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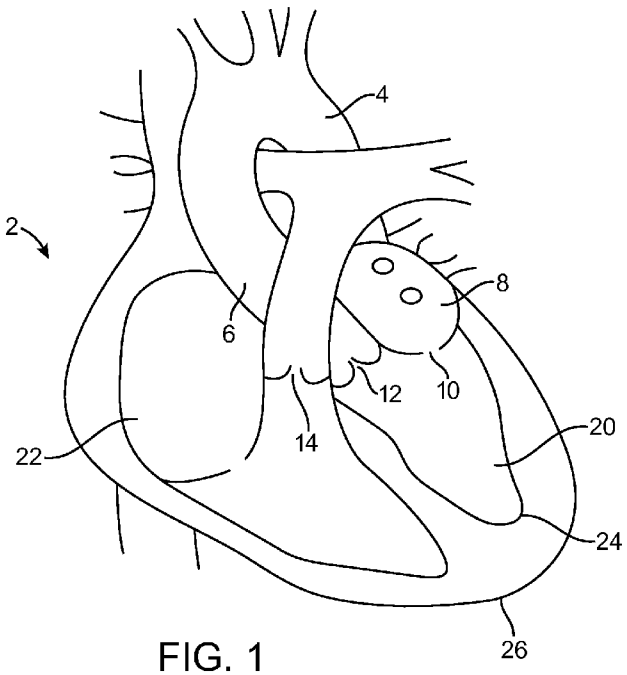

FIG. 1

(57) Abstract: One embodiment is directed to a system for providing surgical access across a wall of a tissue structure, comprising a delivery member, a first helical member, an anchor member removably coupled to the helical member distal end, and a suture member coupled distally to a portion of the anchor member and extending proximally to a position wherein at least a portion of it may be freely manipulated by an operator; wherein upon rotation of the delivery member in a first direction, the first helical member and coupled anchor member are advanced across at least a portion of the wall of the tissue structure, pulling along the distal portion of the suture member in a deployed suture pattern which remains coupled to the anchor member, the deployed suture pattern being characterized in that it is substantially helical with between about one and three helical loops.

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SYSTEM FOR PROVIDING SURGICAL ACCESS

FIELD OF THE INVENTION

This invention is related generally to tissue structure access and wound closure systems, and more particularly to configurations for accessing and closing walls of tissue structures, such as the walls of the cavities of the heart during a trans-apical procedure.

BACKGROUND

Minimally invasive diagnostic and interventional procedure prevalence in US and foreign hospitals continues to increase, as does the demand for certain procedures which involve placement of relatively large devices into targeted locations within tissue structures of criticality. Procedures such as aortic valve replacement conventionally have been addressed with open surgical procedures which are highly invasive. More recently, such procedures have been attempted using natural lumen (i.e., through large blood vessels after an initial surgical transcutaneous or percutaneous access to such vessels) access and delivery systems. Referring to Figure 1, such systems typically are configured, for example, to reach the aortic valve (12) location inside of the heart (2) from an antegrade approach, which generally requires navigating instrumentation through three of the four chambers of the beating heart (the right atrium 22, left atrium 8, and left ventricle 20, by way of the mitral valve 10 and atrial septum), or from a retrograde approach, which generally requires navigating instrumentation along the aortic arch, from the descending aorta (4) to the ascending aorta (6) and adjacent the aortic valve (12). Each of these approaches presents certain clinical challenges to the surgical team, some of which may be avoided by using what is referred to as a transapical approach, whereby the surgeon creates transcutaneous access to the region around the apex of the heart (26) with a surgical thoracotomy, followed by direct access to the left ventricle (20) using a needle or other device aimed to access the left ventricle (20) around the left ventricular apex (24), which may be followed by one or more dilating instruments to create a temporary access port to the left ventricle. One embodiment of a conventional access procedure is illustrated in Figure 2, wherein a needle device (34) is puncturing the muscular heart wall (30) to gain access to the left ventricle (20) around the location of the left ventricular apex (24). Also shown is a guidewire (36) which may be advanced (38) toward and through the aortic valve (12) to assist with diagnostic and interventional aspects of the procedure. Using these and other instruments such as dilators, this left ventricular access port may be utilized, for example, to replace an aortic valve if

bleeding and tissue damage around the access port can be successfully mitigated during such procedure. Subsequent to such a procedure, the instrumentation needs to be removed and the access port closed, usually leaving a prothetic valve or portion thereof behind. The successful closure of a transapical wound on a beating heart of a patient is obviously of high criticality to such a procedure, as is the minimization of loss of blood. Conventional transapical closure techniques typically involve the placement of small sutures to create a purse-string type effect to close the wound as the instrumentation is withdrawn, and it may be very difficult to repeatably create acceptable closures using these techniques without a larger thoracotomy or improved instrumentation. In other words, one of the key challenges to transapical intervention remains transapical wound closure. Indeed, it is believed that transapical access may provide enhanced stability and control during procedures such as aortic valve replacement, due to the fact that the operator may have a relatively direct mechanical connection with the pertinent instrumentation, relative to the connection that he may have using, for example, an antegrade or retrograde vascular approach with more compliant catheter type tools. For this reason, it is even more desirable to successfully address the challenges of transapical access and closure. Further, it would be desirable to have a wound or access closure technology that was applicable not only to transapical access port closure, but also other closure demands pertinent to other surgical interventions of the human body wherein wounds or ports are created, such as in gastrointestinal or gynecological surgery.

SUMMARY OF THE INVENTION

One embodiment is directed to a system for providing surgical access across a wall of a tissue structure, comprising a delivery member having proximal and distal ends; a first helical member having proximal and distal ends and a helical shape, the proximal end coupled to the delivery member distal end, the distal end extending distally of the delivery member distal end; an anchor member removably coupled to the helical member distal end; and a suture member coupled distally to a portion of the anchor member and extending proximally to a position wherein at least a portion of it may be freely manipulated by an operator; wherein upon rotation of the delivery member in a first direction, the first helical member and coupled anchor member are advanced across at least a portion of the wall of the tissue structure, pulling along the distal portion of the suture member in a deployed suture pattern which remains coupled to the anchor member, the deployed suture pattern being

characterized in that it is substantially helical and represents a number of helical loops encapsulated by the wall of the tissue structure that is greater than about one helical loop, and is less than about three helical loops. Upon rotation of the delivery member in a second direction opposite to the first direction, a reverse load may be applied to the delivery member and coupled first helical member which causes the anchor member to become decoupled from the first helical member, such that further rotation in the second direction causes removal of the first helical member and delivery member while the anchor member and suture member distal portion remain positioned across the portion of the wall of the tissue structure. The anchor member may have at least one shape feature that is configured to slide past nearby tissue structures during inward insertion loading associated with rotation of the first helical member in the first direction, and to resist movement relative to the nearby tissue structures upon application of outward extraction loading associated with rotation of the first helical member in the second direction. At least a portion of the anchor member may be configured to rotate relative to wall of the tissue structure upon application of a tensioning load to the suture member. The first helical member and coupled anchor member may be advanced in a substantially helical pathway. The proximal end of the suture member may extend proximally beyond the deployed suture pattern into a local suture length storage reservoir coupled to the delivery member containing an additional length of suture, the reservoir being configured such that upon rotation of the delivery member in the first direction, the anchor member pulls along the distal portion of the suture member causing at least a portion of the additional length of suture to be extended out from the local suture length storage reservoir. The local suture length storage reservoir may be coupled to the delivery member in a configuration wherein advancement of the first helical member does not substantially advance the reservoir relative to the wall of the tissue structure. The system may further comprise a sleeve member movably coupled to the delivery member such that the deliver member is threaded through a lumen defined by the sleeve member, wherein the sleeve member is coupled to the local suture length storage reservoir. The first helical member may define an inner helix diameter that is substantially constant across the length of the helical member. The first helical member may define an inner helix diameter that varies across the length of the helical member. The inner helix diameter may be between about 5mm and about 60mm. The inner helix diameter may be between about 10mm and about 20mm. The first helical member may be comprised of an elongate member formed into the helical shape, the elongate member having an outer diameter. The elongate member may have a cross sectional shape selected from the group consisting of: a circular cross section,

an elliptical cross section, a square cross section, and a rectangular cross section. The outer diameter may be between about 0.5mm and about 3mm. The helical shape may comprise a number of helical turns advanceable into tissue that is between about 1 and about 3. The helical shape may have a substantially constant helix pitch along the length of the helical shape. The helical shape may have a substantially variable helix pitch along the length of the helical shape. The helical shape may have a substantially constant helix pitch along the length of the helical shape. The helical shape may have a substantially variable helix pitch along the length of the helical shape. The helix pitch may be between about 5mm and about 20mm. The helix pitch may be between about 7mm and about 13mm. The distal end of the first helical member may comprise a sharpened tip configured to easily dive into and cross portions of the wall of the tissue structure. The distal end of the first helical member may comprise an anchor coupling portion wherein the outer diameter of the elongate member is decreased to accommodate slidable coupling of the anchor member. The outer diameter of anchor member may be substantially similar to that of the portions of the elongate member proximal to the anchor coupling portion. The helical shape may be defined by a helix pitch, the helix pitch being selected based upon a targeted depth of traversal through the wall of the tissue structure that will result in the deployed suture pattern. The targeted depth of traversal may be configured to entirely cross the wall of the tissue structure, leaving the anchor member on an opposite side of the wall. The targeted depth of traversal may be configured to only partially cross the wall of the tissue structure, leaving the anchor member in a midsubstance location within the wall. The elongate member may comprise a solid cross-sectional construct. The elongate member may comprise a tubular construct having an inner diameter and as well as the outer diameter. The elongate member may comprise a material selected from the group consisting of: stainless steel, nitinol alloy, titanium, cobalt chrome, and polymer composite. The elongate member may comprise a material selected from the group consisting of: stainless steel, nitinol alloy, titanium, cobalt chrome, and polymer composite. The anchor member may comprise a main body portion comprising a solid or tubular construct. The shape feature may be configured to slide past nearby tissue structures during inward insertion loading comprises a tapered distal tip. The shape feature may be configured to resist movement relative to the nearby tissue structures upon application of outward extraction loading comprises a projecting portion configured to extend to a projecting position beyond an outer diameter of the rest of the anchor member when tension is applied to the intercoupled suture member. The projecting portion may comprise a portion of the anchor member that has been deformed out into the projecting position. The projecting

portion may comprise a piece of material that has been coupled to the anchor member to assume the projecting position. The system may further comprise two or more projecting portions. The projecting portion may comprise a superelastic alloy that is shape set to the projecting position and configured to be deliverable in an elastically compressed form within a superelastic thermal range for the alloy. The suture member may be coupled to an eyelet coupled to the anchor member. The eyelet may be positioned such that tension on the suture member urges the anchor into rotational movement relative to surrounding portions of the wall of the tissue structure when the suture member is pulled in tension relative to the anchor member. The anchor may have a longitudinal axis, and wherein the eyelet is placed at a position spaced apart from the longitudinal axis. The eyelet may be coupled to a ring member defining a ring aperture through which at least a portion of the anchor is positioned. The ring member may be coupled to the anchor using a coupling selected from the group consisting of: an adhesive coupling, a press-fit coupling, and a tack-welding coupling. The anchor may comprise a metal selected from the group consisting of: titanium, nickel, stainless steel, cobalt chrome, and alloys thereof. The anchor may comprise a durable polymer selected from the group consisting of: polyethylene terepthalate, polyethylene, high density polyethylene, polypropylene, polytetrafluoroethylene, expanded polytetrafluoroethylene, poly (ethylene-co-vinyl acetate), poly(butyl methacrylate), and co-polymers thereof. The anchor may comprise a bioresorbable polymer selected from the group consisting of: polylactic acid, polyglycolic acid, polylactic-co-glycolic acid, polylactic acid-co-caprolactone, poly (block-ethylene oxide-block-lactide-co-glycolide), polyethylene glycol, polyethylene oxide, poly (block-ethylene oxide-block-propylene oxide-block-ethylene oxide), polyvinyl pyrrolidone, polyorthoester, polyanhydride, polyhydroxy valerate, polyhydroxy butyrate, and co-polymers thereof. The anchor may comprise a biological graft material. The biological graft material may have an origin selected from the group consisting of: another human, the particular human, a non-human animal. The anchor may comprise a bioresorbable material selected from the group consisting of: porcine collagen matrix, human collagen matrix, equine collagen fleece, gelatin, polyhyaluronic acid, heparin, poly (glucose), poly(alginic acid), chitin, chitosan, cellulose, methyl cellulose, hydroxyethylcellulose, hydroxypropylcellulose, carboxymethylcellulose; polylysine, polyglutamic acid, albumin, hydroxy apatite, cortical bone, cancellous bone, trabecular bone, bioceramic, ligament tissue, tendon tissue, dura tissue, fascia tissue, pericardium tissue, thrombin, and fibrin. The local suture length storage reservoir comprises an enclosure for storing one or more loops of suture member length. The additional length of suture may be between about 20 millimeters and

about 500 millimeters. The enclosure may comprise a membrane configured to partially encapsulate the one or more loops of suture member length, and allow the one or more loops to be pulled out of the enclosure when under tensile loading from the anchor and helical members. The system may further comprise a suture tensioning member coupled to the suture member between a proximal end of the suture member and a distal end of the suture member, the suture tensioning member configured to apply a compressive load to an exposed proximal aspect of the wall of the tissue structure when a distal end of the suture tensioning member is placed against the exposed proximal aspect of the wall and the suture member is tensioned proximally of the suture tensioning member. The suture tensioning member may comprise an elongate tubular member defining a lumen therethrough, the suture member being threaded through the lumen. The system may further comprise a temporary suture member clamp coupleable to a proximal portion of the suture member and configured to retain tension upon a portion of suture member distal to the suture member clamp that is threaded through the lumen of the elongate tubular member. The suture tensioning member may have two modes of operation, a first mode wherein the suture tensioning member may be moved bidirectionally relative to the suture member, and a second mode wherein the suture tensioning member may only be moved unidirectionally relative to the suture member, and wherein the suture tensioning member comprises a manually-operated mode-switching member configured to controllably switch the suture tensioning member from the first mode to the second mode. The system may further comprise a tissue interface indentor member coupled to the delivery member and operatively coupled to the first helical member, the tissue interface indentor member comprising a distally protruding shape feature configured to contact one or more portions of the tissue structure adjacent to the distal end of the helical member and change an available angle of penetration between such portions and the distal tip of the first helical member as the distal tip is inserted into the tissue structure. The distally protruding shape feature may be configured to concentrate interfacial stresses upon the tissue structure such that the portions of the tissue structure adjacent the distal end of the first helical member become locally strained about the distally protruding shape feature as the distally protruding shape feature is advanced into contact with the adjacent tissue structure portions; and wherein the contact between the adjacent tissue structure portions and the distally protruding shape feature locally increases the available angle of penetration defined between the first helical member and a surface of the adjacent tissue structure portions. At least one surface of the distally protruding shape feature may comprise a surface configuration selected from the group consisting of: a portion of a spherical surface, a linear

ramp surface, an arcuate ramp surface, a multi-stepped ramp surface, and a single-stepped ramp surface. The surface configuration may be helically wrapped about a longitudinal axis of the first helical member. At least one surface of the distally protruding shape feature may comprise a substantially perpendicular leading surface. The distally protruding shape feature may have a cross sectional profile comprising a cross sectional shape selected from the list consisting of: a rectangle, a square, a half circle, a triangle, a polygon, a rounded rectangular shape, a rounded square shape, and a multi-arcuate shape. The distally protruding shape feature and distal tip of the elongate needle member may be operatively coupled such that the distal tip is movably coupled through a portion of the distally protruding shape feature. The distal tip may substantially bisect the portion of the distally protruding shape feature. The distally protruding shape feature and distal tip of the elongate needle member may be operatively coupled such that the distal tip is movably coupled adjacent a portion of the distally protruding shape feature. The distal tip of the elongate needle member may be configured to follow a path substantially parallel to the surface configuration of the distally protruding shape feature. The distally protruding shape feature may comprise one or more tissue traction features configured to prevent relative motion between the distally protruding shape feature and portions of the tissue structure with which it may be directly interfaced. At least one of the one of the one or more tissue traction features may comprise a barb. The system may further comprise a helical member guiding member having proximal and distal ends and being coupled to the first helical member, wherein the distal end of the helical member guiding member is substantially straight and defines a longitudinal axis that is substantially coincident with a longitudinal axis defined through the first helical member. The helical member guiding member may be coupled to the delivery member, which is coupled to the helical member. The helical member guiding member may be immediately coupled to the helical member. The distal end of the helical member guiding member may comprise an aperture fluidly coupled to a lumen defined through the helical member guiding member and leading proximally to a detection position wherein an operator may visually detect fluid which may be present at the aperture. The aperture may be positioned along the longitudinal axis of the helical member guiding member that is keyed to mark a distal protrusion position of a structure portion selected from the group consisting of: the distal end of the helical member; the distal end of the anchor member; and the proximal end of the anchor member. The system may further comprise a second aperture fluidly coupled to a second lumen defined through the helical member guiding member and leading proximally to a second detection position wherein an operator may visually detect fluid which may be

present at the second aperture. The helical member guiding member may comprise a sensor selected from the group consisting of: an OCT sensor, an ultrasound sensor, an RF impedance sensor, a partial pressure of oxygen sensor, and a pressure sensor. The system may further comprise a second helical member having proximal and distal ends, the proximal end coupled to the delivery member distal end, the distal end extending distally of the delivery member distal end. The second helical member may define an inner helix diameter that is substantially constant across the length of the helical member. The second helical member may define an inner helix diameter that varies across the length of the helical member. The inner helix diameters of the first and second helical members may be substantially equal. The inner helix diameters of the first and second helical members may be substantially unequal. The first and second helical members may define longitudinal axes that are substantially coaxial. The system may further comprise a second anchor member removably coupled to the distal end of the second helical member. The system may further comprise a second suture member coupled to the second helical member.

Another embodiment is directed to a system for providing surgical access across a wall of a tissue structure, comprising: a delivery member having proximal and distal ends; a first helical member having proximal and distal ends and a helical shape, the proximal end coupled to the delivery member distal end, the distal end extending distally of the delivery member distal end; an anchor member removably coupled to the helical member distal end; and a suture member coupled distally to a portion of the anchor member and extending proximally to a position wherein at least a portion of it may be freely manipulated by an operator; wherein the proximal end of the suture member extends proximally beyond the deployed suture pattern into a local suture length storage reservoir coupled to the delivery member, the reservoir containing an additional length of suture and being configured such that upon rotation of the delivery member in the first direction, the anchor member pulls along the distal portion of the suture member causing at least a portion of the additional length of suture to be extended out from the local suture length storage reservoir, and causing the distal portion of the suture member to form a deployed suture pattern which remains coupled to the anchor member. Upon rotation of the delivery member in a second direction opposite to the first direction, a reverse load may be applied to the delivery member and coupled first helical member which causes the anchor member to become decoupled from the first helical member, such that further rotation in the second direction causes removal of the first helical member and delivery member while the anchor member and suture member distal

portion remain positioned across the portion of the wall of the tissue structure. The deployed suture pattern may be characterized in that it is substantially helical and represents a number of helical loops encapsulated by the wall of the tissue structure that is greater than about one helical loop, and is less than about three helical loops. The anchor member may have at least one shape feature that is configured to slide past nearby tissue structures during inward insertion loading associated with rotation of the first helical member in the first direction, and to resist movement relative to the nearby tissue structures upon application of outward extraction loading associated with rotation of the first helical member in the second direction. At least a portion of the anchor member may be configured to rotate relative to wall of the tissue structure upon application of a tensioning load to the suture member. The first helical member and coupled anchor member may be advanced in a substantially helical pathway. The local suture length storage reservoir may be coupled to the delivery member in a configuration wherein advancement of the first helical member does not substantially advance the reservoir relative to the wall of the tissue structure. The system may further comprise a sleeve member movably coupled to the delivery member such that the deliver member is threaded through a lumen defined by the sleeve member, wherein the sleeve member is coupled to the local suture length storage reservoir. The first helical member may define an inner helix diameter that is substantially constant across the length of the helical member. The first helical member may define an inner helix diameter that varies across the length of the helical member. The inner helix diameter may be between about 5mm and about 60mm. The inner helix diameter may be between about 10mm and about 20mm. The first helical member may be comprised of an elongate member formed into the helical shape, the elongate member having an outer diameter. The elongate member may have a cross sectional shape selected from the group consisting of: a circular cross section, an elliptical cross section, a square cross section, and a rectangular cross section. The outer diameter may be between about 0.5mm and about 3mm. The helical shape may comprise a number of helical turns advanceable into tissue that is between about 1 and about 3. The helical shape may have a substantially constant helix pitch along the length of the helical shape. The helical shape may have a substantially variable helix pitch along the length of the helical shape. The helical shape may have a substantially constant helix pitch along the length of the helical shape. The helical shape may have a substantially variable helix pitch along the length of the helical shape. The helix pitch may be between about 5mm and about 20mm. The helix pitch may be between about 7mm and about 13mm. The distal end of the first helical member may comprise a sharpened tip configured to easily dive into and cross

portions of the wall of the tissue structure. The distal end of the first helical member may comprise an anchor coupling portion wherein the outer diameter of the elongate member is decreased to accommodate slidable coupling of the anchor member. The outer diameter of anchor member may be substantially similar to that of the portions of the elongate member proximal to the anchor coupling portion. The helical shape may be defined by a helix pitch, the helix pitch being selected based upon a targeted depth of traversal through the wall of the tissue structure that will result in the deployed suture pattern. The targeted depth of traversal may be configured to entirely cross the wall of the tissue structure, leaving the anchor member on an opposite side of the wall. The targeted depth of traversal may be configured to only partially cross the wall of the tissue structure, leaving the anchor member in a midsubstance location within the wall. The elongate member may comprise a solid cross-sectional construct. The elongate member may comprise a tubular construct having an inner diameter and as well as the outer diameter. The elongate member may comprise a material selected from the group consisting of: stainless steel, nitinol alloy, titanium, cobalt chrome, and polymer composite. The elongate member may comprise a material selected from the group consisting of: stainless steel, nitinol alloy, titanium, cobalt chrome, and polymer composite. The anchor member may comprise a main body portion comprising a solid or tubular construct. The shape feature may be to slide past nearby tissue structures during inward insertion loading comprises a tapered distal tip. The shape feature may be configured to resist movement relative to the nearby tissue structures upon application of outward extraction loading comprises a projecting portion configured to extend to a projecting position beyond an outer diameter of the rest of the anchor member when tension is applied to the intercoupled suture member. The projecting portion may comprise a portion of the anchor member that has been deformed out into the projecting position. The projecting portion may comprise a piece of material that has been coupled to the anchor member to assume the projecting position. The system may further comprise two or more projecting portions. The projecting portion may comprise a superelastic alloy that is shape set to the projecting position and configured to be deliverable in an elastically compressed form within a superelastic thermal range for the alloy. The suture member may be coupled to an eyelet coupled to the anchor member. The eyelet may be positioned such that tension on the suture member urges the anchor into rotational movement relative to surrounding portions of the wall of the tissue structure when the suture member is pulled in tension relative to the anchor member. The anchor may have a longitudinal axis, and the eyelet may be placed at a position spaced apart from the longitudinal axis. The eyelet may be coupled to a ring member

defining a ring aperture through which at least a portion of the anchor is positioned. The ring member may be coupled to the anchor using a coupling selected from the group consisting of: an adhesive coupling, a press-fit coupling, and a tack-welding coupling. The anchor may comprise a metal selected from the group consisting of: titanium, nickel, stainless steel, cobalt chrome, and alloys thereof. The anchor may comprise a durable polymer selected from the group consisting of: polyethylene terepthalate, polyethylene, high density polyethylene, polypropylene, polytetrafluoroethylene, expanded polytetrafluoroethylene, poly (ethylene-co-vinyl acetate), poly(butyl methacrylate), and co-polymers thereof. The anchor may comprise a bioresorbable polymer selected from the group consisting of: polylactic acid, polyglycolic acid, polylactic-co-glycolic acid, polylactic acid-co-caprolactone, poly (block-ethylene oxide-block-lactide-co-glycolide), polyethylene glycol, polyethylene oxide, poly (block-ethylene oxide-block-propylene oxide-block-ethylene oxide), polyvinyl pyrrolidone, polyorthoester, polyanhydride, polyhydroxy valerate, polyhydroxy butyrate, and co-polymers thereof. The anchor may comprise a biological graft material. The biological graft material may have an origin selected from the group consisting of: another human, the particular human, a non-human animal. The anchor may comprise a bioresorbable material selected from the group consisting of: porcine collagen matrix, human collagen matrix, equine collagen fleece, gelatin, polyhyaluronic acid, heparin, poly (glucose), poly(alginic acid), chitin, chitosan, cellulose, methyl cellulose, hydroxyethylcellulose, hydroxypropylcellulose, carboxymethylcellulose; polylysine, polyglutamic acid, albumin, hydroxy apatite, cortical bone, cancellous bone, trabecular bone, bioceramic, ligament tissue, tendon tissue, dura tissue, fascia tissue, pericardium tissue, thrombin, and fibrin. The local suture length storage reservoir may comprise an enclosure for storing one or more loops of suture member length. The additional length of suture may be between about 50 millimeters and about 200 millimeters. The enclosure may comprise a membrane configured to partially encapsulate the one or more loops of suture member length, and allow the one or more loops to be pulled out of the enclosure when under tensile loading from the anchor and helical members. The system may further comprise a suture tensioning member coupled to the suture member between a proximal end of the suture member and a distal end of the suture member, the suture tensioning member configured to apply a compressive load to an exposed proximal aspect of the wall of the tissue structure when a distal end of the suture tensioning member is placed against the exposed proximal aspect of the wall and the suture member is tensioned proximally of the suture tensioning member. The suture tensioning member may comprise an elongate tubular member defining a lumen therethrough, the suture member being threaded

through the lumen. The system may further comprise a temporary suture member clamp coupleable to a proximal portion of the suture member and configured to retain tension upon a portion of suture member distal to the suture member clamp that is threaded through the lumen of the elongate tubular member. The suture tensioning member may have two modes of operation, a first mode wherein the suture tensioning member may be moved bidirectionally relative to the suture member, and a second mode wherein the suture tensioning member may only be moved unidirectionally relative to the suture member, and wherein the suture tensioning member comprises a manually-operated mode-switching member configured to controllably switch the suture tensioning member from the first mode to the second mode. The system may further comprise a tissue interface indentor member coupled to the delivery member and operatively coupled to the first helical member, the tissue interface indentor member comprising a distally protruding shape feature configured to contact one or more portions of the tissue structure adjacent to the distal end of the helical member and change an available angle of penetration between such portions and the distal tip of the first helical member as the distal tip is inserted into the tissue structure. The distally protruding shape feature may be configured to concentrate interfacial stresses upon the tissue structure such that the portions of the tissue structure adjacent the distal end of the first helical member become locally strained about the distally protruding shape feature as the distally protruding shape feature is advanced into contact with the adjacent tissue structure portions; and wherein the contact between the adjacent tissue structure portions and the distally protruding shape feature locally increases the available angle of penetration defined between the first helical member and a surface of the adjacent tissue structure portions. At least one surface of the distally protruding shape feature may comprise a surface configuration selected from the group consisting of: a portion of a spherical surface, a linear ramp surface, an arcuate ramp surface, a multi-stepped ramp surface, and a single-stepped ramp surface. The surface configuration may be helically wrapped about a longitudinal axis of the first helical member. At least one surface of the distally protruding shape feature comprises a substantially perpendicular leading surface. The distally protruding shape feature may have a cross sectional profile comprising a cross sectional shape selected from the list consisting of: a rectangle, a square, a half circle, a triangle, a polygon, a rounded rectangular shape, a rounded square shape, and a multi-arcuate shape. The distally protruding shape feature and distal tip of the helical member may be operatively coupled such that the distal tip is movably coupled through a portion of the distally protruding shape feature. The distal tip substantially may bisect the portion of the distally protruding shape feature. The

distally protruding shape feature and distal tip of the helical member may be operatively coupled such that the distal tip is movably coupled adjacent a portion of the distally protruding shape feature. The distal tip of the helical member may be configured to follow a path substantially parallel to the surface configuration of the distally protruding shape feature. The distally protruding shape feature may comprise one or more tissue traction features configured to prevent relative motion between the distally protruding shape feature and portions of the tissue structure with which it may be directly interfaced. At least one of the one of the one or more tissue traction features may comprise a barb. The system may further comprise a helical member guiding member having proximal and distal ends and being coupled to the first helical member, wherein the distal end of the helical member guiding member is substantially straight and defines a longitudinal axis that is substantially coincident with a longitudinal axis defined through the first helical member. The helical member guiding member may be coupled to the delivery member, which is coupled to the helical member. The helical member guiding member may be immediately coupled to the helical member. The distal end of the helical member guiding member may comprise an aperture fluidly coupled to a lumen defined through the helical member guiding member and leading proximally to a detection position wherein an operator may visually detect fluid which may be present at the aperture. The aperture may be positioned along the longitudinal axis of the helical member guiding member that is keyed to mark a distal protrusion position of a structure portion selected from the group consisting of: the distal end of the helical member; the distal end of the anchor member; and the proximal end of the anchor member. The system may further comprise a second aperture fluidly coupled to a second lumen defined through the helical member guiding member and leading proximally to a second detection position wherein an operator may visually detect fluid which may be present at the second aperture. The helical member guiding member may comprise a sensor selected from the group consisting of: an OCT sensor, an ultrasound sensor, an RF impedance sensor, a partial pressure of oxygen sensor, and a pressure sensor. The system may further comprise a second helical member having proximal and distal ends, the proximal end coupled to the delivery member distal end, the distal end extending distally of the delivery member distal end. The second helical member may define an inner helix diameter that is substantially constant across the length of the helical member. The second helical member may define an inner helix diameter that varies across the length of the helical member. The inner helix diameters of the first and second helical members may be substantially equal. The inner helix diameters of the first and second helical members may be substantially unequal. The first and second

helical members define longitudinal axes that are substantially coaxial. The system may further comprise a second anchor member removably coupled to the distal end of the second helical member. The system may further comprise a second suture member coupled to the second helical member.

Another embodiment is directed to a system for providing surgical access across a wall of a tissue structure, comprising: a delivery member having proximal and distal ends; a first helical member having proximal and distal ends and a helical shape, the proximal end coupled to the delivery member distal end, the distal end extending distally of the delivery member distal end; an anchor member removably coupled to the helical member distal end; a suture member coupled distally to a portion of the anchor member and extending proximally to a position wherein at least a portion of it may be freely manipulated by an operator; and a tissue interface indentor member coupled to the delivery member and operatively coupled to the first helical member, the tissue interface indentor member comprising a distally protruding shape feature configured to contact one or more portions of the tissue structure adjacent to the distal end of the helical member and change an available angle of penetration between such portions and the distal tip of the first helical member as the distal tip is inserted into the tissue structure; wherein upon rotation of the delivery member in a first direction, the indentor member is urged against the tissue structure and the first helical member and coupled anchor member are advanced across at least a portion of the wall of the tissue structure, pulling along the distal portion of the suture member in a deployed suture pattern which remains coupled to the anchor member. Upon rotation of the delivery member in a second direction opposite to the first direction, a reverse load may be applied to the delivery member and coupled first helical member which causes the anchor member to become decoupled from the first helical member, such that further rotation in the second direction causes removal of the first helical member and delivery member while the anchor member and suture member distal portion remain positioned across the portion of the wall of the tissue structure. The deployed suture pattern may be characterized in that it is substantially helical and represents a number of helical loops encapsulated by the wall of the tissue structure that is greater than about one helical loop, and is less than about three helical loops. The anchor member may have at least one shape feature that is configured to slide past nearby tissue structures during inward insertion loading associated with rotation of the first helical member in the first direction, and to resist movement relative to the nearby tissue structures upon application of outward extraction loading associated with rotation of the first

helical member in the second direction. At least a portion of the anchor member may be configured to rotate relative to wall of the tissue structure upon application of a tensioning load to the suture member. The first helical member and coupled anchor member may be advanced in a substantially helical pathway. The proximal end of the suture member may extend proximally beyond the deployed suture pattern into a local suture length storage reservoir coupled to the delivery member containing an additional length of suture, the reservoir being configured such that upon rotation of the delivery member in the first direction, the anchor member pulls along the distal portion of the suture member causing at least a portion of the additional length of suture to be extended out from the local suture length storage reservoir. The local suture length storage reservoir may be coupled to the delivery member in a configuration wherein advancement of the first helical member does not substantially advance the reservoir relative to the wall of the tissue structure. The system may further comprise a sleeve member movably coupled to the delivery member such that the deliver member is threaded through a lumen defined by the sleeve member, wherein the sleeve member is coupled to the local suture length storage reservoir. The first helical member may define an inner helix diameter that is substantially constant across the length of the helical member. The first helical member may define an inner helix diameter that varies across the length of the helical member. The inner helix diameter may be between about 5mm and about 60mm. The inner helix diameter may be between about 10mm and about 20mm. The first helical member may be comprised of an elongate member formed into the helical shape, the elongate member having an outer diameter. The elongate member may have a cross sectional shape selected from the group consisting of: a circular cross section, an elliptical cross section, a square cross section, and a rectangular cross section. The outer diameter may be between about 0.5mm and about 3mm. The helical shape may comprise a number of helical turns advanceable into tissue that is between about 1 and about 3. The helical shape may have a substantially constant helix pitch along the length of the helical shape. The helical shape may have a substantially variable helix pitch along the length of the helical shape. The helical shape may have a substantially constant helix pitch along the length of the helical shape. The helical shape may have a substantially variable helix pitch along the length of the helical shape. The helix pitch may be between about 5mm and about 20mm. The helix pitch may be between about 7mm and about 13mm. The distal end of the first helical member may comprise a sharpened tip configured to easily dive into and cross portions of the wall of the tissue structure. The distal end of the first helical member may comprise an anchor coupling portion wherein the outer diameter of the elongate member is

decreased to accommodate slidable coupling of the anchor member. The outer diameter of anchor member may be substantially similar to that of the portions of the elongate member proximal to the anchor coupling portion. The helical shape may be defined by a helix pitch, the helix pitch being selected based upon a targeted depth of traversal through the wall of the tissue structure that will result in the deployed suture pattern. The targeted depth of traversal may be configured to entirely cross the wall of the tissue structure, leaving the anchor member on an opposite side of the wall. The targeted depth of traversal may be configured to only partially cross the wall of the tissue structure, leaving the anchor member in a midsubstance location within the wall. The elongate member may comprise a solid cross-sectional construct. The elongate member may comprise a tubular construct having an inner diameter and as well as the outer diameter. The elongate member may comprise a material selected from the group consisting of: stainless steel, nitinol alloy, titanium, cobalt chrome, and polymer composite. The elongate member may comprise a material selected from the group consisting of: stainless steel, nitinol alloy, titanium, cobalt chrome, and polymer composite. The anchor member may comprise a main body portion comprising a solid or tubular construct. The shape feature may be configured to slide past nearby tissue structures during inward insertion loading comprises a tapered distal tip. The shape feature may be configured to resist movement relative to the nearby tissue structures upon application of outward extraction loading comprises a projecting portion configured to extend to a projecting position beyond an outer diameter of the rest of the anchor member when tension is applied to the intercoupled suture member. The projecting portion comprises a portion of the anchor member that has been deformed out into the projecting position. The projecting portion may comprise a piece of material that has been coupled to the anchor member to assume the projecting position. The system may further comprise two or more projecting portions. The projecting portion may comprise a superelastic alloy that is shape set to the projecting position and configured to be deliverable in an elastically compressed form within a superelastic thermal range for the alloy. The suture member may be coupled to an eyelet coupled to the anchor member. The eyelet may be positioned such that tension on the suture member urges the anchor into rotational movement relative to surrounding portions of the wall of the tissue structure when the suture member is pulled in tension relative to the anchor member. The anchor may have a longitudinal axis, and wherein the eyelet is placed at a position spaced apart from the longitudinal axis. The eyelet may be coupled to a ring member defining a ring aperture through which at least a portion of the anchor is positioned. The ring member may be coupled to the anchor using a coupling selected from the group

consisting of: an adhesive coupling, a press-fit coupling, and a tack-welding coupling. The anchor may comprise a metal selected from the group consisting of: titanium, nickel, stainless steel, cobalt chrome, and alloys thereof. The anchor may comprise a durable polymer selected from the group consisting of: polyethylene terepthalate, polyethylene, high density polyethylene, polypropylene, polytetrafluoroethylene, expanded polytetrafluoroethylene, poly (ethylene-co-vinyl acetate), poly(butyl methacrylate), and co-polymers thereof. The anchor may comprise a bioresorbable polymer selected from the group consisting of: polylactic acid, polyglycolic acid, polylactic-co-glycolic acid, polylactic acid-co-caprolactone, poly (block-ethylene oxide-block-lactide-co-glycolide), polyethylene glycol, polyethylene oxide, poly (block-ethylene oxide-block-propylene oxide-block-ethylene oxide), polyvinyl pyrrolidone, polyorthoester, polyanhydride, polyhydroxy valerate, polyhydroxy butyrate, and co-polymers thereof. The anchor may comprise a biological graft material. The biological graft material may have an origin selected from the group consisting of: another human, the particular human, a non-human animal. The anchor may comprise a bioresorbable material selected from the group consisting of: porcine collagen matrix, human collagen matrix, equine collagen fleece, gelatin, polyhyaluronic acid, heparin, poly (glucose), poly(alginic acid), chitin, chitosan, cellulose, methyl cellulose, hydroxyethylcellulose, hydroxypropylcellulose, carboxymethylcellulose; polylysine, polyglutamic acid, albumin, hydroxy apatite, cortical bone, cancellous bone, trabecular bone, bioceramic, ligament tissue, tendon tissue, dura tissue, fascia tissue, pericardium tissue, thrombin, and fibrin. The local suture length storage reservoir may comprise an enclosure for storing one or more loops of suture member length. The additional length of suture may be between about 20 millimeters and about 500 millimeters. The enclosure may comprise a membrane configured to partially encapsulate the one or more loops of suture member length, and allow the one or more loops to be pulled out of the enclosure when under tensile loading from the anchor and helical members. The system may further comprise a suture tensioning member coupled to the suture member between a proximal end of the suture member and a distal end of the suture member, the suture tensioning member configured to apply a compressive load to an exposed proximal aspect of the wall of the tissue structure when a distal end of the suture tensioning member is placed against the exposed proximal aspect of the wall and the suture member is tensioned proximally of the suture tensioning member. The suture tensioning member may comprise an elongate tubular member defining a lumen therethrough, the suture member being threaded through the lumen. The system may further comprise a temporary suture member clamp coupleable to a proximal portion of the suture member and configured to

retain tension upon a portion of suture member distal to the suture member clamp that is threaded through the lumen of the elongate tubular member. The suture tensioning member may have two modes of operation, a first mode wherein the suture tensioning member may be moved bidirectionally relative to the suture member, and a second mode wherein the suture tensioning member may only be moved unidirectionally relative to the suture member, and wherein the suture tensioning member comprises a manually-operated mode-switching member configured to controllably switch the suture tensioning member from the first mode to the second mode. The distally protruding shape feature may be configured to concentrate interfacial stresses upon the tissue structure such that the portions of the tissue structure adjacent the distal end of the first helical member become locally strained about the distally protruding shape feature as the distally protruding shape feature is advanced into contact with the adjacent tissue structure portions; and wherein the contact between the adjacent tissue structure portions and the distally protruding shape feature locally increases the available angle of penetration defined between the first helical member and a surface of the adjacent tissue structure portions. At least one surface of the distally protruding shape feature may comprise a surface configuration selected from the group consisting of: a portion of a spherical surface, a linear ramp surface, an arcuate ramp surface, a multi-stepped ramp surface, and a single-stepped ramp surface. The surface configuration may be helically wrapped about a longitudinal axis of the first helical member. At least one surface of the distally protruding shape feature may comprise a substantially perpendicular leading surface. The distally protruding shape feature may have a cross sectional profile comprising a cross sectional shape selected from the list consisting of: a rectangle, a square, a half circle, a triangle, a polygon, a rounded rectangular shape, a rounded square shape, and a multi-arcuate shape. The distally protruding shape feature and distal tip of the helical member may be operatively coupled such that the distal tip is movably coupled through a portion of the distally protruding shape feature. The distal tip substantially may bisect the portion of the distally protruding shape feature. The distally protruding shape feature and distal tip of the helical member may be operatively coupled such that the distal tip is movably coupled adjacent a portion of the distally protruding shape feature. The distal tip of the helical member may be configured to follow a path substantially parallel to the surface configuration of the distally protruding shape feature. The distally protruding shape feature may comprise one or more tissue traction features configured to prevent relative motion between the distally protruding shape feature and portions of the tissue structure with which it may be directly interfaced. At least one of the one of the one or more tissue traction features may comprise a

barb. The system may further comprise a helical member guiding member having proximal and distal ends and being coupled to the first helical member, wherein the distal end of the helical member guiding member is substantially straight and defines a longitudinal axis that is substantially coincident with a longitudinal axis defined through the first helical member. The helical member guiding member is coupled to the delivery member, which is coupled to the helical member. The helical member guiding member may be immediately coupled to the helical member. The distal end of the helical member guiding member may comprise an aperture fluidly coupled to a lumen defined through the helical member guiding member and leading proximally to a detection position wherein an operator may visually detect fluid which may be present at the aperture. The aperture may be positioned along the longitudinal axis of the helical member guiding member that is keyed to mark a distal protrusion position of a structure portion selected from the group consisting of: the distal end of the helical member; the distal end of the anchor member; and the proximal end of the anchor member. The system may further comprise a second aperture fluidly coupled to a second lumen defined through the helical member guiding member and leading proximally to a second detection position wherein an operator may visually detect fluid which may be present at the second aperture. The helical member guiding member may comprise a sensor selected from the group consisting of: an OCT sensor, an ultrasound sensor, an RF impedance sensor, a partial pressure of oxygen sensor, and a pressure sensor. The system may further comprise a second helical member having proximal and distal ends, the proximal end coupled to the delivery member distal end, the distal end extending distally of the delivery member distal end. The second helical member may define an inner helix diameter that is substantially constant across the length of the helical member. The second helical member may define an inner helix diameter that varies across the length of the helical member. The inner helix diameters of the first and second helical members may be substantially equal. The inner helix diameters of the first and second helical members may be substantially unequal. The first and second helical members may define longitudinal axes that are substantially coaxial. The system may further comprise a second anchor member removably coupled to the distal end of the second helical member. The system may further comprise a second suture member coupled to the second helical member.

Another embodiment is directed to a system for providing surgical access across a wall of a tissue structure, comprising: a delivery member having proximal and distal ends; a plurality of helical members , each having proximal and distal ends and a helical shape, each

proximal end coupled to the delivery member distal end, each distal end extending distally of the delivery member distal end; a plurality of anchor members removably coupled to the helical member distal ends; and a plurality of suture members coupled distally to a portion of one of the anchor members and extending proximally to a position wherein at least a portion of each may be freely manipulated by an operator; wherein upon rotation of the delivery member in a first direction, the helical members and coupled anchor members are advanced across at least a portion of the wall of the tissue structure, pulling along the distal portions of the suture members in a deployed suture pattern which remains coupled to the anchor member. Upon rotation of the delivery member in a second direction opposite to the first direction, a reverse load is applied to the delivery member and coupled helical members which causes the anchor members to become decoupled from the helical members, such that further rotation in the second direction causes removal of the helical members and delivery member while the anchor members and suture member distal portions remain positioned across the portion of the wall of the tissue structure. The deployed suture pattern may be characterized in that in the aggregate it represents a number of helical loops encapsulated by the wall of the tissue structure that is greater than about one helical loop, and is less than about three helical loops. The deployed suture pattern may be characterized in that at least one of the suture members defines a substantially helical pathway in the wall of the tissue structure and represents a number of helical loops encapsulated by the wall of the tissue structure that is greater than about one helical loop, and is less than about three helical loops. The plurality of helical members may comprise two, the plurality of anchor members may comprise two, and the plurality of suture members may comprise two. The plurality of helical members may comprise three, the plurality of anchor members may comprise three, and the plurality of suture members may comprise three. At least one of the anchor members may have at least one shape feature that is configured to slide past nearby tissue structures during inward insertion loading associated with rotation of a first helical member in the first direction, and to resist movement relative to the nearby tissue structures upon application of outward extraction loading associated with rotation of the first helical member in the second direction. At least a portion of one of the anchor members may be configured to rotate relative to wall of the tissue structure upon application of a tensioning load to the associated suture member. The helical members and coupled anchor members may be advanced in a plurality of substantially helical pathways. The proximal end of at least one of the suture members may extend proximally beyond the deployed suture pattern into a local suture length storage reservoir coupled to the delivery member containing an additional length of

suture, the reservoir being configured such that upon rotation of the delivery member in the first direction, the anchor member coupled to the suture member pulls along the distal portion of the suture member causing at least a portion of the additional length of suture to be extended out from the local suture length storage reservoir. The local suture length storage reservoir may be coupled to the delivery member in a configuration wherein advancement of any of the helical members does not substantially advance the reservoir relative to the wall of the tissue structure. The system may further comprise a sleeve member movably coupled to the delivery member such that the deliver member is threaded through a lumen defined by the sleeve member, wherein the sleeve member is coupled to the local suture length storage reservoir. A first helical member may define an inner helix diameter that is substantially constant across the length of the helical member. A first helical member may define an inner helix diameter that varies across the length of the helical member. The inner helix diameter may be between about 5mm and about 60mm. The inner helix diameter may be between about 10mm and about 20mm. A first helical member may be comprised of an elongate member formed into the helical shape, the elongate member having an outer diameter. The elongate member may have a cross sectional shape selected from the group consisting of: a circular cross section, an elliptical cross section, a square cross section, and a rectangular cross section. The outer diameter may be between about 0.5mm and about 3mm. The helical shape may comprise a number of helical turns advanceable into the wall of the tissue structure that is between about 1 and about 3. The helical shape may have a substantially constant helix pitch along the length of the helical shape. The helical shape may have a substantially variable helix pitch along the length of the helical shape. The helical shape may have a substantially constant helix pitch along the length of the helical shape. The helical shape may have a substantially variable helix pitch along the length of the helical shape. The helix pitch may be between about 5mm and about 20mm. The helix pitch may be between about 7mm and about 13mm. The distal end of a first helical member may comprise a sharpened tip configured to easily dive into and cross portions of the wall of the tissue structure. The distal end of the first helical member may comprise an anchor coupling portion wherein the outer diameter of the elongate member is decreased to accommodate slidable coupling of one of the anchor members. The outer diameter of the anchor member may be substantially similar to that of the portions of the elongate member proximal to the anchor coupling portion. The helical shapes may be defined by helical pitches selected based upon targeted depths of traversal through the wall of the tissue structure that will result in the deployed suture pattern. The helical shape associated with the at least one of the suture

members may be defined by a helical pitch selected based upon a targeted depth of traversal through the wall of the tissue structure that will result in the deployed suture pattern. At least one of the targeted depths of traversal may be configured to entirely cross the wall of the tissue structure, leaving an anchor member on an opposite side of the wall. At least one of the targeted depths of traversal may be configured to only partially cross the wall of the tissue structure, leaving an anchor member in a midsubstance location within the wall. The elongate member may comprise a solid cross-sectional construct. The elongate member may comprise a tubular construct having an inner diameter and as well as the outer diameter. The elongate member may comprise a material selected from the group consisting of: stainless steel, nitinol alloy, titanium, cobalt chrome, and polymer composite. The elongate member may comprise a material selected from the group consisting of: stainless steel, nitinol alloy, titanium, cobalt chrome, and polymer composite. At least one anchor member may comprise a main body portion comprising a solid or tubular construct. The shape feature configured to slide past nearby tissue structures during inward insertion loading may comprise a tapered distal tip. The shape feature configured to resist movement relative to the nearby tissue structures upon application of outward extraction loading may comprise a projecting portion configured to extend to a projecting position beyond an outer diameter of the rest of the anchor member when tension is applied to the intercoupled suture member. The projecting portion may comprise a portion of the anchor member that has been deformed out into the projecting position. The projecting portion may comprise a piece of material that has been coupled to the anchor member to assume the projecting position. The system may further comprise two or more projecting portions. The projecting portion may comprise a superelastic alloy that is shape set to the projecting position and configured to be deliverable in an elastically compressed form within a superelastic thermal range for the alloy. At least one of the suture members may be coupled to an eyelet coupled to an anchor member. The eyelet may be positioned such that tension on the coupled suture member urges the anchor into rotational movement relative to surrounding portions of the wall of the tissue structure when the suture member is pulled in tension relative to the anchor member. The anchor may have a longitudinal axis, and the eyelet may be placed at a position spaced apart from the longitudinal axis. The eyelet may be coupled to a ring member defining a ring aperture through which at least a portion of the anchor is positioned. The ring member may be coupled to the anchor using a coupling selected from the group consisting of: an adhesive coupling, a press-fit coupling, and a tack-welding coupling. The anchor may comprise a metal selected from the group consisting of: titanium, nickel, stainless steel, cobalt chrome,

and alloys thereof. The anchor may comprise a durable polymer selected from the group consisting of: polyethylene terepthalate, polyethylene, high density polyethylene, polypropylene, polytetrafluoroethylene, expanded polytetrafluoroethylene, poly (ethylene-co-vinyl acetate), poly(butyl methacrylate), and co-polymers thereof. The anchor may comprise a bioresorbable polymer selected from the group consisting of: polylactic acid, polyglycolic acid, polylactic-co-glycolic acid, polylactic acid-co-caprolactone, poly (block-ethylene oxide-block-lactide-co-glycolide), polyethylene glycol, polyethylene oxide, poly (block-ethylene oxide-block-propylene oxide-block-ethylene oxide), polyvinyl pyrrolidone, polyorthoester, polyanhydride, polyhydroxy valerate, polyhydroxy butyrate, and co-polymers thereof. The anchor may comprise a biological graft material. The biological graft material may have an origin selected from the group consisting of: another human, the particular human, a non-human animal. The anchor may comprise a bioresorbable material selected from the group consisting of: porcine collagen matrix, human collagen matrix, equine collagen fleece, gelatin, polyhyaluronic acid, heparin, poly (glucose), poly(alginic acid), chitin, chitosan, cellulose, methyl cellulose, hydroxyethylcellulose, hydroxypropylcellulose, carboxymethylcellulose; polylysine, polyglutamic acid, albumin, hydroxy apatite, cortical bone, cancellous bone, trabecular bone, bioceramic, ligament tissue, tendon tissue, dura tissue, fascia tissue, pericardium tissue, thrombin, and fibrin. The local suture length storage reservoir may comprise an enclosure for storing one or more loops of suture member length. The additional length of suture may be between about 20 millimeters and about 500 millimeters. The enclosure may comprise a membrane configured to partially encapsulate the one or more loops of suture member length, and allow the one or more loops to be pulled out of the enclosure when under tensile loading from the anchor and helical members. The system may further comprise a suture tensioning member coupled at least one of the suture members between a proximal end of the suture member and a distal end of the suture member, the suture tensioning member configured to apply a compressive load to an exposed proximal aspect of the wall of the tissue structure when a distal end of the associated suture tensioning member is placed against the exposed proximal aspect of the wall and the suture member is tensioned proximally of the suture tensioning member. The suture tensioning member may comprise an elongate tubular member defining a lumen therethrough, the suture member being threaded through the lumen. The system may further comprise a temporary suture member clamp coupleable to a proximal portion of the suture member and configured to retain tension upon a portion of suture member distal to the suture member clamp that is threaded through the lumen of the elongate tubular member. The suture tensioning member

may have two modes of operation, a first mode wherein the suture tensioning member may be moved bidirectionally relative to the suture member, and a second mode wherein the suture tensioning member may only be moved unidirectionally relative to the suture member, and wherein the suture tensioning member comprises a manually-operated mode-switching member configured to controllably switch the suture tensioning member from the first mode to the second mode. The system may further comprise a tissue interface indentor member coupled to the delivery member and operatively coupled to one or more of the helical members, the tissue interface indentor member comprising a plurality of distally protruding shape features configured to contact one or more portions of the tissue structure adjacent to each of the distal ends of the helical members and change an available angle of penetration between such portions and the distal tips of the helical members as the distal tips are inserted into the tissue structure. The distally protruding shape features may be configured to concentrate interfacial stresses upon the tissue structure such that the portions of the tissue structure adjacent the distal ends of the helical members become locally strained about the distally protruding shape features as the distally protruding shape features are advanced into contact with the adjacent tissue structure portions; and wherein the contact between the adjacent tissue structure portions and the distally protruding shape features locally increase the available angle of penetration defined between each of the helical members and a surface of the adjacent tissue structure portions. At least one surface of the one of the distally protruding shape feature may comprise a surface configuration selected from the group consisting of: a portion of a spherical surface, a linear ramp surface, an arcuate ramp surface, a multi-stepped ramp surface, and a single-stepped ramp surface. The surface configuration may be helically wrapped about a longitudinal axis of one of the helical members. At least one surface of one of the distally protruding shape features may comprise a substantially perpendicular leading surface. At least one of the distally protruding shape features may have a cross sectional profile comprising a cross sectional shape selected from the list consisting of: a rectangle, a square, a half circle, a triangle, a polygon, a rounded rectangular shape, a rounded square shape, and a multi-arcuate shape. At least one of the distally protruding shape features and distal tip of the associated helical member may be operatively coupled such that the distal tip is movably coupled through a portion of the distally protruding shape feature. The distal tip substantially may bisect the portion of the distally protruding shape feature. The distally protruding shape features and distal tips of the helical members may be operatively coupled such that the distal tips are movably coupled adjacent to portions of the distally protruding shape features. The distal tip of the helical member may

be configured to follow a path substantially parallel to the surface configuration of the distally protruding shape feature. The distally protruding shape features may comprise one or more tissue traction features configured to prevent relative motion between the distally protruding shape features and portions of the tissue structure with which they may be directly interfaced. At least one of the one of the one or more tissue traction features may comprise a barb. The system may further comprise a helical member guiding member having proximal and distal ends and being coupled to one or more of the helical members, wherein the distal end of the helical member guiding member is substantially straight and defines a longitudinal axis that is substantially coincident with a longitudinal axis defined through the helical members. The helical member guiding member may be coupled to the delivery member, which is coupled to the one or more helical members. The helical member guiding member may be immediately coupled to the one or more helical members. The distal end of the helical member guiding member may comprise an aperture fluidly coupled to a lumen defined through the helical member guiding member and leading proximally to a detection position wherein an operator may visually detect fluid which may be present at the aperture. The aperture may be positioned along the longitudinal axis of the helical member guiding member that is keyed to mark a distal protrusion position of a structure portion selected from the group consisting of: the distal end of one of the helical members; the distal end of one of the anchor members; and the proximal end of one of the anchor members. The system may further comprise a second aperture fluidly coupled to a second lumen defined through the helical member guiding member and leading proximally to a second detection position wherein an operator may visually detect fluid which may be present at the second aperture. The helical member guiding member may comprise a sensor selected from the group consisting of: an OCT sensor, an ultrasound sensor, an RF impedance sensor, a partial pressure of oxygen sensor, and a pressure sensor.

Another embodiment is directed to a system for advancing a needle into a tissue structure, comprising: an elongate needle member having a tapered distal tip; an insertion member having proximal and distal ends, the distal end being coupled to the elongate needle member, and the proximal end being configured to be manipulated by an operator; and a tissue interface indentor member coupled to the insertion member and operatively coupled to the elongate needle member, the tissue interface indentor member comprising a distally protruding shape feature configured to contact one or more portions of the tissue structure adjacent to the distal tip of the elongate needle member and change an available angle of

penetration between such portions and the distal tip of the elongate needle member as the distal tip is inserted into tissue structure. The elongate needle member may comprise a shape selected from the group consisting of: a substantially straight shape, an arcuate shape, and a helical shape. The elongate needle member may comprise a first helical member that defines an inner helix diameter that is substantially constant across the length of the helical member. The elongate needle member may comprise a first helical member that defines an inner helix diameter that varies across the length of the helical member. The inner helix diameter may be between about 5mm and about 60mm. The inner helix diameter may be between about 10mm and about 20mm. The elongate needle member may comprise a first helical member that is comprised of an elongate member formed into the helical shape, the elongate member having an outer diameter. The elongate member may have a cross sectional shape selected from the group consisting of: a circular cross section, an elliptical cross section, a square cross section, and a rectangular cross section. The outer diameter may be between about 0.5mm and about 3mm. The helical shape may comprise a number of helical turns advanceable into tissue relative to the insertion member that is between about 1 and about 3. The helical shape may have a substantially constant helix pitch along the length of the helical shape. The helical shape may have a substantially variable helix pitch along the length of the helical shape. The helical shape may have a substantially constant helix pitch along the length of the helical shape. The helical shape may have a substantially variable helix pitch along the length of the helical shape. The helix pitch may be between about 5mm and about 20mm. The helix pitch may be between about 7mm and about 13mm. The distal end of the first helical member may comprise a sharpened tip configured to easily dive into and cross portions of the tissue structure. The elongate member may comprise a solid cross-sectional construct. The elongate member may comprise a tubular construct having an inner diameter and as well as the outer diameter. The elongate member may comprise a material selected from the group consisting of: stainless steel, nitinol alloy, titanium, cobalt chrome, and polymer composite. The elongate member may comprise a material selected from the group consisting of: stainless steel, nitinol alloy, titanium, cobalt chrome, and polymer composite. The insertion member may comprise a substantially rigid construct. The insertion member may comprise a flexible construct. The distally protruding shape feature may be configured to concentrate interfacial stresses upon the tissue structure such that the portions of the tissue structure adjacent the distal tip of the elongate needle member become locally strained about the distally protruding shape feature as the distally protruding shape feature is advanced into contact with the adjacent tissue structure portions; and wherein the contact between the

adjacent tissue structure portions and the distally protruding shape feature locally increases the available angle of penetration defined between the needle and a surface of the adjacent tissue structure portions. At least one surface of the distally protruding shape feature may comprise a surface configuration selected from the group consisting of: a portion of a spherical surface, a linear ramp surface, an arcuate ramp surface, a multi-stepped ramp surface, and a single-stepped ramp surface. The surface configuration may be helically wrapped about a longitudinal axis of the helical member. At least one surface of the distally protruding shape feature may comprise a substantially perpendicular leading surface. The distally protruding shape feature may have a cross sectional profile comprising a cross sectional shape selected from the list consisting of: a rectangle, a square, a half circle, a triangle, a polygon, a rounded rectangular shape, a rounded square shape, and a multi-arcuate shape. The distally protruding shape feature and distal tip of the elongate needle member may be operatively coupled such that the distal tip is movably coupled through a portion of the distally protruding shape feature. The distal tip substantially may bisect the portion of the distally protruding shape feature. The distally protruding shape feature and distal tip of the elongate needle member may be operatively coupled such that the distal tip is movably coupled adjacent a portion of the distally protruding shape feature. The distal tip of the elongate needle member may be configured to follow a path substantially parallel to the surface configuration of the distally protruding shape feature. The distally protruding shape feature may comprise one or more tissue traction features configured to prevent relative motion between the distally protruding shape feature and portions of the tissue structure with which it may be directly interfaced. At least one of the one of the one or more tissue traction features may comprise a barb.

Another embodiment is directed to a system for tensioning a suture member that crosses a portion of a tissue structure, comprising: a tensioning member base having a tissue interface surface configured to engage a portion of the tissue structure when coupled to a suture member that may be threaded through the tensioning member base and into the tissue structure; a suture clamping member configured to be switched from a first mode, wherein a suture may be tensioned back and forth through a space defined at least in part by the clamping member, to a second mode, wherein a suture may only be tensioned in one direction relative to the suture clamping member; and a mode switching member movably coupled to the suture clamping member and configured to be operable to switch the suture clamping member from the first mode to the second mode. The suture clamping member

may be movably coupled to the tensioning member base. The suture clamping member may be coupled to the tensioning member base by a suture member coupled to both the clamping member and tensioning member. The suture clamping member may comprise a proximal end and a distal end, the proximal end being rotatably coupled to the tensioning member base. The distal end may be configured to swing about a hinge point at the coupling between the proximal end and the tensioning member base. The distal end may be swung from an open position relative to the tensioning member base, wherein a length of suture may be passed through an opening defined between the distal end of the clamping member and the tensioning member base, to a closed position, wherein a length of suture becomes pinch-immobilized between the distal end of the clamping member and the tensioning member base. The clamping member and tensioning member base may be configurable to the first mode by positioning the distal end of the clamping member in the open position, and to the second mode by positioning the distal end of the clamping member in the closed position. The system may further comprise a spring member intercoupled between the clamping member and the tensioning member base and configured to bias the distal end of the clamping member into the closed position. The tensioning member base may comprise a series of apertures for passing a length of a suture member therethrough, such that frictional loads are imparted on the suture member as it is pulled in either direction that may be relatively easily overcome with manual loading of the suture member. The system may further comprise a length of a suture member threaded through the series of apertures in a pattern comprising a number of complete loops that is between about 1 loop and about 2 loops. The tensioning mode switching member may comprise an elongate rod having proximal and distal ends, the elongate rod distal end being removably coupled to the clamp member in a manner that the distal end of the clamp member is held in the open position relative to the tensioning member base until the elongate rod distal end is controllably decoupled from the clamp member, thereby allowing the clamp member distal end to assume the closed position relative to the tensioning member base. The rod distal end may comprise a threaded interface configured to be rotatably mated with a threaded aperture formed in the clamping member. The proximal end of the elongate rod may comprise a manual twisting interface to facilitate rotation of the elongate rod to induce decoupling of the elongate rod and clamping member. The suture clamping member may define a controllably closeable gap through which the suture member may be passed, such that in an open position, the suture member may be moved freely through the gap in both directions, and in a closed position wherein the gap is closed, the suture member may be pinch-immobilized relative to the

clamping member by the closed gap. The clamping member may be biased to assume the closed position, but may be held in the open position by the mode switching member. The mode switching member may comprise an elongate rod having proximal and distal ends, the elongate rod distal end being removably coupled to the clamping member in a configuration wherein the gap of the clamping member is maintained in the open position, and wherein a controlled decoupling of the elongate rod distal end from the clamping member allows for the gap of the clamping member to assume the closed position. At least a portion of the clamping member may be directly coupled to the tensioning member base. The system may further comprise an elongate tubular member defining a lumen therethrough, through which a suture member may be threaded and tensioned from a proximal position reachable by an operator, the elongate tubular member being interposed between the tensioning member base and the proximal position and configured to allow for compression of the tensioning member base between the tissue structure and the proximal position by loading the suture member in tension and the elongate tubular member in compression at the proximal position. The system may further comprise a temporary suture member clamp coupleable to a proximal portion of a suture member adjacent the proximal position and configured to retain tension upon a portion of suture member distal to the suture member clamp that is threaded through the lumen of the elongate tubular member. The temporary suture member clamp may comprise a releasable mechanical pinch clamp. The temporary suture member clamp may comprise a reel rotatably coupled to a housing, the housing being configured to be manually held by an operator. The reel and housing may be rotatably coupled in two selectable modes, such that in a first mode, the reel may freely rotate bidirectionally relative to the housing, and in a second mode, the reel may only be rotated unidirectionally relative to the housing. The system may further comprise a mode selecting member that may be manually manipulated by an operator to switch the reel and housing rotational coupling mode back and forth between the first and second modes. The system may further comprise a fabric pledget sock configured to substantially encapsulate at least the tissue interface surface of the tensioning member base and encourage biointegration of the tensioning member base and adjacent portions of the tissue structure. The fabric pledget sock may comprise a durable polymer selected from the group consisting of: polyethylene terepthalate, polyethylene, high density polyethylene, polypropylene, polytetrafluoroethylene, expanded polytetrafluoroethylene, poly (ethylene-co-vinyl acetate), poly(butyl methacrylate), and co-polymers thereof. The fabric pledget sock may comprise a bioresorbable polymer selected from the group consisting of: polylactic acid, polyglycolic acid, polylactic-co-glycolic acid, polylactic acid-co-

caprolactone, poly (block-ethylene oxide-block-lactide-co-glycolide), polyethylene glycol, polyethylene oxide, poly (block-ethylene oxide-block-propylene oxide-block-ethylene oxide), polyvinyl pyrrolidone, polyorthoester, polyanhydride, polyhydroxy valerate, polyhydroxy butyrate, and co-polymers thereof. The fabric pledget sock may comprise a bioresorbable material selected from the group consisting of: porcine collagen matrix, human collagen matrix, equine collagen fleece, gelatin, polyhyaluronic acid, heparin, poly (glucose), poly(alginic acid), chitin, chitosan, cellulose, methyl cellulose, hydroxyethylcellulose, hydroxypropylcellulose, carboxymethylcellulose; polylysine, polyglutamic acid, albumin, hydroxy apatite, cortical bone, cancellous bone, trabecular bone, bioceramic, ligament tissue, tendon tissue, dura tissue, fascia tissue, pericardium tissue, thrombin, and fibrin.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 illustrates aspects of the human heart anatomy.

Figure 2 illustrates a conventional transapical access procedure.

Figures 3A to 3K illustrate various aspects of an experimental configuration.

Figures 4A to 4P illustrate various aspects of a compound helical closure configuration featuring a single helical member.

Figures 5A to 5I illustrate various aspects of a compound helical closure configuration featuring two helical members configured to simultaneously deploy two sutures and two anchor elements.

Figure 6 illustrates an embodiment wherein one or more tools may be installed and utilized before installation of a helical closure assembly.

Figures 7A to 7B illustrate a two-suture helical closure with anchoring elements deployed partially across the subject tissue wall.

Figures 8A to 8B illustrate a two-suture helical closure with anchoring elements across the subject tissue wall.

Figure 9A illustrates a suture embodiment having barbs along a significant portion of its length; Figure 9B illustrates a suture embodiment having barbs only on its distal portion.

Figures 10A to 10F illustrate aspects of an experiment utilizing embodiments such as those shown in Figures 3A to 3H.

Figures 11A to 11J illustrate aspects of an experiment utilizing embodiments such as those shown in Figures 4A to 4N.

Figures 12A to 12C depict techniques for implementing various embodiments of the subject helical closure configurations.

Figure 13 illustrates one needle structure embodiment having a channel formed therein for localized suture storage.

Figure 14 illustrates one needle and suture arrangement wherein a sawtooth pattern is utilized for localized length storage functionality.

Figures 15A-15J illustrate various aspects of a compound helical closure configuration featuring a single helical member and a one-way tension retainer.

Figure 16 illustrates a technique for implementing various embodiments of the subject helical closure configurations.

Figures 17A-17F illustrate various aspects of a compound helical closure configuration featuring a pair of helical members and a controllably-locking tension retainer.

Figure 18 illustrates a technique for implementing various embodiments of the subject helical closure configurations.

Figures 19A-19Z-8 illustrate various aspects of a compound helical closure configuration featuring a pair of helical members and a two-way / one-way controllably-advanceable tension retainer.

Figure 20 illustrates a technique for implementing various embodiments of the subject helical closure configurations.

Figure 21 illustrates various aspects of one embodiment of a helical closure configuration having a relatively shallow angle of approach.

Figure 22 illustrates various aspects of one embodiment of a helical closure configuration having a relatively large effective angle of approach.

Figures 23A and 23B illustrate aspects of one embodiment of a helical closure configuration having a relatively large effective angle of approach and features to decrease slipping of nearby tissue structures.

Figure 24 illustrates a technique for implementing various embodiments of the subject helical closure configurations.

Figure 25 illustrates a configuration wherein slack is utilized both proximally and distally to a deployed helical suture pattern.

Figure 26 illustrates a technique for implementing various embodiments of the subject helical closure configurations.

Figure 27 illustrates a technique for implementing various embodiments of the subject helical closure configurations.

Figures 28A-28D illustrate configurations wherein temporary suture member fixation may be employed.

Figure 29 illustrates a technique for implementing various embodiments of the subject helical closure configurations.

Figure 30 illustrates a technique for implementing various embodiments of the subject helical closure configurations.

Figure 31 illustrates a technique for implementing various embodiments of the subject helical closure configurations.

Figure 32 illustrates an embodiment of an anchor member featuring a flex tail configuration.

DETAILED DESCRIPTION

Referring to Figures 3A through 3H, various embodiments associated with a transapical access and closure system are depicted, including certain experimental and illustrative configurations. As shown in Figure 3A, a transapical access assembly is depicted comprising a needle (34) placed through an elongate dilator member (42), which is slidably positioned through a working lumen of an introducer sheath (44) which may be manipulated using a proximal handle or hub (46). The assembly has been placed through a thoracotomy created in the chest wall (40) of a patient, and directed toward a location on the heart (2) that is determined to be close to the apex (24) of the left ventricle (20) using information derived from sources such as anatomic markers, preoperative diagnostic imaging information, such as radiography and/or fluoroscopy, and intraoperative imaging information derived, for example, from radiography, endoscopy, and/or fluoroscopic imaging of portions of the access assembly which may be radioopaque (or radioopaque markers which may be fastened to portions of the assembly in one embodiment). Referring to Figure 3B, a close-up view of certain structures depicted in Figure 3A is shown. Figure 3C illustrates that with a transventrical, or more specifically, transapical, approach, the elongate guiding member (34), such as a needle (which may be subsequently utilized to advance a guidewire), may be the first structure advanced (50) into or across the heart wall (48). Figure 3D illustrates a close up detail view of one embodiment wherein an elongate guiding member comprises a straight needle (32) that has been advanced (50) across the heart wall (48) with a suture (52) helically wrapped around it and terminating near the distal end of the straight needle (32) with an anchor element (54). In experiments, we have found that certain variations of such a configuration may be utilized to advance a suture (52) into a position partially or entirely across a tissue wall (48) with the spiral configuration retained on the way in (indeed, tension, friction, and pressure applied to the helically wound suture 52 tends to keep it in its helical configuration during entry; additional proximal tension on the suture 52 may also be utilized to assist in retention of the spiral configuration). Further, we have demonstrated that by

withdrawing the needle (32), the anchor element (54) retains the distal suture (52) position and the suture (52) is unfurled and left behind in a substantially helical or "coiled" configuration. Figures 3E and 3F, for example, illustrate that upon withdrawal (56) of the straight needle (32) and release of suture tension which may be keeping the suture helically in place relative to the guiding member (34), the anchor element (54) configured to prevent withdrawal of the distal end of the suture (52) and the unfurling action of the suture leave a coiled or helical suture (52) configuration in place. We have also found that the retained helical suture (52) pattern accommodates significant longitudinal expansion (i.e., in the range of 200% to 300% strain) without applying significant slicing type loads to nearby tissue structures, as demonstrated in Figures 3G and 3H, wherein the helical suture (52) pattern is substantially retained as the tissue wall (48) or pertinent portion thereof is strained from an initial length of "L" to a length of "L+deltaL". Referring to Figure 3G, with the suture in its deployed coiled configuration with adjacent tissues substantially unloaded, the coil diameter of the helical suture configuration is may be represented by "CD1" (61). Referring to Figure 3H, with elongation (64, 62) of the nearby tissue structure (48), the localized length storage provided by the coiled configuration provides extra length fairly uniformly across the suture, which prevents cutting loads against the nearby tissue, and which results in a smaller coil diameter (63) as further length is extracted out of the coiled configuration, ultimately leading to a substantially uncoiled, or completely uncoiled, linear suture configuration without additional localized suture length storage. This notion of localized length storage may be utilized quite effectively in surgical procedures wherein it may be desirable to incrementally and efficiently close ports, wounds, and the like without laceration of nearby tissue, which may be associated with more conventional suture-tightening configurations. In other words, many conventional "purse-string" type suture configurations lead to simultaneous motion and loading at the interface between suture material and tissue, which can lead to undesirable cutting of the tissue. With adequate localized length storage, incremental tightening may be conducted with significantly reduced risk of tissue cutting due to the fact that the coiling facilitates tightening with reduced interfacial loading until the very end of the tightening range, at which point very little motion is required to complete the requisite tightening paradigm (depending upon the pertinent tissue structures, desired loading, etc). Referring to Figures 3I-3K, this helical configuration for localized length storage may be utilized not only with straight needle members (32), as in Figure 3I, but also with curved needle members (28), as in Figure 3J, and helical needle members (66), as in Figure 3K.

Figures 4A-4P depict aspects of one embodiment of a compound helical closure configuration utilizing a suture (52) helically wound ("first" or "suture helix") around a helical needle member (66 – "second" or "needle helix"), as previously shown in Figure 3K. Further embodiments are described in Figures 5A-9B, while Figures 10A-11J depict images of some of our confirming experiments, and Figures 12A-12C depict aspects of methods for utilizing related configurations in surgical procedure embodiments.

Referring to Figure 4A, a deployment, or delivery, member (14) is shown with a compound helical configuration at its distal end, comprising a suture, or suture member, (52) helically wound around a helical member (66). A tensioning element, such as an elongate tubular member defining a lumen therethrough, (16) is proximally coupled to the suture (52), and a manual tensioning interface (18) is coupled to the proximal aspect of the tensioning element (16) to allow an operator to apply tension to the suture (52) from a proximal location. Figure 4B shows a close-up view of the distal portion of the deployment configuration of Figure 4A, with the compound helical suture (52) configuration, distal anchoring element (54), and elongate tracking member, or "helical member guiding member", (68) more visible. The elongate tracking member (68) may be utilized in an "over the wire" or "over the needle" configuration relative to an associated needle or guidewire, and particularly in the scenario of a guidewire (which is generally substantially more flexible than a needle), is configured to maintain the tracking of the helical needle member (66) during advancement (i.e., to prevent "walking around" of the helical needle, as may be possible with only a flexible guidewire for tracking). The distal end of the helical member guiding member (68) may be substantially straight, as depicted, and define a longitudinal axis that is substantially coincident with that of the helical member. The helical member guiding member may be coupled to the delivery member, which is coupled the helical member, as shown; the helical member guiding member may also be immediately coupled to the helical member.

Referring to Figure 4C, a configuration such as that depicted in Figures 4A and 4B may be utilized to deploy a compound helical suture across a tissue structure wall (48) or portion thereof. In the depicted embodiment, an elongate guiding member (34) such as a needle or guidewire has already been advanced across the wall (48), but in other embodiments, this need not be the case (i.e., the tracking member 68 itself may serve as a guiding member to keep the assembly on track). Indeed, one of the key advantages of the depicted configuration is that it may be deployed to pre-install a helical closure suture configuration that may be generally inspected and examined before the installation or insertion of other diagnostic and/or interventional tools. In other words, before taking the

risk of installing and utilizing generally larger tools, which require a larger wound, a closure paradigm may be pre-installed and inspected beforehand, thus taking some of the risk out of the procedure.

Referring again to Figure 4C, in the depicted embodiment, an elongate guiding member (34) has been installed, and the elongate tracking member (68) is being guided in an "over the wire" form as the deployment member (14) is advanced (70) and rotated (72). Referring to Figure 4D, with further advancement (70) and rotation (72) to rotationally advance the helical member (66), the suture (52) compound helical portion is advanced across a portion of the tissue wall (48) and the anchoring element (54) is positioned within the tissue wall (54). In one embodiment, the assembly may be loaded in both compression and rotation (i.e., both pushed and torque simultaneously); in another embodiment, only a rotational load is used to advance the assembly. Preferably the distal ends of the needle members are sharpened to easily dive into a cross portions of the subject tissue structure, and the anchor members are configured to have at least one shape feature that is configured to slide in easier than it is to slide out (i.e., it preferably will resist retraction, either through a barbed type of feature, or by changing position and/or orientation relative to the surrounding tissue, as with a toggle bolt type of configuration, as described in further detail below). Preferably a reversal in needle member direction relative to the surrounding tissue applies a reverse load on the anchor members which causes them to decouple from their insertion positions upon the helical needle members. In one embodiment, the needle member comprises an anchor coupling portion that is locally decreased in outer diameter to accommodate slidable coupling through a lumen defined through an anchor, such that the outer diameter of the anchor during advancement/delivery may be sized substantially similar to the outer diameter of the helical needle

In another embodiment, the anchoring element may be advanced completely across the tissue wall (48), as illustrated, for example, in Figures 8A and 8B. The embodiment of Figure 4D also features several sensors configured to facilitate an operator's awareness of the positioning of the helical member (66) relative to the subject tissue. In the depicted embodiment, a first RF sensor (85) is coupled to the distal aspect of the helical needle member (66) to capture electrocardiogram ("EKG") related signals which are detectable at the outer surface of the heart (the first RF sensor 85 may be operatively coupled via a lead 87 disposed through the needle 66 and through the proximal deployment member 14 to an EKG-related signal processing system 92, such as those available from the Prucka division of General Electric, Co.). With such a configuration, as the helical needle (66) first comes into

contact with the outside of the heart, such contact may be detected. The configuration in Figure 4D also features a similar second RF sensor (86) similarly coupled to the EKG system (92) via a lead (90) and positioned at the distal aspect of the deployment member (14) such that it will contact the outside of the heart or other tissue structure (48) when the helical member (66) is fully advanced (70, 72). The depicted embodiment also features an optical coherence tomography ("OCT") system (94) configured to use interferometry computation and an optical fiber (88) terminated at a lens (86) to compute proximity to the nearby tissue wall (48) and other structural thresholds, such as the opposite wall of the tissue structure. As described above, the suture (52) may be tensioned (80) during deployment to retain the helical interfacing of the suture (52) with the helical member (66).

Referring to Figure 4E, with the compound helical aspect of the suture (52) in a desired location across the tissue wall (48), the deployment member (14) may be retracted by withdrawing (76) and counterrotating (74) it (or, as discussed above, simply counterrotating) while any proximally applied tension on the suture (52) is released, thus applying a reverse load to the anchor member which causes it to become decoupled from the helical needle member (66) and assume a load resisting configuration (by rotating, expanding, loading a barb or other projecting member, etc, as described below), causing the suture (52) to separate from the needle member (66) and remain coiled in place, still coupled to the anchor member, as shown in Figure 4F. As noted above in reference to the advancement of the helical needle assembly, the assembly may be advanced or retracted using either a combination of compressive or tensile loading (i.e., slight pulling for retraction or pushing for advancement – on a proximal manual interface) added to rotational loading (i.e., torque to a proximal manual interface either clockwise or counterclockwise) – or with only rotational loading (i.e., simply screwing the assembly in and out without concomitant tensile or compressive loading). Figure 4F shows the deployment member (14) and helical member (66) completely withdrawn from the tissue wall (48), leaving behind the anchor element (54) and the suture (52) in a compound helical pattern ("compound" in that the suture remains helically coiled, and the coil remains in a helical configuration). Figure 4G shows the deployment member (14) and helical member (66) completely removed, with the elongate guiding member (34) remaining in place, along with the deployed compound helical suture (52) and suture anchor element (54).

Figure 4H depicts an orthogonal view of the deployed compound helical suture (52) and suture anchor element (54), which are configured at deployment, by virtue of the geometry of the helical member (66), to have an outer shape width that may be represented as

"W" (96). The un-tensioned compound helical suture (52) configuration has an unloaded coil diameter of "CD1" (61). As described above in reference to our experimental findings, this deployment paradigm provides significant flexibility for diagnostic and interventional paradigms that follow, as the tissue/suture/anchor assembly may be strained in many directions quite significantly without disturbing the generally compound helical deployment of the suture, and with significantly less risk of lacerating tissue during expansion or tightening due to the localized length storage provided by the coil configuration. For example, as shown in Figure 4I, a dilator (42) is advanced (100) over the elongate guiding member (34). The relatively large outer shape of the dilator urges (98) the surrounding tissue outward, and generally causes the orthogonal dimension of the larger suture helix to become greater than "W", but generally does not take the suture (52) out of the compound helical configuration. With the localized length storage being utilized to provide the extra length needed to increase to a larger included tool diameter, the suture (52) coil diameter decreases. Referring to Figure 4J, an even larger tool (102), say having outer diameter of "W+deltaW" (104) may follow after the dilator (element 42 of Figure 4H) has been proximally removed (i.e., through a sheath with hemostatic valve). This larger tool shape further locally urges (106) the tissue outward (the larger diameter causing further decrease of the coil diameter due to further take up of the localized length storage; perhaps to a new, smaller coil diameter of "CD2"), but the compound helical patterning of the suture (52) is retained while the tool (102) is in place to, for example, deploy a prosthetic heart valve, etc. Referring to Figure 4K, when a tightening and/or closure of the wound is desired (for example, it may be desirable to tighten the wound to prevent leaks during the diagnostic and/or interventional steps using the aforementioned tool 102), the proximal aspect of the suture (52) may be tensioned (108), causing both of the involved helical shapes to shrink: the larger helical shape of the coils shrinks around the engaged tool, and the coiling helix itself shrinks away with tensioning as the localized length storage is used up. This combined helical shrinking action causes the captured wound or defect to close, as shown in Figures 4L and 4M, wherein the tapered shape of a dilator inserted (i.e., through a hemostatically valved sheath) after withdrawal of the tool (element 102 in Figure 4I) may be utilized along with a successive tightening (108) interplay with the suture (52) to close the wound or defect behind the withdrawing (110) dilator (42). In other words, successive rounds of dilator withdrawal (110), then suture tightening (108) may be utilized to incrementally close the wound or defect. The suture (52) in Figures 4L-4P is shown with the localized length storage effected used up, and the suture forming a generally uncoiled configuration as it continues to hold the larger helical pattern around the

captured wound and tools. Referring to Figure 4M, with the needle (34) and dilator (42) retracted, a guidewire (36) may be left in place and the wound substantially closed around the guidewire (36), as shown in Figures 4M-4O, to provide an easy return access subsequent to a period of observation. For example, in an embodiment wherein a prosthetic valve has been placed with the aforementioned tools (102), it may be desirable to close the wound and leave a guidewire (36) in place during a few minutes of observation of the valve prosthesis in situ, to confirm adequate function while also having a fast and efficient return means (the guidewire 36) should this be required.

Referring to Figure 4N, with only the anchor element (54), guidewire (36), and suture (52) left behind, the suture (52) may be tied into a knot and terminated at the proximal wall of the tissue structure (48), or a terminating device (114) may be advanced (116) along the suture and snugged into place against the wall (i.e., to retain a desired level of tension in the deployed suture 52), followed by cutting of the proximal un-needed portion of the suture, as shown in Figure 4O. In another embodiment, two or more compound helical sutures may be similarly deployed in sequence before advancement of the dilator (42) and/or tool (102); for example, in one embodiment, two compound helical sutures may be sequentially deployed in different helical directions; in another embodiment, the two may be in the same helical direction but at slightly different winding offsets; many embodiments are within the scope of the invention. Referring to Figure 4P, subsequent to confirmation that no additional intervention is necessary, the guidewire (36) may be removed (37).

Referring to Figures 5A and 5B, an embodiment is depicted wherein two helical members (66, 67) coupled to the same deployment member (15) but having different helical radii (see, for example, the top orthogonal view of Figure 5C) may be utilized to simultaneously install, via rotation (180) and insertion (182), two compound helical sutures (52, 53), each having its own anchoring element (118, 120). The distal portion of such construct showing the helical members (66, 67) and anchors (118, 120), but not the compound helically wound sutures (elements 52 and 53 of Figure 5A) is shown in orthogonal close-up view. Referring to Figures 5E-5I, various anchoring element configurations (118, 122, 126, 122, 130) may be utilized to retain a distal suture end within or across a tissue structure wall. Each of the configurations of Figures 5E through 5H has a geometry that prefers to be advanced in one direction, but resists retraction in the opposite direction when placed against viscoelastic tissue, such as that of the heart or other human tissues. Element 122 represents one or more coupling holes to facilitate coupling with the pertinent suture (52, 53). The configuration of Figure 5I is a simple knot (130) tied in the end of the suture (52)

with enough geometric bulk to prevent pullback through the subject tissue. Referring to Figure 32, another anchor member embodiment is depicted, this one (406) comprising a tubular body comprising Nitinol superalloy heat formed in an arcuate/helical shape to match the helical needle member to which it is to be paired, with a Nitinol flex tail (404) configured to resist retraction, and a tapered leading geometry (402) configured to assist with easy insertion/advancement. A titanium suture coupling ring, or ring member, (398) defining a suture-coupling aperture (408) is coupled to the body using a press fit, welded (such as tack welded), or adhesive junction. The flex tail (404) is configured to flex inward toward the helical needle member during insertion, and to flex outward to resist retraction and assist the anchor member body (400) in rotating to an orientation approximately perpendicular to that assumed by the anchor member body (400) during insertion (i.e., toggling to a reorientation that resists retraction). Preferably the eyelet (408) is optimally positioned to urge the anchor member body into rotational movement relative to the surrounding tissue upon tensile loading of the intercoupled suture member. In the depicted embodiment, the eyelet (408) is displaced apart from a longitudinal axis of the body and approximately in the middle of the body longitudinally. Another embodiment may comprise two or more flex tails. The superalloy (such as Nitinol) flex tail, or tails, may be shape set to a projecting position (i.e., projecting out and away from the body), but configured to be delivered in an elastically compressed form (i.e., with the tail deflected toward the body of the anchor member) within the superelastic thermal range for the alloy.

The anchor may comprise a metal selected from the group consisting of: titanium, stainless steel, cobalt chrome, and alloys thereof. The anchor may comprise a durable polymer selected from the group consisting of: polyethylene terepthalate, polyethylene, high density polyethylene, polypropylene, polytetrafluoroethylene, expanded polytetrafluoroethylene, poly (ethylene-co-vinyl acetate), poly(butyl methacrylate), and co-polymers thereof. The anchor member may comprise a bioresorbable polymer selected from the group consisting of: polylactic acid, polyglycolic acid, polylactic-co-glycolic acid, polylactic acid-co-caprolactone, poly (block-ethylene oxide-block-lactide-co-glycolide), polyethylene glycol, polyethylene oxide, poly (block-ethylene oxide-block-propylene oxide-block-ethylene oxide), polyvinyl pyrrolidone, polyorthoester, polyanhydride, polyhydroxy valerate, polyhydroxy butyrate, and co-polymers thereof. The anchor member may comprise a biological graft material, such as one that has an origin selected from the group consisting of: another human, the particular human, a non-human animal. The anchor member may comprise a bioresorbable material selected from the group consisting of: porcine collagen

matrix, human collagen matrix, equine collagen fleece, gelatin, polyhyaluronic acid, heparin, poly (glucose), poly(alginic acid), chitin, chitosan, cellulose, methyl cellulose, hydroxyethylcellulose, hydroxypropylcellulose, carboxymethylcellulose; polylysine, polyglutamic acid, albumin, hydroxy apatite, cortical bone, cancellous bone, trabecular bone, bioceramic, ligament tissue, tendon tissue, dura tissue, fascia tissue, pericardium tissue, thrombin, and fibrin.

Referring to Figure 6, an another embodiment, a configuration such as those described in relation to Figures 4A-4N or 5A-5I may be advanced into position relative to a tissue wall after a tool (102) or other structure has been deployed across the wall (48). Referring to Figures 7A-7B, a configuration such as those described in reference to Figures 5A-5I or 6 may be utilized to close a wound or defect after withdrawal of a tool (102), leaving behind only sutures (52, 53) and anchoring elements (118, 120). Referring to Figures 8A-8B, it is important to note that the anchors need not be deployed within the midsubstance of the tissue structure to facilitate a successful closure, but may be deployed across such structure, to reside at the opposide side of the subject wall (48). Referring to Figure 9A, in one embodiment, the suture (52) may feature barbs (132) to prevent slipping relative to the tissue structure (48) after deployment. Referring to Figure 9B, a suture (52) embodiment is depicted wherein only distal barbs (132) are utilized, and wherein the slip prevention provided by such barbs (132) obviates the need for an anchoring element (in other words, the embodiment shown in Figure 9B is a "suture only" embodiment).

Referring to Figures 10A-10F, several images are depicted to illustrate the experiments we have completed to establish the flexibility and functionality of configurations such as those described in reference to Figures 3A-3H and 4A-4N. Referring to Figure 10A, an elongate guiding member (34) is depicted with a suture (52) helically coupled thereto and terminated with a knot type anchoring element (130). Referring to Figure 10B, with proximal tensioning of the suture (52) and advancement of the construct through a simulated tissue structure (48) (which happens to be conveniently translucent for experimental purposes), the helical patterning of the suture (52) relative to the elongate member (34) is retained along substantially the entire length of the elongate member (34) during insertion (i.e., there is no "bunching"). Referring to Figures 10C and 10D, with a release of the tensioning on the suture (52) and proximal withdrawal (134) of the elongate member (34), the suture (52) stays in place in its helical configuration. Referring to Figures 10E and 10F, with relatively significant strain (exemplified here by a strain from length L 60 to length L+deltaL 62; recall that strains as high as 200% to 300% or more may be accomodated), the helical patterning of

the suture (52) is generally retained. With the strain applied (from Figure 10E to Figure 10F), the coil diameter (61) shrinks from CD1 to CD1 (63) as the localized length storage is used up.

Referring to Figures 11A-11F, several images are depicted to illustrate the experiments we have completed to establish the flexibility and functionality of configurations such as those described in reference to Figures 4A-4P. Referring to Figure 11A, a deployment member (14) coupled to a single helical member (66) and tracking member (68) is depicted, with the tracking member (68) being advanced over an elongate guiding member (34) that has been deployed across a muscle tissue wall (48). A single suture (52) is helically wound around the helical member (66) and terminated with a knot anchoring element (130). Figure 11B shows the construct being advanced and helically rotated into the tissue wall (48) with a tension being retained on the suture (52) from a proximal location. Referring to Figure 11C, on the opposite side of the tissue wall (48), the anchoring knot element (130) has reached the other side adjacent to the location wherein the elongate guiding member (34) passes out of the tissue wall (48). Importantly, a uniform radial margin of tissue is retained between the helical needle (66) and the center of the wound adjacent the elongate guiding member (34) (i.e., the suture is not lacerating through the tissue). Referring to Figure 11D, with release of the tension on the suture (52) and withdrawal/counterrotation of the deployment assembly (66, 68, 14), the deployed suture (52) retains its compound helical configuration within the muscle tissue. Figure 11E depicts a dilator (42) being advanced through the deployed suture compound helix, and Figure 11F depicts further advancement to illustrate that relatively significant dilation may be required to accommodate various diagnostic and/or interventional tools for various procedures – and that the compound helical suture configuration is quite flexible in accommodating such large dilations, while retaining the ability to be controllably tightened from a proximal location at any time. It is worth noting that in our experiments, proximal tightening of a single helical suture configuration (i.e., deployed with a helical needle but not with helical coiling in a helical pattern) resulted in significant undesirable laceration of the tissue (particularly the tissue captured between the helical needle/suture and the wound centerpoint), something that we have not found with the compound helical deployment, due to the localized length storage provided with the coiling. Figure 11G shows that a relatively large wound or port has been created following removal of the dilator (42). Referring to Figure 11H, with a simple sheath (136) to isolate the free proximal portion of the suture (52), tensioning of the suture (52) to execute a closure or partial closure may be initiated. Referring to Figure 11i, with further tensioning of the suture

(52), the wound or port is closed around the elongate guiding member (34). Referring to Figure 11J, on the opposite side of the wall, the suture (52) and anchor element (130) based closure execution is evident.

Referring to Figures 12A-12C, techniques for utilizing the subject configurations are illustrated. Referring to Figure 12A, after preoperative diagnostics and patient preparation (138), access may be created (140) to the subject tissue structure (for example, a thoracotomy may be created to access the wall of the heart, the heart wall being the subject of the subsequent wall crossing and closure). The subject tissue structure may be at least partially crossed (142) using an elongate guiding member such as a needle, which may be navigated utilizing various imaging, sensing, and/or navigation modalities. The needle may be followed by a guidewire (i.e., a guidewire advanced through the needle). One or more helical needle/suture assemblies may be advanced (144) across a portion of the tissue wall following the elongate guiding member (or in another embodiment, without the assistant of a guiding member); then the helical member may be axially and rotationally withdrawn to place an anchoring element and compound helical suture into a configuration wherein they may be subsequently utilized to effect a closure (146), and such configuration may be confirmed (148) before further interventional steps. Subsequent to confirmation that a closure configuration appears to be ready, a dilator (150) and/or other tools (152) may be advanced through the suture helix, thereby expanding the suture helix so that pertinent diagnostic and/or interventional steps may be accomplished, such as the installation of a heart valve. Subsequently, the dilator may be re-inserted (i.e., using a hemostatically-valved sheath) in place of the diagnostic and/or interventional tools (154), and the tapered outer shape of the dilator may be utilized to effect an incremental tightening of the wound or port. A guidewire may be left in place as a "test closure" is accomplished around the guidewire to permit observation of the intervention while also permitting easy re-access. The closure may be completed with full withdrawal of the dilator, needle, and guidewire, and proximal fixation of the suture end or ends to retain tension (156).

Referring to Figure 12B, an embodiment similar to that of Figure 12A is depicted, with the exception that traversal of the deployment assembly may be detected using sensors such as an EKG (electrocardiogram) electrode or a proximity/contact sensor, such as an ultrasound transducer and analysis system and/or an OCT fiber and signal processing system (158). In another embodiment such as that described in reference to Figure 4D, another EKG-signal related sensor coupled to a distal portion of the needle may be utilized to detect initial contact of the needle and heart wall.

Referring to Figure 12C, an embodiment similar to that of Figure 12A is depicted, with the exception that after crossing the subject tissue structure with an elongate guiding member (142), a dilator and other tools are advanced into place and utilized (160, 162) before deployment of any compound helical sutures through advancement of pertinent helical members/sutures/anchors (164) and withdrawal (166) of the helical members to leave the sutures and anchors behind. With one or more compound helical sutures and anchor elements in place, the tools may be withdrawn, and an incremental tightening/closure effected (168), followed by completion of the closure and fixation of the pertinent proximal suture ends (156).

Referring to Figure 13, localized length storage of suture material (52) relative to a needle structure (28, 32, 66) may be facilitated wherein the needle structure (28, 32, 66) defines a channel into which the suture material (52) may be fitted during deployment; preferable the fit with such channel is loose enough that the suture material (52) will deploy (184) easily out of the channel as the needle structure (28, 32, 66) is withdrawn.

Various suture (52) materials may be utilized in accordance with the subject invention, including resorbable and nonresorbable polymeric sutures, woven sutures, highly stretchable sutures (the "stretch" of which may be utilized to facilitate localized length storage functionality), and metallic sutures or suture-like structures, such as fine gauge nitinol wire configured to form a compound helix as described above. Referring to Figure 14, a sawtooth pattern of a suture (52) may be utilized for localized length storage functionality in relation to a needle device (32). In the depicted embodiment, after insertion, a proximal tag (188) coupled to a removable coupling member (186) that temporarily holds a "zig zag" or "sawtooth" suture length storage pattern in place may be pulled (190), allowing the suture (52) to uncouple from the needle (32), akin to the unfurling action of the aforementioned compound helical configurations.

Referring to Figures 15A-20, various aspects of additional embodiments of helical needle configurations for effecting suture-based closure procedures are illustrated. Figures 15A-16 illustrate aspects of a configuration wherein a single helical needle member may be utilized to advance a suture, and wherein a 1-way tension retainer may be separated from a deployment assembly to become a suture-tension-retaining prosthesis against the outside of the subject tissue structure. Figures 17A-18 illustrate aspects of a configuration wherein a twin helical needle configuration may be utilized to advance two suture members, and wherein a pair of implantable controllably-locking tension retainers may be used in concert with a pair of load-spreading engagement members to retain tension and/or positioning of the

suture members in situ. Figures 19A-20 illustrate aspects of a configuration wherein a twin helical needle configuration may be utilized to advance two suture members, and wherein a pair of implantable 2-way/1-way controllably-advanceable tension retainers may be used in concert with a pair of thrombogenic members to retain tension and facilitate biological fixation of the suture members in situ.

Referring to Figure 15A, an assembly is depicted for deploying a single suture member (52) with a distally affixed anchor member (54) coupled to a helical needle member (66) in manner similar to those described above, with the exception that the proximal portion of the suture member (52) is configured to lead away from the proximal end of the exposed helical needle member (66), into an implantable 1-way tension retainer (200), through a tubular elongate tensioning element (16) removably housed within a slot formed in the elongate deployment member (14), and to a manual tensioning interface (18), such as the small finger handle configuration shown in Figure 15A. Referring to Figure 15B, a close-up view of the configuration of Figure 15A is shown to further illustrate the relationship of the suture member (52) to the tubular elongate tensioning element (16) and implantable 1-way tension retainer (200), both of which are temporarily and removably housed within portions of the elongate deployment member (14). The distal portion of the suture member (52) is shown in a compound helical configuration (i.e., the suture member 52 is helically wrapped around a helical needle member 66), but as described above, this suture may also be deployed in a single helical configuration, wherein the distal suture member (52) portion is simply aligned with the helical winds of the helical needle member (for example, using a suture-retaining slot formed in the helical needle member 66) to form a single helical suture pattern very similar to the helical pattern of the helical needle member (66). For illustrative purposes, compound helical configurations are shown in the embodiments of Figures 15A-15J, 17A-17F, and 19A-19Z-8.

Referring again to Figure 15B, after the helical needle member (66) and associated anchor member (54) and distal portion of the suture member (52) have been driven at least part of the way across the subject tissue structure, as described above, the deployment member (14) may be backed off in a reverse rotational direction to leave behind the anchor member (54) and distal portion of the suture member (52). When ultimate closure of the associated wound is desired, an assembly comprising the manual tensioning interface (18), elongate tensioning element (16), and implantable 1-way tension retainer (200) may be manually separated away from the handle-like body of the elongate deployment member, and the manual tensioning interface (18) may be pulled relative to the somewhat flexible, yet

somewhat stiff in column compression tubular structure of the elongate tensioning element (16) to push the implantable 1-way tension retainer (200) down the suture distally toward the exposed outer wall of the subject tissue structure where it may be cinched into place and left to retain tension on the implanted portion of the suture member (52), after which the elongate tensioning element (16) and manual tensioning interface (18) maybe removed away proximally so that any remaining proximal ends of the suture member (52) may be clipped or tied off, similar to the scenario described above in reference to Figures 4N and 4O.

Figures 15C through 15J illustrate some of the complexities of the 1-way tension retainer (200) and its association with the helical needle member (66), elongate deployment member (14), and suture member (52). Referring to Figure 15C, the elongate tensioning element (item 16 of Figure 15B) has been removed to show the pathway of the suture element (52) proximal of the 1-way tension retainer (200), as well as an additional looped tension element (202) configured to assist with the application of compressive loads to the elongate tensioning element (item 16 of Figure 15B). Figure 15D shows an end view depicting the same structure as shown in Figure 15C, to illustrate the pathways of the suture member (52) and additional looped tension element (202). Referring to Figures 15E and 15F, two different views of a 1-way tension retainer (200) are shown along with an associated suture member (52). As shown in Figure 15E, the 1-way tension retainer (200) comprises an assembly of a housing and a movable door member (204) configured to hinge about a pivot. With the suture member (52) threaded around the door member (204) in a pattern as illustrated in a close up and partial views of Figures 15G-15J, the configuration allows for the suture member to be pulled tight in one direction, but not in the other direction, because the other direction causes the door to pivot down into a clamping configuration versus one portion of the suture member (52) such that the suture member becomes immobile relative to the door member (204) or housing (206). In one embodiment, the door member (204) may be biased to close against the housing (206) with a spring, such as a cantilever or coil type spring, such that a level of compression is always applied upon the portion of the suture member (52) passing through the interface of the door member (204) and housing (206). In other words, in such a configuration, the door member (204) and housing (206) may be biased to clamp down upon the suture member (52).

Referring to Figure 16, a process for utilizing technology such as that depicted in Figures 15A-15J is illustrated. As shown in Figure 16, after preoperative diagnostics and patient preparation (138), access may be created (140) to the subject tissue structure (for example, a thoracotomy may be created to access the wall of the heart, the heart wall being

the subject of the subsequent wall crossing and closure). The subject tissue structure may be at least partially crossed (142) using an elongate guiding member such as a needle, which may be navigated utilizing various imaging, sensing, and/or navigation modalities. The needle may be followed by a guidewire (i.e., a guidewire advanced through the needle). One or more helical needle/suture assemblies may be advanced (144) across a portion of the tissue wall following the elongate guiding member (or in another embodiment, without the assistant of a guiding member); depth of positioning (145) of one or more of the pertinent structures (such as the distal needle tips, anchor member positions, or the like) may be monitored (using an aperture 220 and associated lumen such as that described below in reference to Figure 17B – or a pressure transducer configured to sense pressure at a chosen distal location, the transducer preferably operatively coupled to a means for signaling an operator, such as a small proximally-positioned light that toggles between red and green colors when the given pressure threshold for completed insertion/deployment has been reached); with full insertion/deployment completed, the helical member may be axially and rotationally withdrawn to place an anchoring element and compound helical suture into a configuration wherein they may be subsequently utilized to effect a closure (146), and such configuration may be confirmed (148) before further interventional steps. Subsequent to confirmation that a closure configuration appears to be ready, a dilator (150) and/or other tools (152) may be advanced through the suture helix, thereby expanding the suture helix so that pertinent diagnostic and/or interventional steps may be accomplished, such as the installation of a heart valve. Subsequently, the dilator may be re-inserted (i.e., using a hemostatically-valved sheath) in place of the diagnostic and/or interventional tools (208), and the tapered outer shape of the dilator may be utilized to effect an incremental tightening of the wound or port, using, for example, one or more 1-way tension retainers (200). A guidewire may be left in place as a "test closure" is accomplished around the guidewire to permit observation of the intervention while also permitting easy re-access. The closure may be completed with full withdrawal of the dilator, needle, and guidewire, tightening of the one or more 1-way tension retainers (200), and proximal fixation of the suture end or ends to retain tension (210).

Referring to Figures 17A-20, another embodiment is shown wherein a two needle (66, 67) configuration may be utilized to simultaneously insert two suture members and two associated anchor members. The assembly depicted in Figure 17A includes a sleeve (212) slidably coupled over the elongate delivery member (16). The sleeve (212) may be freely rotatable and longitudinally slidable to assist with atraumatic interfacing of the instrumentation versus nearby tissue structures such as a chest wall wound and nearby

calcified tissue. A manual tensioning interface (18) is coupled to the proximal end of one or more of the suture members, and a touhy assembly (214) may be configured to allow for valved switching of tools and elongate members, such as a guidewire and various catheters. A relatively large surface engagement member (216) is configured to be urged against the subject tissue wall between the tissue and a suture tensioning structure, such as a 1-way tension retainer as described above in reference to Figures 15A-16, or such as the controllably-locking tension retainer (218) shown in greater detail in Figures 17B-17F.

Referring to the close-up orthogonal view of Figure 17B, the relatively flat engagement member (216) and controllably-locking tension retainer (218) are shown, along with an aperture (220) which may be present in any of the aforementioned or depicted variations of the elongate tracking member (68). The aperture may be fluidly coupled to a lumen down the center of the elongate tracking member, and such lumen may become proximally exposed (for example, by a simple exit from the deployment member 14, or via exposure to a window within the deployment member 14 or other associated member, the window being configured to assist an operator in visualizing blood or other fluid that may bleed back through the lumen, indicating that the aperture has been exposed to such relatively high pressure fluid), so that an operator can see if blood or other pressurized fluids are coming through the aperture and through the lumen, as a signal that such aperture has been exposed to such pressurized fluids. Two or more apertures may be similarly used in the embodiments depicted here in Figures 17A-17F, and also the embodiments described in reference to Figures 19A-19Z-8, with each aperture fluidly connected to a lumen, which is connected either to a detection window or lumen for viewing a flash of fluid to which the aperture has been exposed – or coupled to a sensor configured to detect the fluid immersion of the aperture, such as an OCT sensor, an ultrasound sensor, an RF impedance sensor, a partial pressure of oxygen sensor, and/or a pressure sensor. One or more apertures and/or sensors may be geometrically keyed to (i.e., configured to indicate protrusion to the level of): the distal end of a helical needle member, the distal end of an anchor member, the proximal end of an anchor member (i.e., to confirm that the anchor has, for example, crossed a threshold of a distal tissue wall). In one embodiment, for example, the aperture (220) may be longitudinally positioned more distally along the elongate tracking member (68) relative to the longitudinal positions of the distal ends of the needle members (66, 67) to provide an operator with a clear indication that the needle ends are a known distance from pressurized fluid on the other side of the subject tissue wall. In another embodiment, such as that depicted in Figure 17B, the aperture (220) may be positioned with a known distance proximal

to the distal ends of the needle members (66, 67) to provide a signal to an operator that the distal ends of the needle members (66, 67) and associated anchor members should be past the threshold of the recently crossed tissue structure wall, and have reached pressurized fluid on the other side of the wall (i.e., such as in the case of crossing a heart wall into one of the cavities of the heart). In another embodiment, multiple apertures may be present to signal various things to an operator. For example, in one embodiment, a small aperture may be positioned most distally to signal that a first longitudinal position of the elongate tracking member and associated needle complex (66, 67) has been achieved, while a larger aperture (providing a noticeably larger flow rate proximally observed by the user) may be located at another known and more proximal location as another signal to the user. In another embodiment, two or more apertures may be associated with two or more unique lumens to provide clear and distinguished signaling.

Referring to Figure 17C, the movable sleeve member has been removed to more clearly show the elongate deployment member (16) as it is coupled to a lock actuation member housing (222) and a suture conduit housing (228). In the depicted embodiment, both of these housings (222, 228) are distally coupled to a lock actuation distal housing shoe (226) which is coupled to the controllably-locking tension retainer (218). Referring to Figure 17D, the controllably-locking tension retainer (218) is positioned adjacent the engagement member (216), which may comprise a thrombogenic material to function somewhat like a surgical pledget to spread out loads and promote clotting and tissue encapsulation. Referring to Figure 17E, the lock actuation housing shoe (226 in Figure 17D) has been removed to reveal the interfacing (234) of the threaded distal portion of the lock actuation member (230) with the controllably-locking tension retainer (218). A simplified orthogonal view is shown in Figure 17F to illustrate that a length of suture may be passed freely through the slot (232) in the spring-biased (i.e., biased to close and thereby close the slot) tension retainer (218) until the lock actuation member (230) is threaded out (i.e., by manually threading it out using a proximal manipulation interface placed proximal of the proximal end of the lock actuation member housing (222) (see, for example, Figure 17C)), after which the close closes upon the captured suture portion, causing a locking of the suture relative to the tension retainer (218). Thus, in operation, the suture member may be proximally tightened using the manual interface (18), after which the lock actuation member (230) may be threaded out to capture a portion of the suture in the slot (232), thereby locking the tension retainer (218) in place, presumably in a configuration wherein it will apply a load to be spread on the nearby tissue structure by the engagement member (216).

In another embodiment, an active compression locking configuration may be used to allow both relative slideability between the locking configuration and interfaced suture material, and conversion (i.e., subsequent to application of a load) to a fixed relationship wherein relative motion is not allowed. In one embodiment, such an active compression locking configuration may comprise a coupled assembly of two portions that may be compressed against each other to convert to a fixed relationship (i.e., akin to a "split shot" that may be moved or slid along a suture line, then clamped into a fastened position relative to the suture line with a pliers or the like). In another embodiment, two movably coupled – or decoupled – members may be compressed or otherwise loaded together (for example, with a crimping tool) to convert from a relative movement configuration between the fastener and suture line, to a clamped configuration that disallows relative motion. Certain medical grade type crimping fasteners are available from the orthopaedics division of Smith & Nephew, Inc., of Memphis, Tennessee.

Referring to Figure 18, a process for utilizing technology such as that depicted in Figures 17A-17F is illustrated. As shown in Figure 18, after preoperative diagnostics and patient preparation (138), access may be created (140) to the subject tissue structure (for example, a thoracotomy may be created to access the wall of the heart, the heart wall being the subject of the subsequent wall crossing and closure). The subject tissue structure may be at least partially crossed (142) using an elongate guiding member such as a needle, which may be navigated utilizing various imaging, sensing, and/or navigation modalities. The needle may be followed by a guidewire (i.e., a guidewire advanced through the needle). One or more helical needle/suture assemblies may be advanced (144) across a portion of the tissue wall following the elongate guiding member (or in another embodiment, without the assistant of a guiding member); depth of positioning (145) of one or more of the pertinent structures (such as the distal needle tips, anchor member positions, or the like) may be monitored (using an aperture 220 and associated lumen such as that described above in reference to Figure 17B – or a pressure transducer configured to sense pressure at a chosen distal location, the transducer preferably operatively coupled to a means for signaling an operator, such as a small proximally-positioned light that toggles between red and green colors when the given pressure threshold for completed insertion/deployment has been reached); with full insertion/deployment completed, the helical member may be axially and rotationally withdrawn to place an anchoring element and compound helical suture into a configuration wherein they may be subsequently utilized to effect a closure (146), and such configuration may be confirmed (148) before further interventional steps. Subsequent to confirmation that

a closure configuration appears to be ready, a dilator (150) and/or other tools (152) may be advanced through the suture helix, thereby expanding the suture helix so that pertinent diagnostic and/or interventional steps may be accomplished, such as the installation of a heart valve. Subsequently, the dilator may be re-inserted (i.e., using a hemostatically-valved sheath) in place of the diagnostic and/or interventional tools (236), and the tapered outer shape of the dilator may be utilized to effect an incremental tightening of the wound or port, using, for example, one or more controllably locking tension retainers (218). A guidewire may be left in place as a "test closure" is accomplished around the guidewire to permit observation of the intervention while also permitting easy re-access. The closure may be completed with full withdrawal of the dilator, needle, and guidewire, tightening of the one or more controllably locking tension retainers (218), and proximal fixation of the suture end or ends to retain tension (238).

Referring to Figures 19A-20, various aspects of another embodiment for utilizing a twin helical needle (66, 67) configuration to install two or more suture members (52, 53) with anchors (54, 55) are depicted. The assembly of Figure 19A includes a proximal housing assembly (240) configured to be comfortably handled and/or held in place by an operator while a manual rotation interface (244) is turned clockwise or counterclockwise (with the other available hand, for example) to advance a coupling member (246) coupled to one or more (in the depicted embodiment a pair of two) helical needle members carrying suture and anchor elements. The proximal portion of the coupling member (246) may have slots or threads (248) formed therein that are configured to mechanically and movably interface with one or more pins (252). The coupling member (246) is configured to advance or retract relative to the proximal housing assembly (240) in response to rotation of the manual rotation interface (244) coupled to the coupling member (246). A distal housing, or sleeve member, (242) guides the distal portion of the coupling member (246), provides a mechanical platform for a specialized end geometry (as described below), and provides a platform for storing additional suture length locally (also as described below). The coupling member (246) may comprise one or more graduation marks (250) to establish how far the coupling member (246) has been inserted relative to the proximal housing assembly (240). In one embodiment, such graduation marks may be utilized as indicators that the needle members (66, 67) have been inserted into the subject tissue wall by a distance equivalent to the typical thickness of a heart wall, or by some other predetermined amount.

Referring to Figure 19B, a different orthogonal view is illustrated to show that the assembly comprises two suture members (52, 53) and two associated suture tensioning

assemblies (254, 255) that may be removably coupled to the proximal housing assembly (240). In the depicted embodiment, they (254, 255) are configured to temporarily reside within slots or recesses formed within the proximal housing assembly (240).

Referring to Figure 19C, an orthogonal view of the distal end of the assembly of Figures 19A or 19B is shown to illustrate a distal interface member (256) that comprises one or more ramp members (258, 260) configured to locally stretch and reorient tissue that is encountered near the distal tips of the needle members (66, 67), to facilitate capture of such tissue by such needle tips, as opposed to laceration of the tissue when the needle tips are dragged along without capturing, puncturing, and protruding into such tissue. In other words, these ramp members locally increase the angle of approach of the needle tips versus the tissue to increase the odds of capture, puncture, and protrusion of the needle tips into the tissue without laceration or scarification. The depicted embodiment shows two ramp members on each side of the needle member (66, 67) tip such that each needle member (66, 67) tip is nearly encapsulated by the associated pair of ramp members (258, 260). In another embodiment, only one ramp member may be used for the same function adjacent each needle member (66, 67). In use, an operator may manually grasp the proximal (240) and/or distal housing, or sleeve member, (242), push the distal interface member (256) against the targeted tissue structure – thus causing the ramp members (258, 260) to engage, locally stretch, and locally reorient nearby tissue structure subportions, and turn the coupling member (246) with the manual rotation interface (244) to advance the helical needle members (66, 67) and the associated anchors (118, 120; or 54, 55, etc) and suture members (52, 53) into the targeted tissue structure in a predictable format.

Also shown in the close-up views of Figures 19C and 19D is the proximal extension of the suture members (52, 54) from the associated anchor members (118, 120) into a local suture length storage membrane or reservoir (262).

Referring to Figure 19D, each of the ramp member pairs (260) may also be referred to as an indentor member comprising one or more distally protruding shape features (in this embodiment the distally protruding shape features are two ramp members; also viewable as one ramp member that is bisected by the emerging helical needles and associated anchor members). These distally protruding shape features are configured to concentrate interfacial stresses upon the tissue structure such that the portions of the tissue structure that are adjacent to the distal ends of the needle/anchor assemblies become locally strained about the distally protruding shape features as these shape features are advanced into contact with the adjacent tissue structure portions. It is this contact configuration that locally increases the effective

angle of penetration between the anchor/needle assemblies and the tissue structure. Various embodiments may include one or more distally protruding shape features or surfaces that comprise portions of a spherical surface, a linear ramp surface (as shown in Figure 19D, for example, wherein the ramping up along each ramp is substantially linear), an arcuate or nonlinear ramp surface (wherein the ramping is nonlinear), or a single or multiple stepped ramp surface (wherein the ramping comprises discrete steps). The ramping angle in the depicted embodiment is generally parallel to the angle formed as the helical needle and associated anchor emerge from the distal interface member (256), but in other embodiments these geometries may not match. The non-ramped aspect of the depicted embodiment comprises a substantially perpendicular leading surface (i.e., perpendicular to the surface of the distal interface member (256) and generally aligned with a longitudinal axis of the helical needle assembly. The depicted ramp members are bisected by the needle members; in another embodiment, the needle members emerge adjacent to, but not directly through the middle of, the ramp members or other protruding shape features. The shape features in the embodiment of Figure 19D are helical wrapped about approximately the same longitudinal axis as the helical member. In other embodiments, they may be wrapped about a different axis. As described below in reference to Figure 23B, the distally protruding shape features may comprise one or more tissue traction features (such as the barbed features 324 depicted in Figure 23B) configured to prevent relative motion between the distally protruding shape feature and portions of the tissue structure with which it may be directly interfaced.

Referring to Figure 19E, this membrane (262) has a slot or cut defined therein that allows additional suture length to be pulled out of the relatively flat membrane reservoir (262), which may be configured initially to contain a few additional loops worth (264) of length of suture material (52). For example, in one embodiment, a local suture length enclosure, such as one comprising a membrane material with one or more access apertures or slots for the suture member to be drawn out and tensioned proximally, may have one or more loops of suture providing an additional length of between about 20 millimeters and about 500 millimeters that may be pulled out, for example, under tensile loading from associated anchor and helical members advancing into a tissue structure relative to the location of the reservoir, which is generally configured to somewhat fixed relative to the position of the proximal wall of the tissue structure in one embodiment. Thus the suture is coupled distally to an anchor member (118, 120), then is routed through the membrane reservoir (262), into a slot in the proximal housing member (240) to enter a suture tensioning assembly (254, 255), the subportions of which are described below. A different orthogonal view of the assembly of

Figure 19E is shown in Figure 19F. A close view of one of the membrane reservoirs (262) and associated suture member (52) pathways is depicted in Figure 19G.

Referring to Figures 19H and 19X, with the proximal housing member (240) hidden away, the suture tensioning assemblies (254, 255) are more clearly visible. Figure 19X also has the distal housing member, or sleeve member, (242) hidden to show the underlying coupling member (246) extending distally to a sleeved (294) coupling with the helical needle members (66, 67), which are configured to rotatably extend out of the apertures in the distal interface member (256), through the ramp members (258, 260) as described above.

Referring back to Figures 19I-19W, aspects of and operation of the suture tensioning assemblies (254, 255) are depicted. Referring to Figure 19I, a suture tensioning assembly is shown comprising a manual tensioning interface (18) coupled to a distal end of the suture member (52). The suture member extends distally from the manual tensioning interface (18), around a length storage and fixation spool fitting (272), through a lumen formed in a small handle member (268), into a lumen formed through the tubular suture tensioning element (16), through a locking member shoe housing (266) coupled to the distal end of the tubular suture tensioning element (16), into a two-way / one-way controllably advanceable tension retainer (265), and out toward the membrane reservoir (not shown in Figure 19I; element 262 in Figure 19H, for example).

Figures 19J-19L show three different orthogonal views of the same two-way / one-way controllably advanceable tension retainer (265) assembly, which comprises a main housing member (280), a door member (278) rotatably coupled to the main housing member (280), a spring (276) configured to bias the door member (278) closed against the main mousing member (280), as in Figures 19J-19L. The suture member (52) is routed through an alignment aperture (282) in the door member (278) such that it is caught, or "grasped", between the closed door member (278) and the associated surface of the main housing member (280). The bottom of the tension retainer (265) assembly may be coupled to a pad (274) which may be configured to de-concentrate interfacial loads between the bottom surface of the main housing member (280) and nearby tissue structures against which the main housing member (280) may be advanced by virtue of suture member (52) tightening. The pad (274) may comprise a material such as Dacron (RTM), or a nonthrombogenic material treated with a thrombogenic chemical agent or medicine, to assist with clot formation and biological fixation and incorporation. As shown in Figures 19M-19O, an actuation member (284) may be temporarily threaded into the door member (278) to urge (i.e., against the spring 276 load biasing the door member to shut) the door member (278)

open relative to the main housing member (280), thus leaving the suture member (52) relatively unconstrained and free to move in both directions relative to the main housing member (280). By backing out (i.e., by threading out in reverse) the actuation member (284), the door becomes unconstrained by the actuation member, and is urged shut by the spring (276), thus capturing the suture member (52) between the door member (278) and the main housing member (280). With the door member (278) shut, the suture member (52) may still be pulled in an upward (i.e., toward the top of the illustration page containing Figures 19M-19O) to cause further tensioning of the assembly against a subject tissue structure wall, because this 1-way directional tensioning urges the door to slightly open and allow motion of the suture member (52) relative to the door member (278) and main housing member (280); on the contrary, tension downward on the suture member when the door member (278) is shut against the suture member (52) only causes the door to shut even tighter, by virtue of the cam-like geometry of the interface between the door member (278) and suture member (52), as shown, for example, in Figures 19N and 19O. Thus, the assembly is controllably switcheable: from a state of two-way movability of suture (52) relative to locking member (265), to a state of one-way movability (i.e., tightening only) of the suture (52) relative to locking member (265) – and this switching from one mode to another mode is conducted by threading in the actuation member (284) to essentially jack open the door to temporarily have the two-way movability mode. Referring to Figures 19P and 19Q, an experimental loading configuration and data related thereto are illustrated. Figure 19Q features two plots (290, 292) of pull force (286) versus suture displacement (288) to show that the the two-way / one-way switcheable locking member is capable of holding significant loads when in the one-way mode with the door member (278) in a shut position against the subject suture member (52).

Referring to Figure 19R, the various portions of the suture tensioning assembly embodiment are shown in a somewhat deconstructed view. In an assembled configuration, the actuation member (284) may be inserted through a lumen formed by the tubular tensioning element (16) and twisted (i.e., using a proximal manual gripping interface 270) to thread the distal portion of the actuation member (284) into the door member (278) of the two-way / one-way controllably advanceable locking member (265). Figures 19S and 19T show close-up views of the interaction of the proximal portions of the suture member (52) with the spool member (272). Figures 19U-19W show other orthogonal views of various states of assembly of the subject suture tensioning assembly (254, 255) embodiment. Figure 19Y-19Z-1 illustrate various orthogonal views of partial assemblies of the distal end of the subject access and closure instrument to show the positions of the needle members (66, 67),

suture members (52, 53), distal interface (256), suture length storage membranes (262, 263), and elongate tracking member (68) aperture (220) relative to each other.

In one embodiment, the spool member (272) may be utilized to transiently lock down a given length of suture into a tensile state, and subsequently to adjust the length to establish a different tensile state. For example, during a process such as that described above in reference to Figure 12A (element 154 in particular) wherein a dilator or other member is incrementally withdrawn as the one or more sutures are incrementally tightened, the spool member (272) may be utilized to temporarily retain various tensile states during such a process. In another embodiment, a releasable pinching clamp may be utilized to have the same function as described herein for the spool member (i.e., to temporarily retain a given tensile state, while also providing relatively easy releasability for repositioning).

Referring to Figures 19Z-2 and 19Z-3, two embodiments of anchor members (296, 298) are depicted. The embodiment in Figure 19Z-2 may be created from a single piece of tubing using, for example, a laser cutter. An eyelet or suture fastening interface (302) comprises a cut-out portion, as does a tail (300), which is configured to rotate the anchor (296) and grab onto nearby tissues when a suture coupled to the eyelet is pulled from a direction toward the tail (300) – somewhat akin to the action of a toggle bolt. Figure 19z-3 depicts a machined version of a similar structure, created from two parts in one embodiment (the tail 304 being a separate part that is fused with the body); the eyelet (306) may be machined. Either embodiment may have a tapered forward geometry (308, 310), formed, for example, by laser cutting or grinding.

Referring to Figures 19Z-4 to 19Z-8, in use, an assembly such as that depicted in Figure 19A may be advanced against a targeted tissue structure wall, and when in an appropriate position, the positioning of the proximal and distal housing members (240, 242) may be maintained while the manual rotation interface (244) is utilized to rotate the needle members (66, 67) distally out through the distal interface member (256) and into the subject tissue wall (not shown), along with the elongate tracking member (68), which, as described above, may assist in preventing "walking" of the needles relative to the targeted portion of the tissue wall, and/or undesirable localized overstraining of the nearby tissue. Figure 19Z-5 shows a close up view of the needles extended out through the distal interface member into what could be a targeted tissue structure, the needles carrying two machined anchor members (298, 299) which may be coupled to two suture members (not shown). As described above, one or more apertures or sensors on various portions of the distal hardware, along with one or more graduation marks (250) on the proximal coupling member (246) hardware, may assist in

providing an operator with precision feedback as to how many turns have been made with the manual rotation interface (244), and how deep the distal hardware is into the nearby tissue. Referring to Figure 19Z-7, with an adequate depth of anchor members and associated suture members achieved, the main bulk of the instrument assembly may be removed by reversing out the helical needle members and withdrawing the proximal instrument housings (240) and associated hardware – while the suture tensioning assemblies (254, 255) are decoupled from such proximal instrument housings (240) and associated hardware, as shown in Figure 19Z-7, to leave behind only the anchors, sutures, and suture tensioning assemblies (254, 255). The sutures (52, 53) may be tightened onto the tissue structure using the associated locking members (such as two-way / one-way controllably advanceable locking members described above), tubular tensioning elements (16), and tensioning of the manual tensioning interfaces (18).

Referring to Figure 20, a process for utilizing technology such as that depicted in Figures 19A-19Z-8 is illustrated. As shown in Figure 20, after preoperative diagnostics and patient preparation (138), access may be created (140) to the subject tissue structure (for example, a thoracotomy may be created to access the wall of the heart, the heart wall being the subject of the subsequent wall crossing and closure). The subject tissue structure may be at least partially crossed (142) using an elongate guiding member such as a needle, which may be navigated utilizing various imaging, sensing, and/or navigation modalities. The needle may be followed by a guidewire (i.e., a guidewire advanced through the needle). One or more helical needle/suture assemblies may be advanced (144) across a portion of the tissue wall following the elongate guiding member (or in another embodiment, without the assistant of a guiding member); depth of positioning (145) of one or more of the pertinent structures (such as the distal needle tips, anchor member positions, or the like) may be monitored (using an aperture 220 and associated lumen such as that described above in reference to Figure 17B – or a pressure transducer configured to sense pressure at a chosen distal location, the transducer preferably operatively coupled to a means for signaling an operator, such as a small proximally-positioned light that toggles between red and green colors when the given pressure threshold for completed insertion/deployment has been reached); with full insertion/deployment completed, the helical member may be axially and rotationally withdrawn to place an anchoring element and compound helical suture into a configuration wherein they may be subsequently utilized to effect a closure (146), and such configuration may be confirmed (148) before further interventional steps. Subsequent to confirmation that a closure configuration appears to be ready, a dilator (150) and/or other tools (152) may be

advanced through the suture helix, thereby expanding the suture helix so that pertinent diagnostic and/or interventional steps may be accomplished, such as the installation of a heart valve. Subsequently, the dilator may be re-inserted (i.e., using a hemostatically-valved sheath) in place of the diagnostic and/or interventional tools (312), and the tapered outer shape of the dilator may be utilized to effect an incremental tightening of the wound or port, using, for example, one or more controllably locking two-way / one-way tension retainers (265). A guidewire may be left in place as a "test closure" is accomplished around the guidewire to permit observation of the intervention while also permitting easy re-access. The closure may be completed with full withdrawal of the dilator, needle, and guidewire, tightening of the one or more controllably locking two-way / one-way tension retainers (265), and proximal fixation of the suture end or ends to retain tension (314).

In the aforementioned illustrations and examples, one or more helical needle members have been discussed. We have discovered that there are various important relationships involved in selecting an optimal helical needle member and suture configuration. For example, referring to Figure 21, we have shown that a very slight angle of approach (316), i.e., with a needle member tip only a few degrees from a tangential relationship relative to a point of entry into a targeted tissue structure (48) (in the depicted configuration, the angle of approach 316 is about 15 degrees) may result in some amount of relative motion between the tissue structure (48) and needle member (66) tip before the tip actually dives across the surface of the tissue structure (48). Such relative motion generally is not desirable, as it may result in relative motion and possible undesirable loading between the pericardium, epicardium, suture member, and needle member. Referring to Figure 22, with a helical needle member (66) having the same helical pitch, one or more ramp members (258) may be utilized to locally reorient the tissue structure (48) at the point of entry of the helical needle member (66), such that the effective angle of approach (318) resulting from the combination of the ramp member (258) reorientation and the orientation of the needle based upon the associated helical pitch is relatively large (in this embodiment, about 70 degrees); we have found that such a relatively large effective angle of approach generally causes the needle member (66) to dive directly into and across the targeted tissue structure (48), as would be desired. Referring to Figures 23A and 23B, in another embodiment, the one or more ramp members (258) may be coupled to one or more traction features (324) (shown best in the close up view of Figure 23B) to further assist in preventing relative sliding motion between the pericardial membrane (320), epicardial surface (322) and aspects of the tool assembly during insertion. In one embodiment, the one or more traction features (324) comprise one or

more barbs or hooklike projections from the ramp member (258) surface. In a heart wall crossing scenario, with the deployment assembly pressed against the pericardial membrane (320) and the elongate tracking member (68) pressed across the pericardial membrane (320) and epicardial surface (322) into the wall of the heart, the ramp member (258) assists with locally adjusting the tissue orientation immediately adjacent the helical member (66) point of entry, as described above, and the one or more traction features press through at least a portion of the pericardial membrane (320) / epicardial surface (322) / heart wall composite to assist with a clean and relatively load-free passage of the needle member (66) tip across the pericardial membrane (320) and epicardial surface (322), and into the wall of the heart. Thus we have created configurations and techniques for successfully advancing one or more helical needle structures into a substantially slippery and viscoelastic tissue structure.

One of the other challenges in effecting an adequate closure when the procedure has been completed is assuring that proximal tensioning of the one or more deployed suture members will indeed effect a closure of the wound through the length of the wound. We define a term "helical turn" to represent the number of full turns a suture or needle travels within a subject tissue structure when viewed from a perspective coaxial to the axis of the helical winding (i.e., one helical turn would be where the needle and/or suture traveled a pathway that appears to create a full 360 degree circle when viewed down the longitudinal axis of the helix; one-half helical turn would appear like a half-circle, or 180 degrees of arcuate travel around the outer shape of the helix). We have found that with myocardial tissue and conventional suture materials, there is an optimal number of helical turns of deployed suture material; below this number, there is not enough suture helically deployed within the tissue structure to pull shut the wound; above this number, there is too much suture deployed into the tissue structure from a friction perspective, such that pulling proximally on the suture member to tension it and close the wound only tensions the proximal few helical wraps, and leaves the distal helical wraps only partially tightened due to the well known "flat belt" power transmission relationship (the ratio of belt type tensions on the tighter side, to those on the more slack side, are equivalent to e to the mu*theta, wherein mu is the friction coefficient and theta is the angle subtended by the contact surface at the pulley) described, for example, at http://en.wikipedia.org/wiki/Belt_(mechanical), – and potentially in a configuration wherein an adequate closure may not be created. Again, with myocardial tissue and conventional suture materials, we have found the ideal number of turns for good closure performance to be between about one-half helical turn and about three helical turns, and more preferably between about 1 helical turn and about 2 helical turns.

Another factor coming into play in selecting the instrumentation configuration is the notion that the anchor may be left distally within the tissue wall, as in the embodiments of Figures 4N or 7B, or distally past the opposite margin of the subject tissue wall, as in the embodiment of Figure 8B. In the latter scenario, there is some slack material left unconstrained with the anchor, while in the former scenarios, there is no unconstrained slack. With dilation of the helical configuration, slack at both sides assists with the flat belt issue (i.e., in accordance with the aforementioned flat belt relationship, the ratio of tensions is equivalent to e to the mu*theta, and if you cut theta in half, you have cut the force required down by e to that factor – quite a significant nonlinear relationship). But note – upon closure, in most configurations (i.e., absent some means for also tensioning from the anchor side of the suture member), the operator is still dealing with a single-sided tensioning flat-belt scenario, and there is an important desire to effect a solid closure at the end of the procedure by tensioning only the proximal end.

Thus there is a confluence of factors at play that result in the hardware configuration selection, including but not limited to: 1) given the thickness of the wall to be crossed, we want to get between one half and two and a half helical turns through that thickness, and more preferably between one and two helical turns; 2) we would prefer to have the needle dive straight into the tissue structure without significant non-puncturing motion before entry; this can be complicated by too shallow an angle of entry; 3) we need to provide enough cross sectional area with the helical windings to accommodate the pertinent interventional hardware, dilation therefor, and helical suture closure thereof without coring out, lacerating, or necrosing the subject tissue; 4) we would prefer to use conventional materials for the suture member and needle members; 5) we will be dealing with a viscoelastic and potentially nonhomogeneous material (tissue). It is worth noting that this challenge is very different from the challenge of helically winding a running stitch along a tissue surface such that the needle tip is constantly diving and exiting the tissue surface – the flat belt friction issues there are completely different (i.e., there is no helix of suture material that is fully encapsulated by the tissue and thus subject to the flat belt relationship issues when tensioned). As described above, the second challenge may be addressed with the inventive ramp members described herein. The remaining challenges may be addressed by processing the scenario as shown in Figure 24.

Referring to Figure 24, after determination of patient-specific parameters, such as subject tissue wall dimensions, density, and irregularities (328), and examination of other mechanical parameters, such as estimated viscoelastic, frictional, and mechanical modulus

properties of the subject tissue and instrumentation (330), a deployment configuration may be matched to the scenario (332) to address the aforementioned challenges, and the surgery may be executed (334). Heart walls, for example, may range anywhere from about 8mm in thickness to about 25mm in thickness. For a relatively thick targeted tissue structure crossing (for example, in the wall of a congestive heart failure patient with an enlarged heart), a relatively large helix pitch may be utilized to cross the appropriate thickness and still place between about one-half and two and a half helical turns, or more preferably between about one and two helical turns, of suture in place for closure. For a relatively thin targeted tissue structure crossing (for example, through a previously infracted area of a ventricle wall of a heart), a more shallow pitch may be utilized to ensure that enough helical turn is placed in the relatively small thickness of the targeted wall tissue to effect a closure. In one embodiment, for a heart wall of average thickness, about 12mm in wall thickness, a twin helical needle configuration comprising two stainless steel needles with a helix pitch of about 8mm, a helix diameter of about 15mm, and an angle of entry (not accounting for ramping members) of about 10 degrees based upon the helical pitch may be utilized to accommodate typical valve replacement interventional tools and effect a closure. Other useful embodiments for thinner heart wall crossing include a 5mm helical pitch (6 degree angle of entry not accounting for ramping members); and a 10mm helical pitch (12 degree angle of entry not accounting for ramping members). For a thicker heart wall, a 13mm pitch provides approximately one to three full helical loops with an approximate 15 degree angle of entry. Each of these embodiments would preferably incorporate one or more ramping members to address the angle of entry challenge, as described above. Other embodiments may include varied needle member helix radii (for example, one 10mm radius helical needle may be paired with one 20mm radius helical needle, both needles carrying a suture member and anchor member).

Yet further embodiments may include helical needle members with inner or outer helical diameters that vary or do not vary relative to length along a longitudinal axis through the center of the helical formation (i.e., such as a tapered helix with a varied inner helix diameter), helical needle members with varying, or not varying, pitch relative to length along the longitudinal axis. Further, helical needle members may be formed from solid versus tubular members formed into helical shapes, and these helical members may have various cross sectional geometries (i.e., a tubular helical member material may have a generally hollow-circular cross section, or a hollow square, rectangle, elliptical, or other cross section; a nontubular, or solid, helical member material may have a generally circular cross section, or a solid square, rectangle, elliptical, or other cross section). All of these variables may be

utilized to form many permutations and combinations of suitable helical members. For example, a nontapered helix may have a constant helical pitch along its length (say, for example, a pitch between about 5mm and about 20mm, or more preferably between about 7mm and about 13mm) – or a variable helical pitch along its length; a tapered helix may have a constant helical pitch along its length – or a variable helical pitch along its length. In one embodiment, an inner helix diameter is between about 5mm and about 60mm, and more preferably between about 10mm and about 20mm. In one embodiment, an outer diameter of a wire or tube (tubular or nontubular/solid) used to form a helical member may have an outer diameter of between about 0.5mm and about 3mm. The helix may comprise materials such as stainless steel, Nitinol alloy, titanium, cobalt chromium, and various polymers and composites.

Further, as depicted in several of the figures associated hereto, two or more helical needle members may be utilized in various access and closure embodiments. In one embodiment, each helix may be geometrically matched to each other in the set, with substantially coaxial longitudinal axes. In other embodiments, as in the embodiment of Figures 5A-5D, for example, helical needle members may have different radii. Further helical needle members may have different helical pitches, different materials, different contructs (as discussed above – solid versus tubular, various cross sectional shapes, variable pitches or helix diameters with length position, etc.).

Referring to Figure 25, an embodiment similar to that depicted in Figure 8A is shown. The embodiment of Figure 25 features the deployment of extra slack suture length not only available proximally to the deployed helical suture pattern (which in the depicted embodiment comprises about two full helical loops substantially encapsulated by the midsubstance of the tissue structure 48), but also distally (i.e., on the opposite side of the targeted tissue structure wall 48). As one or more elongate tools or instruments (102) are passed through the helical suture pattern, slack may be pulled in not only from the proximal side (338), but also from the distal side (336), providing a significant advantage in view of the mechanical overconstraint issues described above in reference to the "flat belt" equation. In other words, in certain embodiments wherein it is possible to provide slack distally as well as proximally (340) in the form of localized length storage or simply some additional length (341), such as between about 3 millimeters and about 48 millimeters, provided distally by advancing the anchor by an additional distance past the threshold of the subject tissue wall before retracting the needle member, such extra distal slack can provide an additional advantage in avoiding flat belt overconstraint, and thus subsequently tensioning of the

helically-deployed suture pattern may be more uniform. A preferred amount of available proximal slack, using some free length of suture member, a localized length storage structure, or otherwise, is between about 5 millimeters and about 24 millimeters.

Referring to Figure 26, a technique for effecting an access and closure using a configuration such as that depicted in Figure 25 is illustrated. Referring to Figure 26, after preoperative diagnostics and patient preparation (138), access may be created (140), and an elongate guiding member advanced (142). One or more helical needle / suture assemblies may then be advanced across the targeted tissue structure – and in this embodiment, across the distal threshold and beyond by a given length, such that there is suture member slack available on both the proximal and distal sides of the tissue structure that may be subsequently pulled in upon expansion of the helical suture pattern (342). The distal slack is created upon withdrawal of the pertinent helical needle, which leaves behind the associated anchor member with the additional suture member slack in tow (344). Subsequently an intervention, such as a valve deployment with or without an introducer type sheath member (i.e., certain valve deployment systems are configured to be passed through a sheath; others are configured to be introduced without a sheath and may be passed directly through the helical suture pattern; working instruments may comprise prosthetic valves, prothetic clips, graspers, dilators, endoscopes, catheters, balloons, occlusion devices, and ablation devices, for example), may be conducted and closure effected (346). Preferably the helical needle and suture configuration is selected to accommodate passage of one or more instruments that may expand the suture helical configuration diameter by between about 10% and about 35% during the intervention (with collapse back to closure thereafter, using tension on the suture member, which may be incremental or cyclical, as described in various embodiments above).

Referring to Figure 27 another access and closure embodiment is illustrated to emphasize that a helical needle configuration may be specifically selected based on anatomical characteristics, such as the thickness of the desired portion of the tissue structure to be crossed. In other words, given the aforementioned discussions of preferences for between about 1 full helical loop and about 3 full helical loops of suture to be deployed to effect desired expandability and contraction/closure properties, the geometry of the helical needle member may be tailored to provide such functionality in view of the amount of tissue to be crossed and subsequently expanded and then collapsed to closure. Referring to Figure 27, preoperative diagnostics and patient preparation may include measurements and planning regarding the thickness of the targeted tissue structure wall to be crossed in the intervention (348). Images may be captured using, for example, ultrasound, computed tomography (CT),

fluoroscopy, magnetic resonance imaging (MRI), radiography, and/or optical coherence tomography (OCT). In another embodiment, measurements may be taken in-situ (i.e., after access has been created 140) with a measuring probe or needle, such as one configured to provide a proximal signal to an operator that the tip has reached a blood-filled cavity, wherein a distal aperature is fluidly coupled to a lumen that leads to a proximal viewing port or window for the operator to see a flash of blood as an indicator that the aperture has reached the blood-filled cavity. Further, needles or probes may be outfitted with one or more ultrasound transducers to provide for in-situ local imaging and associated measurement. Referring again to Figure 27, based upon the measured depth of tissue traversal (i.e., how far across tissue the anchor is to be deployed), a helical pitch for a helical needle may be selected that will place between about 1 and about 3 full helical loops of suture into the desired deployment (350). With access created (140) and an elongate guiding member placed (142), one or more helical needle assemblies may be advanced to place one or more anchors and associated suture members (144). Upon withdrawal of the needles, the desired 1 to 3 helical loops of suture are left to comprise the deployed pattern (352). The suture member deployment may be confirmed, after which various interventional tools may be inserted through the deployed pattern, thereby expanding the pattern and pulling in slack to accommodate the expansion. After the intervention is completed, the tools may be withdrawn, and the closure effected by tensioning the one or more suture members (346).

Referring to Figures 28A-28D, it may be desirable to transiently provide tension on one or more suture members, and to subsequently release the temporary tension in favor or more permanent tensioning, such as through a two-way / one-way controllably advanceable locking member (265), as discussed above. To provide temporary tension fixation before switching such a locking member (265) from a two-way configuration to a one-way configuration, it may be desirable to provide a pinch clamp (354), such as that depicted in Figure 28A, or a suture member reel mechanism (362), such as that depicted in Figure 28B. In other words, it may be desirable during the closure portion of a procedure to temporarily (i.e., with the ability to remove tension or adjust the tensioning position) tension the suture member without committing to the more permanent tensioning provided by switching a two-way / one-way controllably advanceable locking member (265) from two-way suture movement to one-way only suture movement (i.e., by operating an actuation member 284, as described above). The pinch clamp (354) may be manually installed by manual manipulation of the two spring-biased arms (358, 360) which produce a pinching load at a loading interface (356). The suture reel mechanism (362) depicted in Figure 28B may be released with a push

of a button (366) after tightening around a reel (364) in a one-way tightening configuration. Referring to Figure 28C, the temporary tightening mechanisms (354, 362) are shown temporarily retaining tensions on suture members (52, 53) that may be configured as those depicted in Figure 19Z-8 above. Referring to Figure 28D, a close-up orthogonal view with a partial cross section of a suture reel mechanism (362) is depicted. The suture member (52) is passed from a location in the tissue structure through a locking member (265) that is mechanically constrained in its open (i.e., 2-way) configuration by an actuation member (284) connected to a proximal control knob (270). To temporarily tighten the distal suture portion (394), a tension may be applied to the proximal suture portion (396) which causes a ratchet reel (364) to rotate, and the ratcheted outer surface of the ratchet reel to continue to incrementally click past a pawl (370) which prevents rotation of the reel in the opposite direction, along with a suture pinch point (368) where the distal aspects of the reel meets the housing (372). Thus a one-way tightening is effected with the reel/pawl and pinch point configuration. When an operator wishes to release the tension or back off the assembly a bit, he can depress the release button (366), which depresses the pawl (370) and allows the reel (364) to rotate in a reverse direction. When an operator wishes to switch from temporary tensioning to more permanent tensioning, he can use the actuation member knob (270) to operate the actuation member (284) to change the locking member (265) from a two-way suture movement mode to a one-way-only suture movement mode, as described above.

Referring to Figure 29, a method featuring several of the above characteristics is illustrated. After preoperative diagnostics and patient preparation (138), a distal portion of a suture member may be advanced across at least a portion of a targeted tissue structure (374), as described in reference to other embodiments above. With a suture member placed in a desired configuration for an intervention and subsequent closure, a tensioning assembly may be advanced toward the wall of the tissue structure, the assembly comprising a two-way / one-way controllably switcheable locking assembly configuration, such as those described above, which may comprise a tensioning member base (i.e., such as that depicted in Figure 19K as element 280) having a tissue interface surface configured to engage a portion of the tissue structure when coupled to a suture member that may be threaded through the tensioning member base and into the tissue structure; a suture clamping member (i.e., such as that depicted in Figure 19K as element 278) configured to be switched from a first mode, wherein a suture may be tensioned back and forth through a space defined at least in part by the clamping member, to a second mode, wherein a suture may only be tensioned in one direction relative to the suture clamping member; and a mode switching member (i.e., such as

the actuation member 284 or lock actuation member 230 described above) movably coupled to the suture clamping member and configured to be operable to switch the suture clamping member from the first mode to the second mode (376). The physical relationship between the tensioning assembly, suture member, and tissue structure may be modulated (i.e., tightened, loosened, etc) by modulating the position of the tension member base relative to the suture member and tissue structure wall (378). The tensioning mode may be switched to the second mode to permanently proceed toward a final tightening of the suture member (380). The tissue interfacing surface of the tensioning member base may comprise a thrombogenic member as shown, for example, in Figures 19J and 19k (element 274), or in another embodiment, a fabric pledget sock (not shown) may be configured to substantially surround or encapsulate the locking assembly (265) and encourage biointegration of the tensioning member base and adjacent portions of the tissue structure. The sock may comprise a durable polymer selected from the group consisting of: polyethylene terepthalate, polyethylene, high density polyethylene, polypropylene, polytetrafluoroethylene, expanded polytetrafluoroethylene, poly (ethylene-co-vinyl acetate), poly(butyl methacrylate), and co-polymers thereof. Alternatively, the sock may comprise a bioresorbable polymer selected from the group consisting of: polylactic acid, polyglycolic acid, polylactic-co-glycolic acid, polylactic acid-co-caprolactone, poly (block-ethylene oxide-block-lactide-co-glycolide), polyethylene glycol, polyethylene oxide, poly (block-ethylene oxide-block-propylene oxide-block-ethylene oxide), polyvinyl pyrrolidone, polyorthoester, polyanhydride, polyhydroxy valerate, polyhydroxy butyrate, and co-polymers thereof. Alternatively, the sock may comprise a bioresorbable material selected from the group consisting of: porcine collagen matrix, human collagen matrix, equine collagen fleece, gelatin, polyhyaluronic acid, heparin, poly (glucose), poly(alginic acid), chitin, chitosan, cellulose, methyl cellulose, hydroxyethylcellulose, hydroxypropylcellulose, carboxymethylcellulose; polylysine, polyglutamic acid, albumin, hydroxy apatite, cortical bone, cancellous bone, trabecular bone, bioceramic, ligament tissue, tendon tissue, dura tissue, fascia tissue, pericardium tissue, thrombin, and fibrin. The tissue-side interface of the locking assembly may be configured to be interfaced with various tissue types, as described above, including myocardium or pericardium (in which case one of the preferred method steps comprises identifying the pericardium, either directly, such as which a probe, optically – as in using visual inspection, or with tools such as ultrasound or OCT; another step may include removing at least a portion of the pericardium if direct myocardial interfacing is desired for the locking assembly).

Referring to Figure 30, one embodiment of an access and closure technique is illustrated to emphasize the use of tissue interface indentors, such as the aforementioned ramping members, to change the effective local angle of entry between an inserted needle and the subject tissue structure. Referring to Figure 30, after preoperative diagnostics and patient preparation (138), a distal end of a needle insertion assembly may be advanced against a targeted tissue structure, with one or more tissue indentor members, in the form of protruding shape features (i.e. such as ramps, and various other shapes as described above) providing the leading mechanical edges for the assembly, these features locally deforming the interfaced tissue to provide greater effective angles of penetration between the needle members and the tissue (382). Given such configuration, the needle members may then be inserted relative to the rest of the assembly and into the targeted tissue structure, taking advantage of the preferred angle of entry (384).

Referring to Figure 31, one embodiment of an access and closure technique is illustrated to emphasize the importance of planning and selecting a helical needle configuration matched to the tissue geometry to be crossed, as in the embodiment of Figure 27. Referring to Figure 31, preoperative diagnostics and patient preparation may be conducted, which may include measurements of the tissue geometry using direct techniques or image capture techniques, as described above in reference to Figure 27. A guiding member may be installed to a desired guiding depth (386), and using this guiding member as a positional depth guide, a helical member may be advanced into the tissue structure, preferably such that between about 1 and about 3 helical loops are deployed (388). The helical member may then be withdrawn, leaving the suture member pattern in place (390), after which the suture pattern may be expanded and later contracted, such as by tensioning the suture member (392).

It is important to note that while the subject closure technologies and configurations have been described and illustrated in the context of a trans-apical wall defect or port closure, and specifically regarding tissue structures such as the walls and apex of the ventricles of the heart, such technologies may be broadly applied to various other tissue structures wherein a closure following creation or existence of a defect is desired – such as in the gastric mucosa for trans-gastric interventions of various types (for example, following a trans-gastric access of the gall bladder or a trans-colonic retroperitoneal access), or in the uterus for various gynecological interventions (for example, following removal of a fibroid tumor residing in the wall of the uterus). For example, the subject invention may be utilized to assist in the deployment of a prosthesis such as that described in U.S. 7,104,949. Any of the

aforementioned deployed structures, including sutures, anchor members, and ratcheting closure device assembly components, may comprise resorbable materials in addition to the aforementioned nonresorbable materials – to facilitate combinations and permutations which may be completely resorbed, leaving behind a biologically healed transapical access wound.

Various exemplary embodiments of the invention are described herein. Reference is made to these examples in a non-limiting sense. They are provided to illustrate more broadly applicable aspects of the invention. Various changes may be made to the invention described and equivalents may be substituted without departing from the true spirit and scope of the invention. In addition, many modifications may be made to adapt a particular situation, material, composition of matter, process, process act(s) or step(s) to the objective(s), spirit or scope of the present invention. Further, each of the individual variations described and illustrated herein has discrete components and features which may be readily separated from or combined with the features of any of the other several embodiments without departing from the scope or spirit of the present invention.

Any of the devices described for carrying out the subject interventions may be provided in packaged combination for use in executing such interventions. These supply "kits" further may include instructions for use and be packaged in sterile trays or containers as commonly employed for such purposes.

The invention includes methods that may be performed using the subject devices. The methods may comprise the act of providing such a suitable device. Such provision may be performed by the end user. In other words, the "providing" act merely requires the end user obtain, access, approach, position, set-up, activate, power-up or otherwise act to provide the requisite device in the subject method. Methods recited herein may be carried out in any order of the recited events which is logically possible, as well as in the recited order of events.

Exemplary embodiments of the invention, together with details regarding material selection and manufacture have been set forth above. As for other details of the present invention, these may be appreciated in connection with the above-referenced patents and publications. For example, one or more lubricious coatings (e.g., hydrophilic polymers such as polyvinylpyrrolidone-based compositions, fluoropolymers such as tetrafluoroethylene, hydrophilic gel or silicones) may be used in connection with various portions of the devices, such as relatively large interfacial surfaces of movably coupled parts, if desired, for example, to facilitate low friction manipulation or advancement of such objects relative to other portions of the instrumentation or nearby tissue structures. The same may hold true with

respect to method-based embodiments of the invention in terms of additional acts as commonly or logically employed.

In addition, though the invention has been described in reference to several examples optionally incorporating various features, the invention is not to be limited to that which is described or indicated as contemplated with respect to each variation of the invention. Various changes may be made to the invention described and equivalents (whether recited herein or not included for the sake of some brevity) may be substituted without departing from the true spirit and scope of the invention. In addition, where a range of values is provided, it is understood that every intervening value, between the upper and lower limit of that range and any other stated or intervening value in that stated range, is encompassed within the invention.

Also, it is contemplated that any optional feature of the inventive variations described may be set forth and claimed independently, or in combination with any one or more of the features described herein. Reference to a singular item, includes the possibility that there are plural of the same items present. More specifically, as used herein and in claims associated hereto, the singular forms "a," "an," "said," and "the" include plural referents unless the specifically stated otherwise. In other words, use of the articles allow for "at least one" of the subject item in the description above as well as claims associated with this disclosure. It is further noted that such claims may be drafted to exclude any optional element. As such, this statement is intended to serve as antecedent basis for use of such exclusive terminology as "solely," "only" and the like in connection with the recitation of claim elements, or use of a "negative" limitation.

Without the use of such exclusive terminology, the term "comprising" in claims associated with this disclosure shall allow for the inclusion of any additional element--irrespective of whether a given number of elements are enumerated in such claims, or the addition of a feature could be regarded as transforming the nature of an element set forth in such claims. Except as specifically defined herein, all technical and scientific terms used herein are to be given as broad a commonly understood meaning as possible while maintaining claim validity.

CLAIMS

1. A system for providing surgical access across a wall of a tissue structure, comprising:

   a. a delivery member having proximal and distal ends;

   b. a first helical member having proximal and distal ends and a helical shape, the proximal end coupled to the delivery member distal end, the distal end extending distally of the delivery member distal end;

   c. an anchor member removably coupled to the helical member distal end; and

   d. a suture member coupled distally to a portion of the anchor member and extending proximally to a position wherein at least a portion of it may be freely manipulated by an operator;

   wherein upon rotation of the delivery member in a first direction, the first helical member and coupled anchor member are advanced across at least a portion of the wall of the tissue structure, pulling along the distal portion of the suture member in a deployed suture pattern which remains coupled to the anchor member, the deployed suture pattern being characterized in that it is substantially helical and represents a number of helical loops encapsulated by the wall of the tissue structure that is greater than about one helical loop, and is less than about three helical loops.

2. The system of claim 1, wherein upon rotation of the delivery member in a second direction opposite to the first direction, a reverse load is applied to the delivery member and coupled first helical member which causes the anchor member to become decoupled from the first helical member, such that further rotation in the second direction causes removal of the first helical member and delivery member while the anchor member and suture member distal portion remain positioned across the portion of the wall of the tissue structure.

3. The system of claim 1, wherein the anchor member has at least one shape feature that is configured to slide past nearby tissue structures during inward insertion loading associated with rotation of the first helical member in the first direction, and to resist movement relative to the nearby tissue structures upon application of outward

extraction loading associated with rotation of the first helical member in the second direction.

4. The system of claim 1, wherein at least a portion of the anchor member is configured to rotate relative to wall of the tissue structure upon application of a tensioning load to the suture member.

5. The system of claim 1, wherein the first helical member and coupled anchor member are advanced in a substantially helical pathway.

6. The system of claim 1, wherein the proximal end of the suture member extends proximally beyond the deployed suture pattern into a local suture length storage reservoir coupled to the delivery member containing an additional length of suture, the reservoir being configured such that upon rotation of the delivery member in the first direction, the anchor member pulls along the distal portion of the suture member causing at least a portion of the additional length of suture to be extended out from the local suture length storage reservoir.

7. The system of claim 6, wherein the local suture length storage reservoir is coupled to the delivery member in a configuration wherein advancement of the first helical member does not substantially advance the reservoir relative to the wall of the tissue structure.

8. The system of claim 7, further comprising a sleeve member movably coupled to the delivery member such that the deliver member is threaded through a lumen defined by the sleeve member, wherein the sleeve member is coupled to the local suture length storage reservoir.

9. The system of claim 1, wherein the first helical member defines an inner helix diameter that is substantially constant across the length of the helical member.

10. The system of claim 1, wherein the first helical member defines an inner helix diameter that varies across the length of the helical member.

11. The system of claim 9, wherein the inner helix diameter is between about 5mm and about 60mm.

12. The system of claim 11, wherein the inner helix diameter is between about 10mm and about 20mm.

13. The system of claim 1, wherein the first helical member is comprised of an elongate member formed into the helical shape, the elongate member having an outer diameter.

14. The system of claim 13, wherein the elongate member has a cross sectional shape selected from the group consisting of: a circular cross section, an elliptical cross section, a square cross section, and a rectangular cross section.

15. The system of claim 13, wherein the outer diameter is between about 0.5mm and about 3mm.

16. The system of claim 13, wherein the helical shape comprises a number of helical turns advanceable into tissue that is between about 1 and about 3.

17. The system of claim 9, wherein the helical shape has a substantially constant helix pitch along the length of the helical shape.

18. The system of claim 9, wherein the helical shape has a substantially variable helix pitch along the length of the helical shape.

19. The system of claim 10, wherein the helical shape has a substantially constant helix pitch along the length of the helical shape.

20. The system of claim 10, wherein the helical shape has a substantially variable helix pitch along the length of the helical shape.

21. The system of claim 17, wherein the helix pitch is between about 5mm and about 20mm.

22. The system of claim 21, wherein the helix pitch is between about 7mm and about 13mm.

23. The system of claim 1, wherein the distal end of the first helical member comprises a sharpened tip configured to easily dive into and cross portions of the wall of the tissue structure.

24. The system of claim 13, wherein the distal end of the first helical member comprises an anchor coupling portion wherein the outer diameter of the elongate member is decreased to accommodate slidable coupling of the anchor member.

25. The system of claim 24, wherein the outer diameter of anchor member is substantially similar to that of the portions of the elongate member proximal to the anchor coupling portion.

26. The system of claim 1, wherein the helical shape is defined by a helix pitch, the helix pitch being selected based upon a targeted depth of traversal through the wall of the tissue structure that will result in the deployed suture pattern.

27. The system of claim 26, wherein the targeted depth of traversal is configured to entirely cross the wall of the tissue structure, leaving the anchor member on an opposite side of the wall.

28. The system of claim 26, wherein the targeted depth of traversal is configured to only partially cross the wall of the tissue structure, leaving the anchor member in a midsubstance location within the wall.

29. The system of claim 13, wherein the elongate member comprises a solid cross-sectional construct.

30. The system of claim 13, wherein the elongate member comprises a tubular construct having an inner diameter and as well as the outer diameter.

31. The system of claim 29, wherein the elongate member comprises a material selected from the group consisting of: stainless steel, nitinol alloy, titanium, cobalt chrome, and polymer composite.

32. The system of claim 30, wherein the elongate member comprises a material selected from the group consisting of: stainless steel, nitinol alloy, titanium, cobalt chrome, and polymer composite.

33. The system of claim 3, wherein the anchor member comprises a main body portion comprising a solid or tubular construct.

34. The system of claim 33, wherein the shape feature configured to slide past nearby tissue structures during inward insertion loading comprises a tapered distal tip.

35. The system of claim 33, wherein the shape feature configured to resist movement relative to the nearby tissue structures upon application of outward extraction loading comprises a projecting portion configured to extend to a projecting position beyond an outer diameter of the rest of the anchor member when tension is applied to the intercoupled suture member.

36. The system of claim 35, wherein the projecting portion comprises a portion of the anchor member that has been deformed out into the projecting position.

37. The system of claim 35, wherein the projecting portion comprises a piece of material that has been coupled to the anchor member to assume the projecting position.

38. The system of claim 35, further comprising two or more projecting portions.

39. The system of claim 35, wherein the projecting portion comprises a superelastic alloy that is shape set to the projecting position and configured to be deliverable in an elastically compressed form within a superelastic thermal range for the alloy.

40. The system of claim 1, wherein the suture member is coupled to an eyelet coupled to the anchor member.

41. The system of claim 40, wherein the eyelet is positioned such that tension on the suture member urges the anchor into rotational movement relative to surrounding portions of the wall of the tissue structure when the suture member is pulled in tension relative to the anchor member.

42. The system of claim 41, wherein anchor has a longitudinal axis, and wherein the eyelet is placed at a position spaced apart from the longitudinal axis.

43. The system of claim 40, wherein the eyelet is coupled to a ring member defining a ring aperture through which at least a portion of the anchor is positioned.

44. The system of claim 43, wherein the ring member is coupled to the anchor using a coupling selected from the group consisting of: an adhesive coupling, a press-fit coupling, and a tack-welding coupling.

45. The system of claim 1, wherein the anchor comprises a metal selected from the group consisting of: titanium, nickel, stainless steel, cobalt chrome, and alloys thereof.

46. The system of claim 1, wherein the anchor comprises a durable polymer selected from the group consisting of: polyethylene terepthalate, polyethylene, high density polyethylene, polypropylene, polytetrafluoroethylene, expanded polytetrafluoroethylene, poly (ethylene-co-vinyl acetate), poly(butyl methacrylate), and co-polymers thereof.

47. The system of claim 1, wherein the anchor comprises a bioresorbable polymer selected from the group consisting of: polylactic acid, polyglycolic acid, polylactic-co-glycolic acid, polylactic acid-co-caprolactone, poly (block-ethylene oxide-block-lactide-co-glycolide), polyethylene glycol, polyethylene oxide, poly (block-ethylene oxide-block-propylene oxide-block-ethylene oxide), polyvinyl pyrrolidone, polyorthoester, polyanhydride, polyhydroxy valerate, polyhydroxy butyrate, and co-polymers thereof.

48. The system of claim 1, wherein the anchor comprises a biological graft material.

49. The system of claim 48, wherein the biological graft material has an origin selected from the group consisting of: another human, the particular human, a non-human animal.

50. The system of claim 1, wherein the anchor comprises a bioresorbable material selected from the group consisting of: porcine collagen matrix, human collagen matrix, equine collagen fleece, gelatin, polyhyaluronic acid, heparin, poly (glucose), poly(alginic acid), chitin, chitosan, cellulose, methyl cellulose, hydroxyethylcellulose, hydroxypropylcellulose, carboxymethylcellulose; polylysine, polyglutamic acid, albumin, hydroxy apatite, cortical bone, cancellous bone, trabecular bone, bioceramic, ligament tissue, tendon tissue, dura tissue, fascia tissue, pericardium tissue, thrombin, and fibrin.

51. The system of claim 6, wherein the local suture length storage reservoir comprises an enclosure for storing one or more loops of suture member length.

52. The system of claim 6, wherein the additional length of suture is between about 20 millimeters and about 500 millimeters.

53. The system of claim 51, wherein the enclosure comprises a membrane configured to partially encapsulate the one or more loops of suture member length, and allow the

one or more loops to be pulled out of the enclosure when under tensile loading from the anchor and helical members.

54. The system of claim 1, further comprising a suture tensioning member coupled to the suture member between a proximal end of the suture member and a distal end of the suture member, the suture tensioning member configured to apply a compressive load to an exposed proximal aspect of the wall of the tissue structure when a distal end of the suture tensioning member is placed against the exposed proximal aspect of the wall and the suture member is tensioned proximally of the suture tensioning member.

55. The system of claim 54, wherein the suture tensioning member comprises an elongate tubular member defining a lumen therethrough, the suture member being threaded through the lumen.

56. The system of claim 55, further comprising a temporary suture member clamp coupleable to a proximal portion of the suture member and configured to retain tension upon a portion of suture member distal to the suture member clamp that is threaded through the lumen of the elongate tubular member.

57. The system of claim 1, wherein the suture tensioning member has two modes of operation, a first mode wherein the suture tensioning member may be moved bidirectionally relative to the suture member, and a second mode wherein the suture tensioning member may only be moved unidirectionally relative to the suture member, and wherein the suture tensioning member comprises a manually-operated mode-switching member configured to controllably switch the suture tensioning member from the first mode to the second mode.

58. The system of claim 1, further comprising a tissue interface indentor member coupled to the delivery member and operatively coupled to the first helical member, the tissue interface indentor member comprising a distally protruding shape feature configured to contact one or more portions of the tissue structure adjacent to the distal end of the helical member and change an available angle of penetration between such portions and the distal tip of the first helical member as the distal tip is inserted into the tissue structure.

59. The system of claim 58, wherein the distally protruding shape feature is configured to concentrate interfacial stresses upon the tissue structure such that the portions of the

tissue structure adjacent the distal end of the first helical member become locally strained about the distally protruding shape feature as the distally protruding shape feature is advanced into contact with the adjacent tissue structure portions; and wherein the contact between the adjacent tissue structure portions and the distally protruding shape feature locally increases the available angle of penetration defined between the first helical member and a surface of the adjacent tissue structure portions.

60. The system of claim 59, wherein at least one surface of the distally protruding shape feature comprises a surface configuration selected from the group consisting of: a portion of a spherical surface, a linear ramp surface, an arcuate ramp surface, a multi-stepped ramp surface, and a single-stepped ramp surface.

61. The system of claim 60, wherein the surface configuration is helically wrapped about a longitudinal axis of the first helical member.

62. The system of claim 59, wherein at least one surface of the distally protruding shape feature comprises a substantially perpendicular leading surface.

63. The system of claim 59, wherein the distally protruding shape feature has a cross sectional profile comprising a cross sectional shape selected from the list consisting of: a rectangle, a square, a half circle, a triangle, a polygon, a rounded rectangular shape, a rounded square shape, and a multi-arcuate shape.

64. The system of claim 58, wherein the distally protruding shape feature and distal tip of the elongate needle member are operatively coupled such that the distal tip is movably coupled through a portion of the distally protruding shape feature.

65. The system of claim 64,wherein the distal tip substantially bisects the portion of the distally protruding shape feature.

66. The system of claim 58, wherein the distally protruding shape feature and distal tip of the elongate needle member are operatively coupled such that the distal tip is movably coupled adjacent a portion of the distally protruding shape feature.

67. The system of claim 60, wherein the distal tip of the elongate needle member is configured to follow a path substantially parallel to the surface configuration of the distally protruding shape feature.

68. The system of claim 59, wherein the distally protruding shape feature comprises one or more tissue traction features configured to prevent relative motion between the distally protruding shape feature and portions of the tissue structure with which it may be directly interfaced.

69. The system of claim 68, wherein at least one of the one of the one or more tissue traction features comprises a barb.

70. The system of claim 1, further comprising a helical member guiding member having proximal and distal ends and being coupled to the first helical member, wherein the distal end of the helical member guiding member is substantially straight and defines a longitudinal axis that is substantially coincident with a longitudinal axis defined through the first helical member.

71. The system of claim 70, wherein the helical member guiding member is coupled to the delivery member, which is coupled to the helical member.

72. The system of claim 70, wherein the helical member guiding member is immediately coupled to the helical member.

73. The system of claim 70, wherein the distal end of the helical member guiding member comprises an aperture fluidly coupled to a lumen defined through the helical member guiding member and leading proximally to a detection position wherein an operator may visually detect fluid which may be present at the aperture.

74. The system of claim 73, wherein the aperture is positioned along the longitudinal axis of the helical member guiding member that is keyed to mark a distal protrusion position of a structure portion selected from the group consisting of: the distal end of the helical member; the distal end of the anchor member; and the proximal end of the anchor member.

75. The system of claim 70, further comprising a second aperture fluidly coupled to a second lumen defined through the helical member guiding member and leading proximally to a second detection position wherein an operator may visually detect fluid which may be present at the second aperture.

76. The system of claim 70, wherein the helical member guiding member comprises a sensor selected from the group consisting of: an OCT sensor, an ultrasound sensor, an RF impedance sensor, a partial pressure of oxygen sensor, and a pressure sensor.

77. The system of claim 1, further comprising a second helical member having proximal and distal ends, the proximal end coupled to the delivery member distal end, the distal end extending distally of the delivery member distal end.

78. The system of claim 77, wherein the second helical member defines an inner helix diameter that is substantially constant across the length of the helical member.

79. The system of claim 77, wherein the second helical member defines an inner helix diameter that varies across the length of the helical member.

80. The system of claim 77, wherein the inner helix diameters of the first and second helical members are substantially equal.

81. The system of claim 77, wherein the inner helix diameters of the first and second helical members are substantially unequal.

82. The system of claim 77, wherein the first and second helical members define longitudinal axes that are substantially coaxial.

83. The system of claim 77, further comprising a second anchor member removably coupled to the distal end of the second helical member.

84. The system of claim 83, further comprising a second suture member coupled to the second helical member.

85. A system for providing surgical access across a wall of a tissue structure, comprising:

a. a delivery member having proximal and distal ends;

b. a first helical member having proximal and distal ends and a helical shape, the proximal end coupled to the delivery member distal end, the distal end extending distally of the delivery member distal end;

c. an anchor member removably coupled to the helical member distal end; and

d. a suture member coupled distally to a portion of the anchor member and extending proximally to a position wherein at least a portion of it may be freely manipulated by an operator;

wherein the proximal end of the suture member extends proximally beyond the deployed suture pattern into a local suture length storage reservoir coupled to the delivery member, the reservoir containing an additional length of suture and being configured such that upon rotation of the delivery member in the first direction, the anchor member pulls along the distal portion of the suture member causing at least a portion of the additional length of suture to be extended out from the local suture length storage reservoir, and causing the distal portion of the suture member to form a deployed suture pattern which remains coupled to the anchor member.

86. The system of claim 85, wherein upon rotation of the delivery member in a second direction opposite to the first direction, a reverse load is applied to the delivery member and coupled first helical member which causes the anchor member to become decoupled from the first helical member, such that further rotation in the second direction causes removal of the first helical member and delivery member while the anchor member and suture member distal portion remain positioned across the portion of the wall of the tissue structure.

87. The system of claim 85, wherein the deployed suture pattern is characterized in that it is substantially helical and represents a number of helical loops encapsulated by the wall of the tissue structure that is greater than about one helical loop, and is less than about three helical loops.

88. The system of claim 85, wherein the anchor member has at least one shape feature that is configured to slide past nearby tissue structures during inward insertion loading associated with rotation of the first helical member in the first direction, and to resist movement relative to the nearby tissue structures upon application of outward extraction loading associated with rotation of the first helical member in the second direction.

89. The system of claim 85, wherein at least a portion of the anchor member is configured to rotate relative to wall of the tissue structure upon application of a tensioning load to the suture member.

90. The system of claim 85, wherein the first helical member and coupled anchor member are advanced in a substantially helical pathway.

91. The system of claim 85, wherein the local suture length storage reservoir is coupled to the delivery member in a configuration wherein advancement of the first helical member does not substantially advance the reservoir relative to the wall of the tissue structure.

92. The system of claim 91, further comprising a sleeve member movably coupled to the delivery member such that the deliver member is threaded through a lumen defined by the sleeve member, wherein the sleeve member is coupled to the local suture length storage reservoir.

93. The system of claim 85, wherein the first helical member defines an inner helix diameter that is substantially constant across the length of the helical member.

94. The system of claim 85, wherein the first helical member defines an inner helix diameter that varies across the length of the helical member.

95. The system of claim 93, wherein the inner helix diameter is between about 5mm and about 60mm.

96. The system of claim 95, wherein the inner helix diameter is between about 10mm and about 20mm.

97. The system of claim 85, wherein the first helical member is comprised of an elongate member formed into the helical shape, the elongate member having an outer diameter.

98. The system of claim 97, wherein the elongate member has a cross sectional shape selected from the group consisting of: a circular cross section, an elliptical cross section, a square cross section, and a rectangular cross section.

99. The system of claim 97, wherein the outer diameter is between about 0.5mm and about 3mm.

100. The system of claim 97, wherein the helical shape comprises a number of helical turns advanceable into tissue that is between about 1 and about 3.

101. The system of claim 93, wherein the helical shape has a substantially constant helix pitch along the length of the helical shape.

102. The system of claim 93, wherein the helical shape has a substantially variable helix pitch along the length of the helical shape.

103. The system of claim 94, wherein the helical shape has a substantially constant helix pitch along the length of the helical shape.

104. The system of claim 94, wherein the helical shape has a substantially variable helix pitch along the length of the helical shape.

105. The system of claim 101, wherein the helix pitch is between about 5mm and about 20mm.

106. The system of claim 105, wherein the helix pitch is between about 7mm and about 13mm.

107. The system of claim 85, wherein the distal end of the first helical member comprises a sharpened tip configured to easily dive into and cross portions of the wall of the tissue structure.

108. The system of claim 97, wherein the distal end of the first helical member comprises an anchor coupling portion wherein the outer diameter of the elongate member is decreased to accommodate slidable coupling of the anchor member.

109. The system of claim 108, wherein the outer diameter of anchor member is substantially similar to that of the portions of the elongate member proximal to the anchor coupling portion.

110. The system of claim 87, wherein the helical shape is defined by a helix pitch, the helix pitch being selected based upon a targeted depth of traversal through the wall of the tissue structure that will result in the deployed suture pattern.

111. The system of claim 110, wherein the targeted depth of traversal is configured to entirely cross the wall of the tissue structure, leaving the anchor member on an opposite side of the wall.

112. The system of claim 110, wherein the targeted depth of traversal is configured to only partially cross the wall of the tissue structure, leaving the anchor member in a midsubstance location within the wall.

113. The system of claim 97, wherein the elongate member comprises a solid cross-sectional construct.

114. The system of claim 97, wherein the elongate member comprises a tubular construct having an inner diameter and as well as the outer diameter.

115. The system of claim 113, wherein the elongate member comprises a material selected from the group consisting of: stainless steel, nitinol alloy, titanium, cobalt chrome, and polymer composite.

116. The system of claim 114, wherein the elongate member comprises a material selected from the group consisting of: stainless steel, nitinol alloy, titanium, cobalt chrome, and polymer composite.

117. The system of claim 88, wherein the anchor member comprises a main body portion comprising a solid or tubular construct.

118. The system of claim 117, wherein the shape feature configured to slide past nearby tissue structures during inward insertion loading comprises a tapered distal tip.

119. The system of claim 117, wherein the shape feature configured to resist movement relative to the nearby tissue structures upon application of outward extraction loading comprises a projecting portion configured to extend to a projecting position beyond an outer diameter of the rest of the anchor member when tension is applied to the intercoupled suture member.

120. The system of claim 119, wherein the projecting portion comprises a portion of the anchor member that has been deformed out into the projecting position.

121. The system of claim 119, wherein the projecting portion comprises a piece of material that has been coupled to the anchor member to assume the projecting position.

122. The system of claim 119, further comprising two or more projecting portions.

123. The system of claim 119, wherein the projecting portion comprises a superelastic alloy that is shape set to the projecting position and configured to be deliverable in an elastically compressed form within a superelastic thermal range for the alloy.

124. The system of claim 85, wherein the suture member is coupled to an eyelet coupled to the anchor member.

125. The system of claim 124, wherein the eyelet is positioned such that tension on the suture member urges the anchor into rotational movement relative to surrounding portions of the wall of the tissue structure when the suture member is pulled in tension relative to the anchor member.

126. The system of claim 125, wherein anchor has a longitudinal axis, and wherein the eyelet is placed at a position spaced apart from the longitudinal axis.

127. The system of claim 124, wherein the eyelet is coupled to a ring member defining a ring aperture through which at least a portion of the anchor is positioned.

128. The system of claim 127, wherein the ring member is coupled to the anchor using a coupling selected from the group consisting of: an adhesive coupling, a press-fit coupling, and a tack-welding coupling.

129. The system of claim 85, wherein the anchor comprises a metal selected from the group consisting of: titanium, nickel, stainless steel, cobalt chrome, and alloys thereof.

130. The system of claim 85, wherein the anchor comprises a durable polymer selected from the group consisting of: polyethylene terepthalate, polyethylene, high density polyethylene, polypropylene, polytetrafluoroethylene, expanded polytetrafluoroethylene, poly (ethylene-co-vinyl acetate), poly(butyl methacrylate), and co-polymers thereof.

131. The system of claim 85, wherein the anchor comprises a bioresorbable polymer selected from the group consisting of: polylactic acid, polyglycolic acid, polylactic-co-glycolic acid, polylactic acid-co-caprolactone, poly (block-ethylene oxide-block-lactide-co-glycolide), polyethylene glycol, polyethylene oxide, poly (block-ethylene

oxide-block-propylene oxide-block-ethylene oxide), polyvinyl pyrrolidone, polyorthoester, polyanhydride, polyhydroxy valerate, polyhydroxy butyrate, and co-polymers thereof.

132. The system of claim 85, wherein the anchor comprises a biological graft material.

133. The system of claim 132, wherein the biological graft material has an origin selected from the group consisting of: another human, the particular human, a non-human animal.

134. The system of claim 85, wherein the anchor comprises a bioresorbable material selected from the group consisting of: porcine collagen matrix, human collagen matrix, equine collagen fleece, gelatin, polyhyaluronic acid, heparin, poly (glucose), poly(alginic acid), chitin, chitosan, cellulose, methyl cellulose, hydroxyethylcellulose, hydroxypropylcellulose, carboxymethylcellulose; polylysine, polyglutamic acid, albumin, hydroxy apatite, cortical bone, cancellous bone, trabecular bone, bioceramic, ligament tissue, tendon tissue, dura tissue, fascia tissue, pericardium tissue, thrombin, and fibrin.

135. The system of claim 85, wherein the local suture length storage reservoir comprises an enclosure for storing one or more loops of suture member length.

136. The system of claim 85, wherein the additional length of suture is between about 50 millimeters and about 200 millimeters.

137. The system of claim 135, wherein the enclosure comprises a membrane configured to partially encapsulate the one or more loops of suture member length, and allow the one or more loops to be pulled out of the enclosure when under tensile loading from the anchor and helical members.

138. The system of claim 85, further comprising a suture tensioning member coupled to the suture member between a proximal end of the suture member and a distal end of the suture member, the suture tensioning member configured to apply a compressive load to an exposed proximal aspect of the wall of the tissue structure when a distal end of the suture tensioning member is placed against the exposed proximal aspect of the wall and the suture member is tensioned proximally of the suture tensioning member.

139. The system of claim 138, wherein the suture tensioning member comprises an elongate tubular member defining a lumen therethrough, the suture member being threaded through the lumen.

140. The system of claim 138, further comprising a temporary suture member clamp coupleable to a proximal portion of the suture member and configured to retain tension upon a portion of suture member distal to the suture member clamp that is threaded through the lumen of the elongate tubular member.

141. The system of claim 85, wherein the suture tensioning member has two modes of operation, a first mode wherein the suture tensioning member may be moved bidirectionally relative to the suture member, and a second mode wherein the suture tensioning member may only be moved unidirectionally relative to the suture member, and wherein the suture tensioning member comprises a manually-operated mode-switching member configured to controllably switch the suture tensioning member from the first mode to the second mode.

142. The system of claim 85, further comprising a tissue interface indentor member coupled to the delivery member and operatively coupled to the first helical member, the tissue interface indentor member comprising a distally protruding shape feature configured to contact one or more portions of the tissue structure adjacent to the distal end of the helical member and change an available angle of penetration between such portions and the distal tip of the first helical member as the distal tip is inserted into the tissue structure.

143. The system of claim 142, wherein the distally protruding shape feature is configured to concentrate interfacial stresses upon the tissue structure such that the portions of the tissue structure adjacent the distal end of the first helical member become locally strained about the distally protruding shape feature as the distally protruding shape feature is advanced into contact with the adjacent tissue structure portions; and wherein the contact between the adjacent tissue structure portions and the distally protruding shape feature locally increases the available angle of penetration defined between the first helical member and a surface of the adjacent tissue structure portions.

144. The system of claim 143, wherein at least one surface of the distally protruding shape feature comprises a surface configuration selected from the group consisting of: a portion of a spherical surface, a linear ramp surface, an arcuate ramp surface, a multi-stepped ramp surface, and a single-stepped ramp surface.

145. The system of claim 144, wherein the surface configuration is helically wrapped about a longitudinal axis of the first helical member.

146. The system of claim 143, wherein at least one surface of the distally protruding shape feature comprises a substantially perpendicular leading surface.

147. The system of claim 143, wherein the distally protruding shape feature has a cross sectional profile comprising a cross sectional shape selected from the list consisting of: a rectangle, a square, a half circle, a triangle, a polygon, a rounded rectangular shape, a rounded square shape, and a multi-arcuate shape.

148. The system of claim 142, wherein the distally protruding shape feature and distal tip of the helical member are operatively coupled such that the distal tip is movably coupled through a portion of the distally protruding shape feature.

149. The system of claim 148, wherein the distal tip substantially bisects the portion of the distally protruding shape feature.

150. The system of claim 142, wherein the distally protruding shape feature and distal tip of the helical member are operatively coupled such that the distal tip is movably coupled adjacent a portion of the distally protruding shape feature.

151. The system of claim 144, wherein the distal tip of the helical member is configured to follow a path substantially parallel to the surface configuration of the distally protruding shape feature.

152. The system of claim 143, wherein the distally protruding shape feature comprises one or more tissue traction features configured to prevent relative motion between the distally protruding shape feature and portions of the tissue structure with which it may be directly interfaced.

153. The system of claim 152, wherein at least one of the one of the one or more tissue traction features comprises a barb.

154. The system of claim 85, further comprising a helical member guiding member having proximal and distal ends and being coupled to the first helical member, wherein the distal end of the helical member guiding member is substantially straight and defines a longitudinal axis that is substantially coincident with a longitudinal axis defined through the first helical member.

155. The system of claim 154, wherein the helical member guiding member is coupled to the delivery member, which is coupled to the helical member.

156. The system of claim 154, wherein the helical member guiding member is immediately coupled to the helical member.

157. The system of claim 154, wherein the distal end of the helical member guiding member comprises an aperture fluidly coupled to a lumen defined through the helical member guiding member and leading proximally to a detection position wherein an operator may visually detect fluid which may be present at the aperture.

158. The system of claim 155, wherein the aperture is positioned along the longitudinal axis of the helical member guiding member that is keyed to mark a distal protrusion position of a structure portion selected from the group consisting of: the distal end of the helical member; the distal end of the anchor member; and the proximal end of the anchor member.

159. The system of claim 154, further comprising a second aperture fluidly coupled to a second lumen defined through the helical member guiding member and leading proximally to a second detection position wherein an operator may visually detect fluid which may be present at the second aperture.

160. The system of claim 154, wherein the helical member guiding member comprises a sensor selected from the group consisting of: an OCT sensor, an ultrasound sensor, an RF impedance sensor, a partial pressure of oxygen sensor, and a pressure sensor.

161. The system of claim 85, further comprising a second helical member having proximal and distal ends, the proximal end coupled to the delivery member distal end, the distal end extending distally of the delivery member distal end.

162. The system of claim 161, wherein the second helical member defines an inner helix diameter that is substantially constant across the length of the helical member.

163. The system of claim 161, wherein the second helical member defines an inner helix diameter that varies across the length of the helical member.

164. The system of claim 161, wherein the inner helix diameters of the first and second helical members are substantially equal.

165. The system of claim 161, wherein the inner helix diameters of the first and second helical members are substantially unequal.

166. The system of claim 161, wherein the first and second helical members define longitudinal axes that are substantially coaxial.

167. The system of claim 161, further comprising a second anchor member removably coupled to the distal end of the second helical member.

168. The system of claim 167, further comprising a second suture member coupled to the second helical member.

169. A system for providing surgical access across a wall of a tissue structure, comprising:

a. a delivery member having proximal and distal ends;

b. a first helical member having proximal and distal ends and a helical shape, the proximal end coupled to the delivery member distal end, the distal end extending distally of the delivery member distal end;

c. an anchor member removably coupled to the helical member distal end;

d. a suture member coupled distally to a portion of the anchor member and extending proximally to a position wherein at least a portion of it may be freely manipulated by an operator; and

e. a tissue interface indentor member coupled to the delivery member and operatively coupled to the first helical member, the tissue interface indentor member comprising a distally protruding shape feature configured to contact one or more portions of the tissue structure adjacent to the distal end of the helical member and change an available angle of penetration between such

portions and the distal tip of the first helical member as the distal tip is inserted into the tissue structure.

wherein upon rotation of the delivery member in a first direction, the indentor member is urged against the tissue structure and the first helical member and coupled anchor member are advanced across at least a portion of the wall of the tissue structure, pulling along the distal portion of the suture member in a deployed suture pattern which remains coupled to the anchor member.

170. The system of claim 169, wherein upon rotation of the delivery member in a second direction opposite to the first direction, a reverse load is applied to the delivery member and coupled first helical member which causes the anchor member to become decoupled from the first helical member, such that further rotation in the second direction causes removal of the first helical member and delivery member while the anchor member and suture member distal portion remain positioned across the portion of the wall of the tissue structure.

171. The system of claim 169, wherein the deployed suture pattern is characterized in that it is substantially helical and represents a number of helical loops encapsulated by the wall of the tissue structure that is greater than about one helical loop, and is less than about three helical loops.

172. The system of claim 169, wherein the anchor member has at least one shape feature that is configured to slide past nearby tissue structures during inward insertion loading associated with rotation of the first helical member in the first direction, and to resist movement relative to the nearby tissue structures upon application of outward extraction loading associated with rotation of the first helical member in the second direction.

173. The system of claim 169, wherein at least a portion of the anchor member is configured to rotate relative to wall of the tissue structure upon application of a tensioning load to the suture member.

174. The system of claim 169, wherein the first helical member and coupled anchor member are advanced in a substantially helical pathway.

175. The system of claim 169, wherein the proximal end of the suture member extends proximally beyond the deployed suture pattern into a local suture length storage reservoir coupled to the delivery member containing an additional length of suture, the reservoir being configured such that upon rotation of the delivery member in the first direction, the anchor member pulls along the distal portion of the suture member causing at least a portion of the additional length of suture to be extended out from the local suture length storage reservoir.

176. The system of claim 175, wherein the local suture length storage reservoir is coupled to the delivery member in a configuration wherein advancement of the first helical member does not substantially advance the reservoir relative to the wall of the tissue structure.

177. The system of claim 176, further comprising a sleeve member movably coupled to the delivery member such that the deliver member is threaded through a lumen defined by the sleeve member, wherein the sleeve member is coupled to the local suture length storage reservoir.

178. The system of claim 169, wherein the first helical member defines an inner helix diameter that is substantially constant across the length of the helical member.

179. The system of claim 169, wherein the first helical member defines an inner helix diameter that varies across the length of the helical member.

180. The system of claim 178, wherein the inner helix diameter is between about 5mm and about 60mm.

181. The system of claim 180, wherein the inner helix diameter is between about 10mm and about 20mm.

182. The system of claim 169, wherein the first helical member is comprised of an elongate member formed into the helical shape, the elongate member having an outer diameter.

183. The system of claim 182, wherein the elongate member has a cross sectional shape selected from the group consisting of: a circular cross section, an elliptical cross section, a square cross section, and a rectangular cross section.

184. The system of claim 182, wherein the outer diameter is between about 0.5mm and about 3mm.

185. The system of claim 182, wherein the helical shape comprises a number of helical turns advanceable into tissue that is between about 1 and about 3.

186. The system of claim 178, wherein the helical shape has a substantially constant helix pitch along the length of the helical shape.

187. The system of claim 178, wherein the helical shape has a substantially variable helix pitch along the length of the helical shape.

188. The system of claim 179, wherein the helical shape has a substantially constant helix pitch along the length of the helical shape.

189. The system of claim 179, wherein the helical shape has a substantially variable helix pitch along the length of the helical shape.

190. The system of claim 186, wherein the helix pitch is between about 5mm and about 20mm.

191. The system of claim 190, wherein the helix pitch is between about 7mm and about 13mm.

192. The system of claim 169, wherein the distal end of the first helical member comprises a sharpened tip configured to easily dive into and cross portions of the wall of the tissue structure.

193. The system of claim 182, wherein the distal end of the first helical member comprises an anchor coupling portion wherein the outer diameter of the elongate member is decreased to accommodate slidable coupling of the anchor member.

194. The system of claim 193, wherein the outer diameter of anchor member is substantially similar to that of the portions of the elongate member proximal to the anchor coupling portion.

195. The system of claim 171, wherein the helical shape is defined by a helix pitch, the helix pitch being selected based upon a targeted depth of traversal through the wall of the tissue structure that will result in the deployed suture pattern.

196. The system of claim 195, wherein the targeted depth of traversal is configured to entirely cross the wall of the tissue structure, leaving the anchor member on an opposite side of the wall.

197. The system of claim 195, wherein the targeted depth of traversal is configured to only partially cross the wall of the tissue structure, leaving the anchor member in a midsubstance location within the wall.

198. The system of claim 182, wherein the elongate member comprises a solid cross-sectional construct.

199. The system of claim 182, wherein the elongate member comprises a tubular construct having an inner diameter and as well as the outer diameter.

200. The system of claim 198, wherein the elongate member comprises a material selected from the group consisting of: stainless steel, nitinol alloy, titanium, cobalt chrome, and polymer composite.

201. The system of claim 199, wherein the elongate member comprises a material selected from the group consisting of: stainless steel, nitinol alloy, titanium, cobalt chrome, and polymer composite.

202. The system of claim 172, wherein the anchor member comprises a main body portion comprising a solid or tubular construct.

203. The system of claim 202, wherein the shape feature configured to slide past nearby tissue structures during inward insertion loading comprises a tapered distal tip.

204. The system of claim 202, wherein the shape feature configured to resist movement relative to the nearby tissue structures upon application of outward extraction loading comprises a projecting portion configured to extend to a projecting position beyond an outer diameter of the rest of the anchor member when tension is applied to the intercoupled suture member.

205. The system of claim 204, wherein the projecting portion comprises a portion of the anchor member that has been deformed out into the projecting position.

206. The system of claim 204, wherein the projecting portion comprises a piece of material that has been coupled to the anchor member to assume the projecting position.

207. The system of claim 204, further comprising two or more projecting portions.

208. The system of claim 204, wherein the projecting portion comprises a superelastic alloy that is shape set to the projecting position and configured to be deliverable in an elastically compressed form within a superelastic thermal range for the alloy.

209. The system of claim 169, wherein the suture member is coupled to an eyelet coupled to the anchor member.

210. The system of claim 209, wherein the eyelet is positioned such that tension on the suture member urges the anchor into rotational movement relative to surrounding portions of the wall of the tissue structure when the suture member is pulled in tension relative to the anchor member.

211. The system of claim 210, wherein anchor has a longitudinal axis, and wherein the eyelet is placed at a position spaced apart from the longitudinal axis.

212. The system of claim 209, wherein the eyelet is coupled to a ring member defining a ring aperture through which at least a portion of the anchor is positioned.

213. The system of claim 212, wherein the ring member is coupled to the anchor using a coupling selected from the group consisting of: an adhesive coupling, a press-fit coupling, and a tack-welding coupling.

214. The system of claim 169, wherein the anchor comprises a metal selected from the group consisting of: titanium, nickel, stainless steel, cobalt chrome, and alloys thereof.

215. The system of claim 169, wherein the anchor comprises a durable polymer selected from the group consisting of: polyethylene terepthalate, polyethylene, high density polyethylene, polypropylene, polytetrafluoroethylene, expanded polytetrafluoroethylene, poly (ethylene-co-vinyl acetate), poly(butyl methacrylate), and co-polymers thereof.

216. The system of claim 169, wherein the anchor comprises a bioresorbable polymer selected from the group consisting of: polylactic acid, polyglycolic acid, polylactic-co-glycolic acid, polylactic acid-co-caprolactone, poly (block-ethylene oxide-block-lactide-co-glycolide), polyethylene glycol, polyethylene oxide, poly (block-ethylene

oxide-block-propylene oxide-block-ethylene oxide), polyvinyl pyrrolidone, polyorthoester, polyanhydride, polyhydroxy valerate, polyhydroxy butyrate, and co-polymers thereof.

217. The system of claim 169, wherein the anchor comprises a biological graft material.

218. The system of claim 217, wherein the biological graft material has an origin selected from the group consisting of: another human, the particular human, a non-human animal.

219. The system of claim 169, wherein the anchor comprises a bioresorbable material selected from the group consisting of: porcine collagen matrix, human collagen matrix, equine collagen fleece, gelatin, polyhyaluronic acid, heparin, poly (glucose), poly(alginic acid), chitin, chitosan, cellulose, methyl cellulose, hydroxyethylcellulose, hydroxypropylcellulose, carboxymethylcellulose; polylysine, polyglutamic acid, albumin, hydroxy apatite, cortical bone, cancellous bone, trabecular bone, bioceramic, ligament tissue, tendon tissue, dura tissue, fascia tissue, pericardium tissue, thrombin, and fibrin.

220. The system of claim 175, wherein the local suture length storage reservoir comprises an enclosure for storing one or more loops of suture member length.

221. The system of claim 175, wherein the additional length of suture is between about 20 millimeters and about 500 millimeters.

222. The system of claim 220, wherein the enclosure comprises a membrane configured to partially encapsulate the one or more loops of suture member length, and allow the one or more loops to be pulled out of the enclosure when under tensile loading from the anchor and helical members.

223. The system of claim 169, further comprising a suture tensioning member coupled to the suture member between a proximal end of the suture member and a distal end of the suture member, the suture tensioning member configured to apply a compressive load to an exposed proximal aspect of the wall of the tissue structure when a distal end of the suture tensioning member is placed against the exposed proximal aspect of the wall and the suture member is tensioned proximally of the suture tensioning member.

224. The system of claim 223, wherein the suture tensioning member comprises an elongate tubular member defining a lumen therethrough, the suture member being threaded through the lumen.

225. The system of claim 224, further comprising a temporary suture member clamp coupleable to a proximal portion of the suture member and configured to retain tension upon a portion of suture member distal to the suture member clamp that is threaded through the lumen of the elongate tubular member.

226. The system of claim 169, wherein the suture tensioning member has two modes of operation, a first mode wherein the suture tensioning member may be moved bidirectionally relative to the suture member, and a second mode wherein the suture tensioning member may only be moved unidirectionally relative to the suture member, and wherein the suture tensioning member comprises a manually-operated mode-switching member configured to controllably switch the suture tensioning member from the first mode to the second mode.

227. The system of claim 169, wherein the distally protruding shape feature is configured to concentrate interfacial stresses upon the tissue structure such that the portions of the tissue structure adjacent the distal end of the first helical member become locally strained about the distally protruding shape feature as the distally protruding shape feature is advanced into contact with the adjacent tissue structure portions; and wherein the contact between the adjacent tissue structure portions and the distally protruding shape feature locally increases the available angle of penetration defined between the first helical member and a surface of the adjacent tissue structure portions.

228. The system of claim 227, wherein at least one surface of the distally protruding shape feature comprises a surface configuration selected from the group consisting of: a portion of a spherical surface, a linear ramp surface, an arcuate ramp surface, a multi-stepped ramp surface, and a single-stepped ramp surface.

229. The system of claim 228, wherein the surface configuration is helically wrapped about a longitudinal axis of the first helical member.

230. The system of claim 227, wherein at least one surface of the distally protruding shape feature comprises a substantially perpendicular leading surface.

231. The system of claim 227, wherein the distally protruding shape feature has a cross sectional profile comprising a cross sectional shape selected from the list consisting of: a rectangle, a square, a half circle, a triangle, a polygon, a rounded rectangular shape, a rounded square shape, and a multi-arcuate shape.

232. The system of claim 227, wherein the distally protruding shape feature and distal tip of the helical member are operatively coupled such that the distal tip is movably coupled through a portion of the distally protruding shape feature.

233. The system of claim 232, wherein the distal tip substantially bisects the portion of the distally protruding shape feature.

234. The system of claim 227, wherein the distally protruding shape feature and distal tip of the helical member are operatively coupled such that the distal tip is movably coupled adjacent a portion of the distally protruding shape feature.

235. The system of claim 228, wherein the distal tip of the helical member is configured to follow a path substantially parallel to the surface configuration of the distally protruding shape feature.

236. The system of claim 227, wherein the distally protruding shape feature comprises one or more tissue traction features configured to prevent relative motion between the distally protruding shape feature and portions of the tissue structure with which it may be directly interfaced.

237. The system of claim 236, wherein at least one of the one of the one or more tissue traction features comprises a barb.

238. The system of claim 169, further comprising a helical member guiding member having proximal and distal ends and being coupled to the first helical member, wherein the distal end of the helical member guiding member is substantially straight and defines a longitudinal axis that is substantially coincident with a longitudinal axis defined through the first helical member.

239. The system of claim 238, wherein the helical member guiding member is coupled to the delivery member, which is coupled to the helical member.

240. The system of claim 238, wherein the helical member guiding member is immediately coupled to the helical member.

241. The system of claim 238, wherein the distal end of the helical member guiding member comprises an aperture fluidly coupled to a lumen defined through the helical member guiding member and leading proximally to a detection position wherein an operator may visually detect fluid which may be present at the aperture.

242. The system of claim 241, wherein the aperture is positioned along the longitudinal axis of the helical member guiding member that is keyed to mark a distal protrusion position of a structure portion selected from the group consisting of: the distal end of the helical member; the distal end of the anchor member; and the proximal end of the anchor member.

243. The system of claim 238, further comprising a second aperture fluidly coupled to a second lumen defined through the helical member guiding member and leading proximally to a second detection position wherein an operator may visually detect fluid which may be present at the second aperture.

244. The system of claim 238, wherein the helical member guiding member comprises a sensor selected from the group consisting of: an OCT sensor, an ultrasound sensor, an RF impedance sensor, a partial pressure of oxygen sensor, and a pressure sensor.

245. The system of claim 169, further comprising a second helical member having proximal and distal ends, the proximal end coupled to the delivery member distal end, the distal end extending distally of the delivery member distal end.

246. The system of claim 245, wherein the second helical member defines an inner helix diameter that is substantially constant across the length of the helical member.

247. The system of claim 245, wherein the second helical member defines an inner helix diameter that varies across the length of the helical member.

248. The system of claim 245, wherein the inner helix diameters of the first and second helical members are substantially equal.

249. The system of claim 245, wherein the inner helix diameters of the first and second helical members are substantially unequal.

250. The system of claim 245, wherein the first and second helical members define longitudinal axes that are substantially coaxial.

251. The system of claim 245, further comprising a second anchor member removably coupled to the distal end of the second helical member.

252. The system of claim 245, further comprising a second suture member coupled to the second helical member.

253. A system for providing surgical access across a wall of a tissue structure, comprising:

a. a delivery member having proximal and distal ends;

b. a plurality of helical members , each having proximal and distal ends and a helical shape, each proximal end coupled to the delivery member distal end, each distal end extending distally of the delivery member distal end;

c. a plurality of anchor members removably coupled to the helical member distal ends; and

d. a plurality of suture members coupled distally to a portion of one of the anchor members and extending proximally to a position wherein at least a portion of each may be freely manipulated by an operator;

wherein upon rotation of the delivery member in a first direction, the helical members and coupled anchor members are advanced across at least a portion of the wall of the tissue structure, pulling along the distal portions of the suture members in a deployed suture pattern which remains coupled to the anchor member.

254. The system of claim 253, wherein upon rotation of the delivery member in a second direction opposite to the first direction, a reverse load is applied to the delivery member and coupled helical members which causes the anchor members to become decoupled from the helical members, such that further rotation in the second direction causes removal of the helical members and delivery member while the anchor members and suture member distal portions remain positioned across the portion of the wall of the tissue structure.

255. The system of claim 253, wherein the deployed suture pattern is characterized in that in the aggregate it represents a number of helical loops encapsulated by the wall of the tissue structure that is greater than about one helical loop, and is less than about three helical loops.

256. The system of claim 253, wherein the deployed suture pattern is characterized in that at least one of the suture members defines a substantially helical pathway in the wall of the tissue structure and represents a number of helical loops encapsulated by the wall of the tissue structure that is greater than about one helical loop, and is less than about three helical loops.

257. The system of claim 253, wherein the plurality of helical members comprises two, the plurality of anchor members comprises two, and the plurality of suture members comprises two.

258. The system of claim 253, wherein the plurality of helical members comprises three, the plurality of anchor members comprises three, and the plurality of suture members comprises three.

259. The system of claim 253, wherein at least one of the anchor members has at least one shape feature that is configured to slide past nearby tissue structures during inward insertion loading associated with rotation of a first helical member in the first direction, and to resist movement relative to the nearby tissue structures upon application of outward extraction loading associated with rotation of the first helical member in the second direction.

260. The system of claim 253, wherein at least a portion of one of the anchor members is configured to rotate relative to wall of the tissue structure upon application of a tensioning load to the associated suture member.

261. The system of claim 253, wherein the helical members and coupled anchor members are advanced in a plurality of substantially helical pathways.

262. The system of claim 253, wherein the proximal end of at least one of the suture members extends proximally beyond the deployed suture pattern into a local suture length storage reservoir coupled to the delivery member containing an additional length of suture, the reservoir being configured such that upon rotation of the delivery

member in the first direction, the anchor member coupled to the suture member pulls along the distal portion of the suture member causing at least a portion of the additional length of suture to be extended out from the local suture length storage reservoir.

263. The system of claim 262, wherein the local suture length storage reservoir is coupled to the delivery member in a configuration wherein advancement of any of the helical members does not substantially advance the reservoir relative to the wall of the tissue structure.

264. The system of claim 263, further comprising a sleeve member movably coupled to the delivery member such that the deliver member is threaded through a lumen defined by the sleeve member, wherein the sleeve member is coupled to the local suture length storage reservoir.

265. The system of claim 253, wherein a first helical member defines an inner helix diameter that is substantially constant across the length of the helical member.

266. The system of claim 253, wherein a first helical member defines an inner helix diameter that varies across the length of the helical member.

267. The system of claim 265, wherein the inner helix diameter is between about 5mm and about 60mm.

268. The system of claim 267, wherein the inner helix diameter is between about 10mm and about 20mm.

269. The system of claim 253, wherein a first helical member is comprised of an elongate member formed into the helical shape, the elongate member having an outer diameter.

270. The system of claim 269, wherein the elongate member has a cross sectional shape selected from the group consisting of: a circular cross section, an elliptical cross section, a square cross section, and a rectangular cross section.

271. The system of claim 269, wherein the outer diameter is between about 0.5mm and about 3mm.

272. The system of claim 269, wherein the helical shape comprises a number of helical turns advanceable into the wall of the tissue structure that is between about 1 and about 3.

273. The system of claim 265, wherein the helical shape has a substantially constant helix pitch along the length of the helical shape.

274. The system of claim 265, wherein the helical shape has a substantially variable helix pitch along the length of the helical shape.

275. The system of claim 266, wherein the helical shape has a substantially constant helix pitch along the length of the helical shape.

276. The system of claim 266, wherein the helical shape has a substantially variable helix pitch along the length of the helical shape.

277. The system of claim 273, wherein the helix pitch is between about 5mm and about 20mm.

278. The system of claim 277, wherein the helix pitch is between about 7mm and about 13mm.

279. The system of claim 253, wherein the distal end of a first helical member comprises a sharpened tip configured to easily dive into and cross portions of the wall of the tissue structure.

280. The system of claim 269, wherein the distal end of the first helical member comprises an anchor coupling portion wherein the outer diameter of the elongate member is decreased to accommodate slidable coupling of one of the anchor members.

281. The system of claim 280, wherein the outer diameter of the anchor member is substantially similar to that of the portions of the elongate member proximal to the anchor coupling portion.

282. The system of claim 255, wherein the helical shapes are defined by helical pitches selected based upon targeted depths of traversal through the wall of the tissue structure that will result in the deployed suture pattern.

283. The system of claim 256, wherein the helical shape associated with the at least one of the suture members is defined by a helical pitch selected based upon a targeted depth of traversal through the wall of the tissue structure that will result in the deployed suture pattern.

284. The system of claim 282, wherein at least one of the targeted depths of traversal is configured to entirely cross the wall of the tissue structure, leaving an anchor member on an opposite side of the wall.

285. The system of claim 282, wherein at least one of the targeted depths of traversal is configured to only partially cross the wall of the tissue structure, leaving an anchor member in a midsubstance location within the wall.

286. The system of claim 269, wherein the elongate member comprises a solid cross-sectional construct.

287. The system of claim 269, wherein the elongate member comprises a tubular construct having an inner diameter and as well as the outer diameter.

288. The system of claim 286, wherein the elongate member comprises a material selected from the group consisting of: stainless steel, nitinol alloy, titanium, cobalt chrome, and polymer composite.

289. The system of claim 287, wherein the elongate member comprises a material selected from the group consisting of: stainless steel, nitinol alloy, titanium, cobalt chrome, and polymer composite.

290. The system of claim 259, wherein at least one anchor member comprises a main body portion comprising a solid or tubular construct.

291. The system of claim 290, wherein the shape feature configured to slide past nearby tissue structures during inward insertion loading comprises a tapered distal tip.

292. The system of claim 290, wherein the shape feature configured to resist movement relative to the nearby tissue structures upon application of outward extraction loading comprises a projecting portion configured to extend to a projecting position beyond an outer diameter of the rest of the anchor member when tension is applied to the intercoupled suture member.

293. The system of claim 292, wherein the projecting portion comprises a portion of the anchor member that has been deformed out into the projecting position.

294. The system of claim 292, wherein the projecting portion comprises a piece of material that has been coupled to the anchor member to assume the projecting position.

295. The system of claim 292, further comprising two or more projecting portions.

296. The system of claim 292, wherein the projecting portion comprises a superelastic alloy that is shape set to the projecting position and configured to be deliverable in an elastically compressed form within a superelastic thermal range for the alloy.

297. The system of claim 253, wherein at least one of the suture members is coupled to an eyelet coupled to an anchor member.

298. The system of claim 297, wherein the eyelet is positioned such that tension on the coupled suture member urges the anchor into rotational movement relative to surrounding portions of the wall of the tissue structure when the suture member is pulled in tension relative to the anchor member.

299. The system of claim 46298 wherein anchor has a longitudinal axis, and wherein the eyelet is placed at a position spaced apart from the longitudinal axis.

300. The system of claim 297, wherein the eyelet is coupled to a ring member defining a ring aperture through which at least a portion of the anchor is positioned.

301. The system of claim 300, wherein the ring member is coupled to the anchor using a coupling selected from the group consisting of: an adhesive coupling, a press-fit coupling, and a tack-welding coupling.

302. The system of claim 253, wherein the anchor comprises a metal selected from the group consisting of: titanium, nickel, stainless steel, cobalt chrome, and alloys thereof.

303. The system of claim 253, wherein the anchor comprises a durable polymer selected from the group consisting of: polyethylene terepthalate, polyethylene, high density polyethylene, polypropylene, polytetrafluoroethylene, expanded polytetrafluoroethylene, poly (ethylene-co-vinyl acetate), poly(butyl methacrylate), and co-polymers thereof.

304. The system of claim 253, wherein the anchor comprises a bioresorbable polymer selected from the group consisting of: polylactic acid, polyglycolic acid, polylactic-co-glycolic acid, polylactic acid-co-caprolactone, poly (block-ethylene oxide-block-lactide-co-glycolide), polyethylene glycol, polyethylene oxide, poly (block-ethylene oxide-block-propylene oxide-block-ethylene oxide), polyvinyl pyrrolidone, polyorthoester, polyanhydride, polyhydroxy valerate, polyhydroxy butyrate, and co-polymers thereof.

305. The system of claim 253, wherein the anchor comprises a biological graft material.

306. The system of claim 305, wherein the biological graft material has an origin selected from the group consisting of: another human, the particular human, a non-human animal.

307. The system of claim 253, wherein the anchor comprises a bioresorbable material selected from the group consisting of: porcine collagen matrix, human collagen matrix, equine collagen fleece, gelatin, polyhyaluronic acid, heparin, poly (glucose), poly(alginic acid), chitin, chitosan, cellulose, methyl cellulose, hydroxyethylcellulose, hydroxypropylcellulose, carboxymethylcellulose; polylysine, polyglutamic acid, albumin, hydroxy apatite, cortical bone, cancellous bone, trabecular bone, bioceramic, ligament tissue, tendon tissue, dura tissue, fascia tissue, pericardium tissue, thrombin, and fibrin.

308. The system of claim 262, wherein the local suture length storage reservoir comprises an enclosure for storing one or more loops of suture member length.

309. The system of claim 262, wherein the additional length of suture is between about 20 millimeters and about 500 millimeters.

310. The system of claim 308, wherein the enclosure comprises a membrane configured to partially encapsulate the one or more loops of suture member length, and allow the one or more loops to be pulled out of the enclosure when under tensile loading from the anchor and helical members.

311. The system of claim 253, further comprising a suture tensioning member coupled at least one of the suture members between a proximal end of the suture member and a distal end of the suture member, the suture tensioning member configured to apply a

compressive load to an exposed proximal aspect of the wall of the tissue structure when a distal end of the associated suture tensioning member is placed against the exposed proximal aspect of the wall and the suture member is tensioned proximally of the suture tensioning member.

312. The system of claim 311, wherein the suture tensioning member comprises an elongate tubular member defining a lumen therethrough, the suture member being threaded through the lumen.

313. The system of claim 312, further comprising a temporary suture member clamp coupleable to a proximal portion of the suture member and configured to retain tension upon a portion of suture member distal to the suture member clamp that is threaded through the lumen of the elongate tubular member.

314. The system of claim 253, wherein the suture tensioning member has two modes of operation, a first mode wherein the suture tensioning member may be moved bidirectionally relative to the suture member, and a second mode wherein the suture tensioning member may only be moved unidirectionally relative to the suture member, and wherein the suture tensioning member comprises a manually-operated mode-switching member configured to controllably switch the suture tensioning member from the first mode to the second mode.

315. The system of claim 253, further comprising a tissue interface indentor member coupled to the delivery member and operatively coupled to one or more of the helical members, the tissue interface indentor member comprising a plurality of distally protruding shape features configured to contact one or more portions of the tissue structure adjacent to each of the distal ends of the helical members and change an available angle of penetration between such portions and the distal tips of the helical members as the distal tips are inserted into the tissue structure.

316. The system of claim 315, wherein the distally protruding shape features are configured to concentrate interfacial stresses upon the tissue structure such that the portions of the tissue structure adjacent the distal ends of the helical members become locally strained about the distally protruding shape features as the distally protruding shape features are advanced into contact with the adjacent tissue structure portions; and wherein the contact between the adjacent tissue structure portions and the distally

protruding shape features locally increase the available angle of penetration defined between each of the helical members and a surface of the adjacent tissue structure portions.

317. The system of claim 316, wherein at least one surface of the one of the distally protruding shape feature comprises a surface configuration selected from the group consisting of: a portion of a spherical surface, a linear ramp surface, an arcuate ramp surface, a multi-stepped ramp surface, and a single-stepped ramp surface.

318. The system of claim 317, wherein the surface configuration is helically wrapped about a longitudinal axis of one of the helical members.

319. The system of claim 316, wherein at least one surface of one of the distally protruding shape features comprises a substantially perpendicular leading surface.

320. The system of claim 316, wherein at least one of the distally protruding shape features has a cross sectional profile comprising a cross sectional shape selected from the list consisting of: a rectangle, a square, a half circle, a triangle, a polygon, a rounded rectangular shape, a rounded square shape, and a multi-arcuate shape.

321. The system of claim 315, wherein at least one of the distally protruding shape features and distal tip of the associated helical member are operatively coupled such that the distal tip is movably coupled through a portion of the distally protruding shape feature.

322. The system of claim 321, wherein the distal tip substantially bisects the portion of the distally protruding shape feature.

323. The system of claim 315, wherein the distally protruding shape features and distal tips of the helical members are operatively coupled such that the distal tips are movably coupled adjacent to portions of the distally protruding shape features.

324. The system of claim 317, wherein the distal tip of the helical member is configured to follow a path substantially parallel to the surface configuration of the distally protruding shape feature.

325. The system of claim 316, wherein the distally protruding shape features comprise one or more tissue traction features configured to prevent relative motion between the

distally protruding shape features and portions of the tissue structure with which they may be directly interfaced.

326. The system of claim 325, wherein at least one of the one of the one or more tissue traction features comprises a barb.

327. The system of claim 253, further comprising a helical member guiding member having proximal and distal ends and being coupled to one or more of the helical members, wherein the distal end of the helical member guiding member is substantially straight and defines a longitudinal axis that is substantially coincident with a longitudinal axis defined through the helical members.

328. The system of claim 327, wherein the helical member guiding member is coupled to the delivery member, which is coupled to the one or more helical members.

329. The system of claim 327, wherein the helical member guiding member is immediately coupled to the one or more helical members.

330. The system of claim 327, wherein the distal end of the helical member guiding member comprises an aperture fluidly coupled to a lumen defined through the helical member guiding member and leading proximally to a detection position wherein an operator may visually detect fluid which may be present at the aperture.

331. The system of claim 330, wherein the aperture is positioned along the longitudinal axis of the helical member guiding member that is keyed to mark a distal protrusion position of a structure portion selected from the group consisting of: the distal end of one of the helical members; the distal end of one of the anchor members; and the proximal end of one of the anchor members.

332. The system of claim 327, further comprising a second aperture fluidly coupled to a second lumen defined through the helical member guiding member and leading proximally to a second detection position wherein an operator may visually detect fluid which may be present at the second aperture.

333. The system of claim 327, wherein the helical member guiding member comprises a sensor selected from the group consisting of: an OCT sensor, an ultrasound sensor, an RF impedance sensor, a partial pressure of oxygen sensor, and a pressure sensor.

334. A system for advancing a needle into a tissue structure, comprising:

a. an elongate needle member having a tapered distal tip;

b. an insertion member having proximal and distal ends, the distal end being coupled to the elongate needle member, and the proximal end being configured to be manipulated by an operator; and

c. a tissue interface indentor member coupled to the insertion member and operatively coupled to the elongate needle member, the tissue interface indentor member comprising a distally protruding shape feature configured to contact one or more portions of the tissue structure adjacent to the distal tip of the elongate needle member and change an available angle of penetration between such portions and the distal tip of the elongate needle member as the distal tip is inserted into tissue structure.

335. The system of claim 334, wherein the elongate needle member comprises a shape selected from the group consisting of: a substantially straight shape, an arcuate shape, and a helical shape.

336. The system of claim 335, wherein the elongate needle member comprises a first helical member that defines an inner helix diameter that is substantially constant across the length of the helical member.

337. The system of claim 335, wherein the elongate needle member comprises a first helical member that defines an inner helix diameter that varies across the length of the helical member.

338. The system of claim 336, wherein the inner helix diameter is between about 5mm and about 60mm.

339. The system of claim 338, wherein the inner helix diameter is between about 10mm and about 20mm.

340. The system of claim 335, wherein the elongate needle member comprises a first helical member that is comprised of an elongate member formed into the helical shape, the elongate member having an outer diameter.

341. The system of claim 340, wherein the elongate member has a cross sectional shape selected from the group consisting of: a circular cross section, an elliptical cross section, a square cross section, and a rectangular cross section.

342. The system of claim 340, wherein the outer diameter is between about 0.5mm and about 3mm.

343. The system of claim 340, wherein the helical shape comprises a number of helical turns advanceable into tissue relative to the insertion member that is between about 1 and about 3.

344. The system of claim 336, wherein the helical shape has a substantially constant helix pitch along the length of the helical shape.

345. The system of claim 336, wherein the helical shape has a substantially variable helix pitch along the length of the helical shape.

346. The system of claim 337, wherein the helical shape has a substantially constant helix pitch along the length of the helical shape.

347. The system of claim 337, wherein the helical shape has a substantially variable helix pitch along the length of the helical shape.

348. The system of claim 344, wherein the helix pitch is between about 5mm and about 20mm.

349. The system of claim 348, wherein the helix pitch is between about 7mm and about 13mm.

350. The system of claim 334, wherein the distal end of the first helical member comprises a sharpened tip configured to easily dive into and cross portions of the tissue structure.

351. The system of claim 340, wherein the elongate member comprises a solid cross-sectional construct.

352. The system of claim 340, wherein the elongate member comprises a tubular construct having an inner diameter and as well as the outer diameter.

353. The system of claim 351, wherein the elongate member comprises a material selected from the group consisting of: stainless steel, nitinol alloy, titanium, cobalt chrome, and polymer composite.

354. The system of claim 352, wherein the elongate member comprises a material selected from the group consisting of: stainless steel, nitinol alloy, titanium, cobalt chrome, and polymer composite.

355. The system of claim 334, wherein the insertion member comprises a substantially rigid construct.

356. The system of claim 334, wherein the insertion member comprises a flexible construct.

357. The system of claim 334, wherein the distally protruding shape feature is configured to concentrate interfacial stresses upon the tissue structure such that the portions of the tissue structure adjacent the distal tip of the elongate needle member become locally strained about the distally protruding shape feature as the distally protruding shape feature is advanced into contact with the adjacent tissue structure portions; and wherein the contact between the adjacent tissue structure portions and the distally protruding shape feature locally increases the available angle of penetration defined between the needle and a surface of the adjacent tissue structure portions.

358. The system of claim 357, wherein at least one surface of the distally protruding shape feature comprises a surface configuration selected from the group consisting of: a portion of a spherical surface, a linear ramp surface, an arcuate ramp surface, a multi-stepped ramp surface, and a single-stepped ramp surface.

359. The system of claim 358, wherein the surface configuration is helically wrapped about a longitudinal axis of the helical member.

360. The system of claim 357, wherein at least one surface of the distally protruding shape feature comprises a substantially perpendicular leading surface.

361. The system of claim 357, wherein the distally protruding shape feature has a cross sectional profile comprising a cross sectional shape selected from the list consisting of: a rectangle, a square, a half circle, a triangle, a polygon, a rounded rectangular shape, a rounded square shape, and a multi-arcuate shape.

362. The system of claim 334, wherein the distally protruding shape feature and distal tip of the elongate needle member are operatively coupled such that the distal tip is movably coupled through a portion of the distally protruding shape feature.

363. The system of claim 362,wherein the distal tip substantially bisects the portion of the distally protruding shape feature.

364. The system of claim 334, wherein the distally protruding shape feature and distal tip of the elongate needle member are operatively coupled such that the distal tip is movably coupled adjacent a portion of the distally protruding shape feature.

365. The system of claim 358, wherein the distal tip of the elongate needle member is configured to follow a path substantially parallel to the surface configuration of the distally protruding shape feature.

366. The system of claim 357, wherein the distally protruding shape feature comprises one or more tissue traction features configured to prevent relative motion between the distally protruding shape feature and portions of the tissue structure with which it may be directly interfaced.

367. The system of claim 366, wherein at least one of the one of the one or more tissue traction features comprises a barb.

368. A system for tensioning a suture member that crosses a portion of a tissue structure, comprising:

a. a tensioning member base having a tissue interface surface configured to engage a portion of the tissue structure when coupled to a suture member that may be threaded through the tensioning member base and into the tissue structure;

b. a suture clamping member configured to be switched from a first mode, wherein a suture may be tensioned back and forth through a space defined at least in part by the clamping member, to a second mode, wherein a suture may only be tensioned in one direction relative to the suture clamping member; and

c. a mode switching member movably coupled to the suture clamping member and configured to be operable to switch the suture clamping member from the first mode to the second mode.

369. The system of claim 368, wherein the suture clamping member is movably coupled to the tensioning member base.

370. The system of claim 368, wherein the suture clamping member may be coupled to the tensioning member base by a suture member coupled to both the clamping member and tensioning member.

371. The system of claim 369, wherein the suture clamping member comprises a proximal end and a distal end, the proximal end being rotatably coupled to the tensioning member base.

372. The system of claim 371, wherein the distal end is configured to swing about a hinge point at the coupling between the proximal end and the tensioning member base.

373. The system of claim 372, wherein the distal end may be swung from an open position relative to the tensioning member base, wherein a length of suture may be passed through an opening defined between the distal end of the clamping member and the tensioning member base, to a closed position, wherein a length of suture becomes pinch-immobilized between the distal end of the clamping member and the tensioning member base.

374. The system of claim 373, wherein the clamping member and tensioning member base are configurable to the first mode by positioning the distal end of the clamping member in the open position, and to the second mode by positioning the distal end of the clamping member in the closed position.

375. The system of claim 373, further comprising a spring member intercoupled between the clamping member and the tensioning member base and configured to bias the distal end of the clamping member into the closed position.

376. The system of claim 368, wherein the tensioning member base comprises a series of apertures for passing a length of a suture member therethrough, such that frictional loads are imparted on the suture member as it is pulled in either direction that may be relatively easily overcome with manual loading of the suture member.

377. The system of claim 376, further comprising a length of a suture member threaded through the series of apertures in a pattern comprising a number of complete loops that is between about 1 loop and about 2 loops.

378. The system of claim 375, wherein the tensioning mode switching member comprises an elongate rod having proximal and distal ends, the elongate rod distal end being removably coupled to the clamp member in a manner that the distal end of the clamp member is held in the open position relative to the tensioning member base until the elongate rod distal end is controllably decoupled from the clamp member, thereby allowing the clamp member distal end to assume the closed position relative to the tensioning member base.

379. The system of claim 378, wherein the rod distal end comprises a threaded interface configured to be rotatably mated with a threaded aperture formed in the clamping member.

380. The system of claim 379, wherein the proximal end of the elongate rod comprises a manual twisting interface to facilitate rotation of the elongate rod to induce decoupling of the elongate rod and clamping member.

381. The system of claim 370, wherein the suture clamping member defines a controllably closeable gap through which the suture member may be passed, such that in an open position, the suture member may be moved freely through the gap in both directions, and in a closed position wherein the gap is closed, the suture member is pinch-immobilized relative to the clamping member by the closed gap.

382. The system of claim 381, wherein the clamping member is biased to assume the closed position, but may be held in the open position by the mode switching member.

383. The system of claim 382, wherein the mode switching member comprises an elongate rod having proximal and distal ends, the elongate rod distal end being removably coupled to the clamping member in a configuration wherein the gap of the clamping member is maintained in the open position, and wherein a controlled decoupling of the elongate rod distal end from the clamping member allows for the gap of the clamping member to assume the closed position.

384. The system of claim 381, wherein at least a portion of the clamping member is directly coupled to the tensioning member base.

385. The system of claim 368, further comprising an elongate tubular member defining a lumen therethrough, through which a suture member may be threaded and tensioned from a proximal position reachable by an operator, the elongate tubular member being interposed between the tensioning member base and the proximal position and configured to allow for compression of the tensioning member base between the tissue structure and the proximal position by loading the suture member in tension and the elongate tubular member in compression at the proximal position.

386. The system of claim 385, further comprising a temporary suture member clamp coupleable to a proximal portion of a suture member adjacent the proximal position and configured to retain tension upon a portion of suture member distal to the suture member clamp that is threaded through the lumen of the elongate tubular member.

387. The system of claim 386, wherein the temporary suture member clamp comprises a releasable mechanical pinch clamp.

388. The system of claim 386, wherein the temporary suture member clamp comprises a reel rotatably coupled to a housing, the housing being configured to be manually held by an operator.

389. The system of claim 388, wherein the reel and housing are rotatably coupled in two selectable modes, such that in a first mode, the reel may freely rotate bidirectionally relative to the housing, and in a second mode, the reel may only be rotated unidirectionally relative to the housing.

390. The system of claim 389, further comprising a mode selecting member that may be manually manipulated by an operator to switch the reel and housing rotational coupling mode back and forth between the first and second modes.

391. The system of claim 368, further comprising a fabric pledget sock configured to substantially encapsulate at least the tissue interface surface of the tensioning member base and encourage biointegration of the tensioning member base and adjacent portions of the tissue structure.

392. The system of claim 391, wherein the fabric pledget sock comprises a durable polymer selected from the group consisting of: polyethylene terepthalate, polyethylene, high density polyethylene, polypropylene, polytetrafluoroethylene, expanded polytetrafluoroethylene, poly (ethylene-co-vinyl acetate), poly(butyl methacrylate), and co-polymers thereof.

393. The system of claim 391, wherein the fabric pledget sock comprises a bioresorbable polymer selected from the group consisting of: polylactic acid, polyglycolic acid, polylactic-co-glycolic acid, polylactic acid-co-caprolactone, poly (block-ethylene oxide-block-lactide-co-glycolide), polyethylene glycol, polyethylene oxide, poly (block-ethylene oxide-block-propylene oxide-block-ethylene oxide), polyvinyl pyrrolidone, polyorthoester, polyanhydride, polyhydroxy valerate, polyhydroxy butyrate, and co-polymers thereof.

394. The system of claim 391, wherein the fabric pledget sock comprises a bioresorbable material selected from the group consisting of: porcine collagen matrix, human collagen matrix, equine collagen fleece, gelatin, polyhyaluronic acid, heparin, poly (glucose), poly(alginic acid), chitin, chitosan, cellulose, methyl cellulose, hydroxyethylcellulose, hydroxypropylcellulose, carboxymethylcellulose; polylysine, polyglutamic acid, albumin, hydroxy apatite, cortical bone, cancellous bone, trabecular bone, bioceramic, ligament tissue, tendon tissue, dura tissue, fascia tissue, pericardium tissue, thrombin, and fibrin.

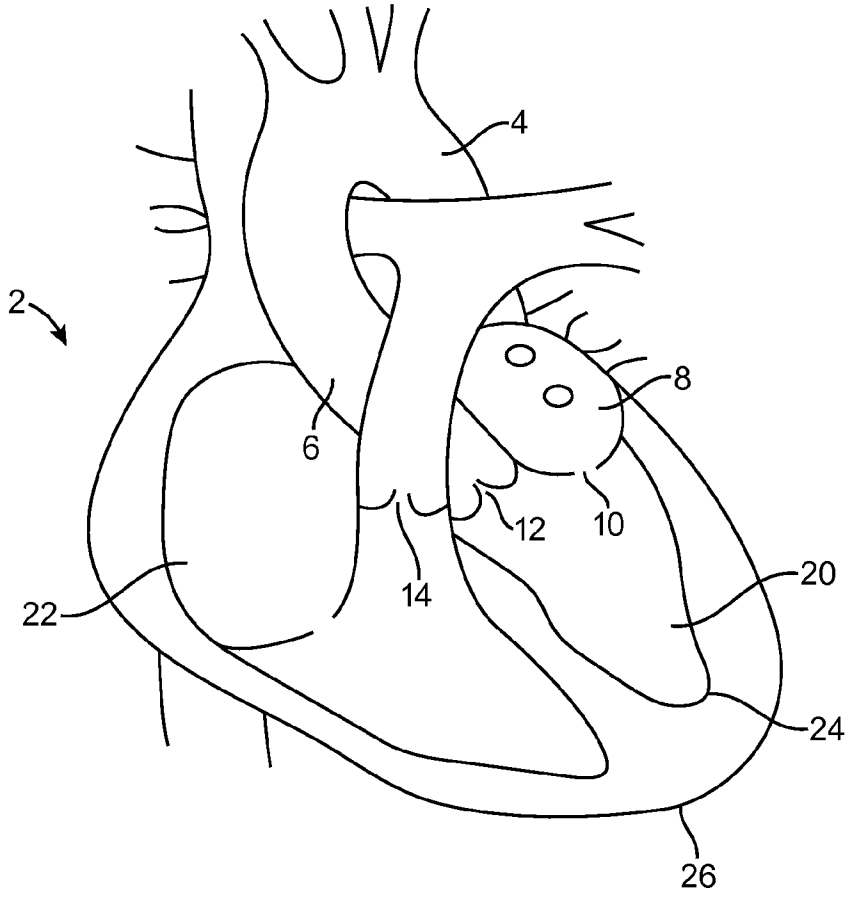


FIG. 1

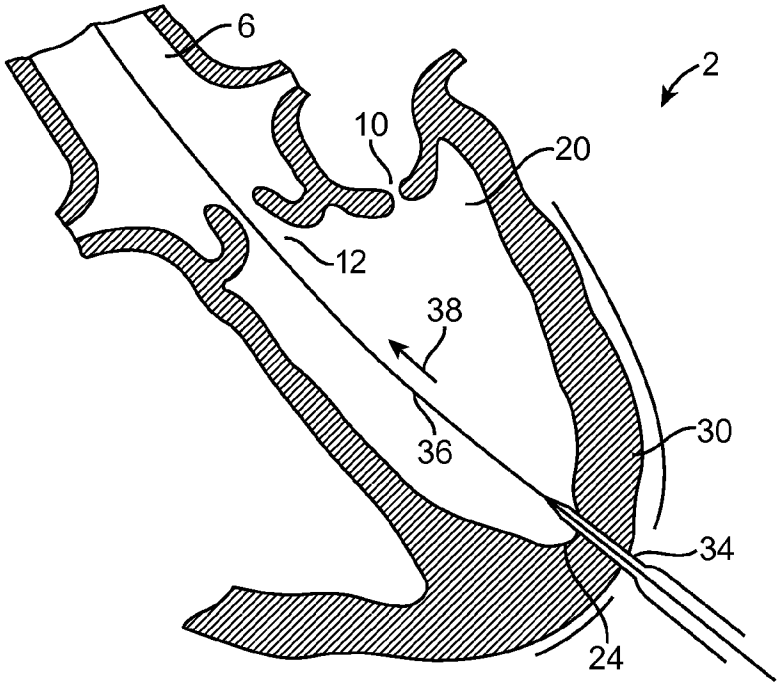


FIG. 2
(PRIOR ART)

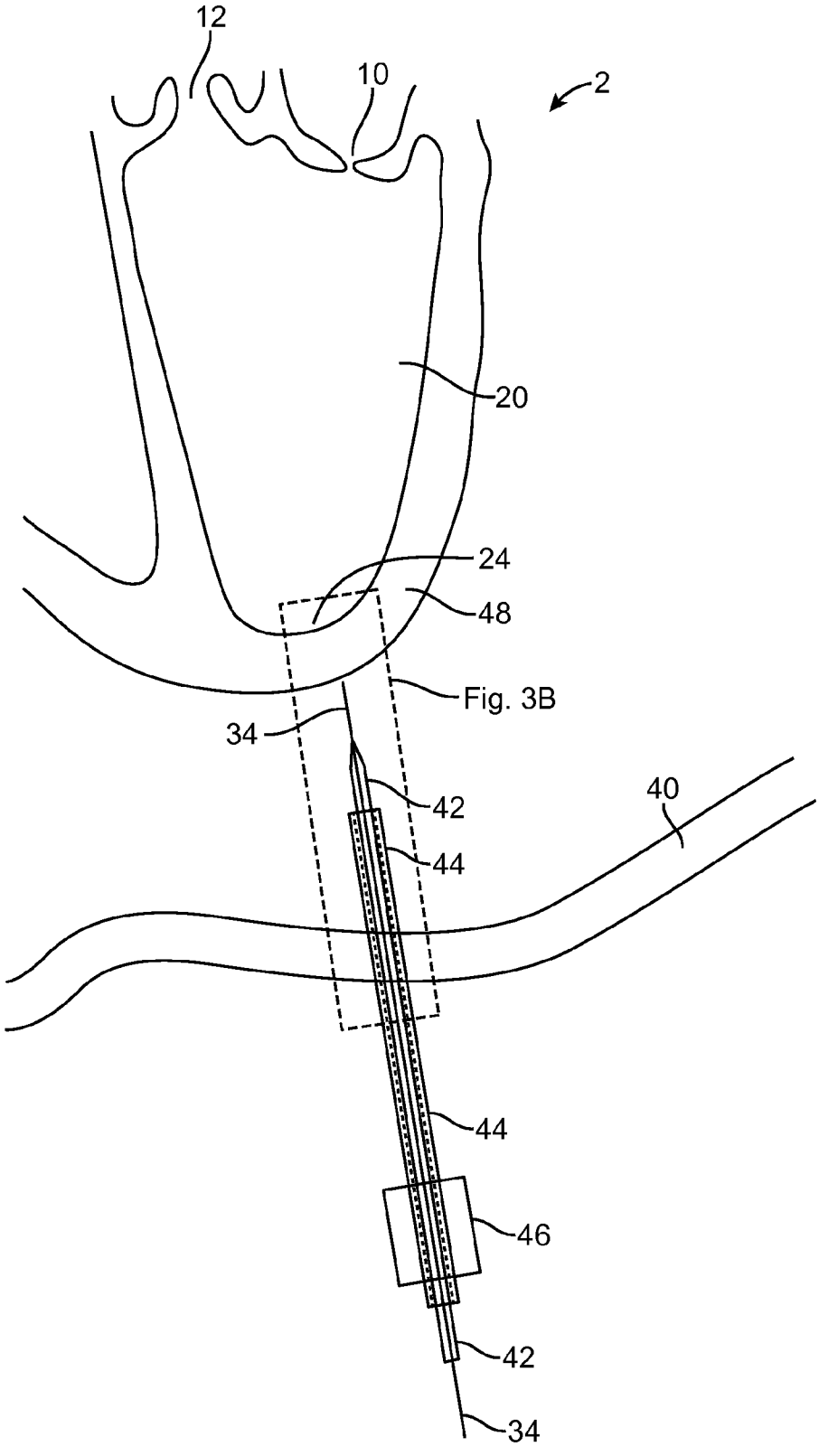


FIG. 3A

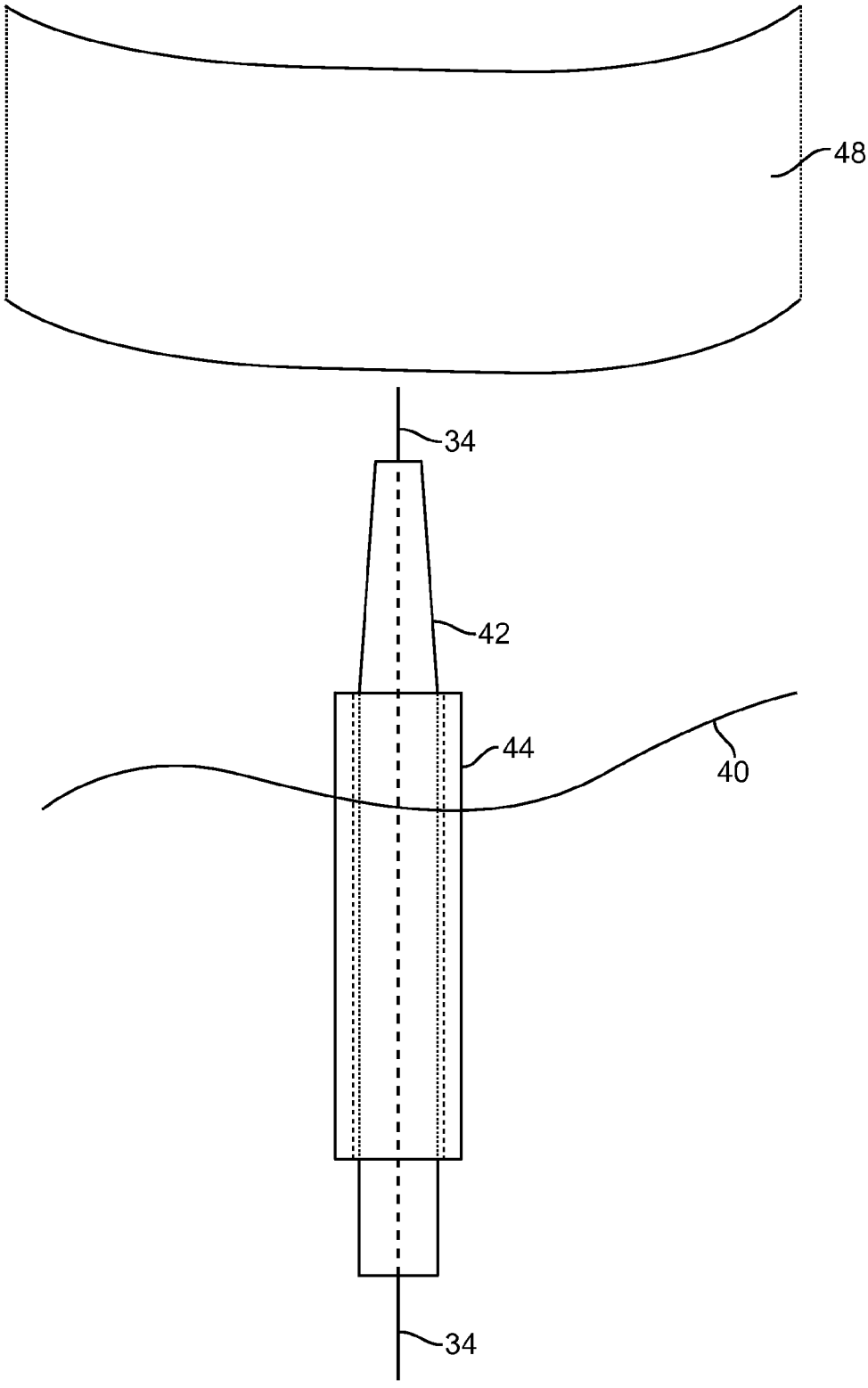


FIG. 3B

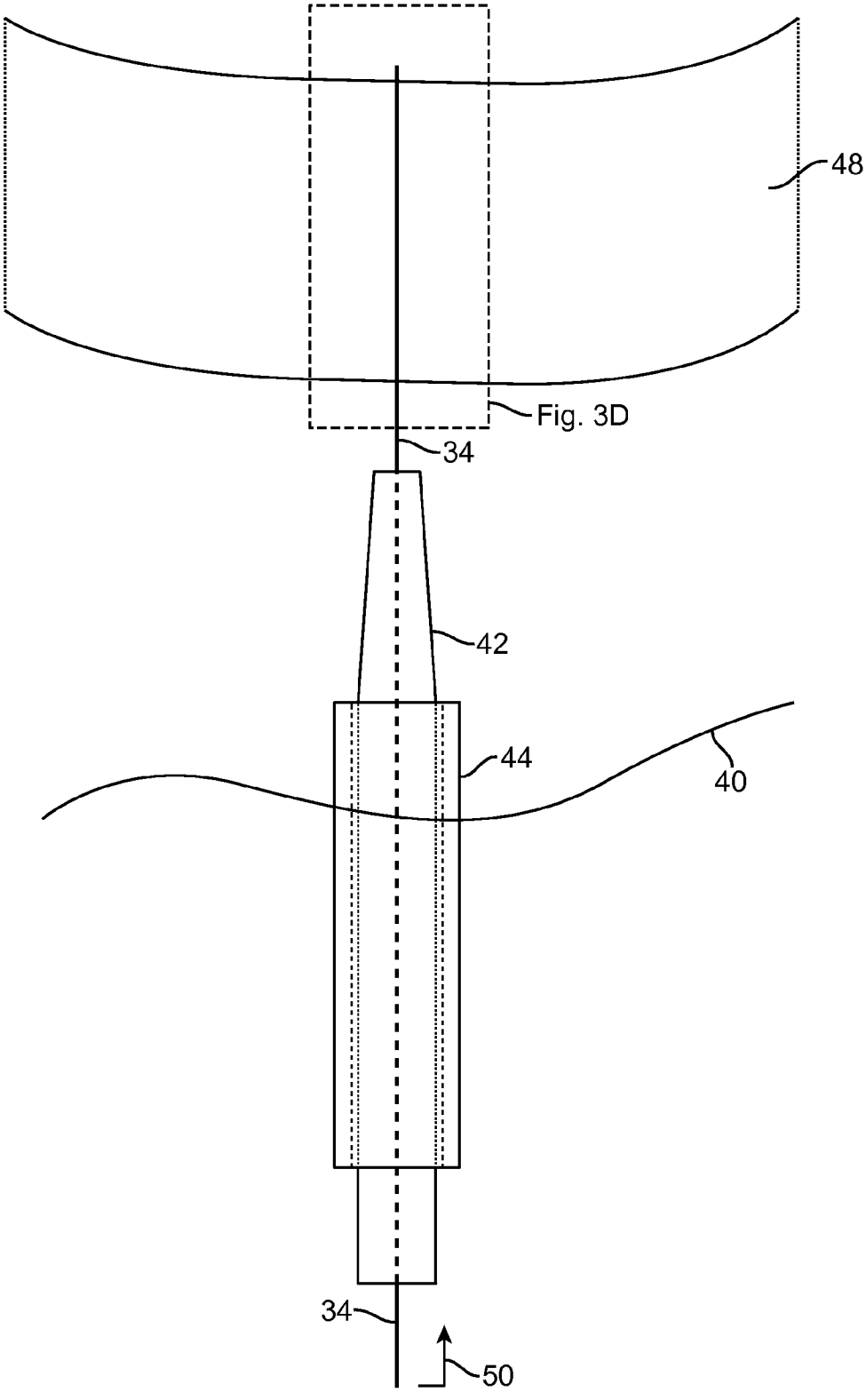


FIG. 3C

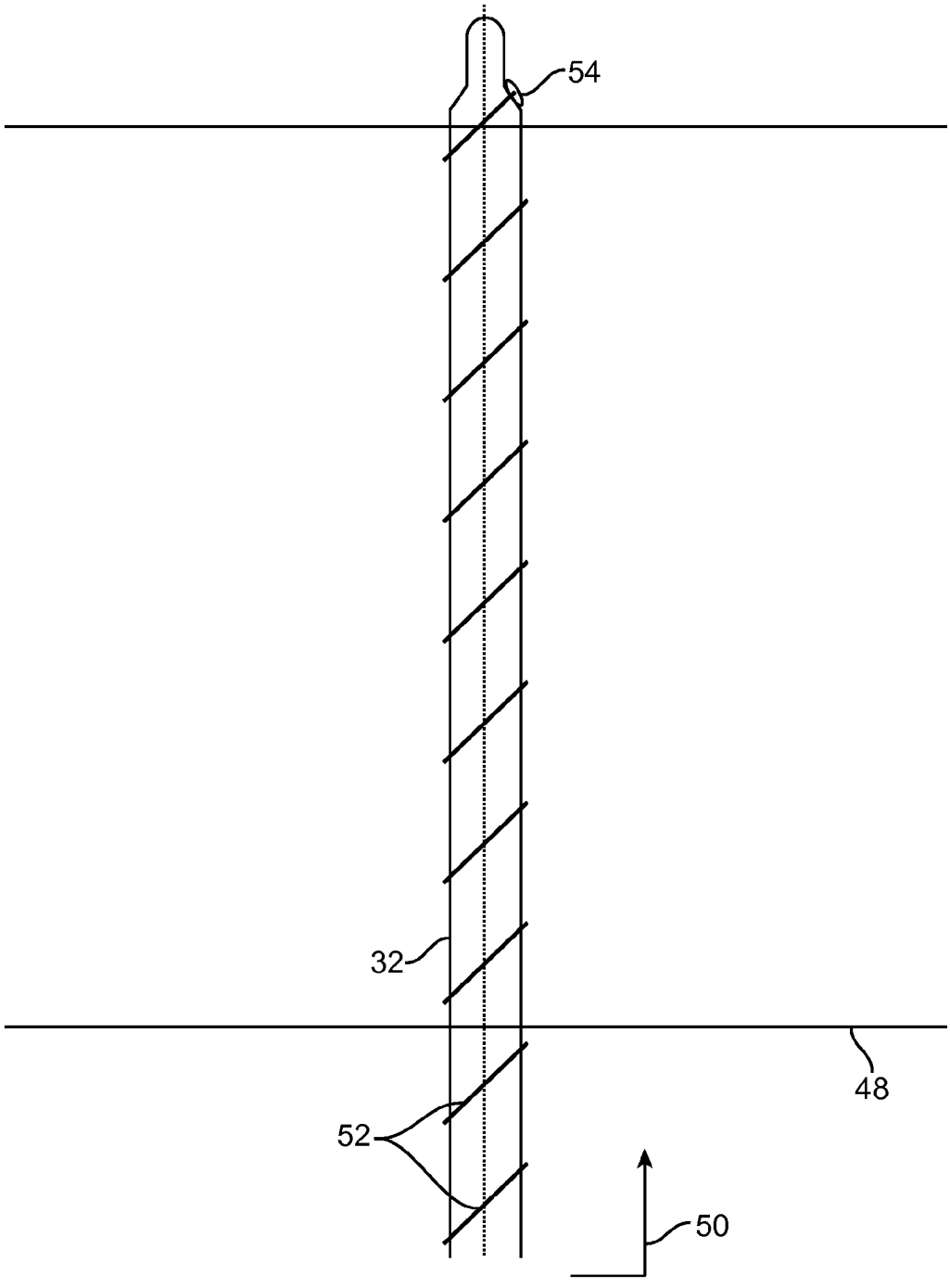


FIG. 3D

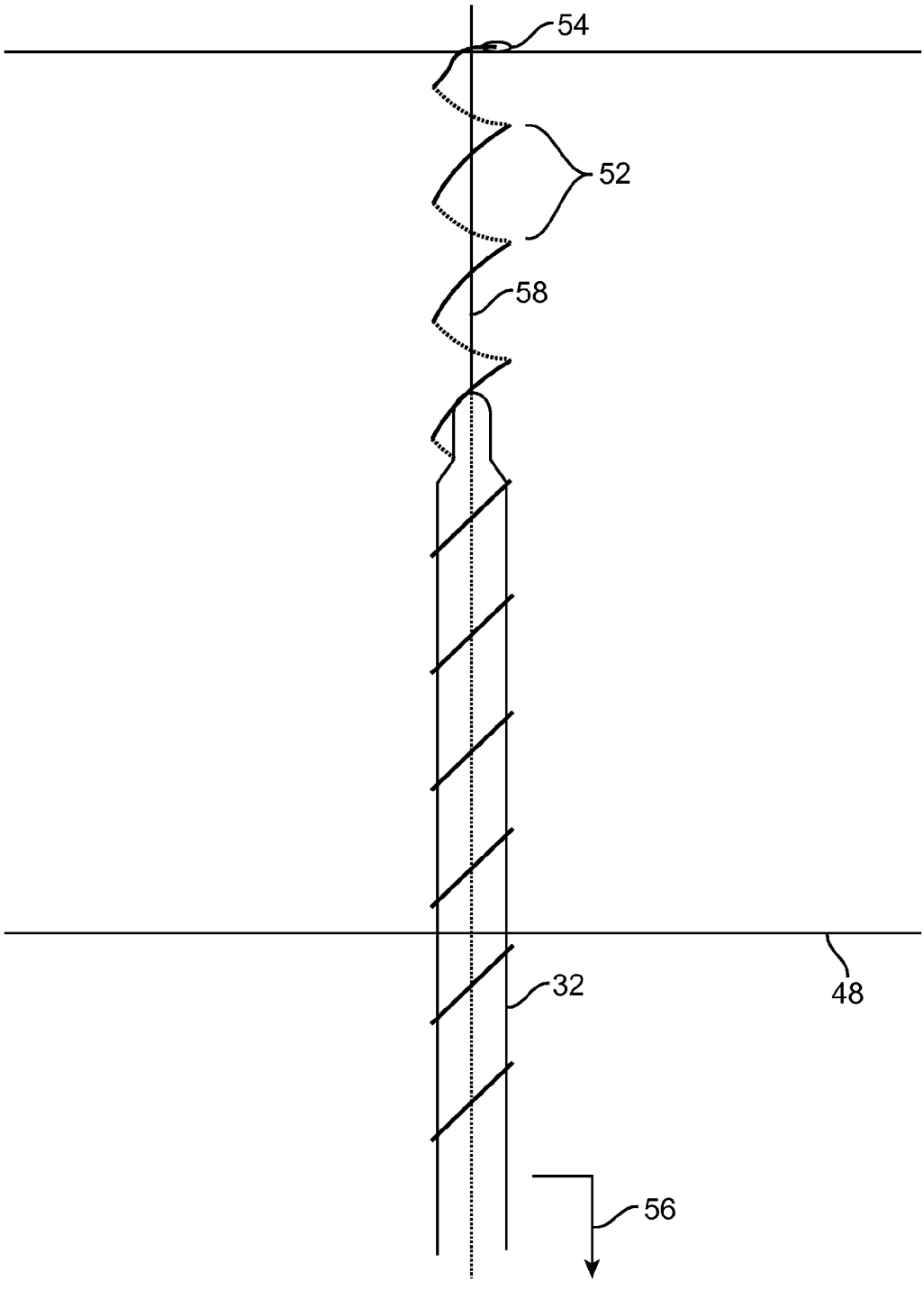


FIG. 3E

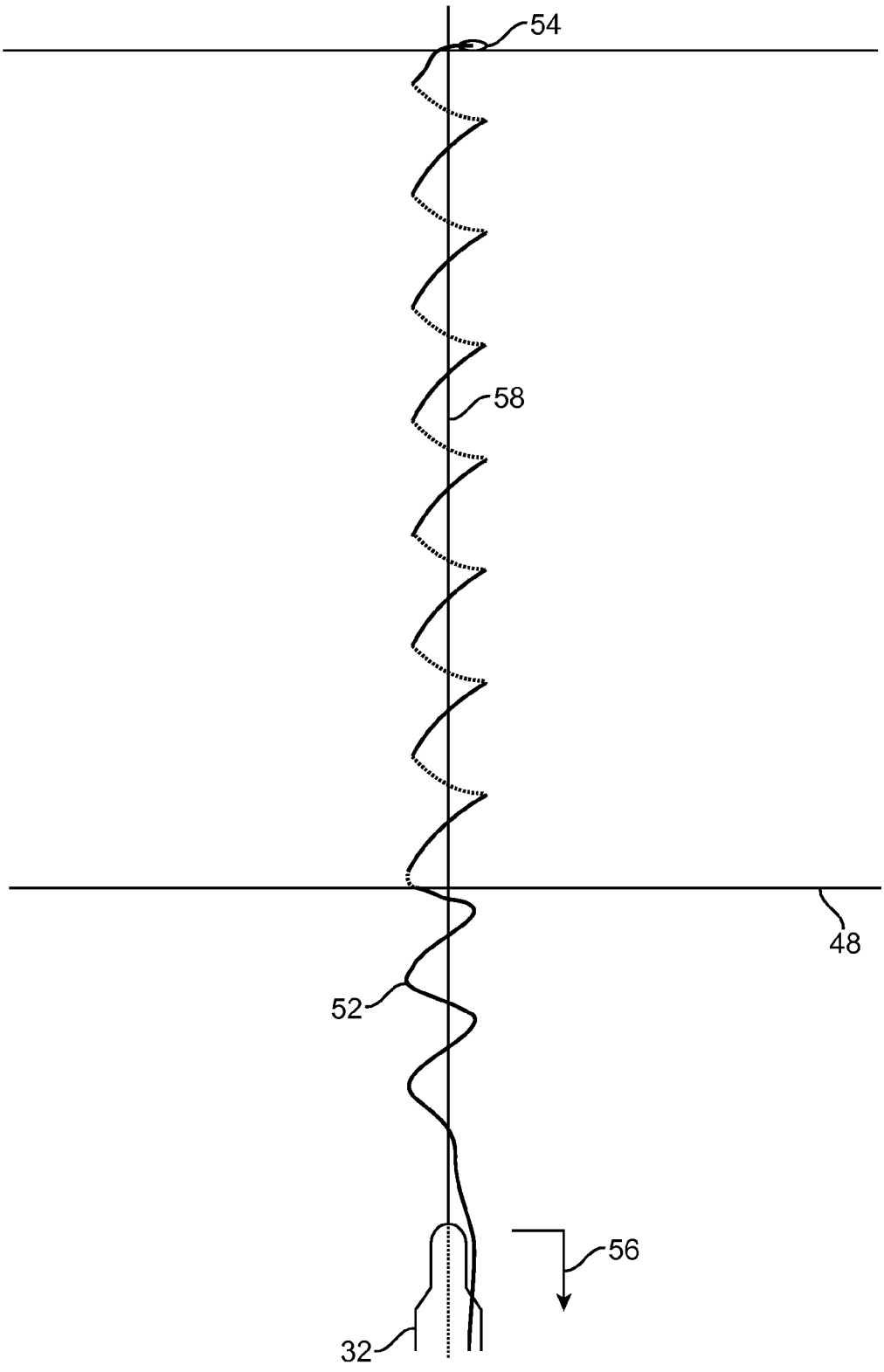


FIG. 3F

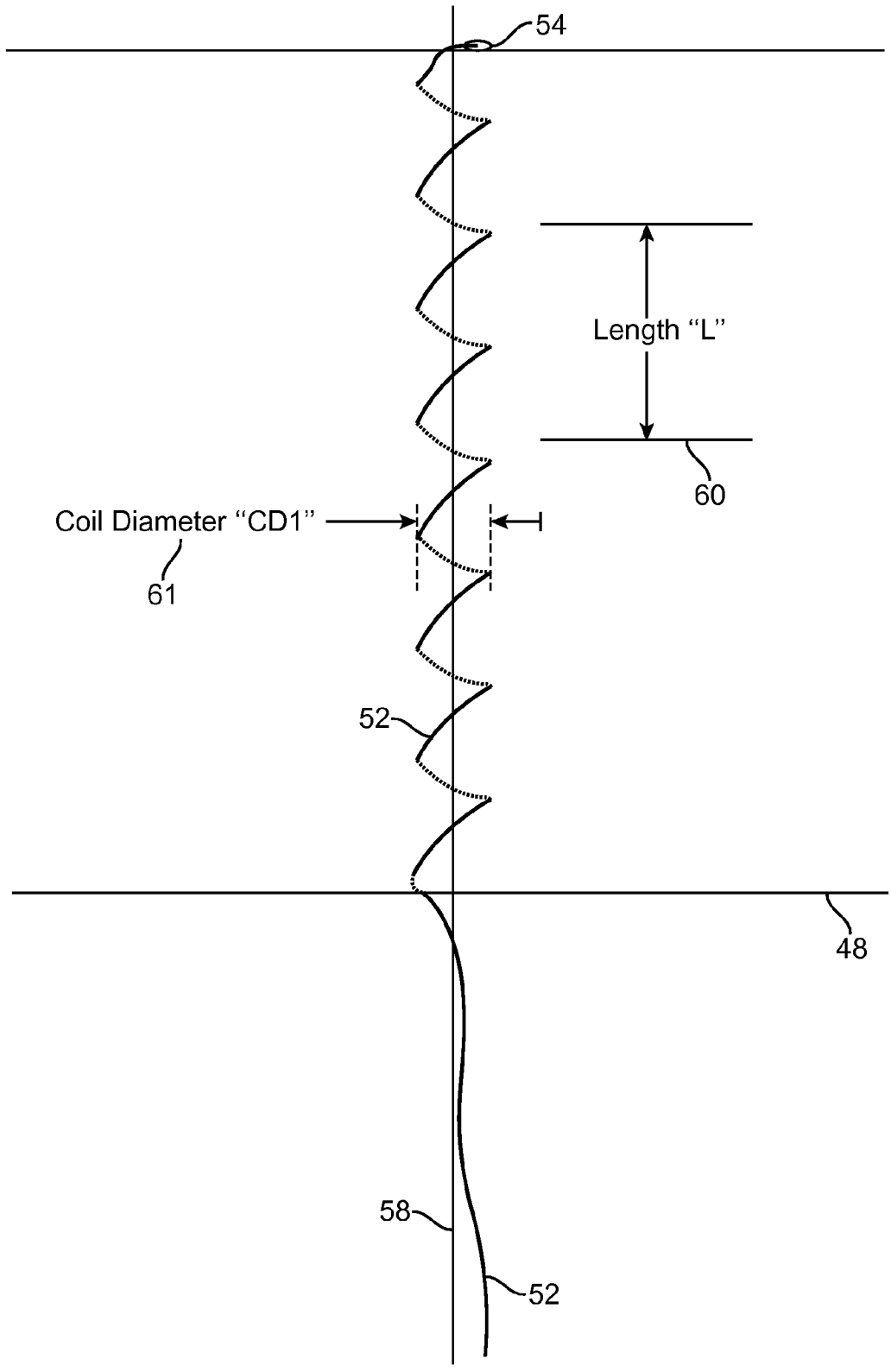


FIG. 3G

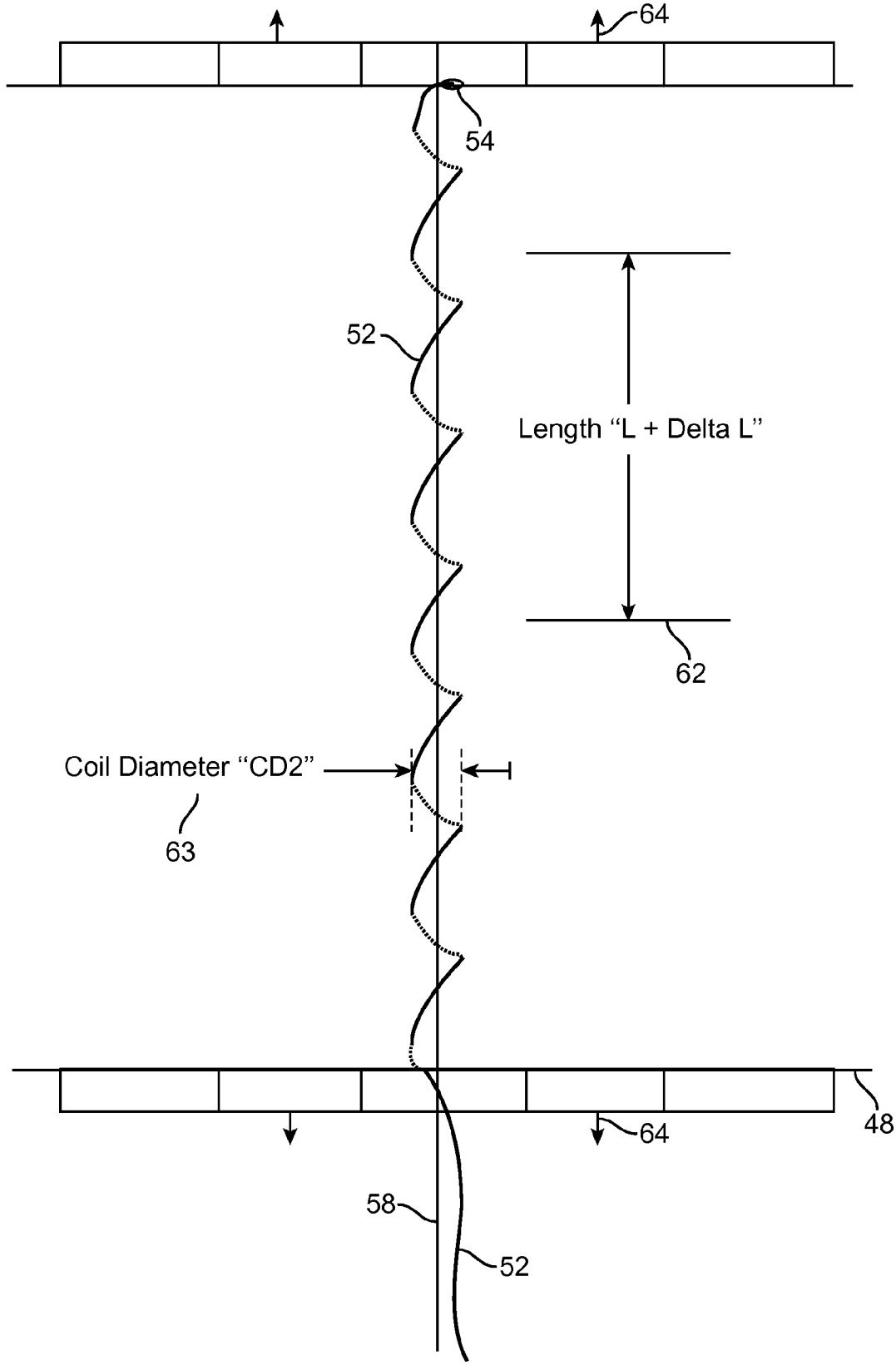


FIG. 3H

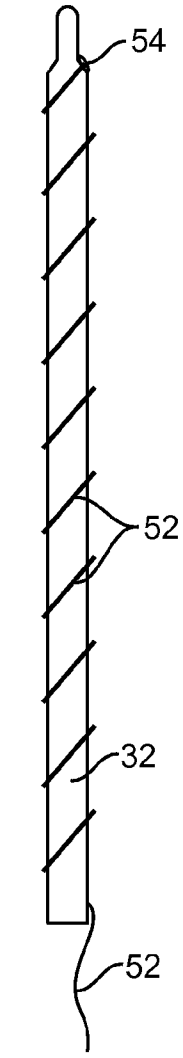


FIG. 3I

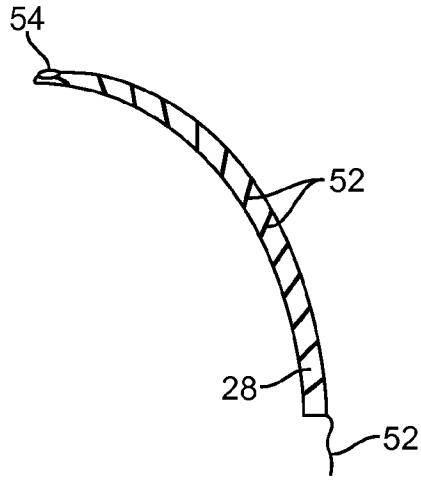


FIG. 3J

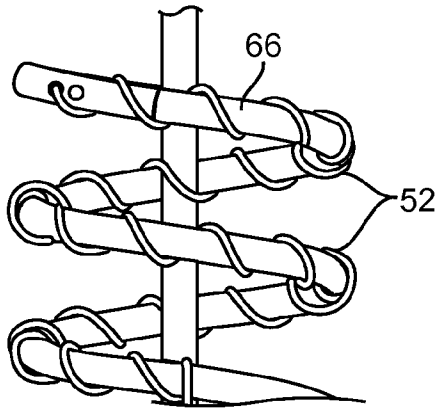


FIG. 3K

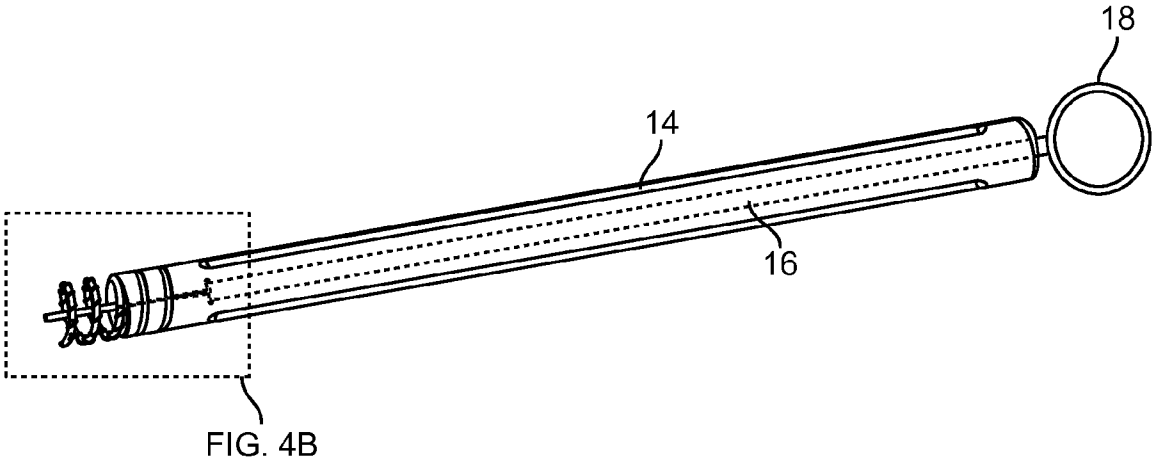


FIG. 4A

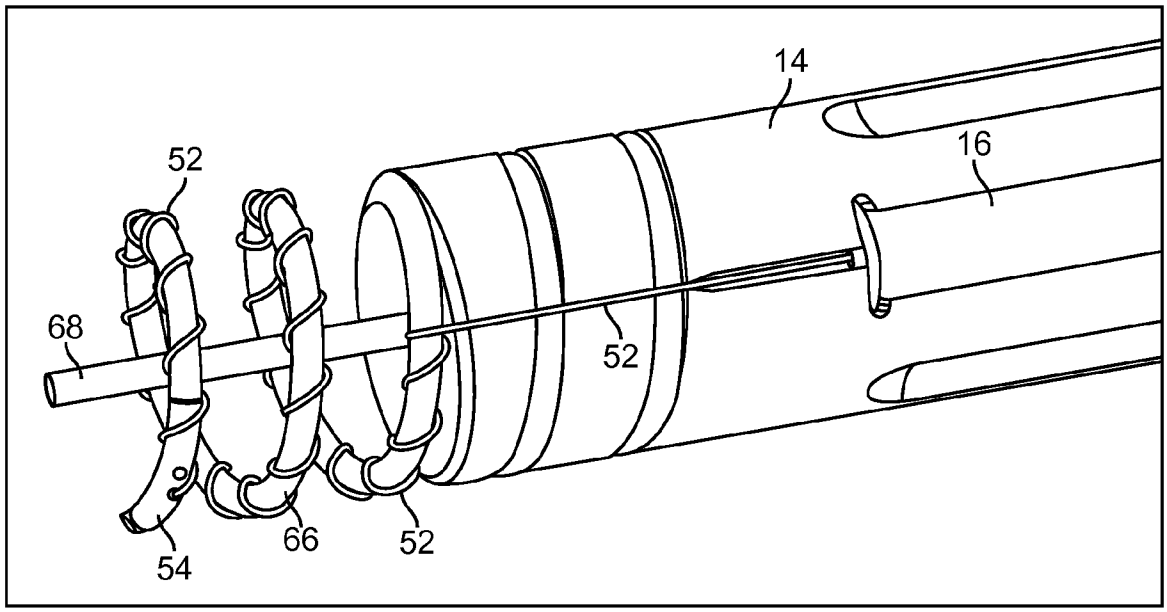


FIG. 4B

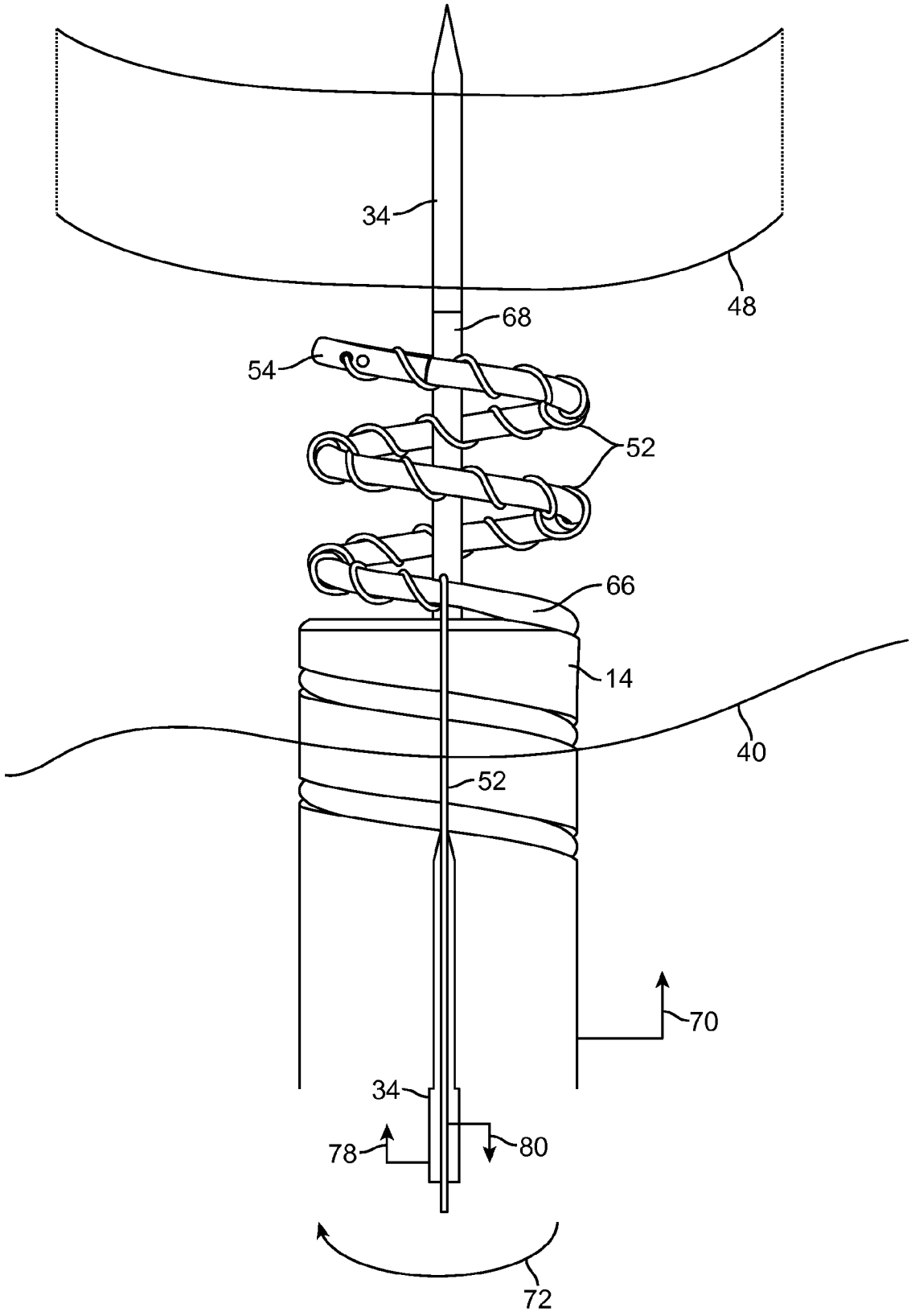
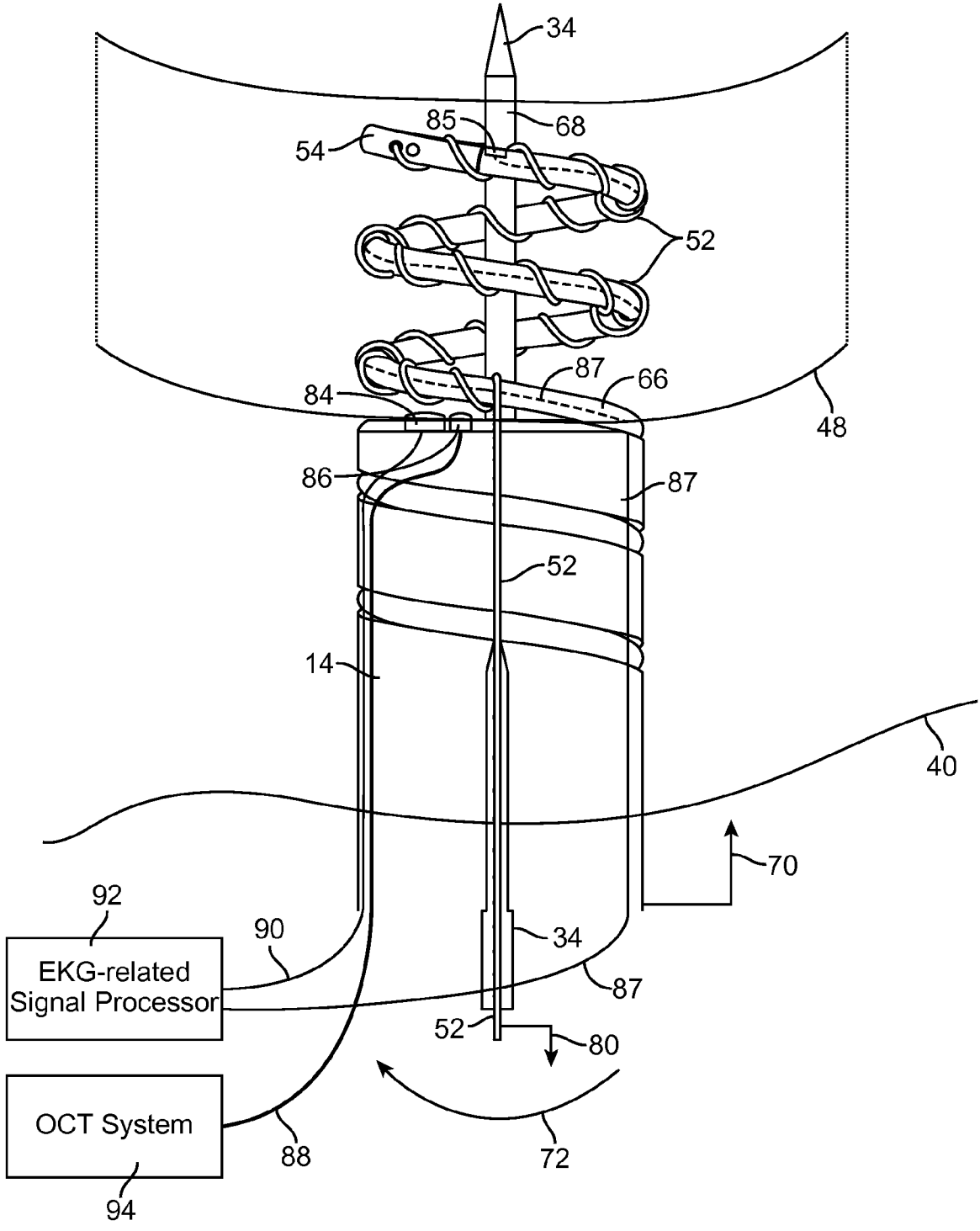


FIG. 4C


34
85
68
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48
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87
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14
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70
92
90
34
EKG-related Signal Processor
87
52
80
OCT System
88
72
94

FIG. 4D

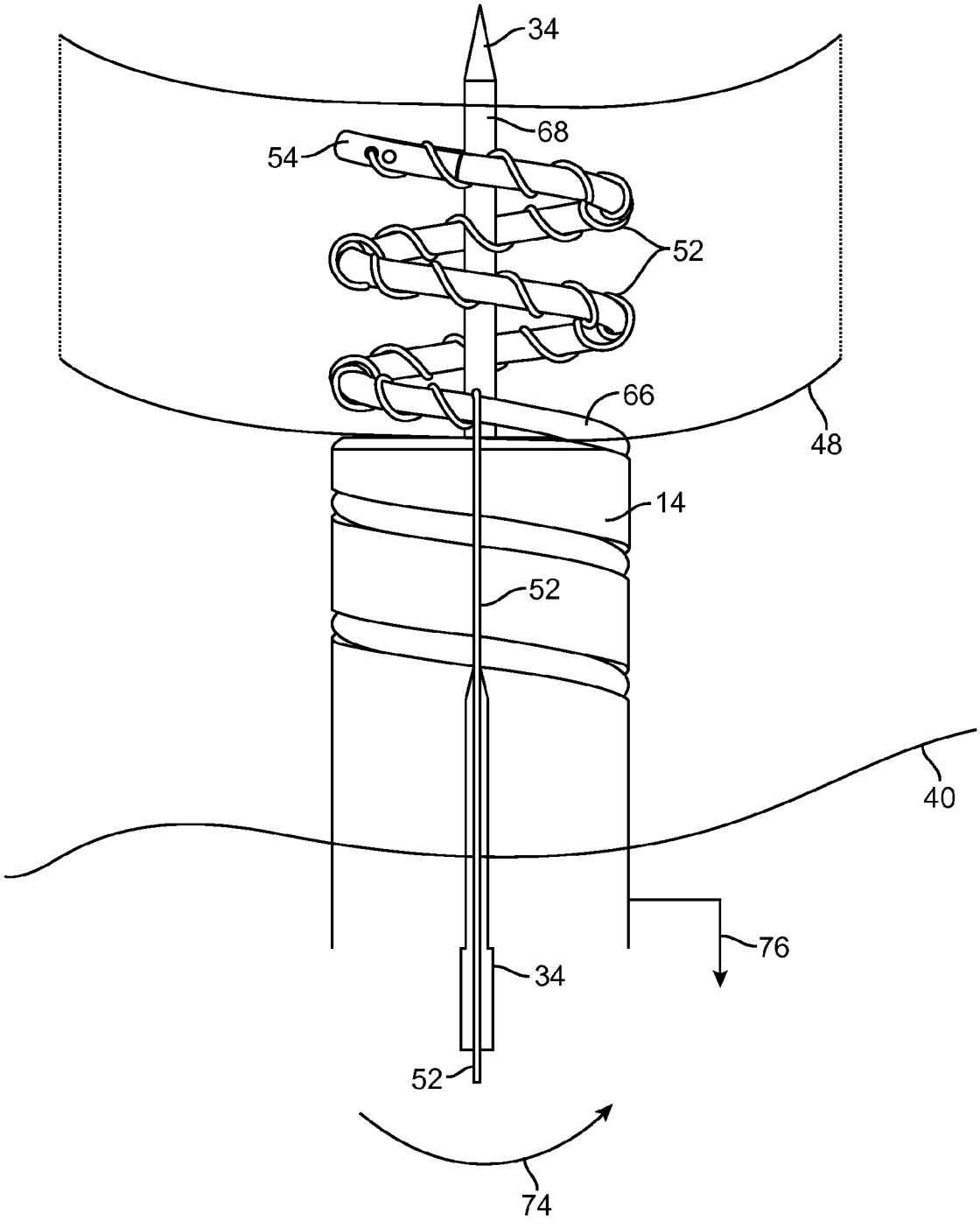

FIG. 4E

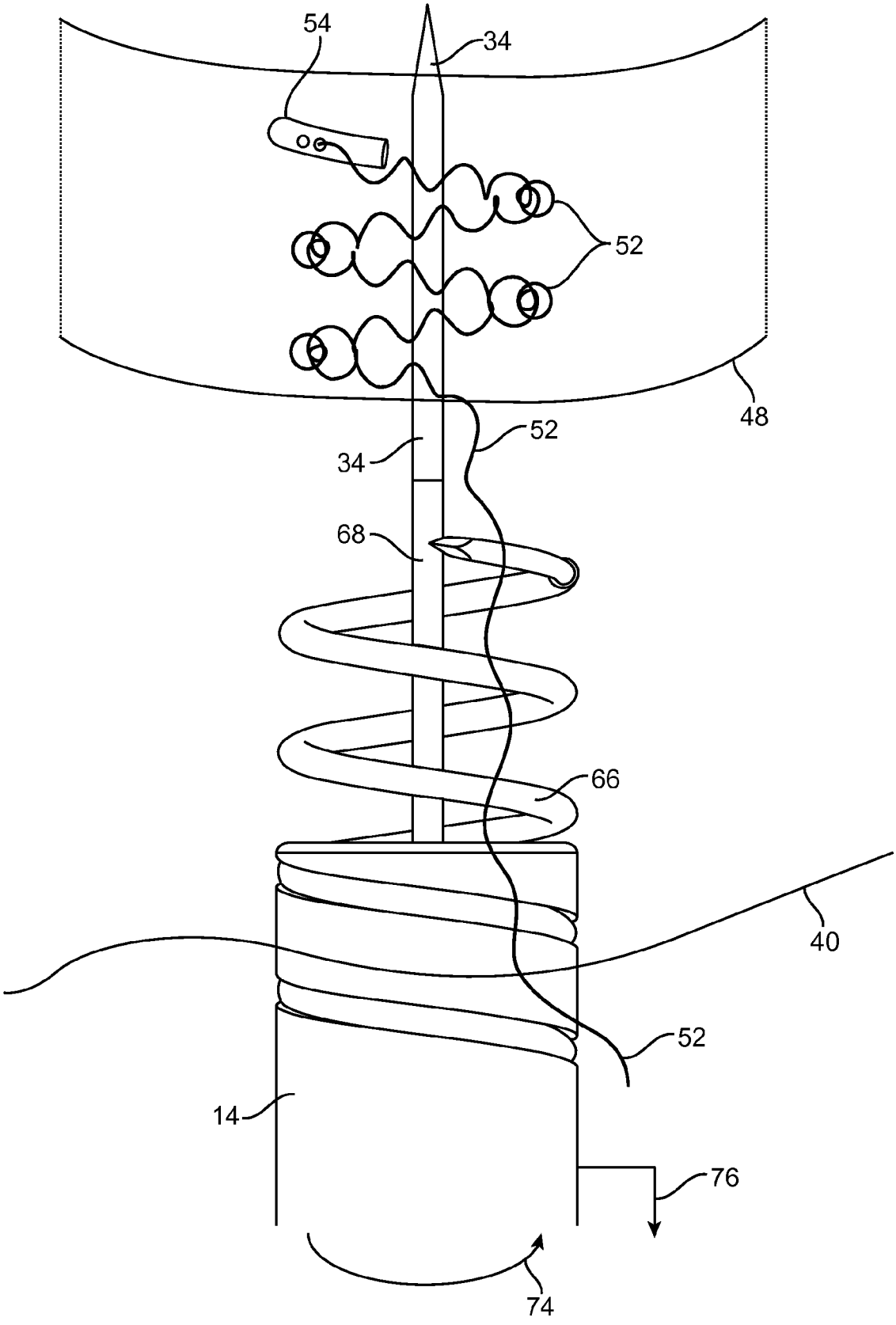

FIG. 4F

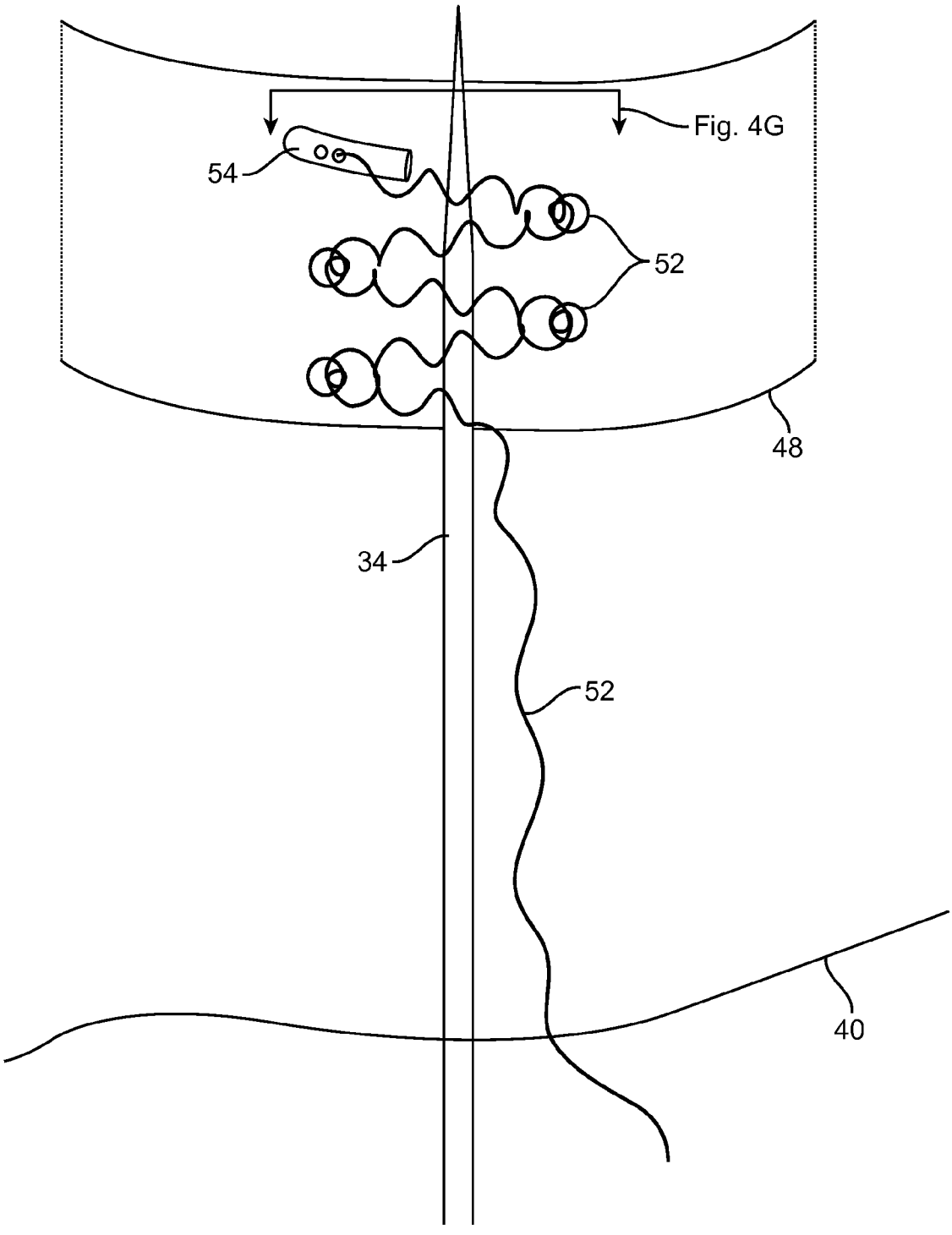

FIG. 4G

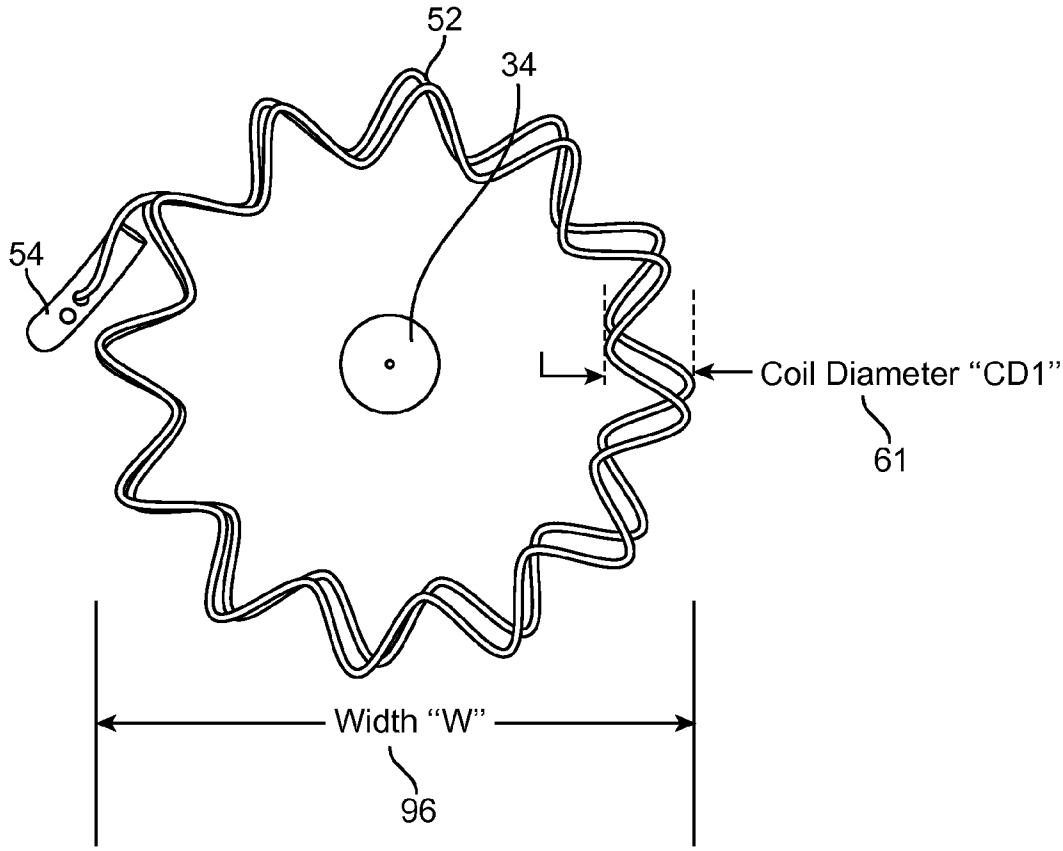

FIG. 4H

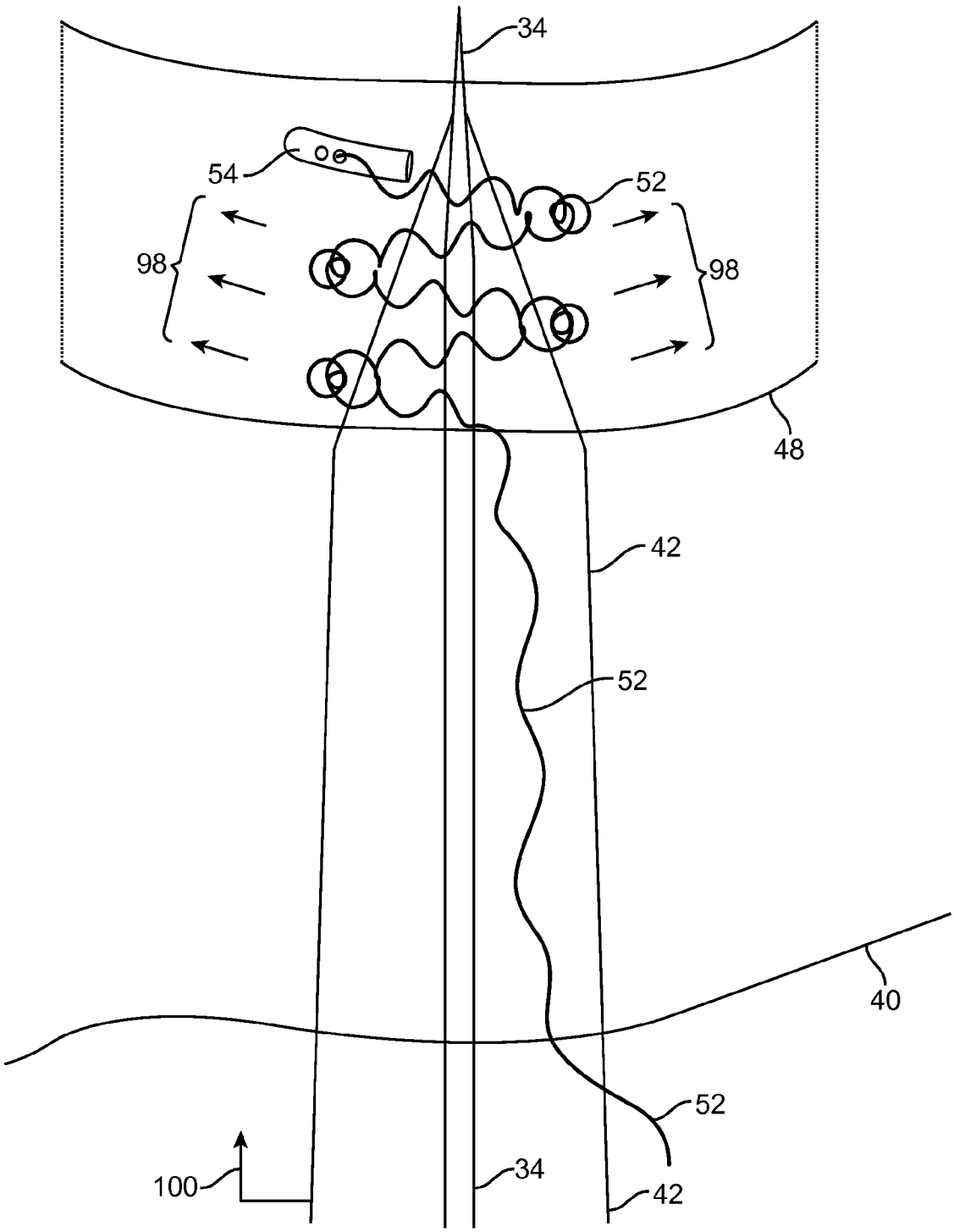

FIG. 4I

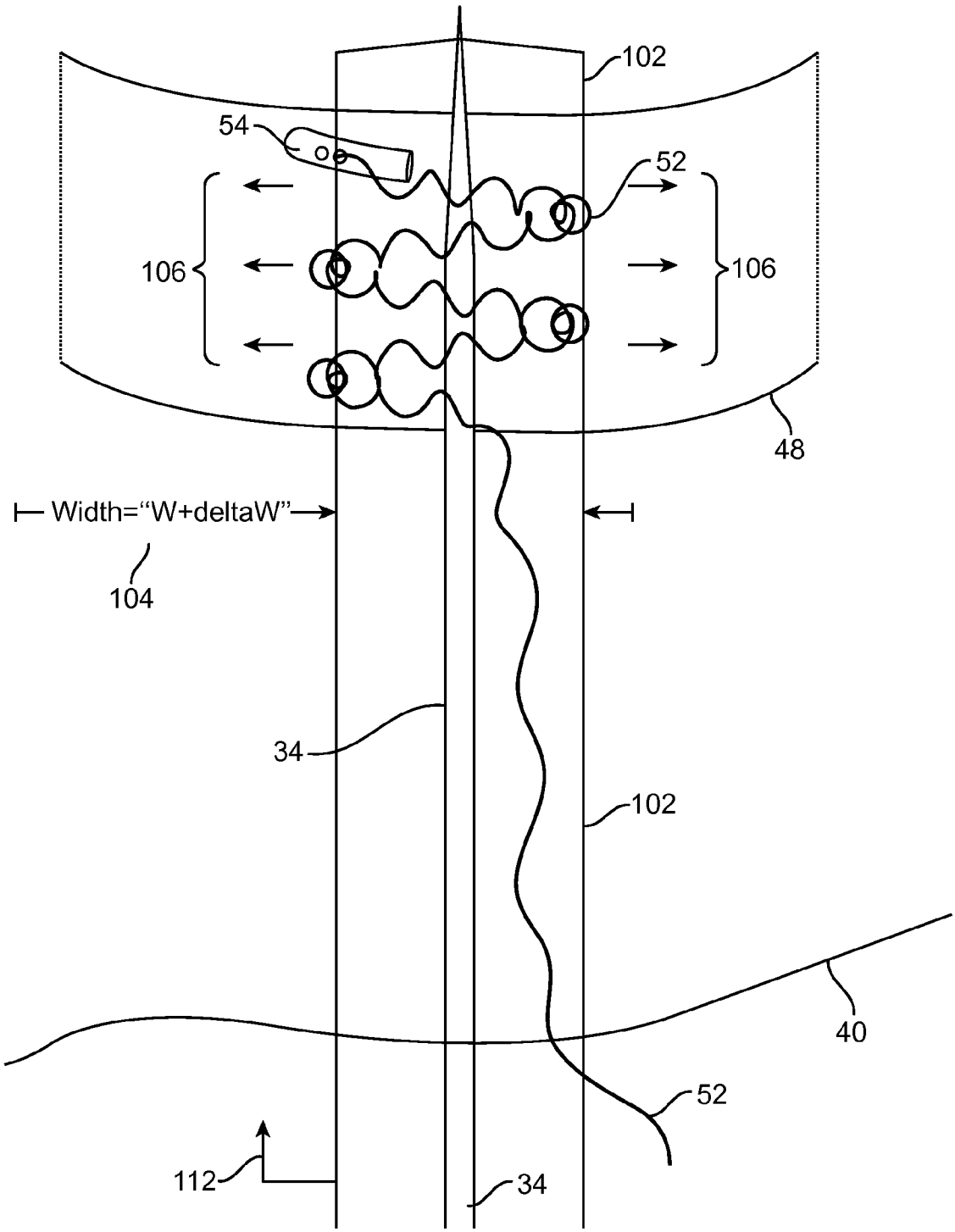

FIG. 4J

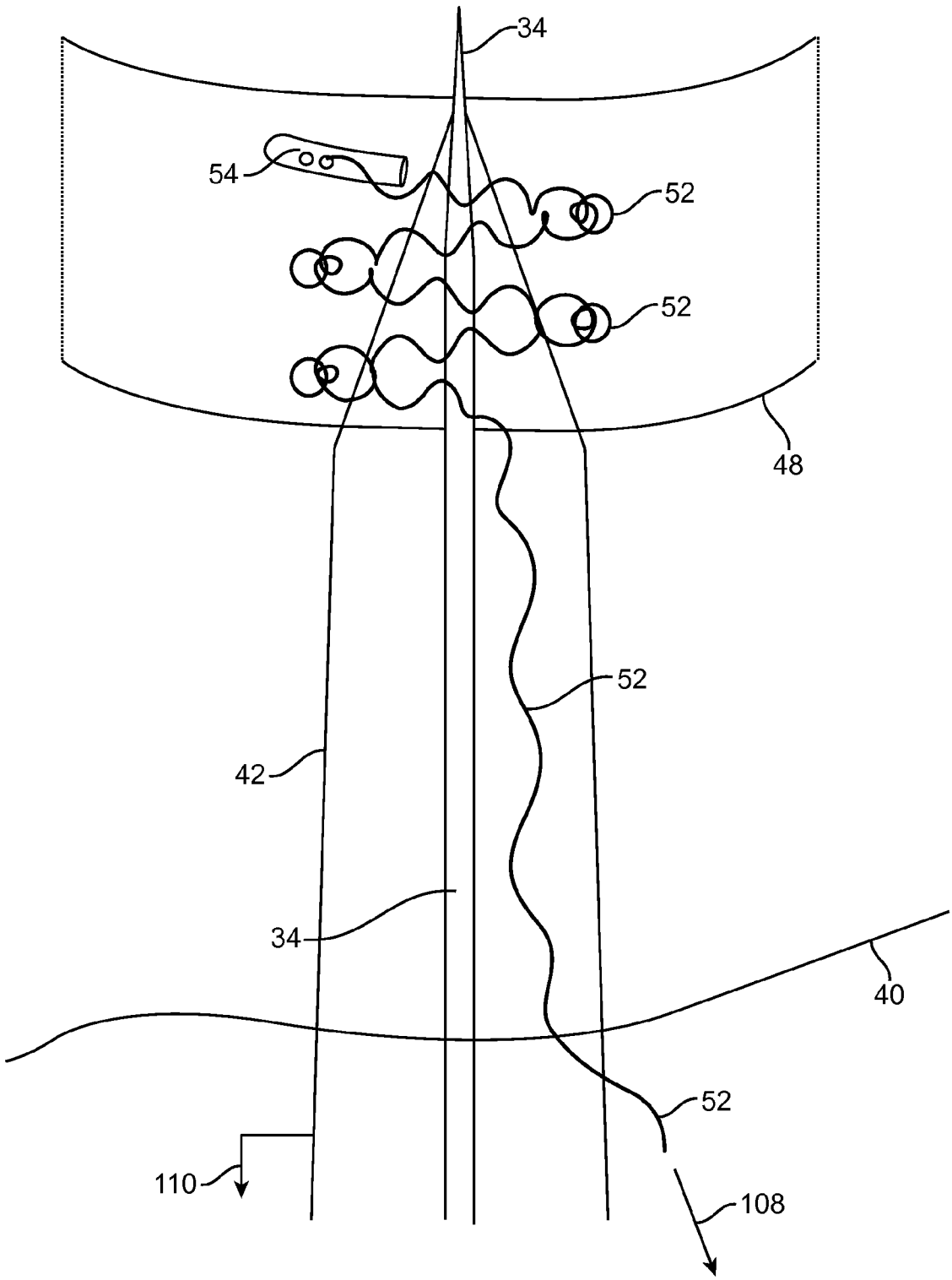

FIG. 4K

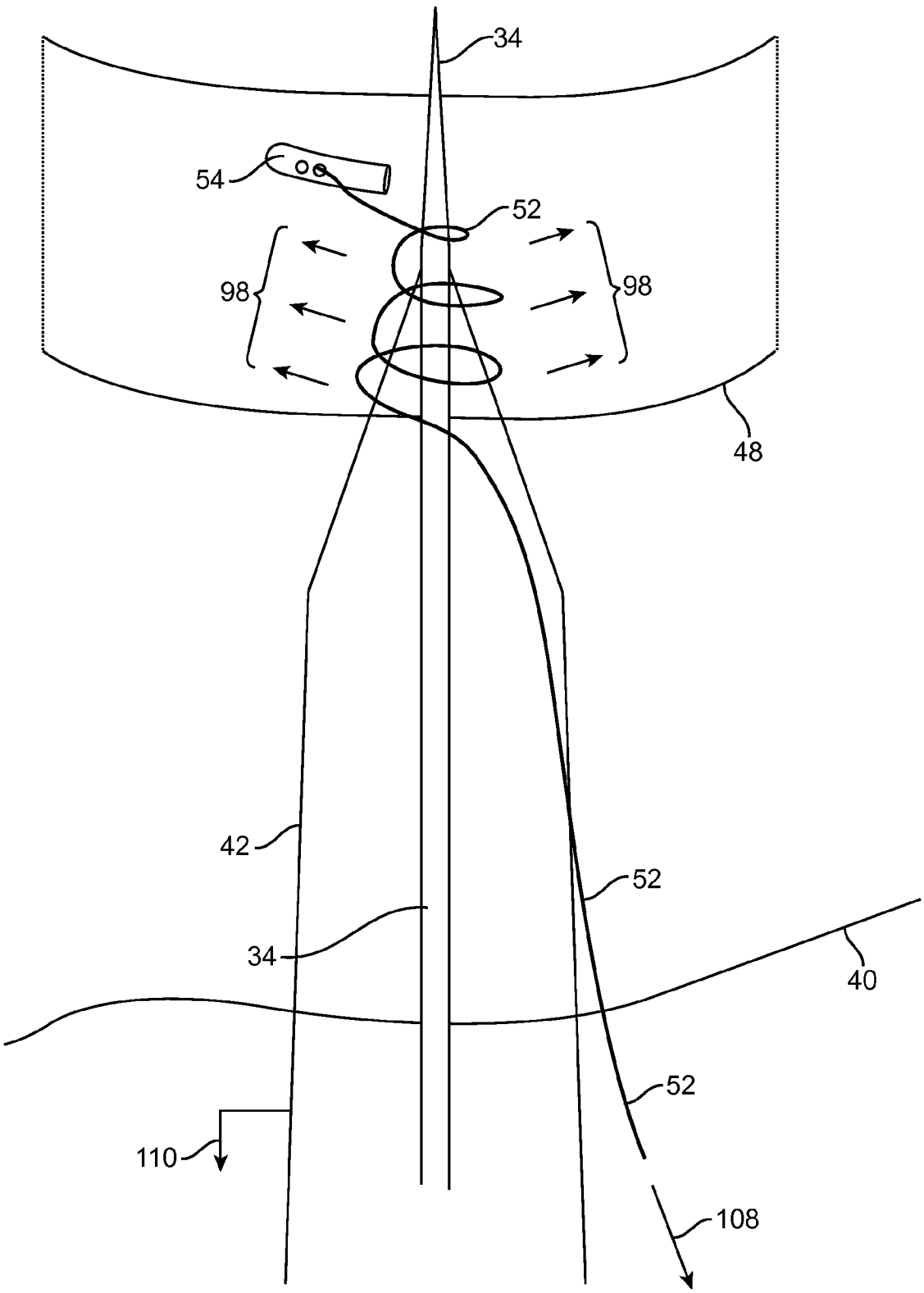

FIG. 4L

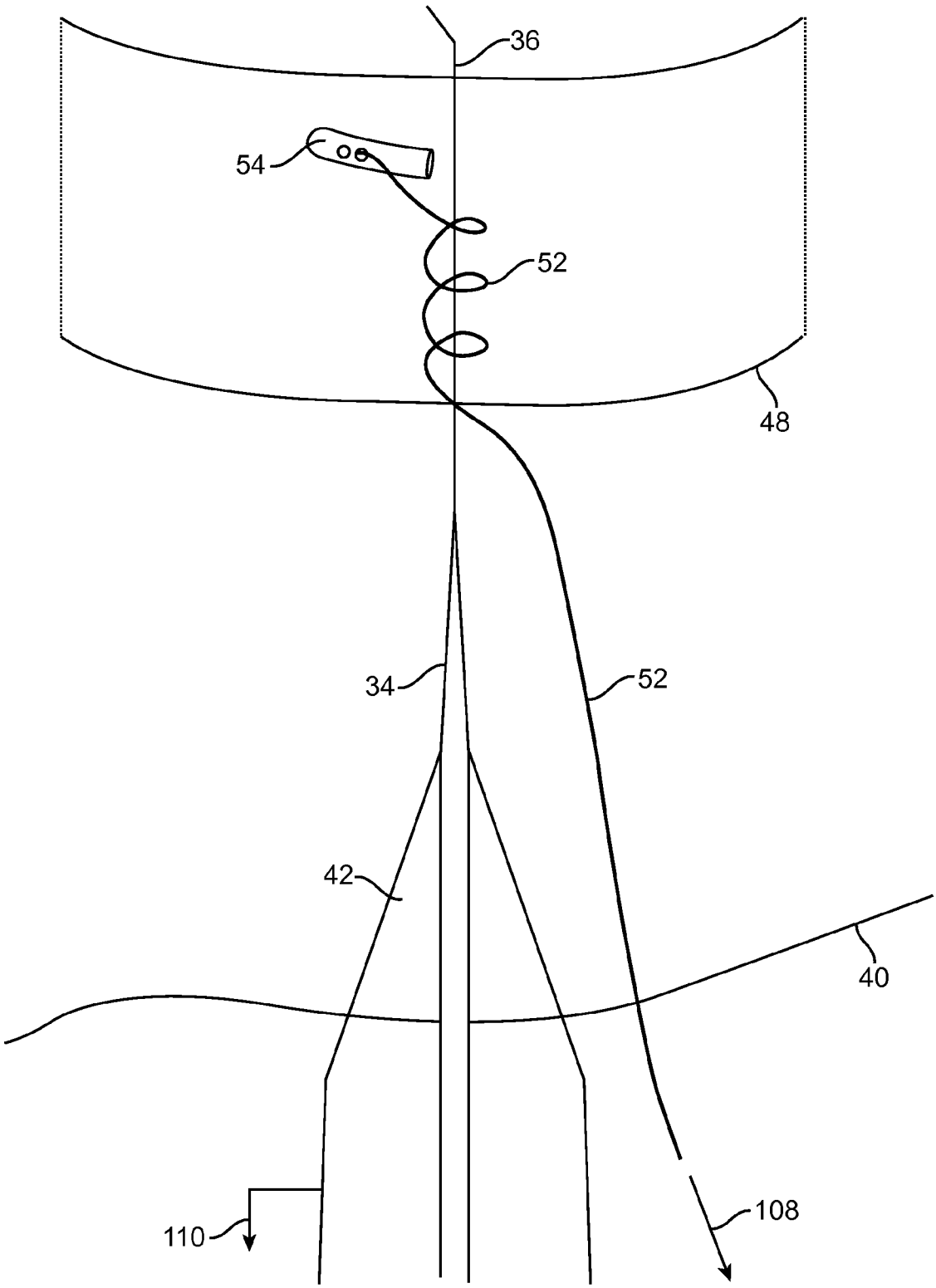

FIG. 4M

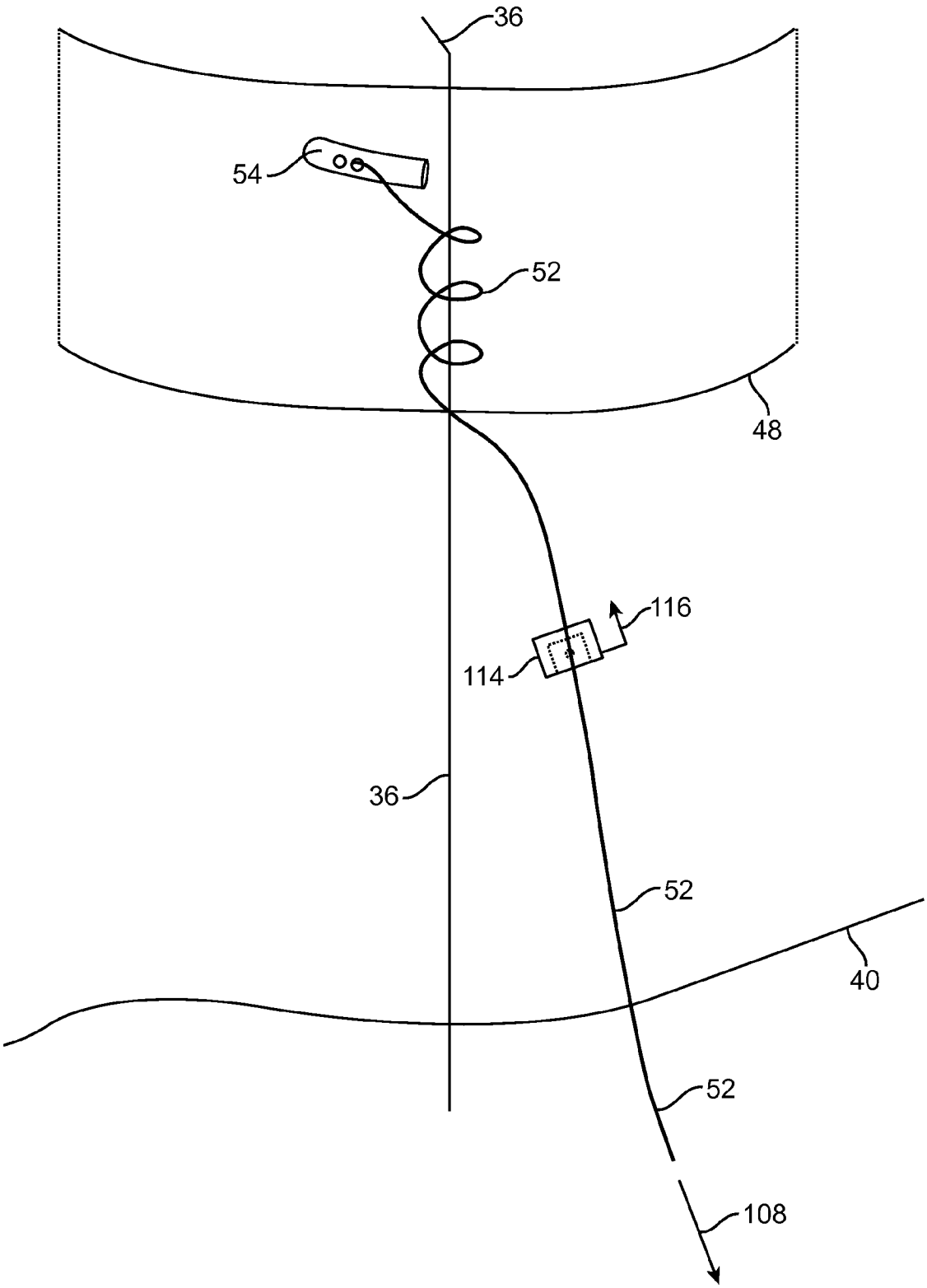

FIG. 4N

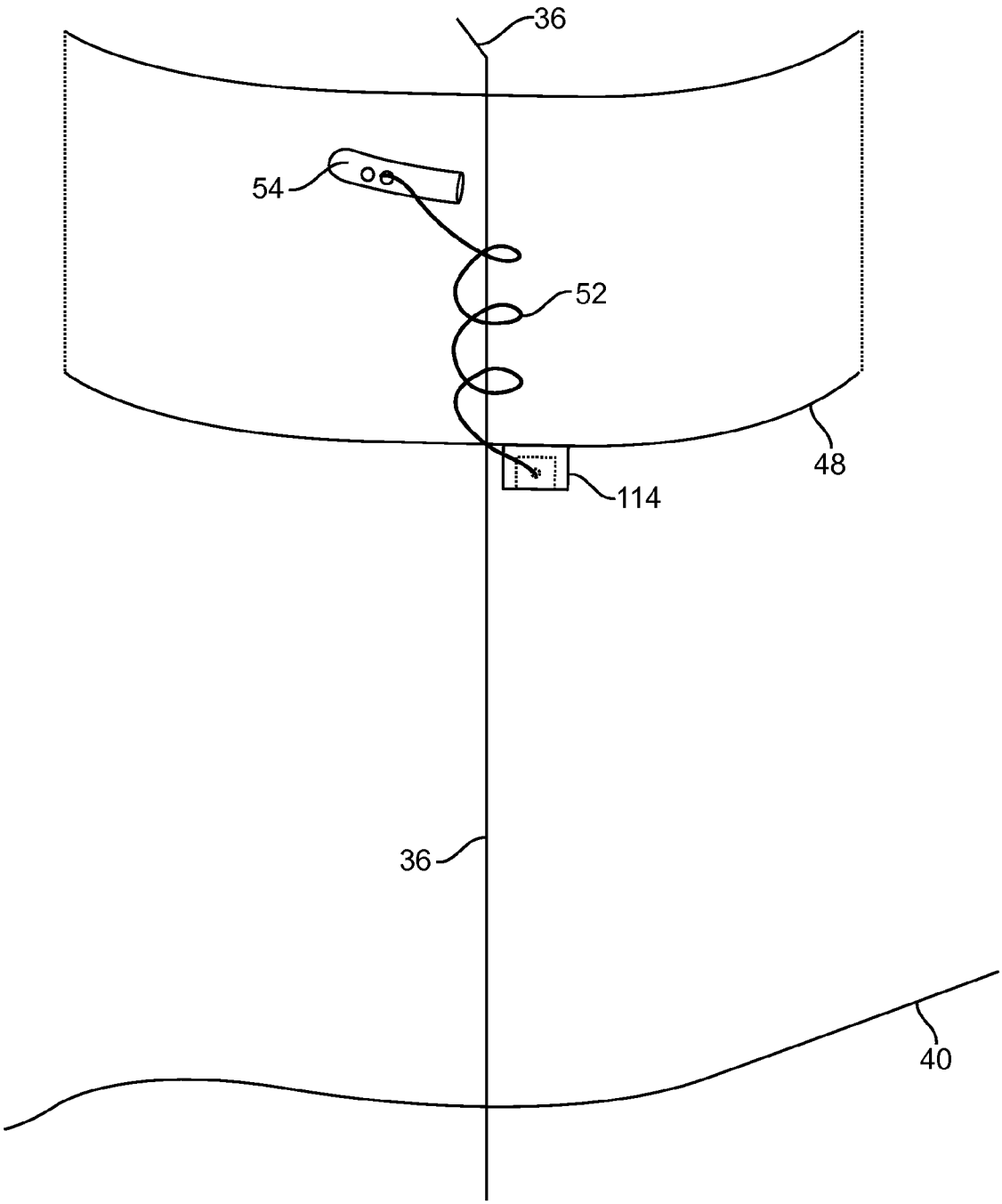

FIG. 4O

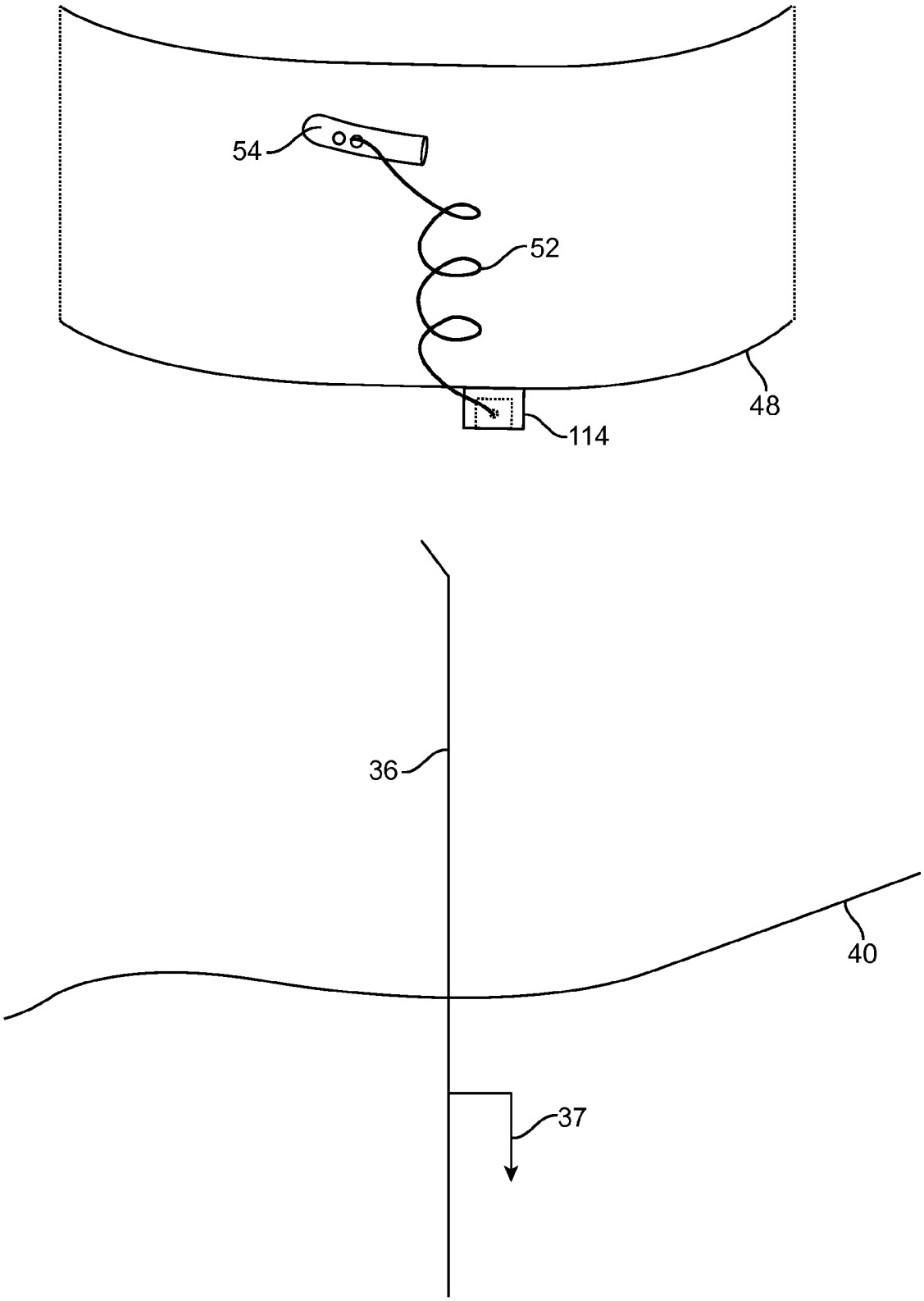

FIG. 4P

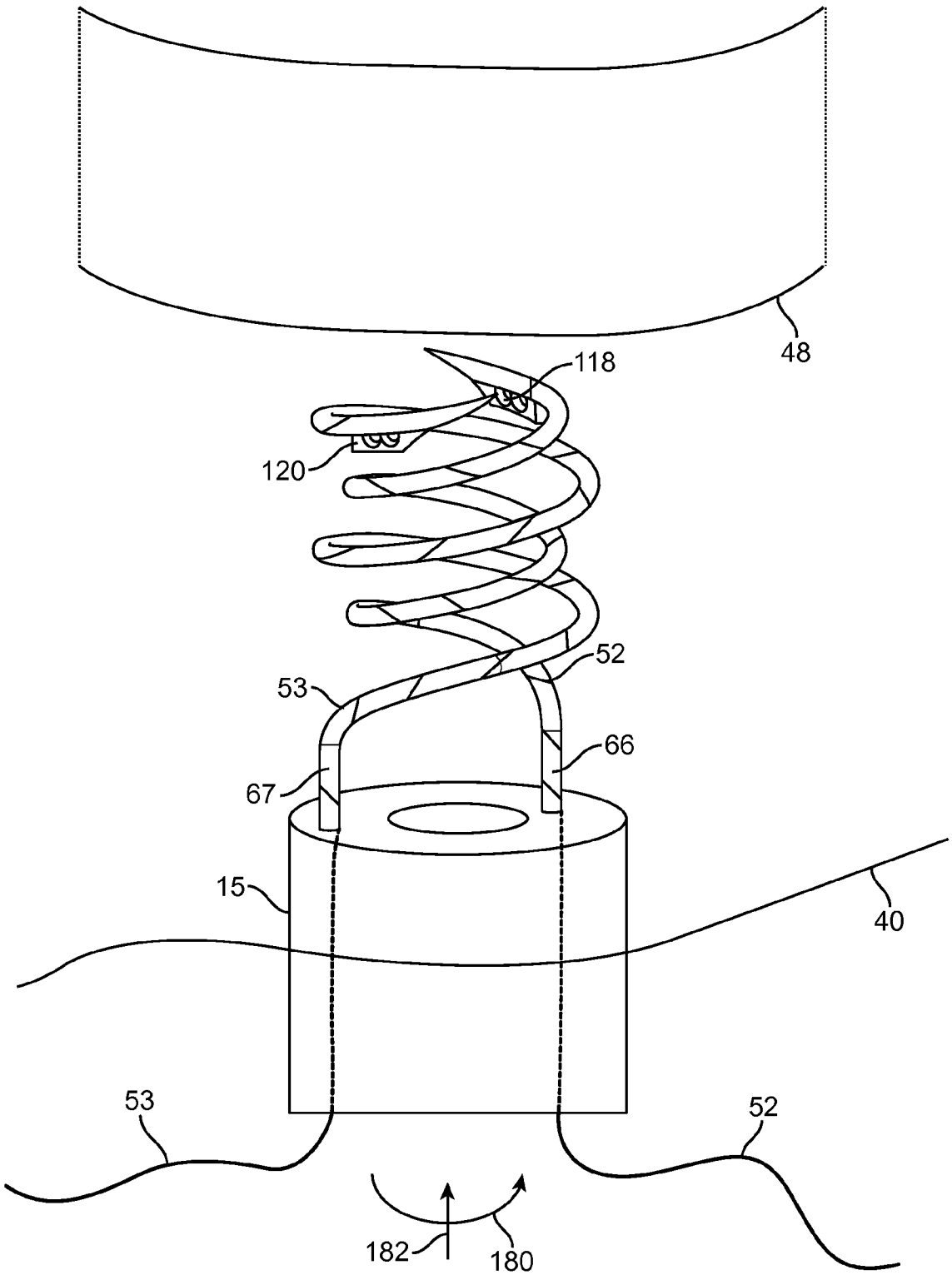

FIG. 5A

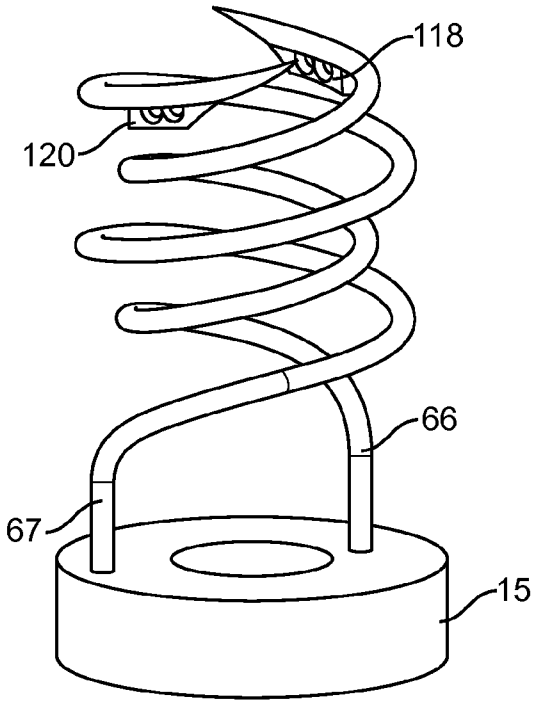

FIG. 5B

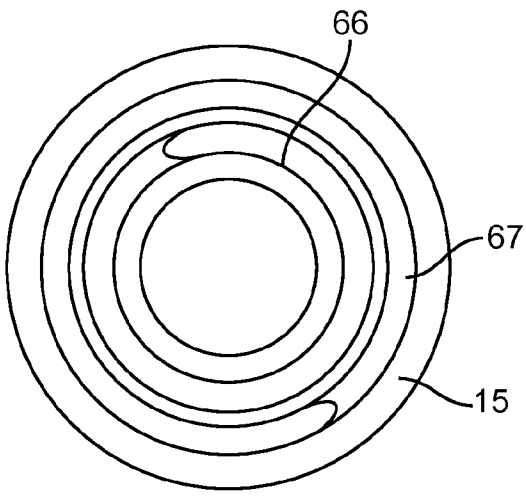

FIG. 5C

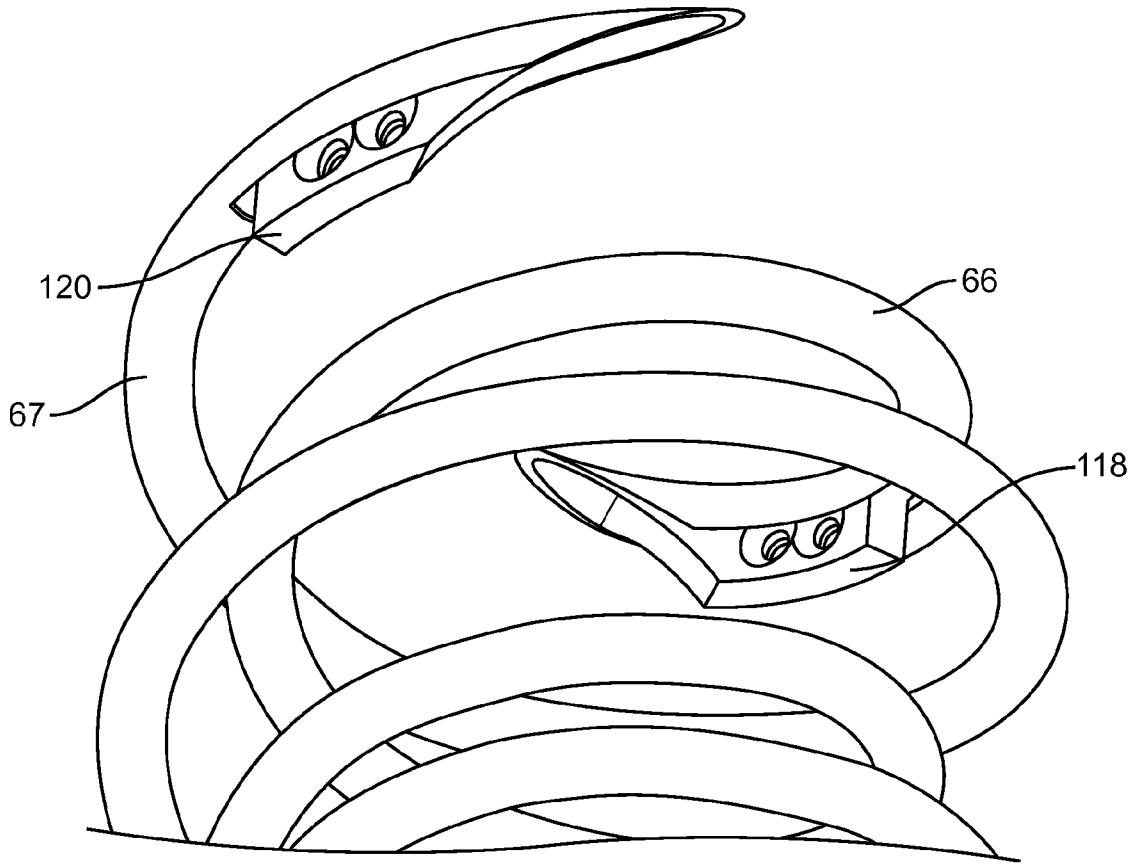

FIG. 5D

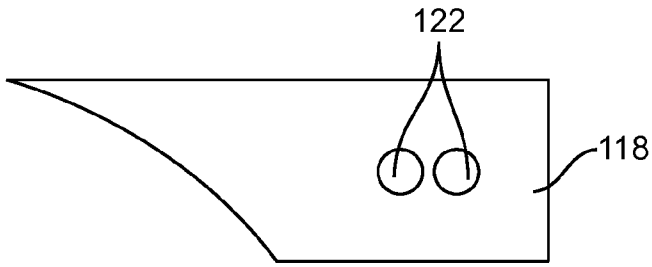

FIG. 5E

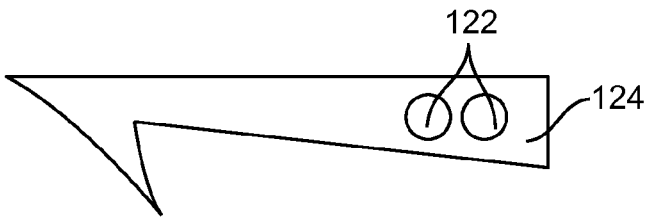

FIG. 5F

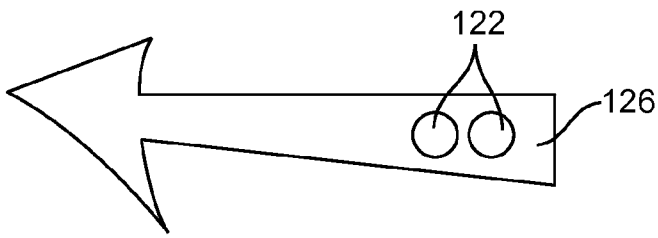

FIG. 5G

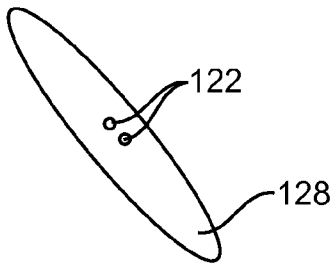

FIG. 5H

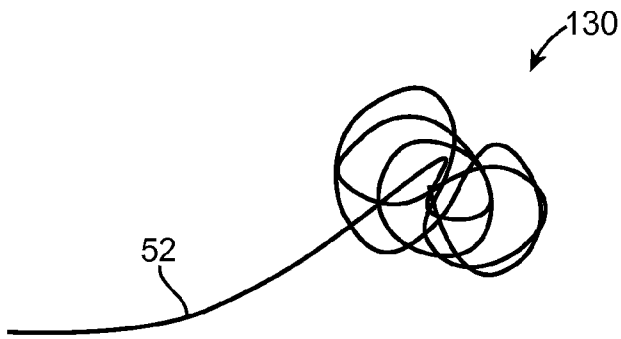

FIG. 5I

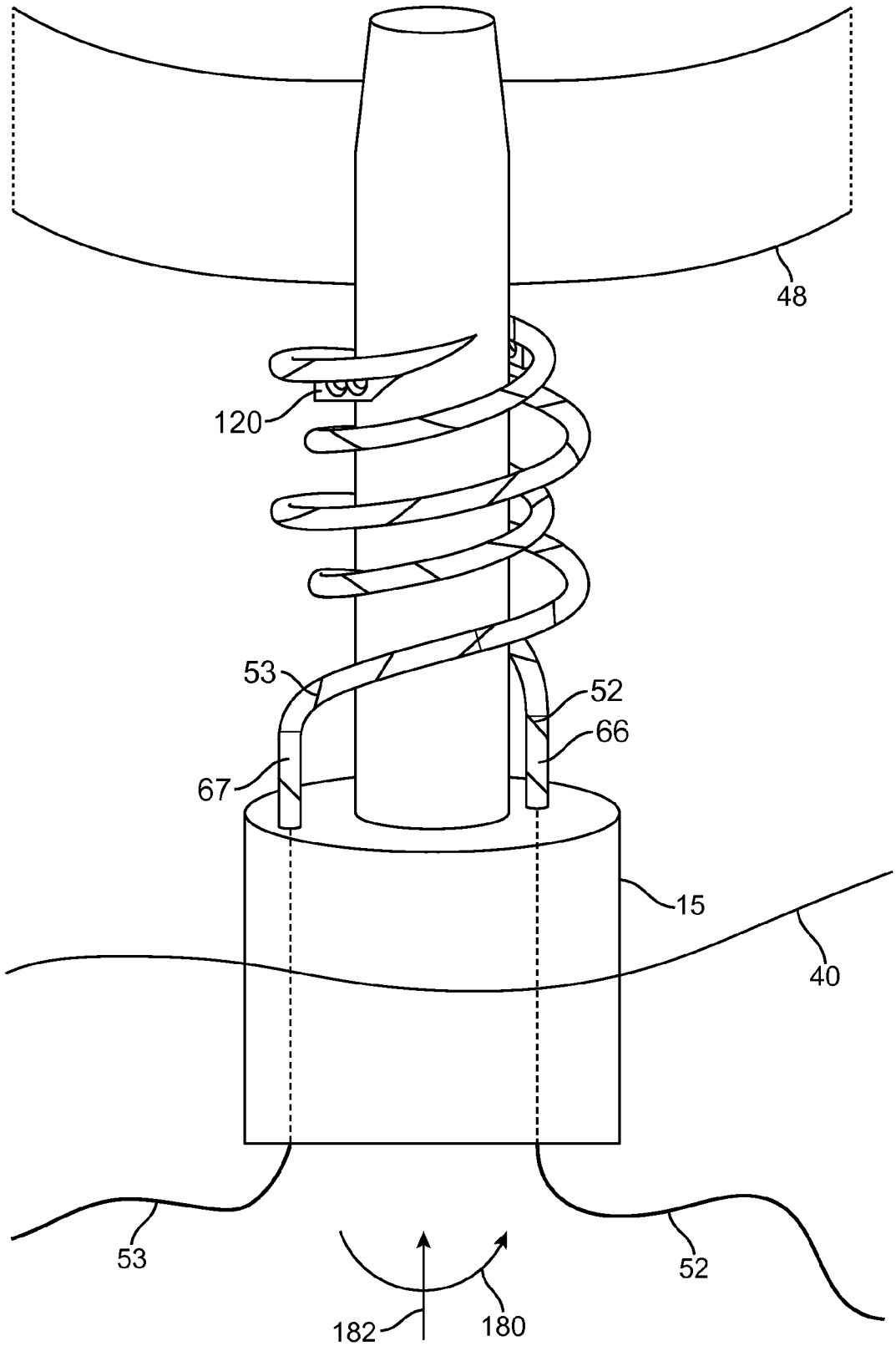

FIG. 6

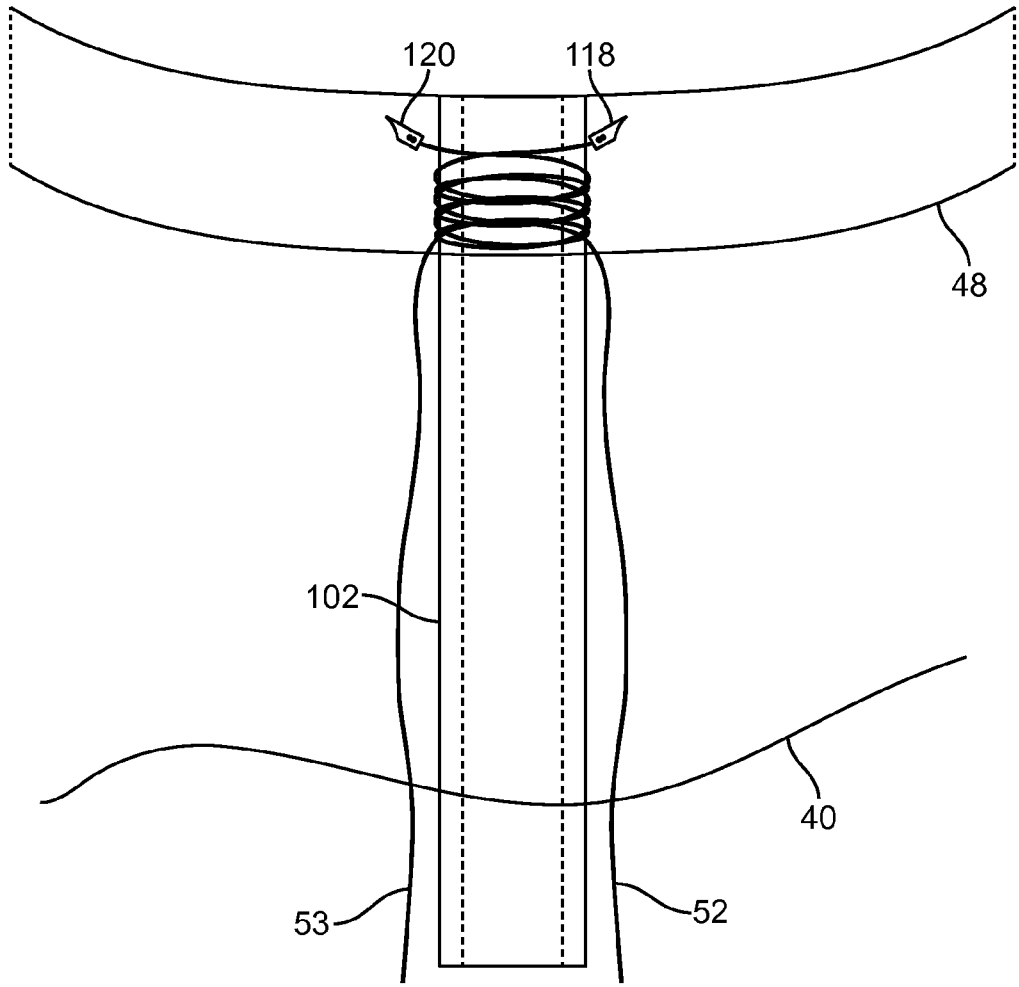

FIG. 7A

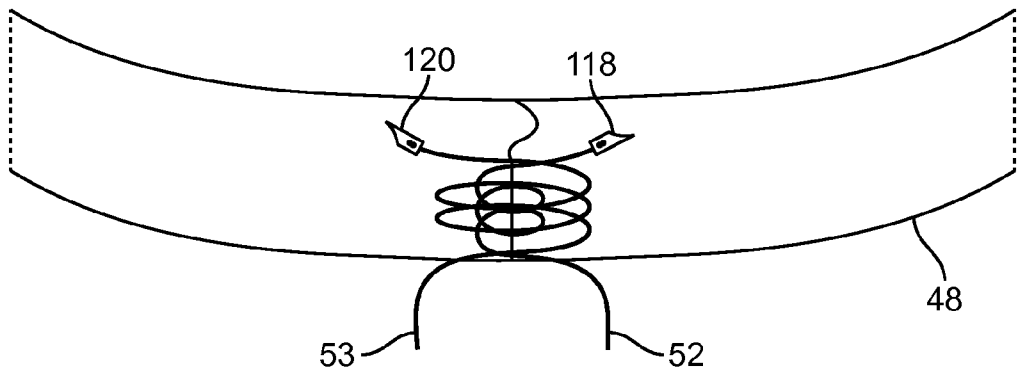

FIG. 7B

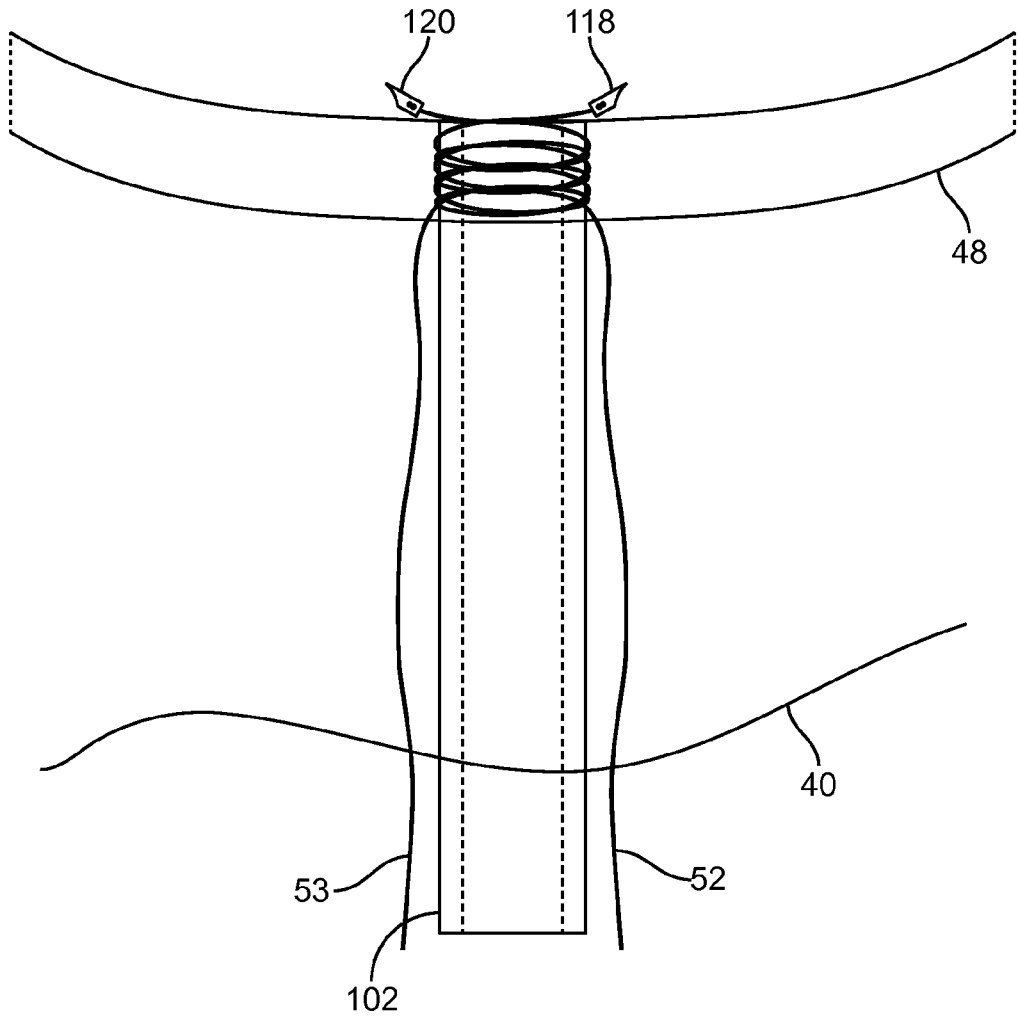

FIG. 8A

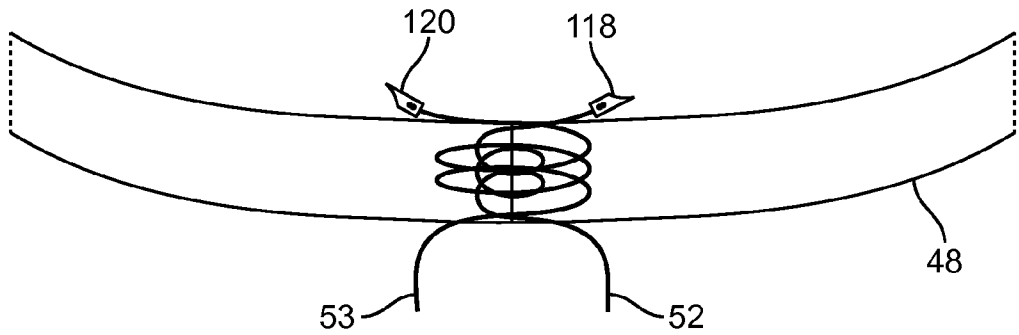

FIG. 8B

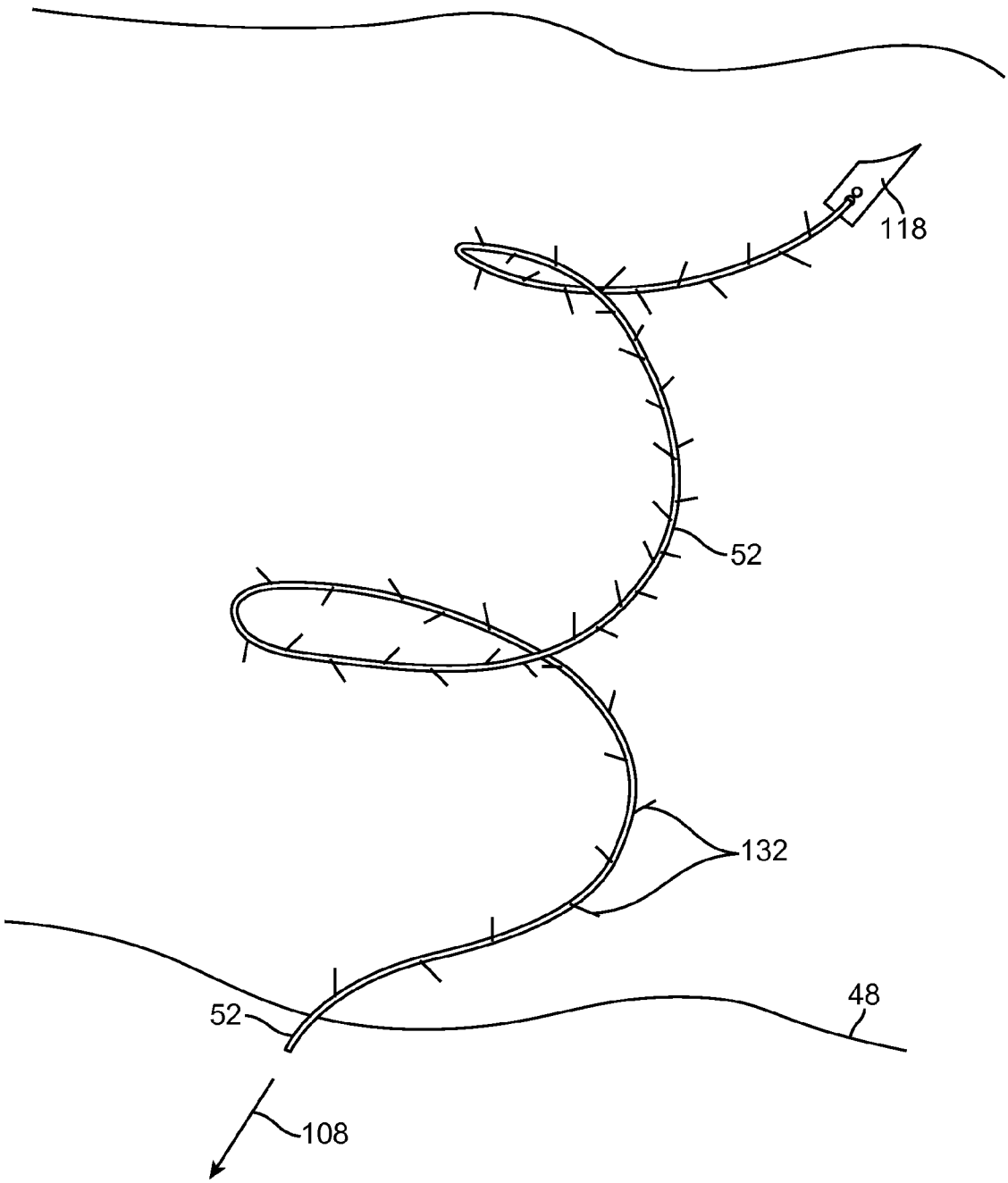

FIG. 9A

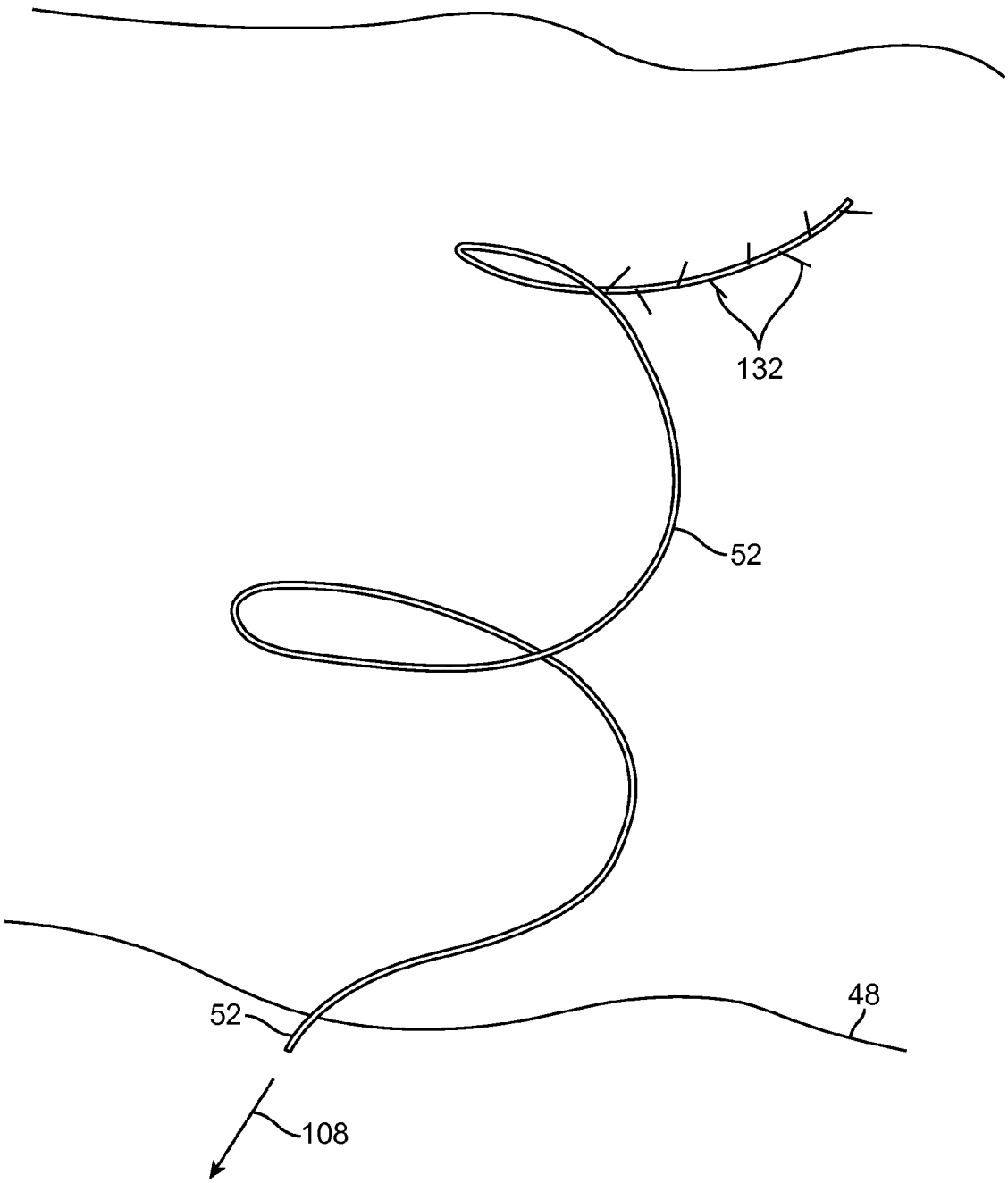

FIG. 9B

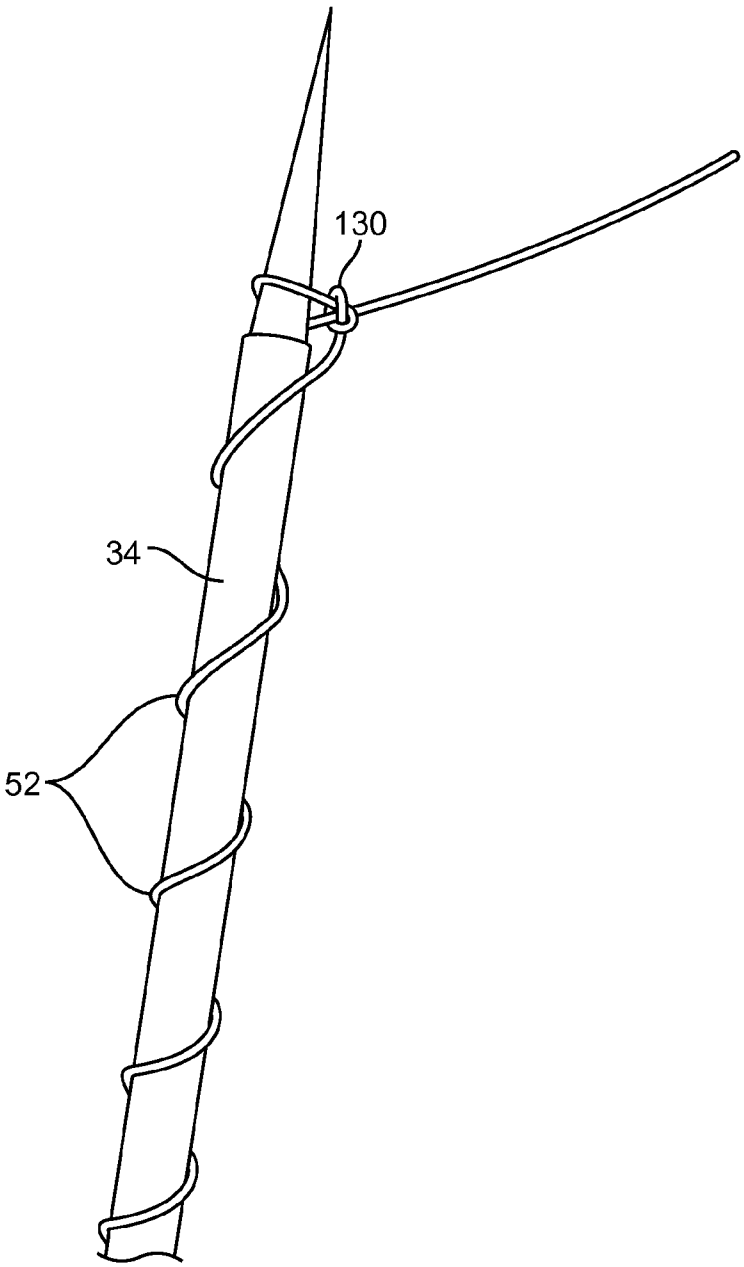

FIG. 10A

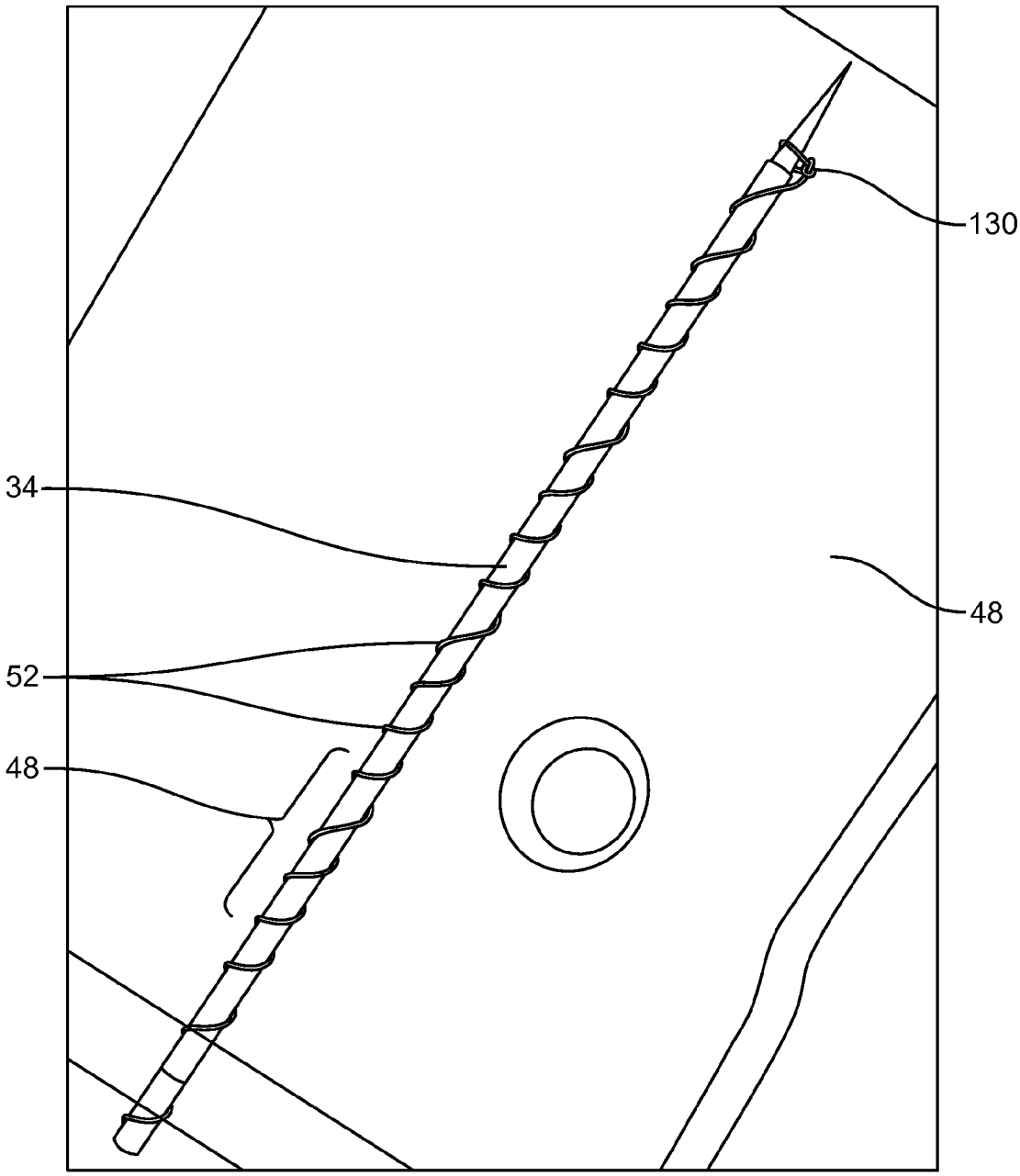

FIG. 10B

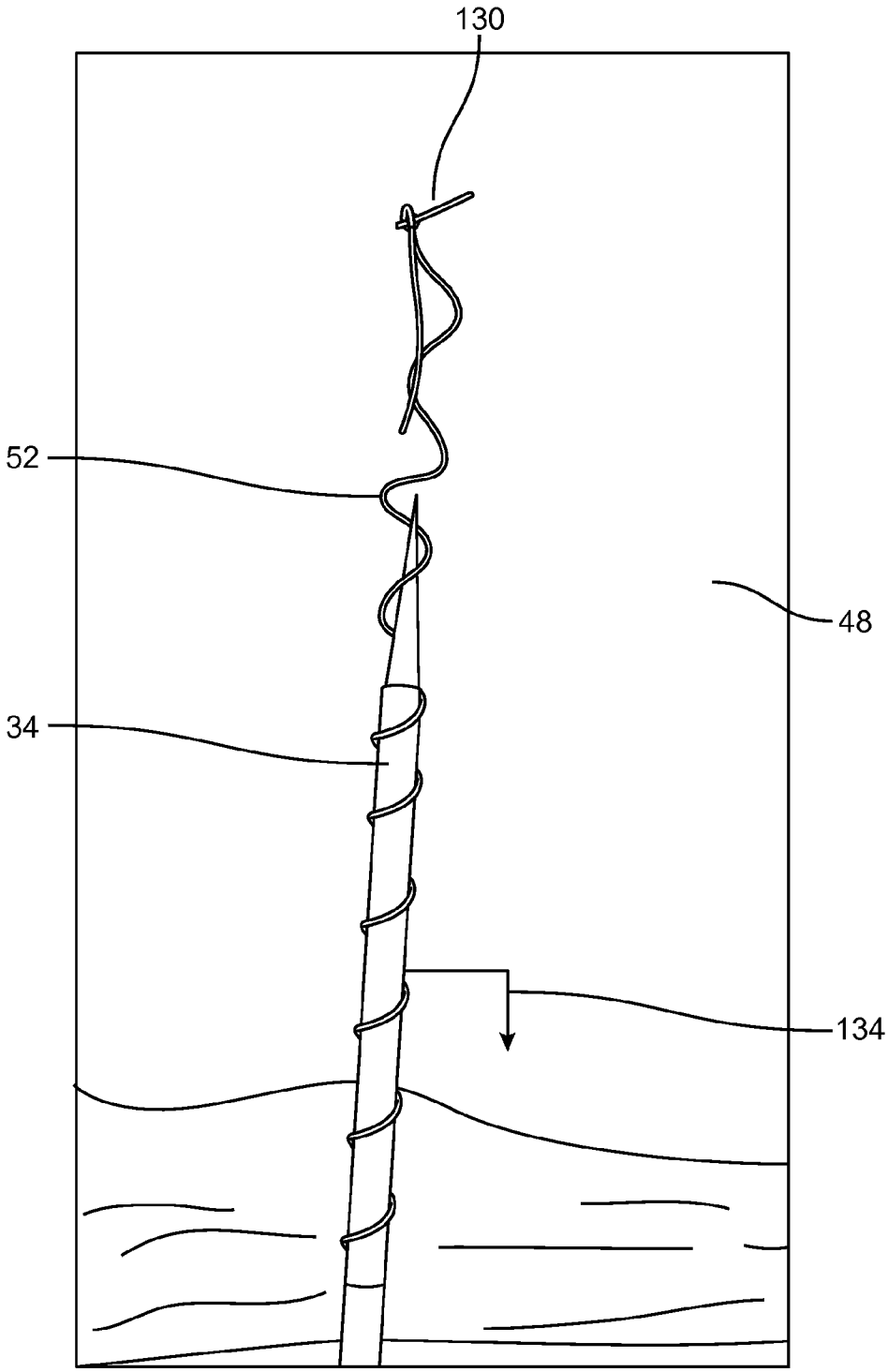

FIG. 10C

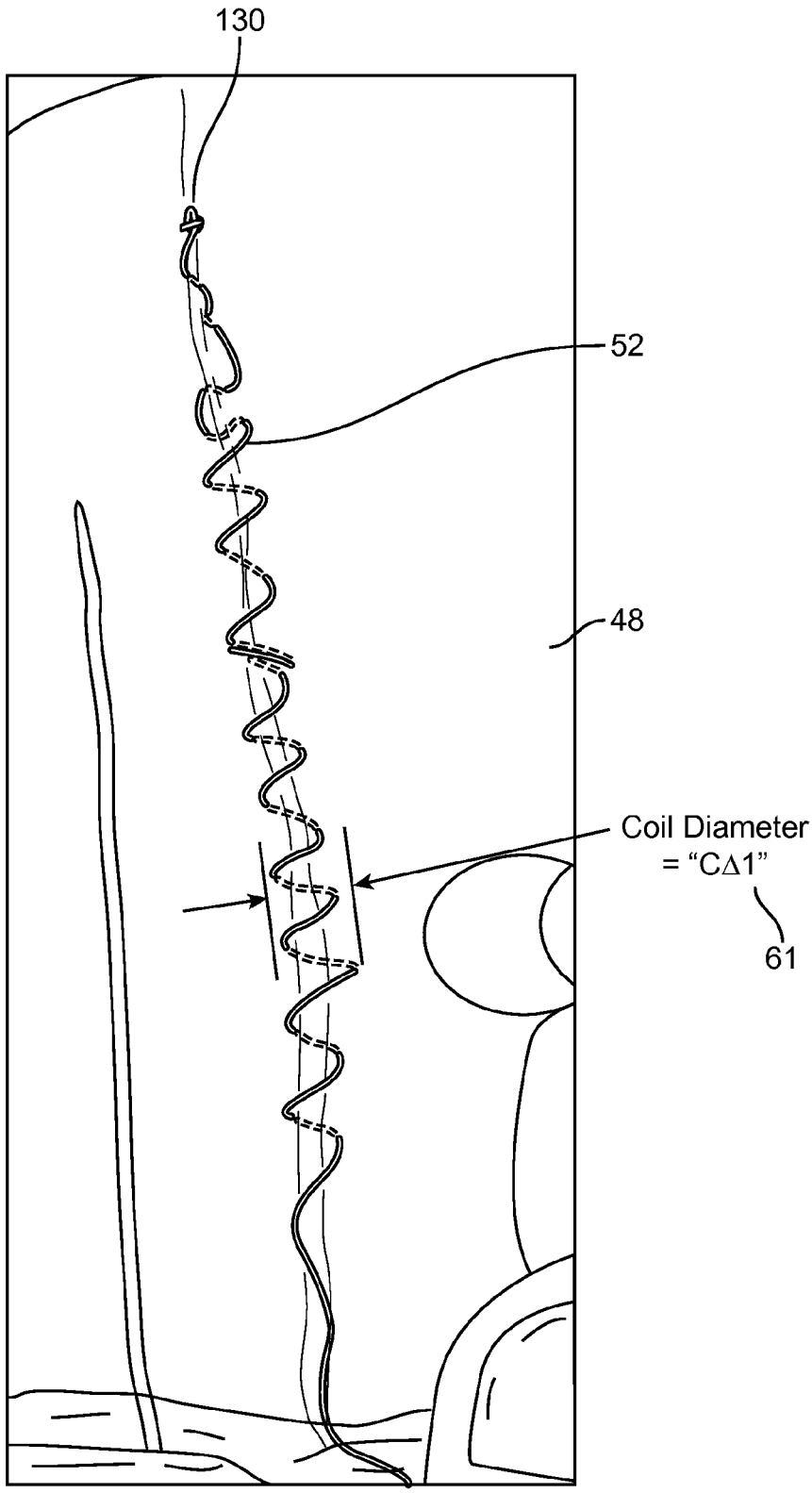

FIG. 10D

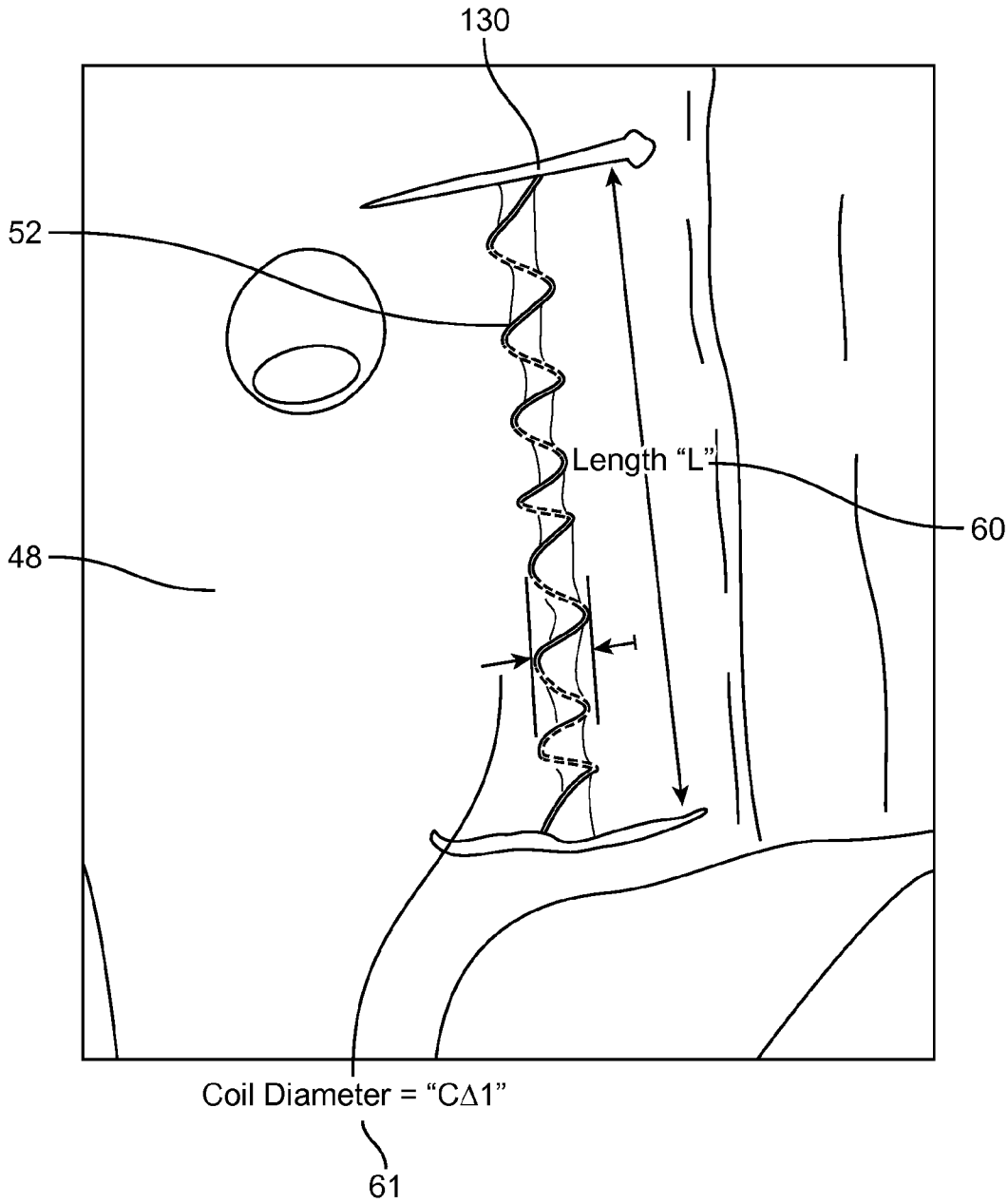

FIG. 10E

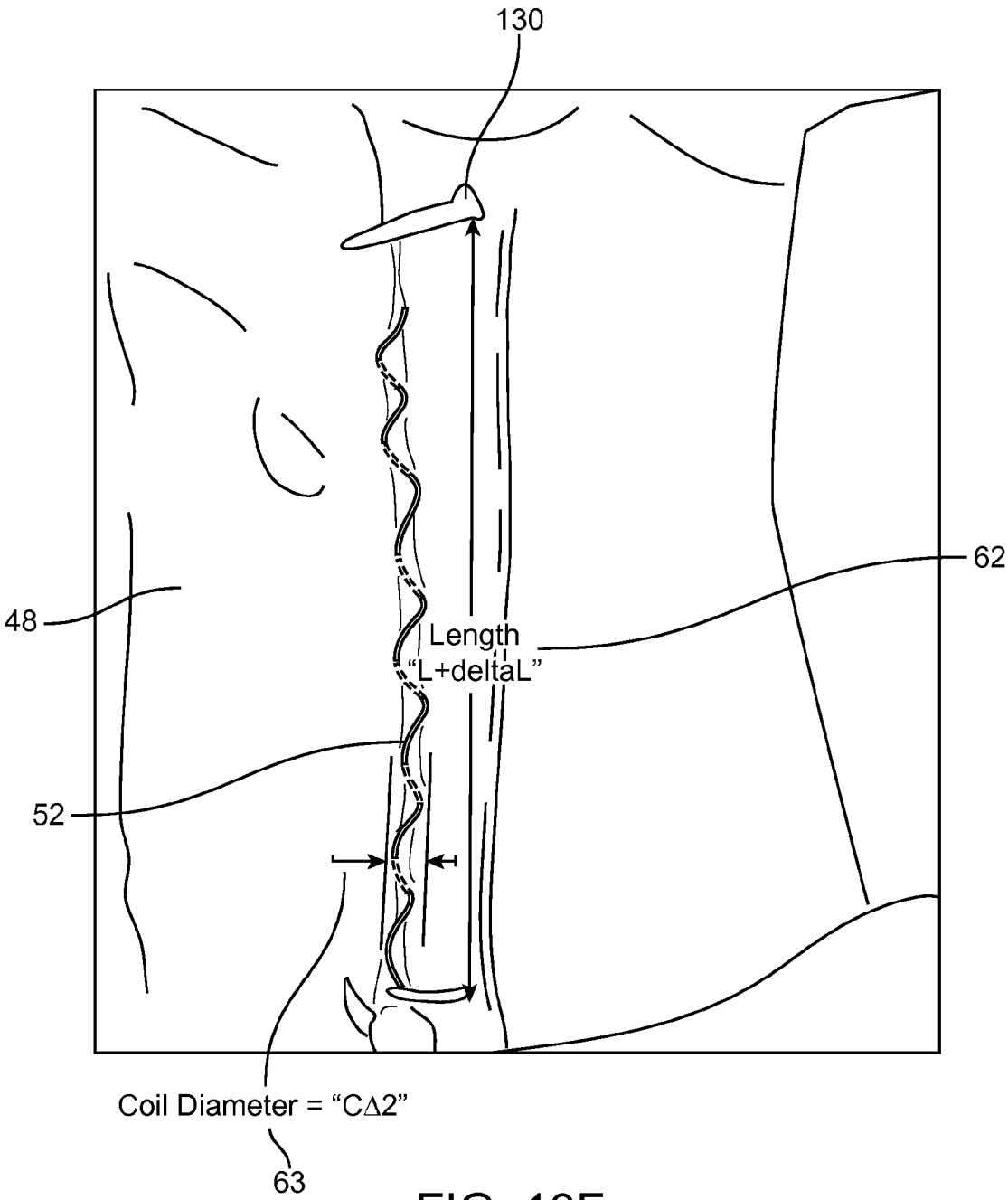

FIG. 10F

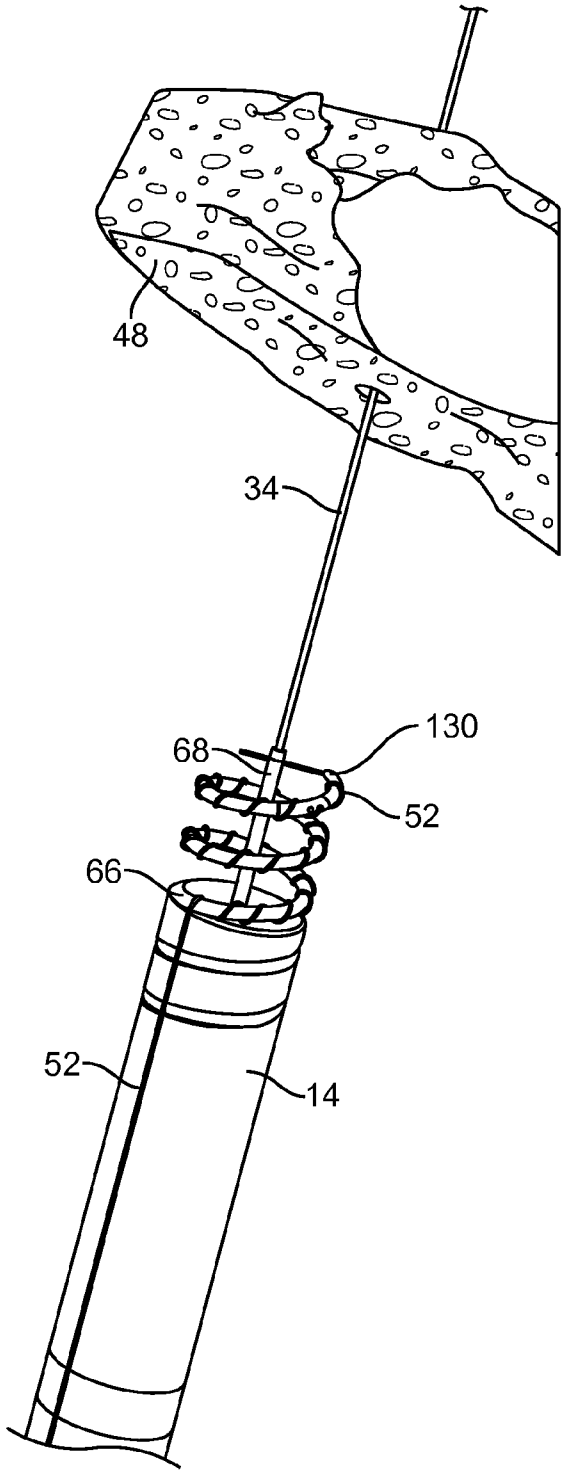

FIG. 11A

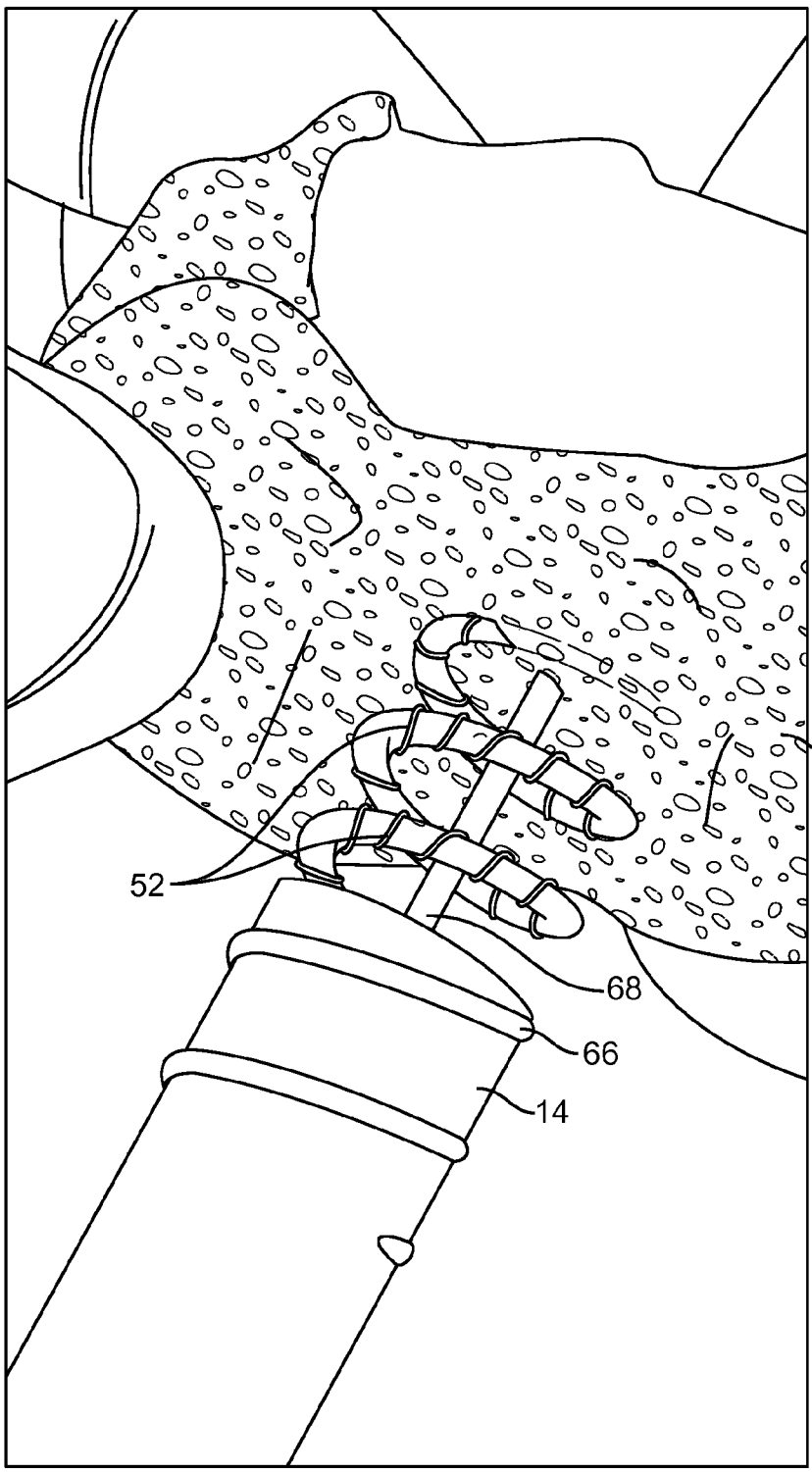

FIG. 11B

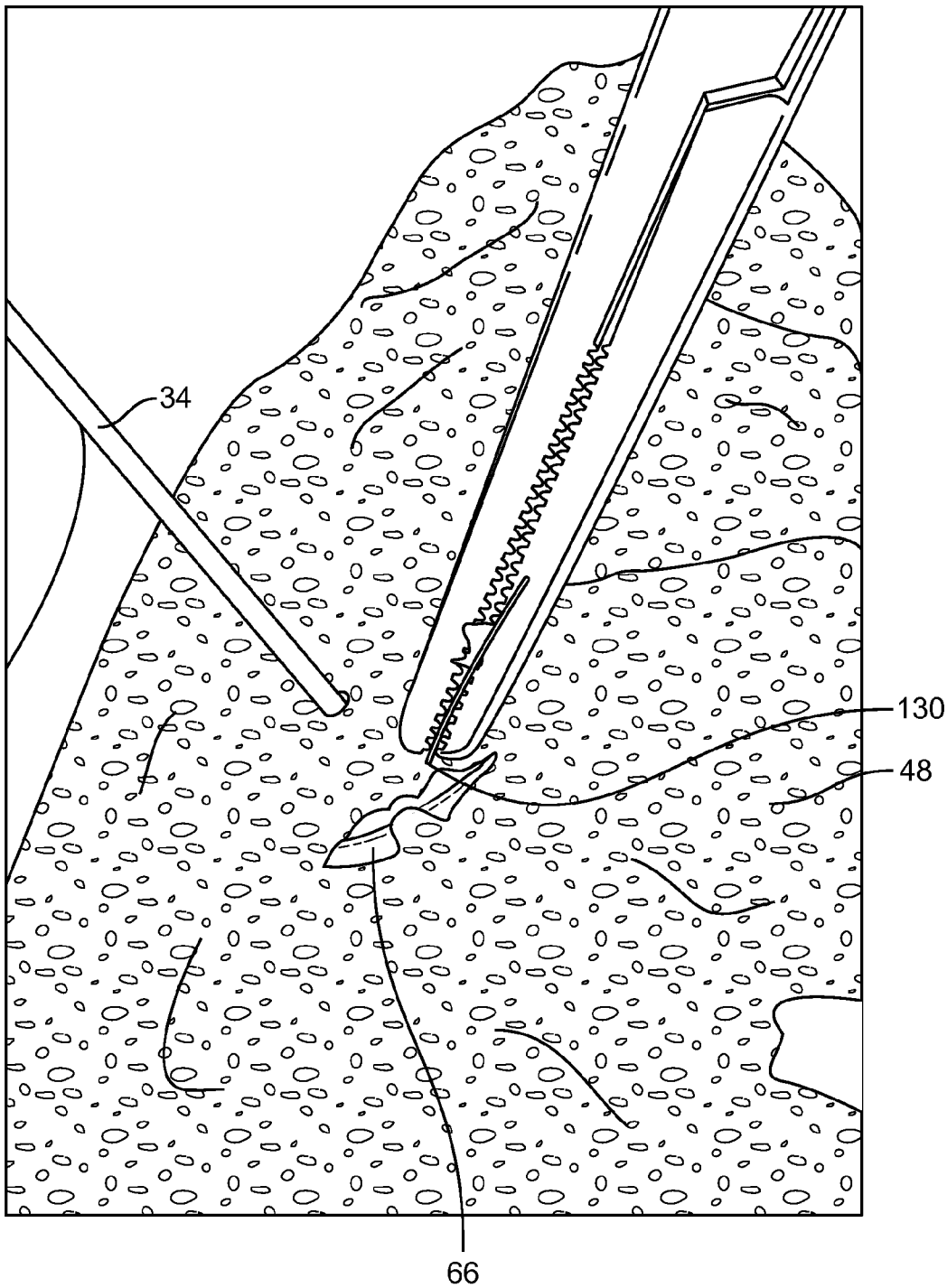

FIG. 11C

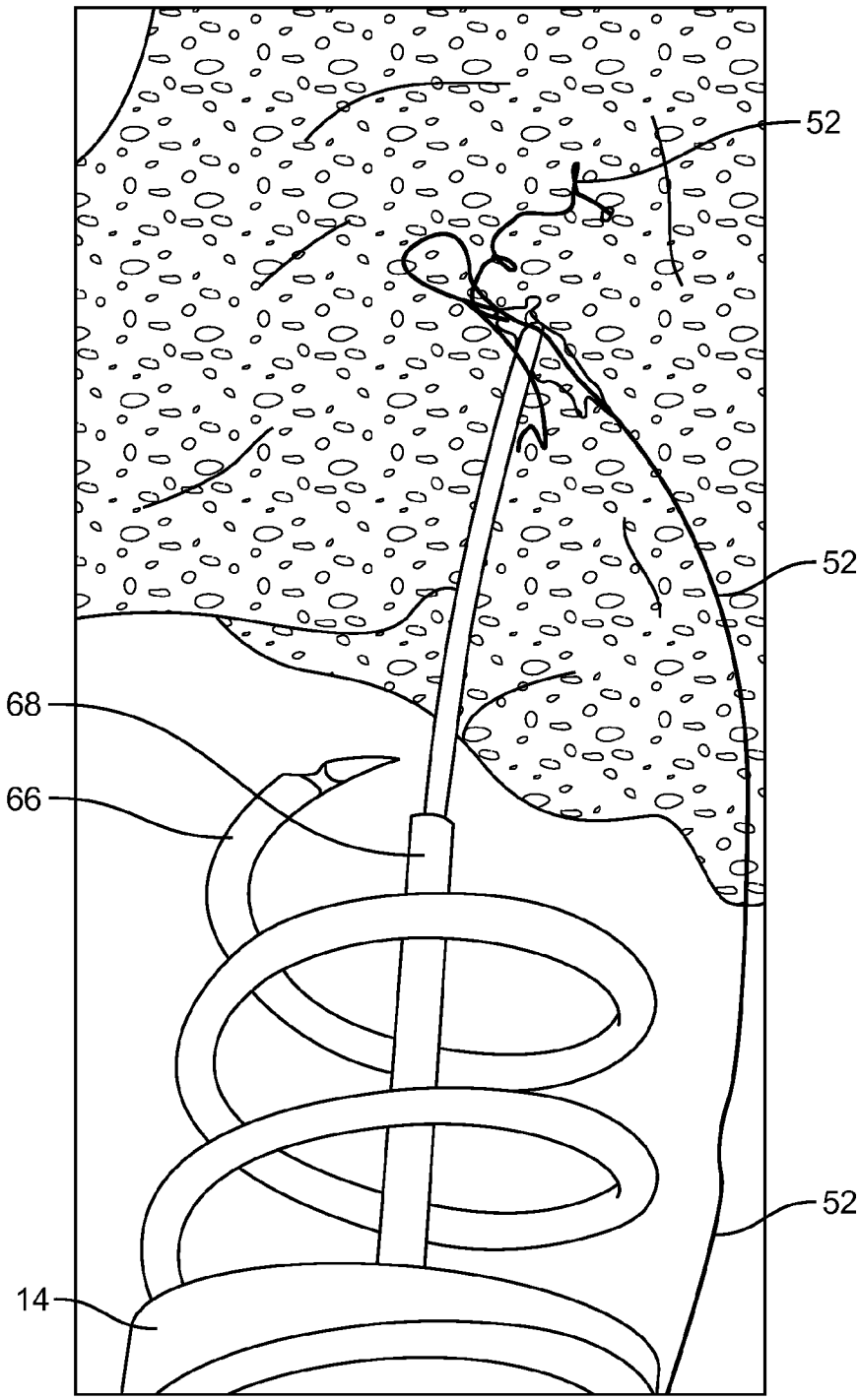

FIG. 11D

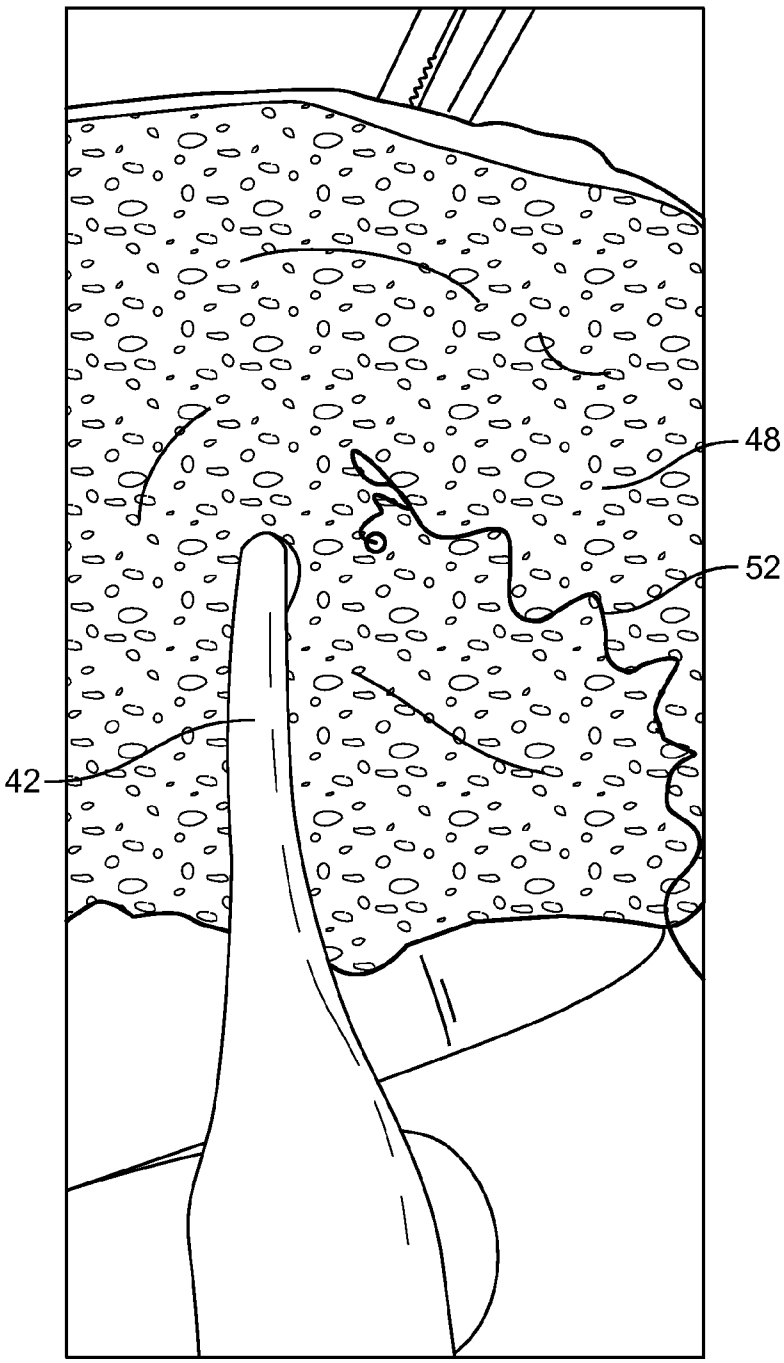

FIG. 11E

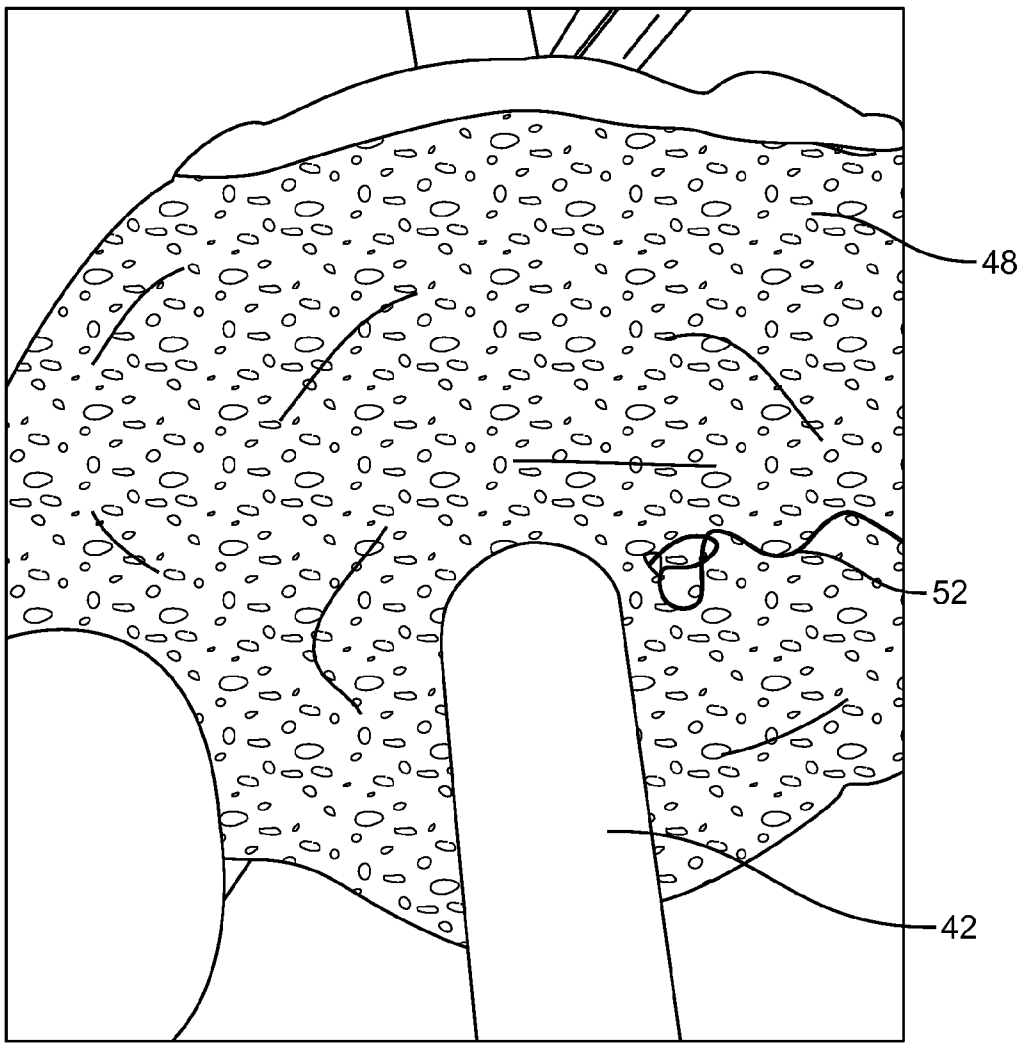

FIG. 11F

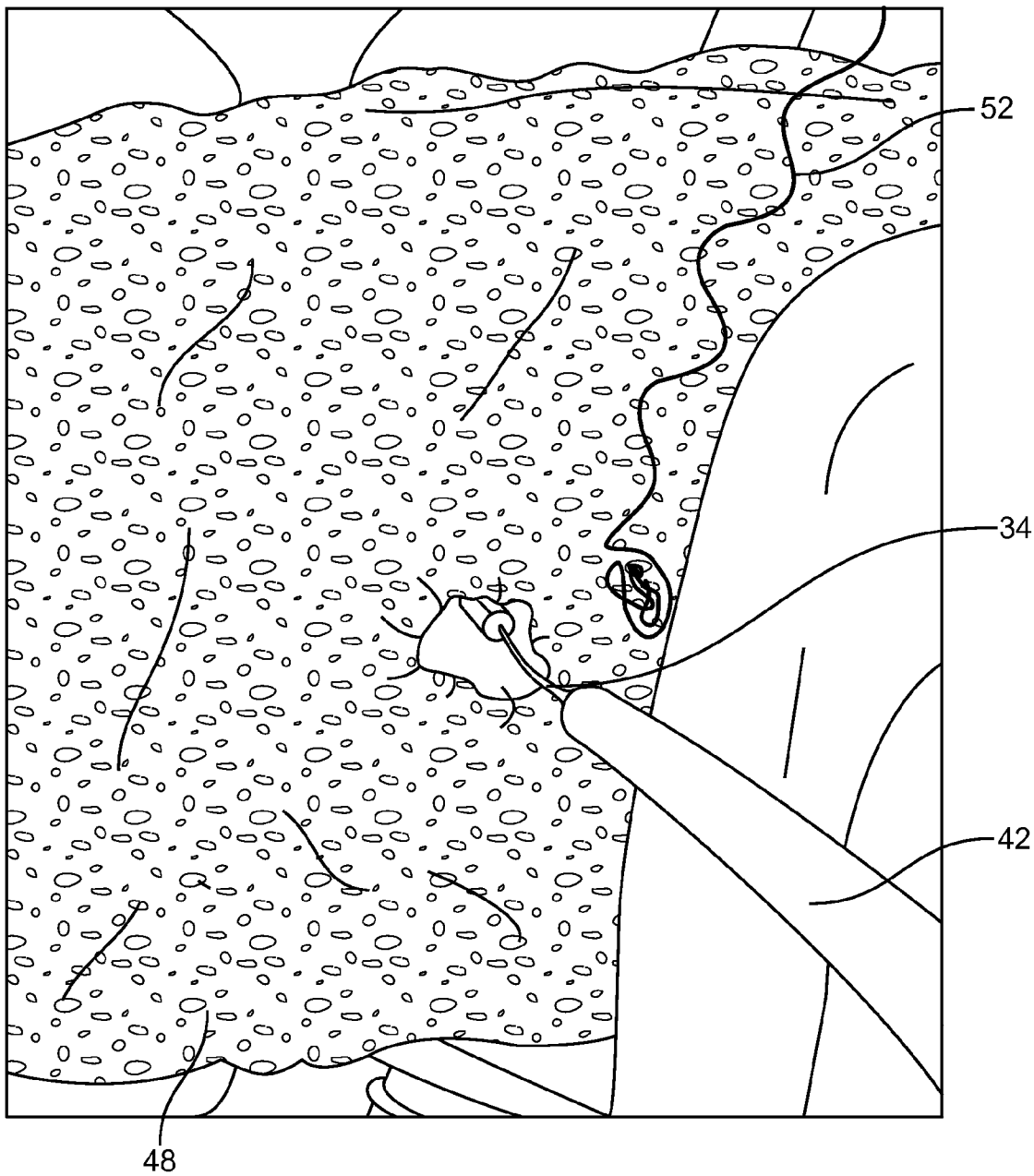

FIG. 11G

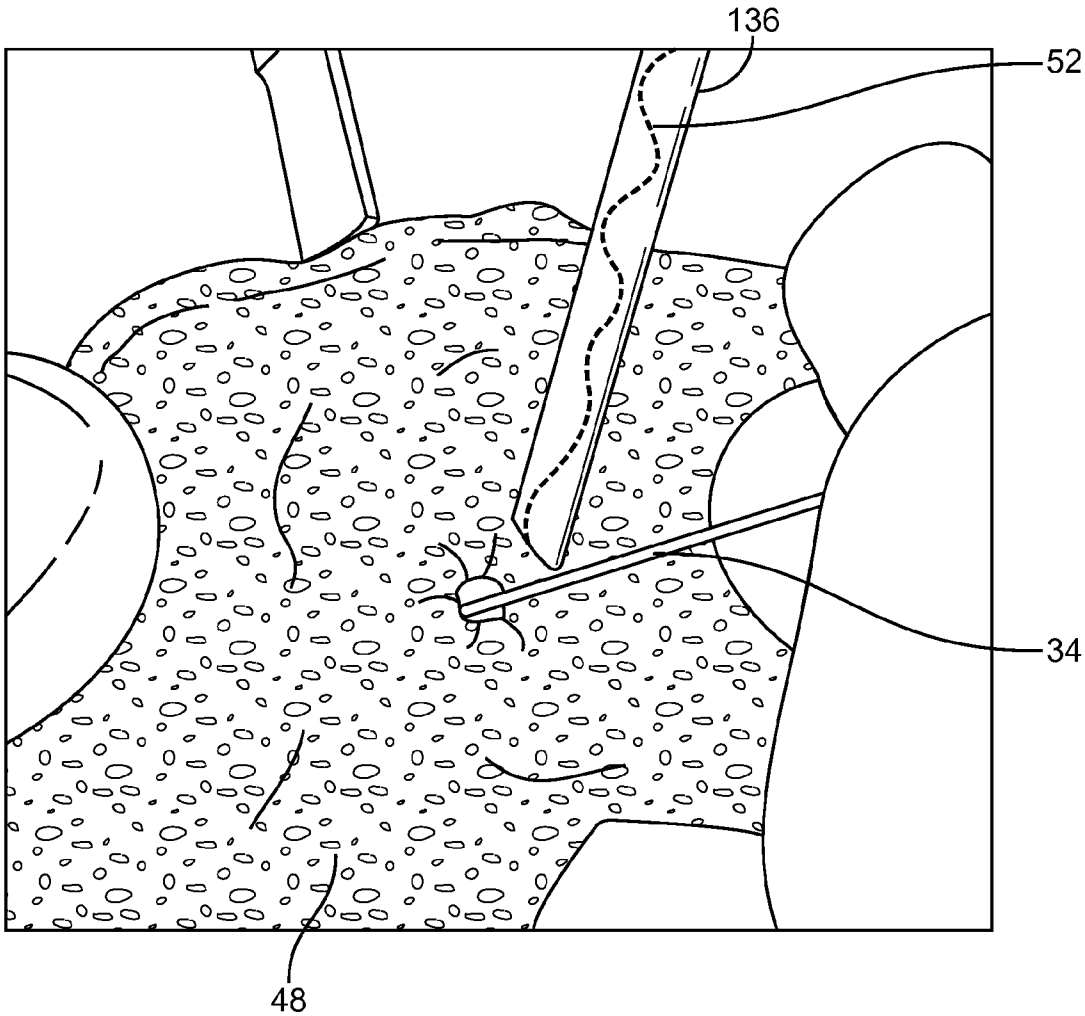

FIG. 11H

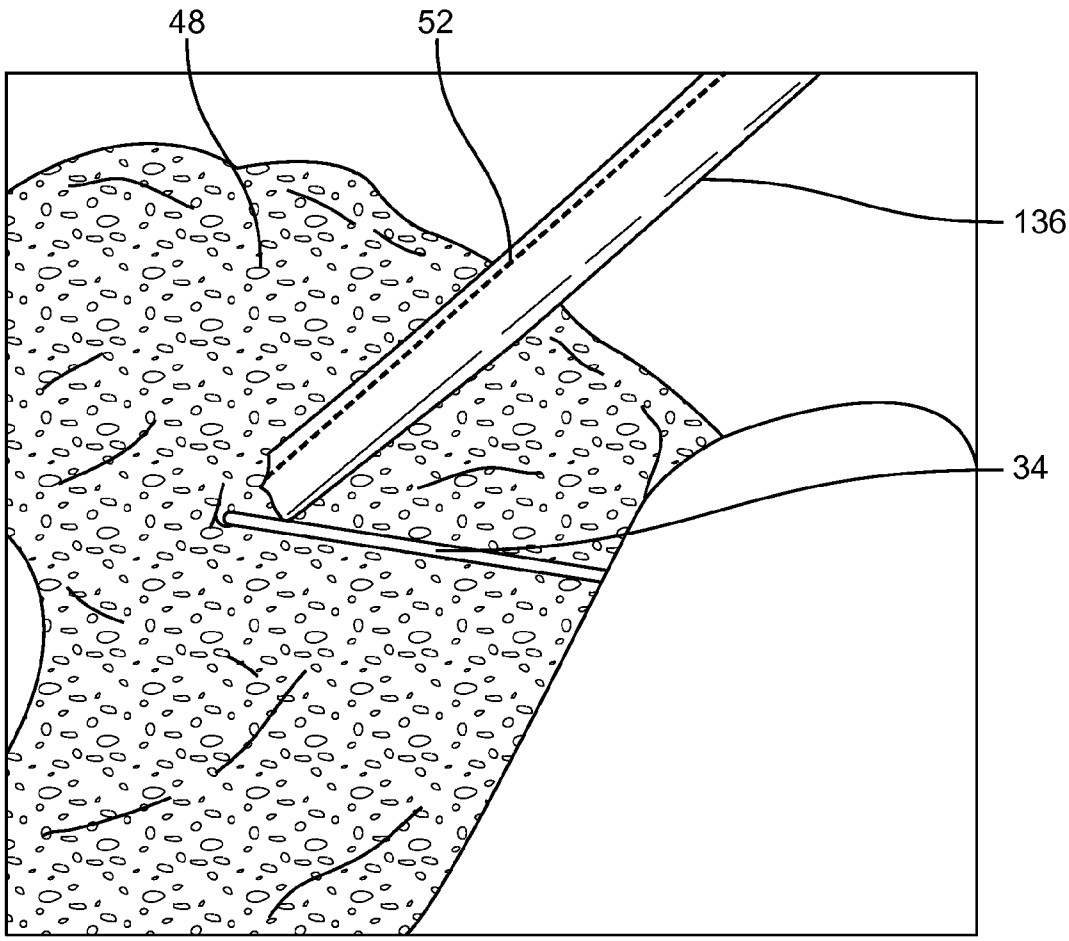

FIG. 11I

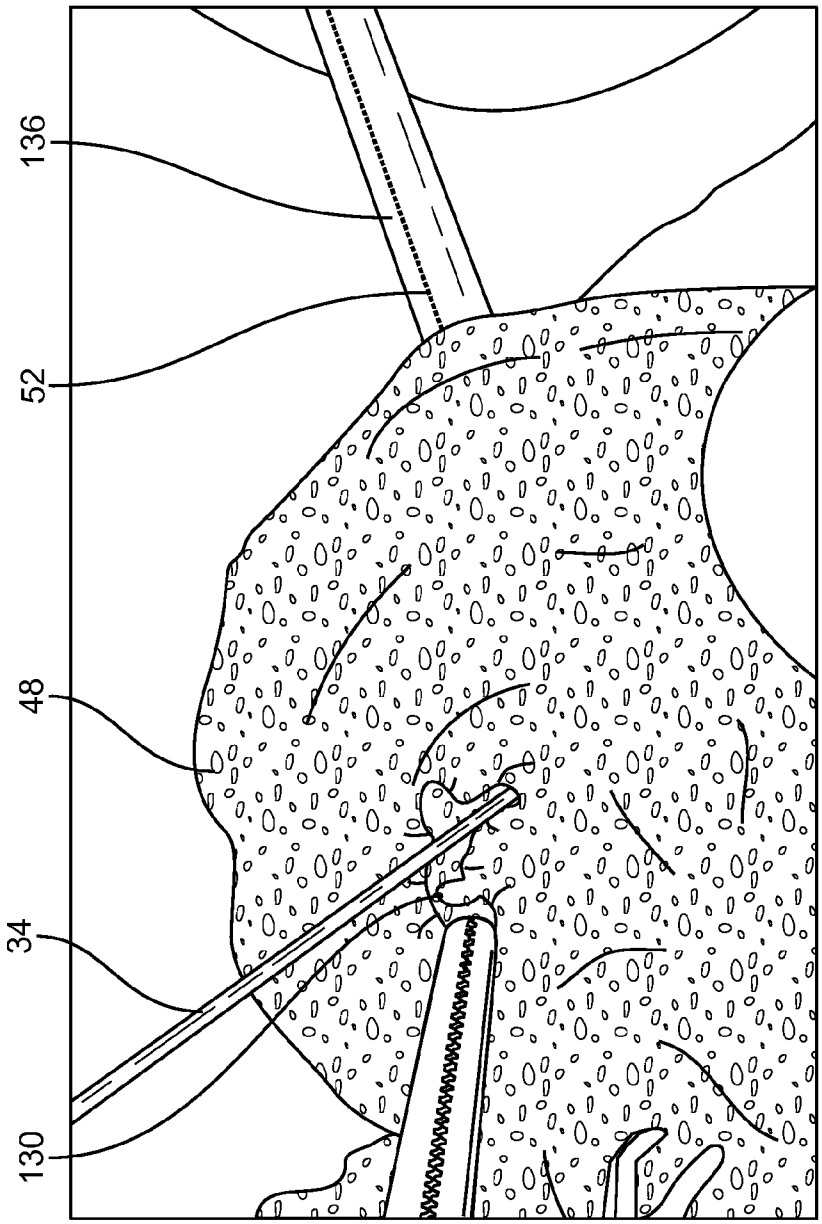

FIG. 11J

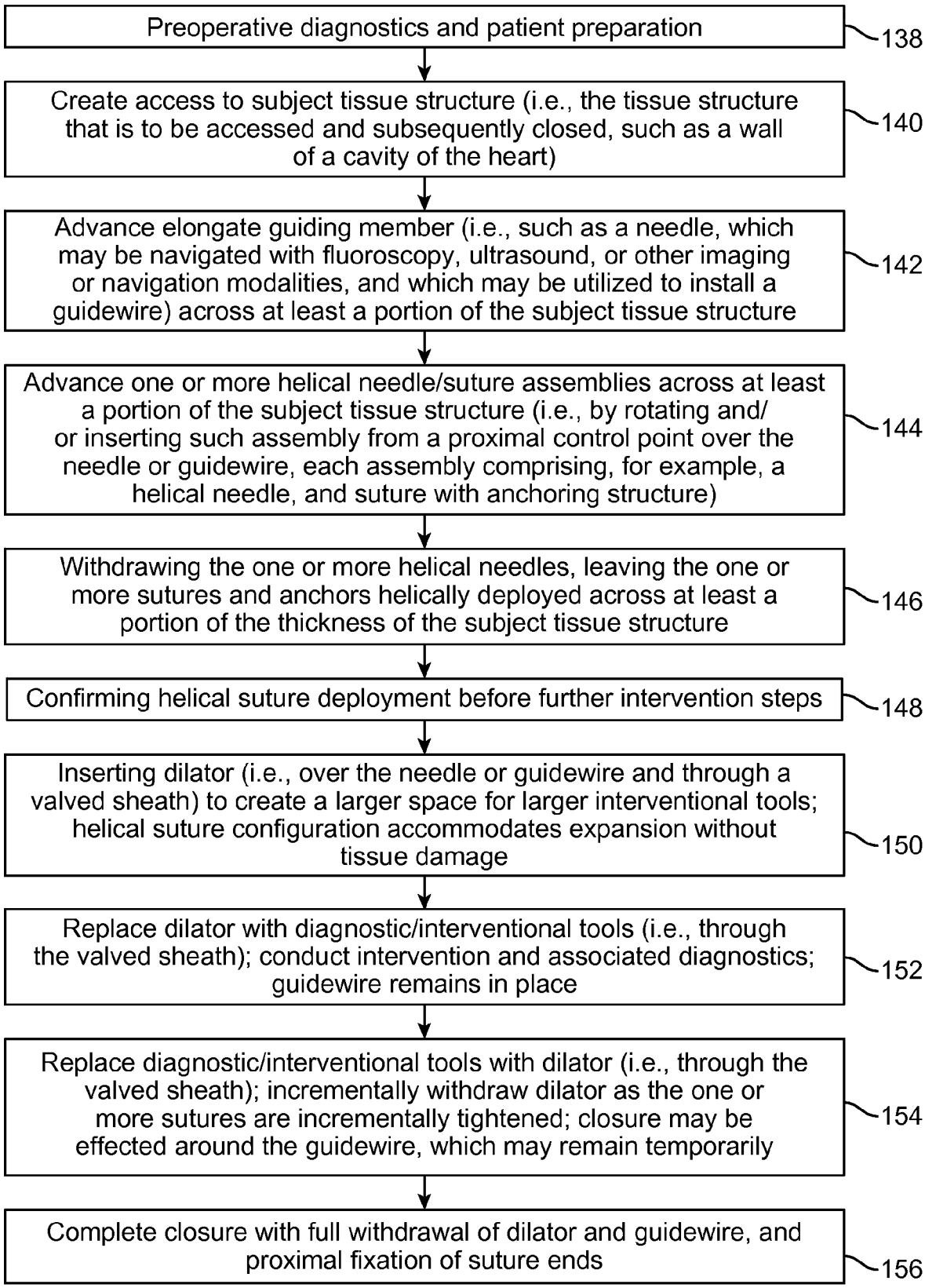
Preoperative diagnostics and patient preparation
138
Create access to subject tissue structure (i.e., the tissue structure that is to be accessed and subsequently closed, such as a wall of a cavity of the heart)
140
Advance elongate guiding member (i.e., such as a needle, which may be navigated with fluoroscopy, ultrasound, or other imaging or navigation modalities, and which may be utilized to install a guidewire) across at least a portion of the subject tissue structure
142
Advance one or more helical needle/suture assemblies across at least a portion of the subject tissue structure (i.e., by rotating and/or inserting such assembly from a proximal control point over the needle or guidewire, each assembly comprising, for example, a helical needle, and suture with anchoring structure)
144
Withdrawing the one or more helical needles, leaving the one or more sutures and anchors helically deployed across at least a portion of the thickness of the subject tissue structure
146
Confirming helical suture deployment before further intervention steps
148
Inserting dilator (i.e., over the needle or guidewire and through a valved sheath) to create a larger space for larger interventional tools; helical suture configuration accommodates expansion without tissue damage
150
Replace dilator with diagnostic/interventional tools (i.e., through the valved sheath); conduct intervention and associated diagnostics; guidewire remains in place
152
Replace diagnostic/interventional tools with dilator (i.e., through the valved sheath); incrementally withdraw dilator as the one or more sutures are incrementally tightened; closure may be effected around the guidewire, which may remain temporarily
154
Complete closure with full withdrawal of dilator and guidewire, and proximal fixation of suture ends
156

FIG. 12A

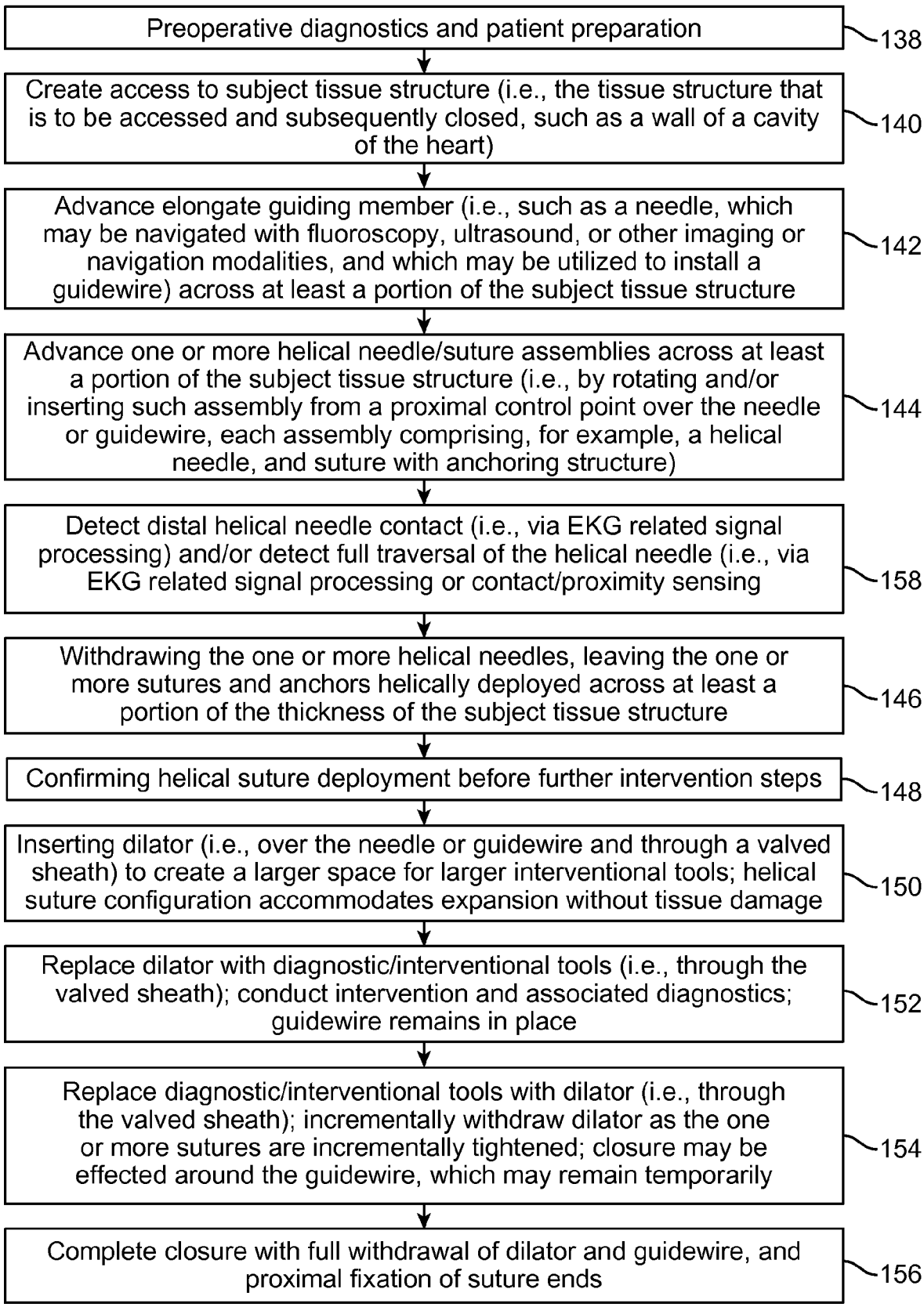
Preoperative diagnostics and patient preparation
138
Create access to subject tissue structure (i.e., the tissue structure that is to be accessed and subsequently closed, such as a wall of a cavity of the heart)
140
Advance elongate guiding member (i.e., such as a needle, which may be navigated with fluoroscopy, ultrasound, or other imaging or navigation modalities, and which may be utilized to install a guidewire) across at least a portion of the subject tissue structure
142
Advance one or more helical needle/suture assemblies across at least a portion of the subject tissue structure (i.e., by rotating and/or inserting such assembly from a proximal control point over the needle or guidewire, each assembly comprising, for example, a helical needle, and suture with anchoring structure)
144
Detect distal helical needle contact (i.e., via EKG related signal processing) and/or detect full traversal of the helical needle (i.e., via EKG related signal processing or contact/proximity sensing
158
Withdrawing the one or more helical needles, leaving the one or more sutures and anchors helically deployed across at least a portion of the thickness of the subject tissue structure
146
Confirming helical suture deployment before further intervention steps
148
Inserting dilator (i.e., over the needle or guidewire and through a valved sheath) to create a larger space for larger interventional tools; helical suture configuration accommodates expansion without tissue damage
150
Replace dilator with diagnostic/interventional tools (i.e., through the valved sheath); conduct intervention and associated diagnostics; guidewire remains in place
152
Replace diagnostic/interventional tools with dilator (i.e., through the valved sheath); incrementally withdraw dilator as the one or more sutures are incrementally tightened; closure may be effected around the guidewire, which may remain temporarily
154
Complete closure with full withdrawal of dilator and guidewire, and proximal fixation of suture ends
156

FIG. 12B

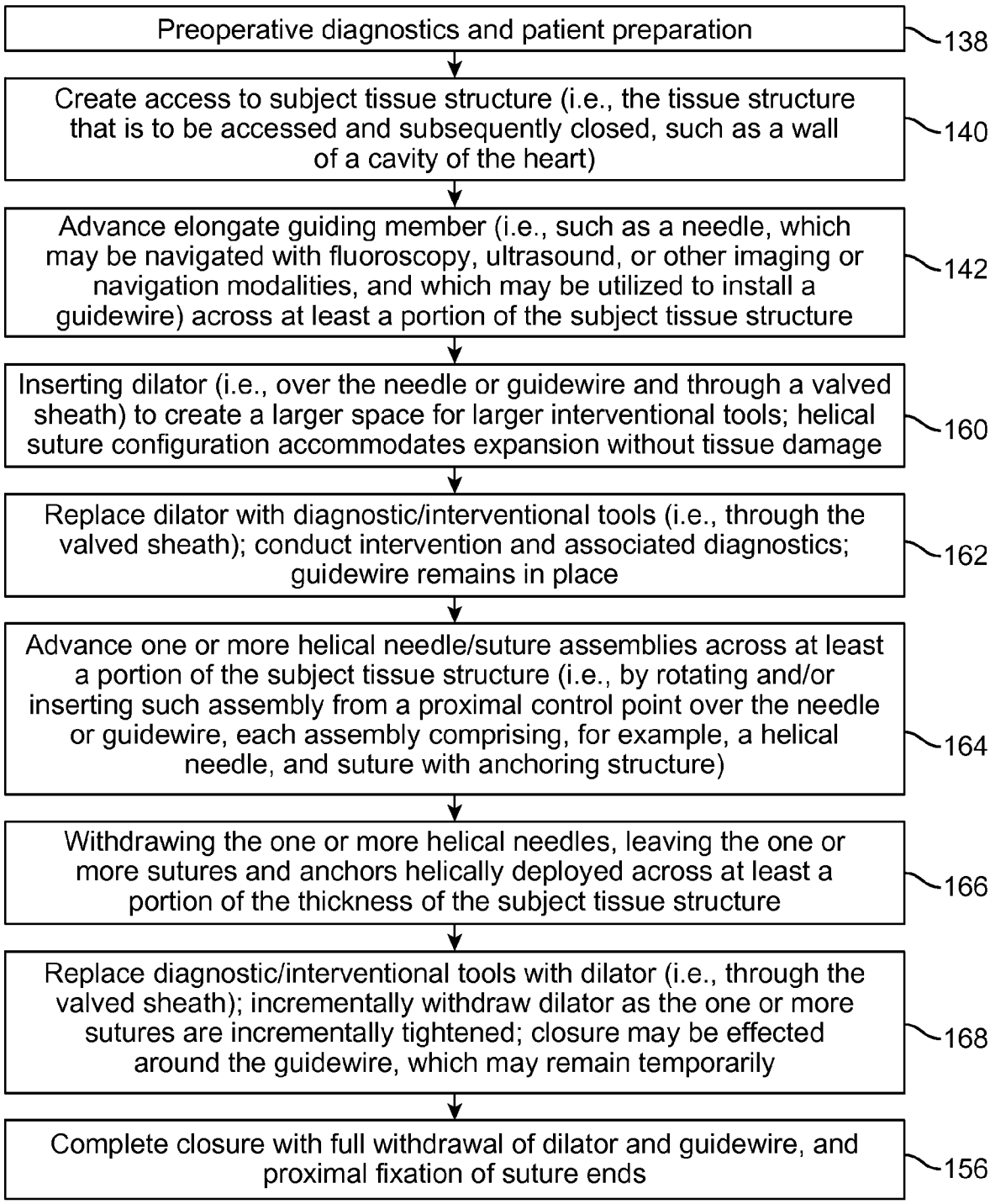
Preoperative diagnostics and patient preparation
138
Create access to subject tissue structure (i.e., the tissue structure that is to be accessed and subsequently closed, such as a wall of a cavity of the heart)
140
Advance elongate guiding member (i.e., such as a needle, which may be navigated with fluoroscopy, ultrasound, or other imaging or navigation modalities, and which may be utilized to install a guidewire) across at least a portion of the subject tissue structure
142
Inserting dilator (i.e., over the needle or guidewire and through a valved sheath) to create a larger space for larger interventional tools; helical suture configuration accommodates expansion without tissue damage
160
Replace dilator with diagnostic/interventional tools (i.e., through the valved sheath); conduct intervention and associated diagnostics; guidewire remains in place
162
Advance one or more helical needle/suture assemblies across at least a portion of the subject tissue structure (i.e., by rotating and/or inserting such assembly from a proximal control point over the needle or guidewire, each assembly comprising, for example, a helical needle, and suture with anchoring structure)
164
Withdrawing the one or more helical needles, leaving the one or more sutures and anchors helically deployed across at least a portion of the thickness of the subject tissue structure
166
Replace diagnostic/interventional tools with dilator (i.e., through the valved sheath); incrementally withdraw dilator as the one or more sutures are incrementally tightened; closure may be effected around the guidewire, which may remain temporarily
168
Complete closure with full withdrawal of dilator and guidewire, and proximal fixation of suture ends
156

FIG. 12C

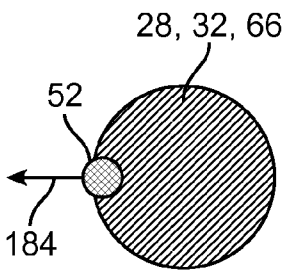

FIG. 13

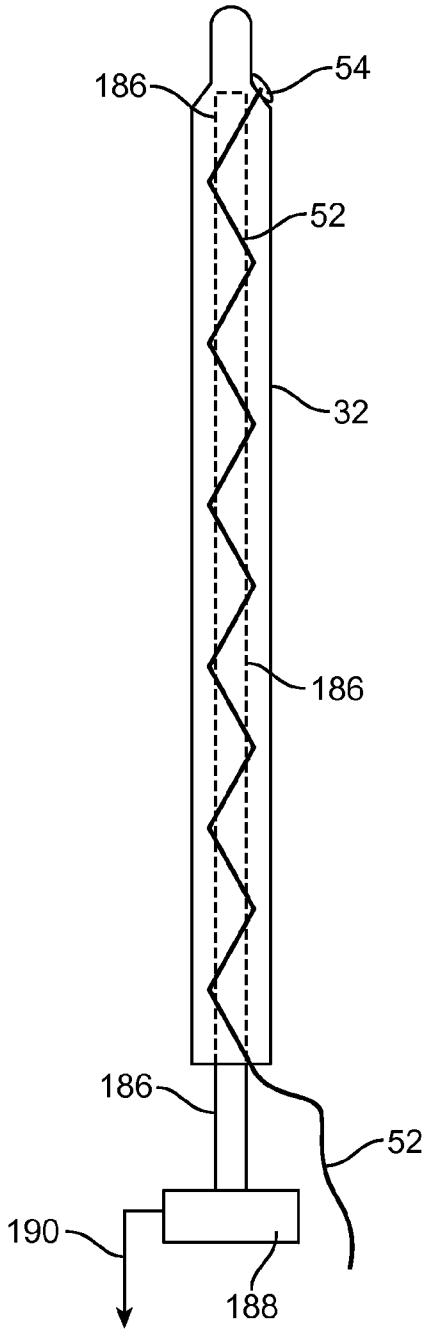

FIG. 14

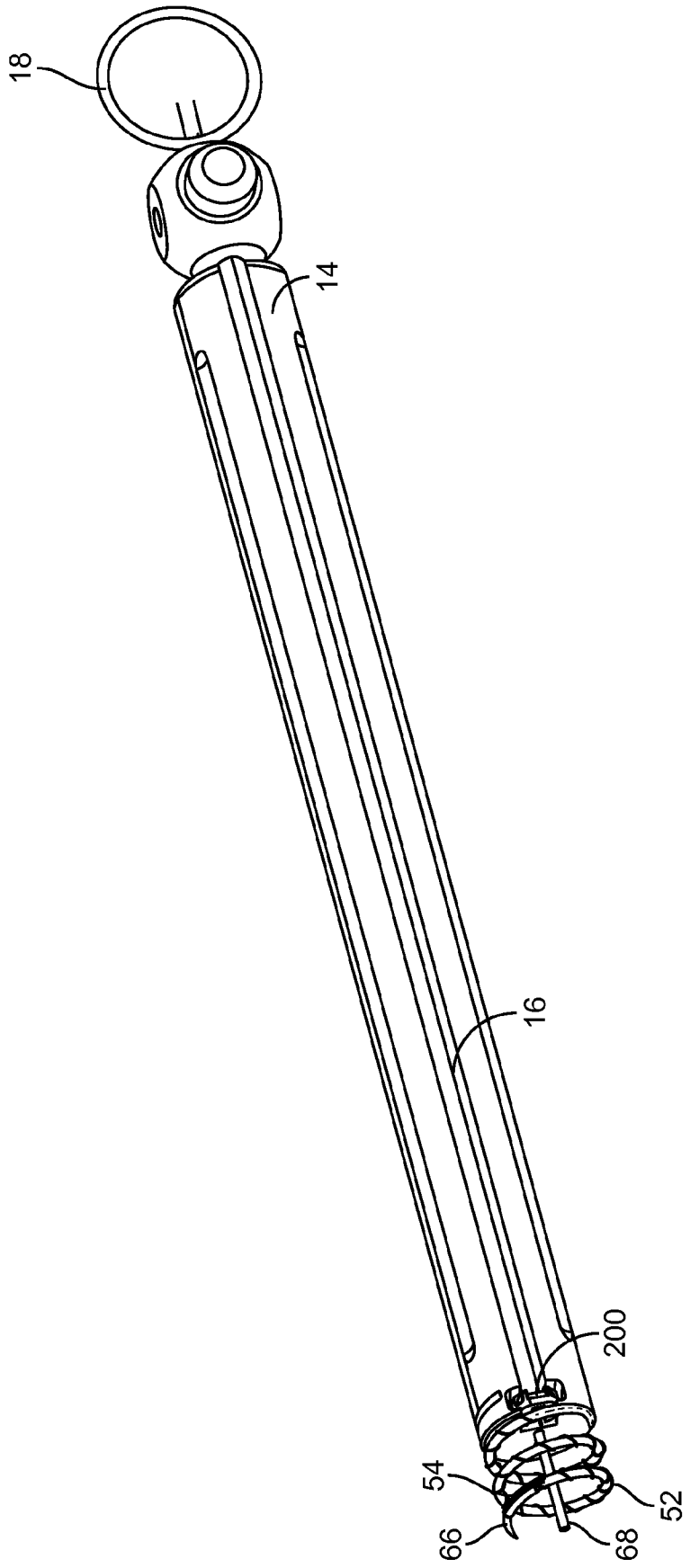

FIG. 15A

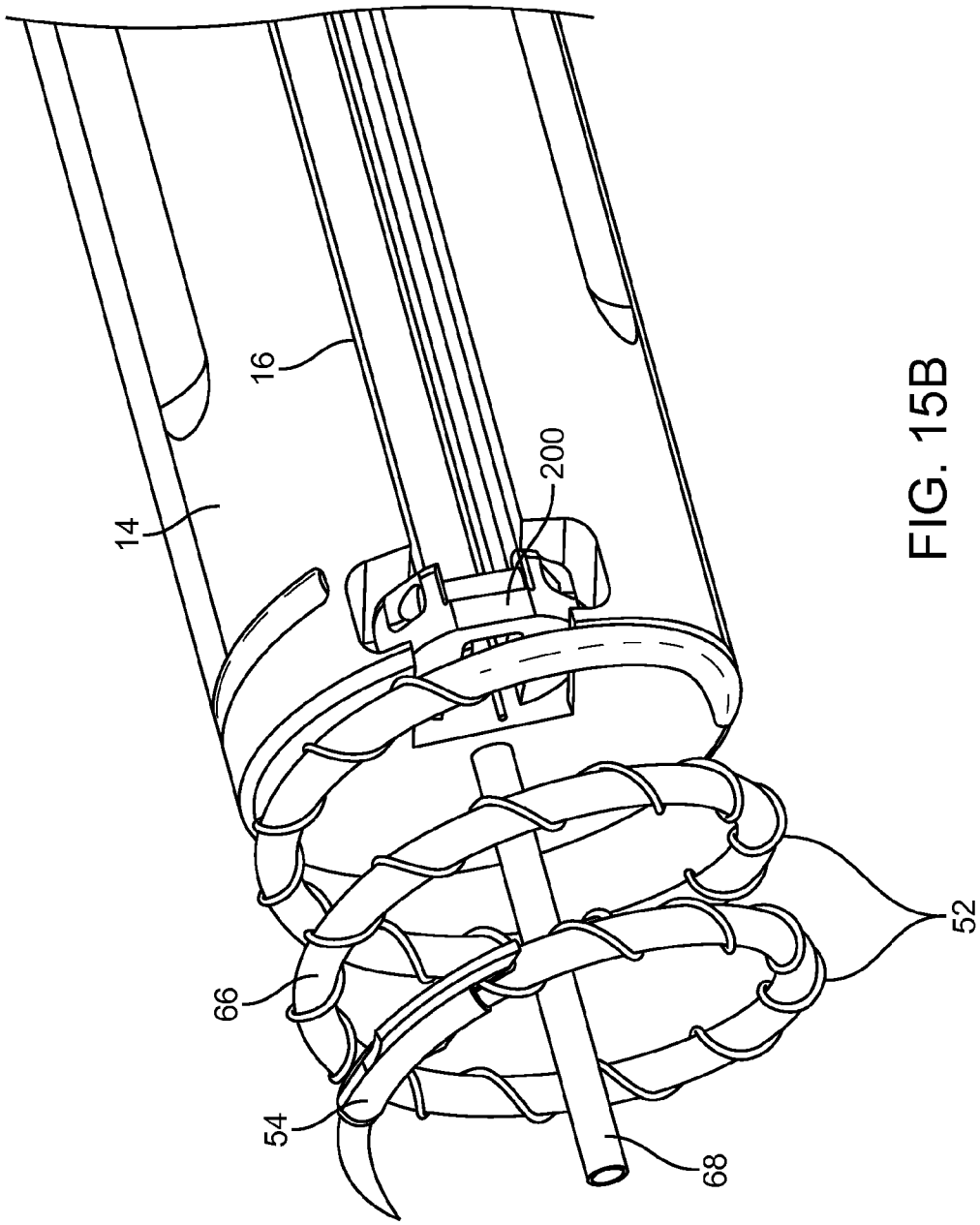

FIG. 15B

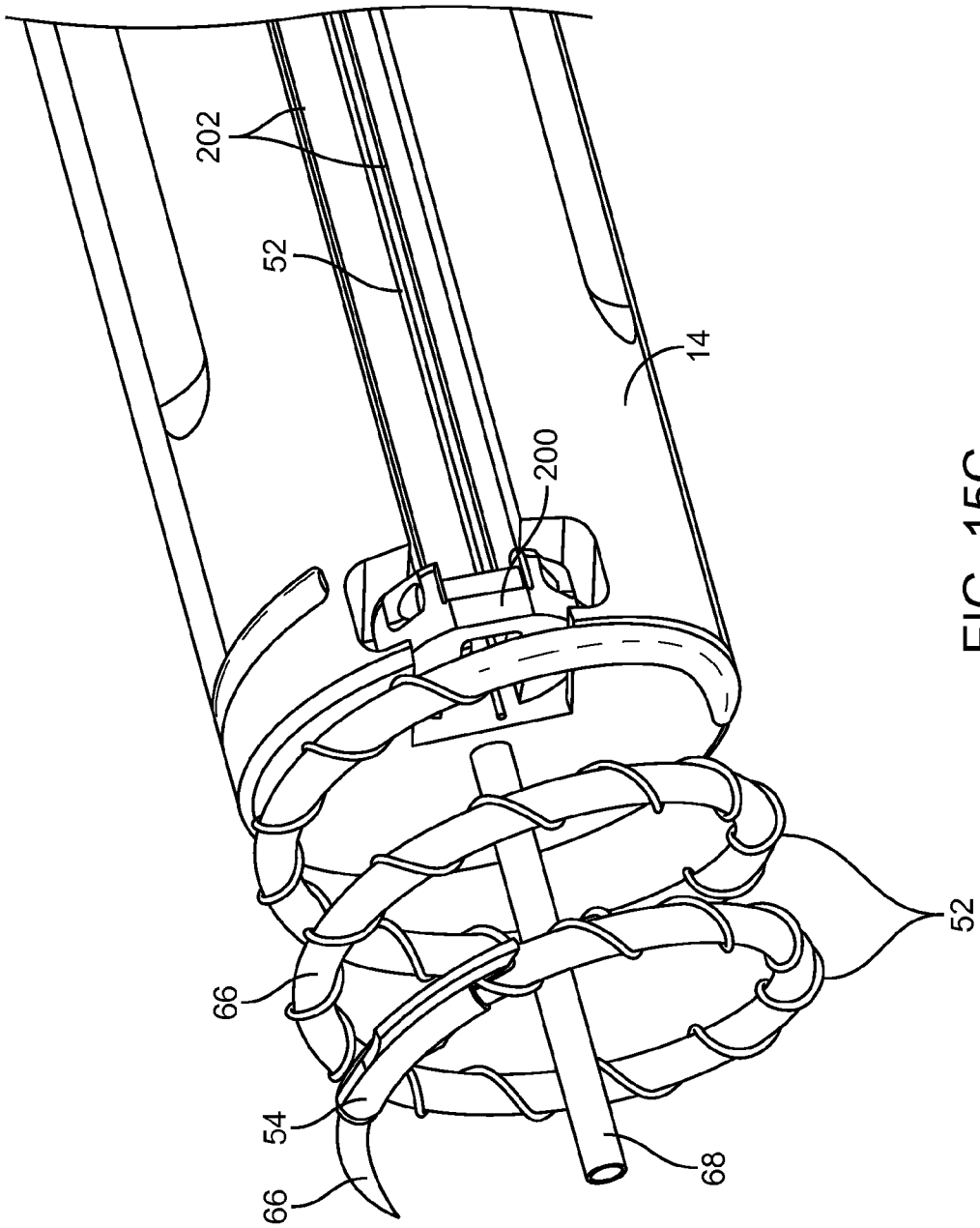

FIG. 15C

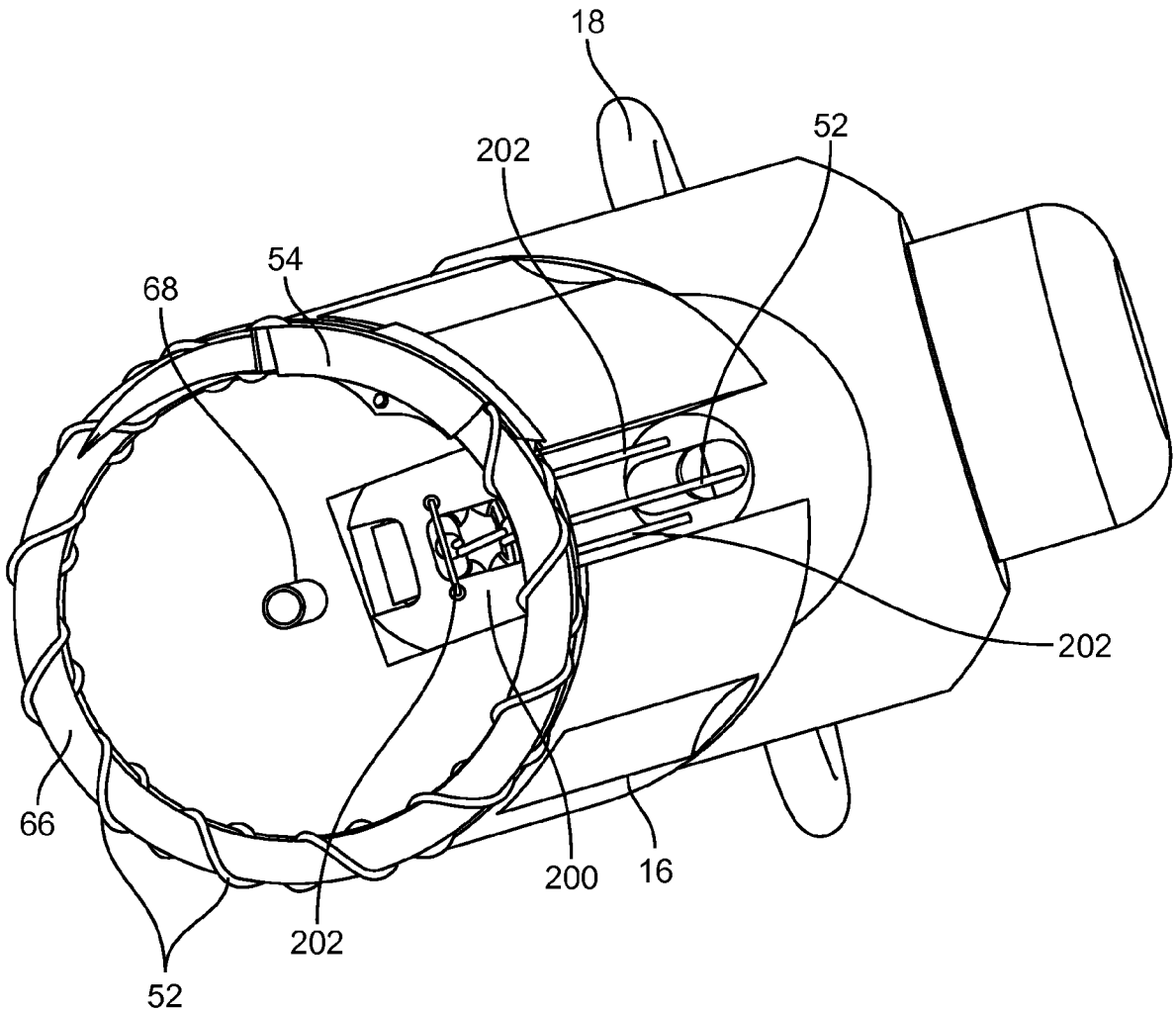

FIG. 15D

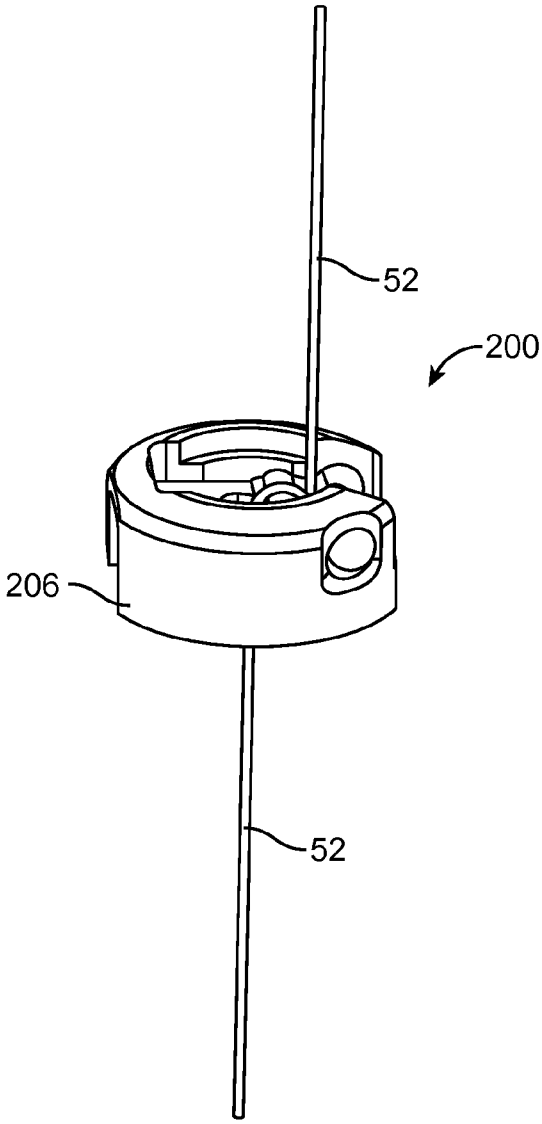

FIG. 15E

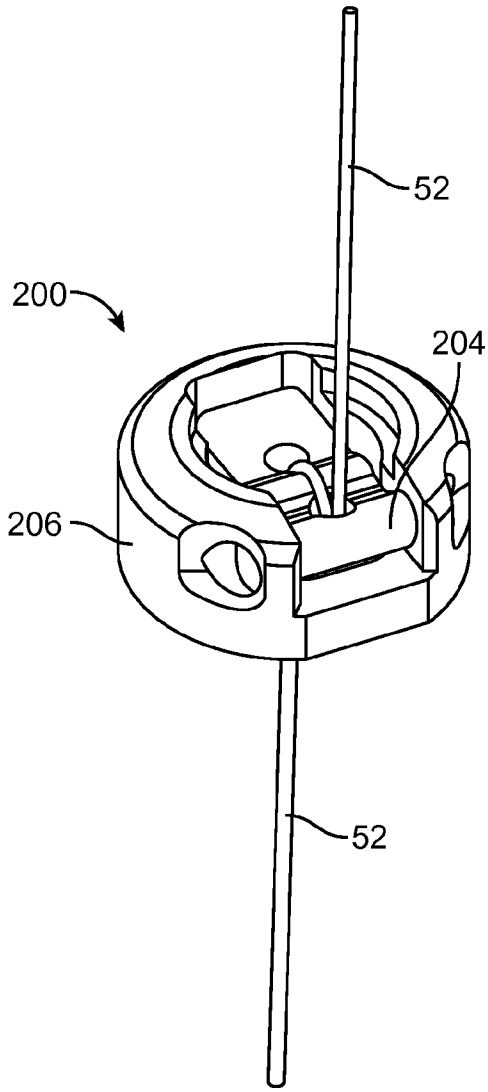

FIG. 15F

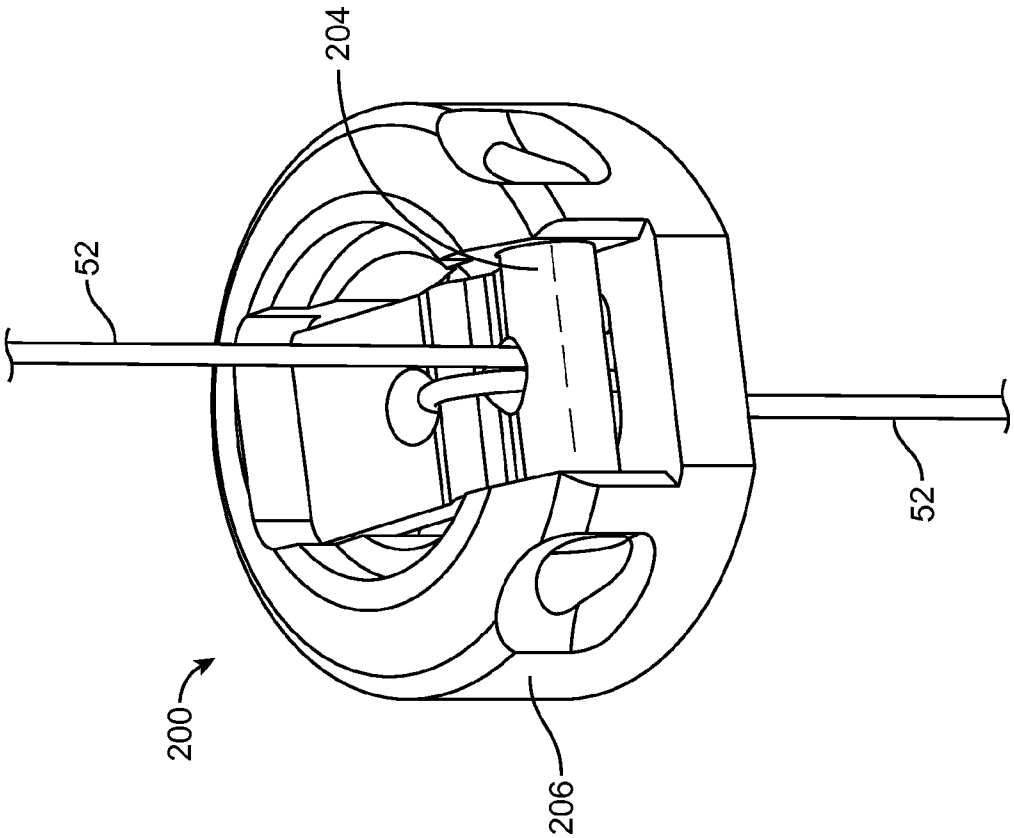

FIG. 15H

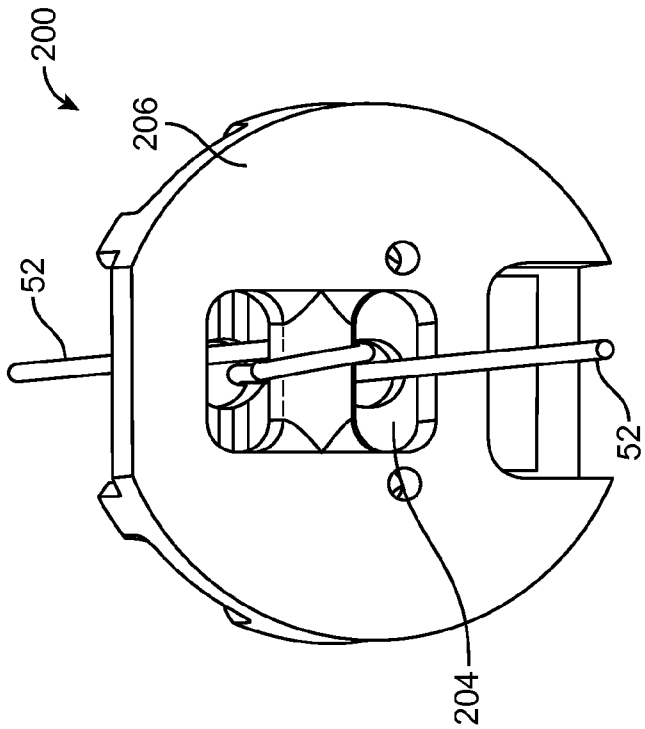

FIG. 15G

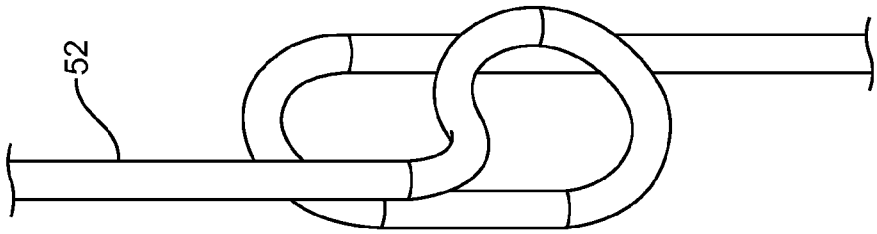

FIG. 15J

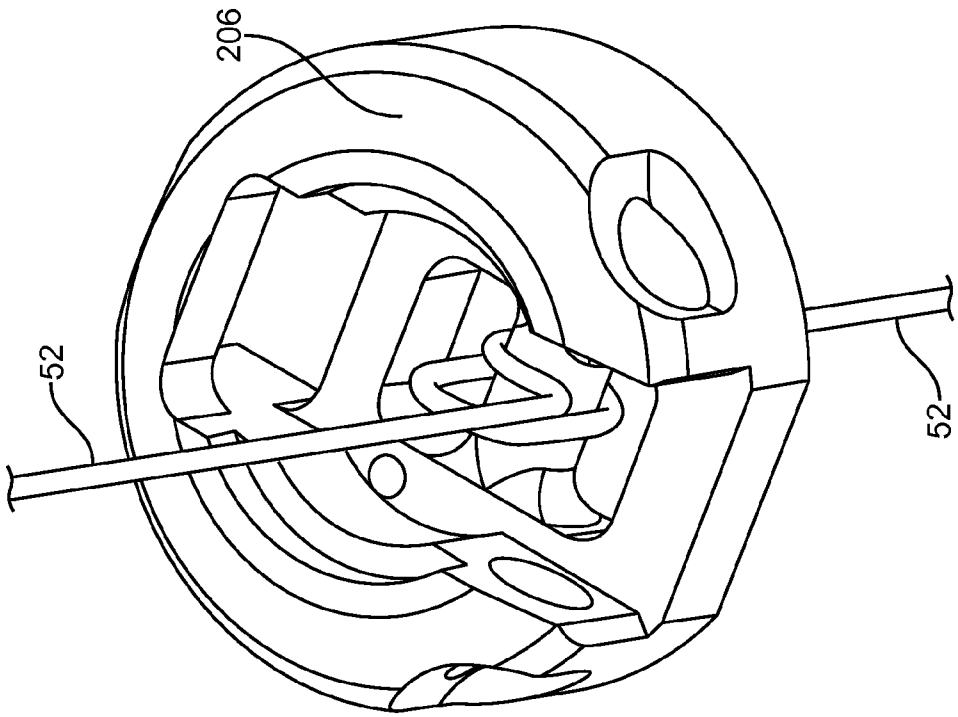

FIG. 15I

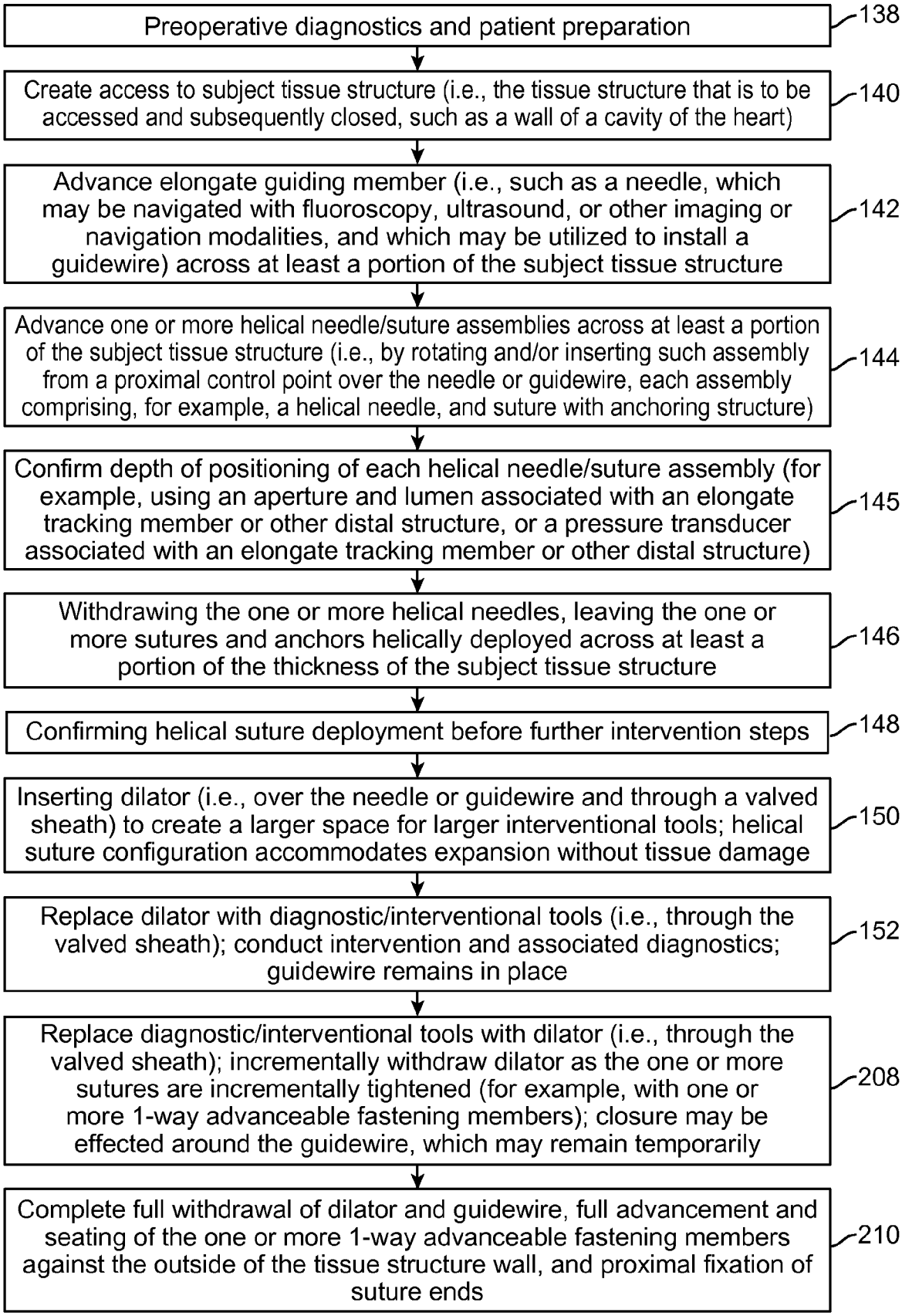
Preoperative diagnostics and patient preparation
138
Create access to subject tissue structure (i.e., the tissue structure that is to be accessed and subsequently closed, such as a wall of a cavity of the heart)
140
Advance elongate guiding member (i.e., such as a needle, which may be navigated with fluoroscopy, ultrasound, or other imaging or navigation modalities, and which may be utilized to install a guidewire) across at least a portion of the subject tissue structure
142
Advance one or more helical needle/suture assemblies across at least a portion of the subject tissue structure (i.e., by rotating and/or inserting such assembly from a proximal control point over the needle or guidewire, each assembly comprising, for example, a helical needle, and suture with anchoring structure)
144
Confirm depth of positioning of each helical needle/suture assembly (for example, using an aperture and lumen associated with an elongate tracking member or other distal structure, or a pressure transducer associated with an elongate tracking member or other distal structure)
145
Withdrawing the one or more helical needles, leaving the one or more sutures and anchors helically deployed across at least a portion of the thickness of the subject tissue structure
146
Confirming helical suture deployment before further intervention steps
148
Inserting dilator (i.e., over the needle or guidewire and through a valved sheath) to create a larger space for larger interventional tools; helical suture configuration accommodates expansion without tissue damage
150
Replace dilator with diagnostic/interventional tools (i.e., through the valved sheath); conduct intervention and associated diagnostics; guidewire remains in place
152
Replace diagnostic/interventional tools with dilator (i.e., through the valved sheath); incrementally withdraw dilator as the one or more sutures are incrementally tightened (for example, with one or more 1-way advanceable fastening members); closure may be effected around the guidewire, which may remain temporarily
208
Complete full withdrawal of dilator and guidewire, full advancement and seating of the one or more 1-way advanceable fastening members against the outside of the tissue structure wall, and proximal fixation of suture ends
210

FIG. 16

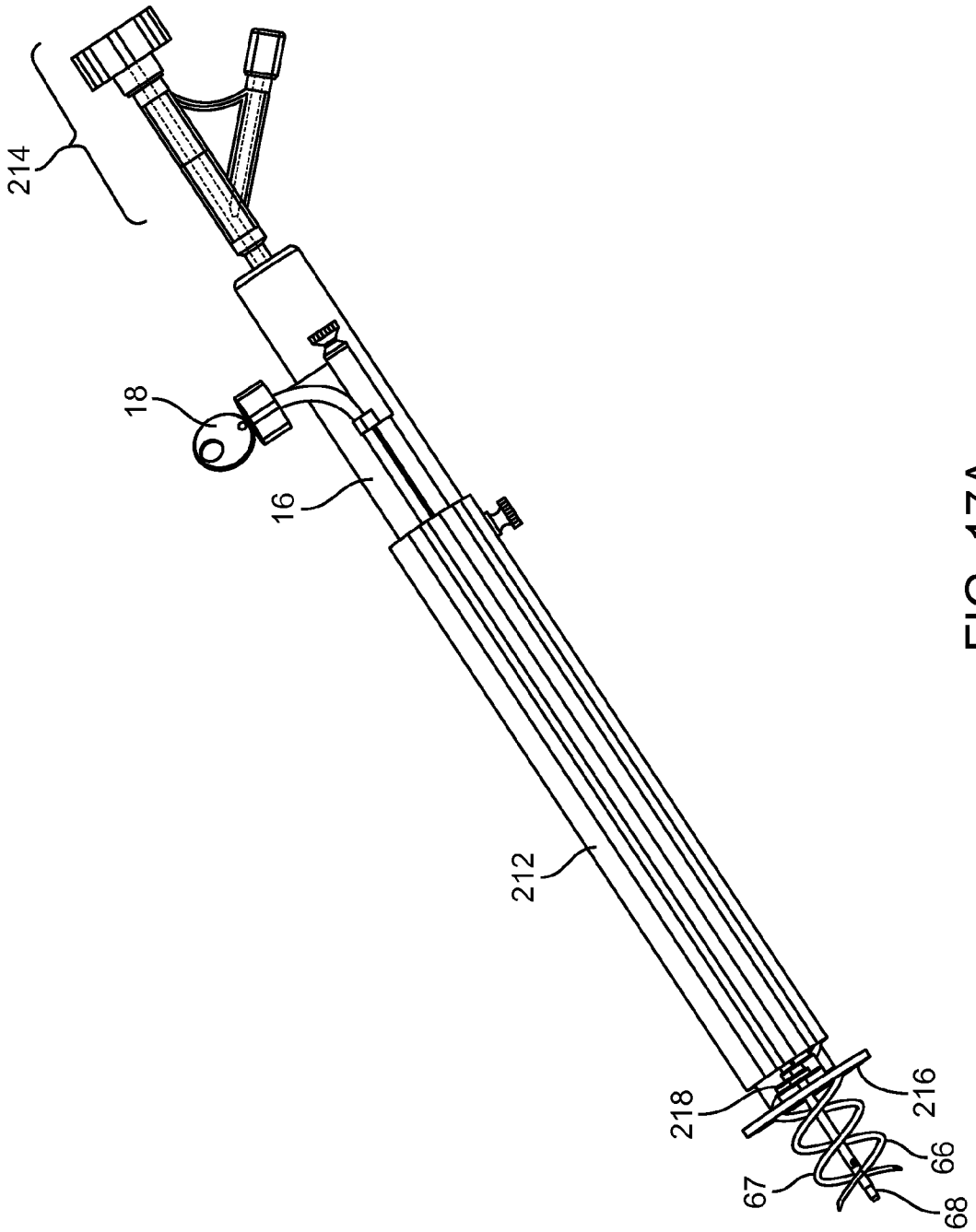

FIG. 17A

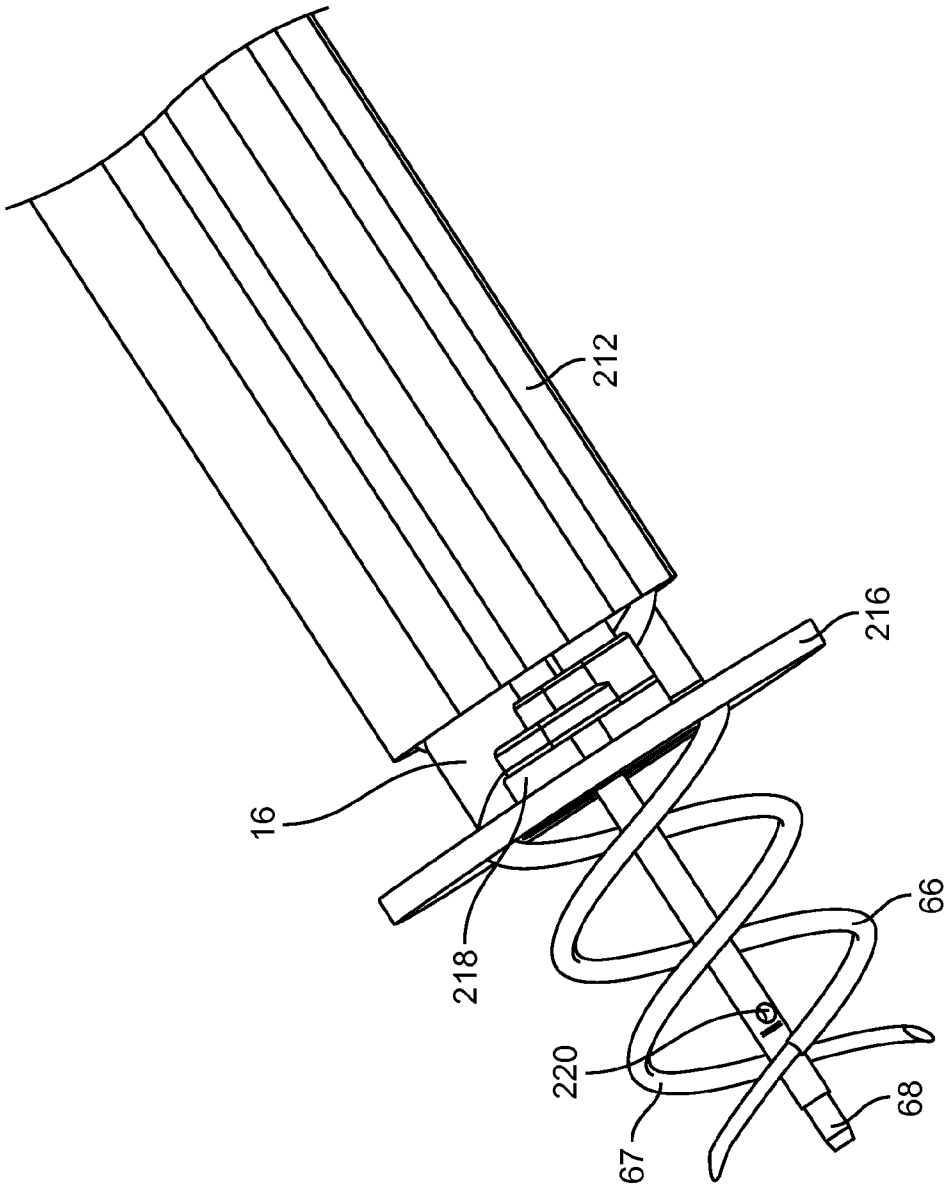

FIG. 17B

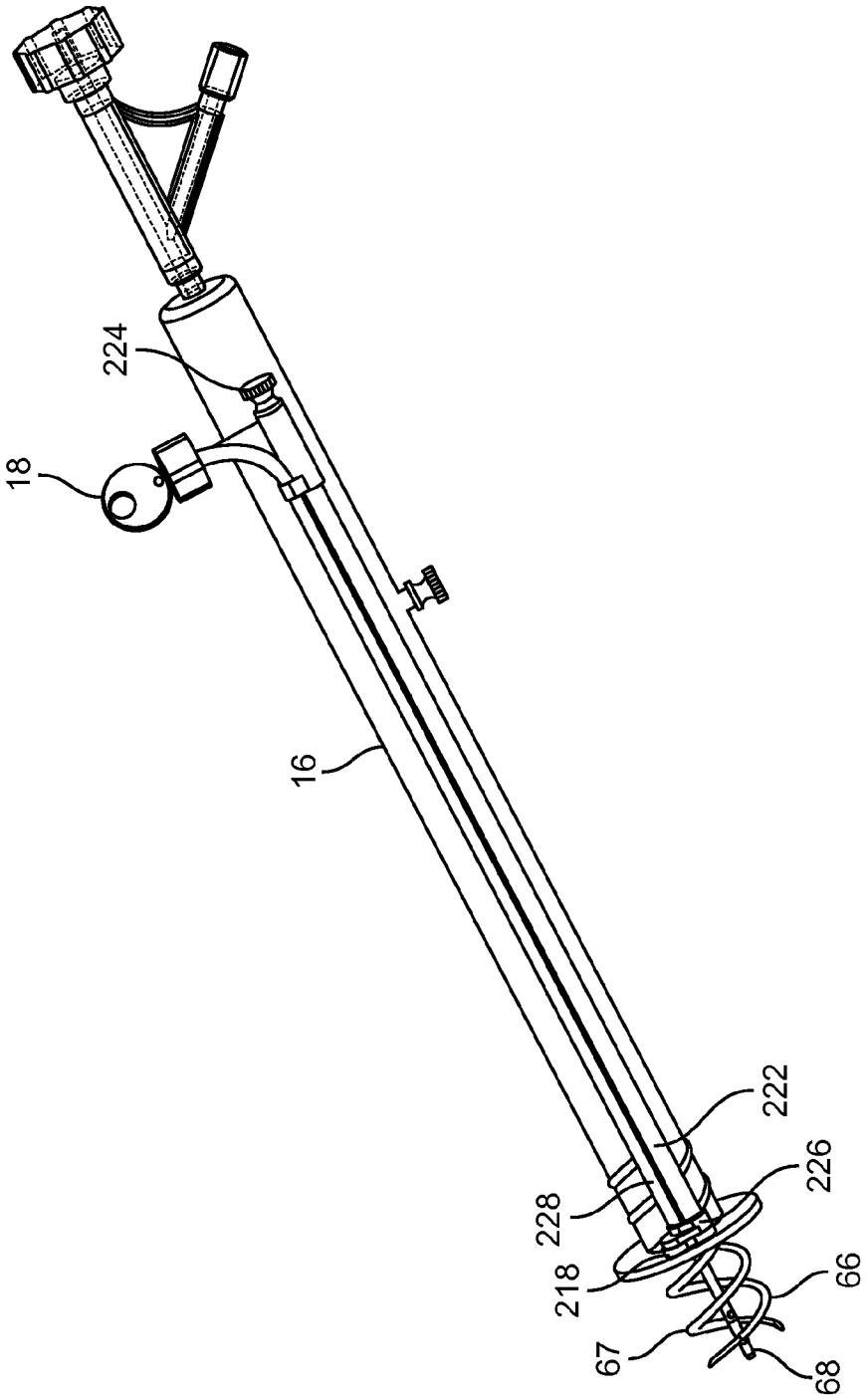

FIG. 17C

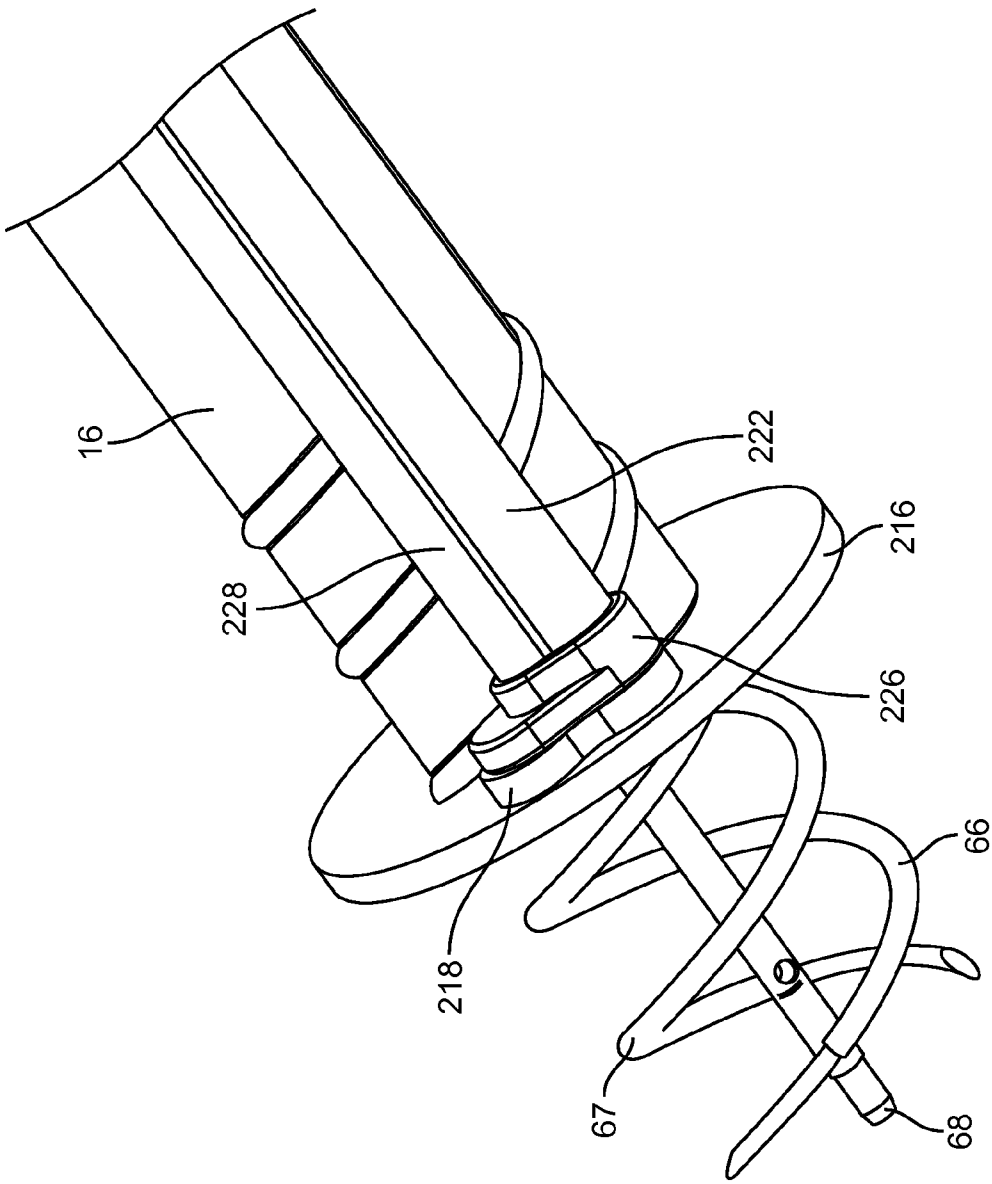

FIG. 17D

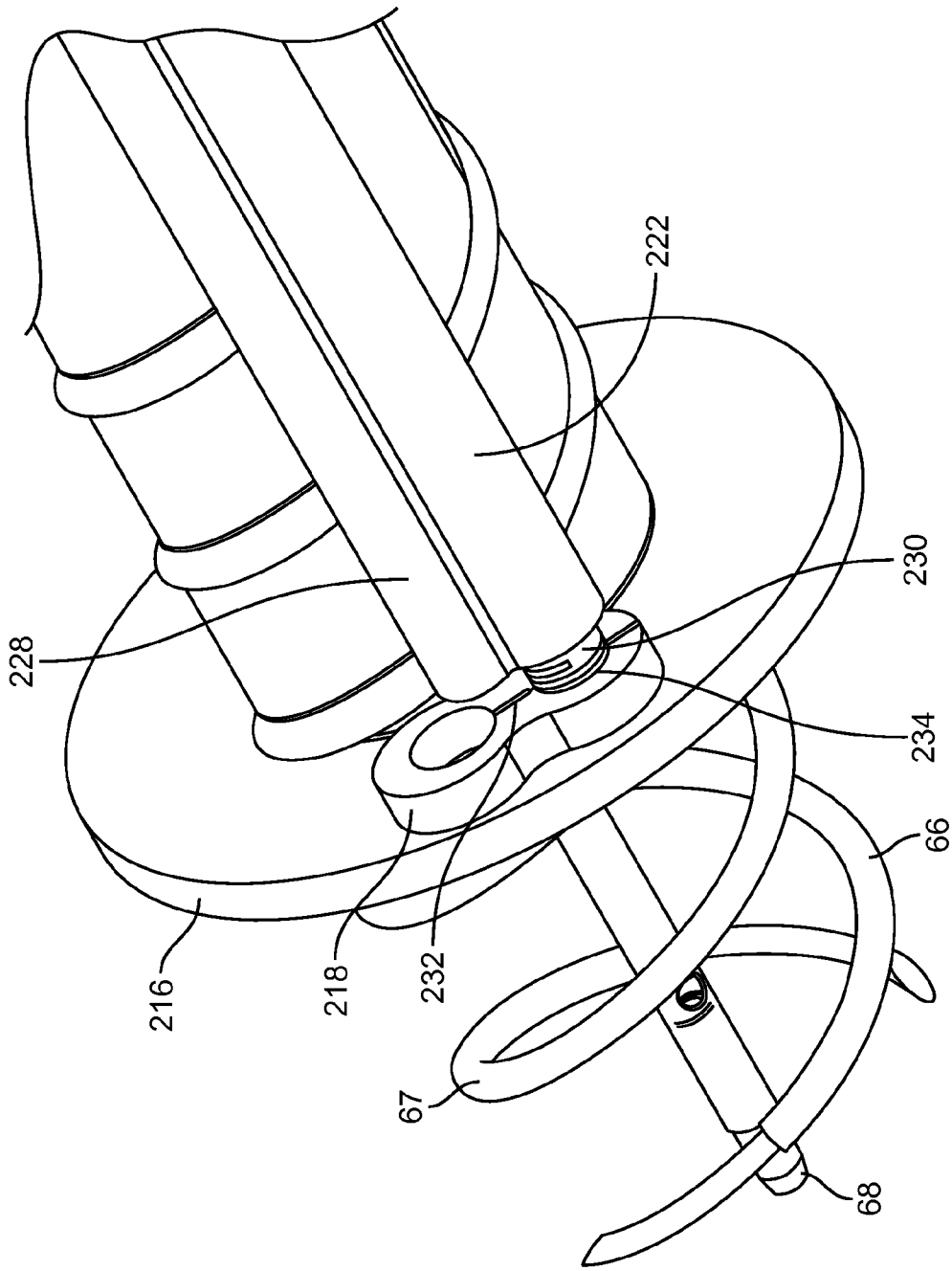

FIG. 17E

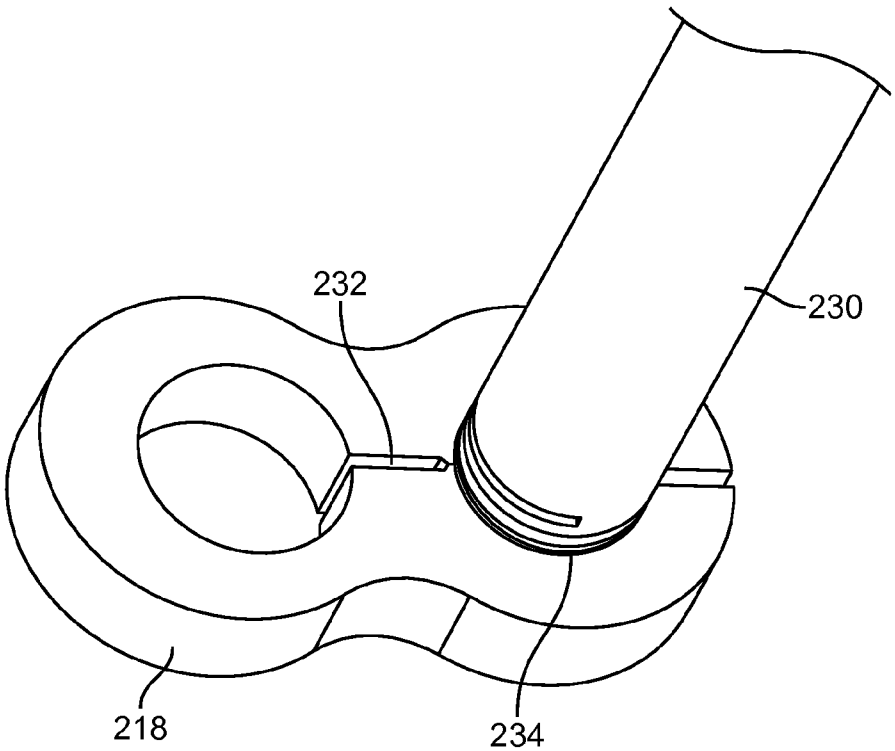

FIG. 17F

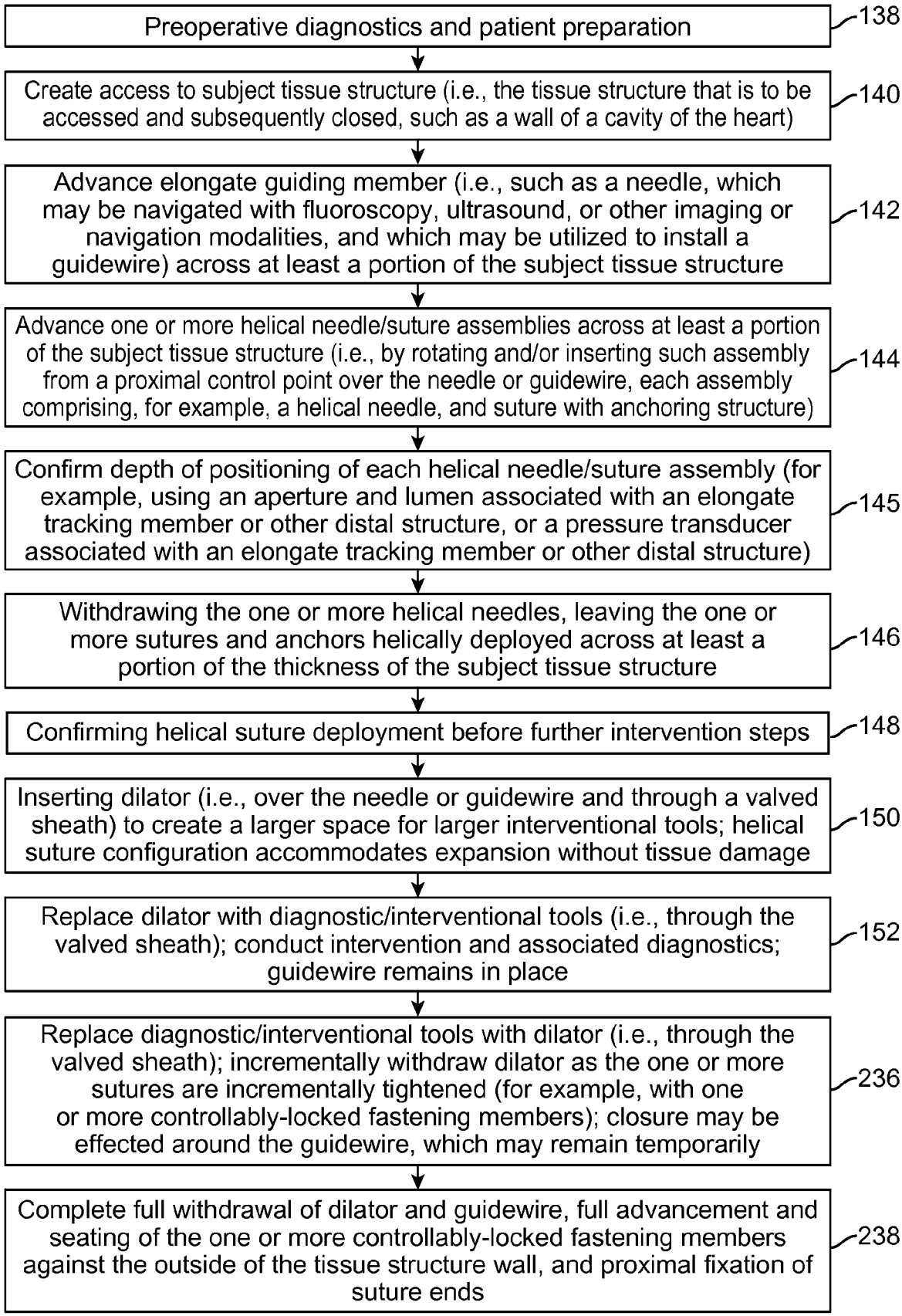
Preoperative diagnostics and patient preparation
138
Create access to subject tissue structure (i.e., the tissue structure that is to be accessed and subsequently closed, such as a wall of a cavity of the heart)
140
Advance elongate guiding member (i.e., such as a needle, which may be navigated with fluoroscopy, ultrasound, or other imaging or navigation modalities, and which may be utilized to install a guidewire) across at least a portion of the subject tissue structure
142
Advance one or more helical needle/suture assemblies across at least a portion of the subject tissue structure (i.e., by rotating and/or inserting such assembly from a proximal control point over the needle or guidewire, each assembly comprising, for example, a helical needle, and suture with anchoring structure)
144
Confirm depth of positioning of each helical needle/suture assembly (for example, using an aperture and lumen associated with an elongate tracking member or other distal structure, or a pressure transducer associated with an elongate tracking member or other distal structure)
145
Withdrawing the one or more helical needles, leaving the one or more sutures and anchors helically deployed across at least a portion of the thickness of the subject tissue structure
146
Confirming helical suture deployment before further intervention steps
148
Inserting dilator (i.e., over the needle or guidewire and through a valved sheath) to create a larger space for larger interventional tools; helical suture configuration accommodates expansion without tissue damage
150
Replace dilator with diagnostic/interventional tools (i.e., through the valved sheath); conduct intervention and associated diagnostics; guidewire remains in place
152
Replace diagnostic/interventional tools with dilator (i.e., through the valved sheath); incrementally withdraw dilator as the one or more sutures are incrementally tightened (for example, with one or more controllably-locked fastening members); closure may be effected around the guidewire, which may remain temporarily
236
Complete full withdrawal of dilator and guidewire, full advancement and seating of the one or more controllably-locked fastening members against the outside of the tissue structure wall, and proximal fixation of suture ends
238

FIG. 18

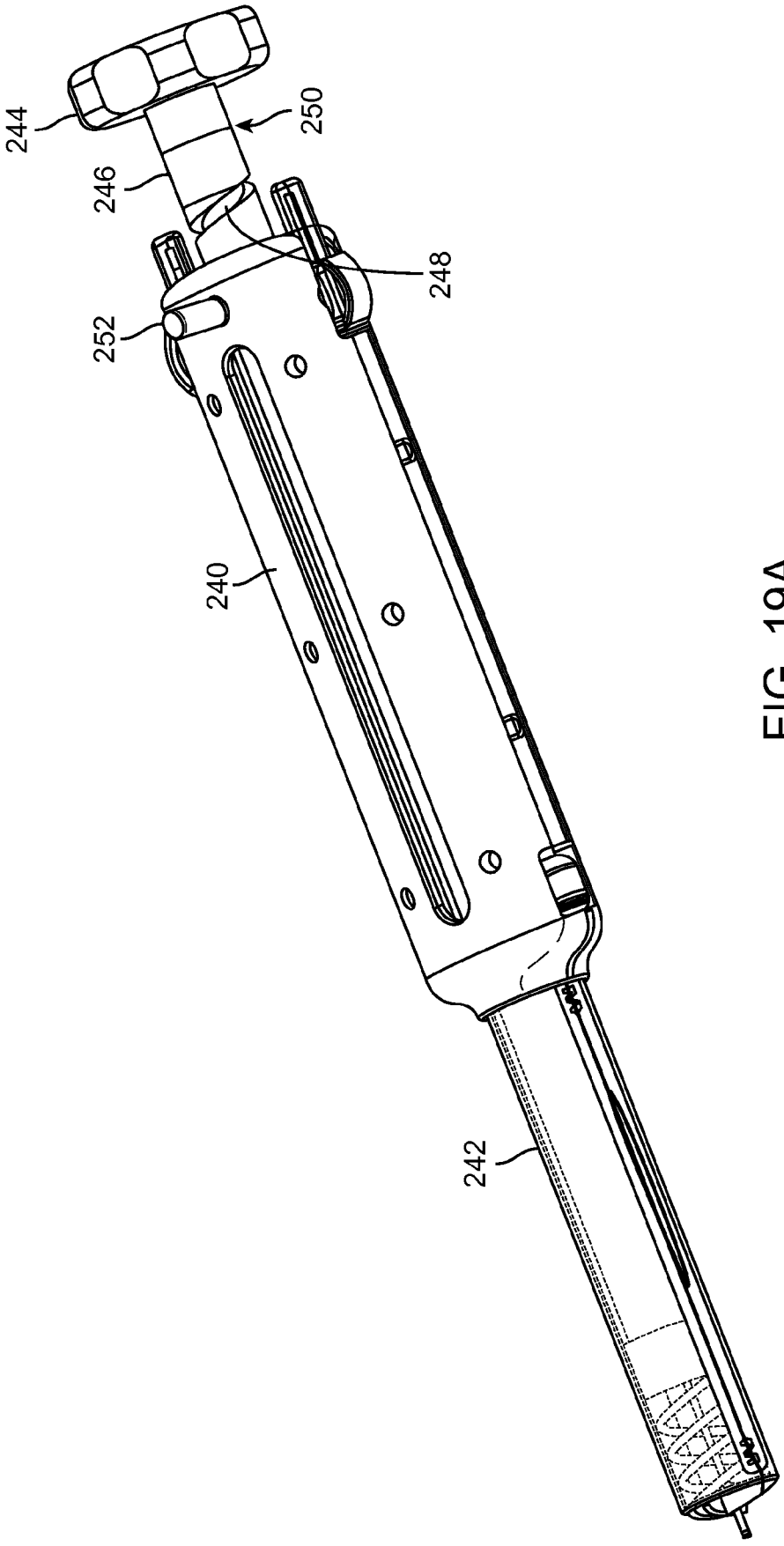

FIG. 19A

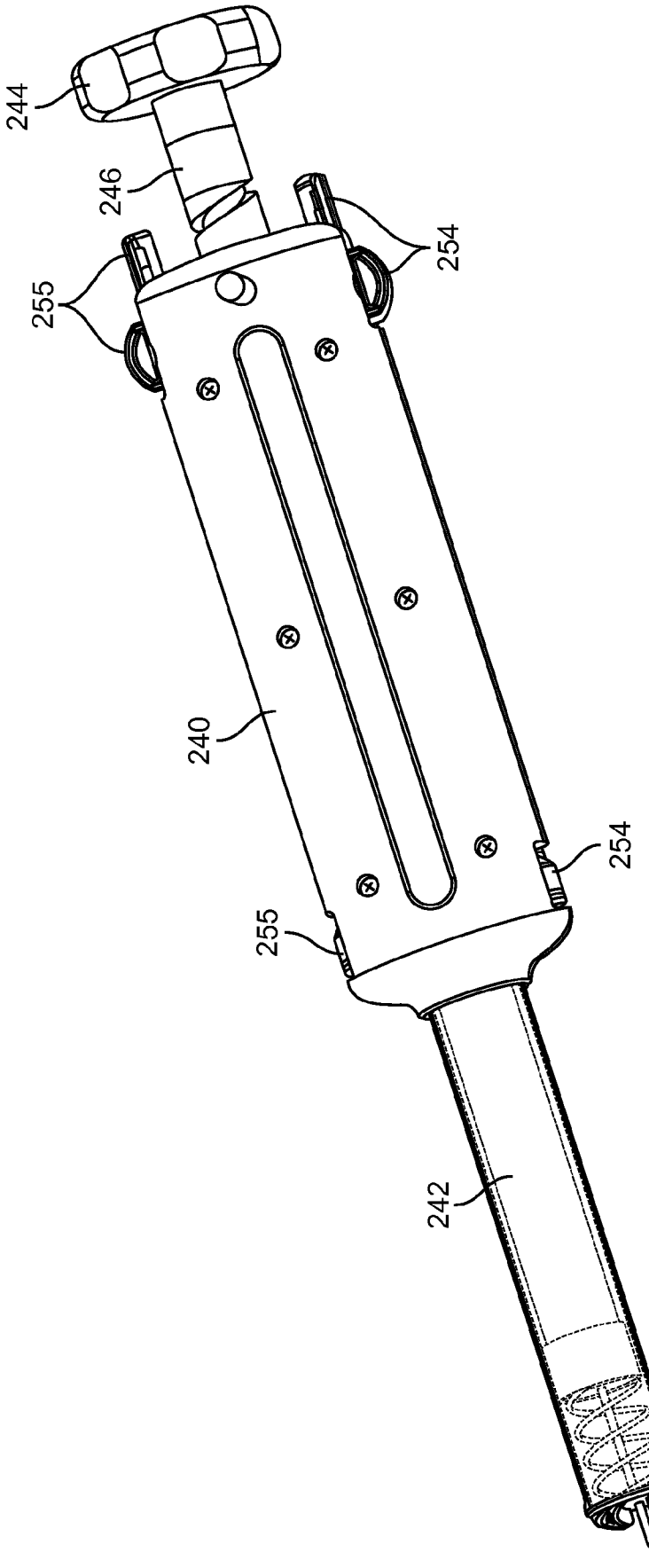

FIG. 19B

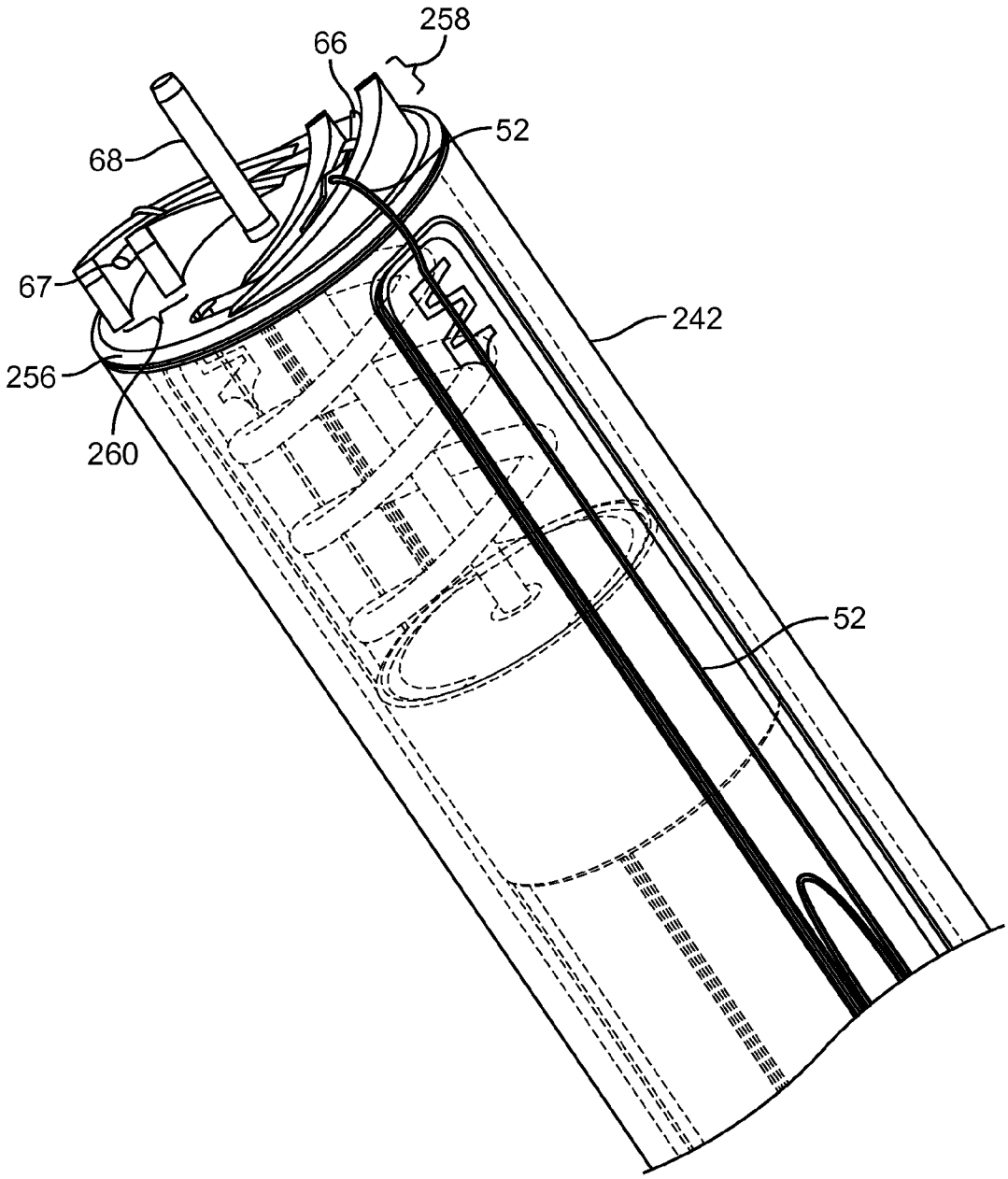

FIG. 19C

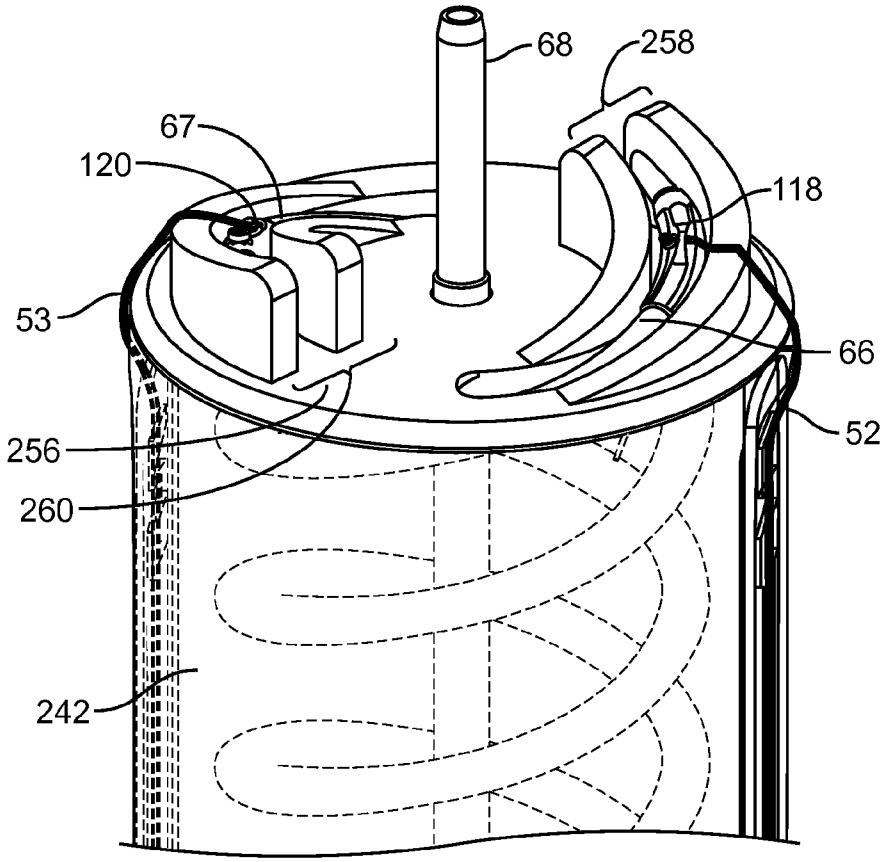

FIG. 19D

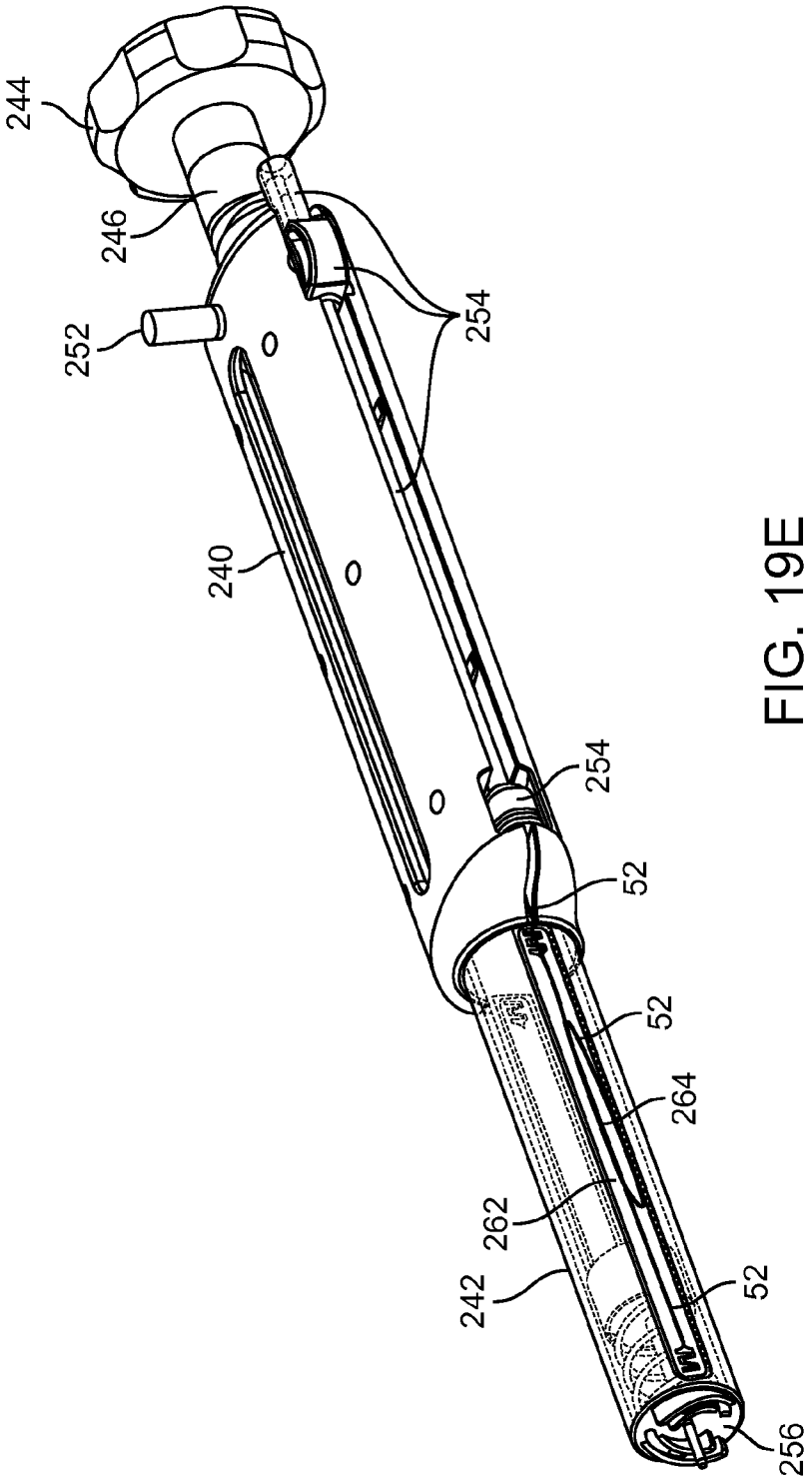

FIG. 19E

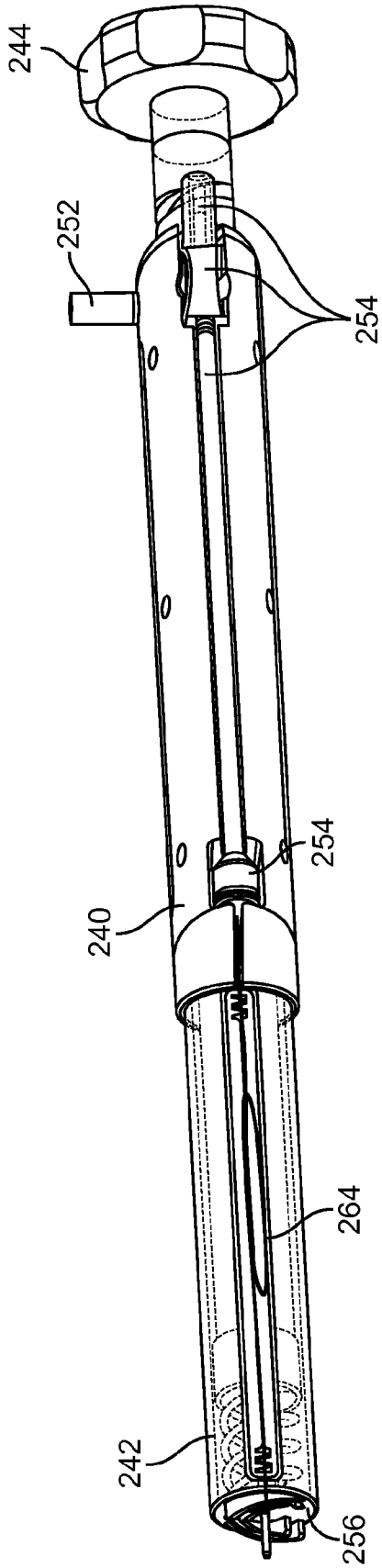

FIG. 19F

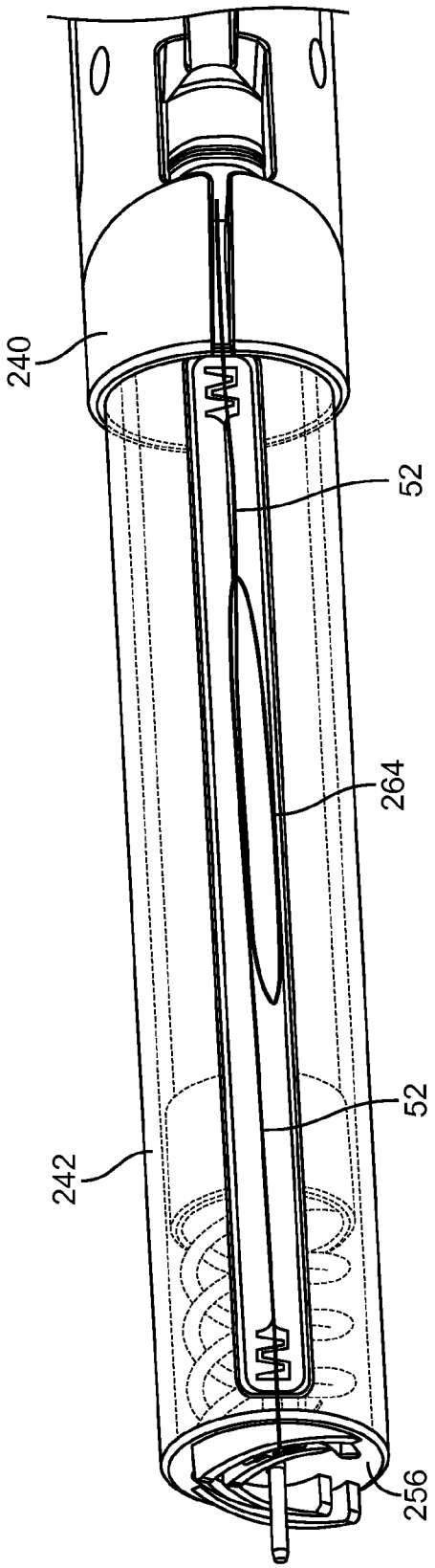

FIG. 19G

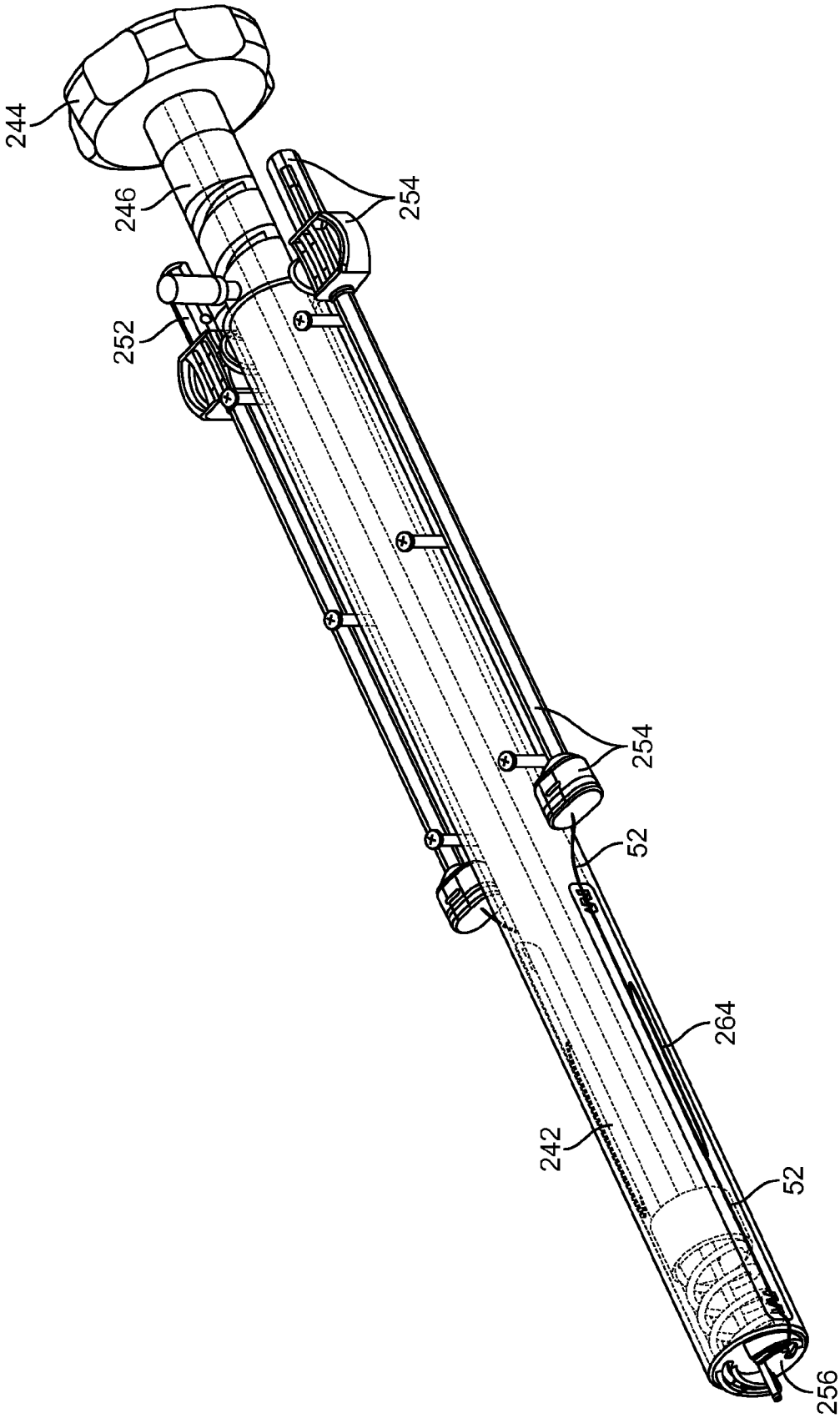

FIG. 19H

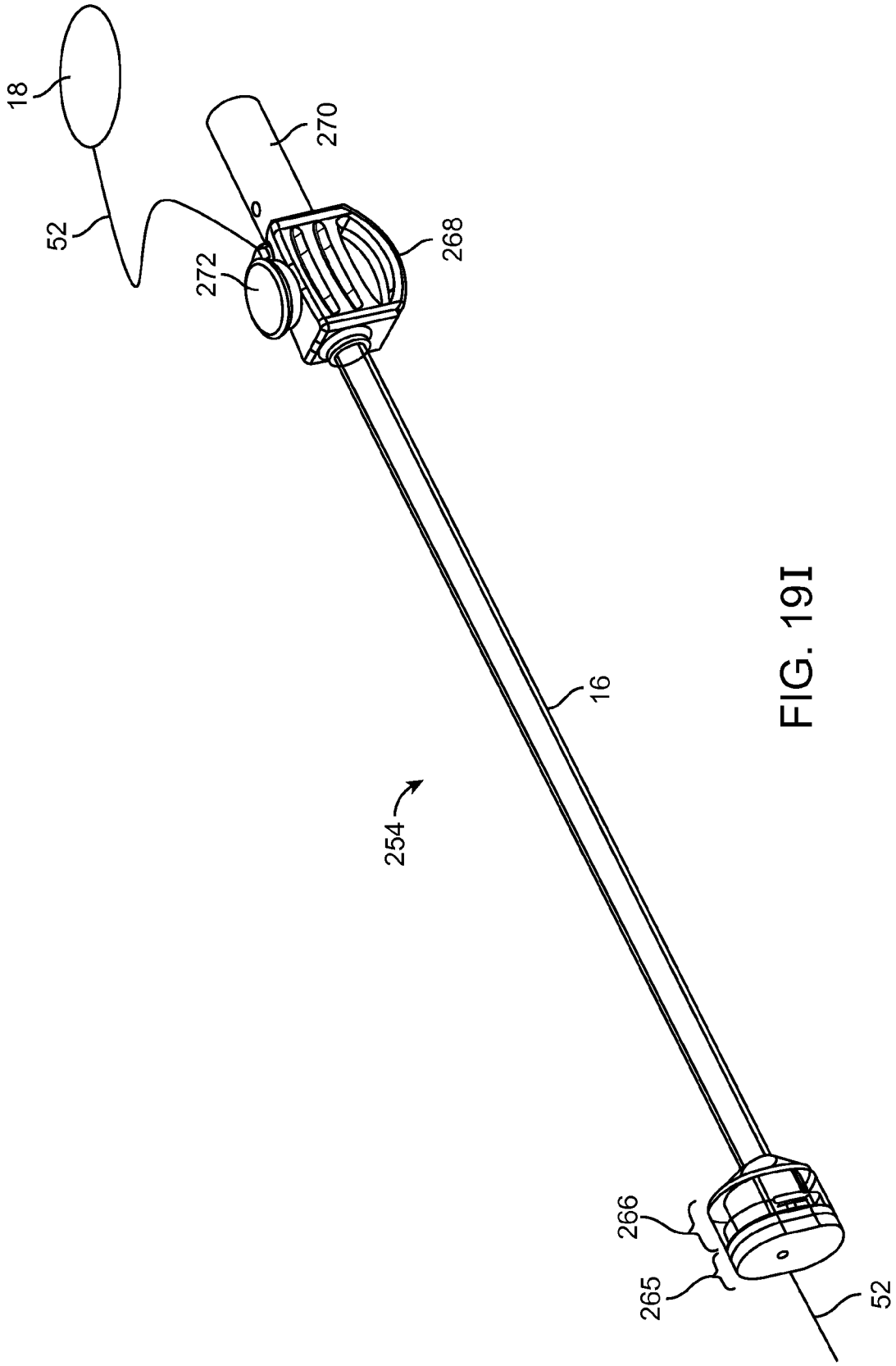

FIG. 19I

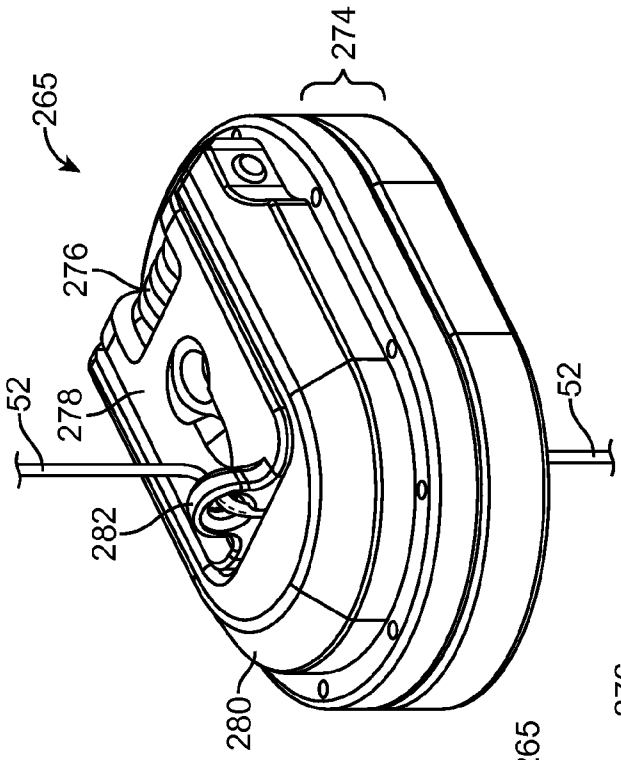

FIG. 19K

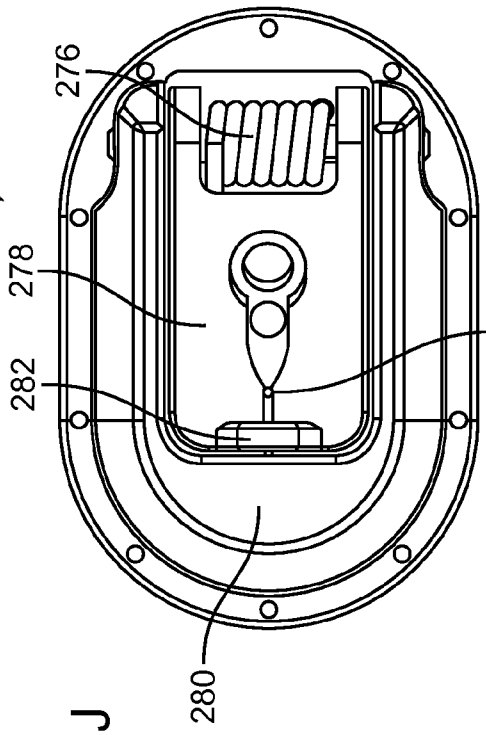

FIG. 19L

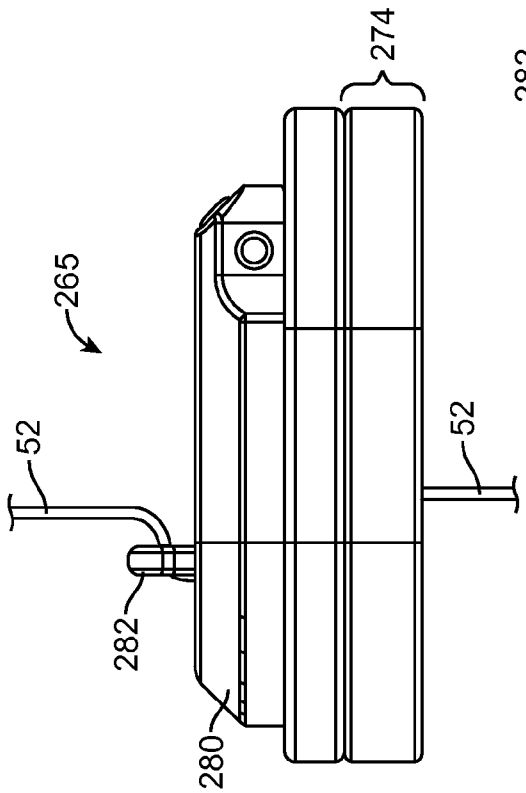

FIG. 19J

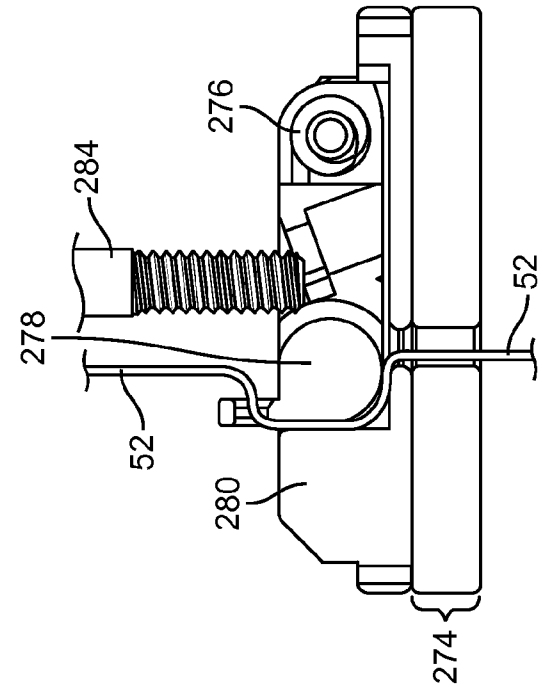

FIG. 19N

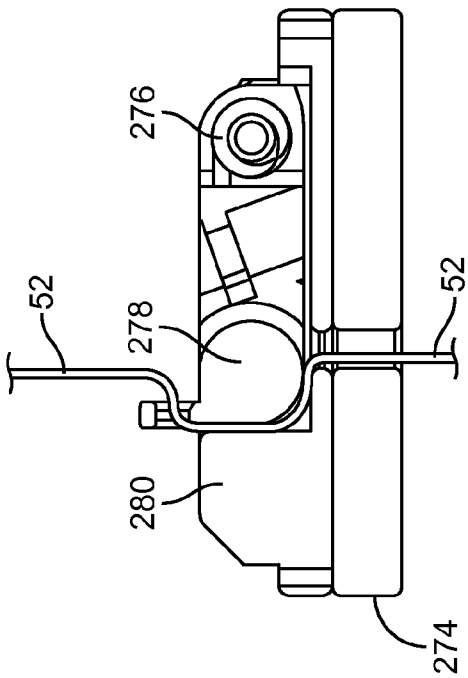

FIG. 19O

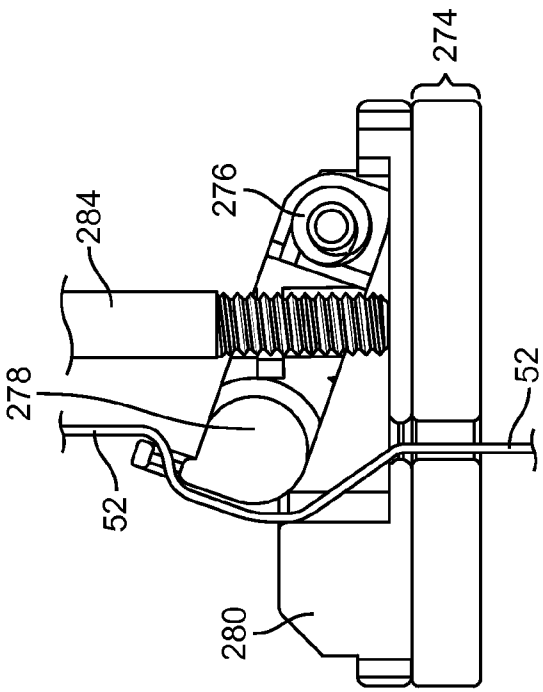

FIG. 19M

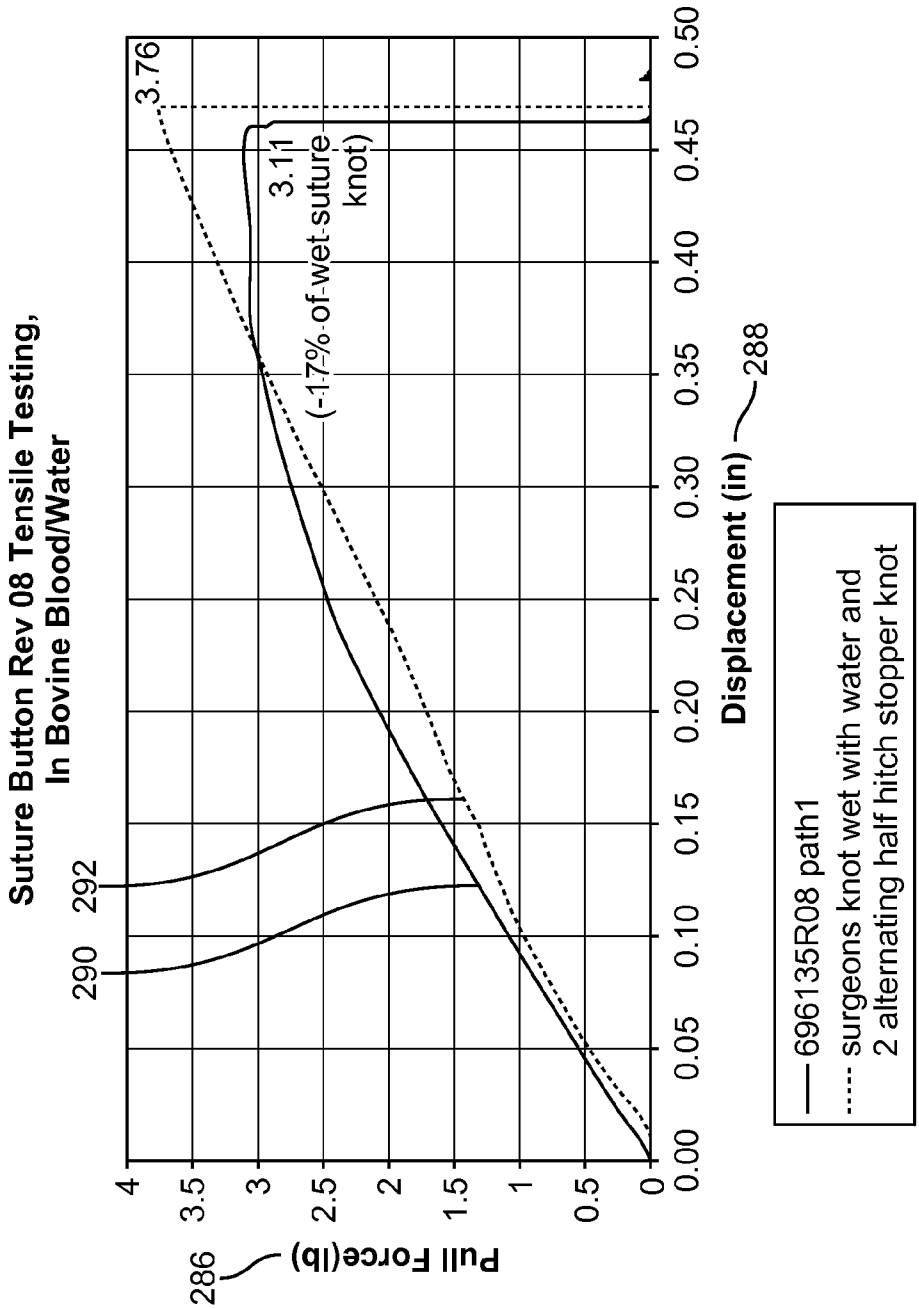

FIG. 19Q

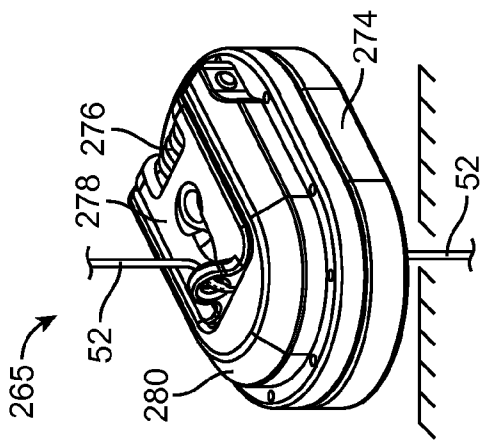

FIG. 19P

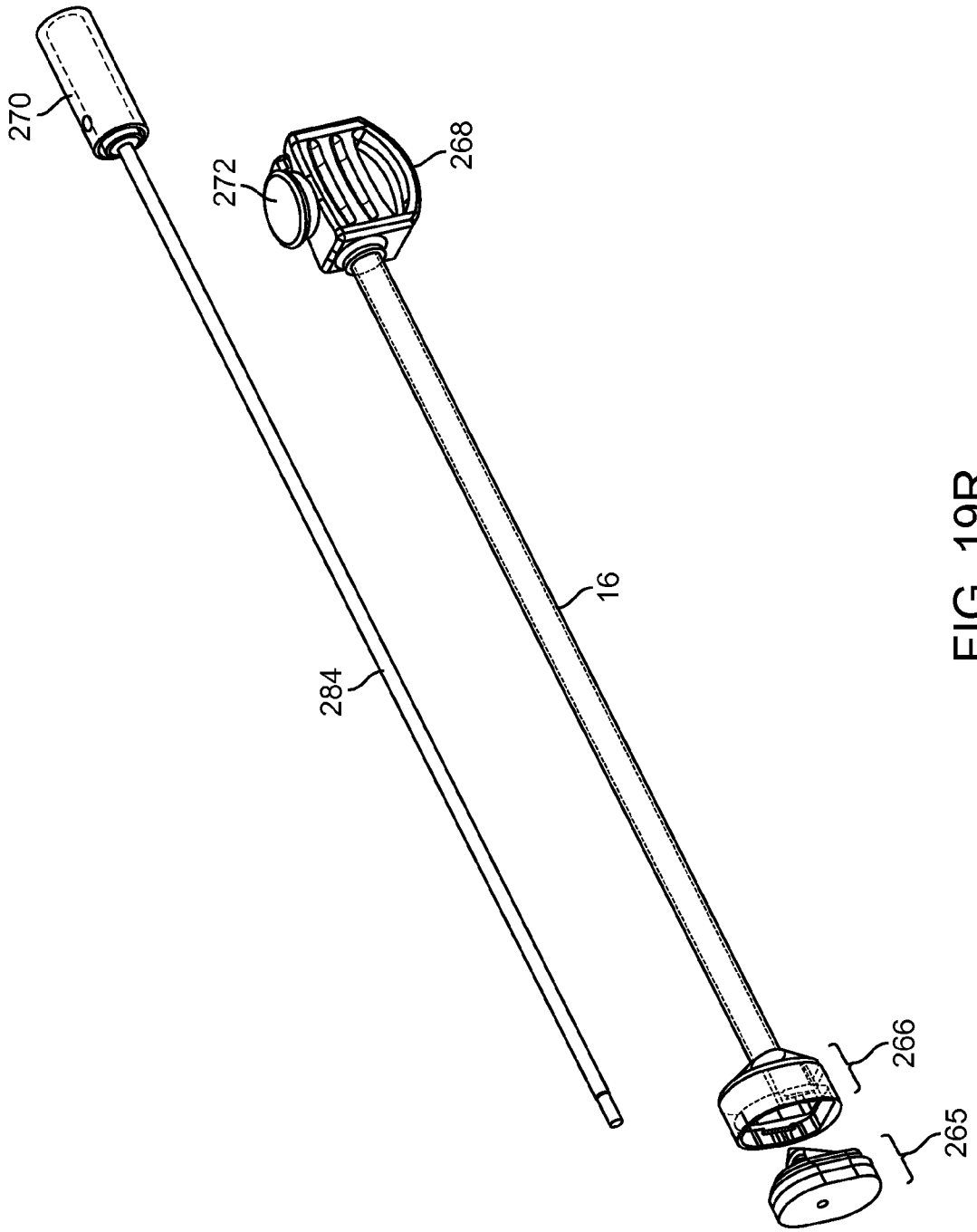

FIG. 19R

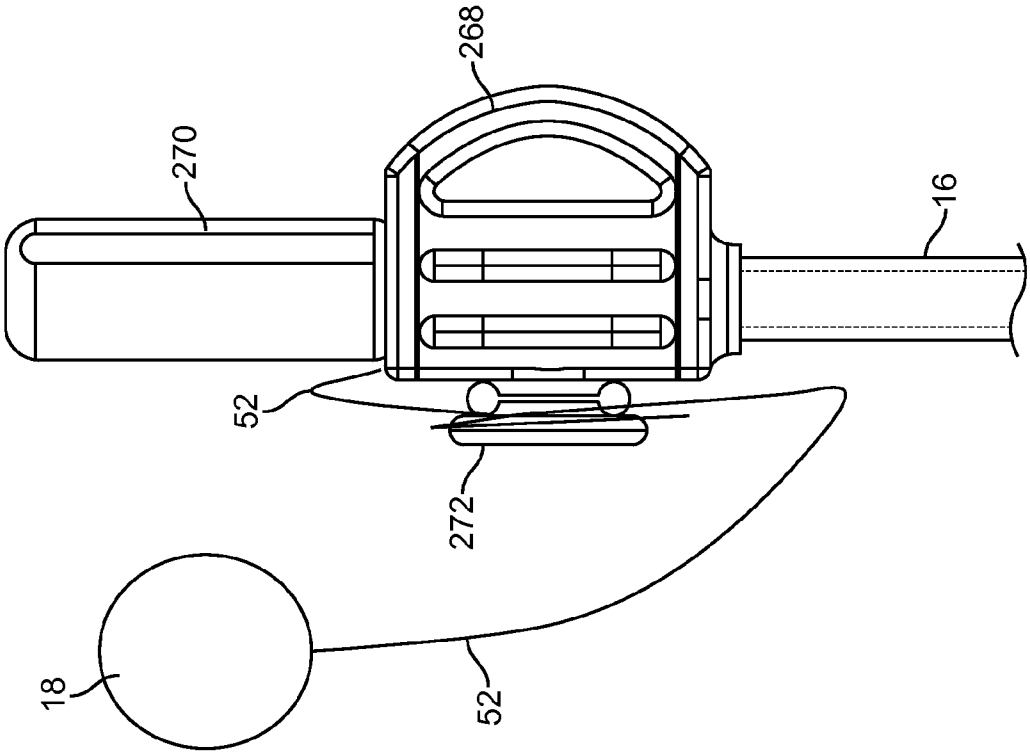

FIG. 19T

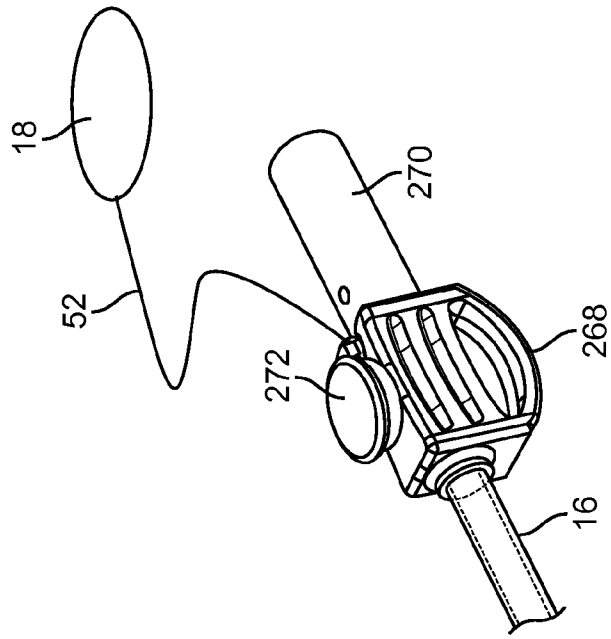

FIG. 19S

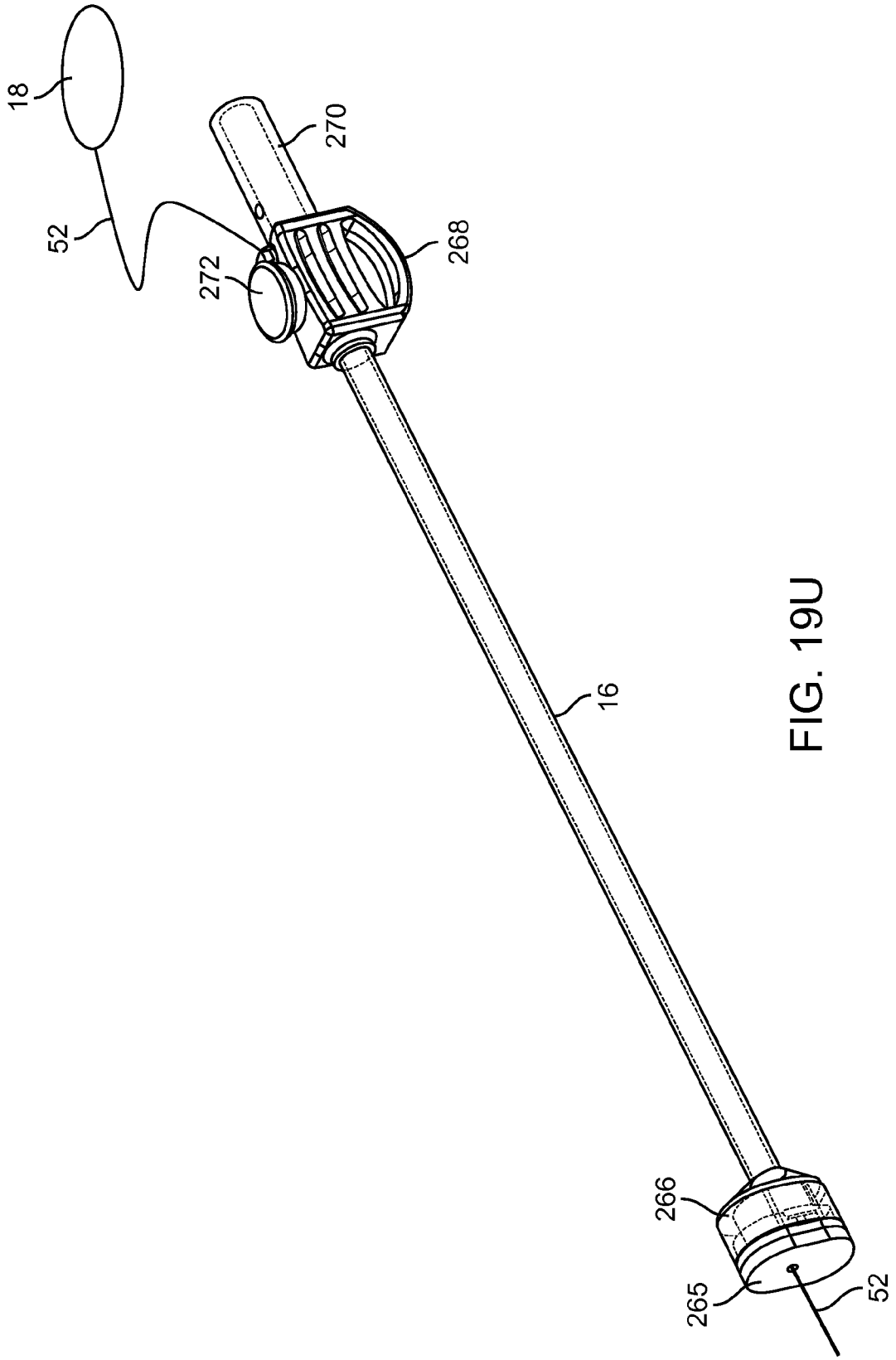

FIG. 19U

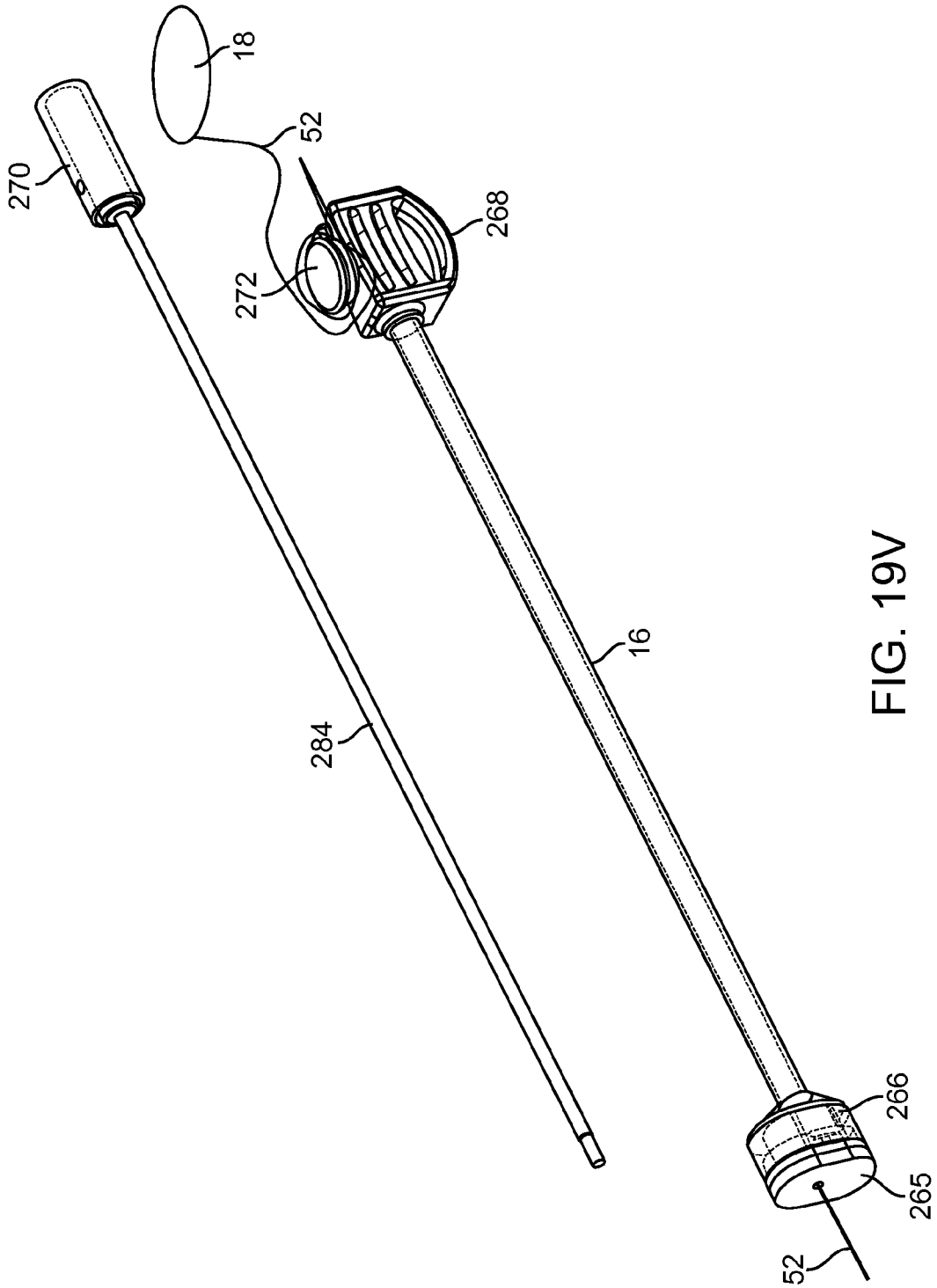

FIG. 19V

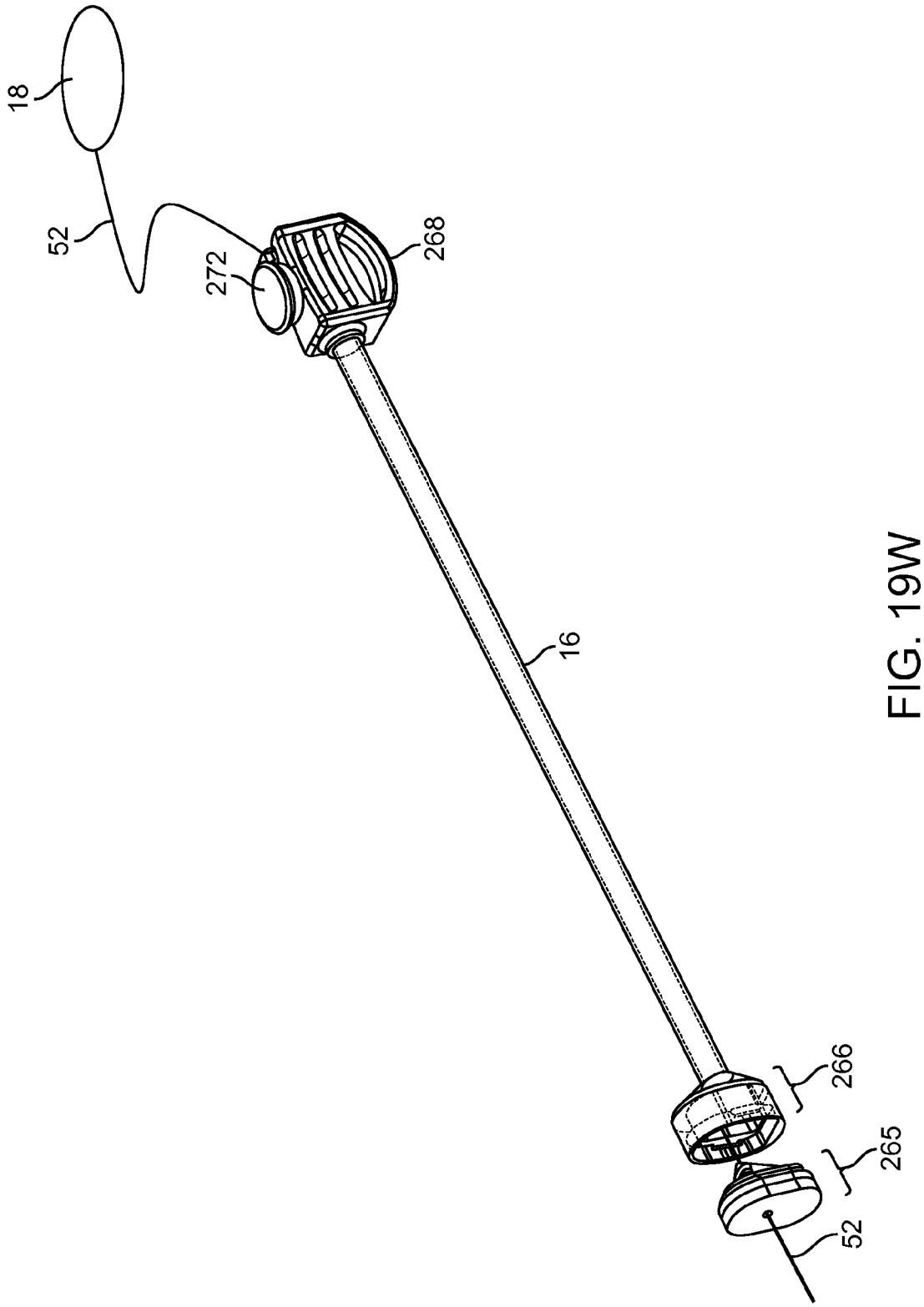

FIG. 19W

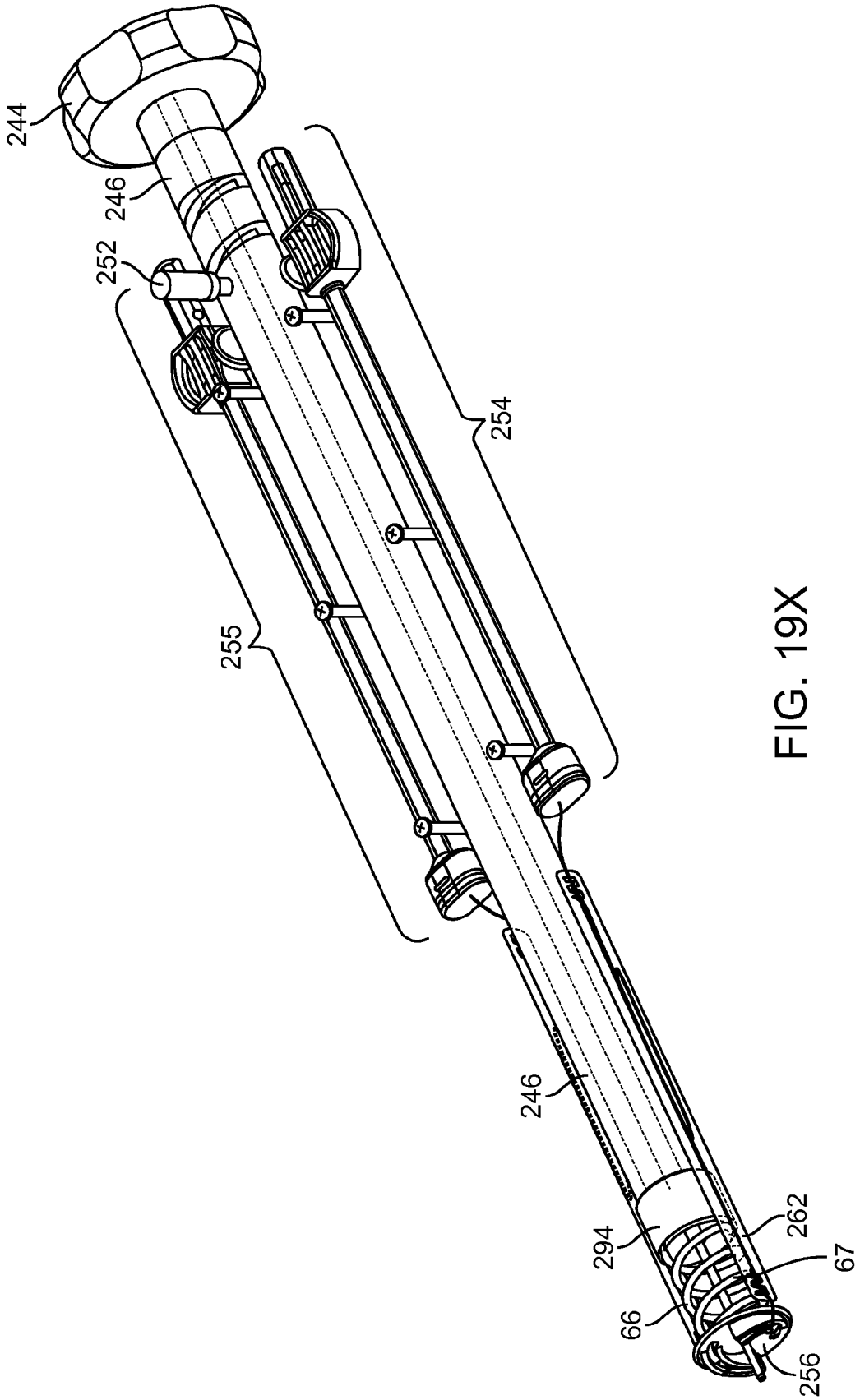

FIG. 19X

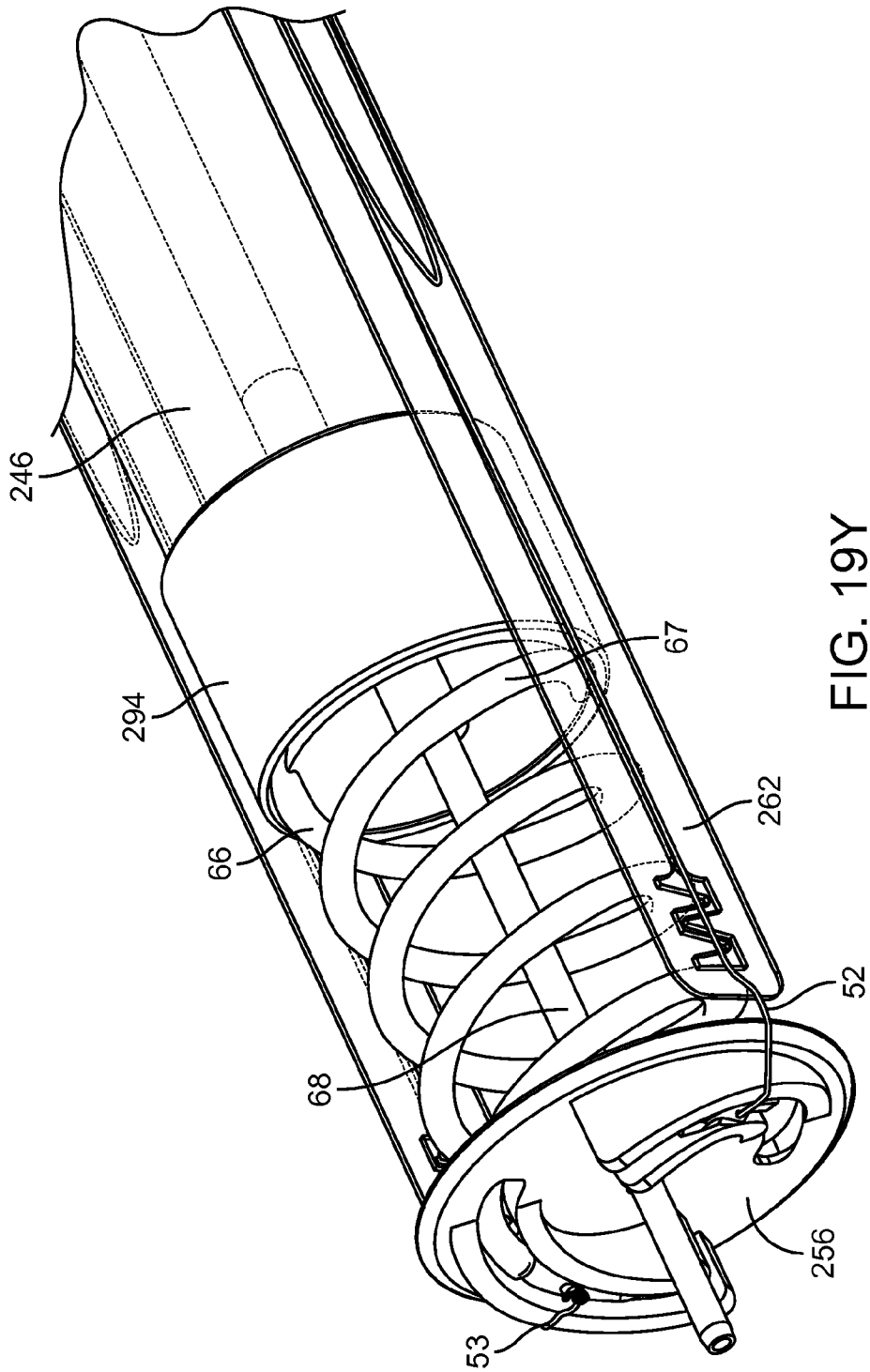

FIG. 19Y

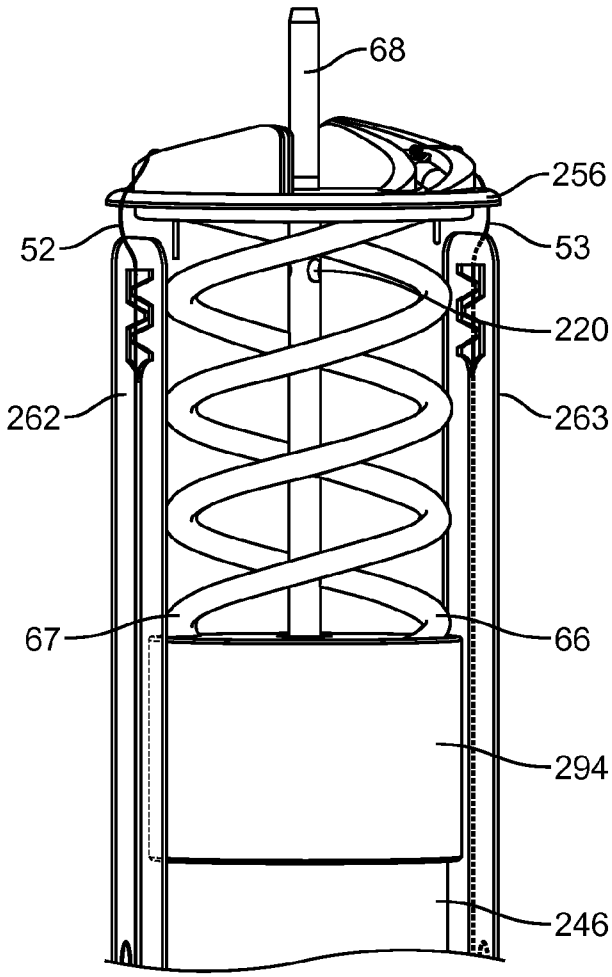

FIG. 19Z

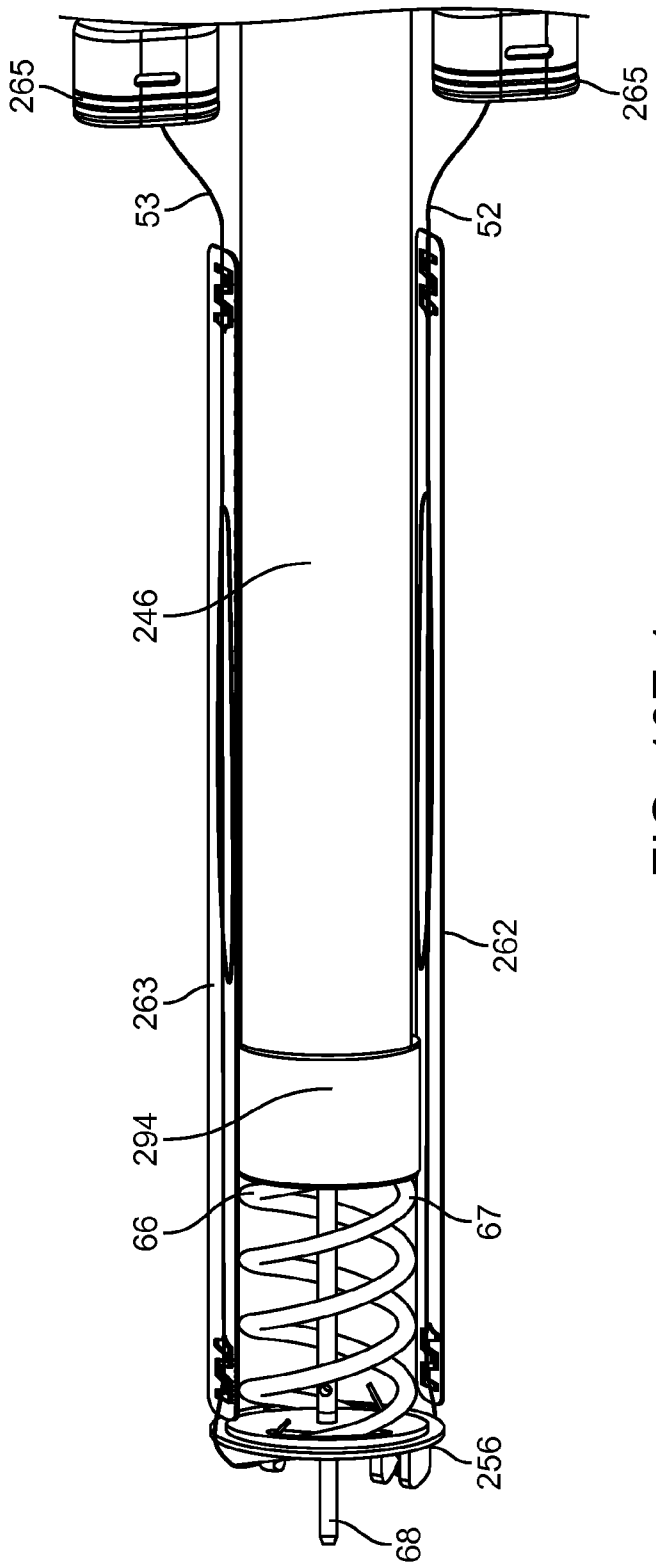

FIG. 19Z-1

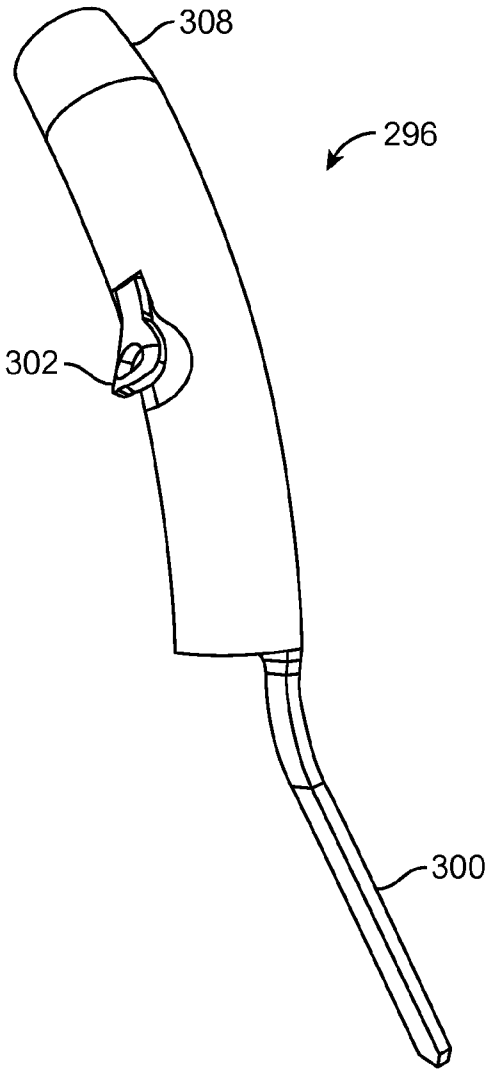

FIG. 19Z-2

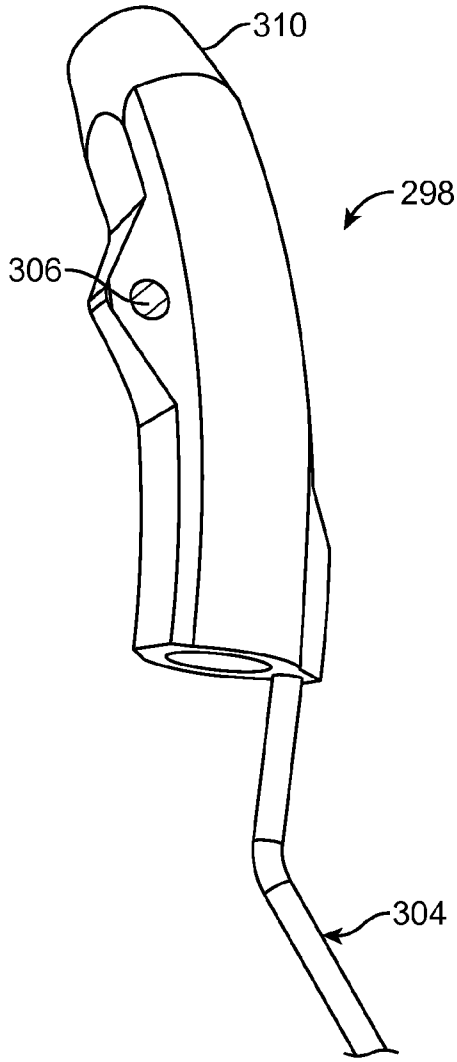

FIG. 19Z-3

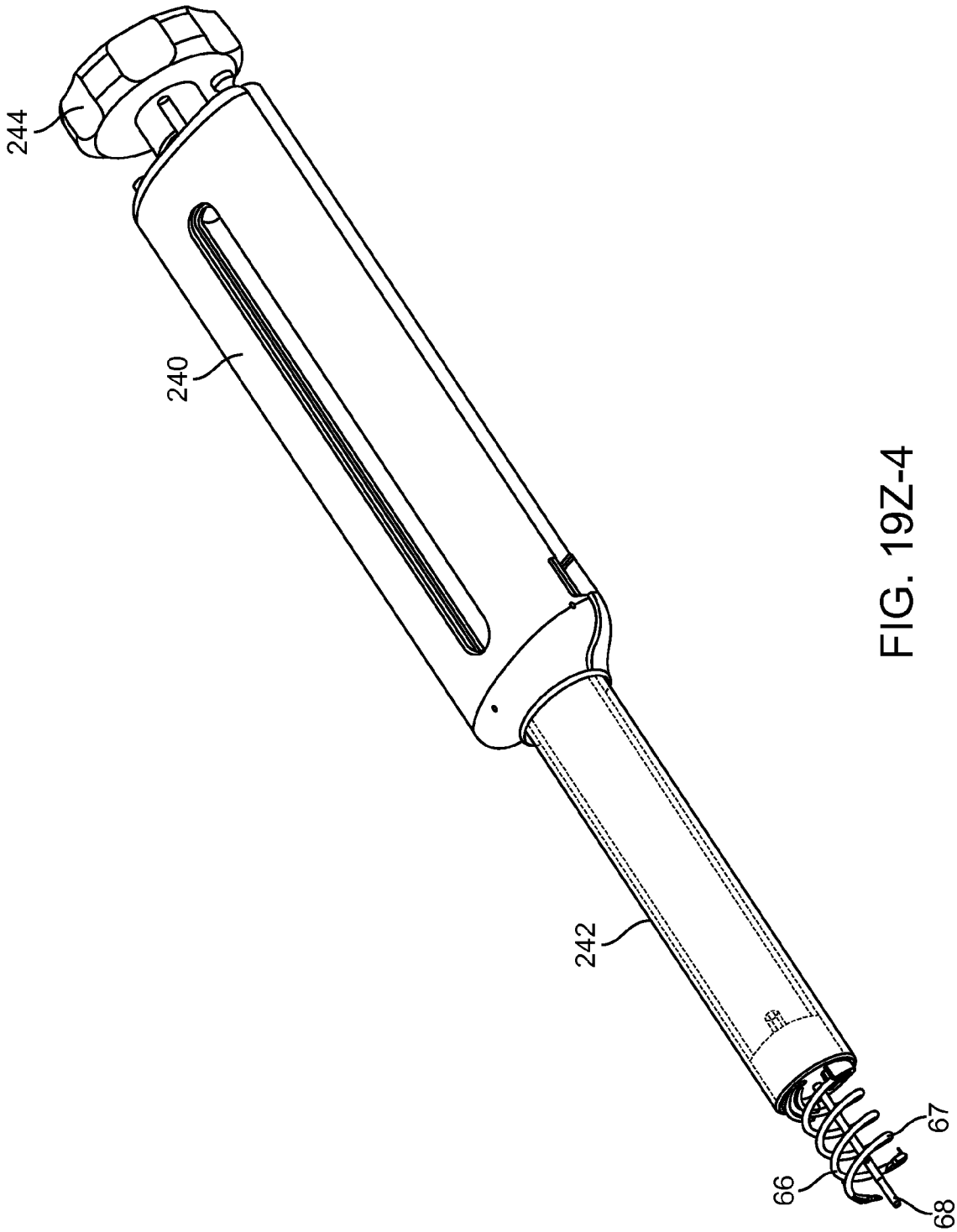

FIG. 19Z-4

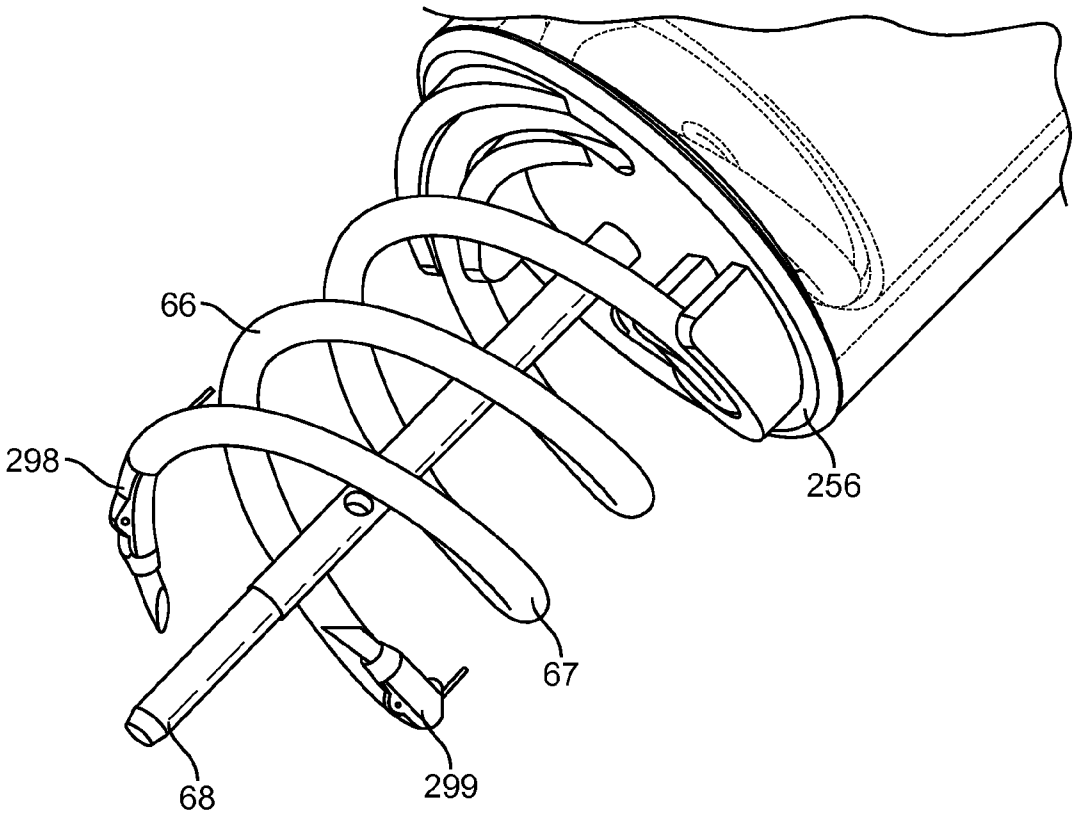

FIG. 19Z-5

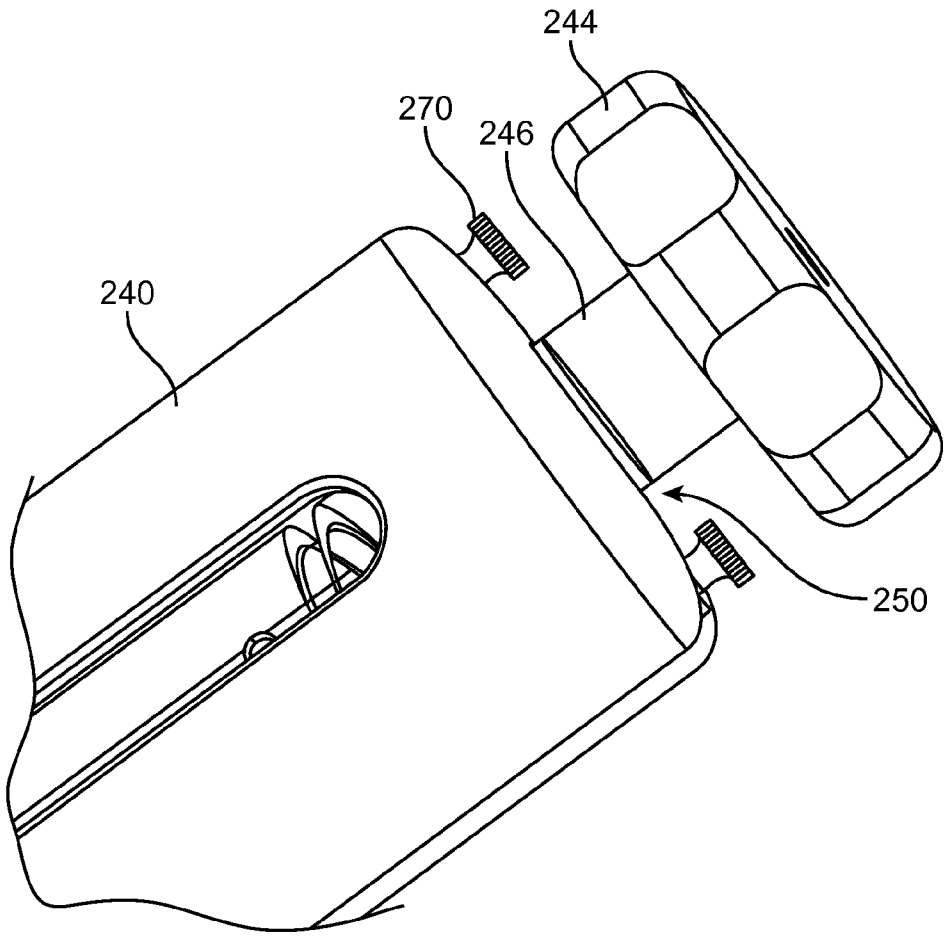

FIG. 19Z-6

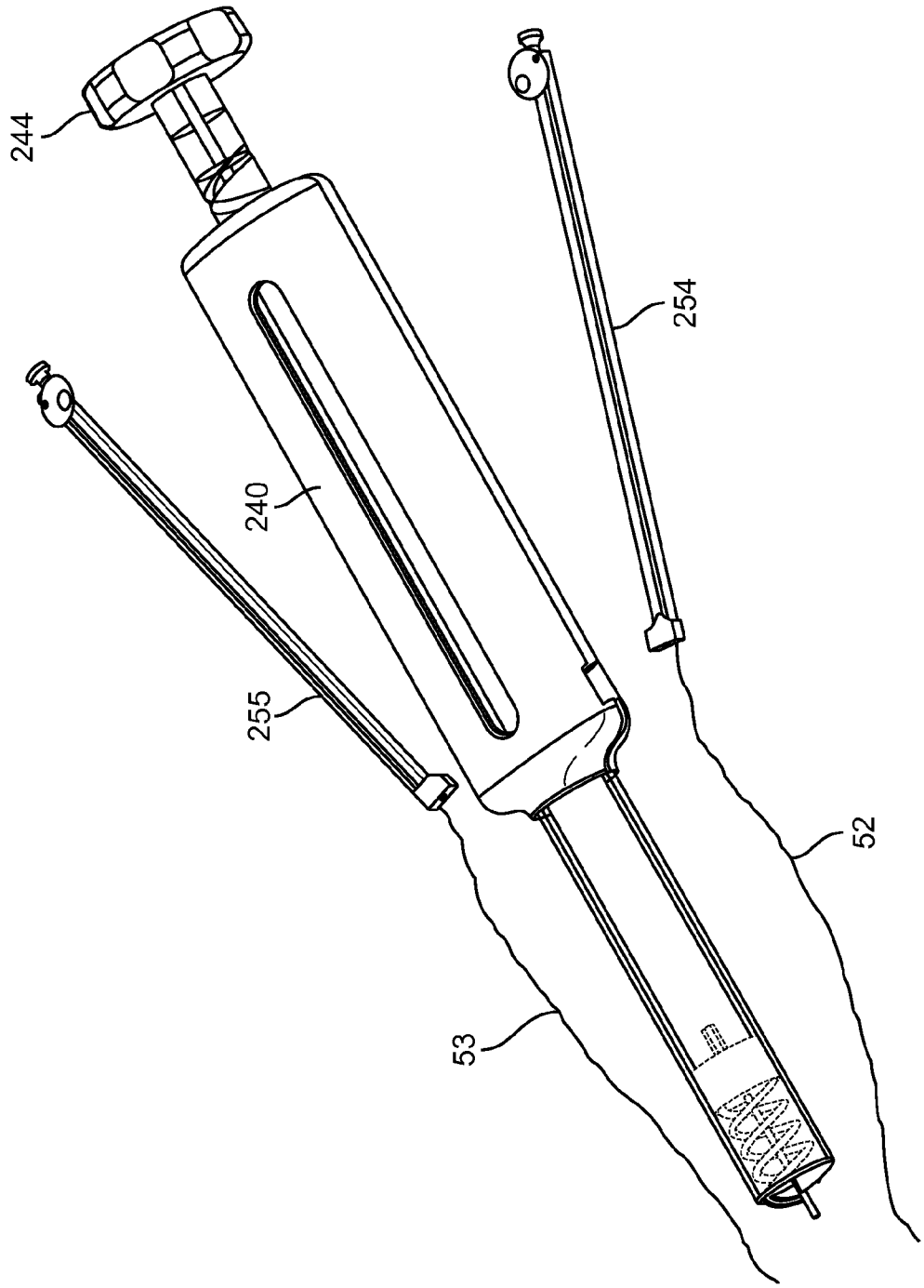

FIG. 19Z-7

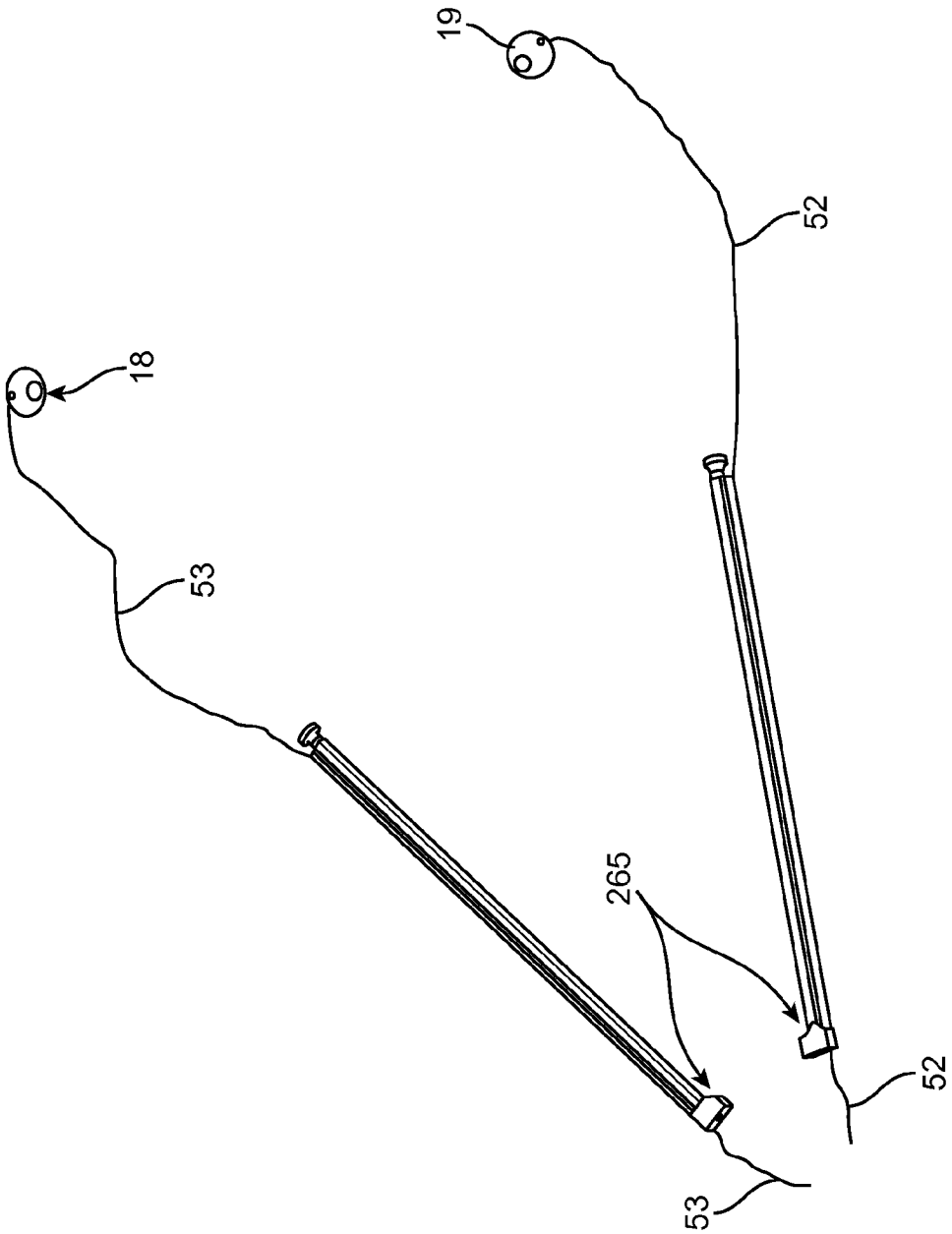

FIG. 19Z-8

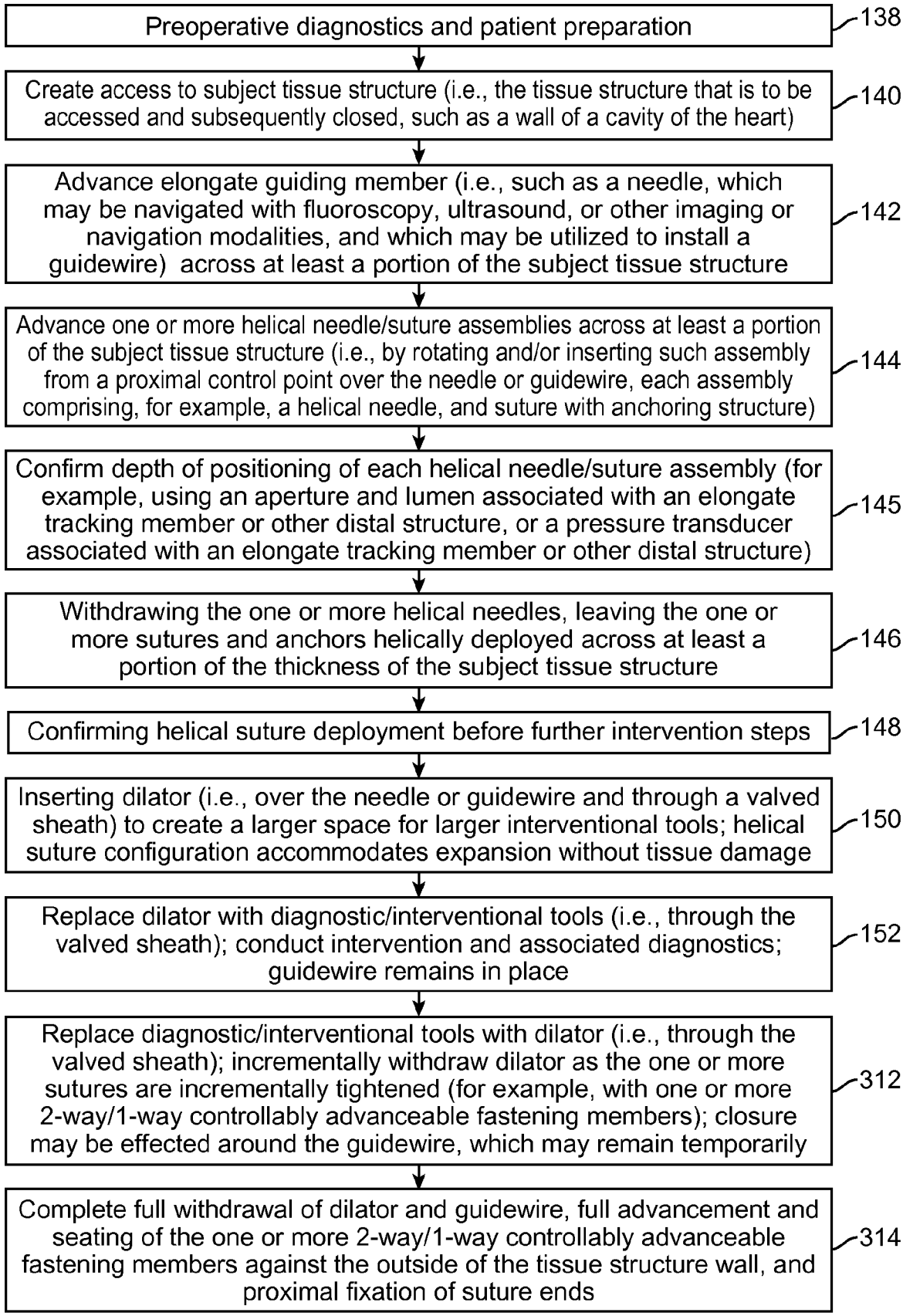
Preoperative diagnostics and patient preparation
138
Create access to subject tissue structure (i.e., the tissue structure that is to be accessed and subsequently closed, such as a wall of a cavity of the heart)
140
Advance elongate guiding member (i.e., such as a needle, which may be navigated with fluoroscopy, ultrasound, or other imaging or navigation modalities, and which may be utilized to install a guidewire) across at least a portion of the subject tissue structure
142
Advance one or more helical needle/suture assemblies across at least a portion of the subject tissue structure (i.e., by rotating and/or inserting such assembly from a proximal control point over the needle or guidewire, each assembly comprising, for example, a helical needle, and suture with anchoring structure)
144
Confirm depth of positioning of each helical needle/suture assembly (for example, using an aperture and lumen associated with an elongate tracking member or other distal structure, or a pressure transducer associated with an elongate tracking member or other distal structure)
145
Withdrawing the one or more helical needles, leaving the one or more sutures and anchors helically deployed across at least a portion of the thickness of the subject tissue structure
146
Confirming helical suture deployment before further intervention steps
148
Inserting dilator (i.e., over the needle or guidewire and through a valved sheath) to create a larger space for larger interventional tools; helical suture configuration accommodates expansion without tissue damage
150
Replace dilator with diagnostic/interventional tools (i.e., through the valved sheath); conduct intervention and associated diagnostics; guidewire remains in place
152
Replace diagnostic/interventional tools with dilator (i.e., through the valved sheath); incrementally withdraw dilator as the one or more sutures are incrementally tightened (for example, with one or more 2-way/1-way controllably advanceable fastening members); closure may be effected around the guidewire, which may remain temporarily
312
Complete full withdrawal of dilator and guidewire, full advancement and seating of the one or more 2-way/1-way controllably advanceable fastening members against the outside of the tissue structure wall, and proximal fixation of suture ends
314

FIG. 20

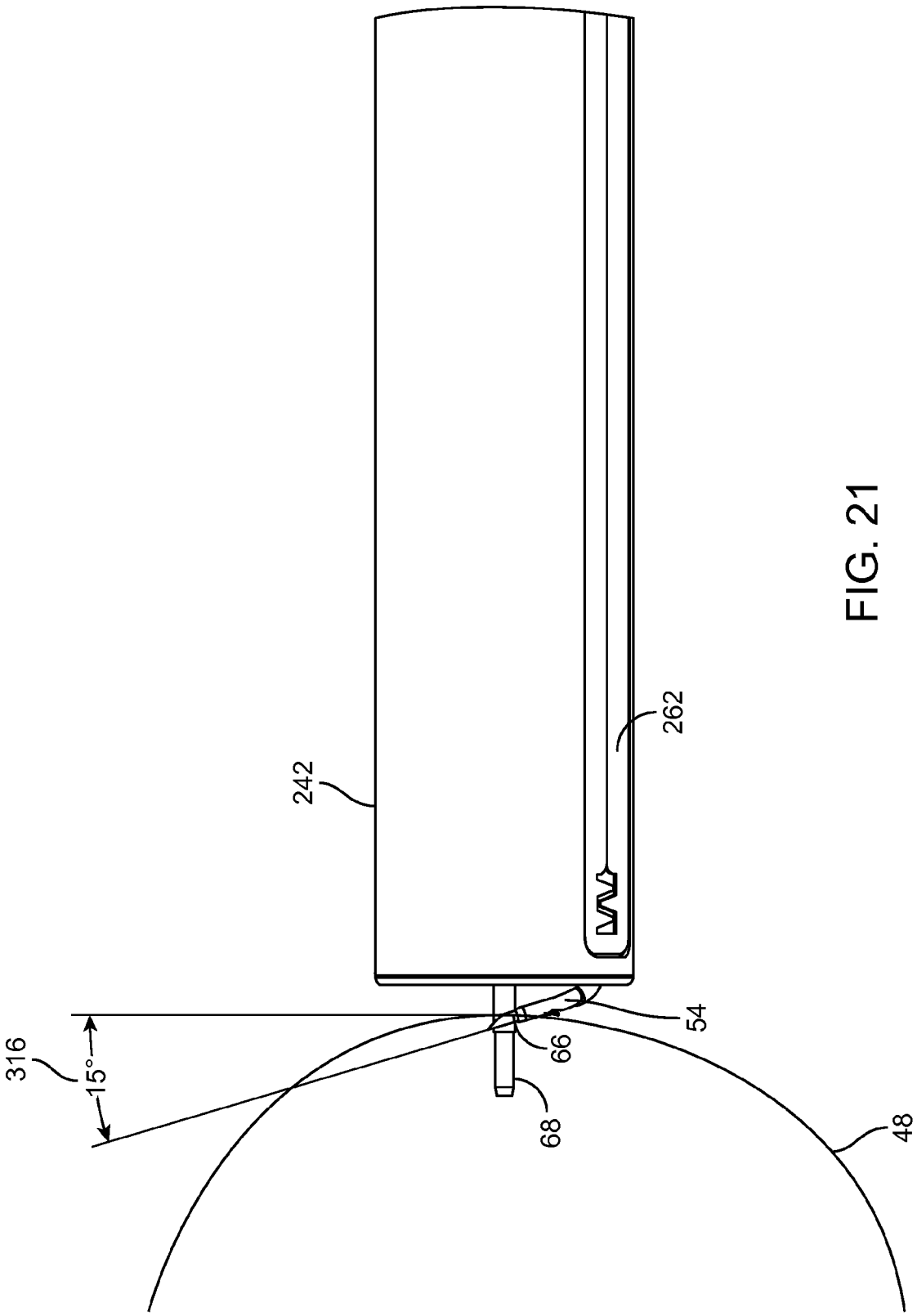

FIG. 21

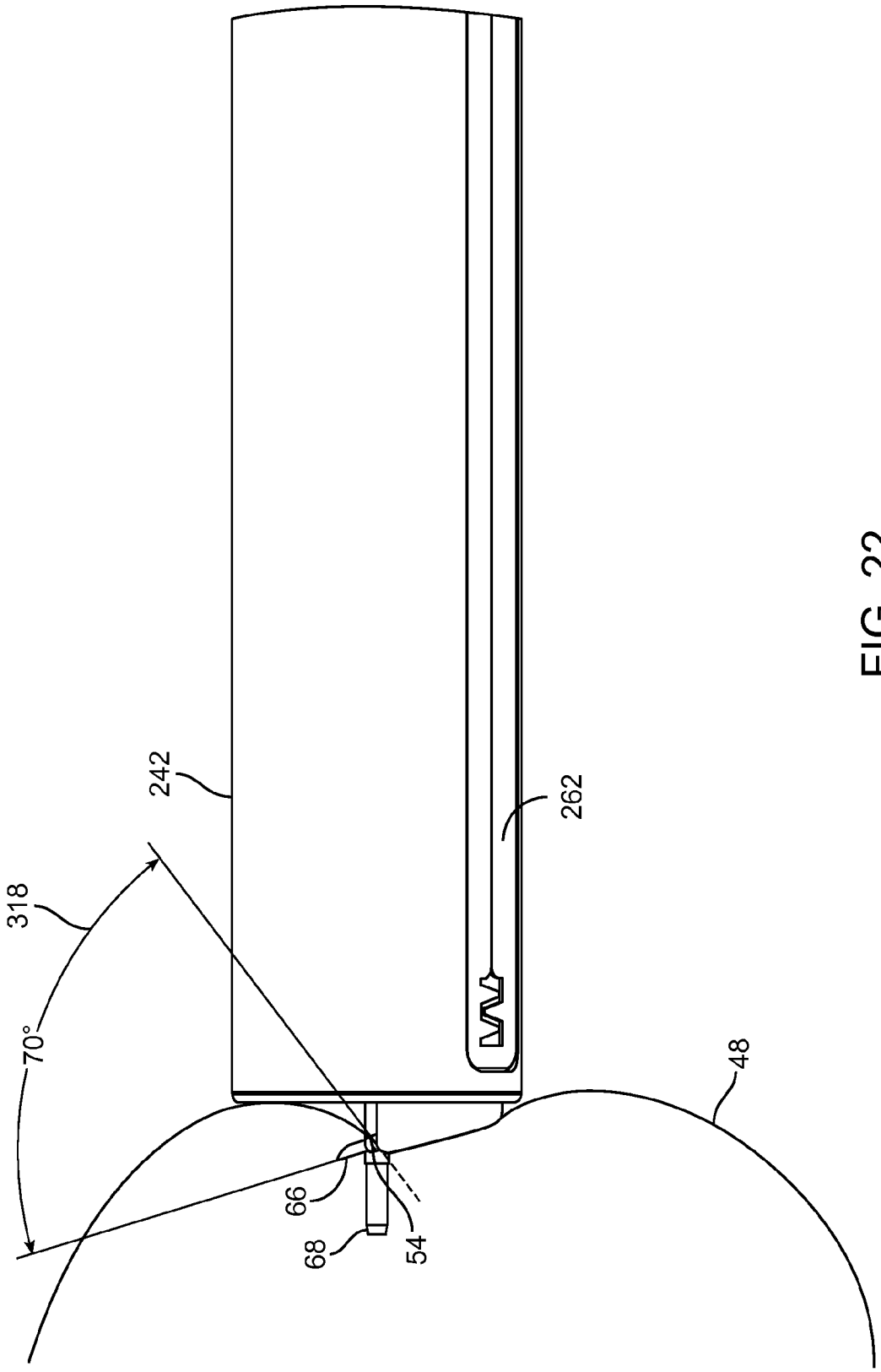

FIG. 22

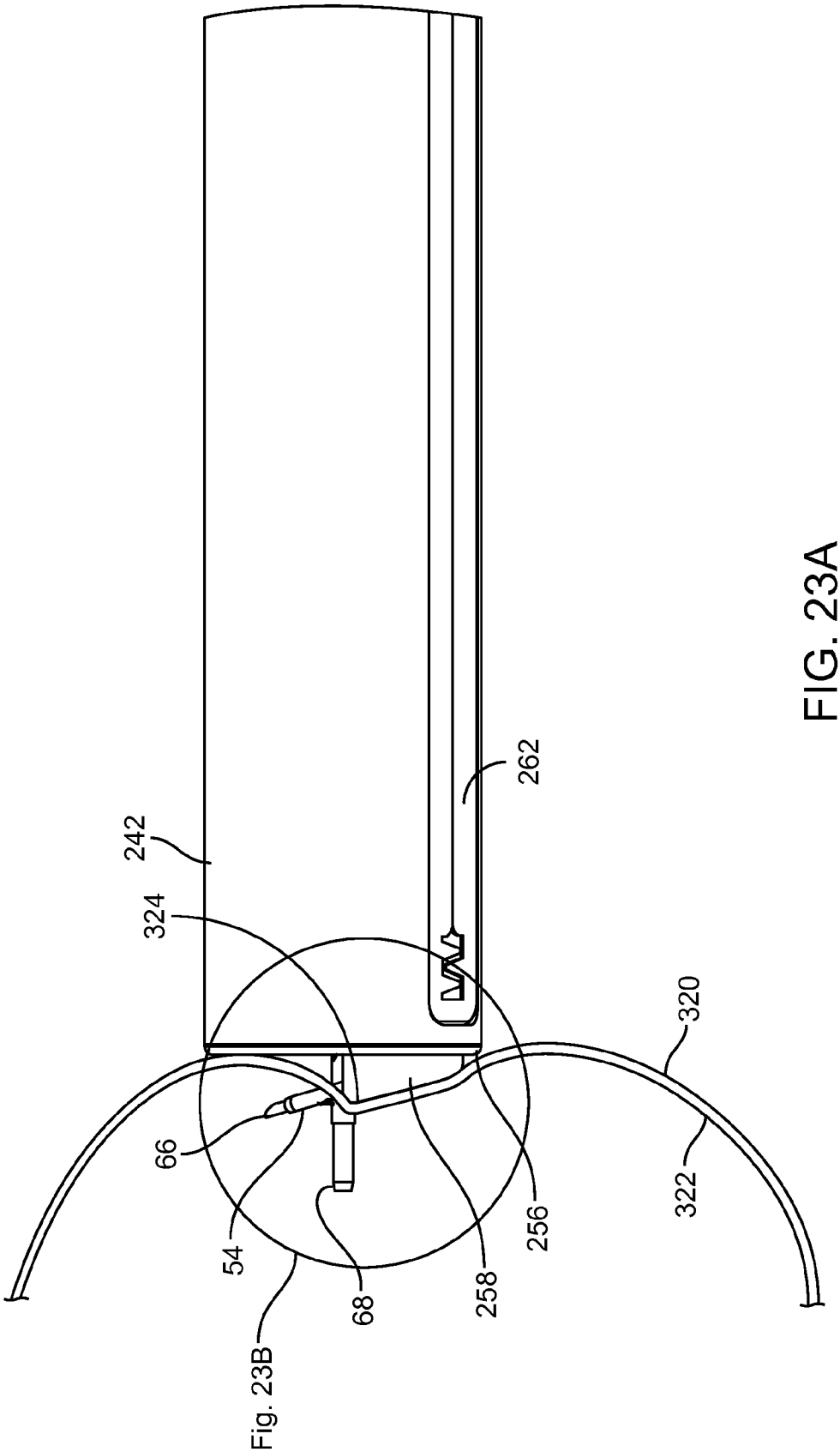

FIG. 23A

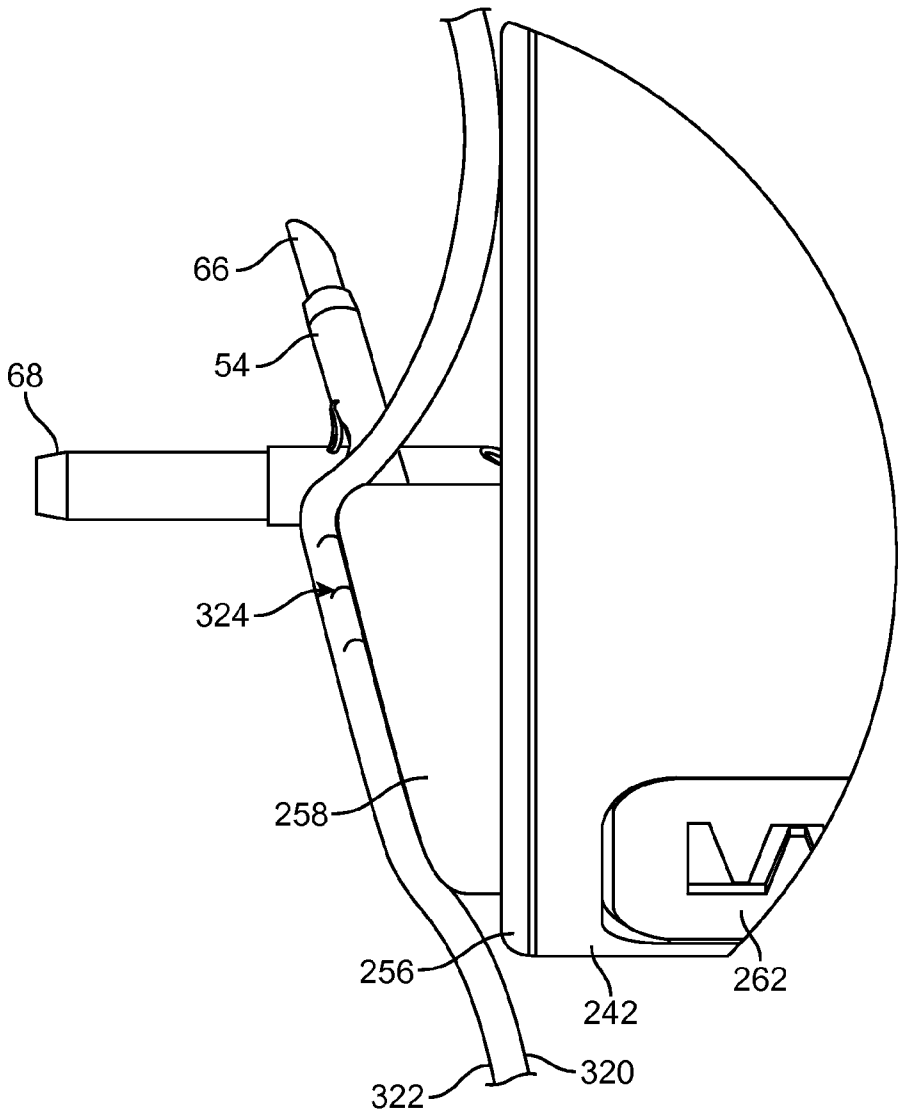

FIG. 23B

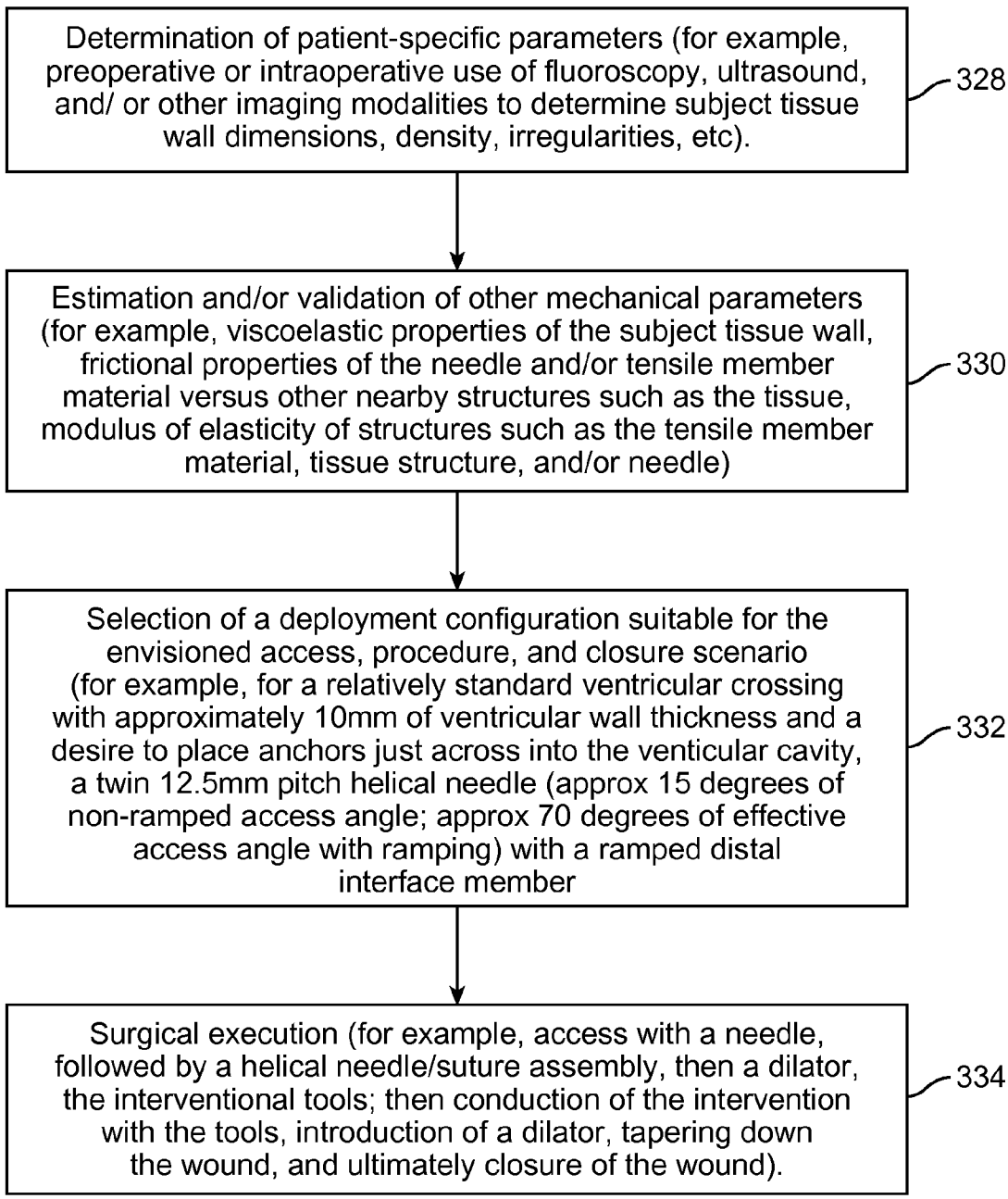
Determination of patient-specific parameters (for example, preoperative or intraoperative use of fluoroscopy, ultrasound, and/ or other imaging modalities to determine subject tissue wall dimensions, density, irregularities, etc).
328
Estimation and/or validation of other mechanical parameters (for example, viscoelastic properties of the subject tissue wall, frictional properties of the needle and/or tensile member material versus other nearby structures such as the tissue, modulus of elasticity of structures such as the tensile member material, tissue structure, and/or needle)
330
Selection of a deployment configuration suitable for the envisioned access, procedure, and closure scenario (for example, for a relatively standard ventricular crossing with approximately 10mm of ventricular wall thickness and a desire to place anchors just across into the venticular cavity, a twin 12.5mm pitch helical needle (approx 15 degrees of non-ramped access angle; approx 70 degrees of effective access angle with ramping) with a ramped distal interface member
332
Surgical execution (for example, access with a needle, followed by a helical needle/suture assembly, then a dilator, the interventional tools; then conduction of the intervention with the tools, introduction of a dilator, tapering down the wound, and ultimately closure of the wound).
334

FIG. 24

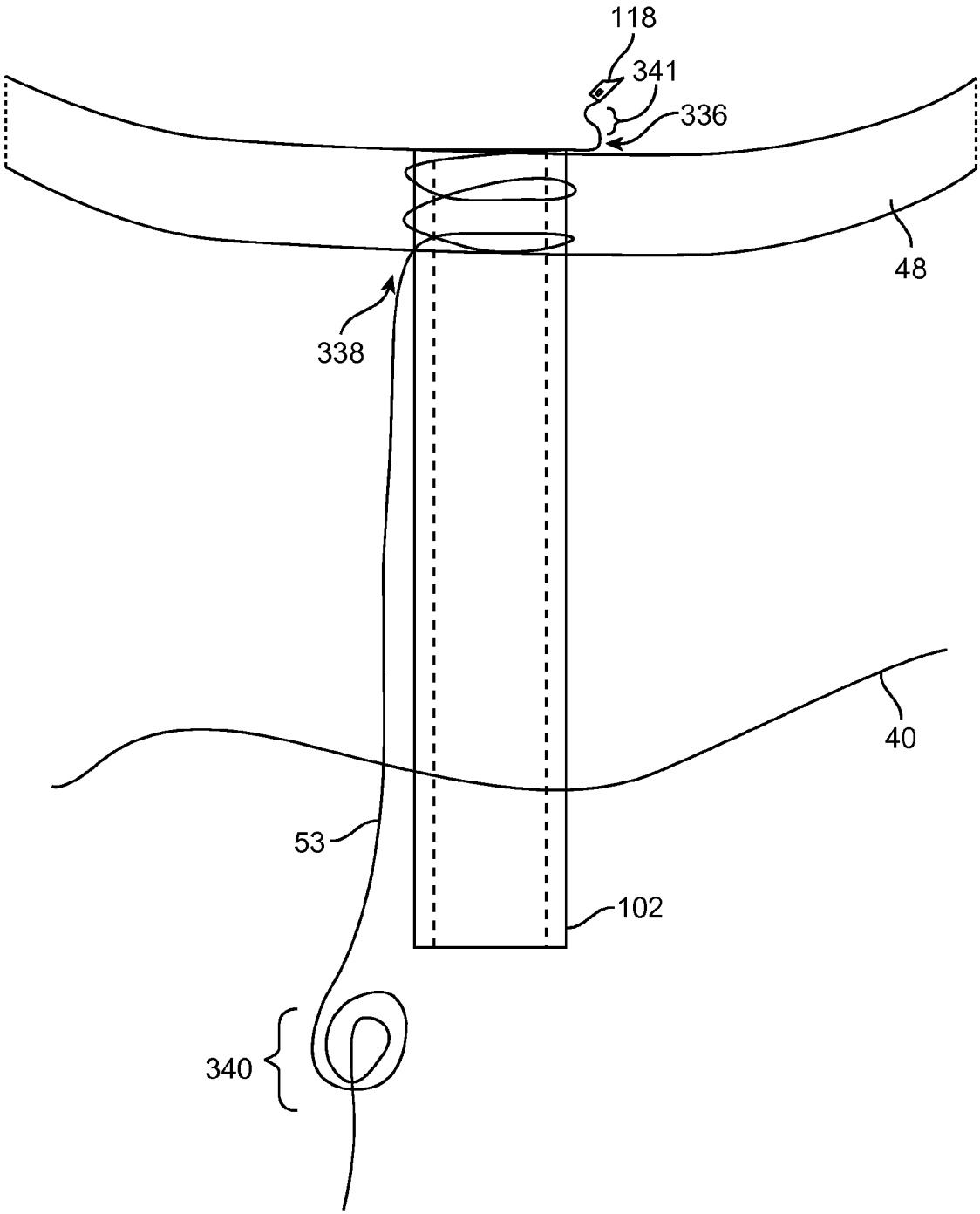

FIG. 25

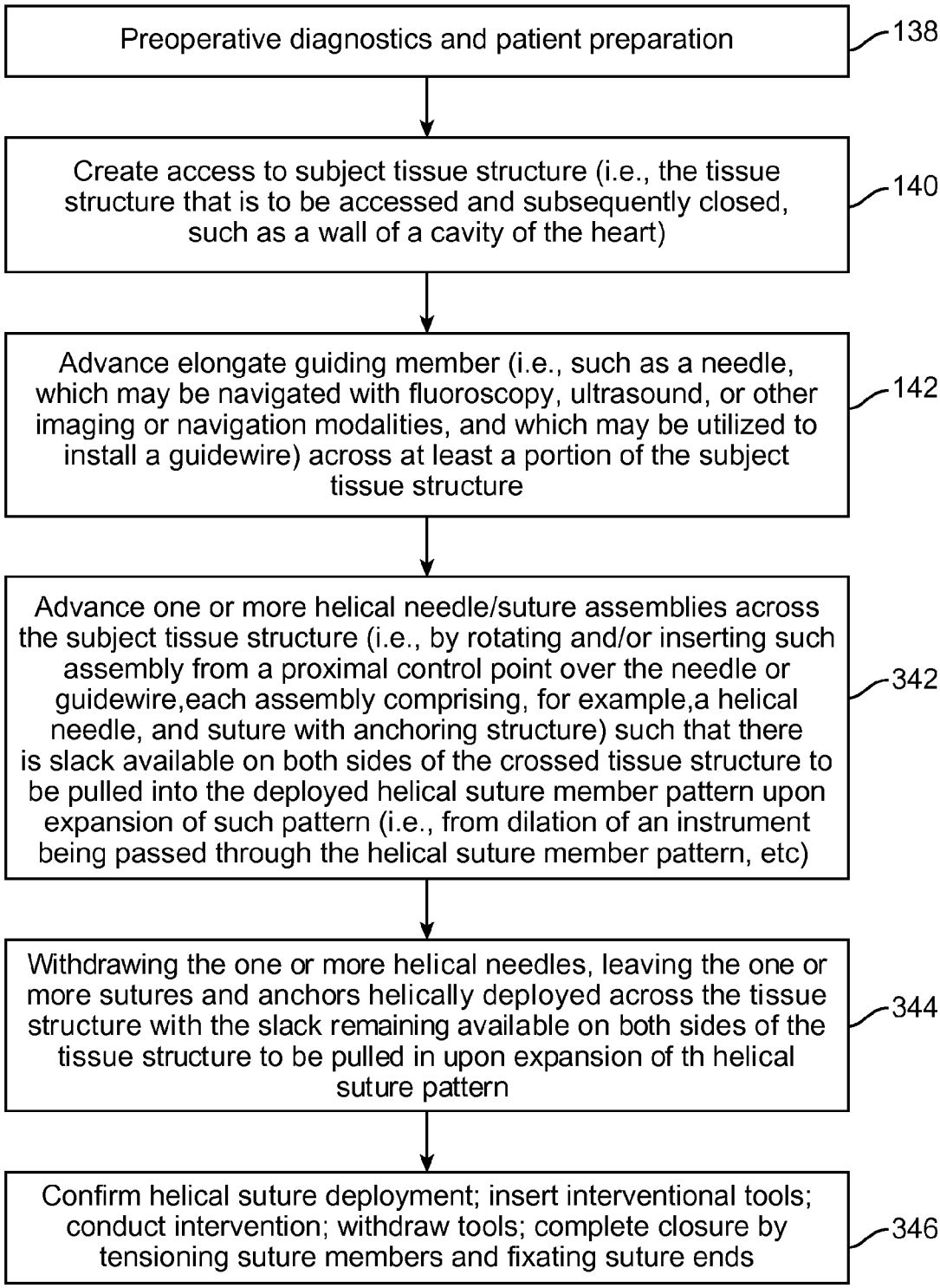
Preoperative diagnostics and patient preparation
138
Create access to subject tissue structure (i.e., the tissue structure that is to be accessed and subsequently closed, such as a wall of a cavity of the heart)
140
Advance elongate guiding member (i.e., such as a needle, which may be navigated with fluoroscopy, ultrasound, or other imaging or navigation modalities, and which may be utilized to install a guidewire) across at least a portion of the subject tissue structure
142
Advance one or more helical needle/suture assemblies across the subject tissue structure (i.e., by rotating and/or inserting such assembly from a proximal control point over the needle or guidewire,each assembly comprising, for example,a helical needle, and suture with anchoring structure) such that there is slack available on both sides of the crossed tissue structure to be pulled into the deployed helical suture member pattern upon expansion of such pattern (i.e., from dilation of an instrument being passed through the helical suture member pattern, etc)
342
Withdrawing the one or more helical needles, leaving the one or more sutures and anchors helically deployed across the tissue structure with the slack remaining available on both sides of the tissue structure to be pulled in upon expansion of th helical suture pattern
344
Confirm helical suture deployment; insert interventional tools; conduct intervention; withdraw tools; complete closure by tensioning suture members and fixating suture ends
346

FIG. 26

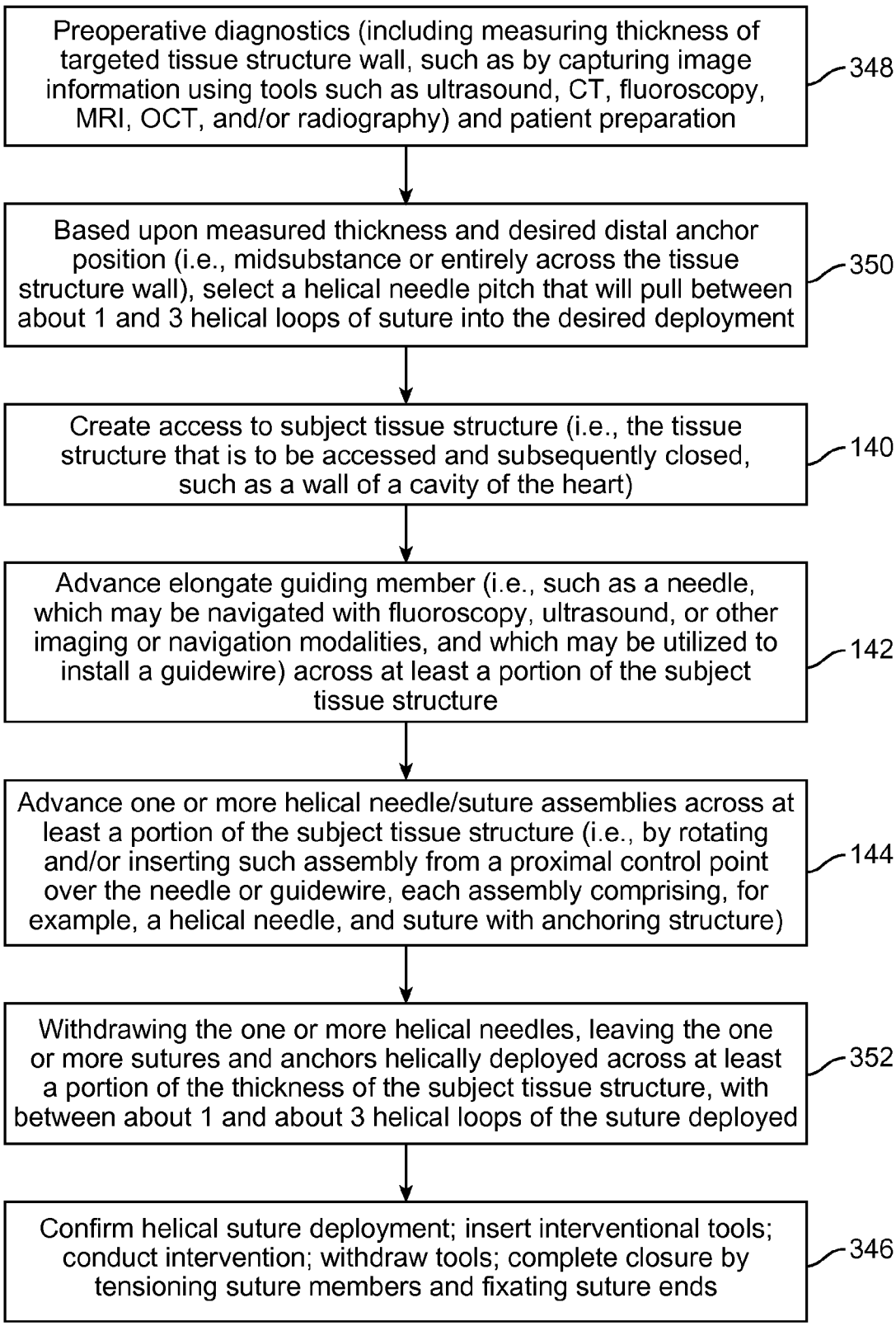
Preoperative diagnostics (including measuring thickness of targeted tissue structure wall, such as by capturing image information using tools such as ultrasound, CT, fluoroscopy, MRI, OCT, and/or radiography) and patient preparation
348
Based upon measured thickness and desired distal anchor position (i.e., midsubstance or entirely across the tissue structure wall), select a helical needle pitch that will pull between about 1 and 3 helical loops of suture into the desired deployment
350
Create access to subject tissue structure (i.e., the tissue structure that is to be accessed and subsequently closed, such as a wall of a cavity of the heart)
140
Advance elongate guiding member (i.e., such as a needle, which may be navigated with fluoroscopy, ultrasound, or other imaging or navigation modalities, and which may be utilized to install a guidewire) across at least a portion of the subject tissue structure
142
Advance one or more helical needle/suture assemblies across at least a portion of the subject tissue structure (i.e., by rotating and/or inserting such assembly from a proximal control point over the needle or guidewire, each assembly comprising, for example, a helical needle, and suture with anchoring structure)
144
Withdrawing the one or more helical needles, leaving the one or more sutures and anchors helically deployed across at least a portion of the thickness of the subject tissue structure, with between about 1 and about 3 helical loops of the suture deployed
352
Confirm helical suture deployment; insert interventional tools; conduct intervention; withdraw tools; complete closure by tensioning suture members and fixating suture ends
346

FIG. 27

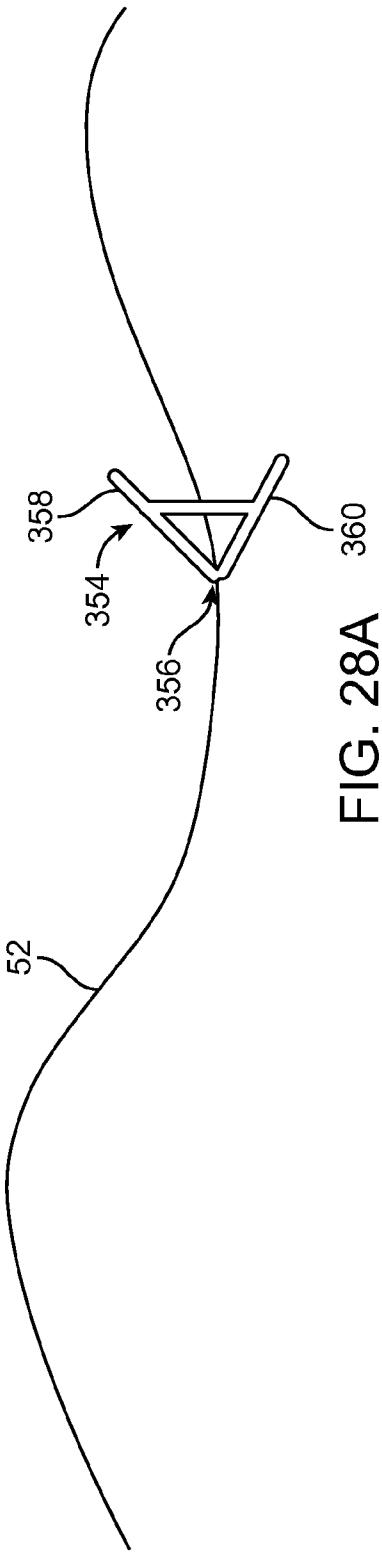

FIG. 28A

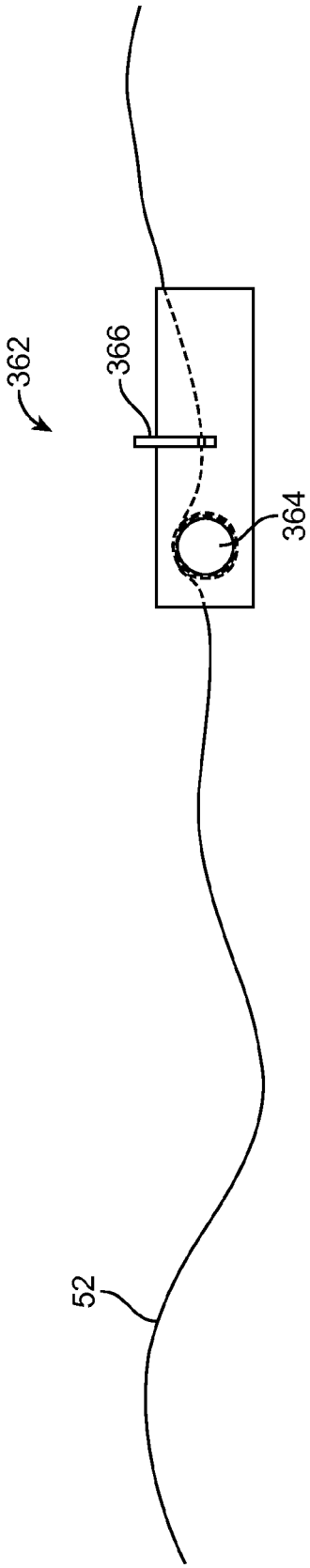

FIG. 28B

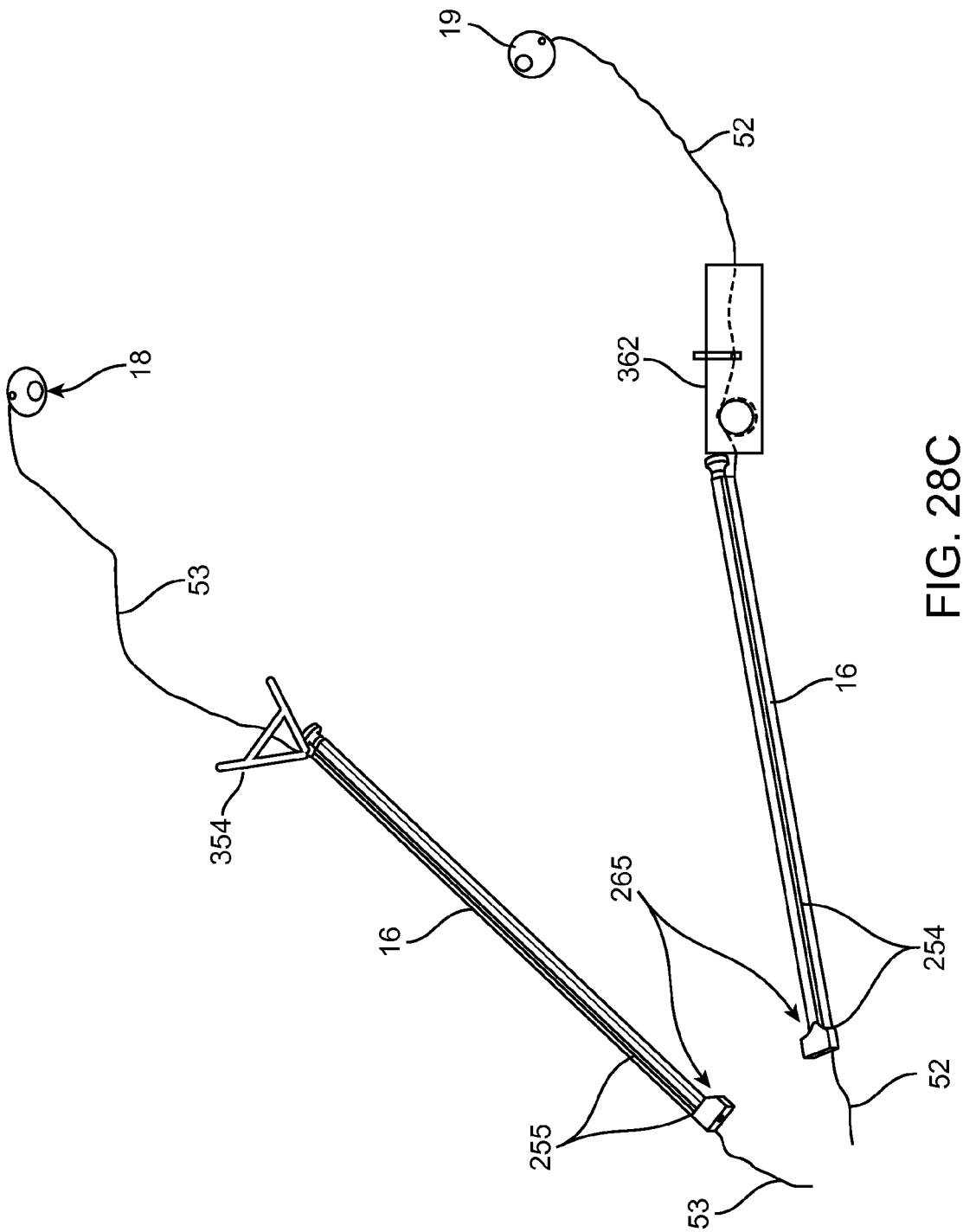

FIG. 28C

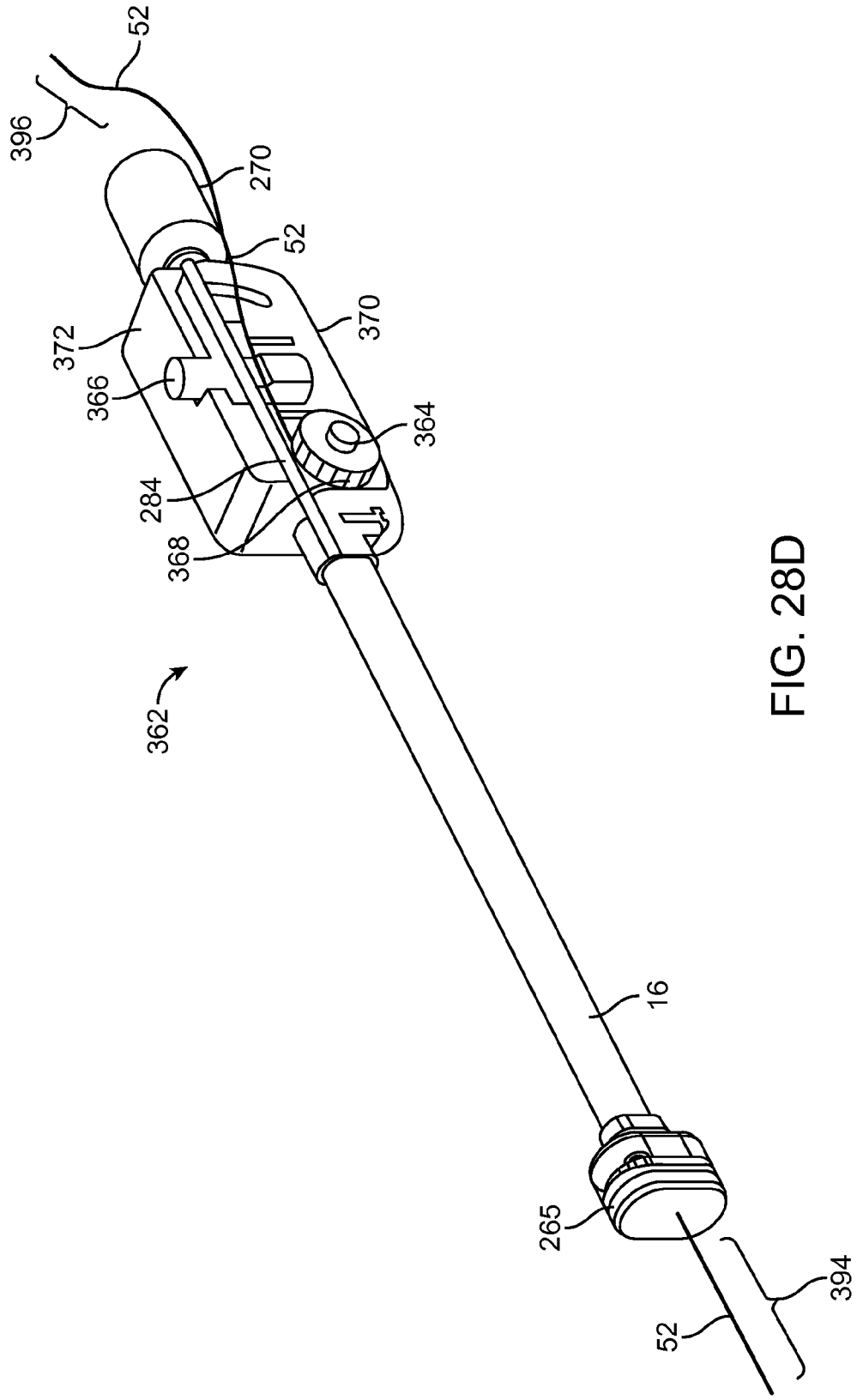

FIG. 28D

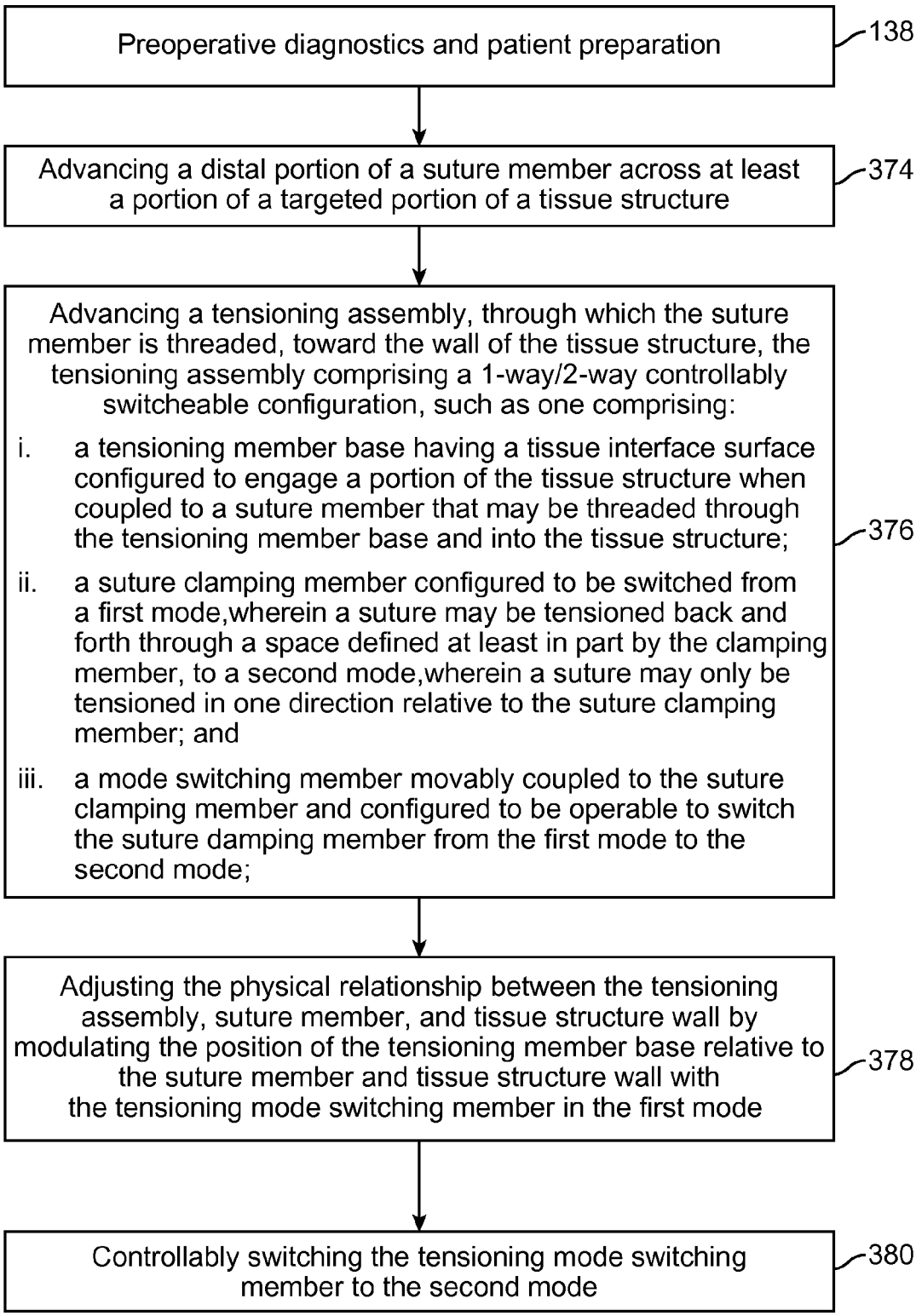
Preoperative diagnostics and patient preparation
138
Advancing a distal portion of a suture member across at least a portion of a targeted portion of a tissue structure
374
Advancing a tensioning assembly, through which the suture member is threaded, toward the wall of the tissue structure, the tensioning assembly comprising a 1-way/2-way controllably switcheable configuration, such as one comprising:
i. a tensioning member base having a tissue interface surface configured to engage a portion of the tissue structure when coupled to a suture member that may be threaded through the tensioning member base and into the tissue structure;
ii. a suture clamping member configured to be switched from a first mode,wherein a suture may be tensioned back and forth through a space defined at least in part by the clamping member, to a second mode,wherein a suture may only be tensioned in one direction relative to the suture clamping member; and
iii. a mode switching member movably coupled to the suture clamping member and configured to be operable to switch the suture damping member from the first mode to the second mode;
376
Adjusting the physical relationship between the tensioning assembly, suture member, and tissue structure wall by modulating the position of the tensioning member base relative to the suture member and tissue structure wall with the tensioning mode switching member in the first mode
378
Controllably switching the tensioning mode switching member to the second mode
380

FIG. 29

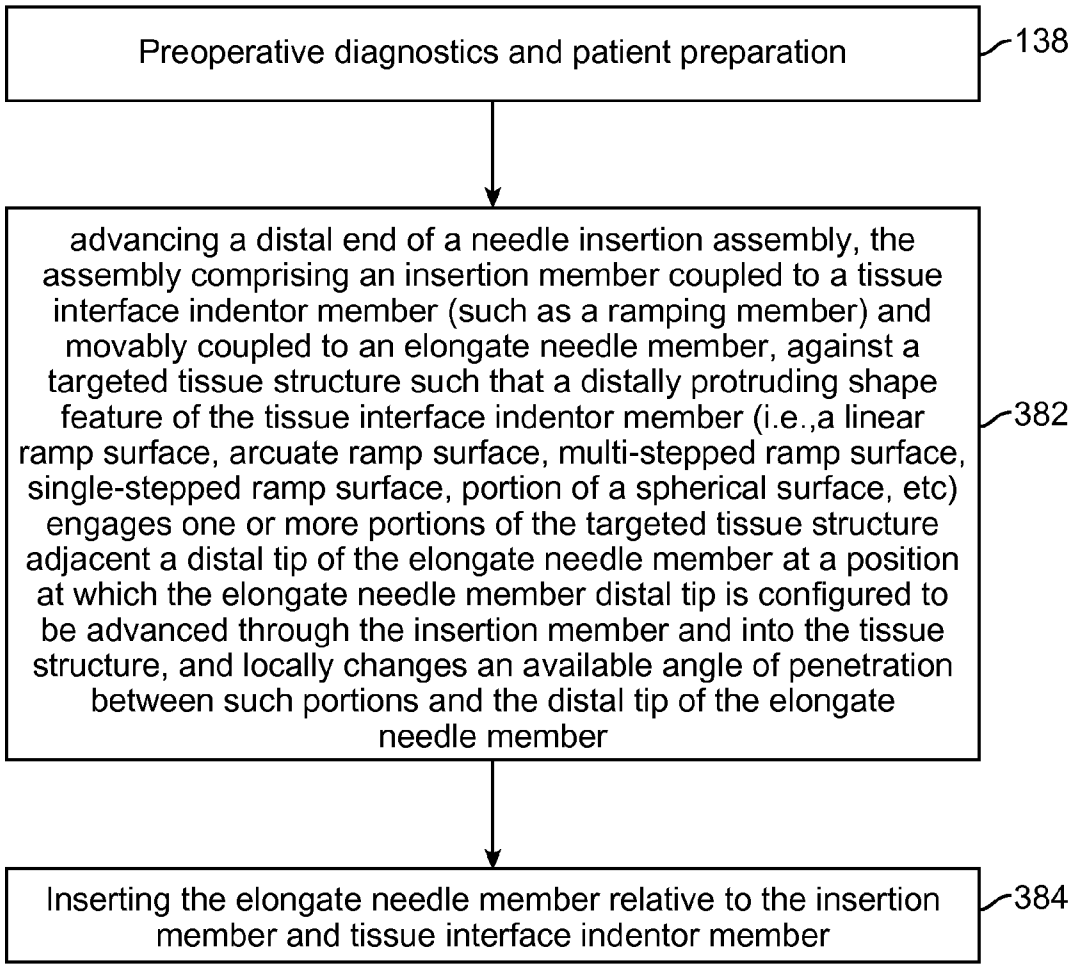
Preoperative diagnostics and patient preparation
138
advancing a distal end of a needle insertion assembly, the assembly comprising an insertion member coupled to a tissue interface indentor member (such as a ramping member) and movably coupled to an elongate needle member, against a targeted tissue structure such that a distally protruding shape feature of the tissue interface indentor member (i.e.,a linear ramp surface, arcuate ramp surface, multi-stepped ramp surface, single-stepped ramp surface, portion of a spherical surface, etc) engages one or more portions of the targeted tissue structure adjacent a distal tip of the elongate needle member at a position at which the elongate needle member distal tip is configured to be advanced through the insertion member and into the tissue structure, and locally changes an available angle of penetration between such portions and the distal tip of the elongate needle member
382
Inserting the elongate needle member relative to the insertion member and tissue interface indentor member
384

FIG. 30

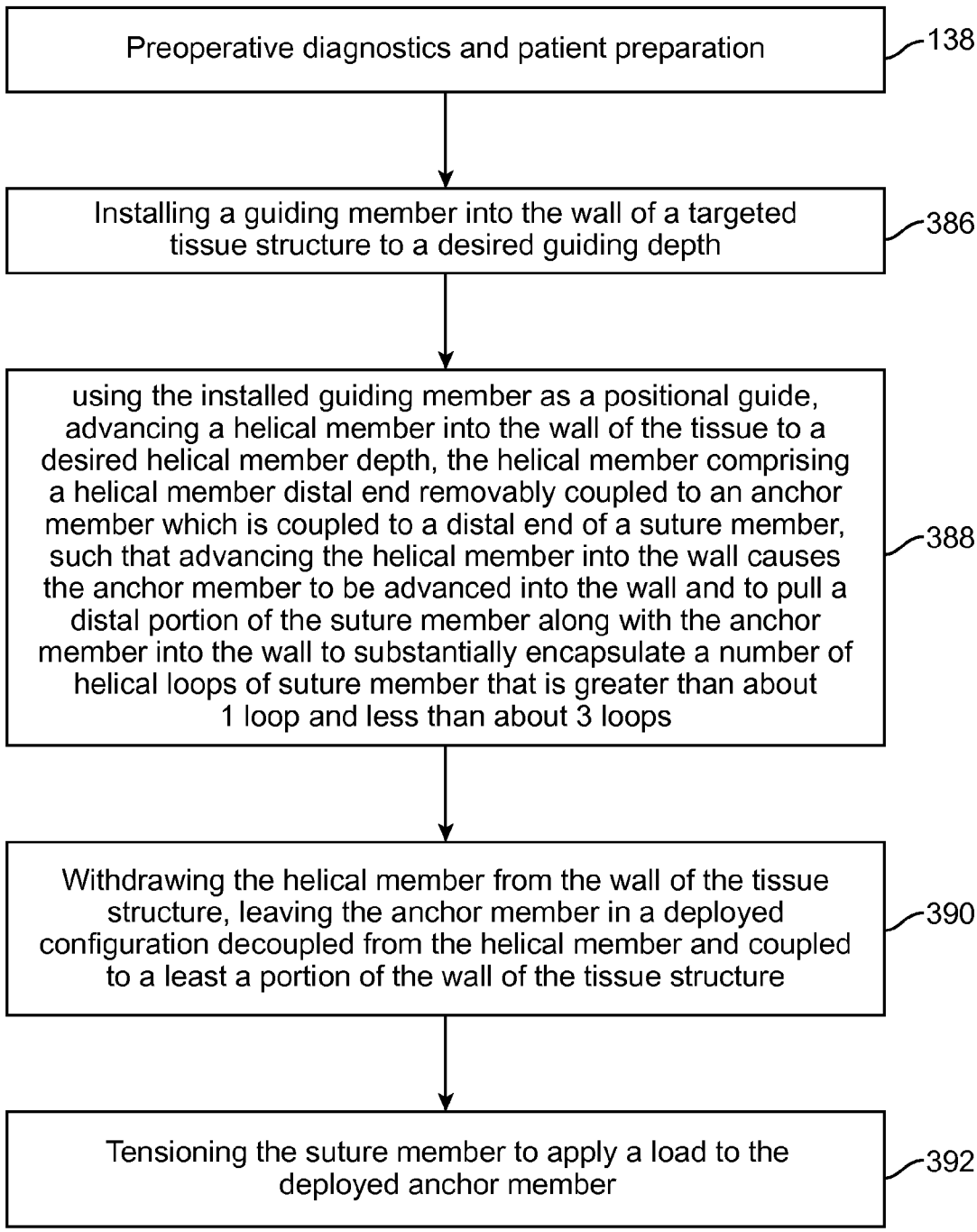
Preoperative diagnostics and patient preparation
138
Installing a guiding member into the wall of a targeted tissue structure to a desired guiding depth
386
using the installed guiding member as a positional guide, advancing a helical member into the wall of the tissue to a desired helical member depth, the helical member comprising a helical member distal end removably coupled to an anchor member which is coupled to a distal end of a suture member, such that advancing the helical member into the wall causes the anchor member to be advanced into the wall and to pull a distal portion of the suture member along with the anchor member into the wall to substantially encapsulate a number of helical loops of suture member that is greater than about 1 loop and less than about 3 loops
388
Withdrawing the helical member from the wall of the tissue structure, leaving the anchor member in a deployed configuration decoupled from the helical member and coupled to a least a portion of the wall of the tissue structure
390
Tensioning the suture member to apply a load to the deployed anchor member
392

FIG. 31

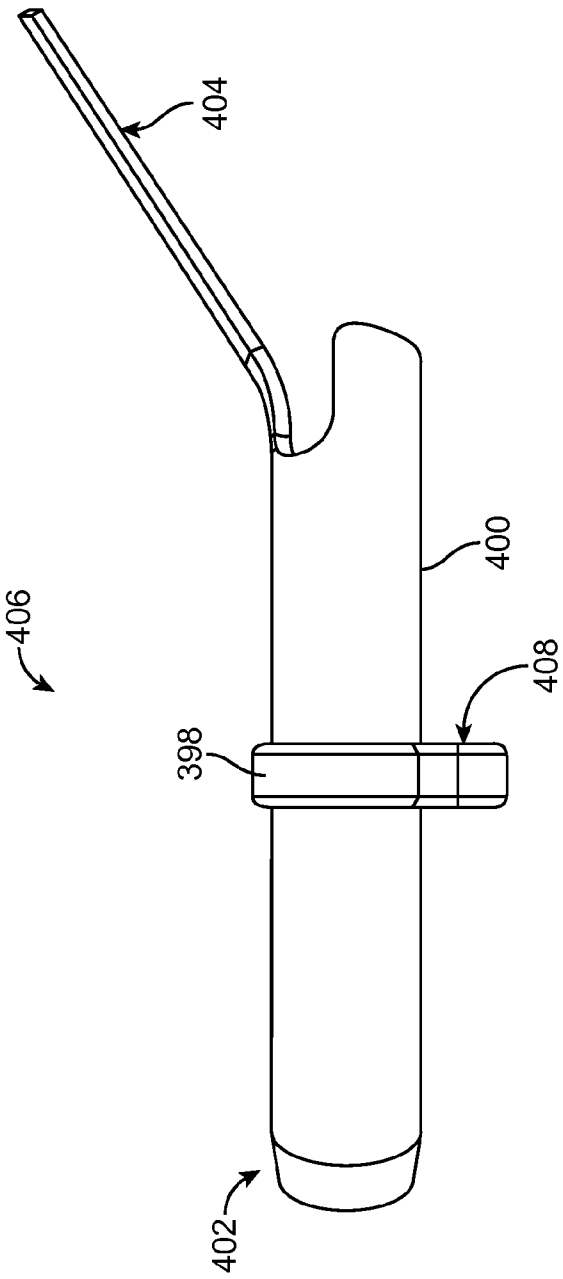

FIG. 32