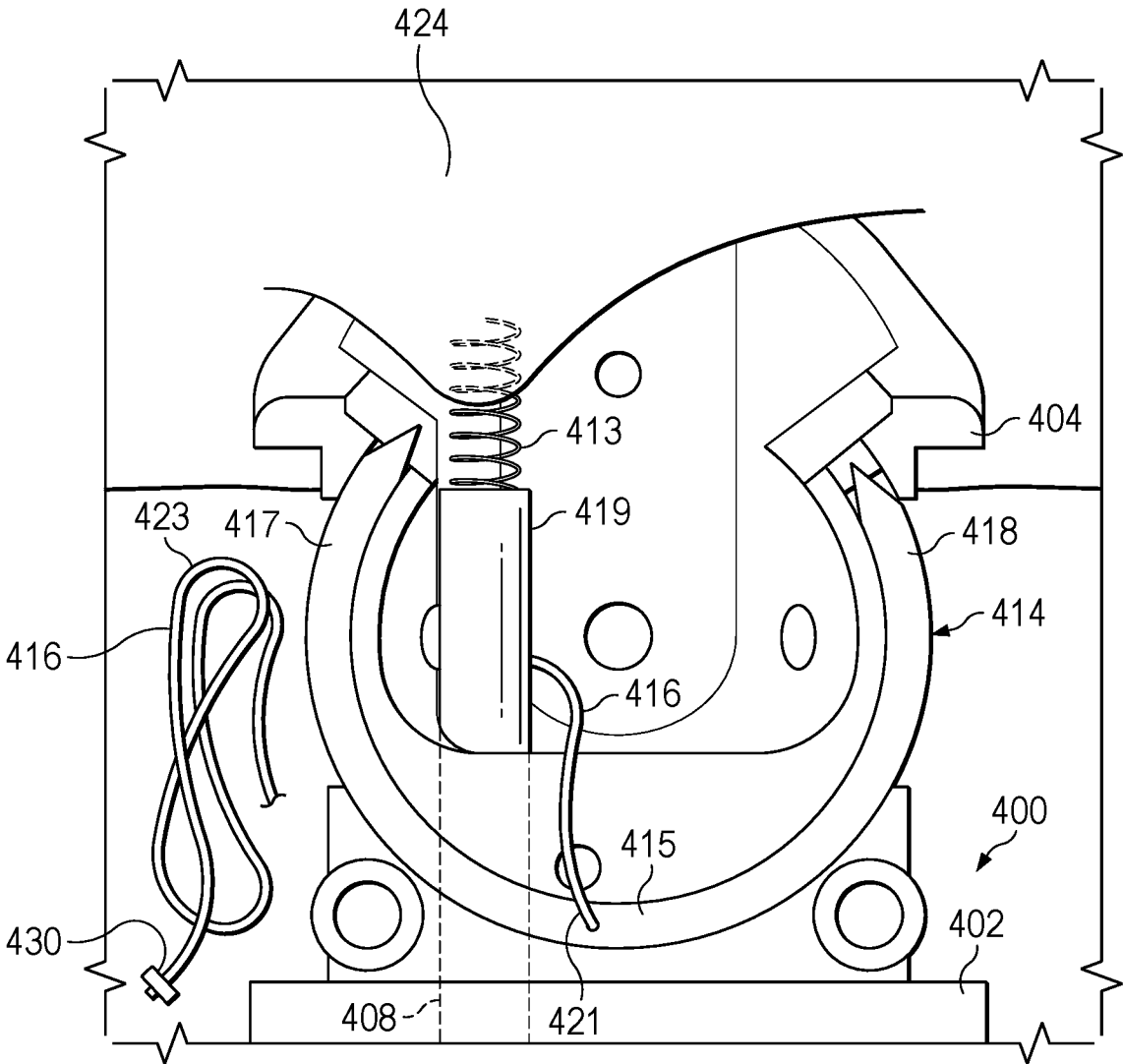


FIG. 7A

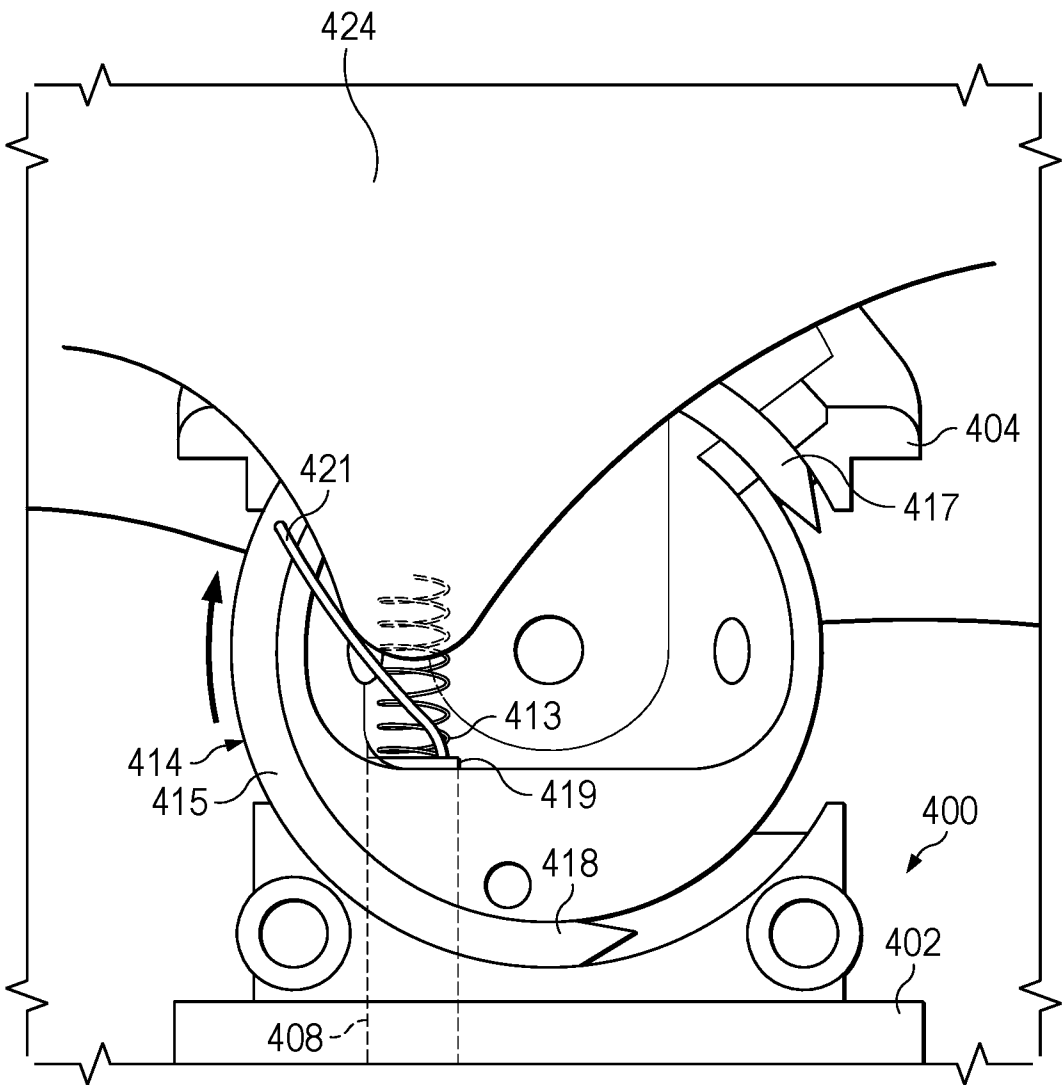


FIG. 7B

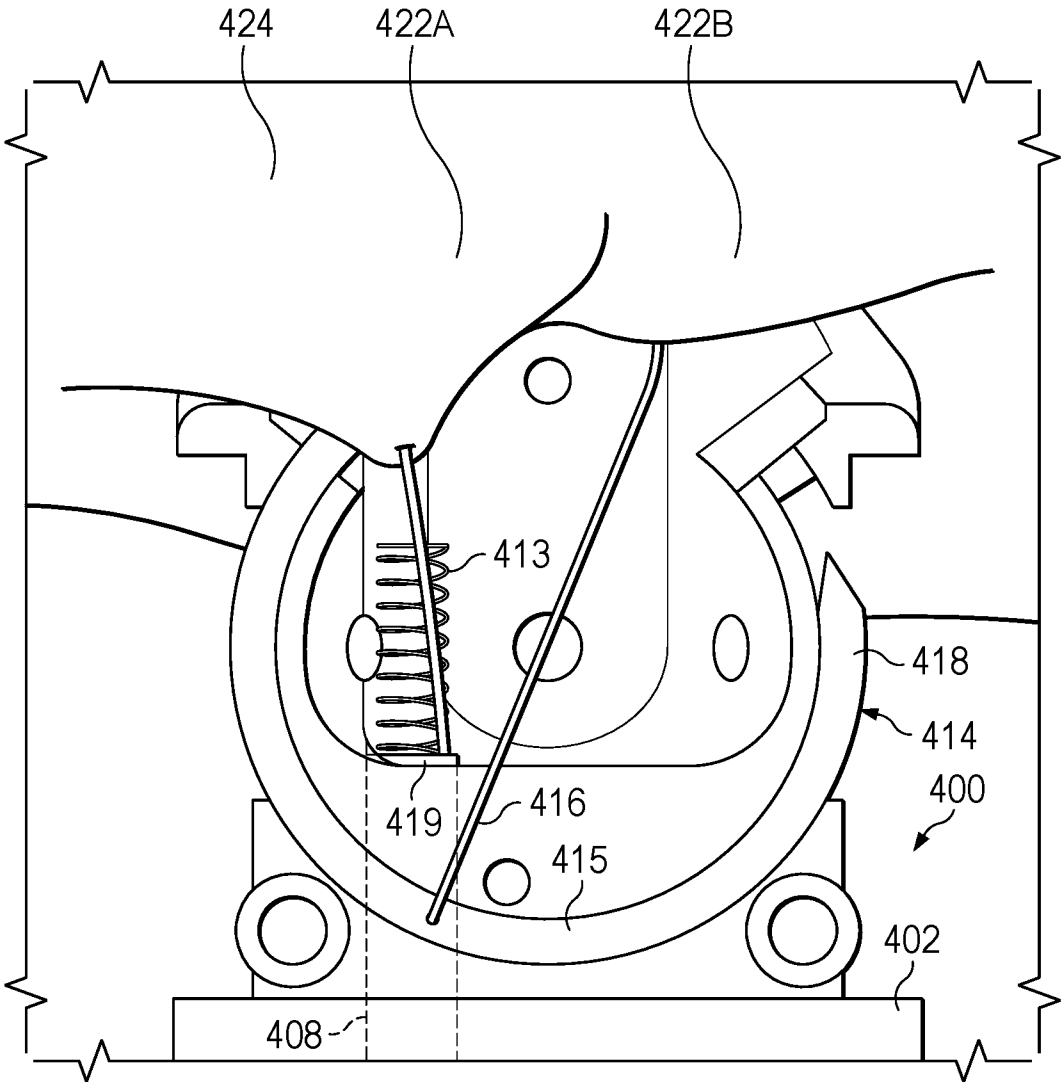


FIG. 7C

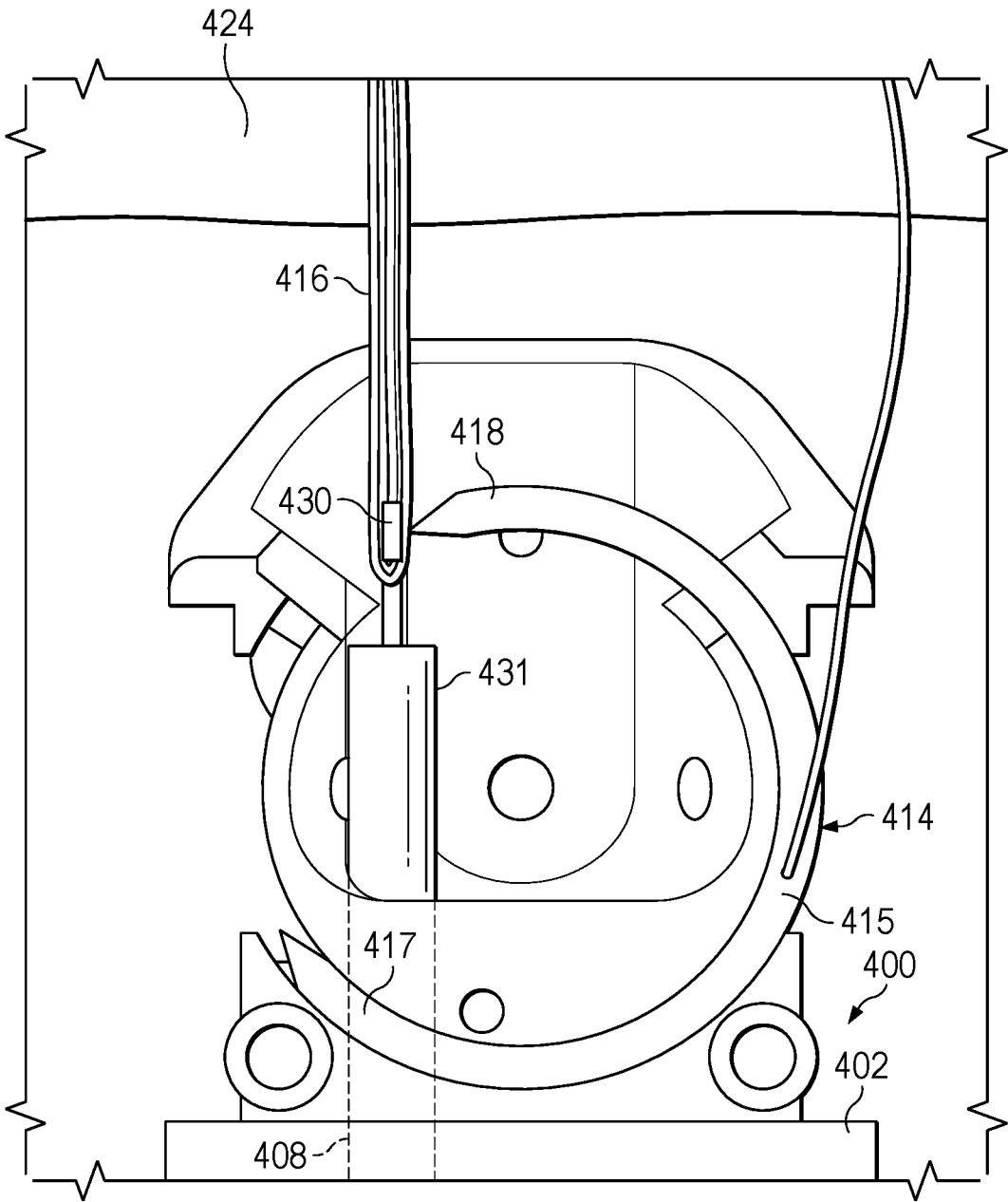


FIG. 7D

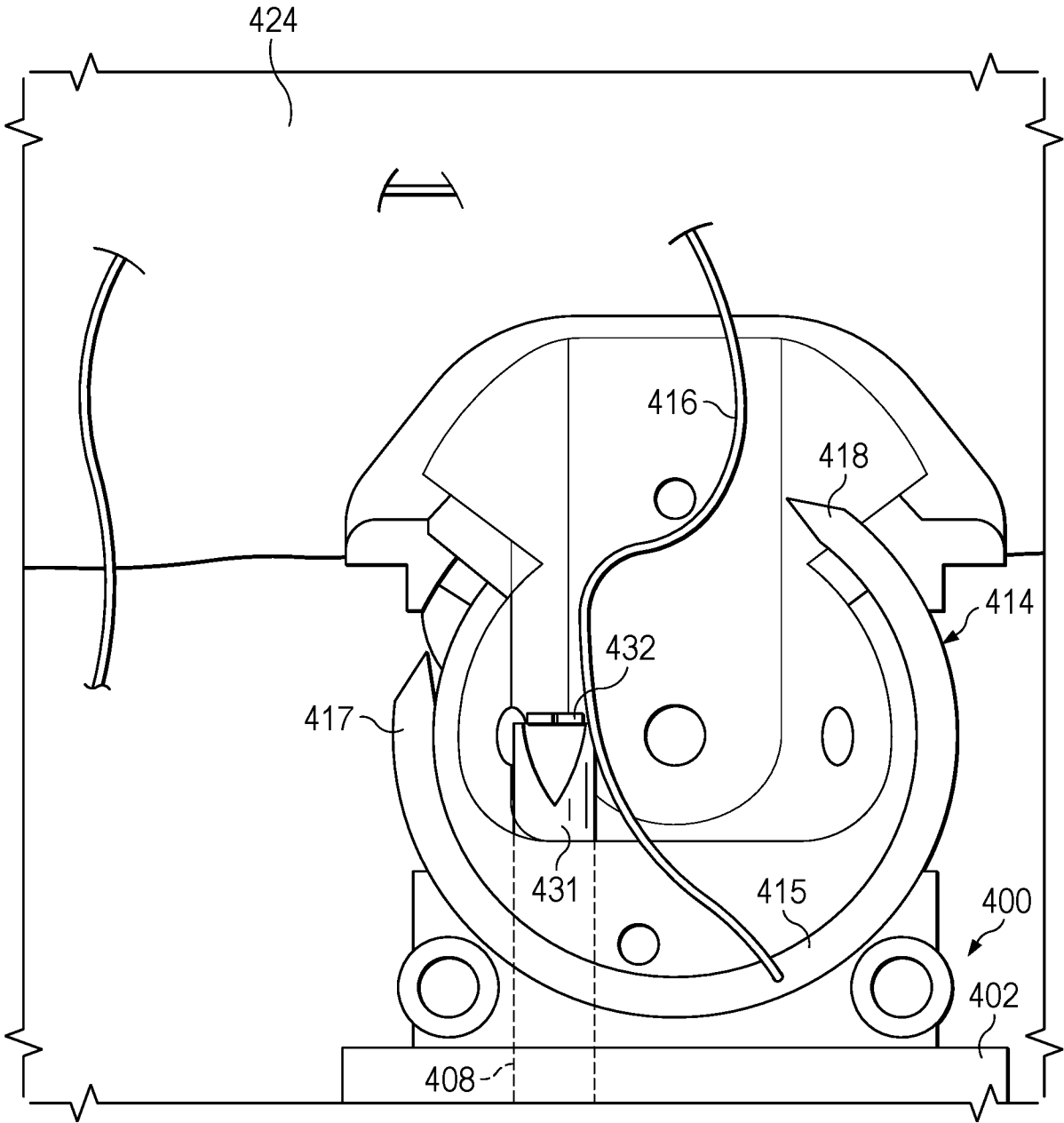


FIG. 7E

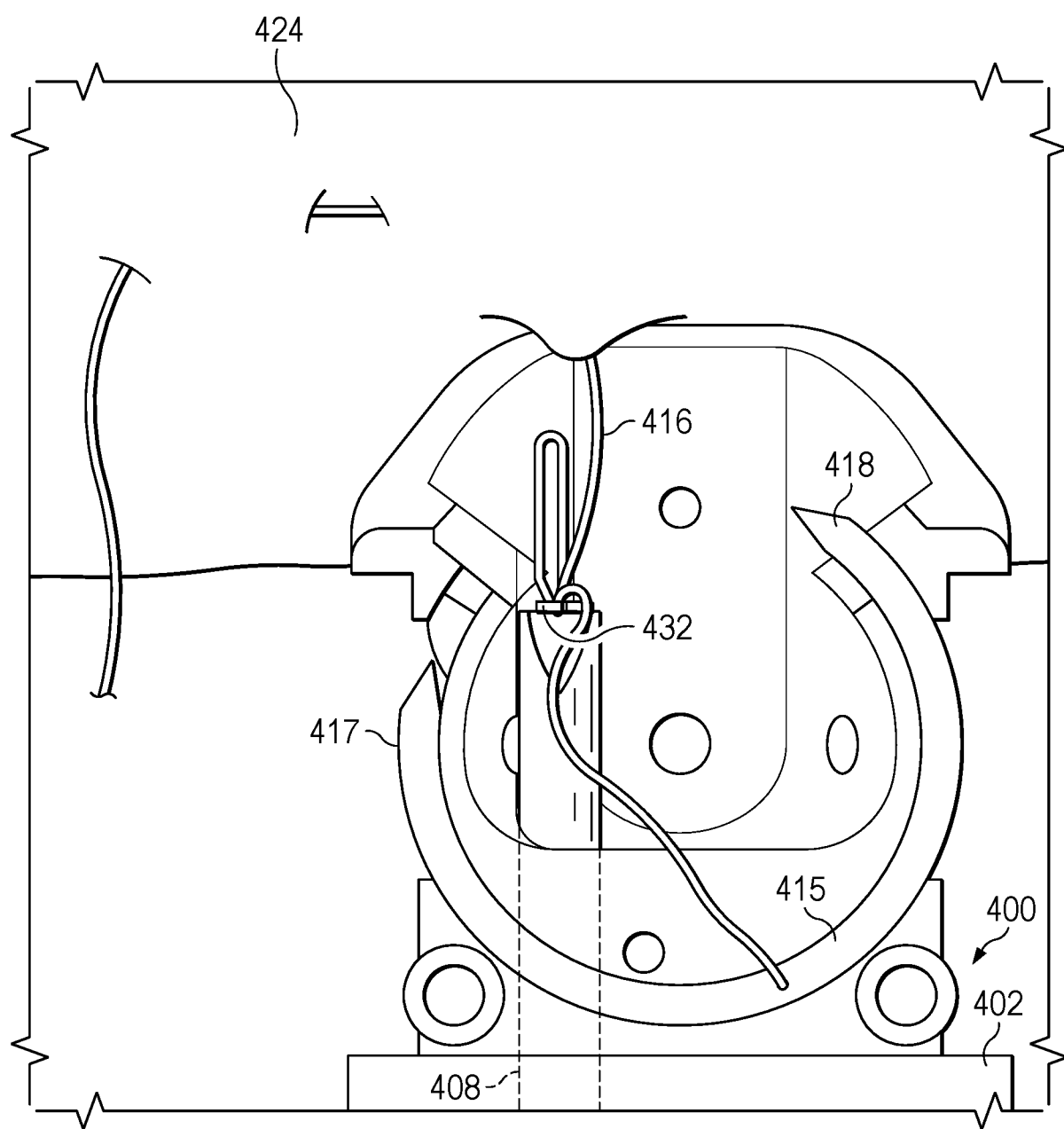


FIG. 7F

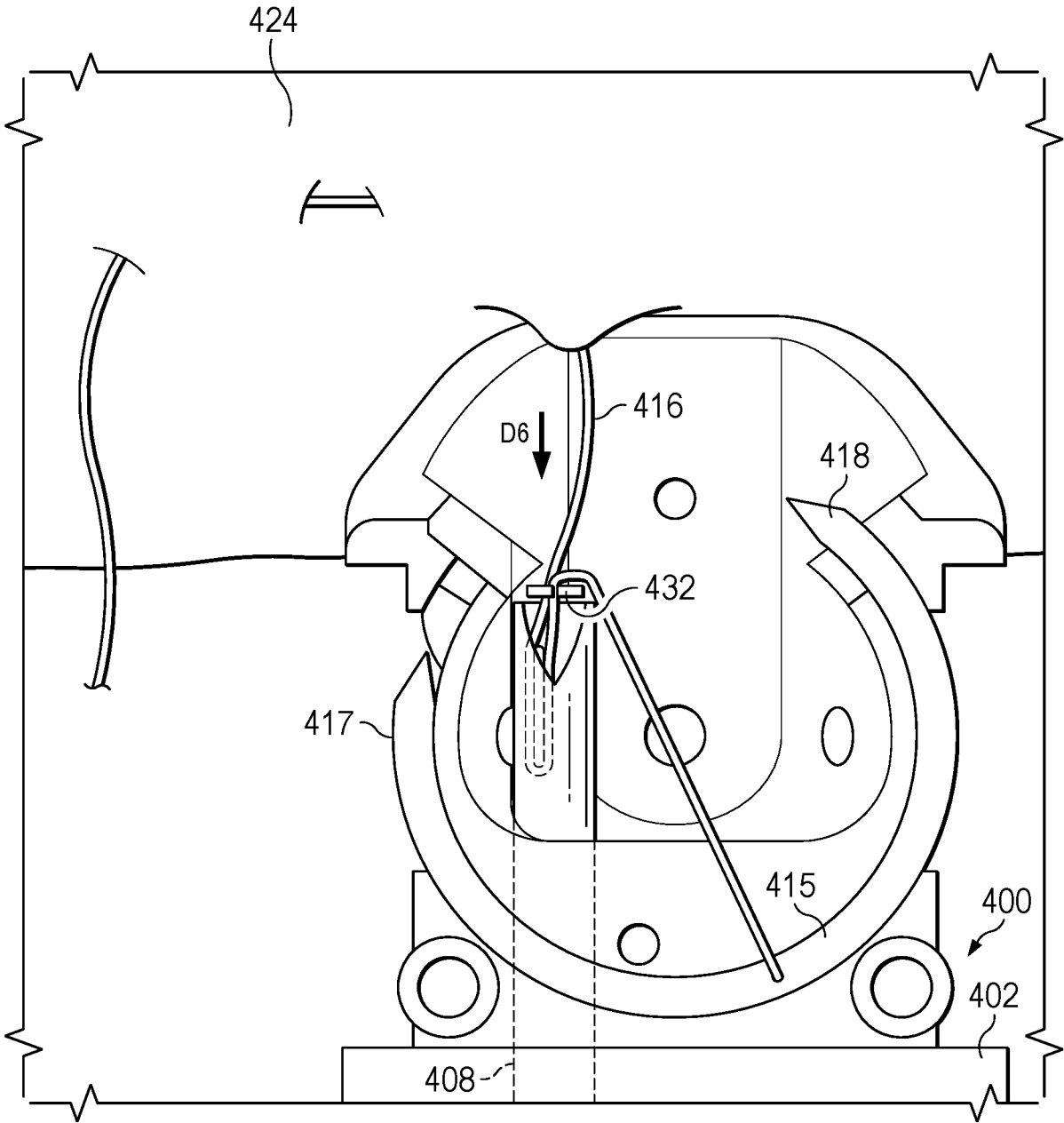


FIG. 7G

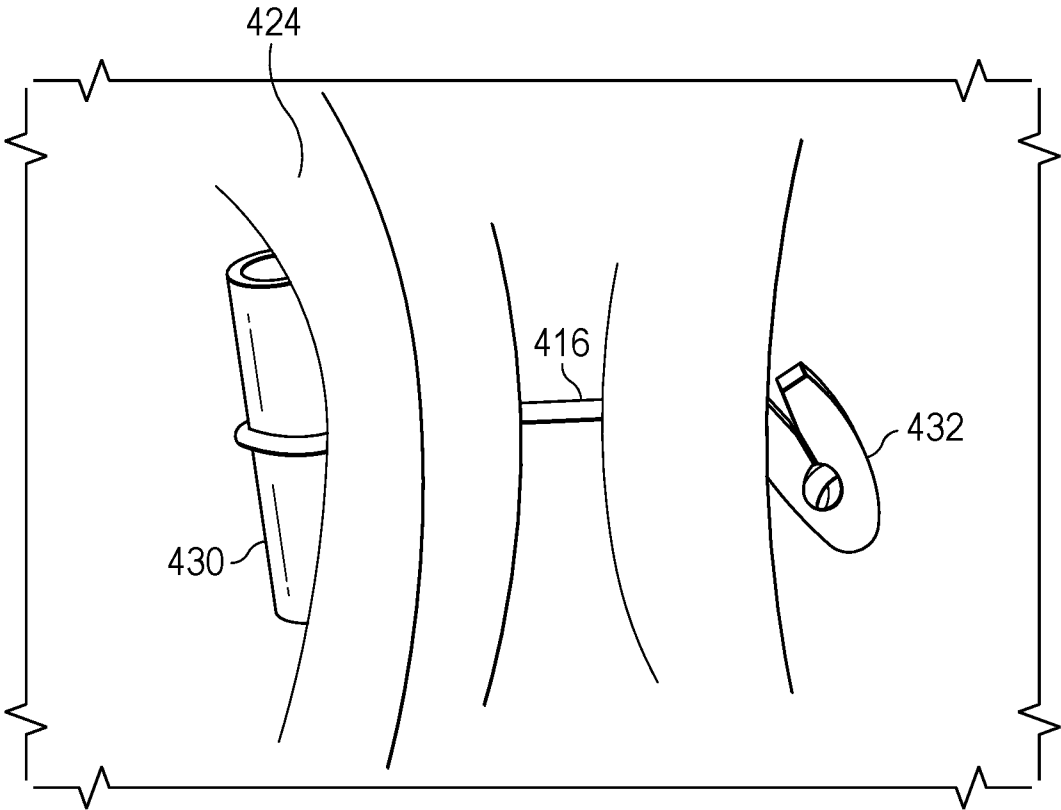


FIG. 7H

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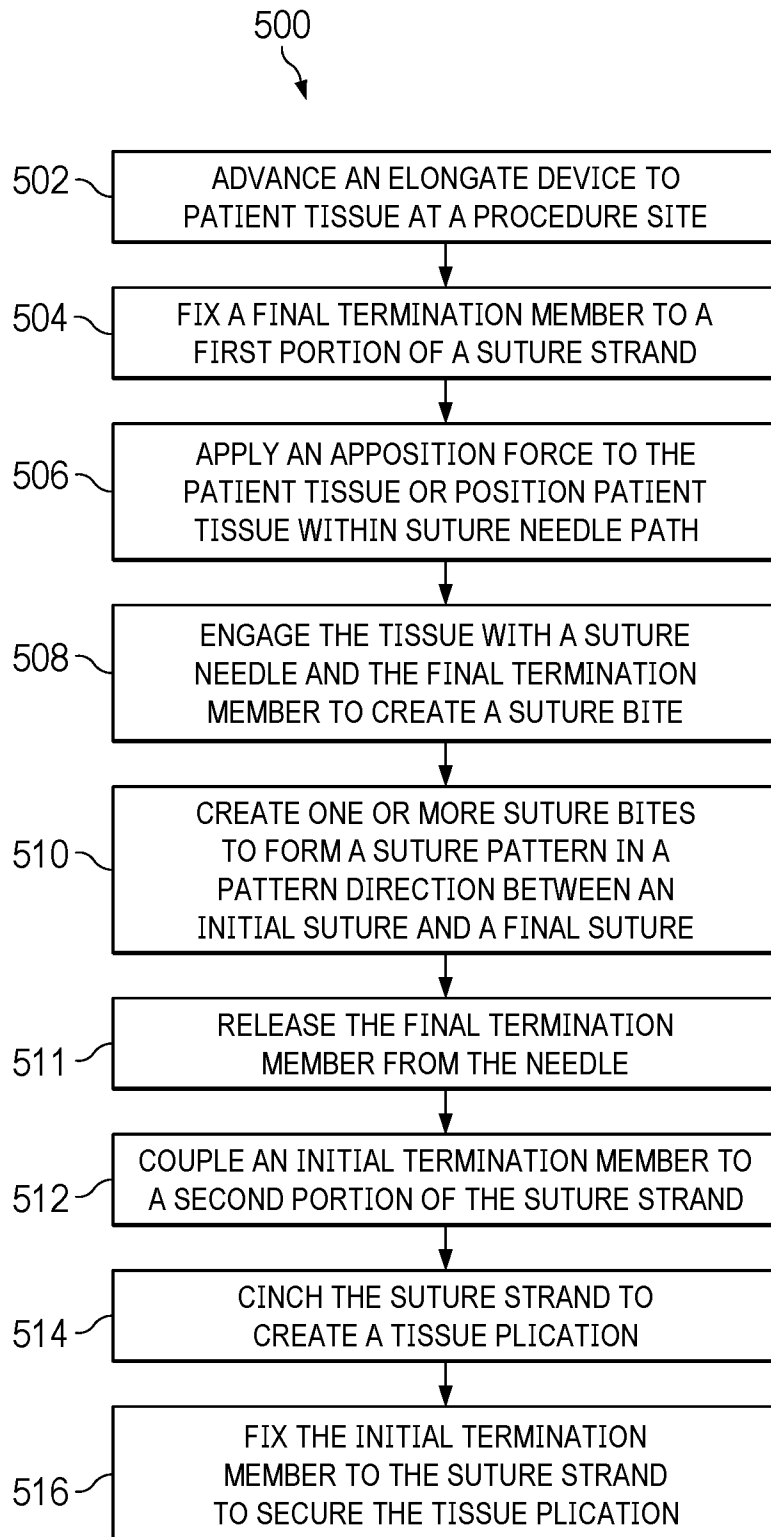


FIG. 8

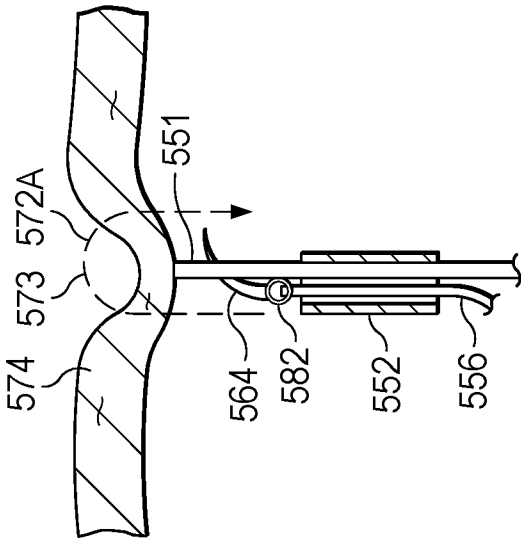


FIG. 9B

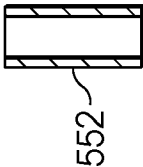
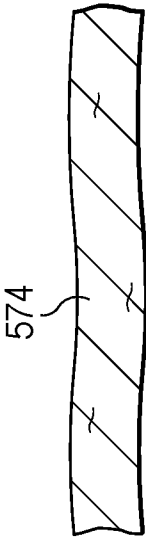


FIG. 9A

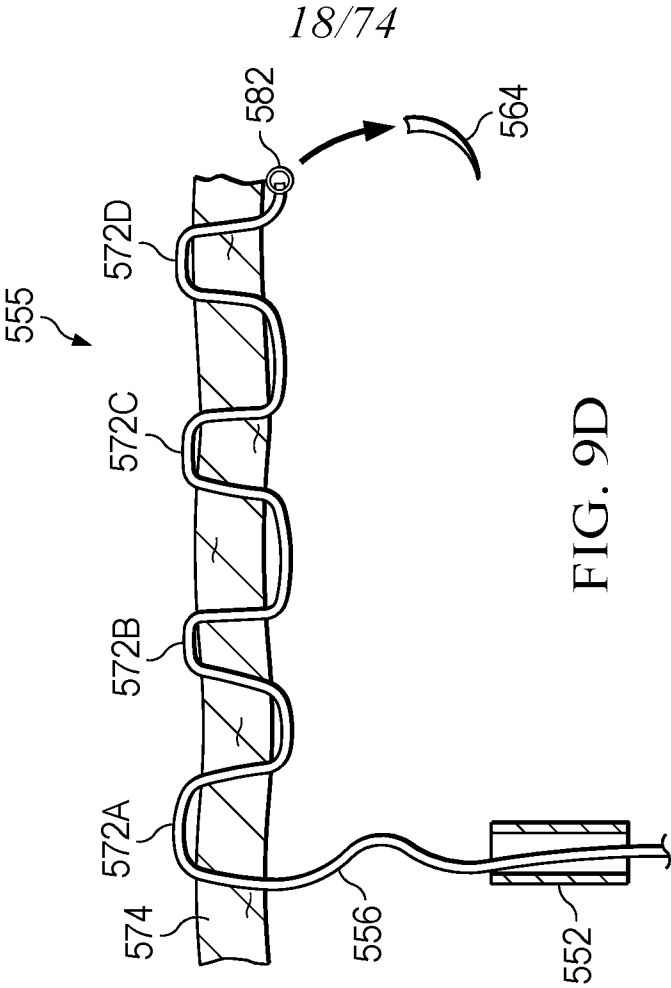


FIG. 9D

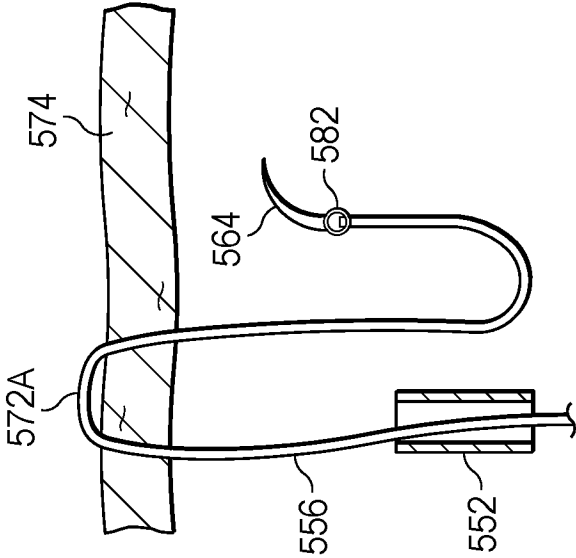
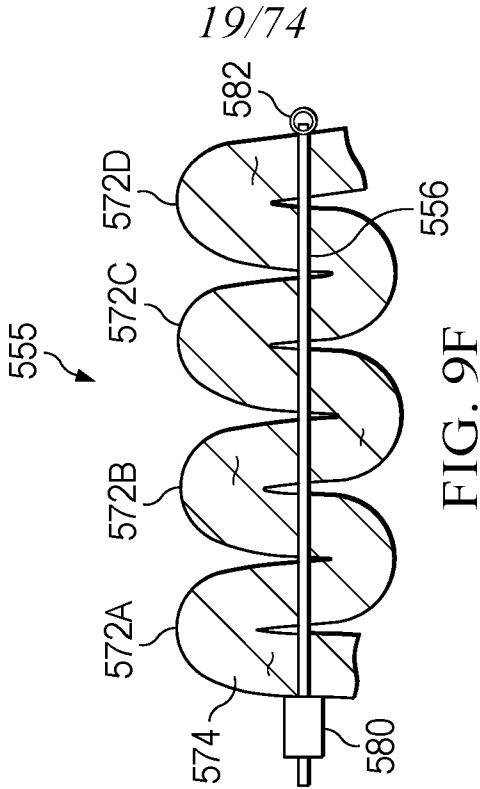
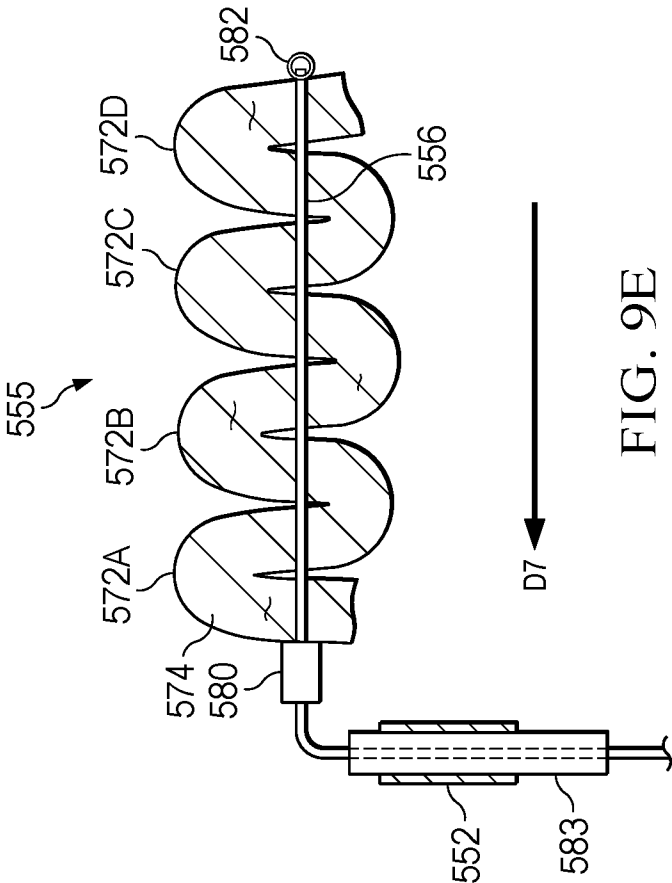


FIG. 9C



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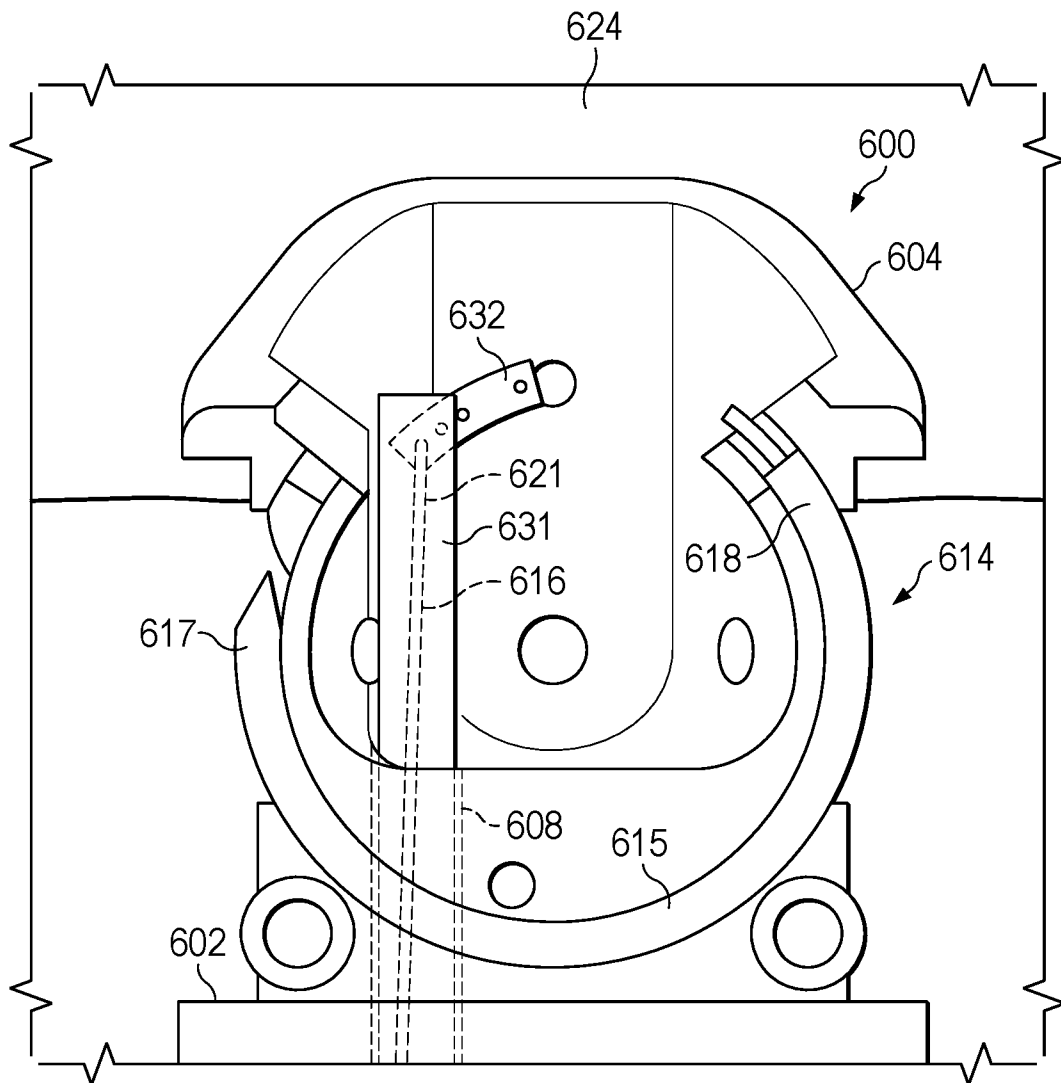


FIG. 10A

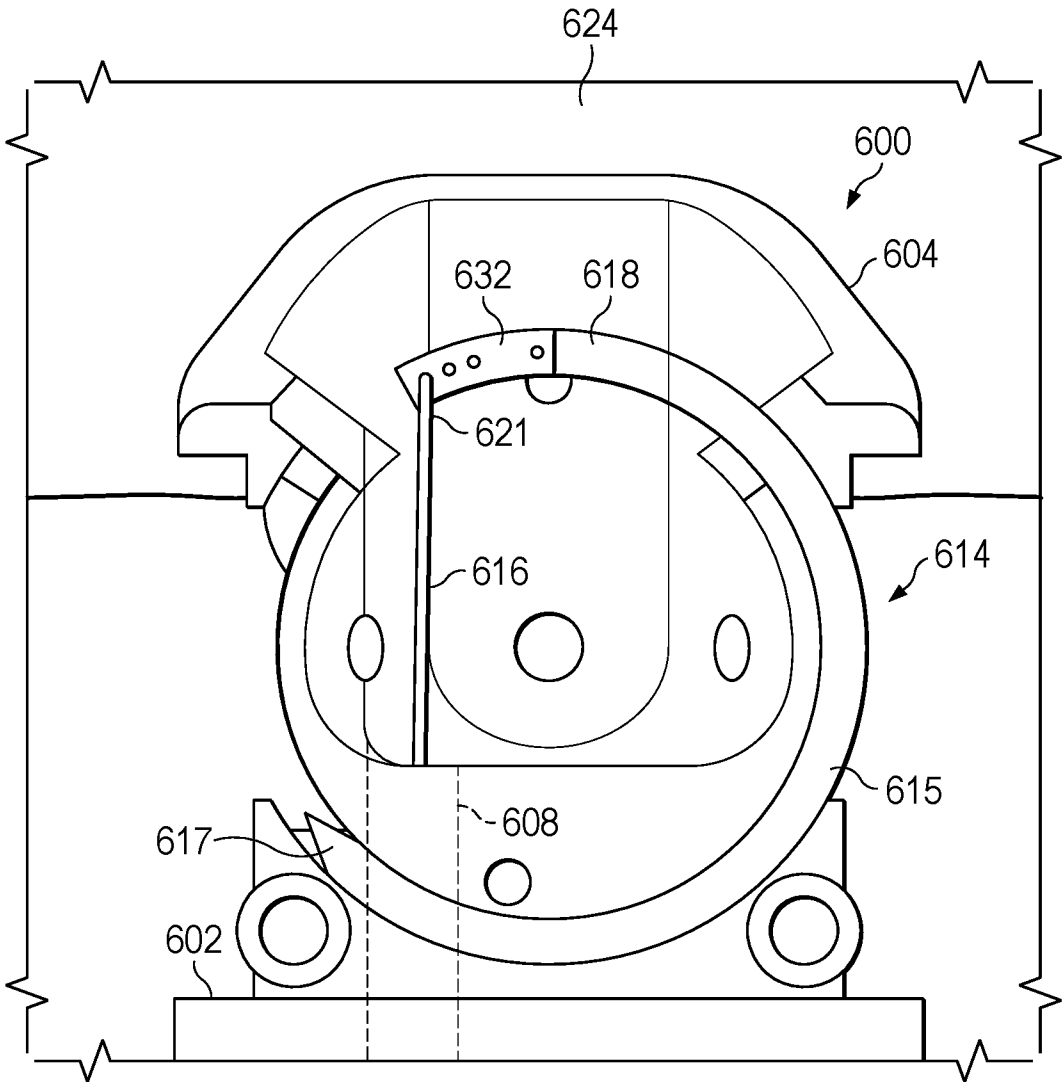


FIG. 10B

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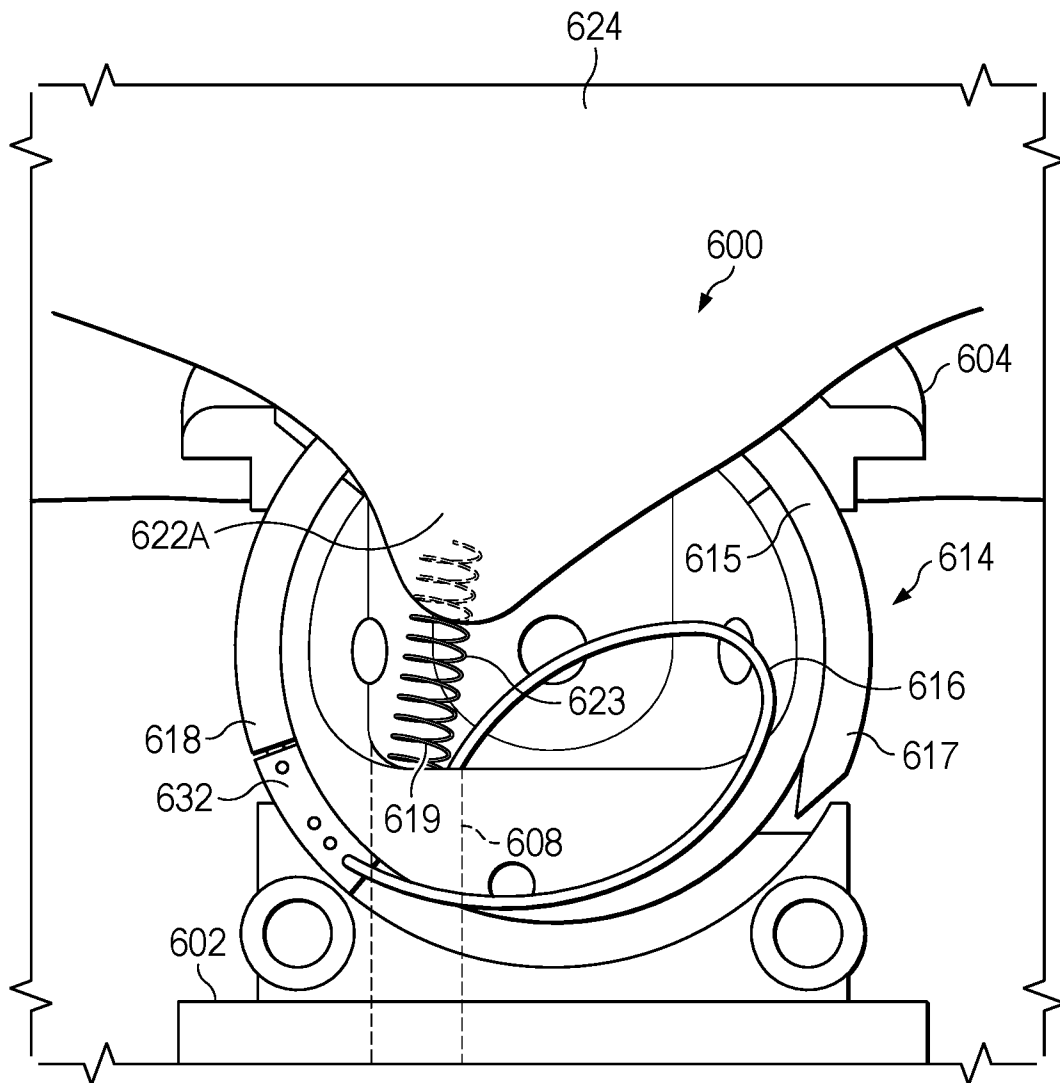


FIG. 10C

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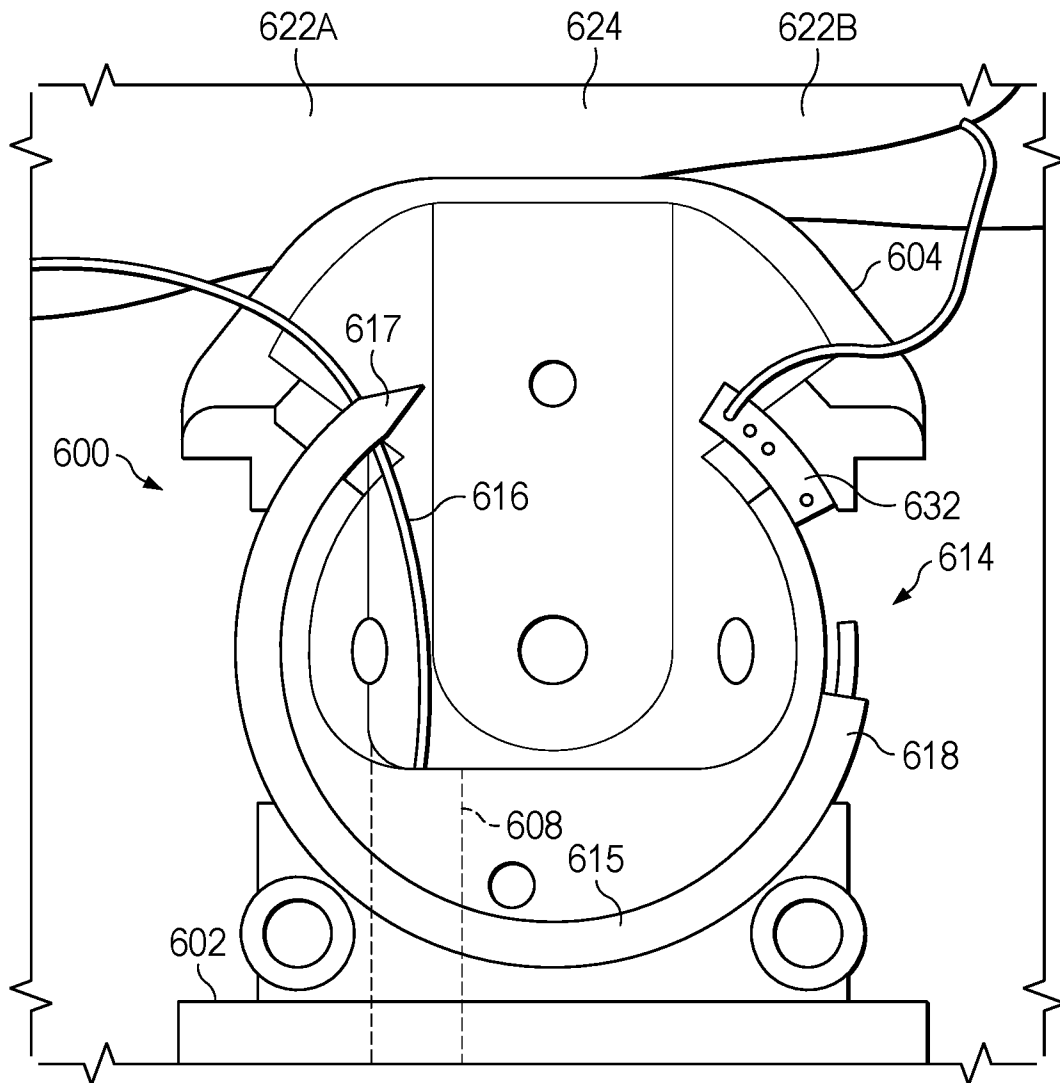


FIG. 10D

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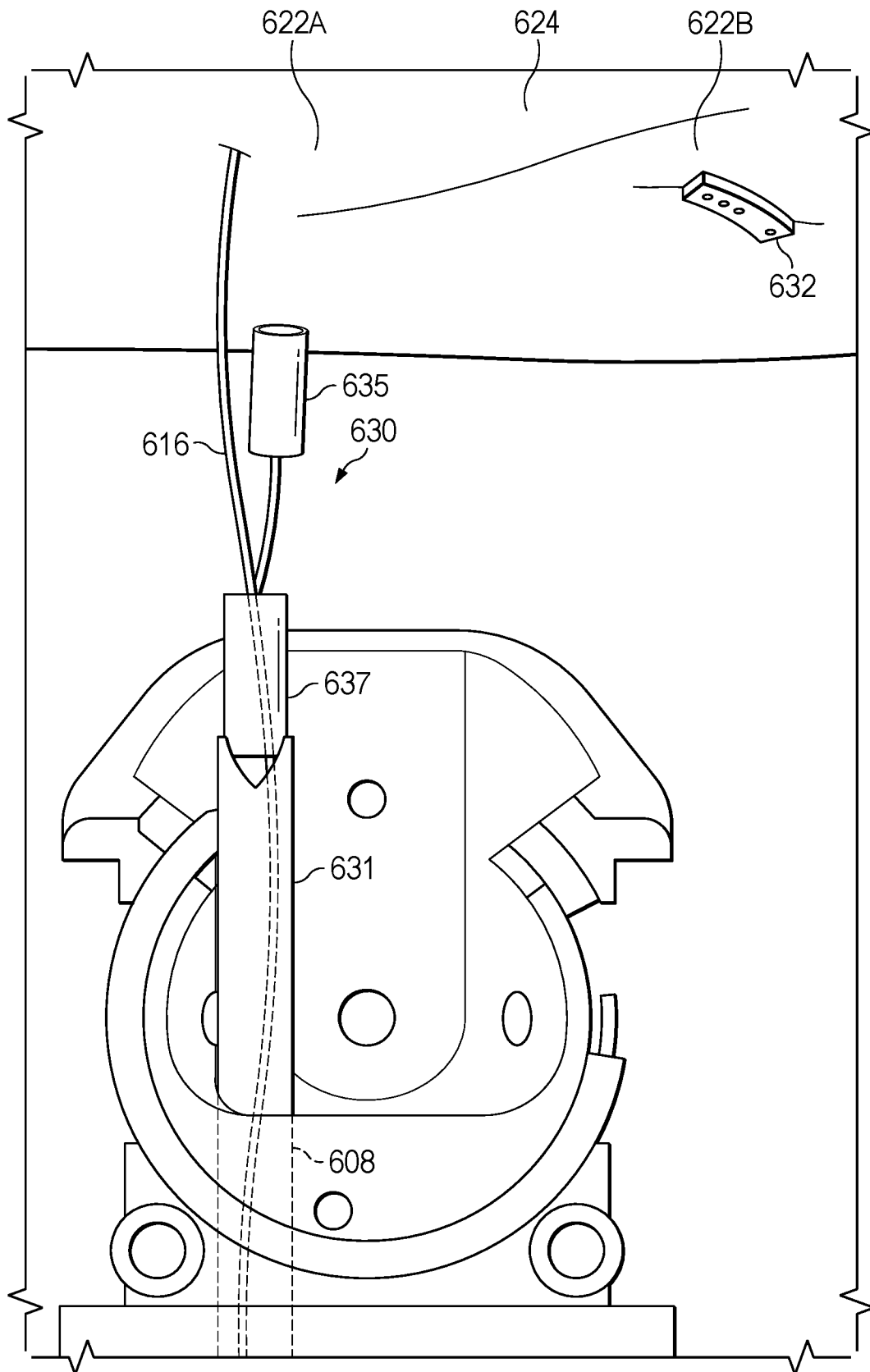


FIG. 10E

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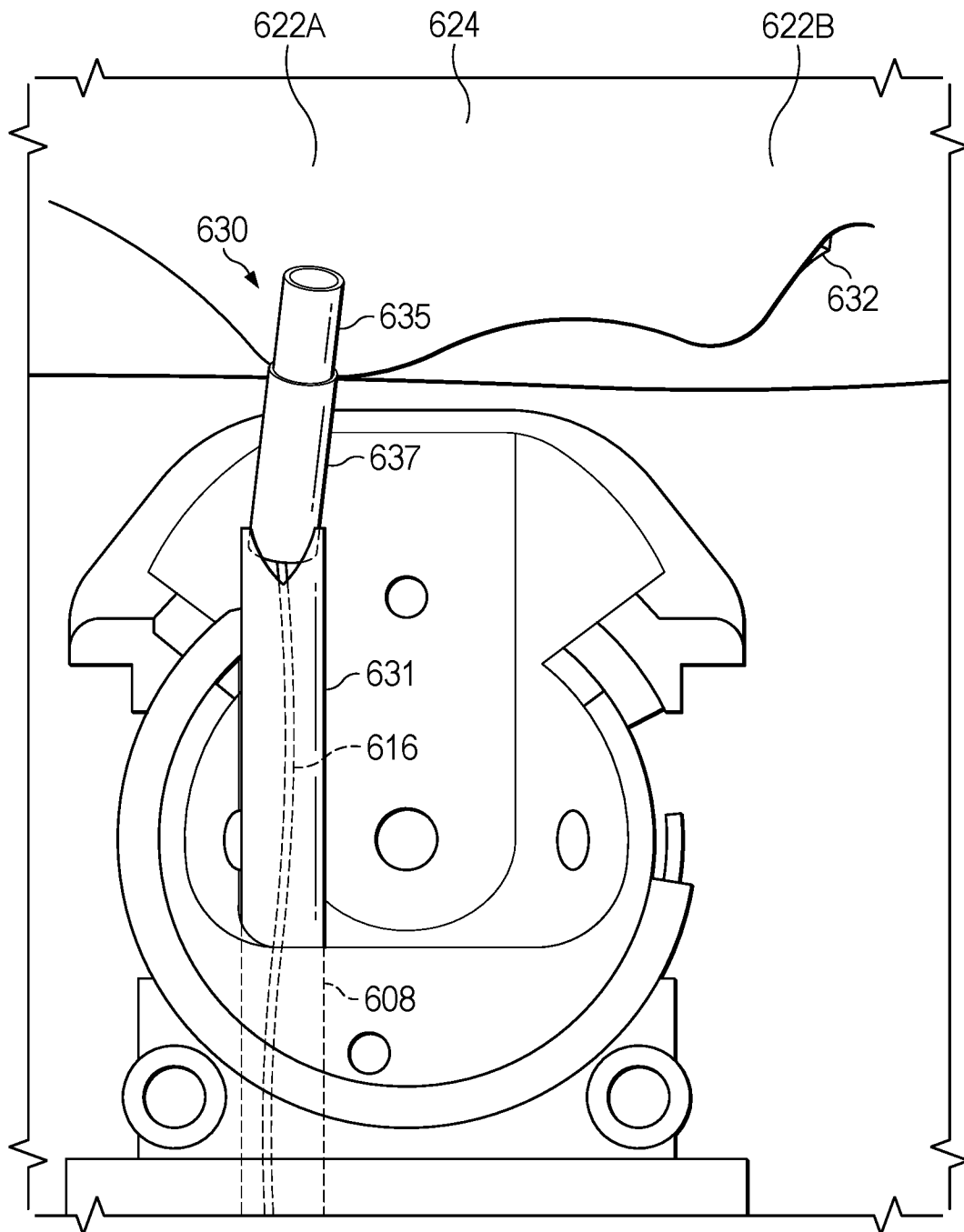


FIG. 10F

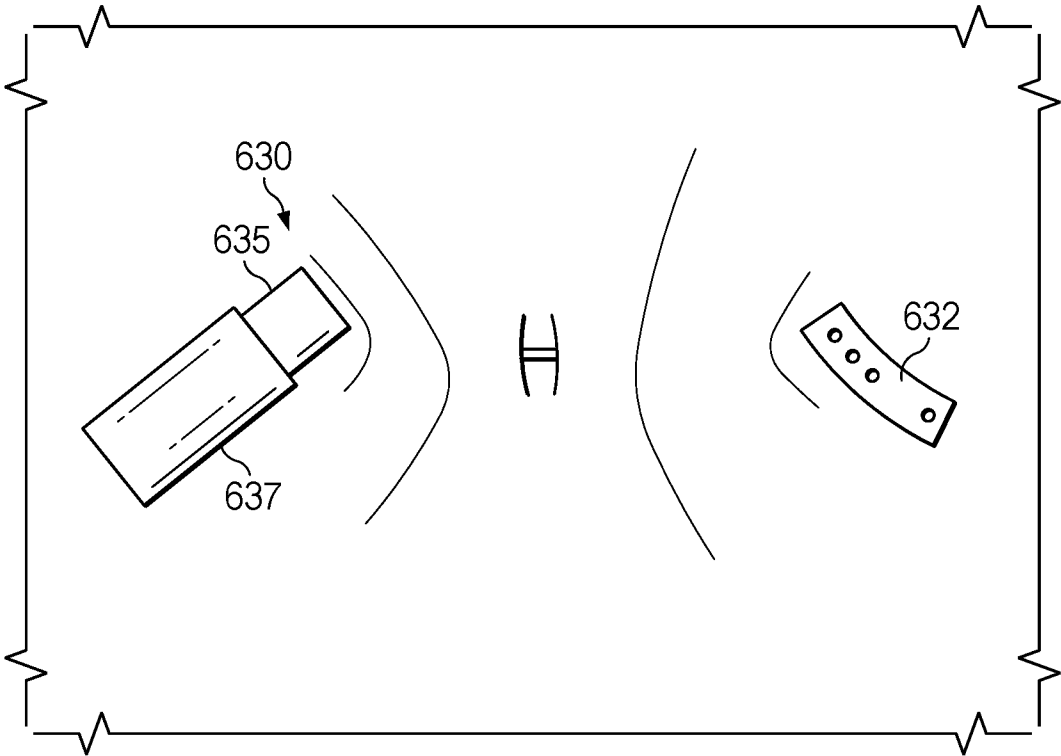


FIG. 10G

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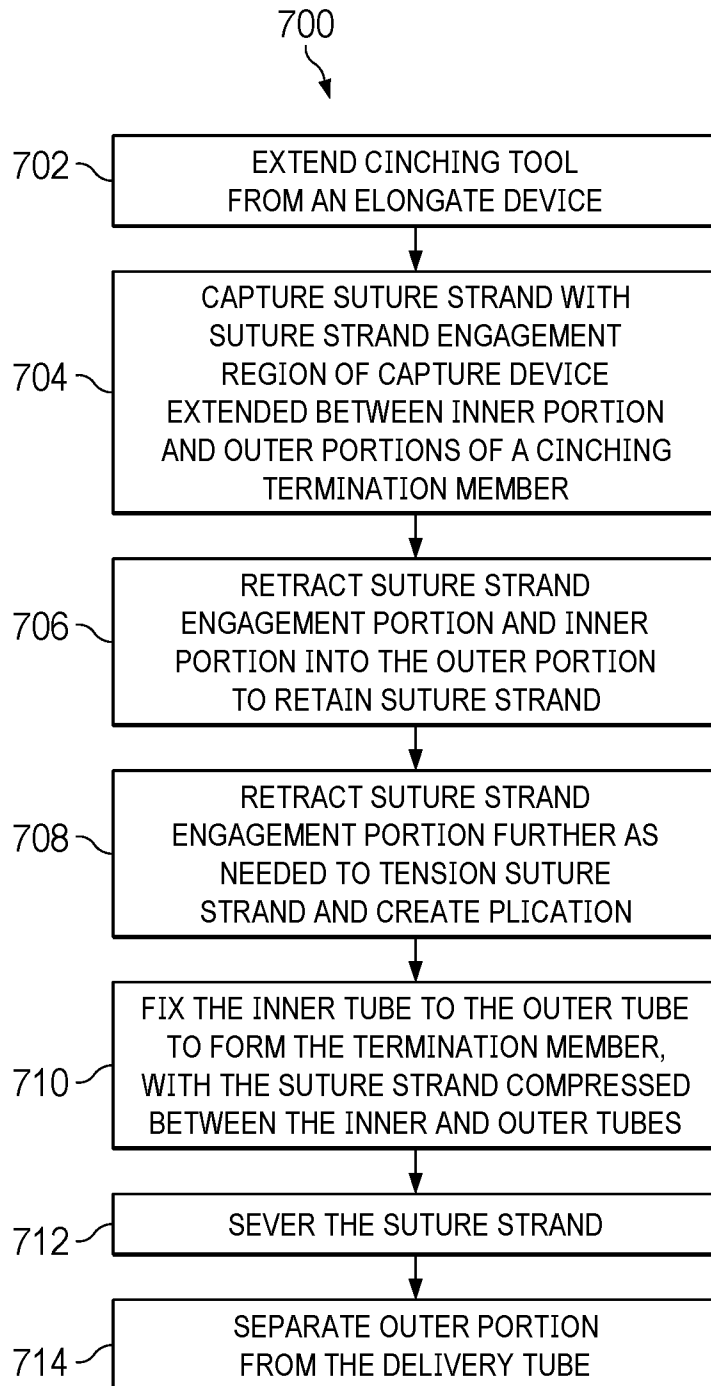
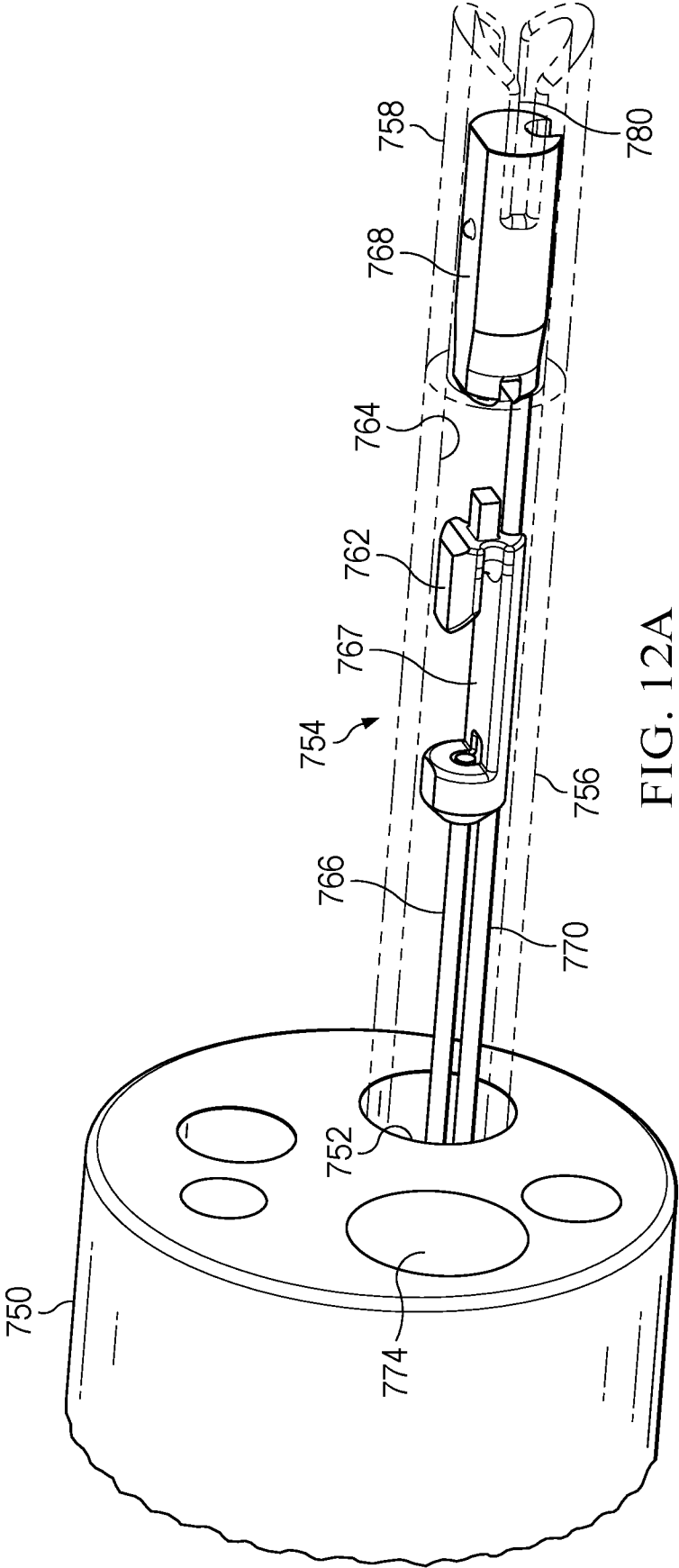


FIG. 11



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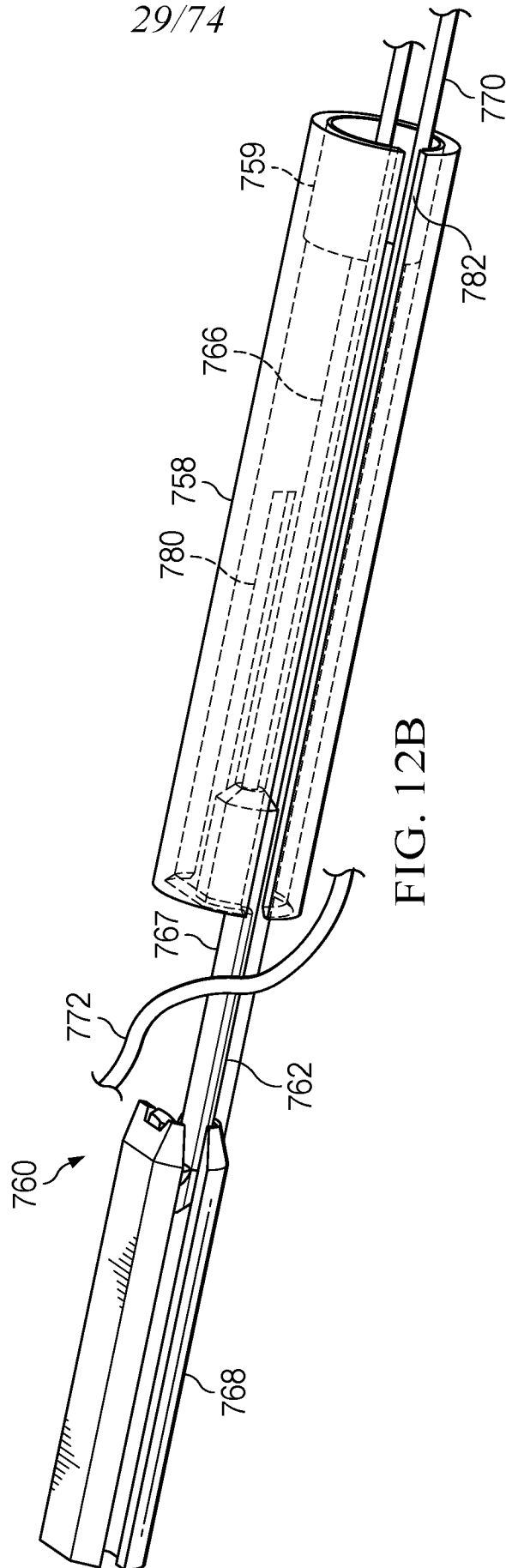


FIG. 12B

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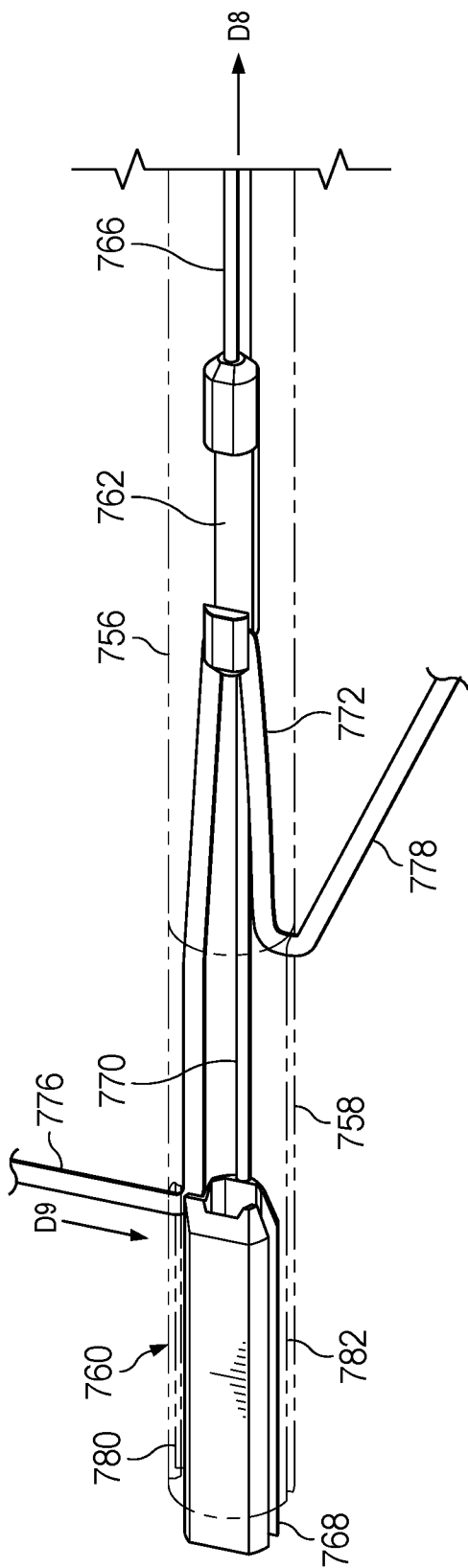
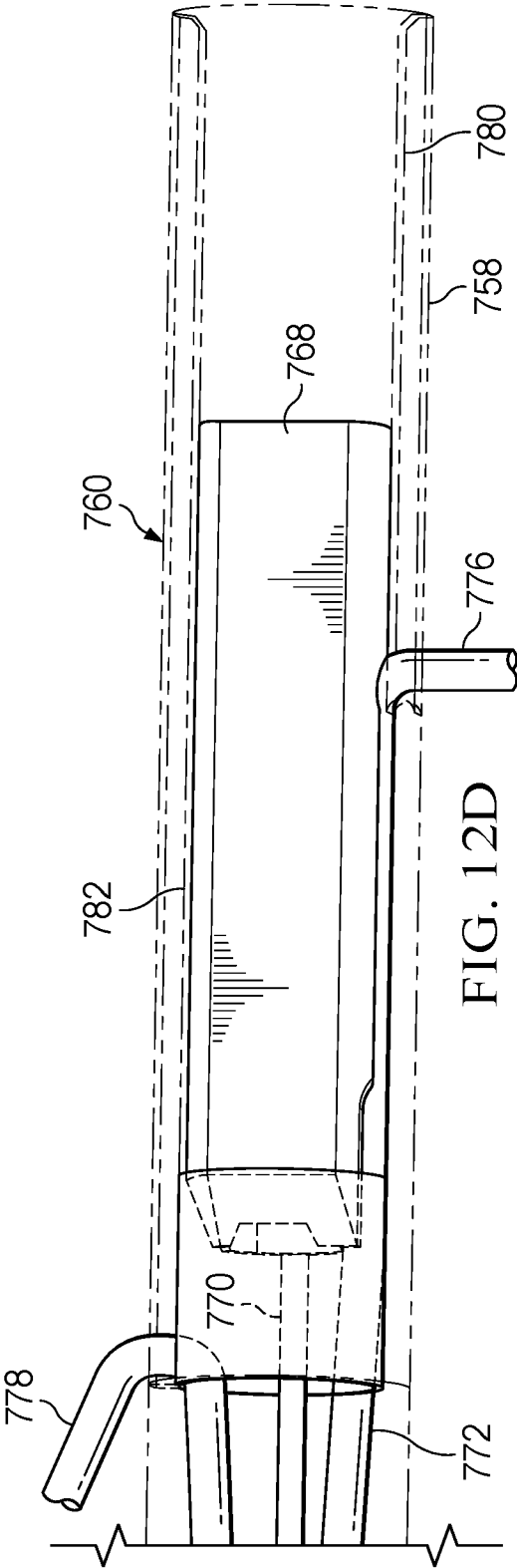


FIG. 12C



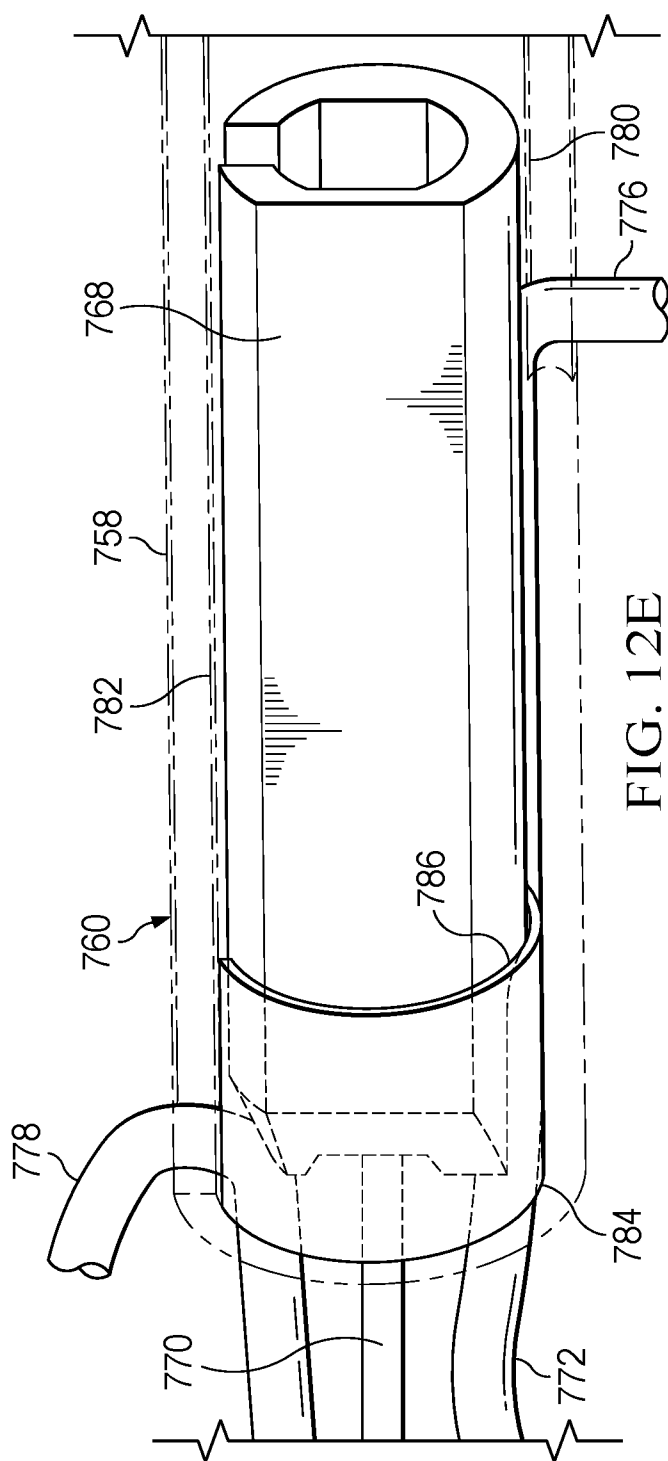


FIG. 12E

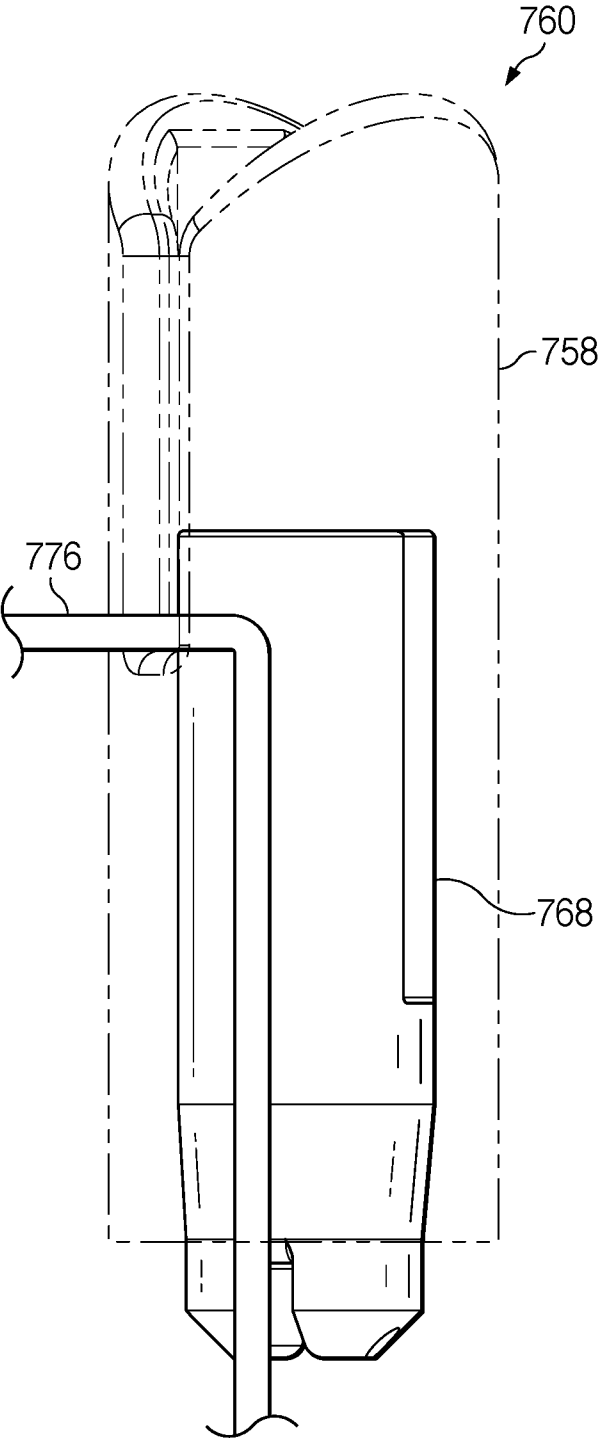
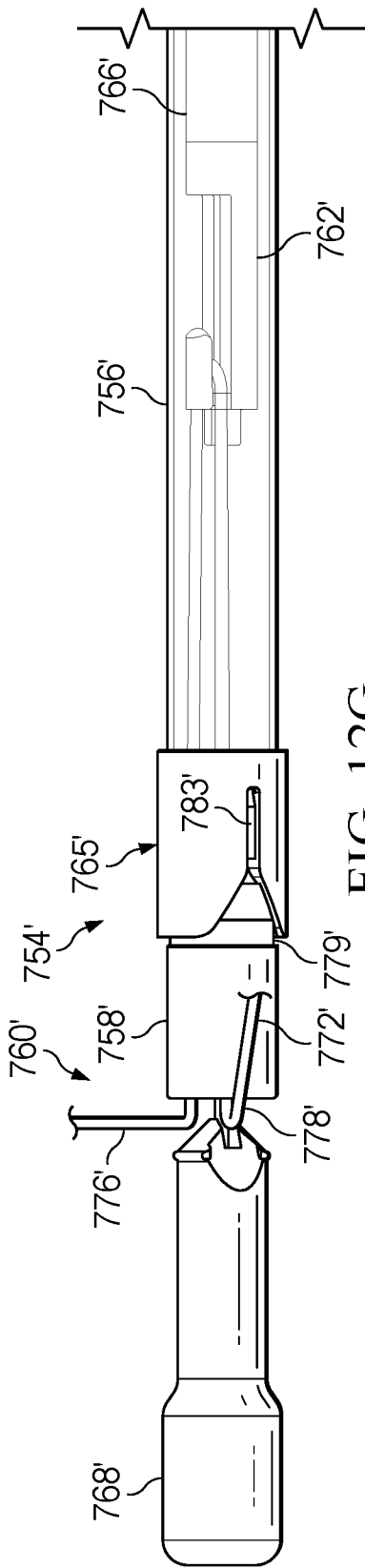
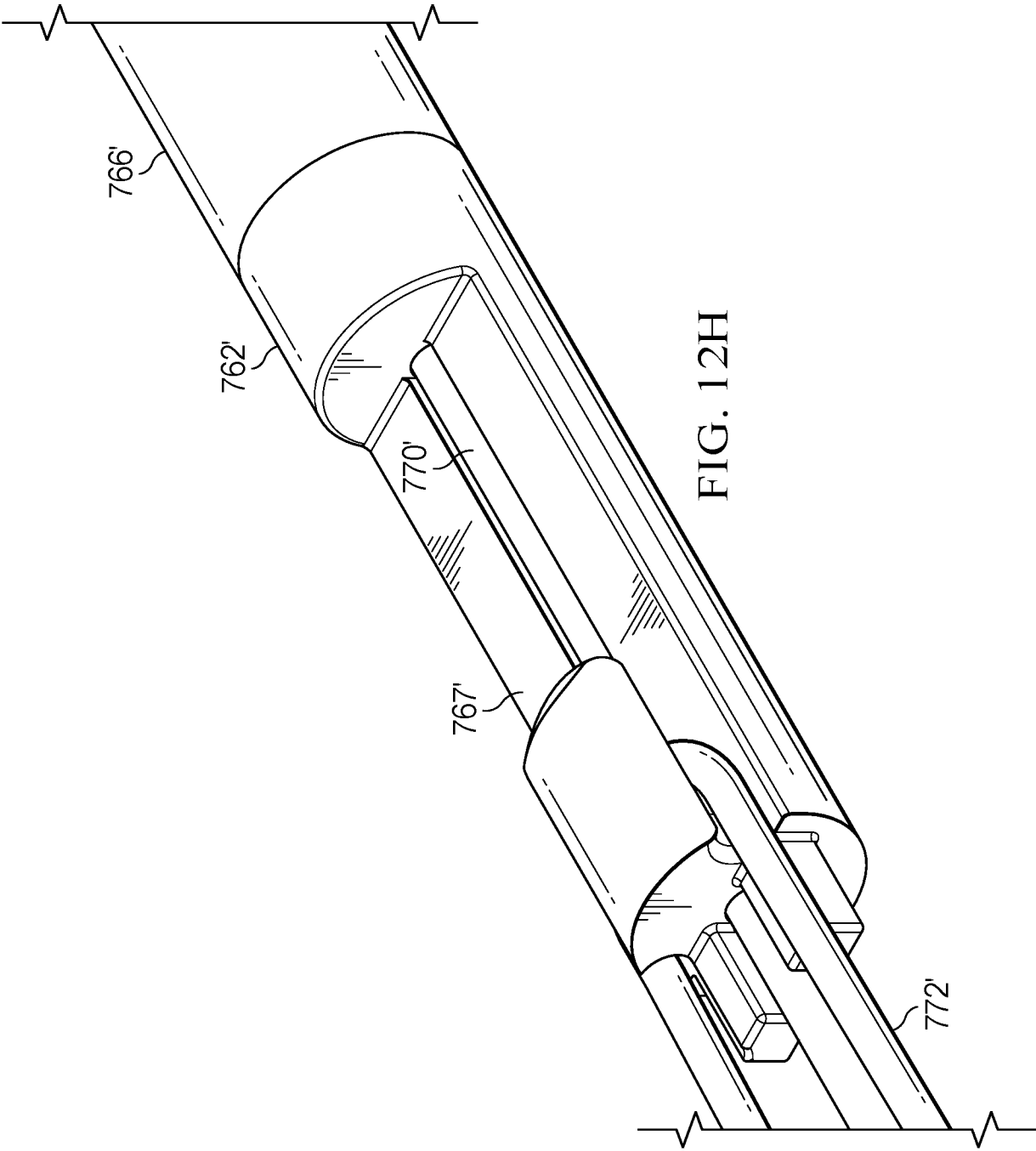
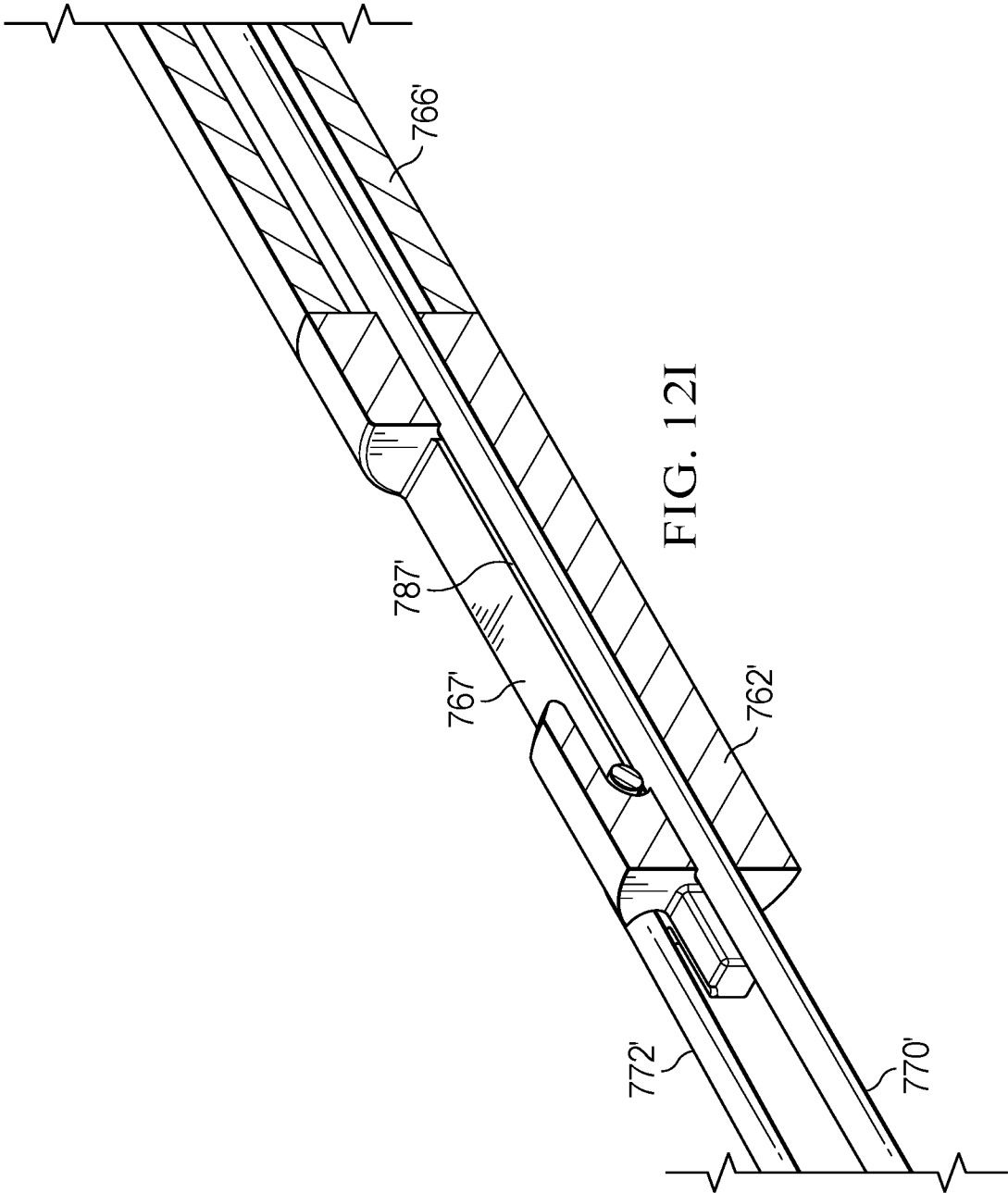


FIG. 12F

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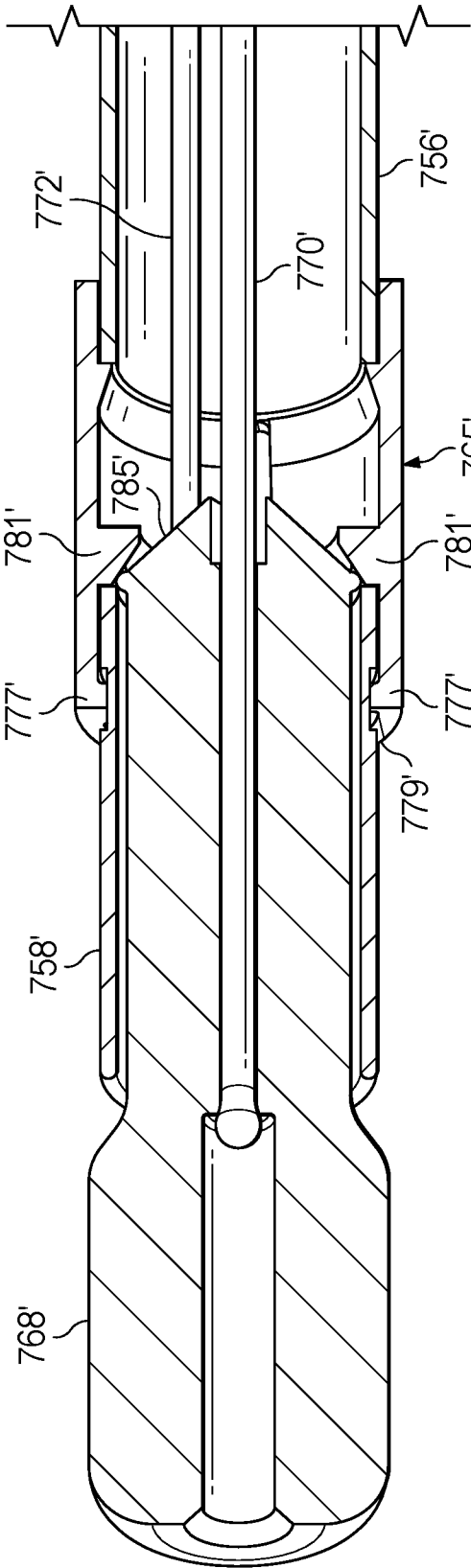


FIG. 12J

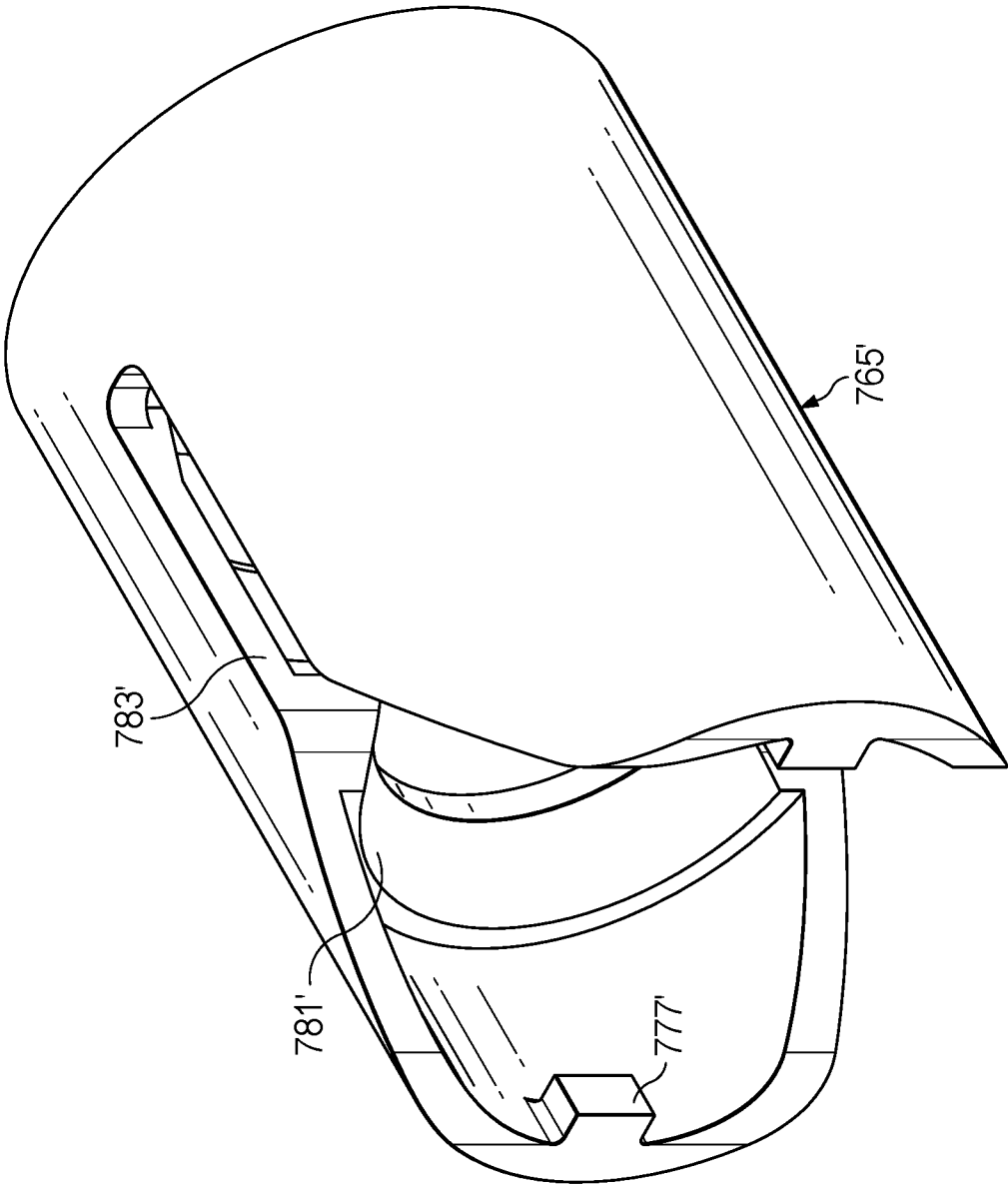


FIG. 12K

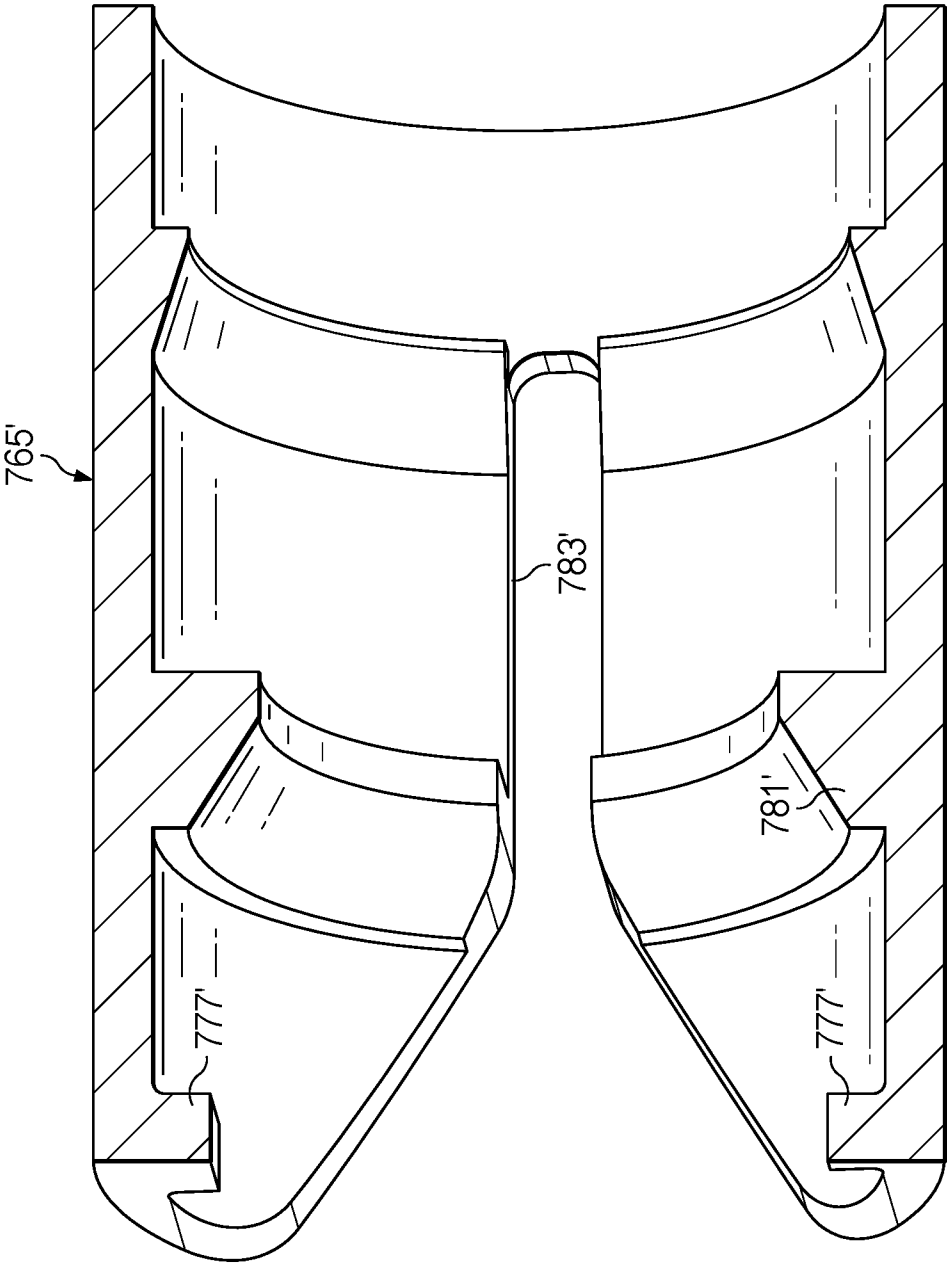


FIG. 12L

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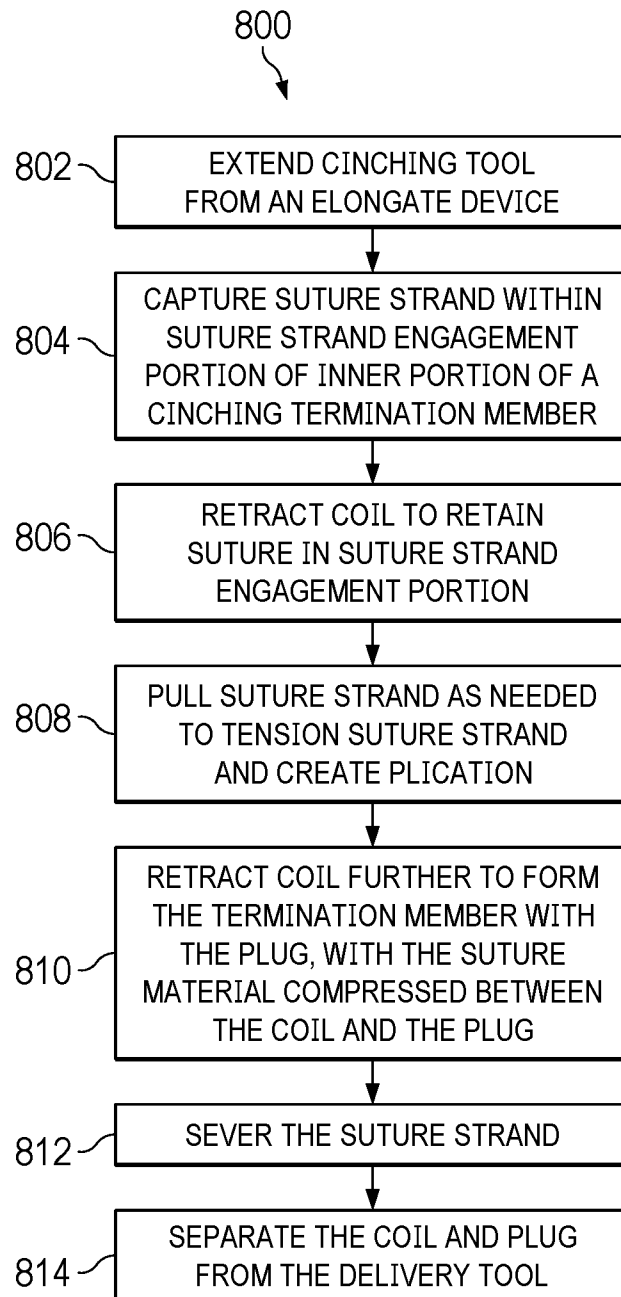


FIG. 13

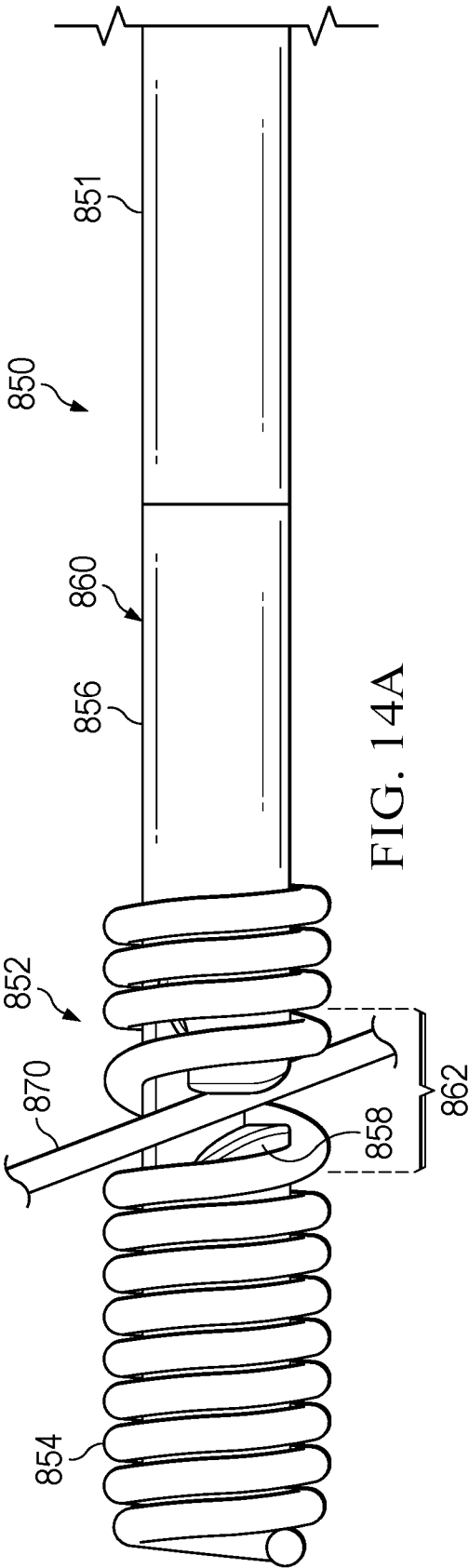


FIG. 14A

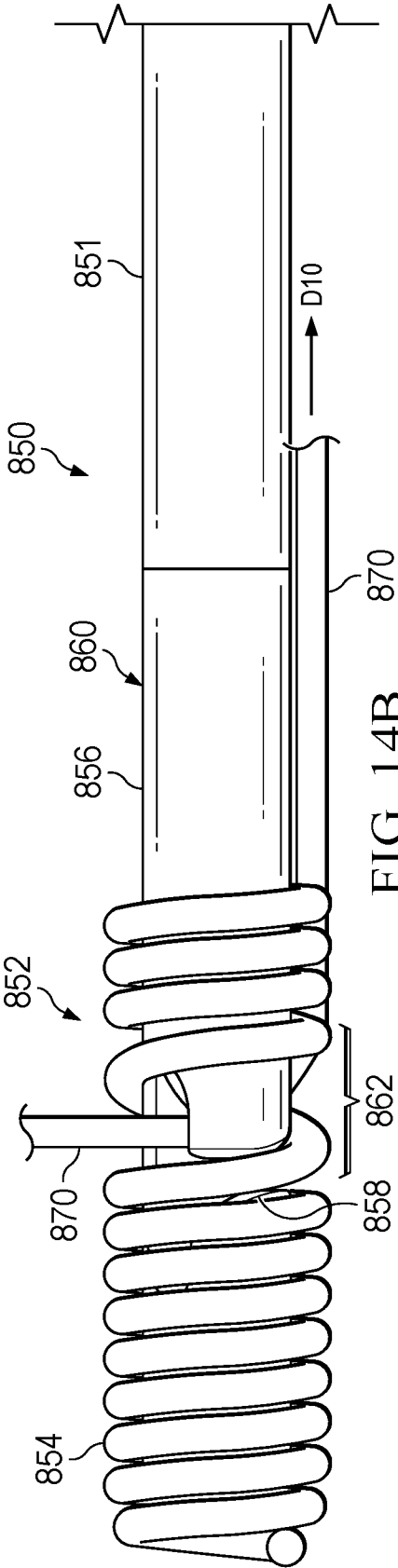


FIG. 14B

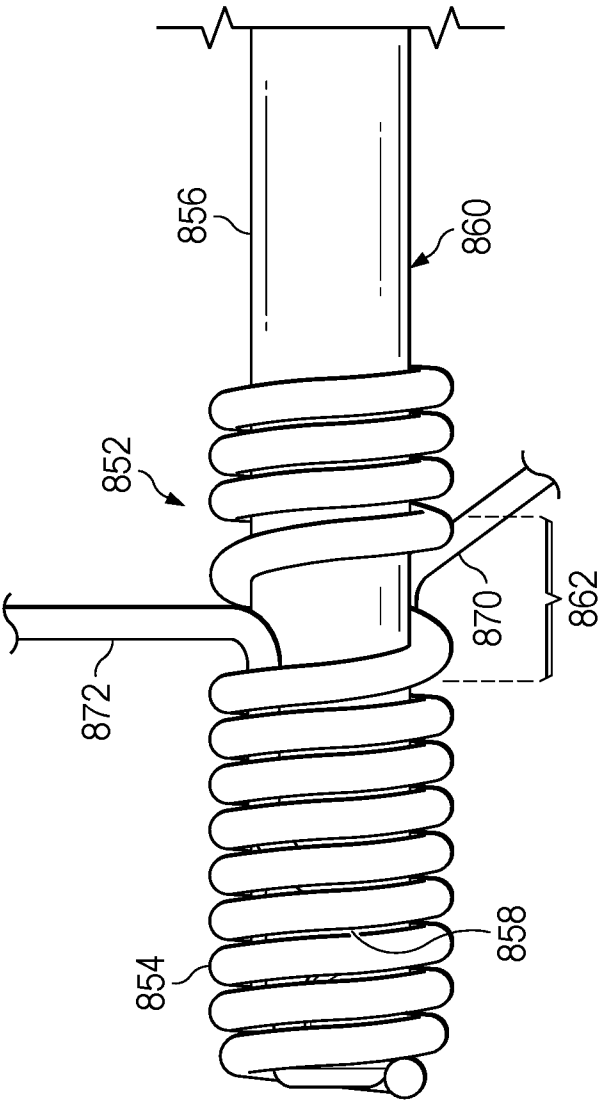


FIG. 14C

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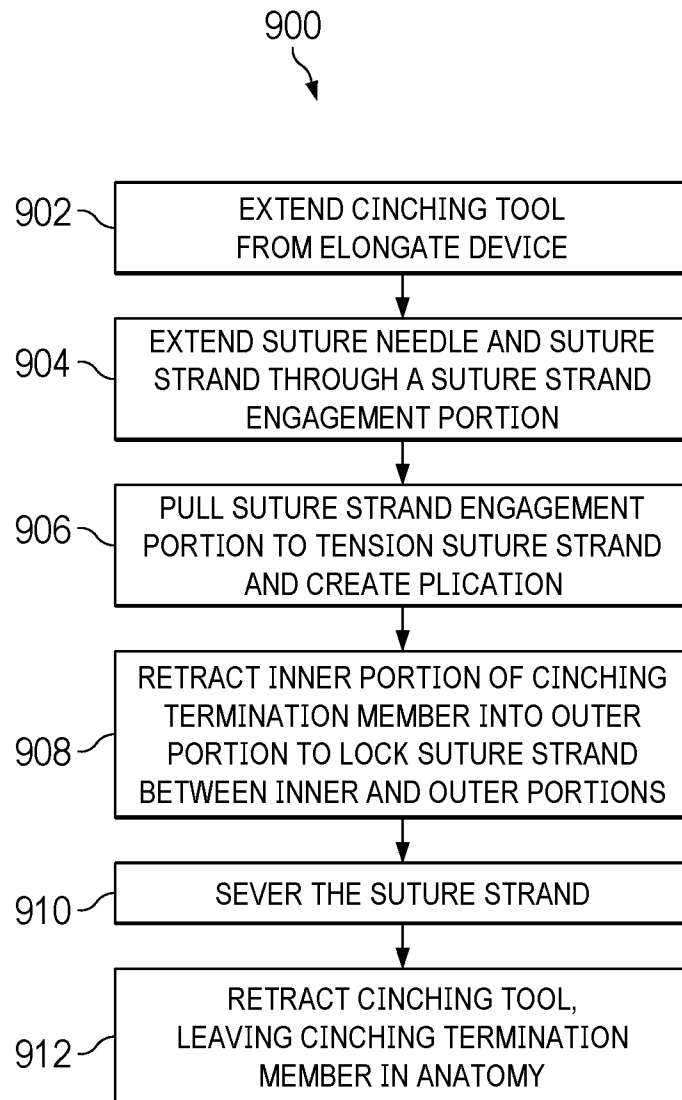


FIG. 15

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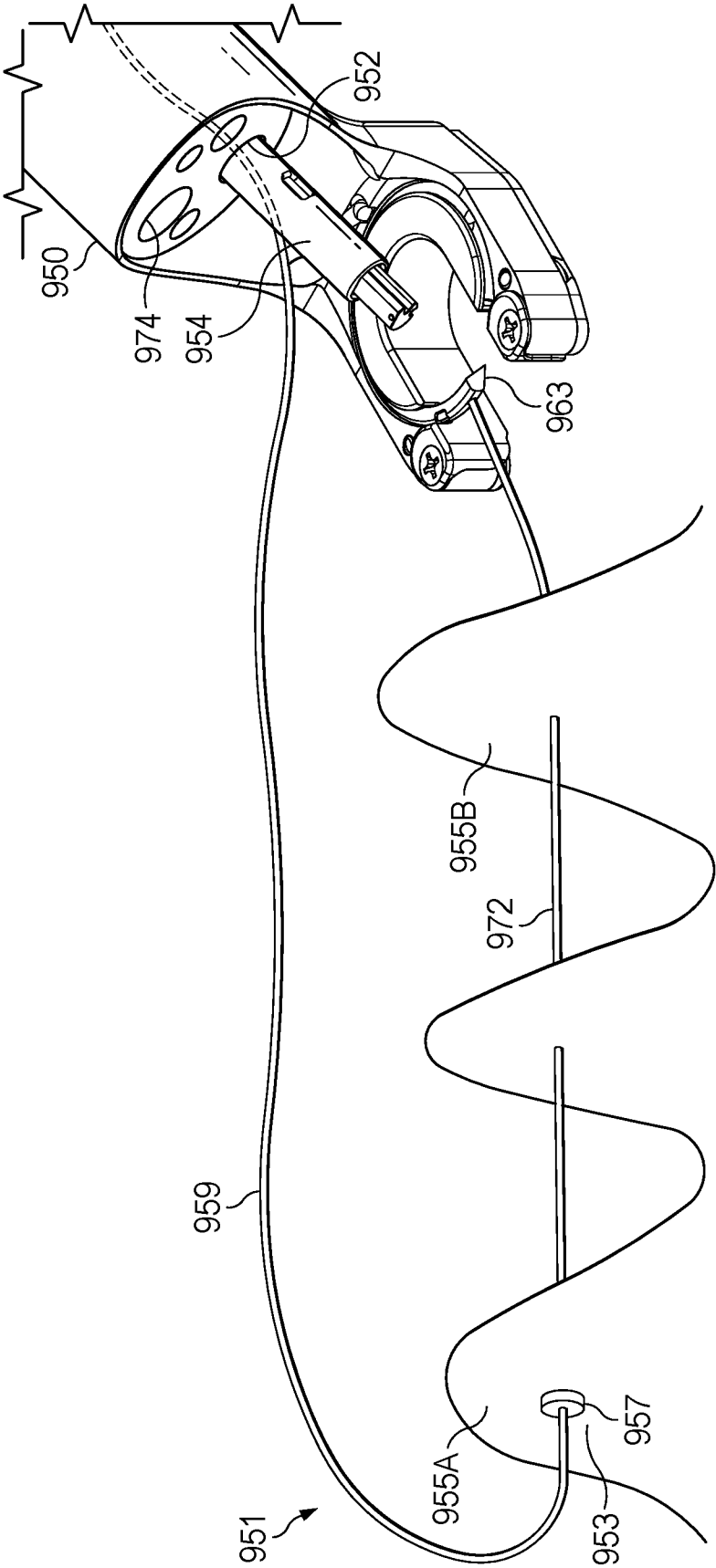


FIG. 16A

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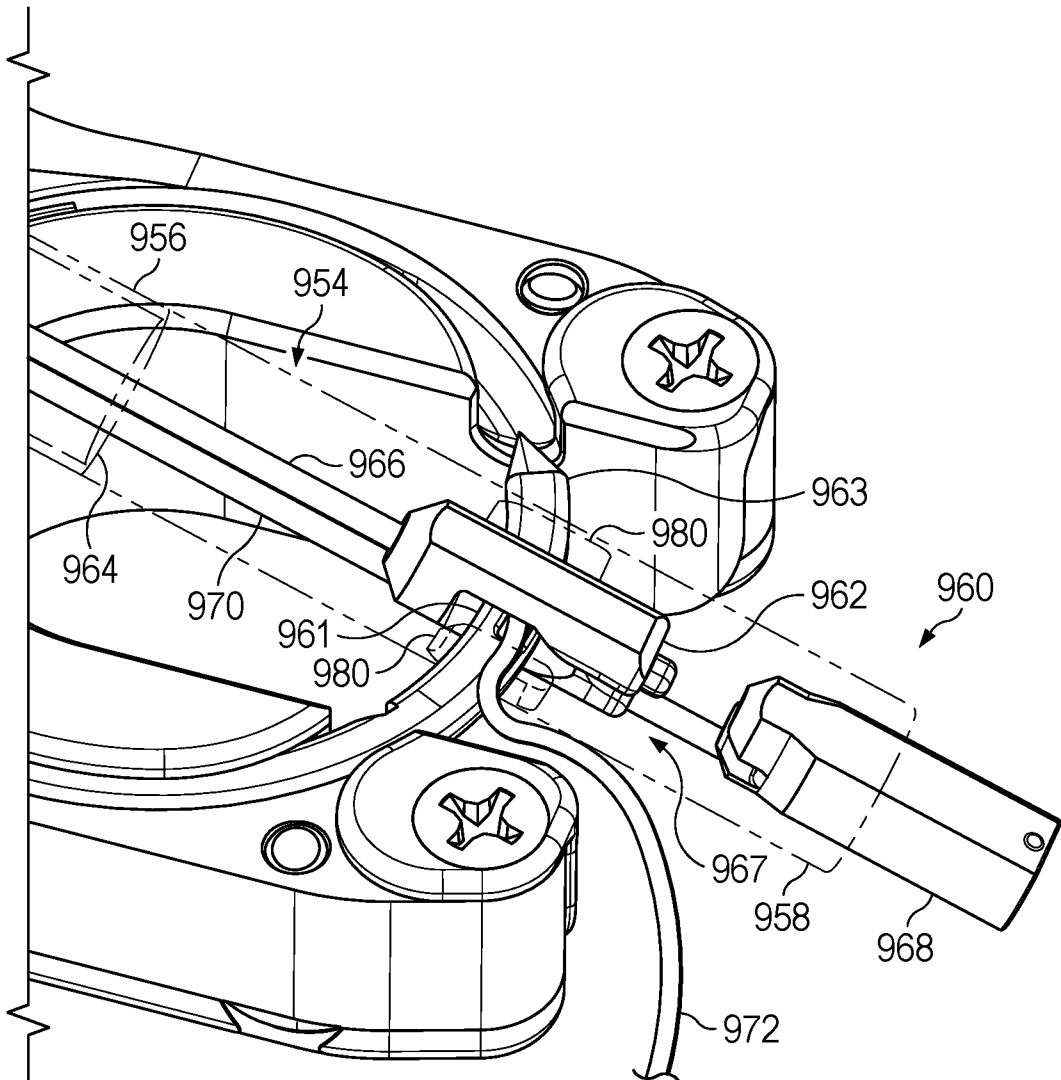


FIG. 16B

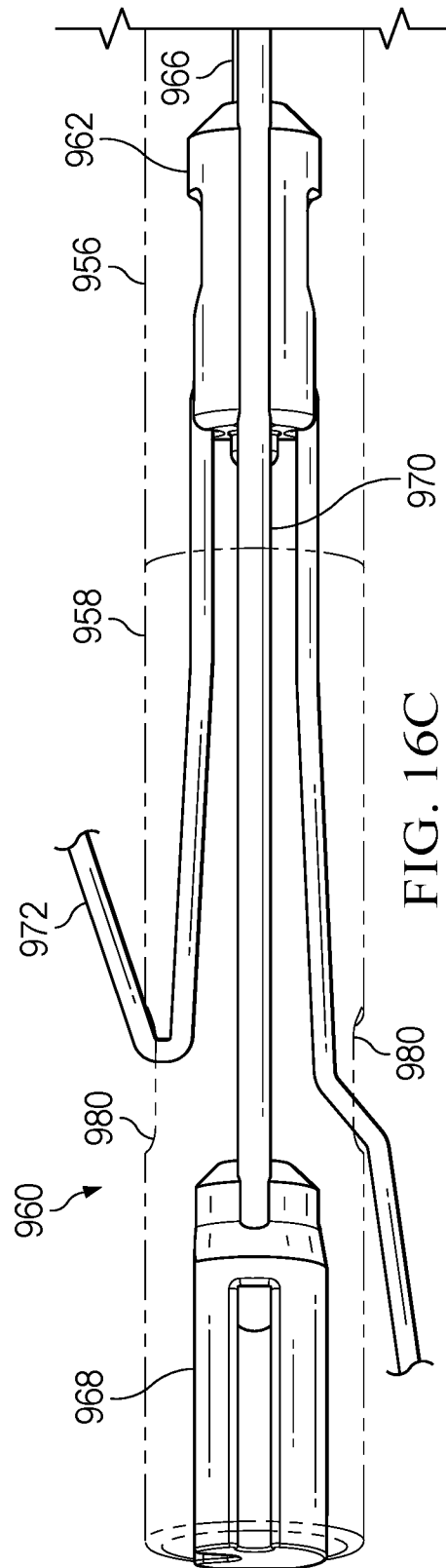


FIG. 16C

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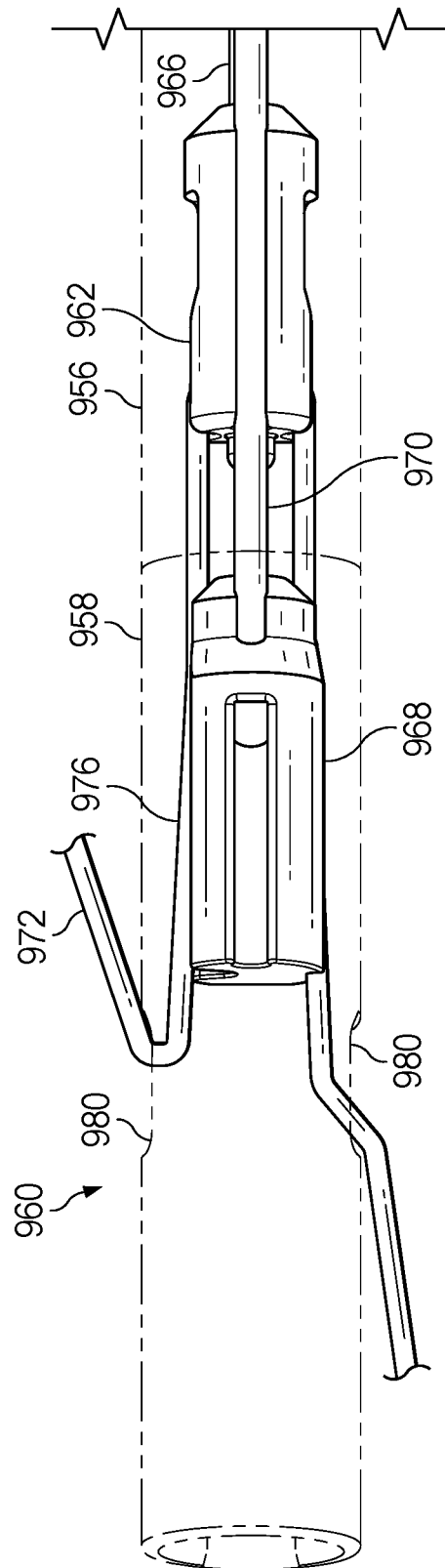


FIG. 16D

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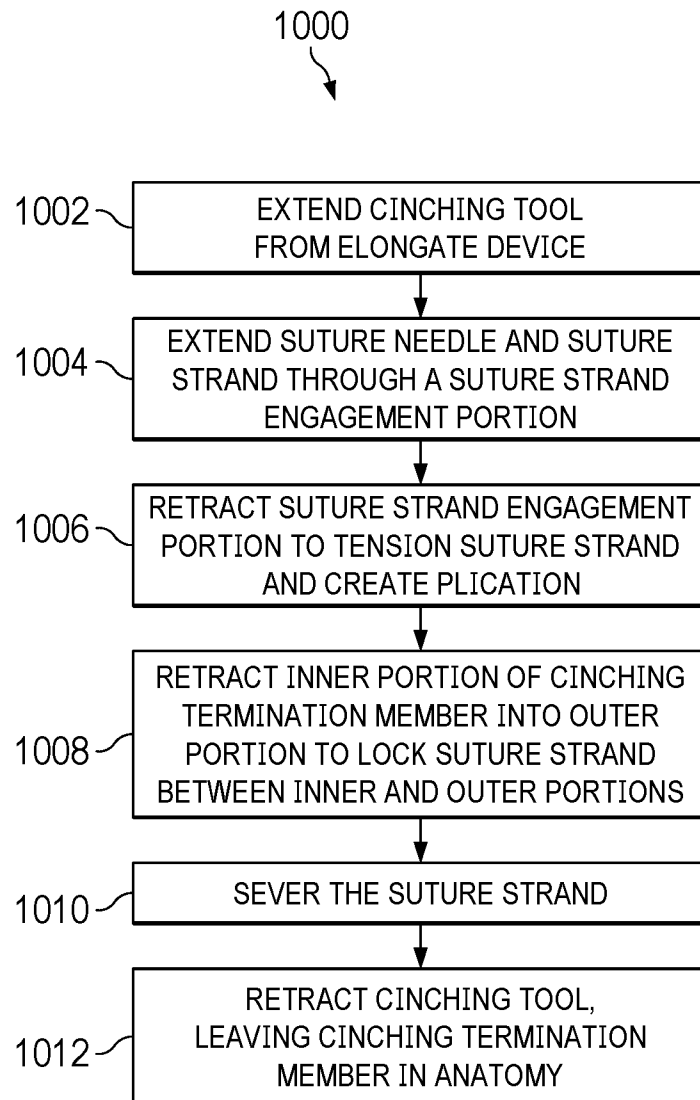


FIG. 17

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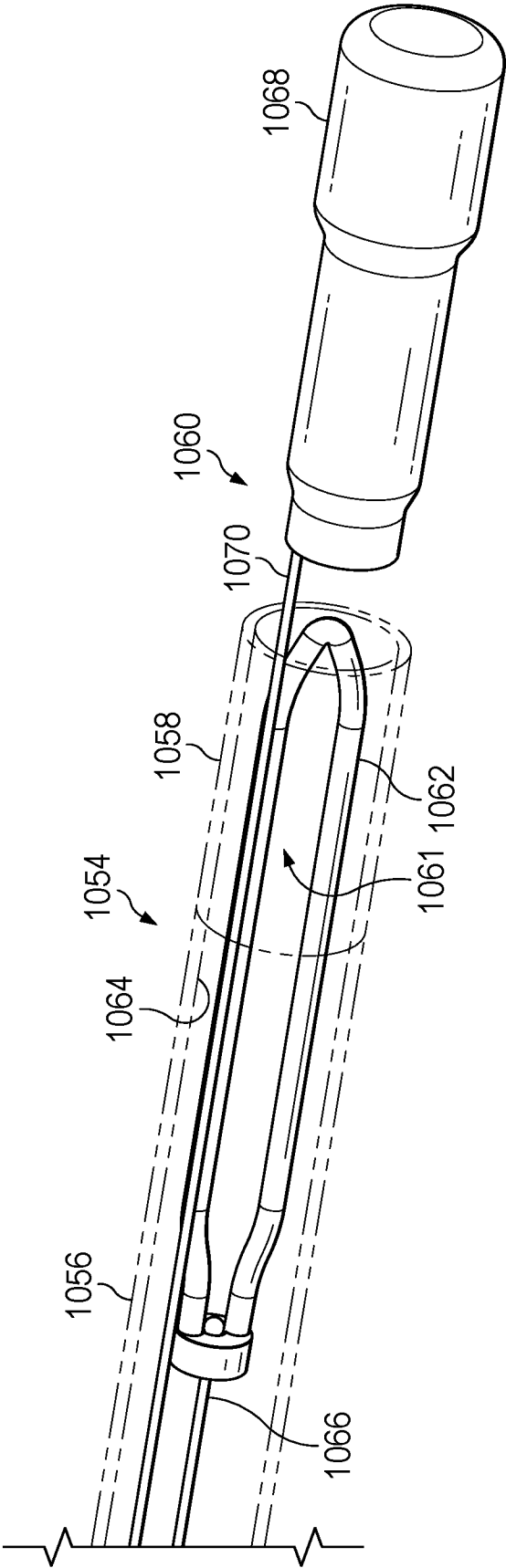


FIG. 18A

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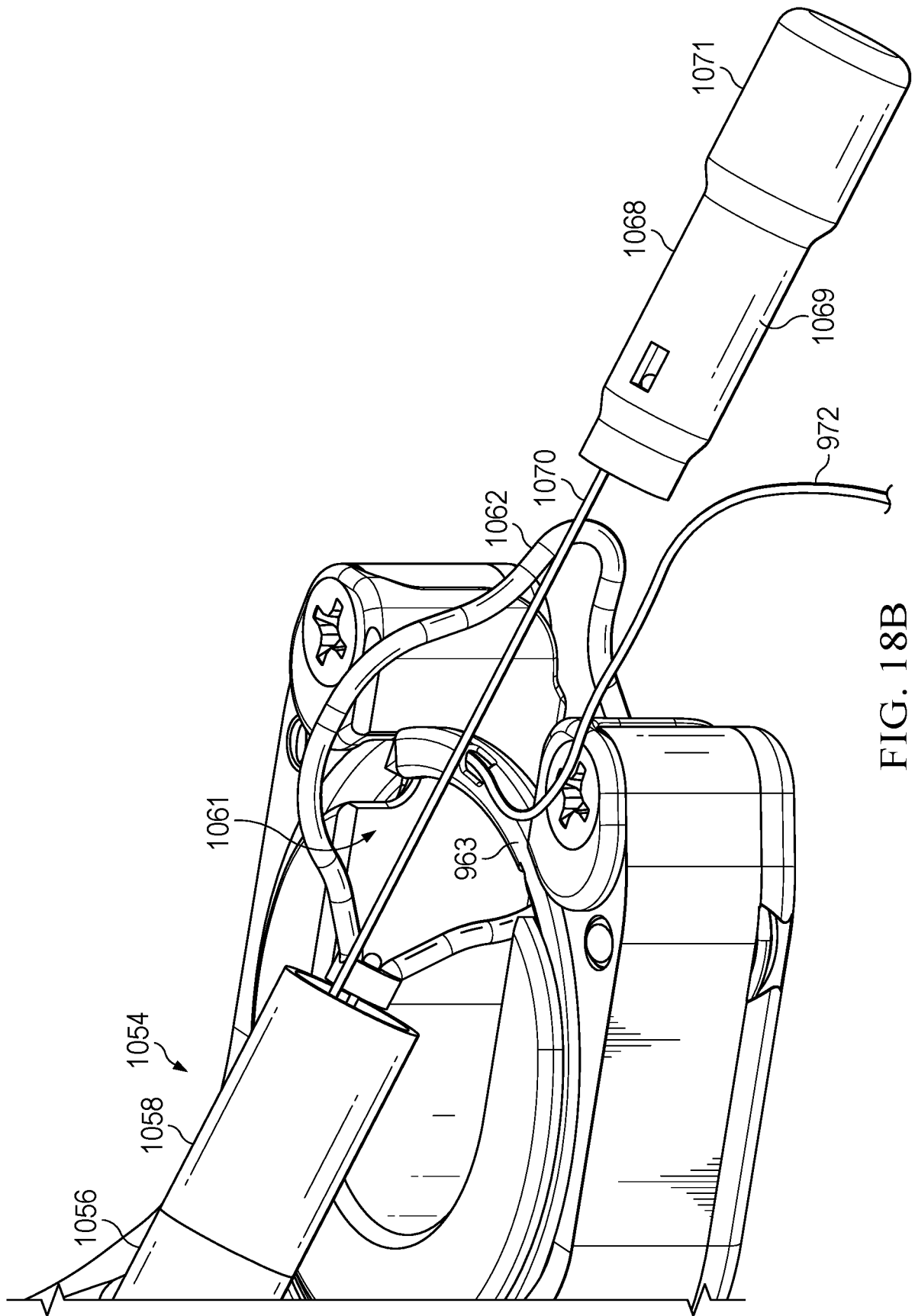


FIG. 18B

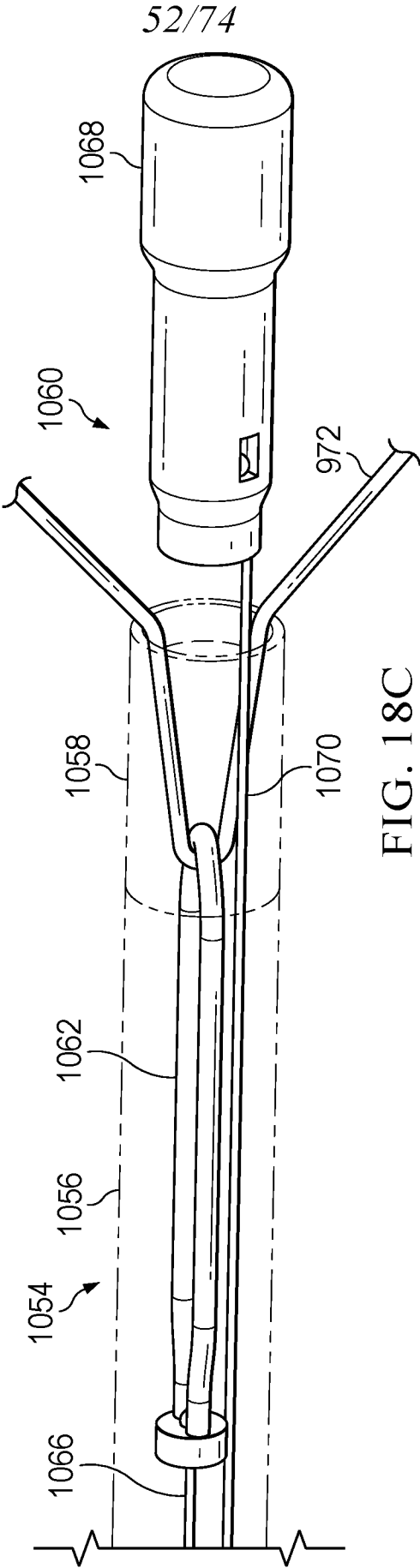


FIG. 18C

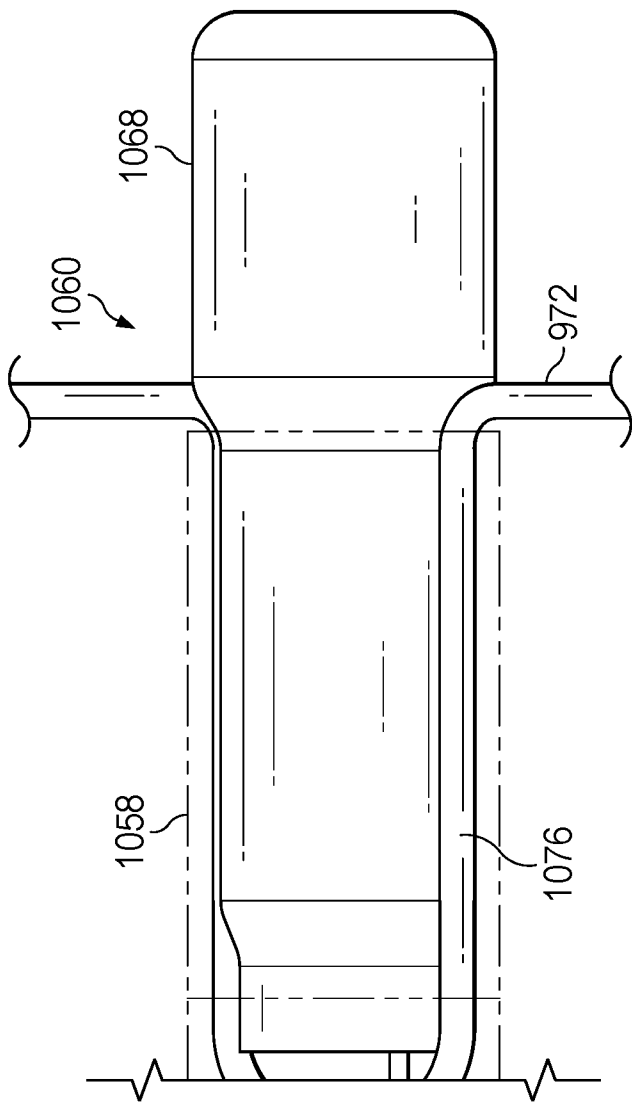


FIG. 18D

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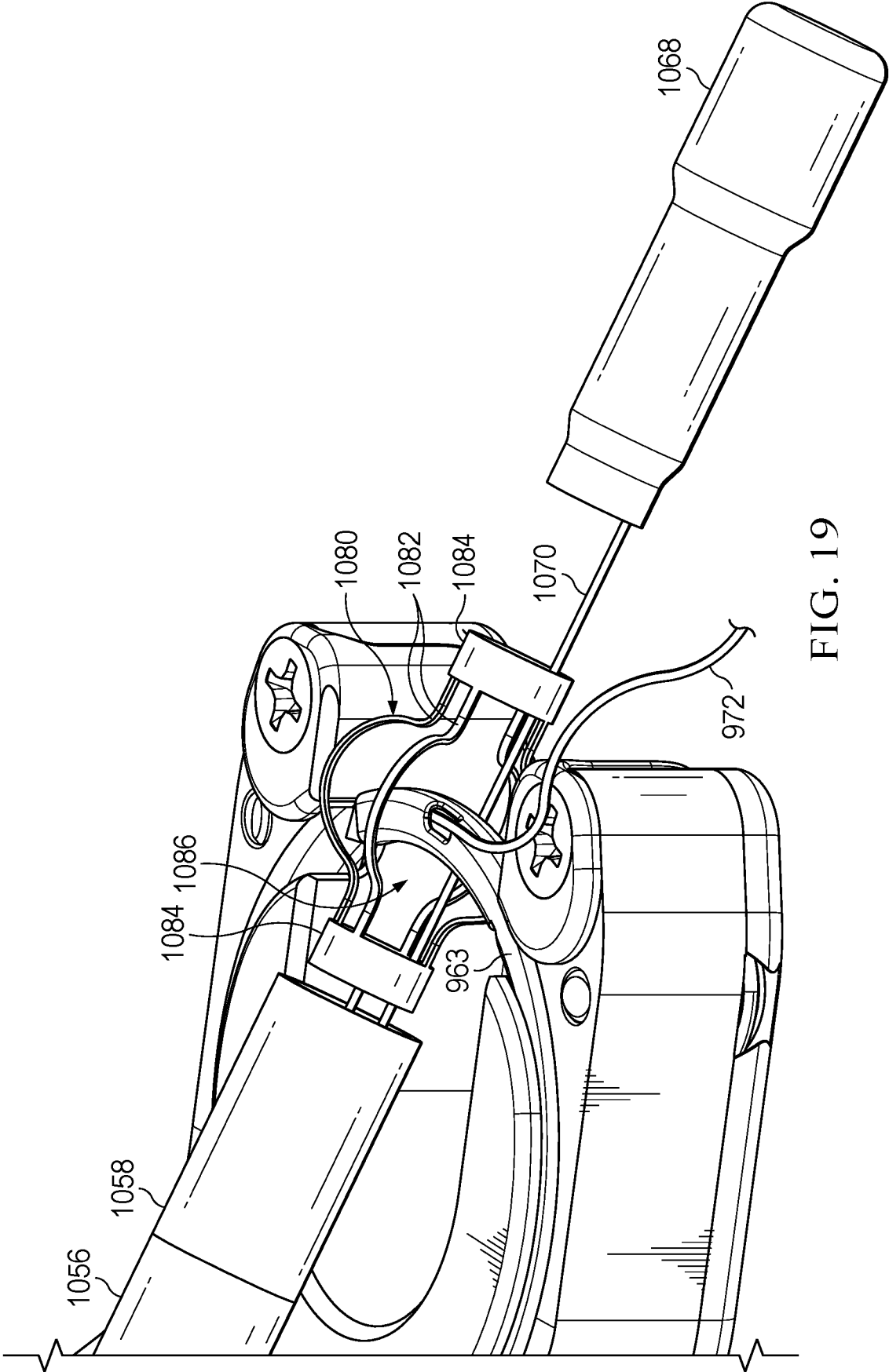


FIG. 19

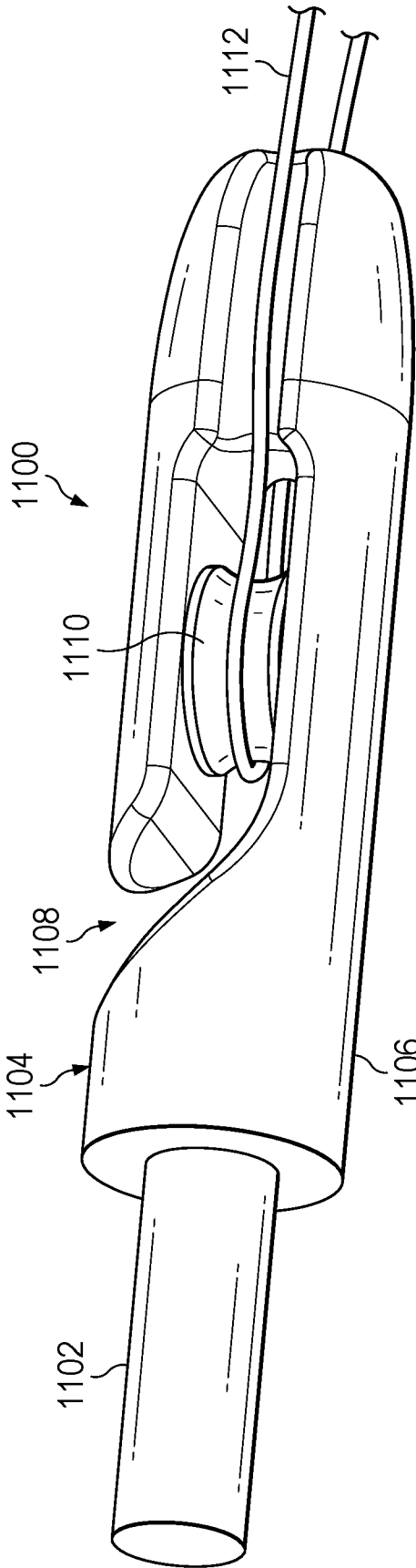
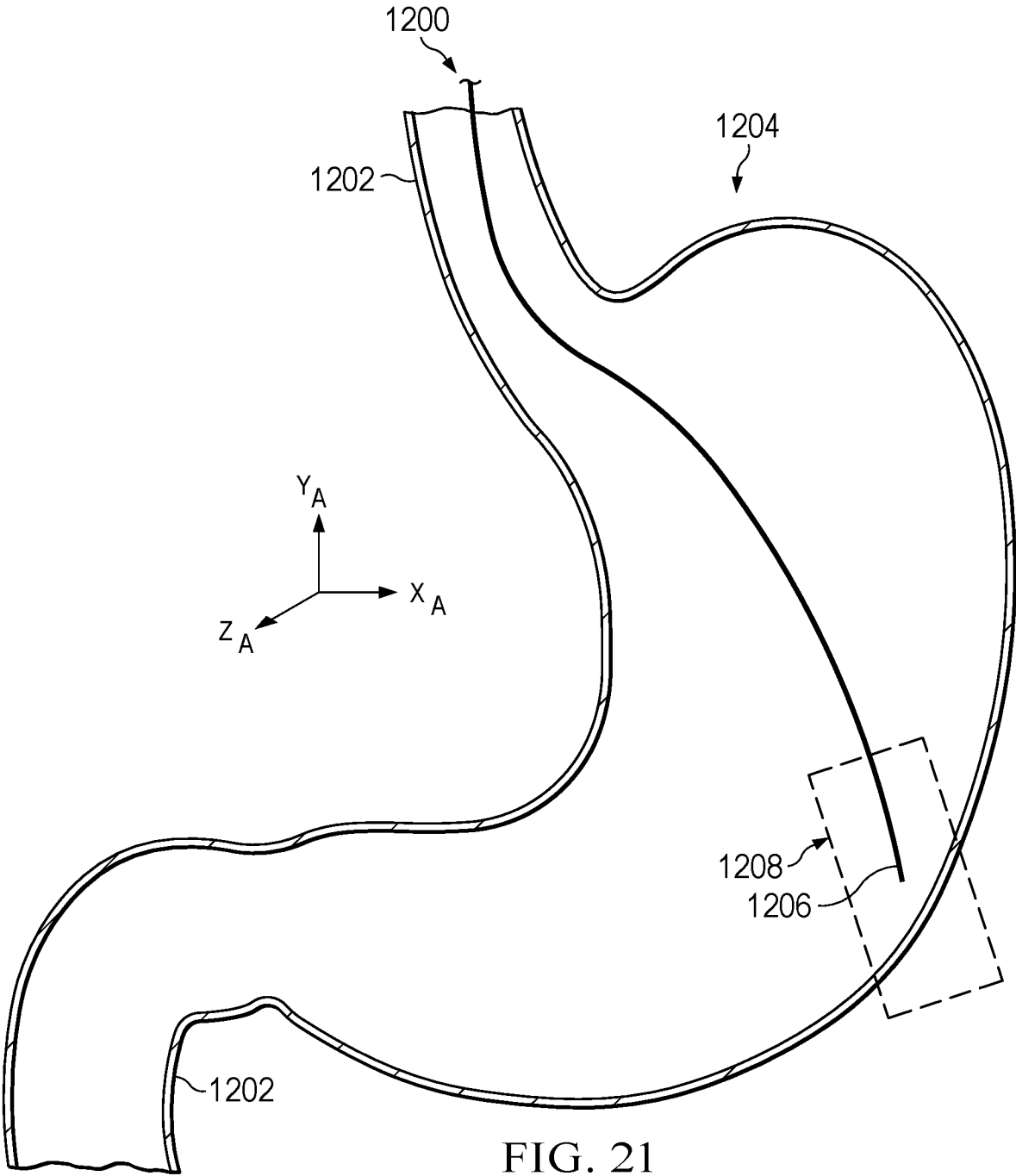


FIG. 20



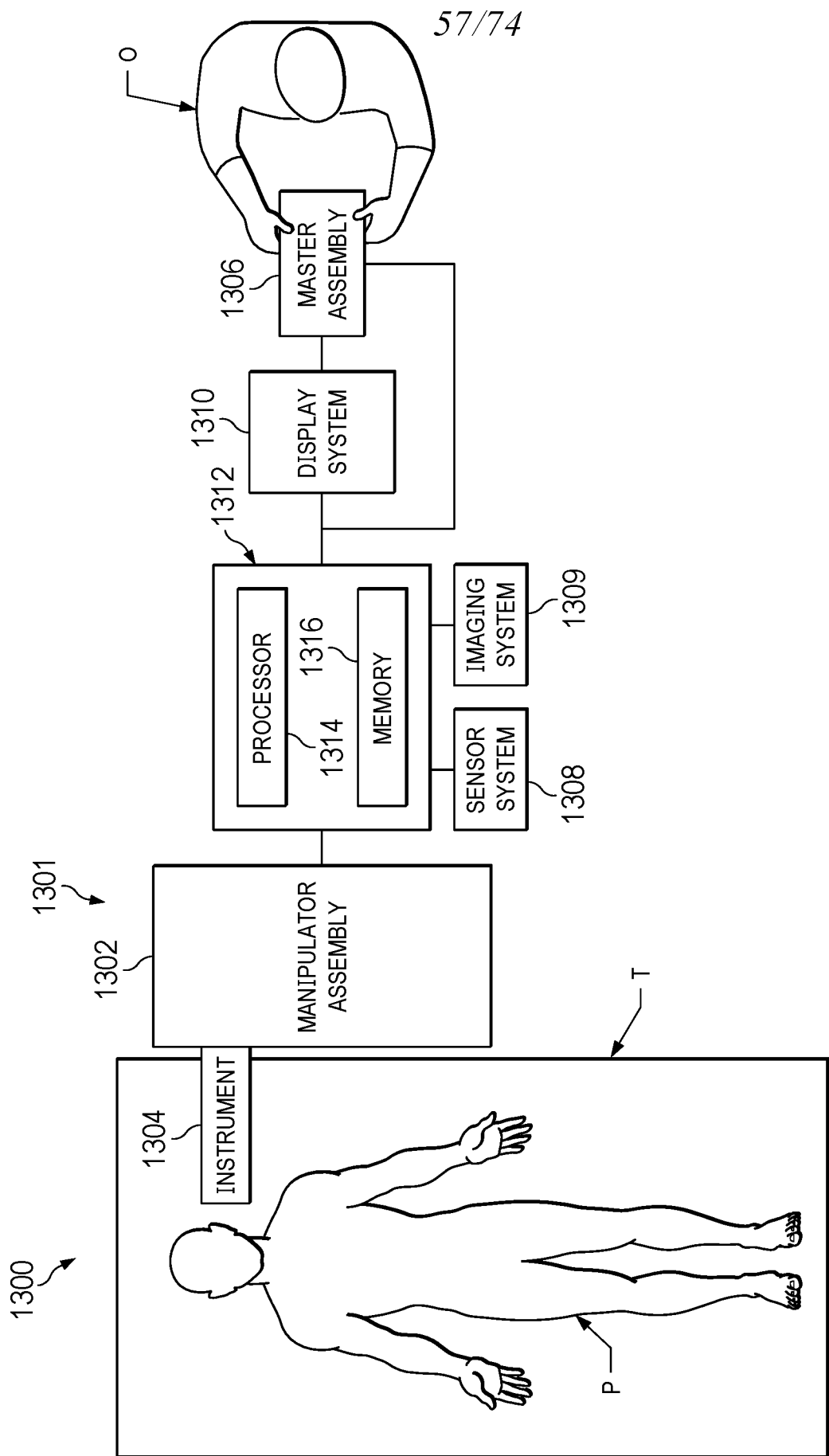
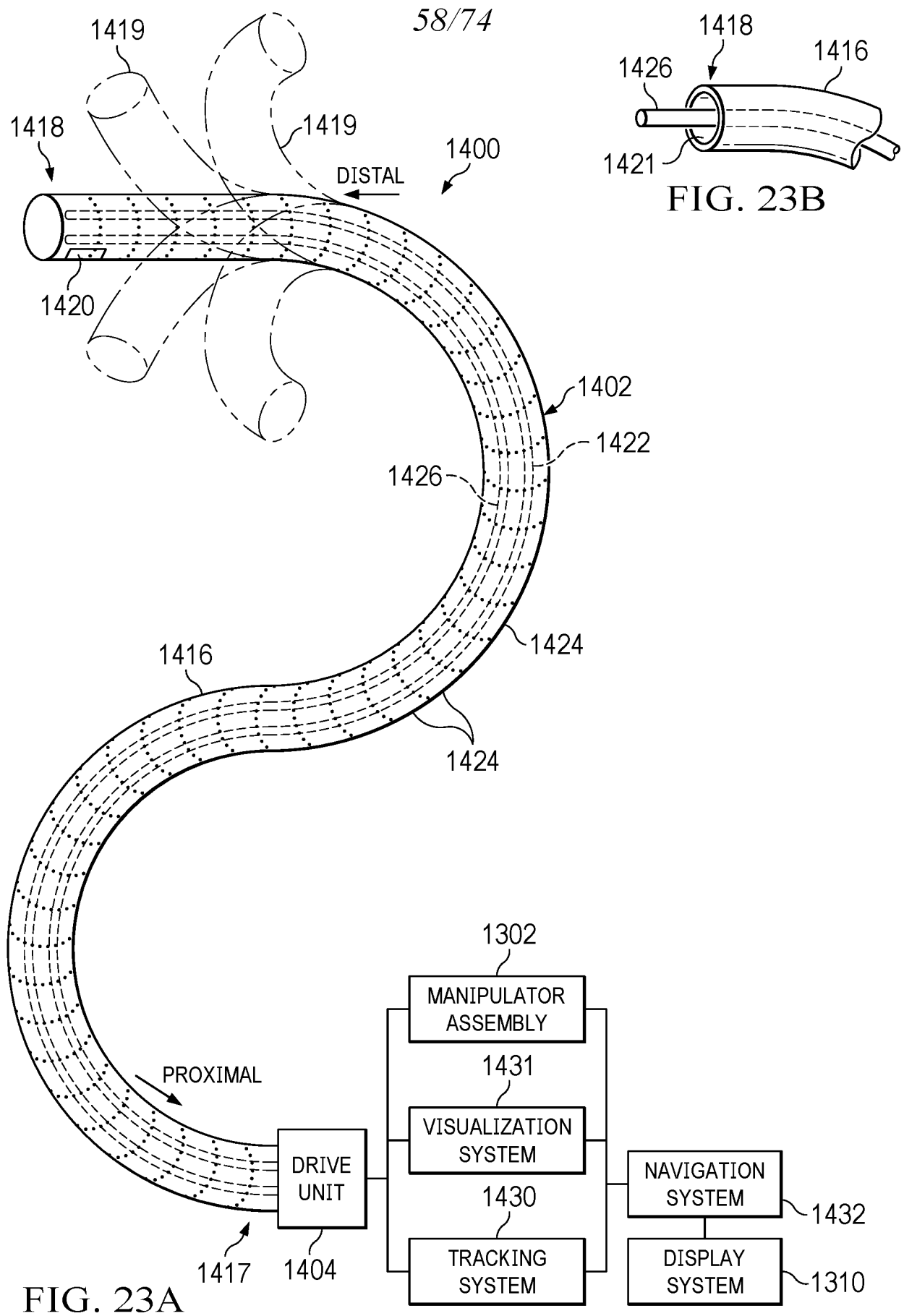


FIG. 22



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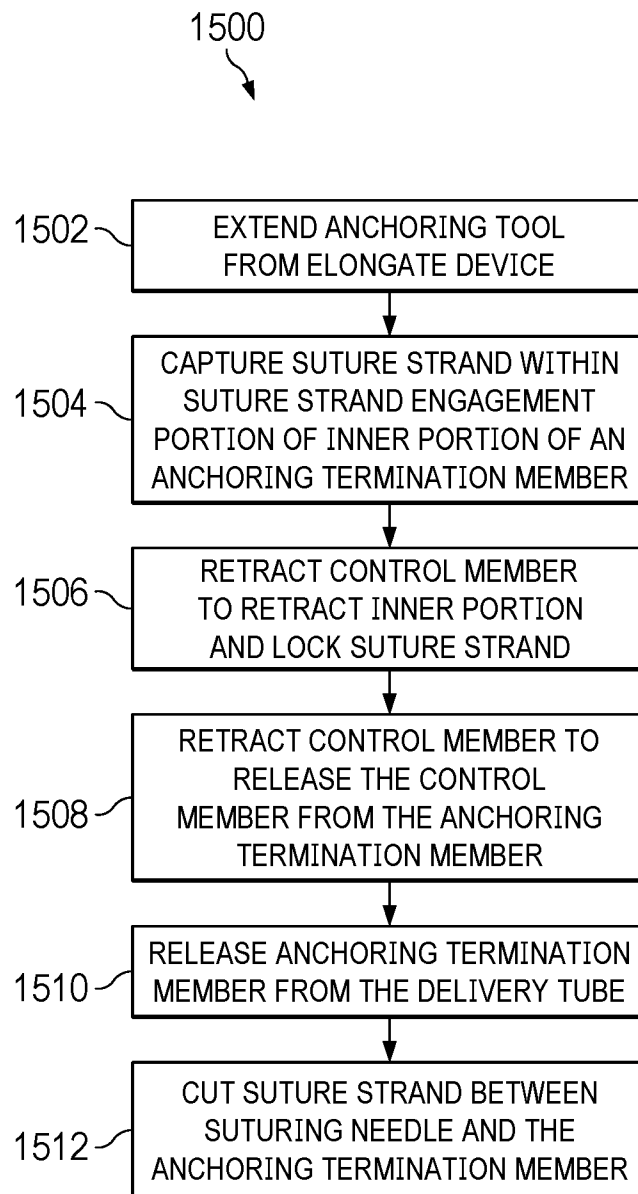


FIG. 24

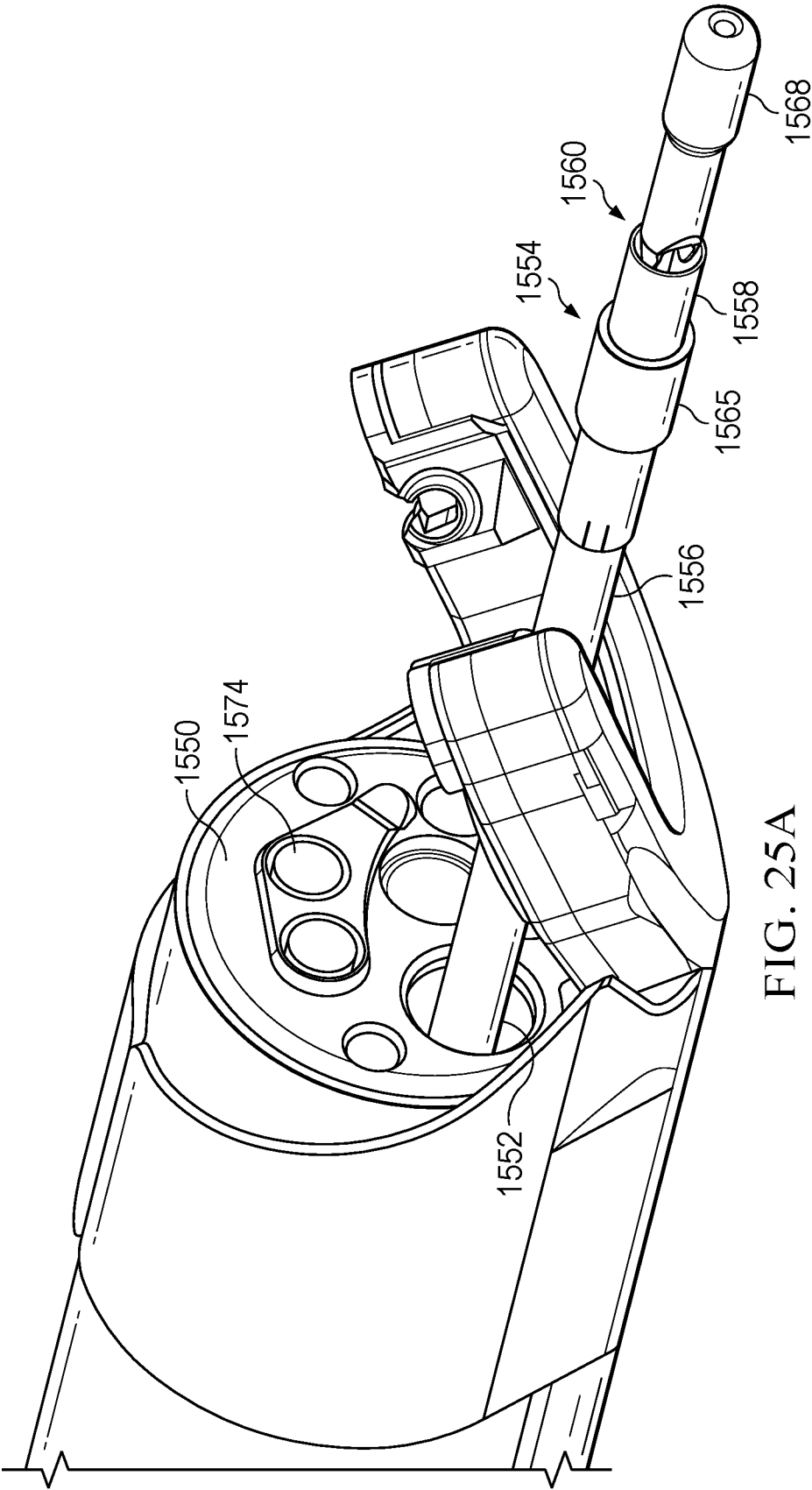


FIG. 25A

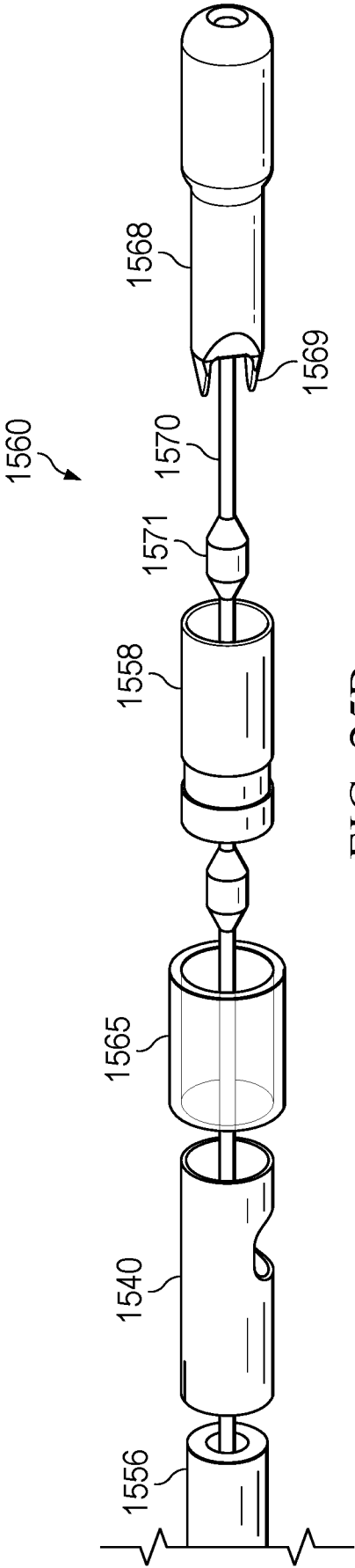


FIG. 25B

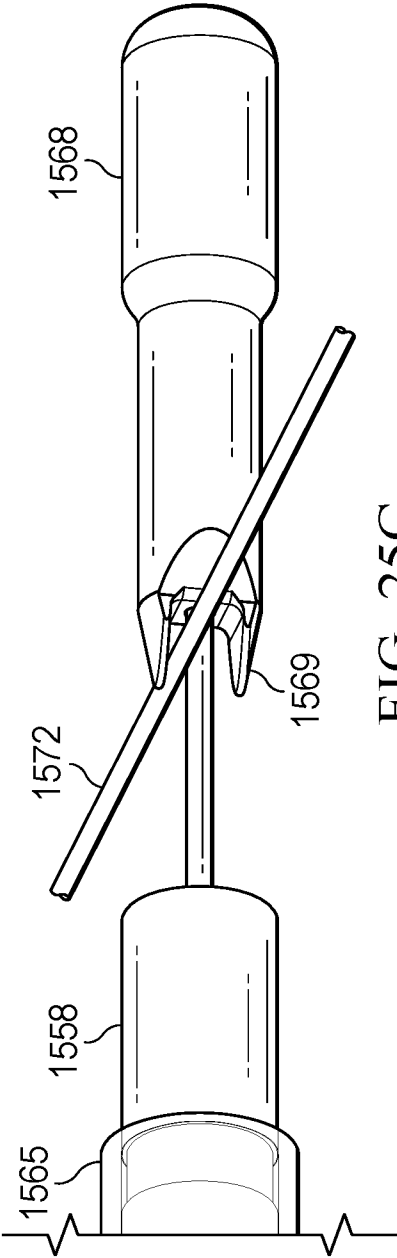


FIG. 25C

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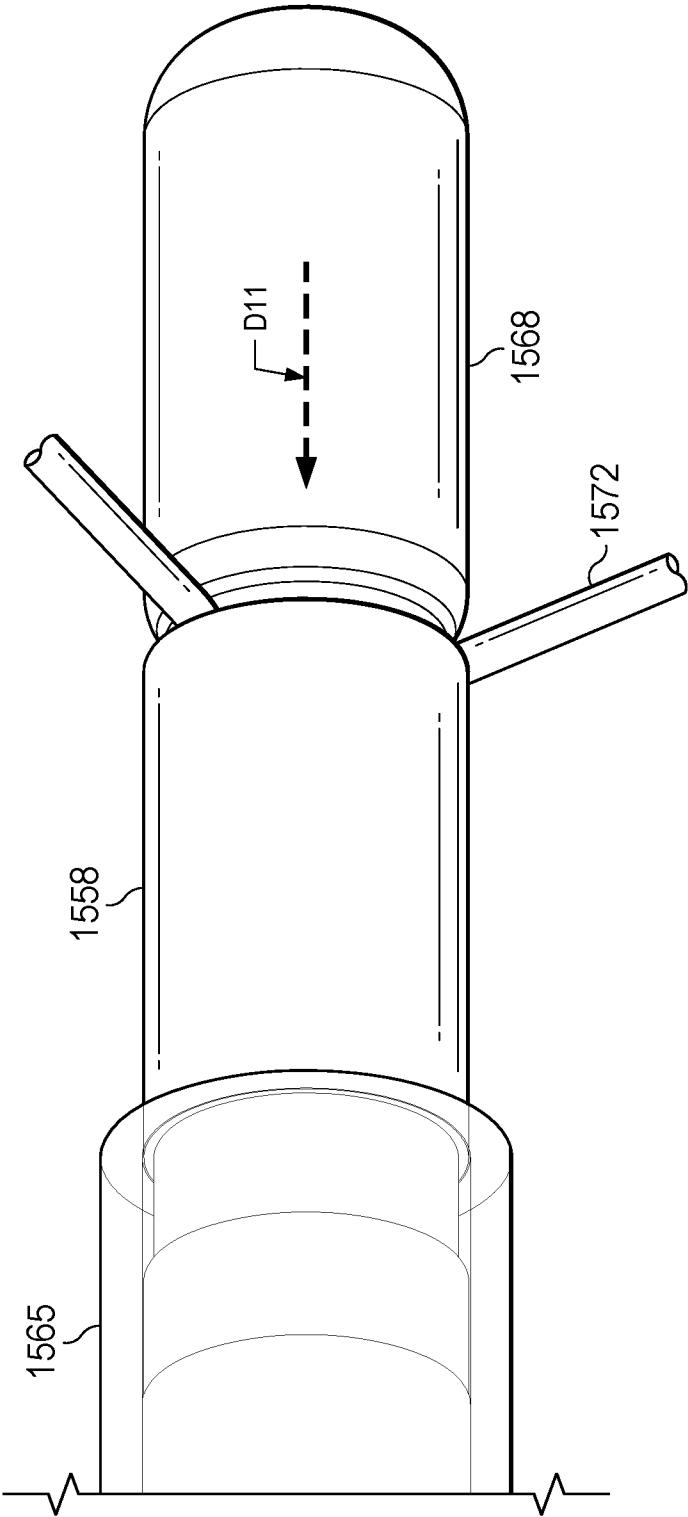


FIG. 25D

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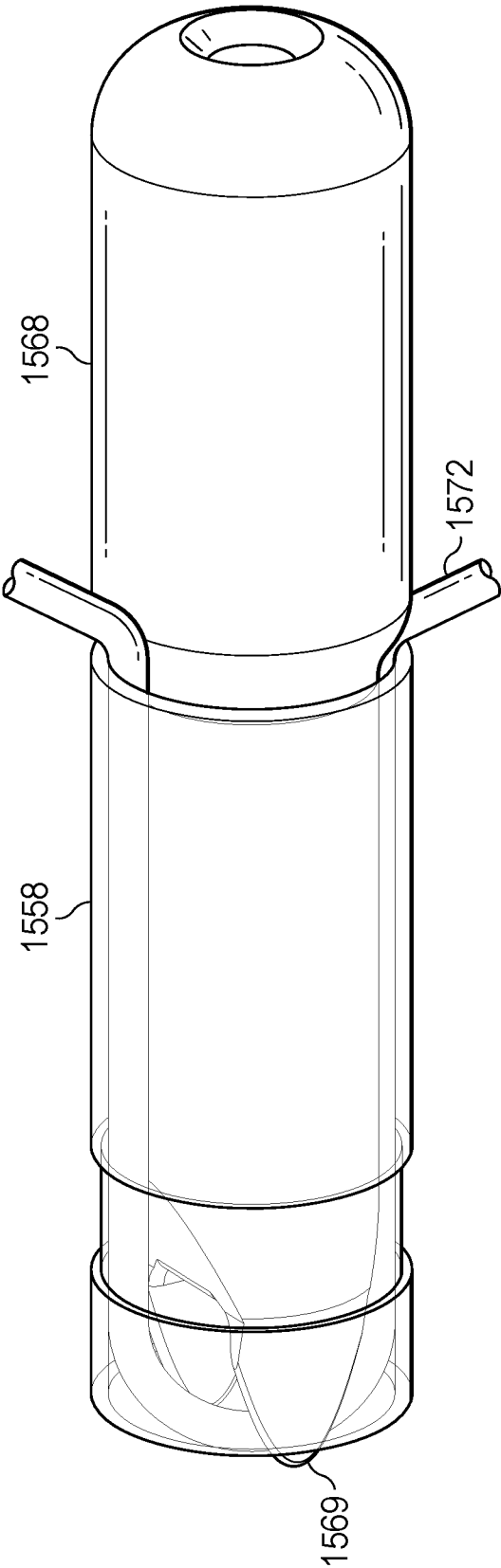


FIG. 25E

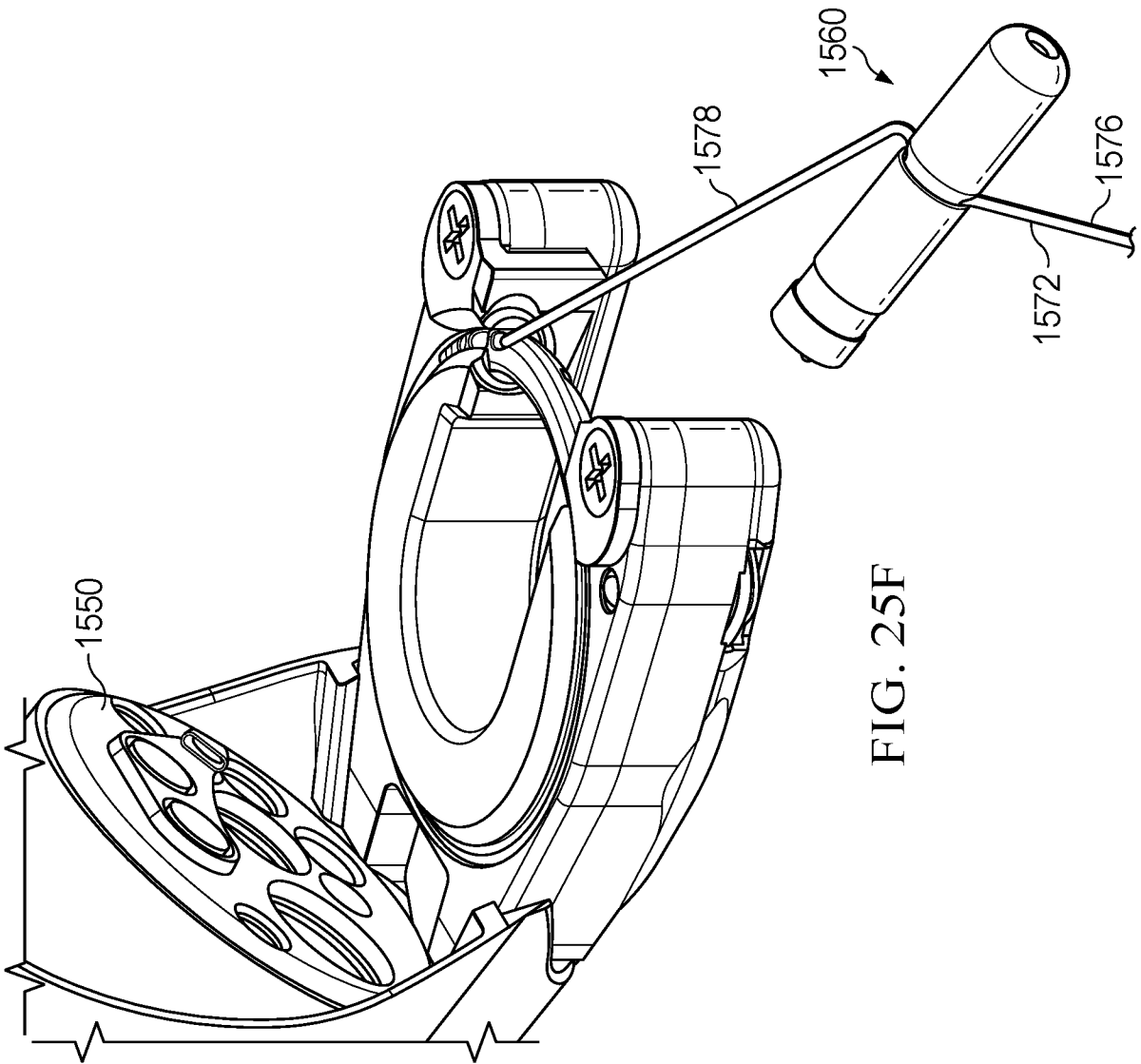


FIG. 25F

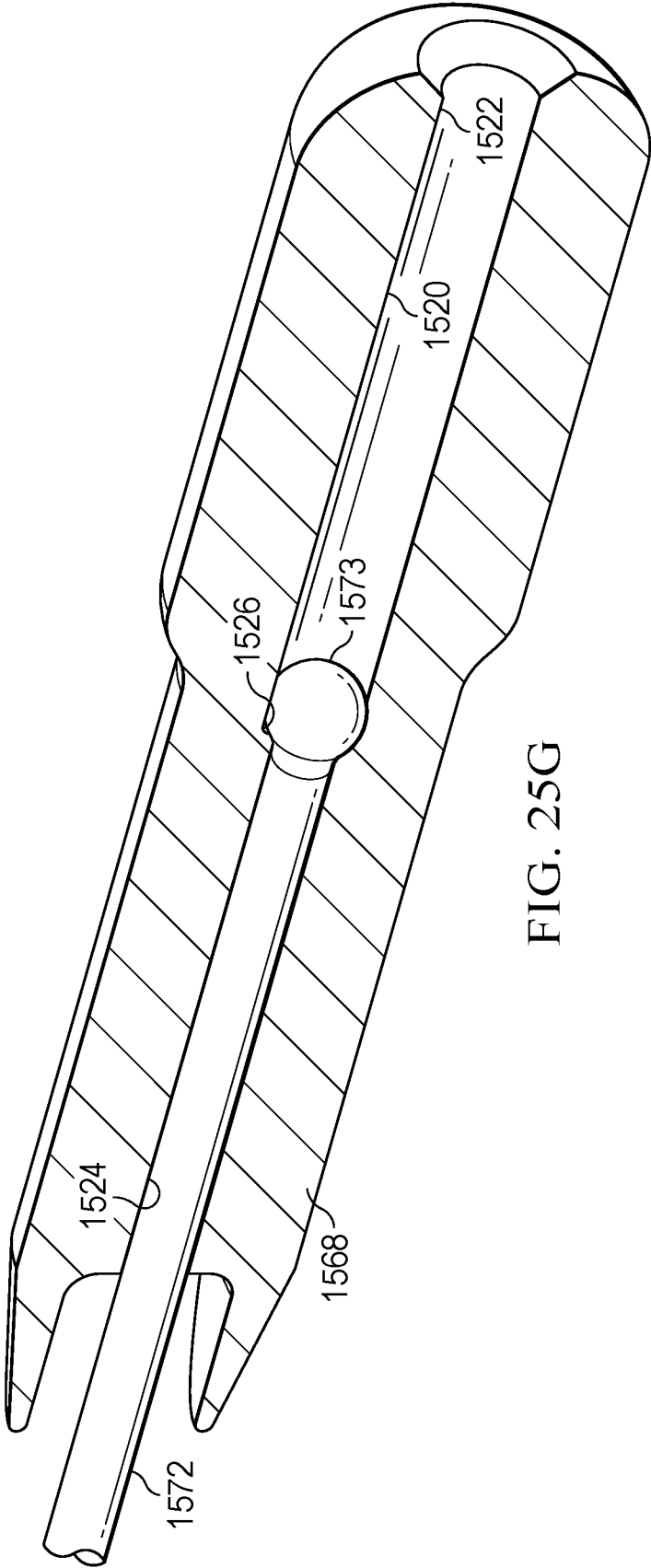
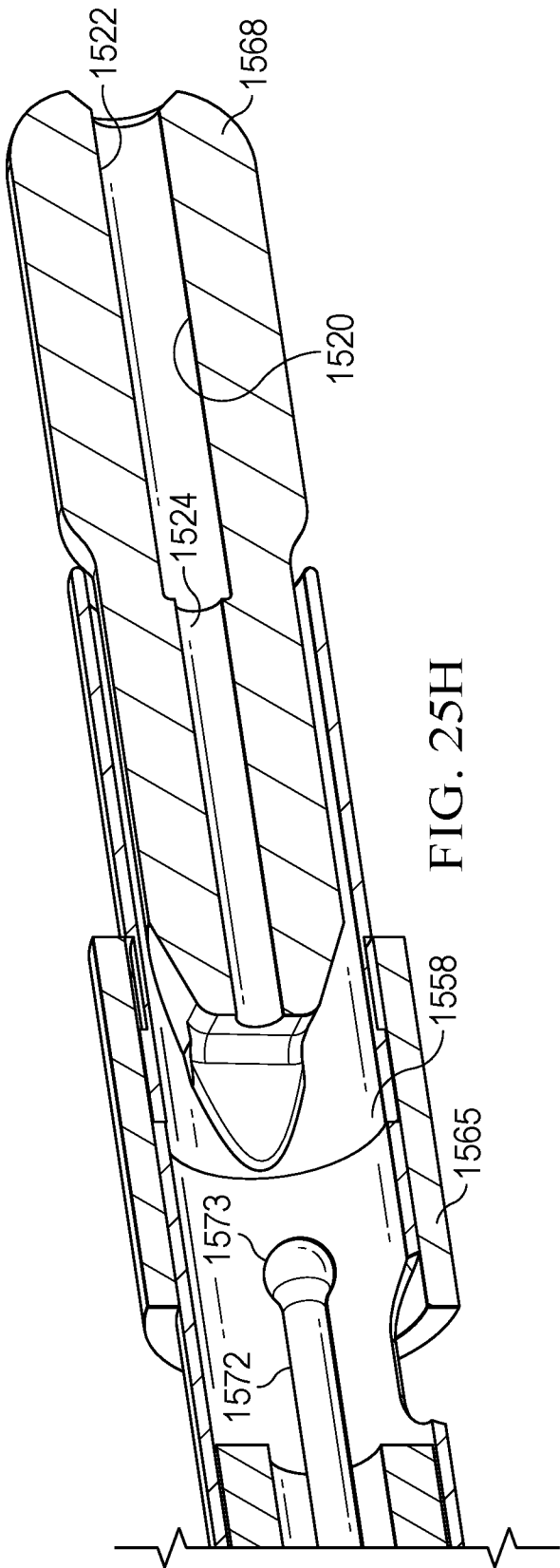
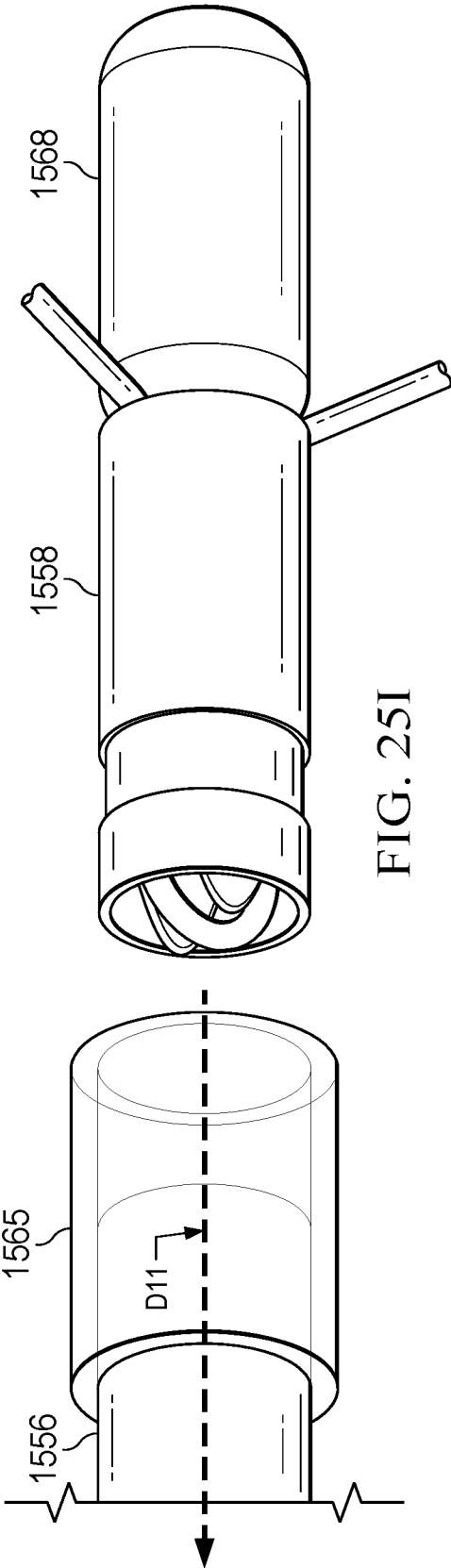


FIG. 25G





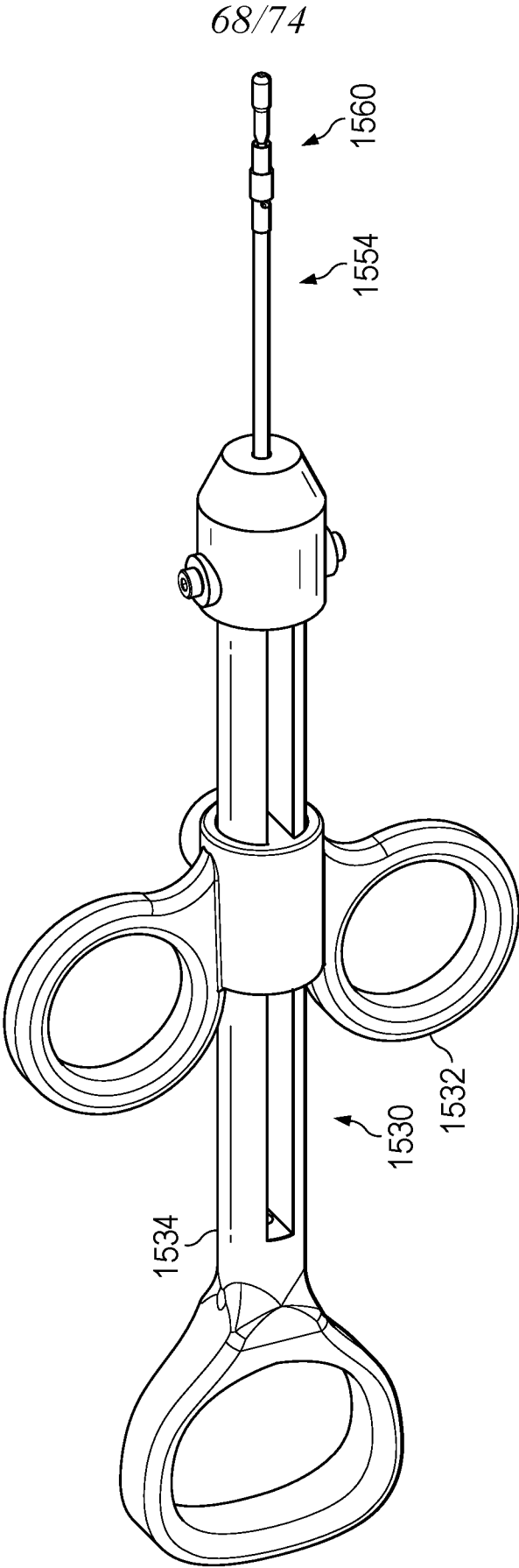


FIG. 25J

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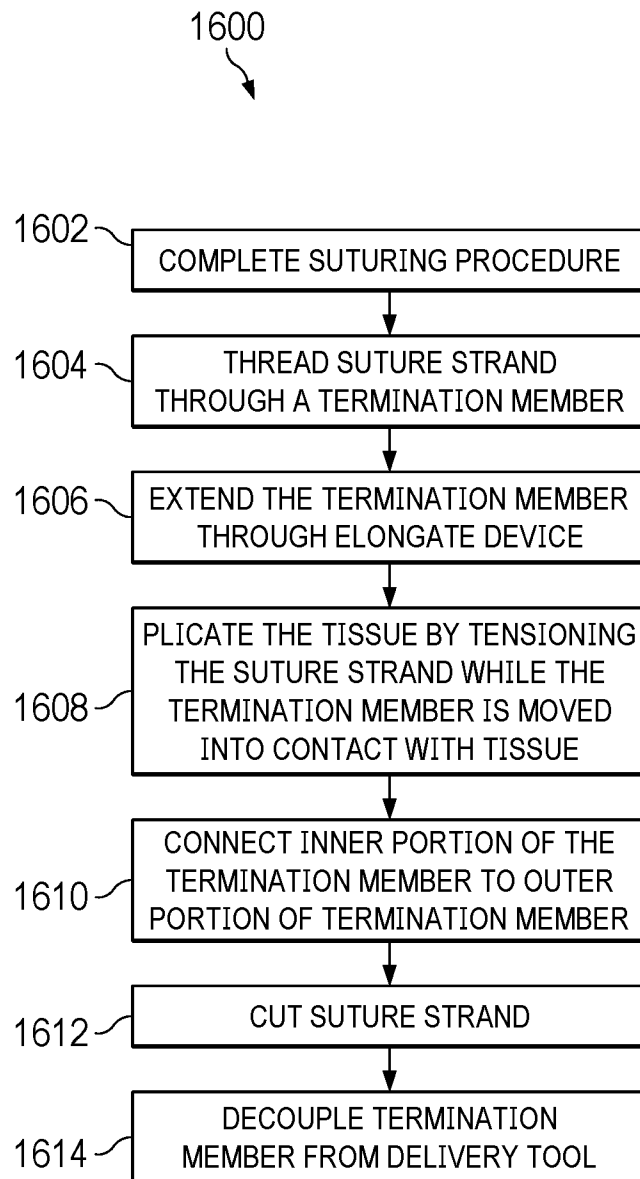
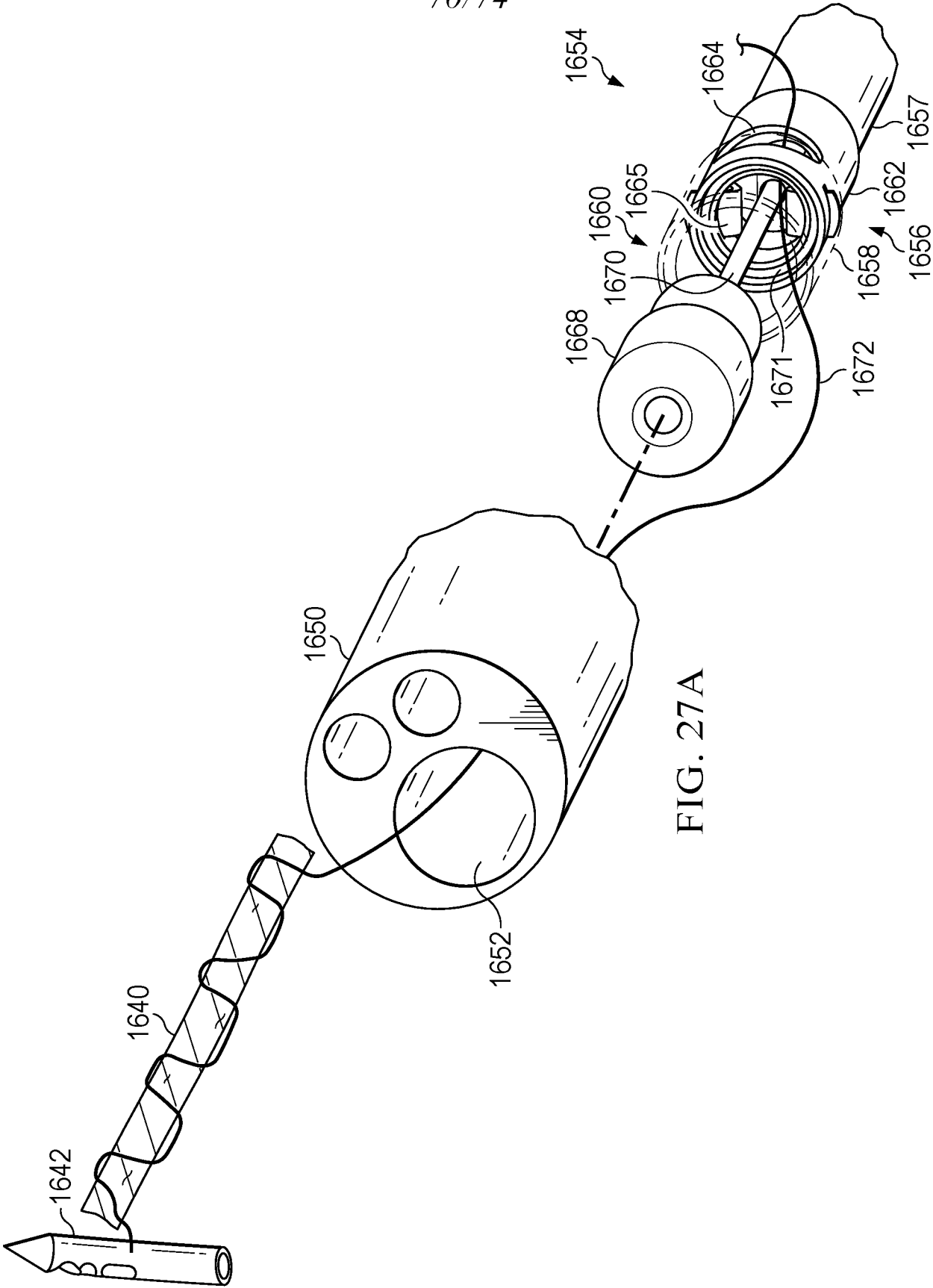


FIG. 26

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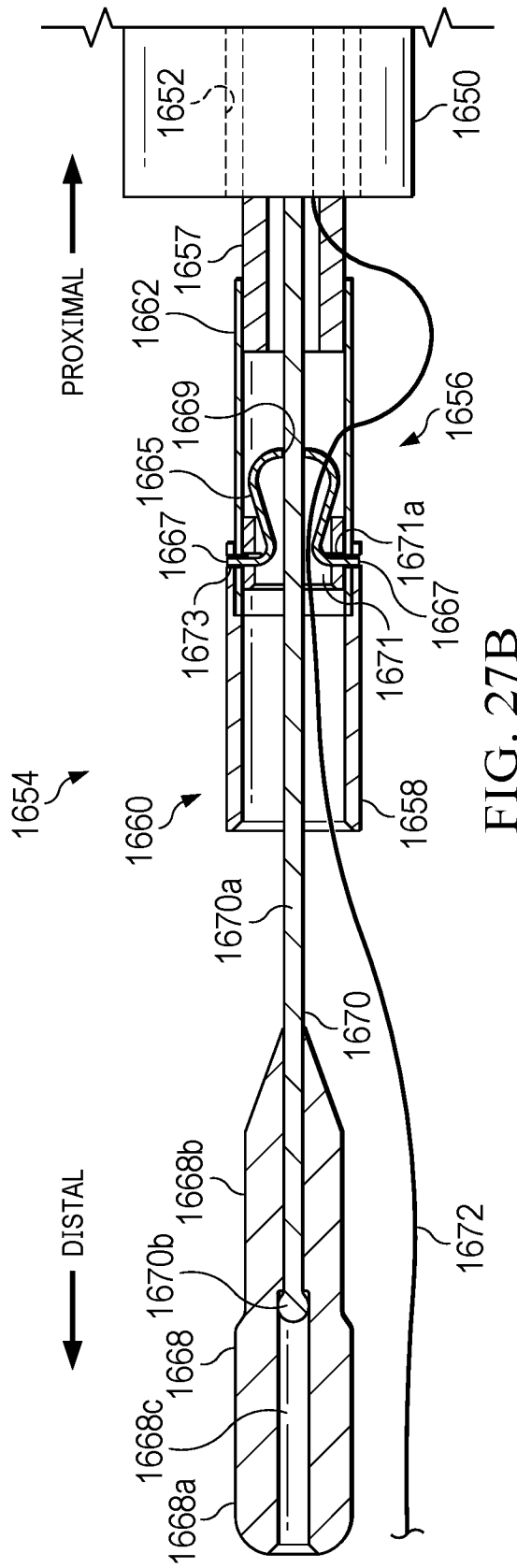


FIG. 27B

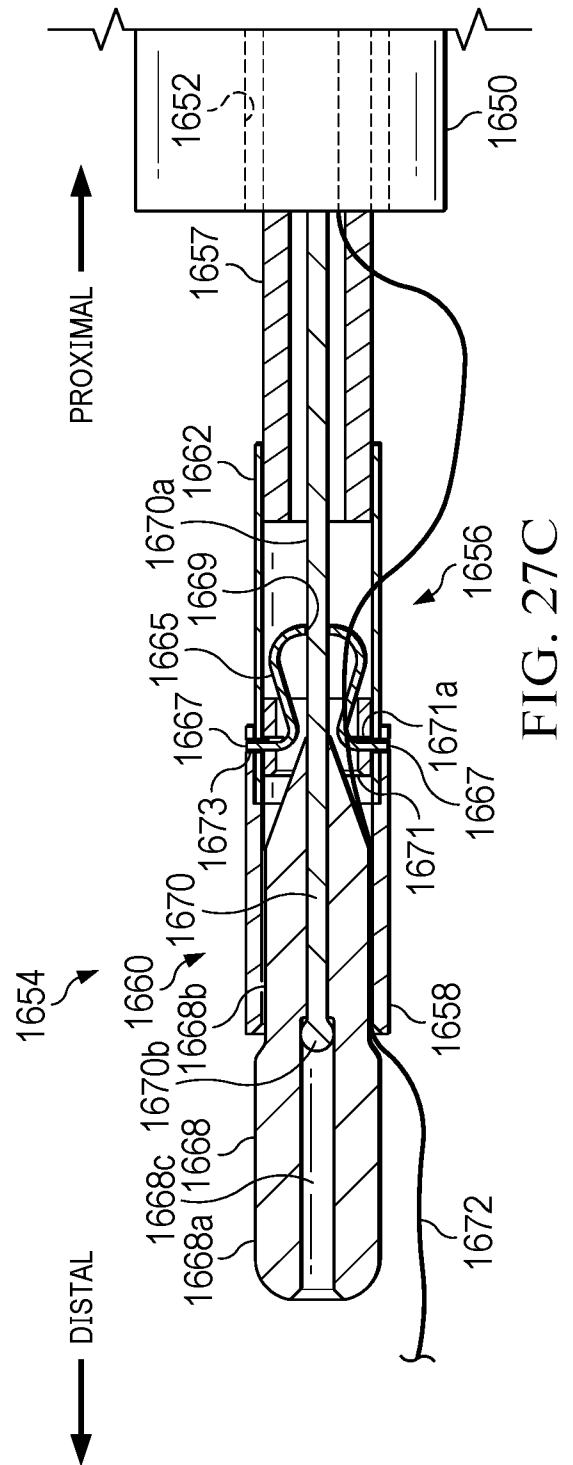


FIG. 27C

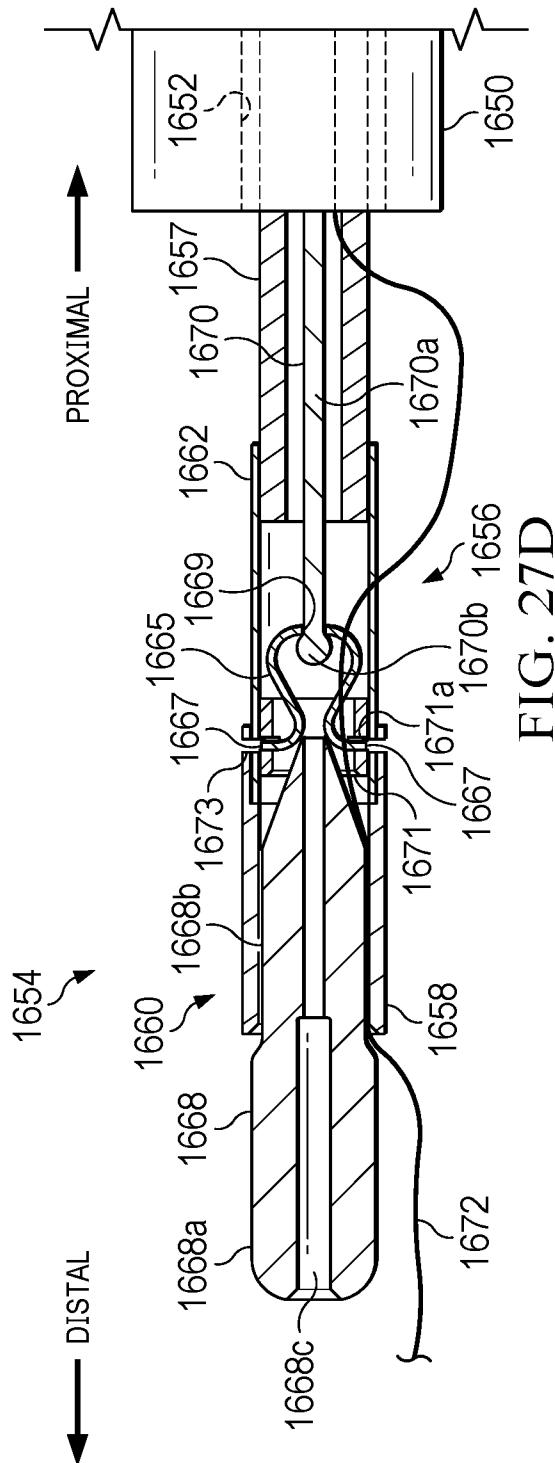


FIG. 27D

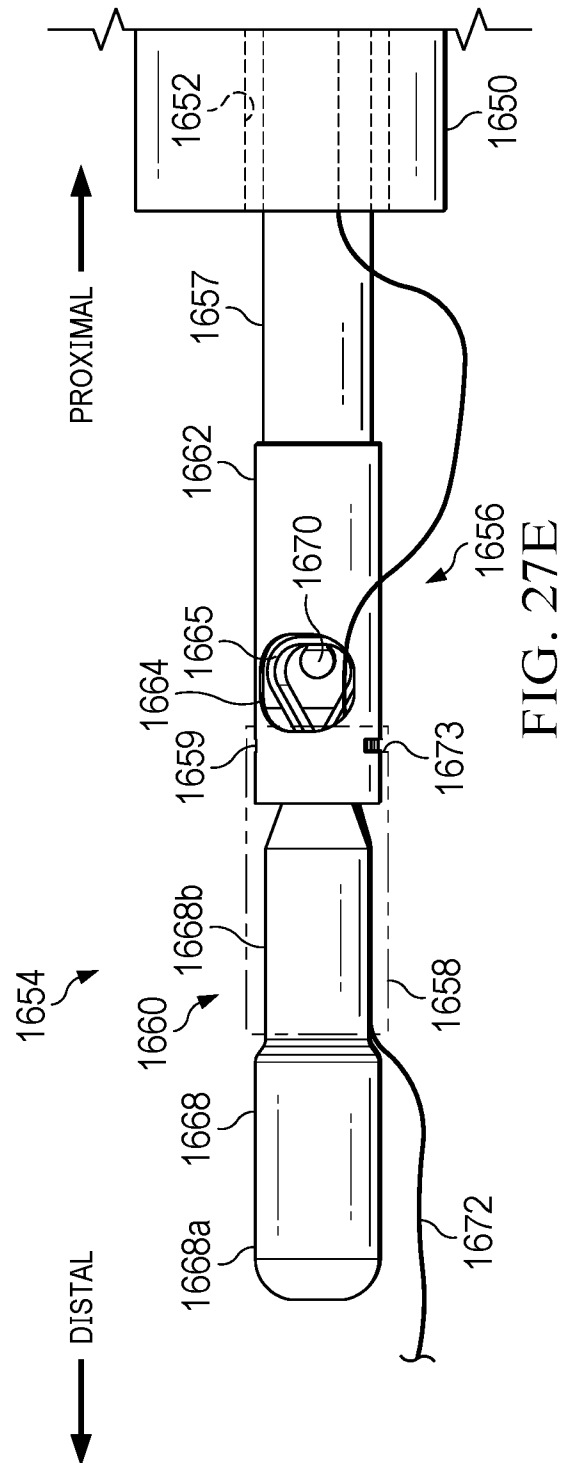
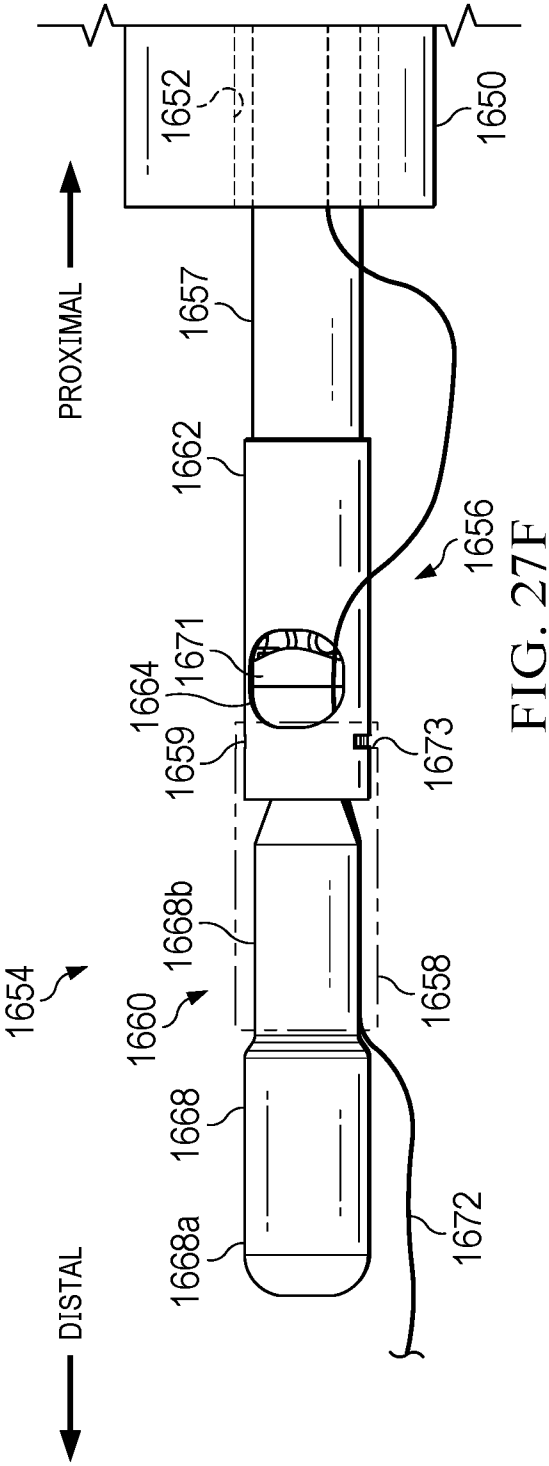


FIG. 27E



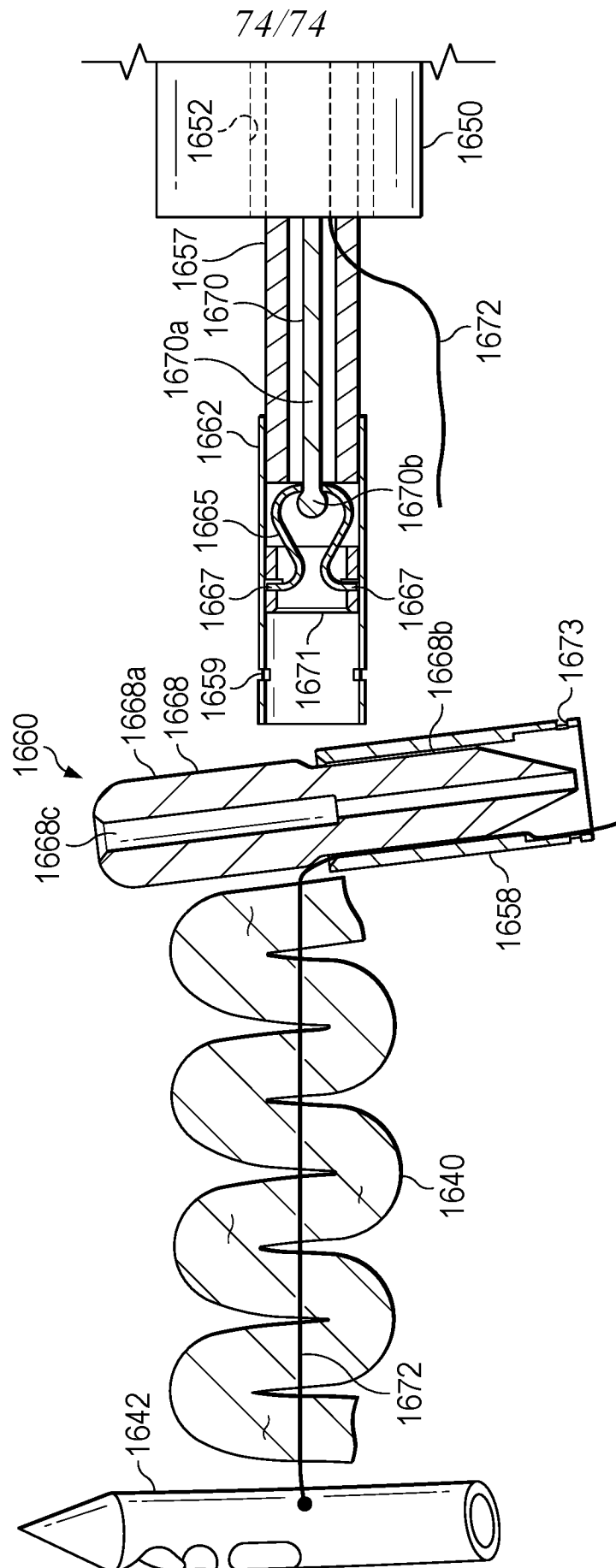


FIG. 27G

PATENT COOPERATION TREATY

PCT

DECLARATION OF NON-ESTABLISHMENT OF INTERNATIONAL SEARCH REPORT

(PCT Article 17(2)(a), Rules 13^{ter}.1(c) and Rule 39)

Applicant's or agent's file reference P06665-WO	IMPORTANT DECLARATION	Date of mailing(day/month/year) 25 November 2024 (25-11-2024)
International application No. PCT/US2024/041325	International filing date(day/month/year) 7 August 2024 (07-08-2024)	(Earliest) Priority date(day/month/year) 8 August 2023 (08-08-2023)
International Patent Classification (IPC) or both national classification and IPC A61B17/04 A61B17/06		
Applicant INTUITIVE SURGICAL OPERATIONS, INC.		

This International Searching Authority hereby declares, according to Article 17(2)(a), that **no international search report will be established** on the international application for the reasons indicated below

1. ☒ The subject matter of the international application relates to:
- a. ☐ scientific theories
 - b. ☐ mathematical theories
 - c. ☐ plant varieties
 - d. ☐ animal varieties
 - e. ☐ essentially biological processes for the production of plants and animals, other than microbiological processes and the products of such processes
 - f. ☐ schemes, rules or methods of doing business
 - g. ☐ schemes, rules or methods of performing purely mental acts
 - h. ☐ schemes, rules or methods of playing games
 - i. ☒ methods for treatment of the human body by surgery or therapy
 - j. ☒ methods for treatment of the animal body by surgery or therapy
 - k. ☐ diagnostic methods practised on the human or animal body
 - l. ☐ mere presentations of information
 - m. ☐ computer programs for which this International Searching Authority is not equipped to search prior art
2. ☒ The failure of the following parts of the international application to comply with prescribed requirements prevents a meaningful search from being carried out:
- ☐ the description ☒ the claims ☐ the drawings
3. ☐ A meaningful search could not be carried out without the sequence listing; the applicant did not, within the prescribed time limit:
- ☐ furnish a sequence listing complying with WIPO Standard ST.26, and such listing was not available to the International Searching Authority in a form, language and manner acceptable to it.
 - ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13^{ter}.1(a).

4. Further comments:

Name and mailing address of the International Searching Authority  European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040	Authorized officer KOCHEVA, Nickoleta Tel:+49 (0)89 2399-8553
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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 203

Pursuant to Article 17(2)(a)(i) PCT, this Authority is not required to search the subject-matter of claims 1-42, since the methods of treating a patient as defined in independent claims 1 and 12 are methods for treatment of the human or animal body by therapy and surgery (2.1 advancing an elongate device to a tissue at a procedure site - see Rule 39.1(iv)).

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.3), should the problems which led to the Article 17(2) PCT declaration be overcome.