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(54) **MULTI-LUMEN-CATHETER RETRACTOR SYSTEM FOR A MINIMALLY-INVASIVE, OPERATIVE GASTROINTESTINAL TREATMENT**

(58) **Field of Classification Search**
CPC ... A61B 1/00085; A61B 1/00087; A61B 1/31; A61B 1/32

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(71) Applicant: **Boston Scientific Scimed, Inc.**, Maple Grove, MN (US)

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(73) Assignee: **Boston Scientific Scimed, Inc.**, Maple Grove, MN (US)

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Primary Examiner — Beverly M Flanagan

(74) *Attorney, Agent, or Firm* — Kacvinsky Daisak Bluni PLLC

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(Continued)

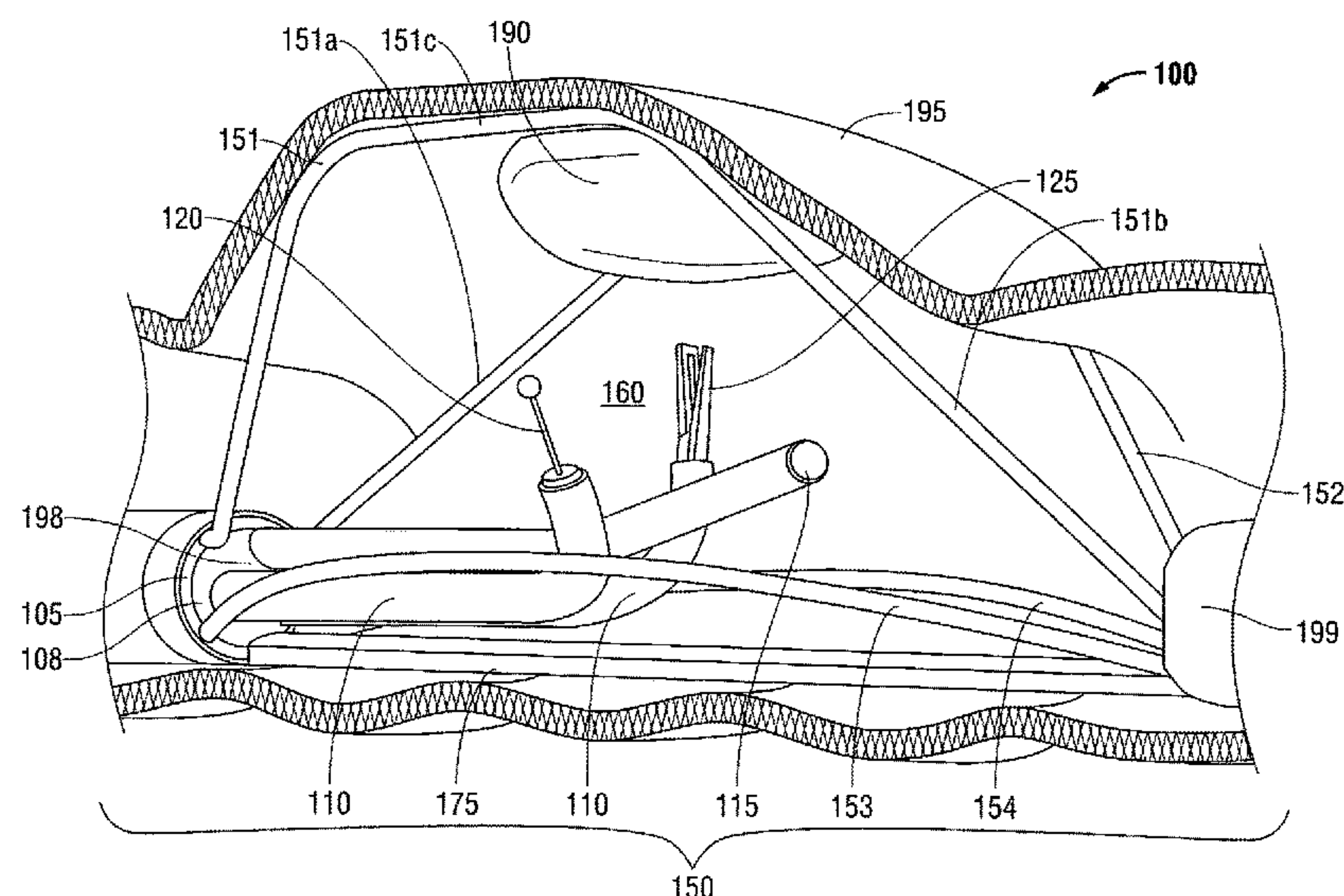
(57) **ABSTRACT**

Improved methods and devices for performing an endoscopic surgery are provided. Systems are taught for operatively treating gastrointestinal disorders endoscopically in a stable, yet dynamic operative environment, and in a minimally-invasive manner. Such systems include, for example, an endoscopic surgical suite. The surgical suite can have a reversibly-expandable retractor that expands to provide a stable, operative environment within a subject. The expansion can be asymmetric around a stabilizer subsystem to maximize space for a tool and an endoscope to each be maneuvered independently to visualize a target tissue and treat the target tissue from outside the patient in a minimally invasive manner.

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A61B 1/005 (2006.01)
(Continued)

(52) **U.S. Cl.**
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(Continued)

28 Claims, 36 Drawing Sheets



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(58) Field of Classification Search			7,169,115	B2	1/2007 Nobis et al.
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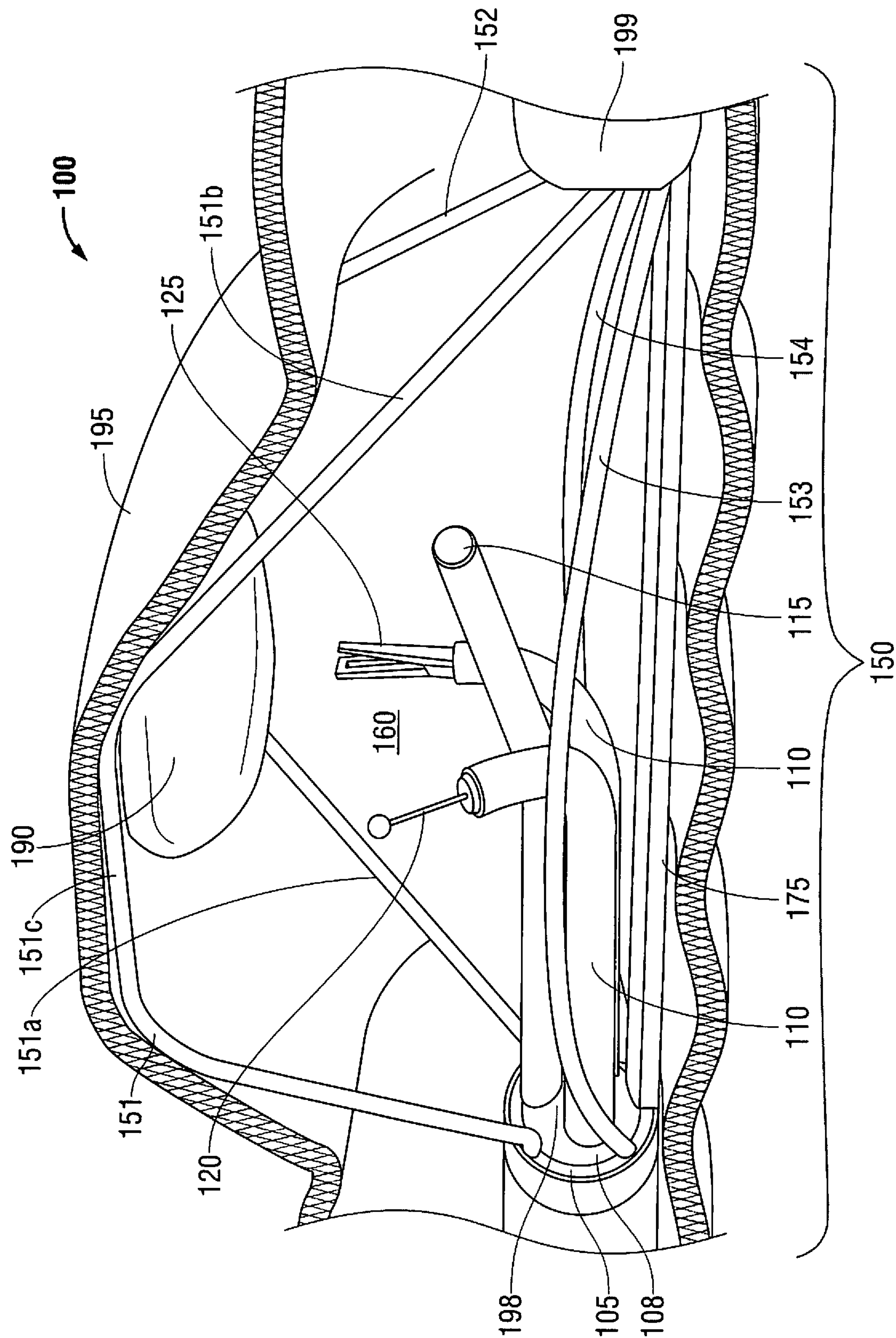


FIG. 1

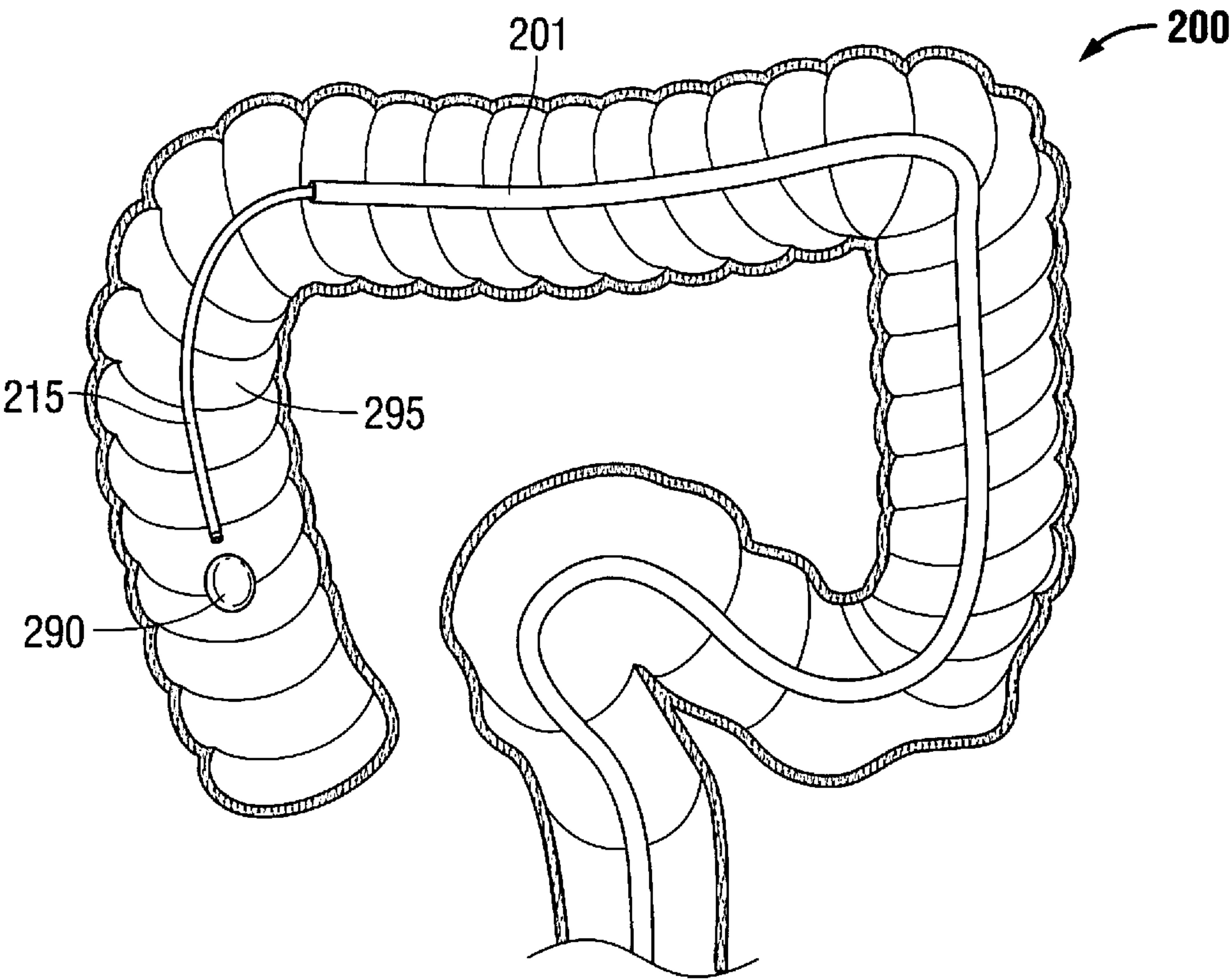


FIG. 2A

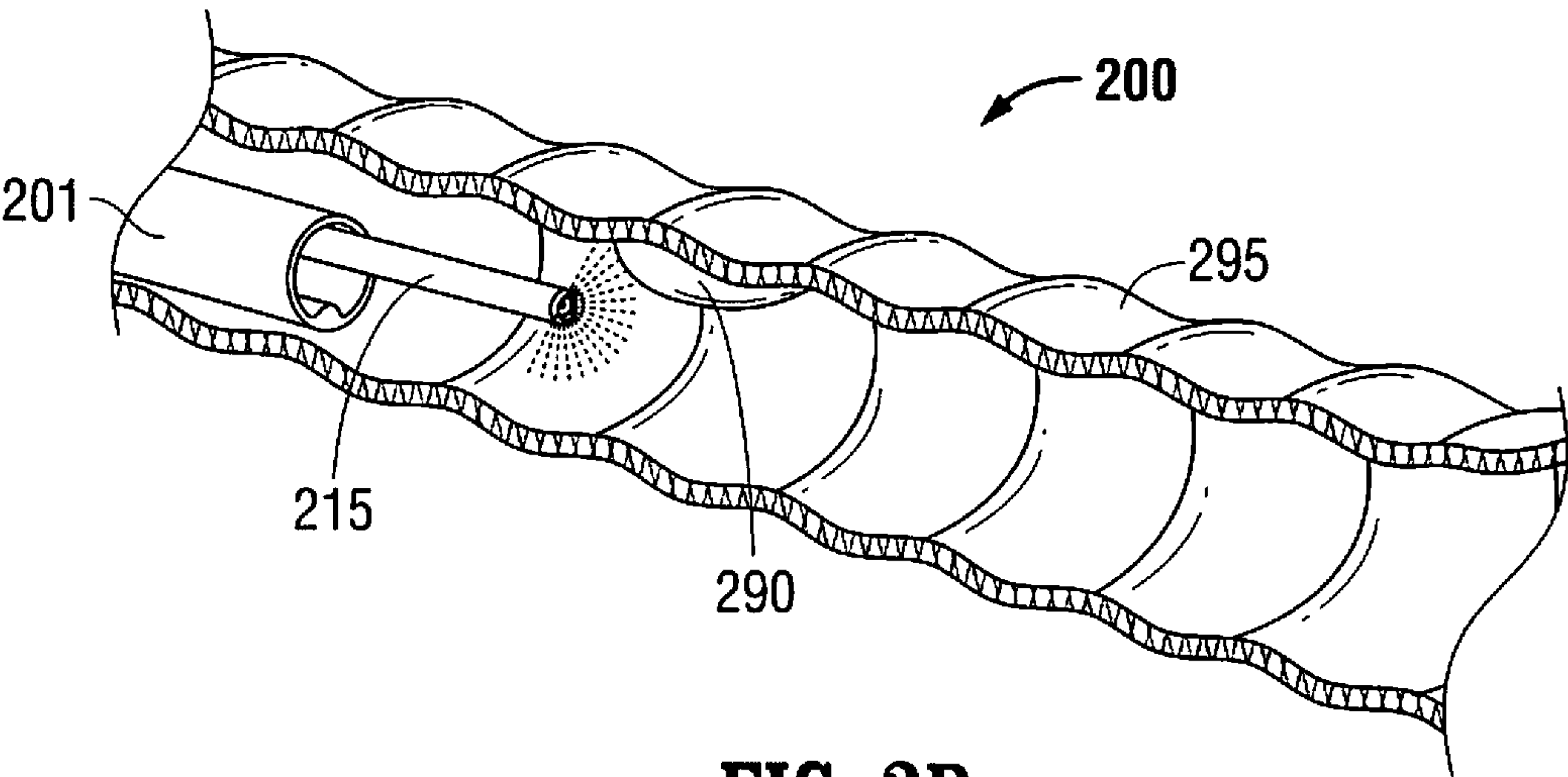


FIG. 2B

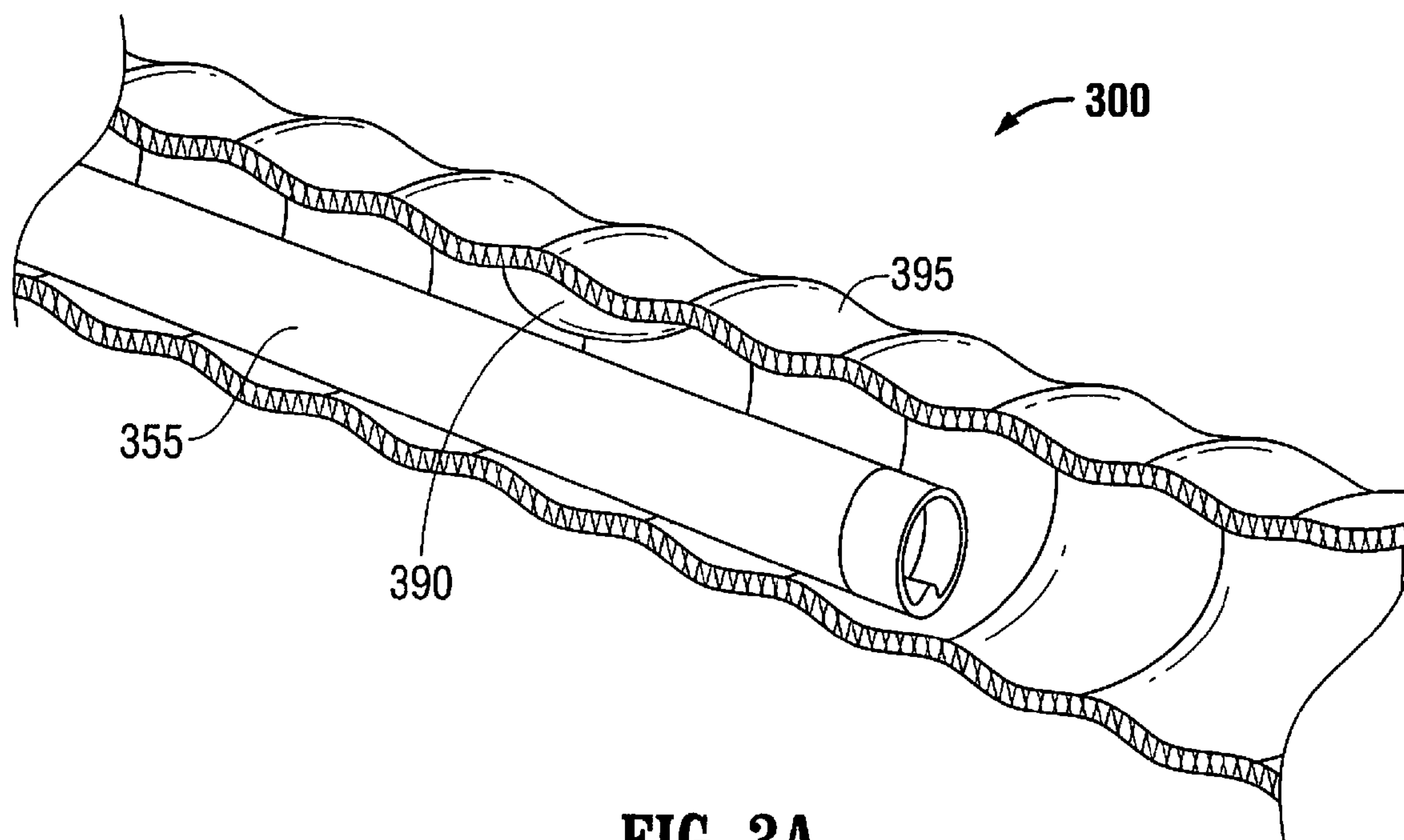


FIG. 3A

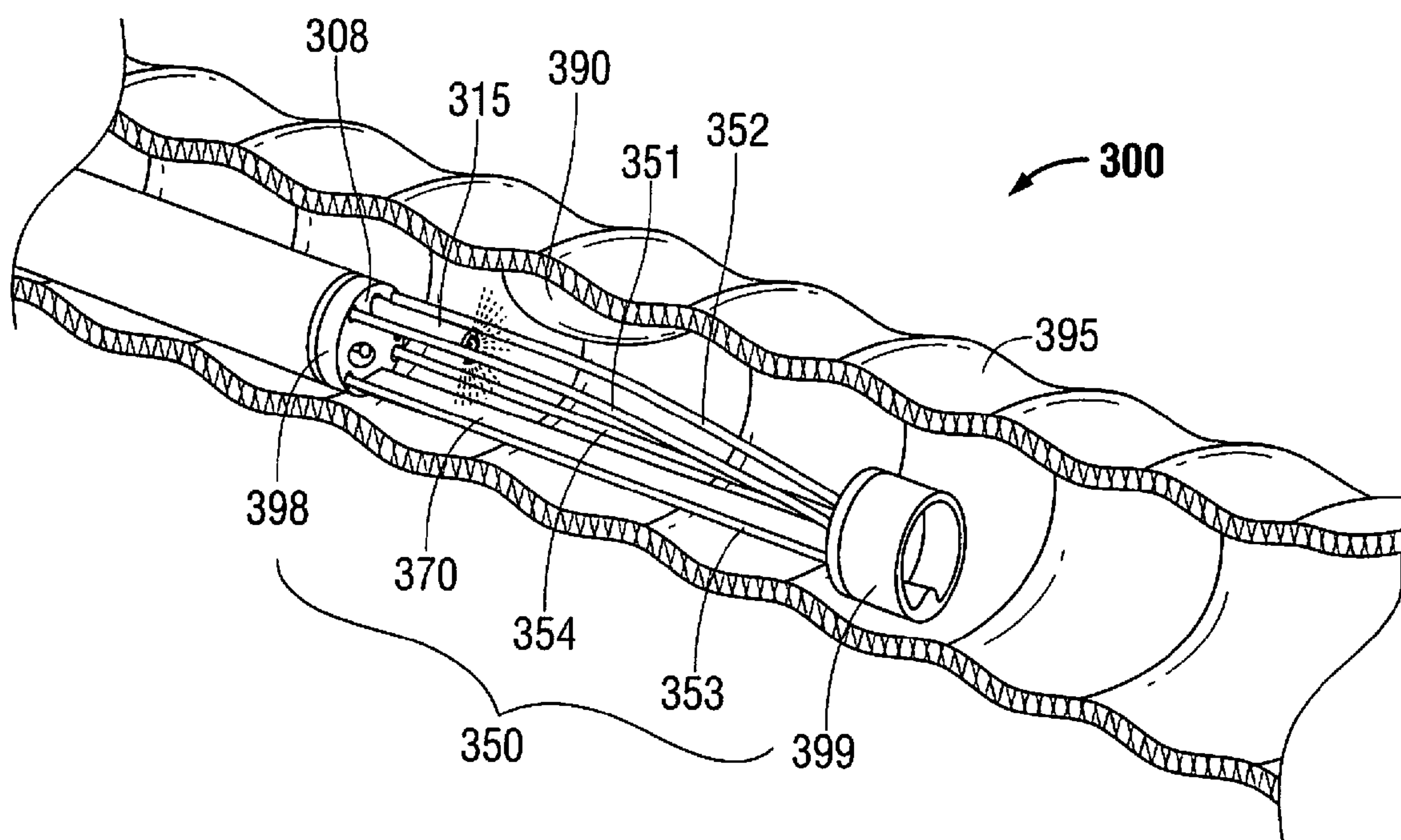


FIG. 3B

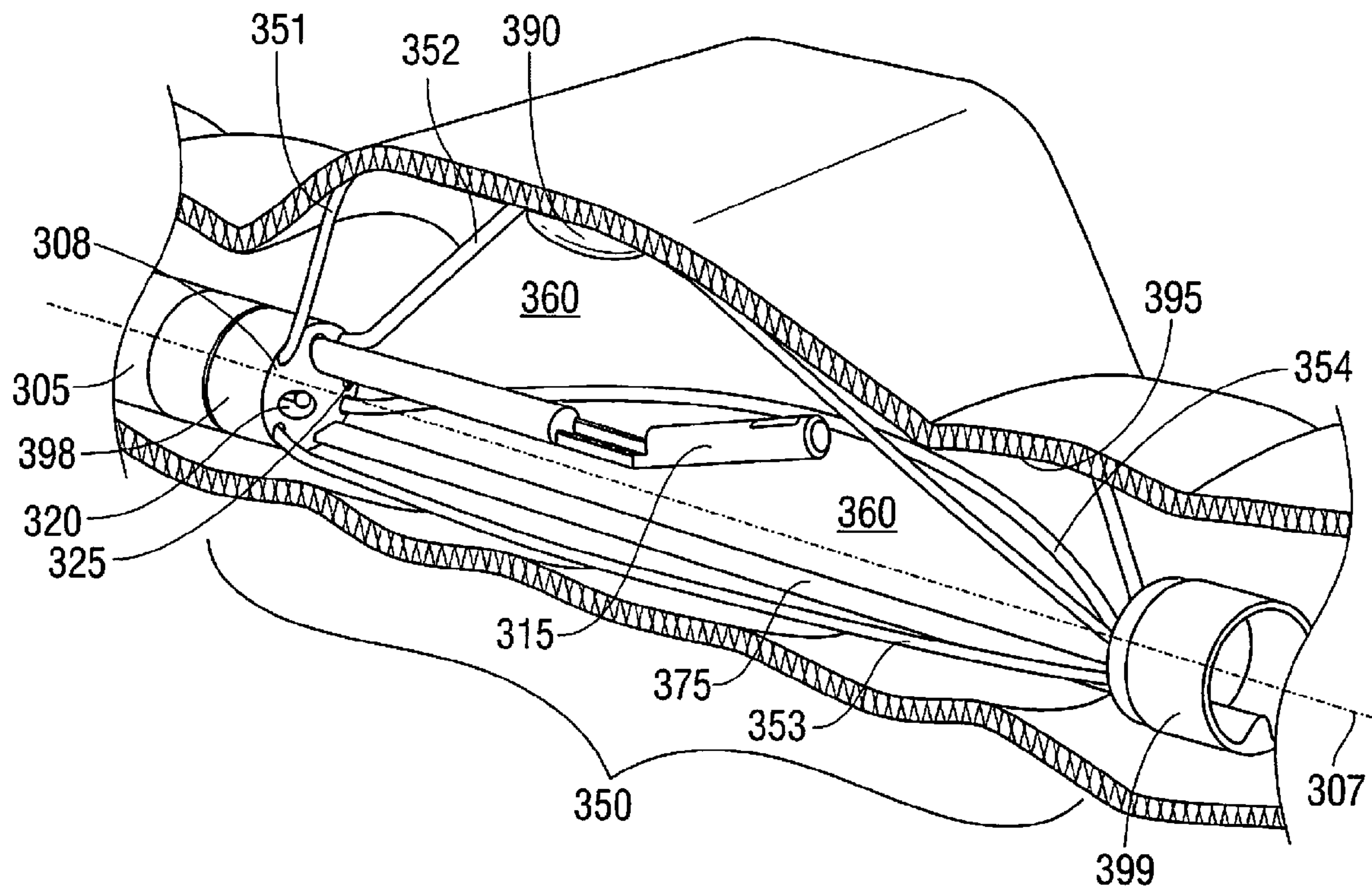


FIG. 3C

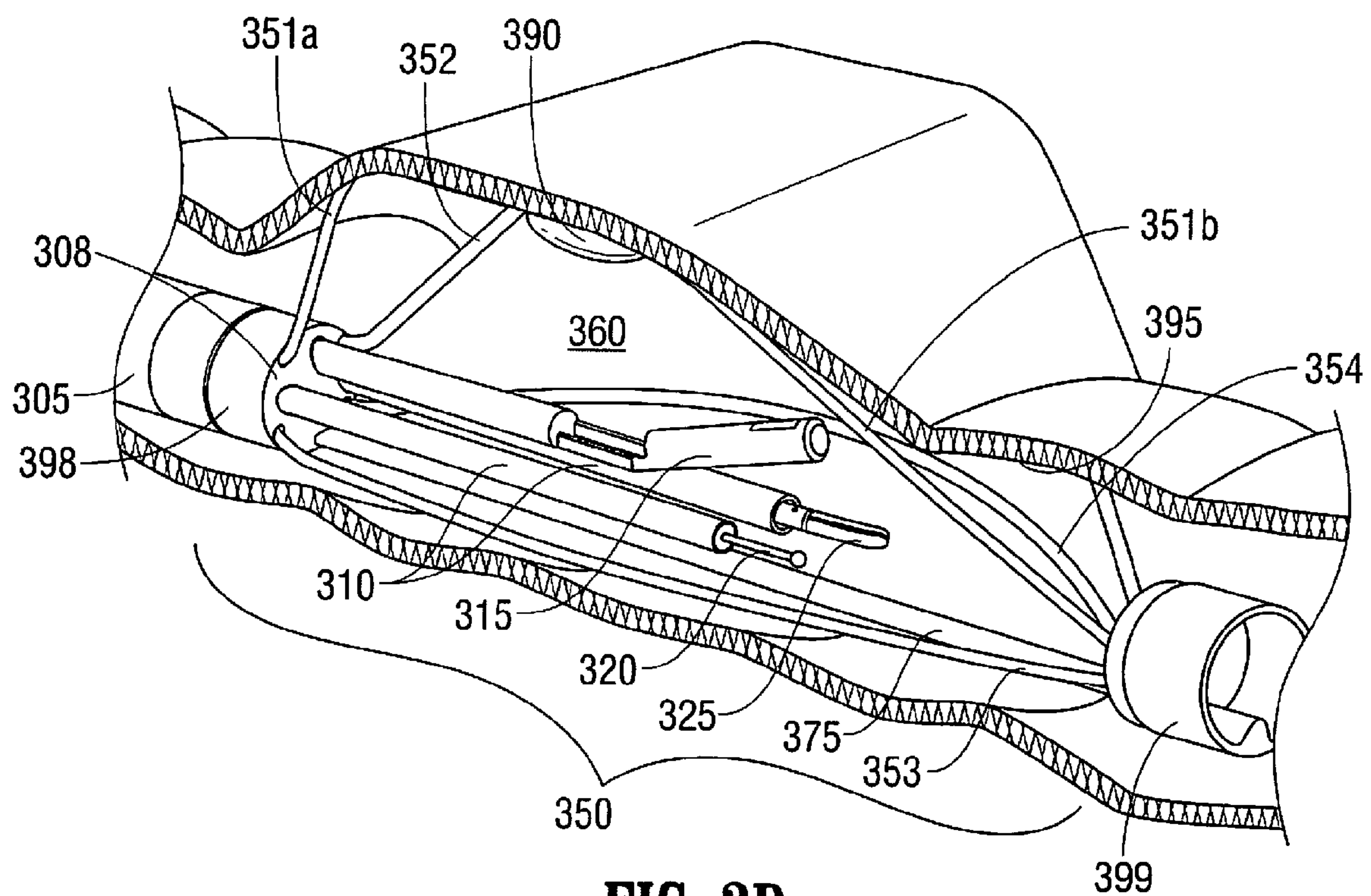


FIG. 3D

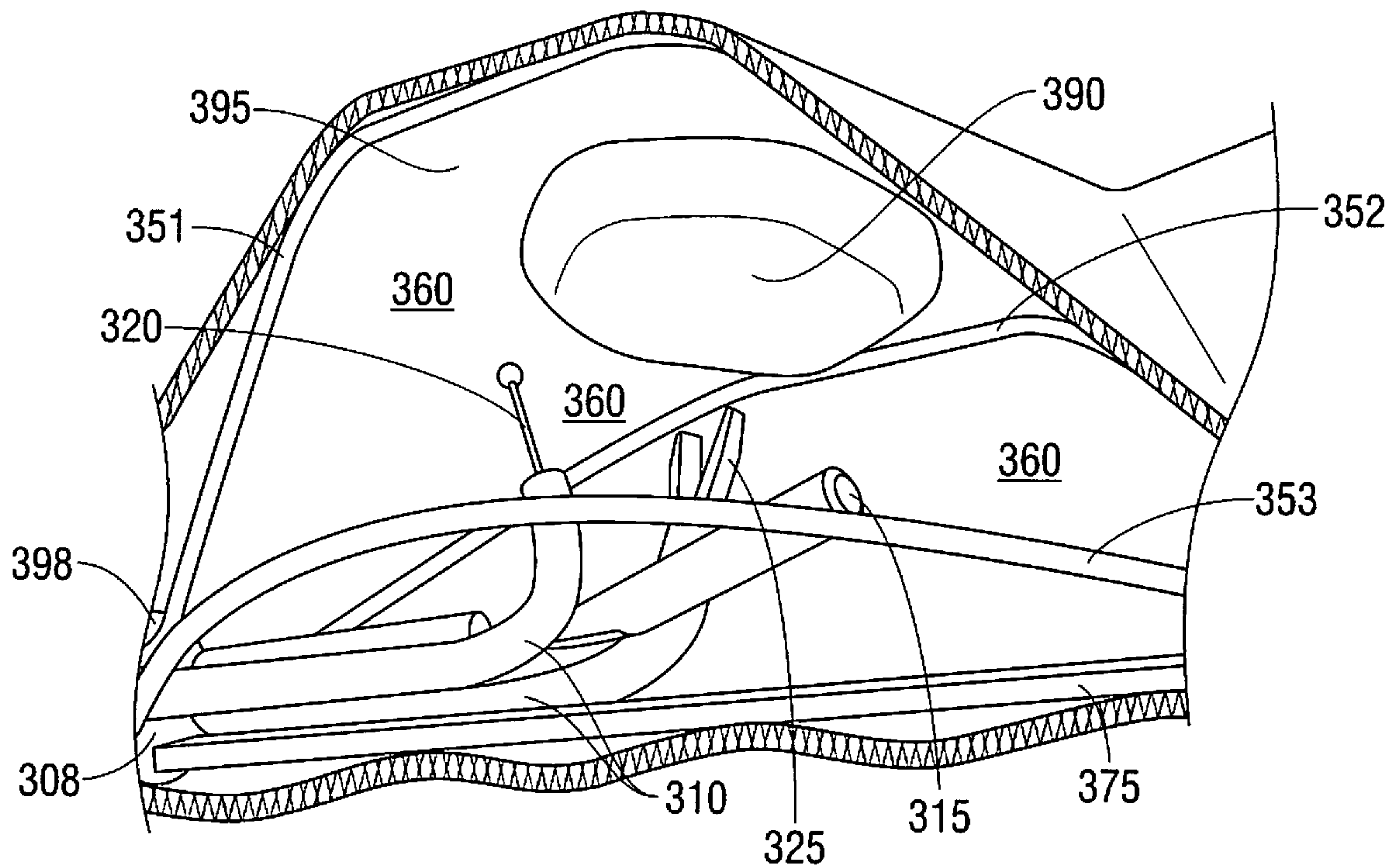


FIG. 3E

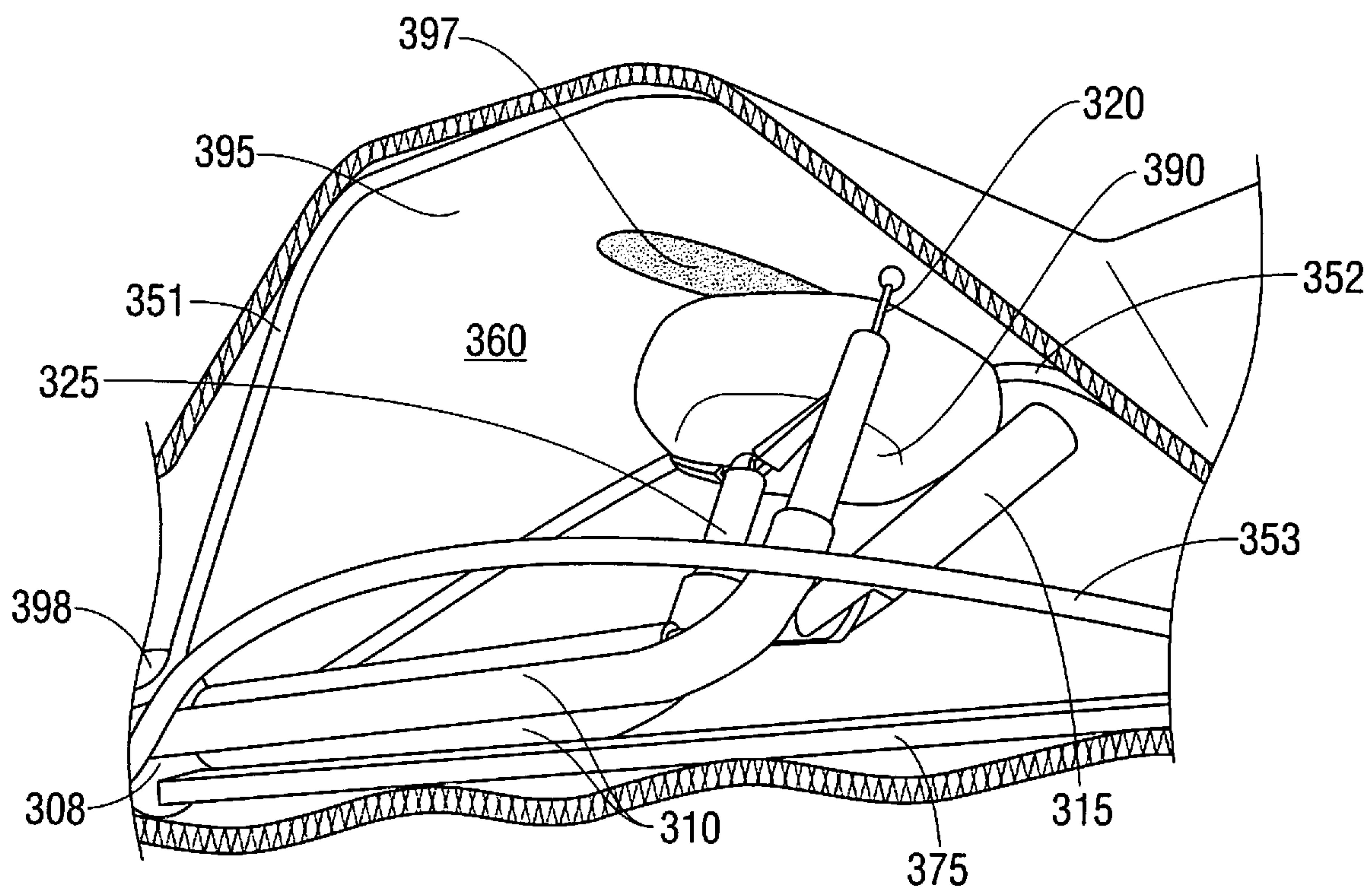


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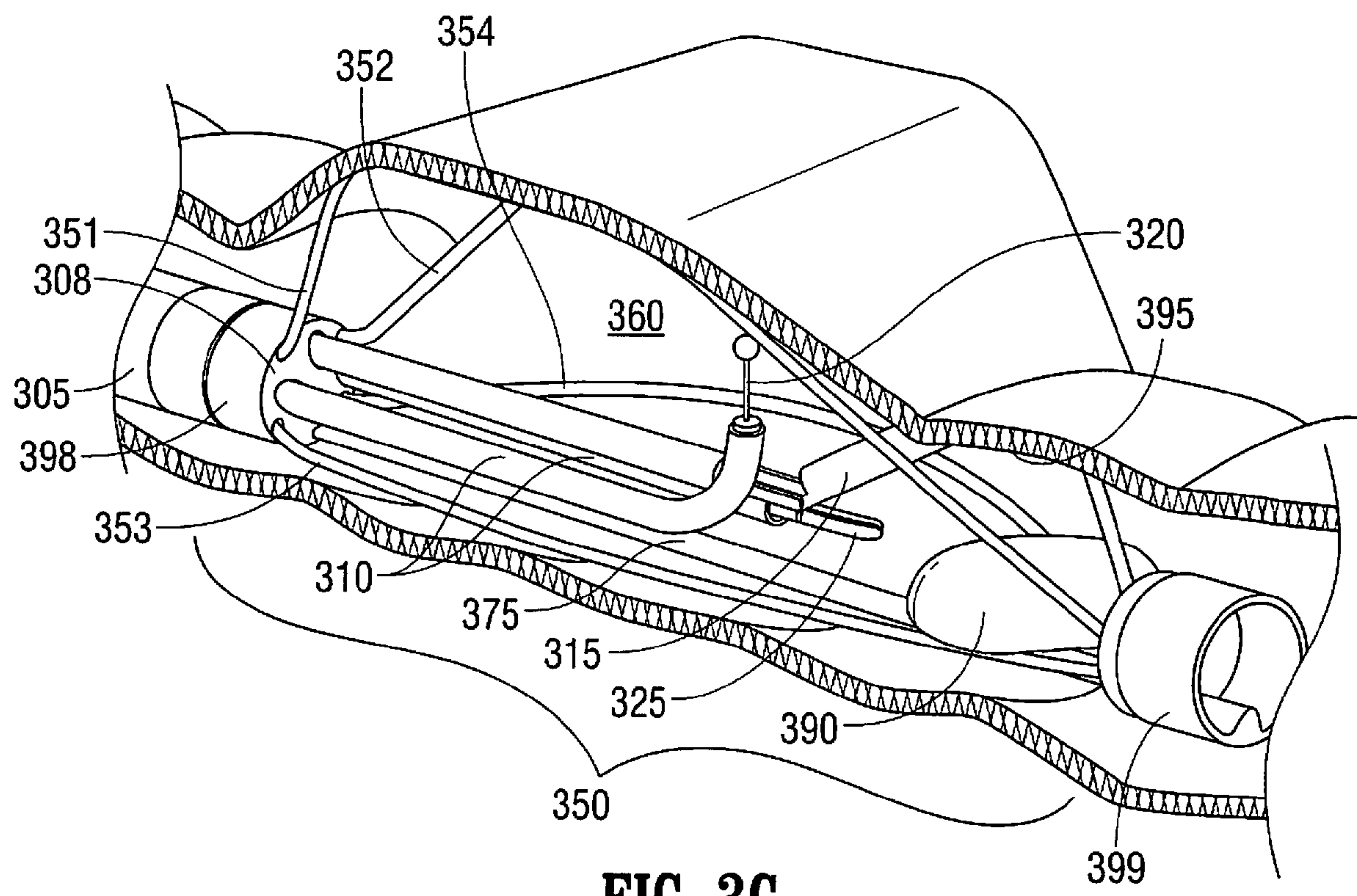


FIG. 3G

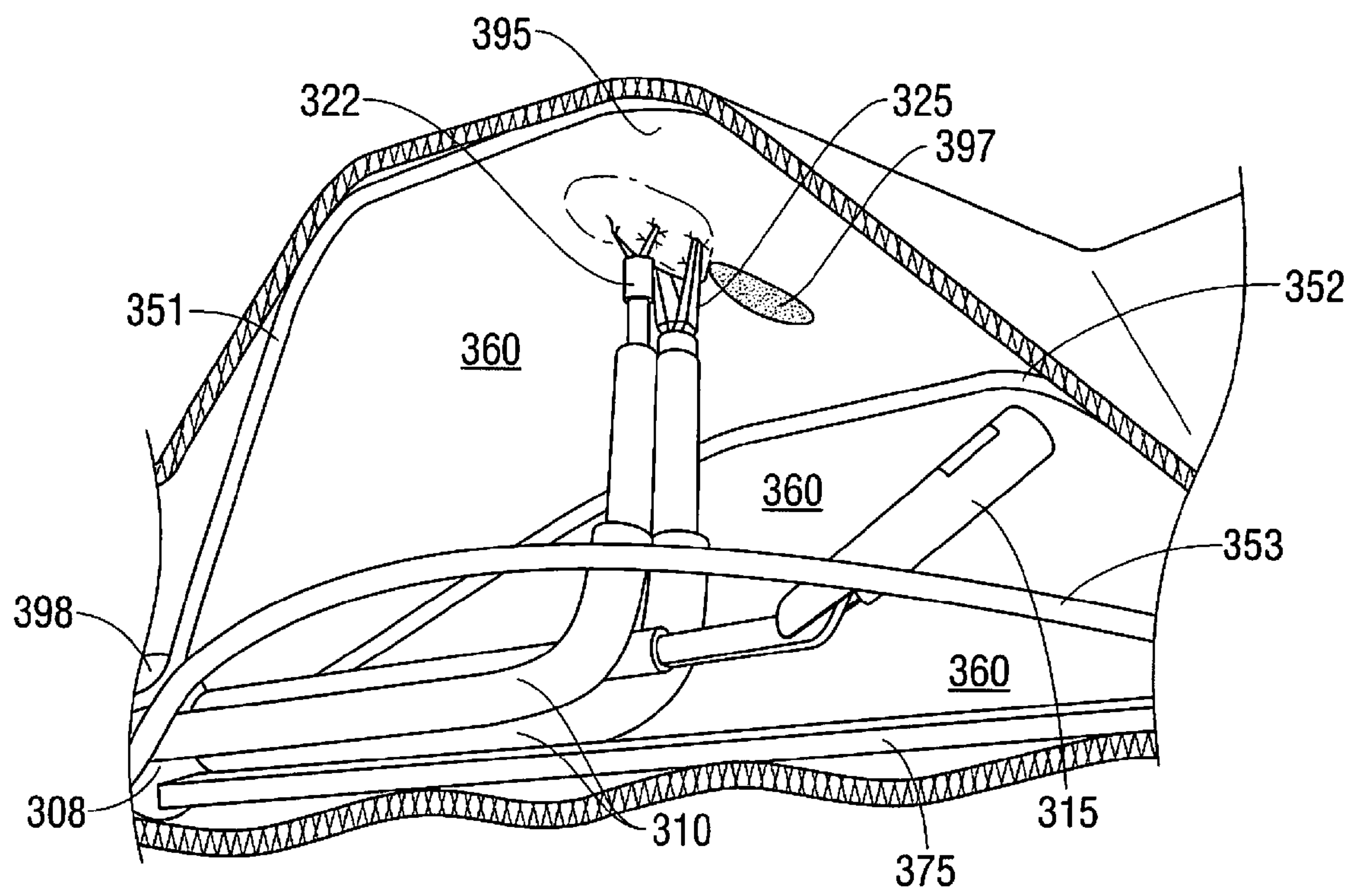


FIG. 3H

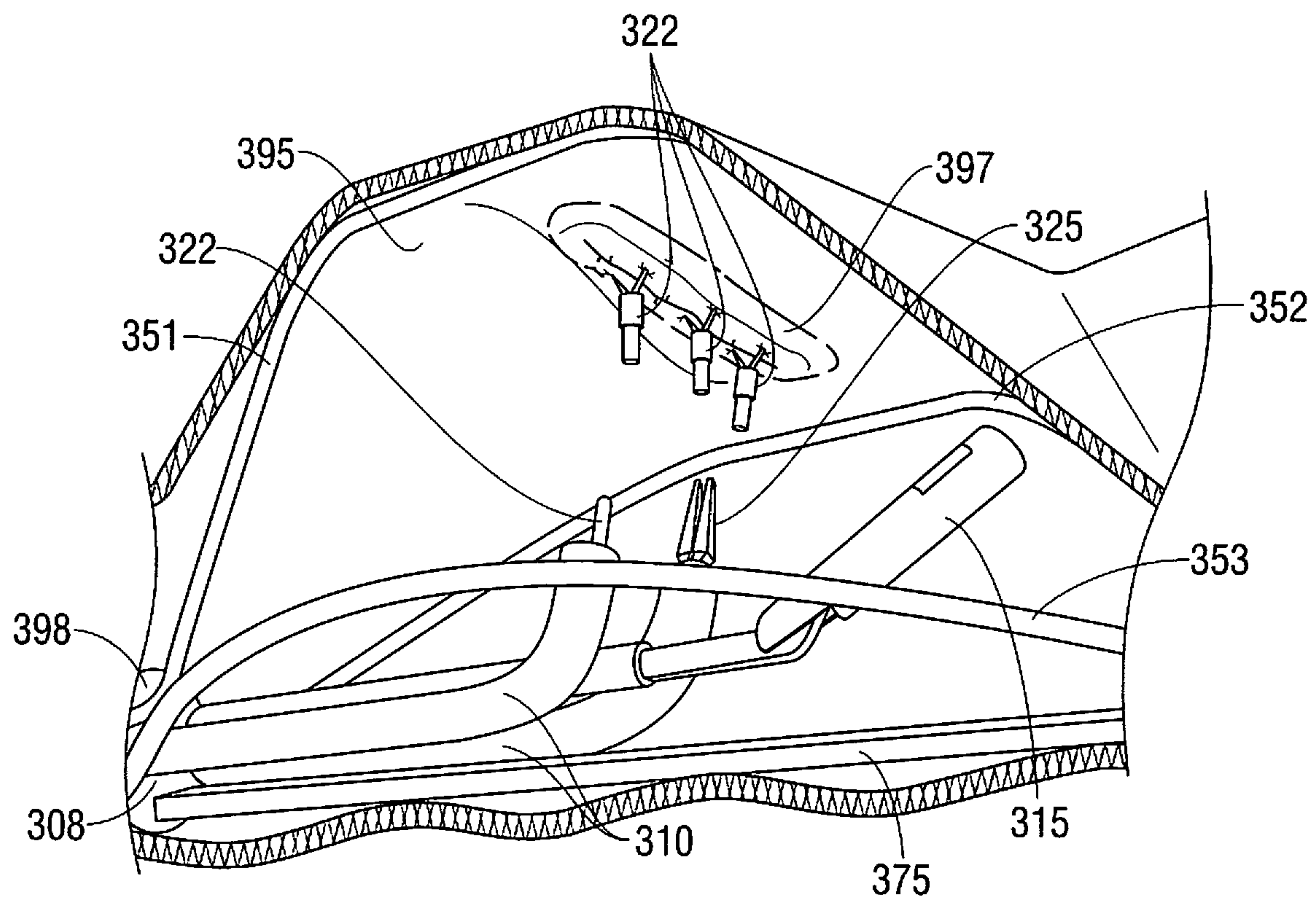


FIG. 3I

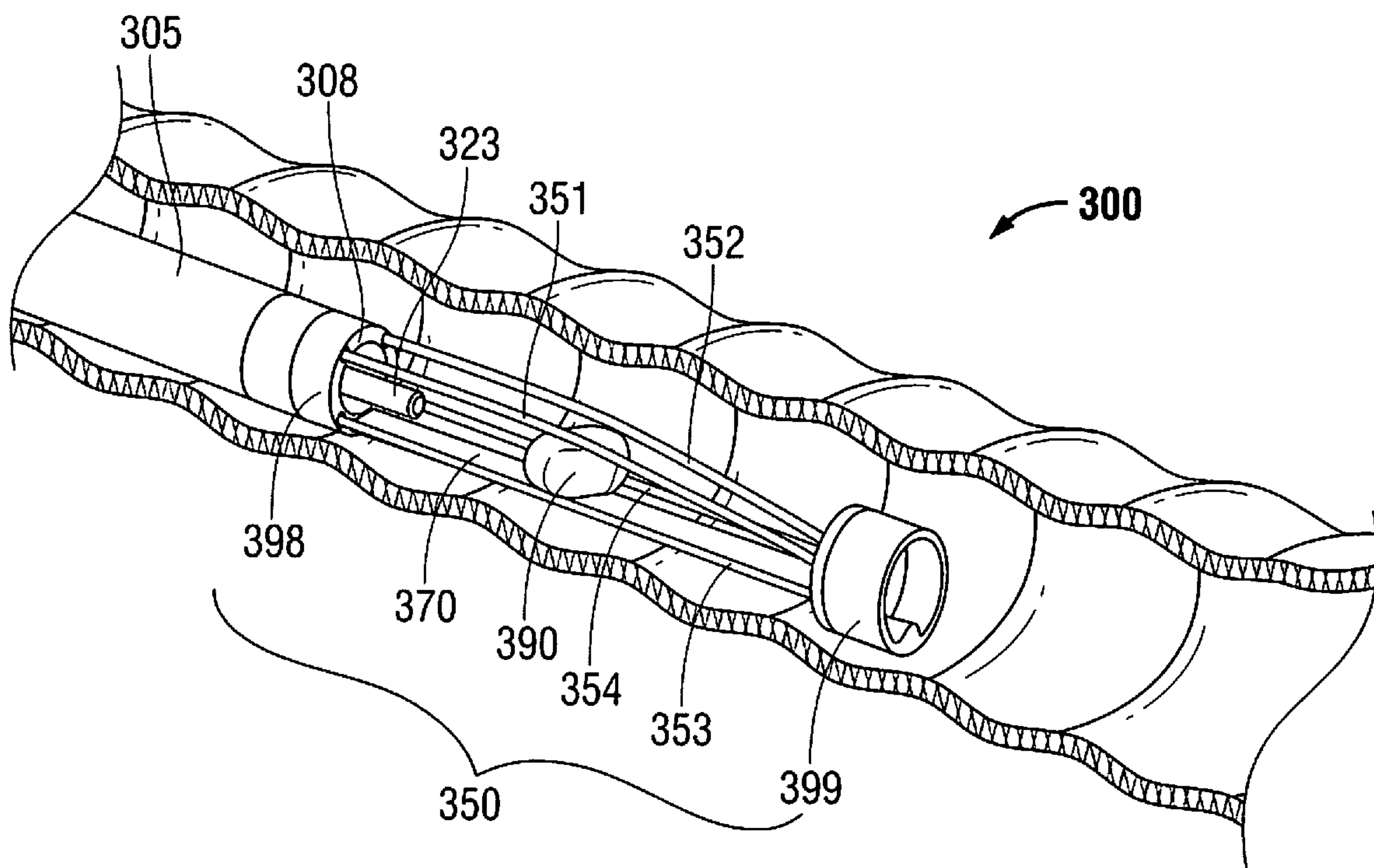


FIG. 3J

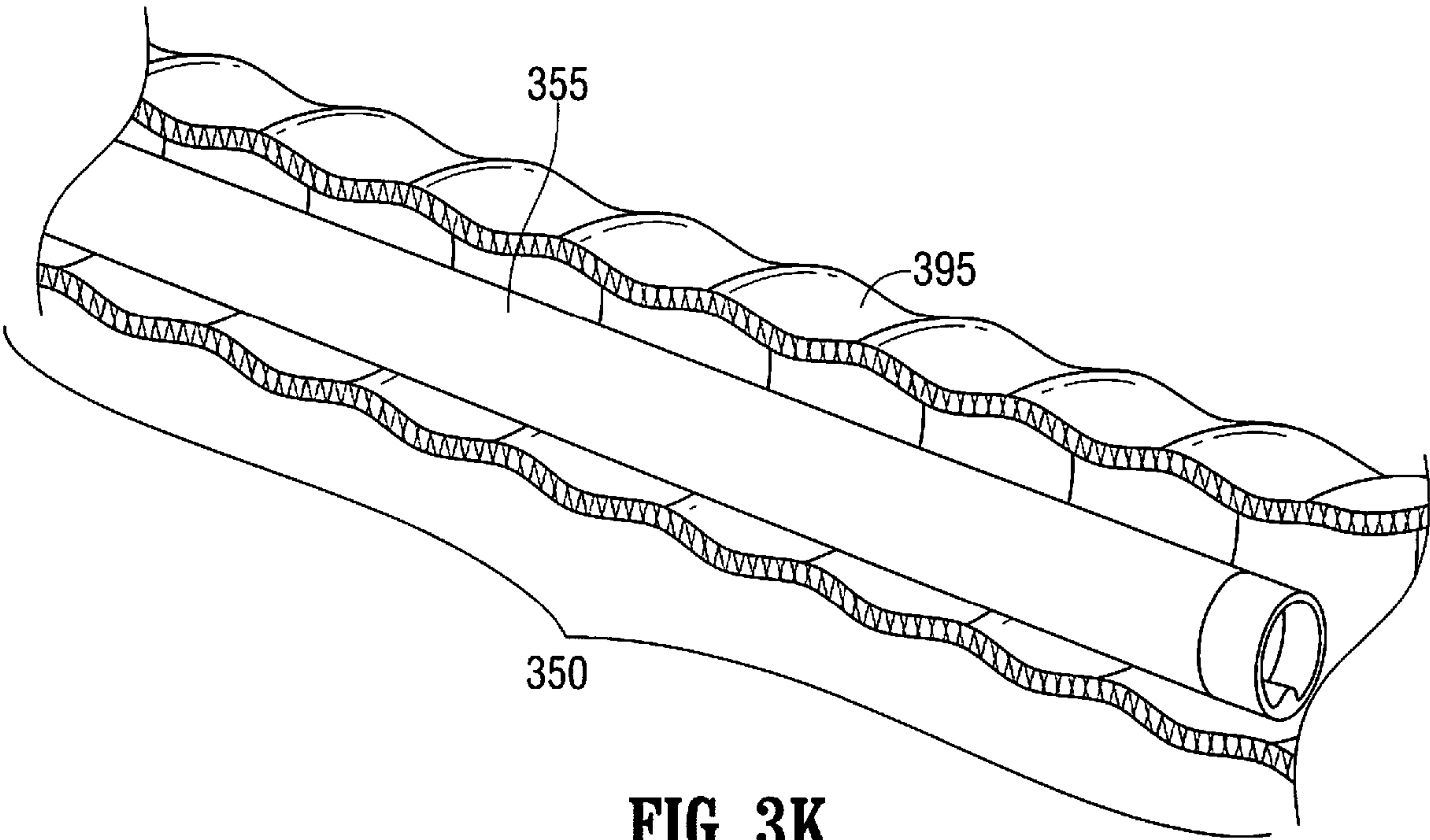


FIG. 3K

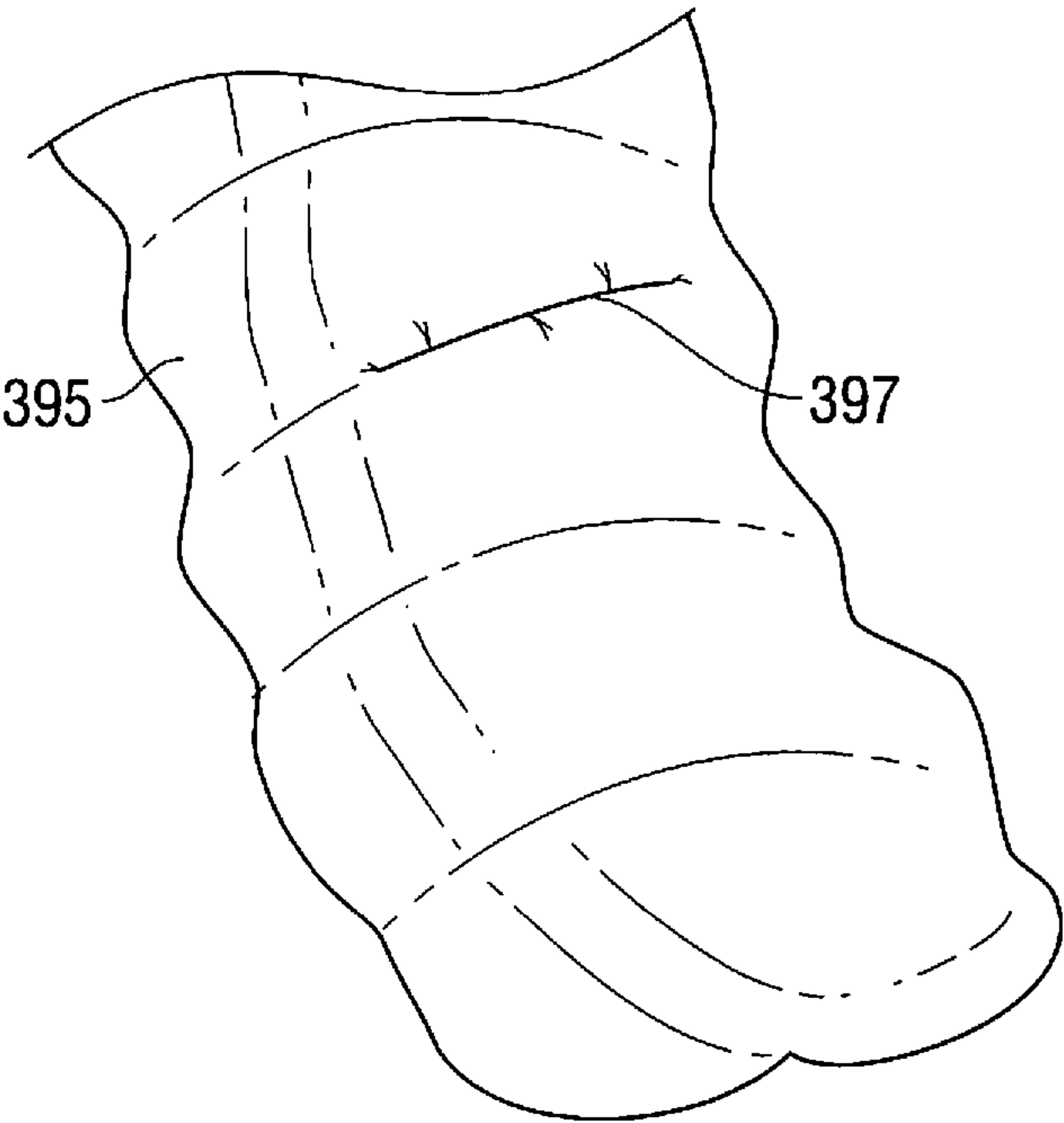


FIG. 3L

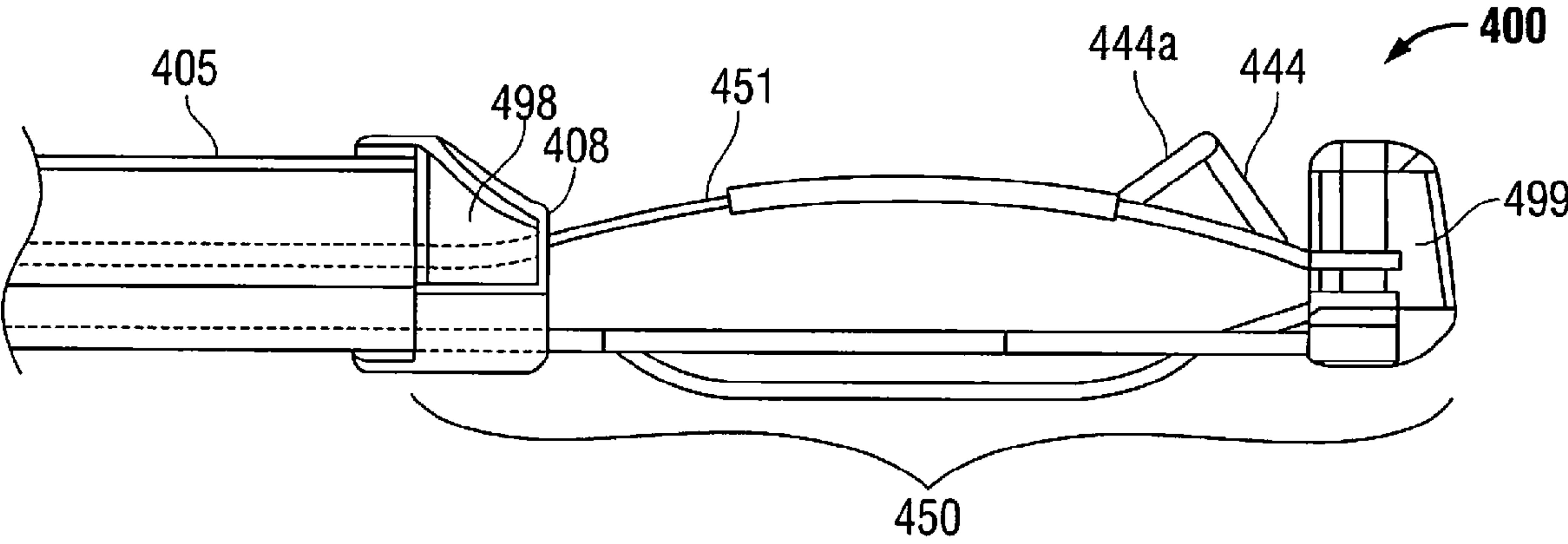


FIG. 4A

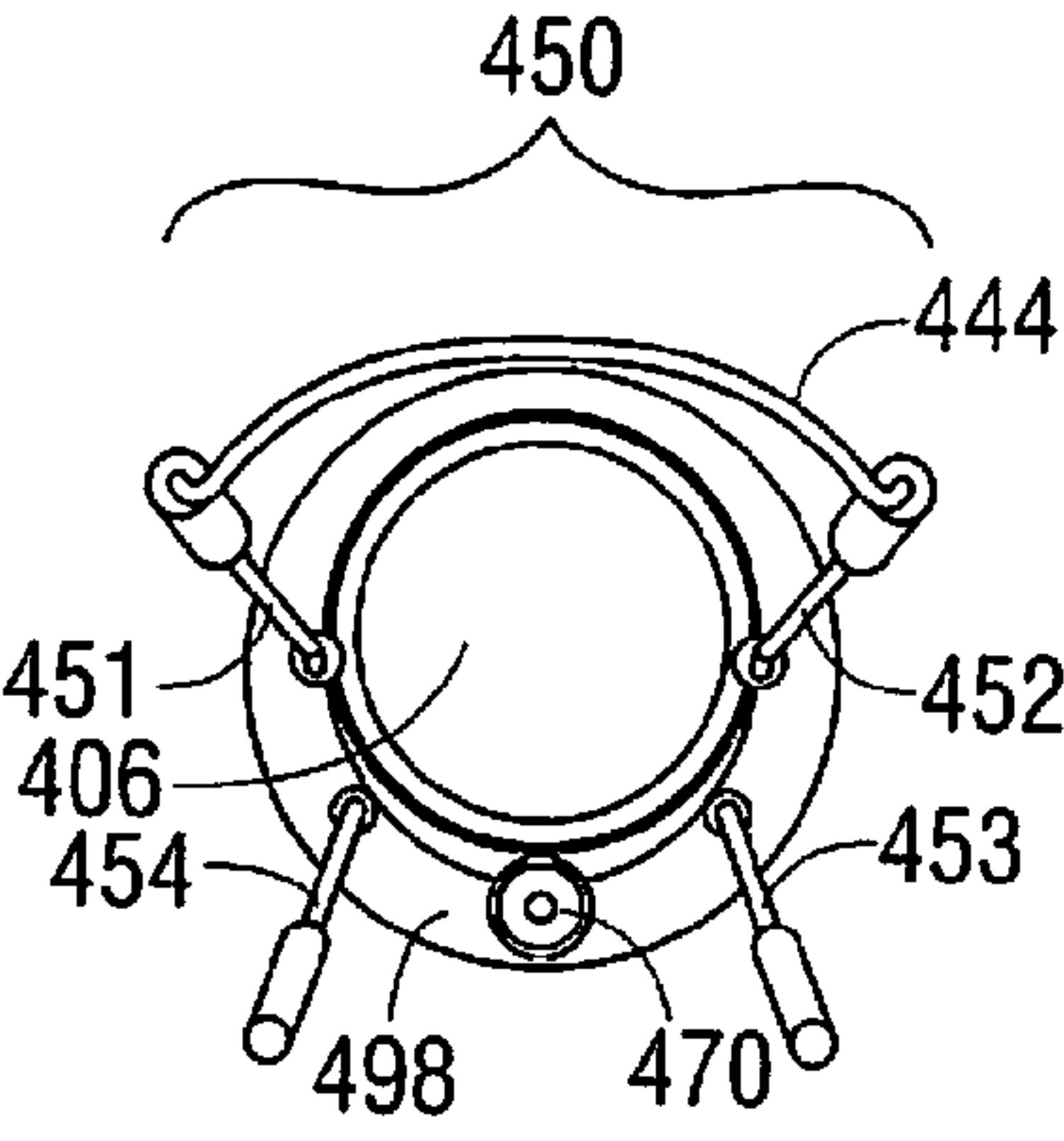


FIG. 4B

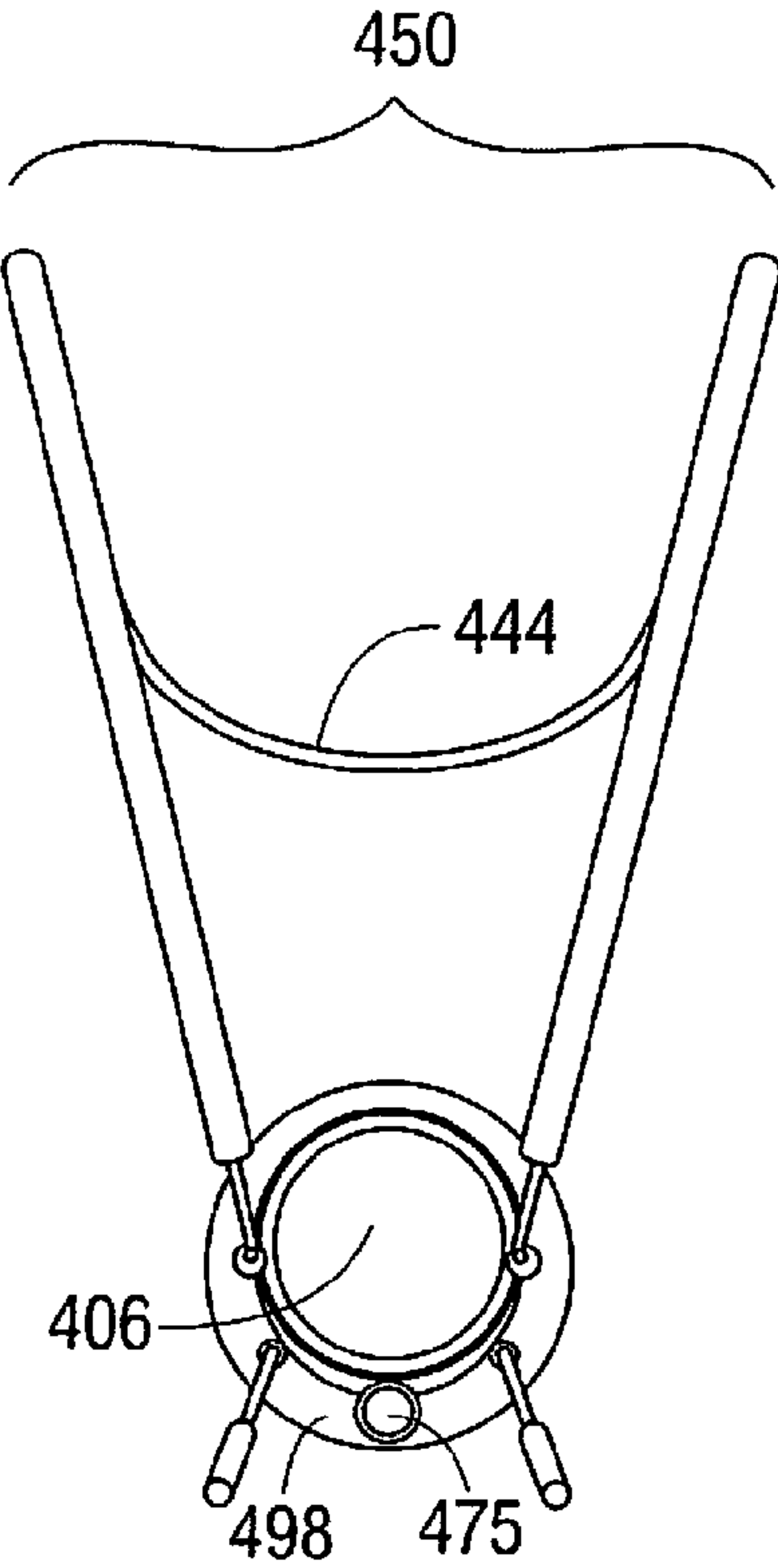


FIG. 4C

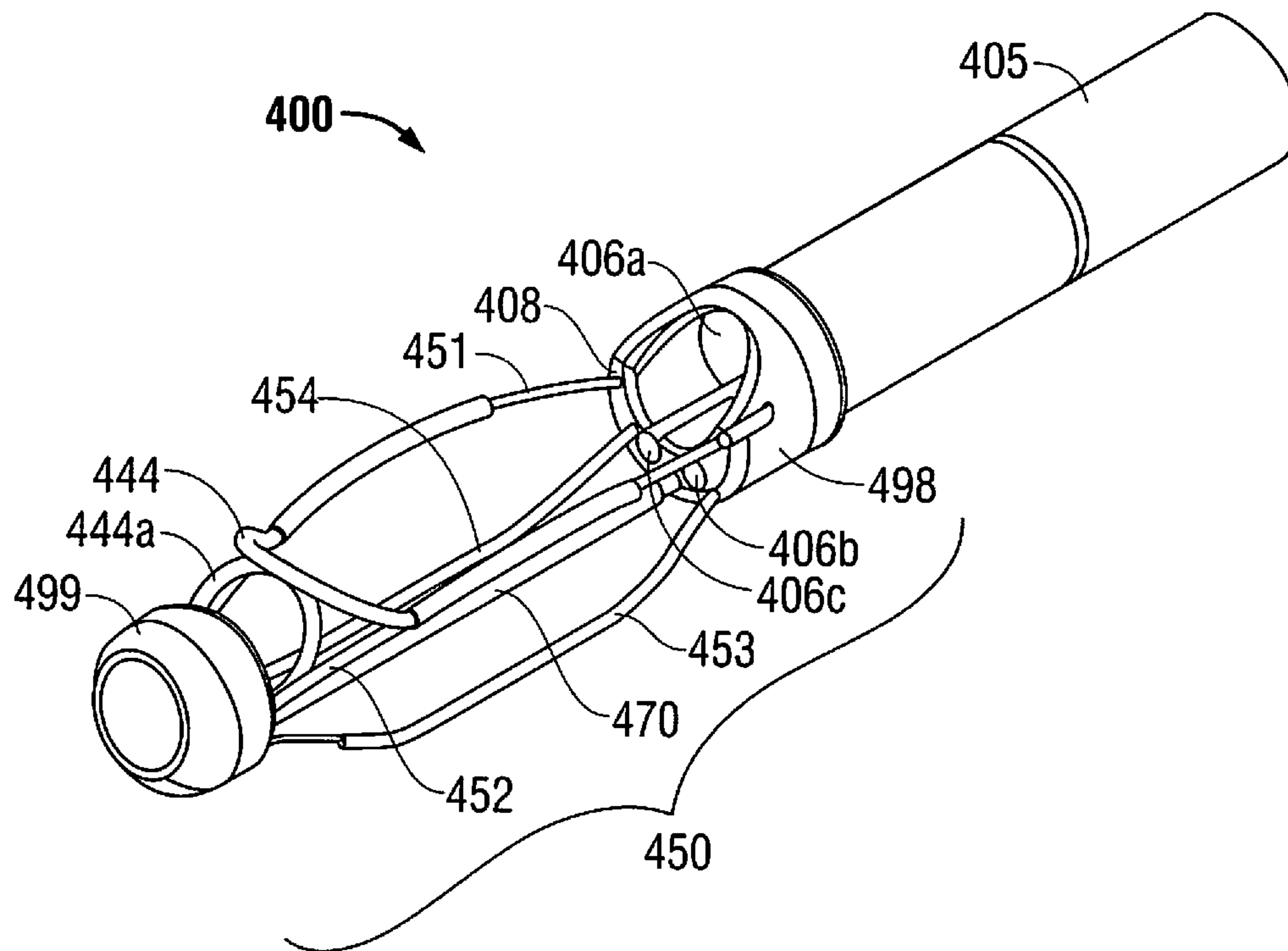


FIG. 4D

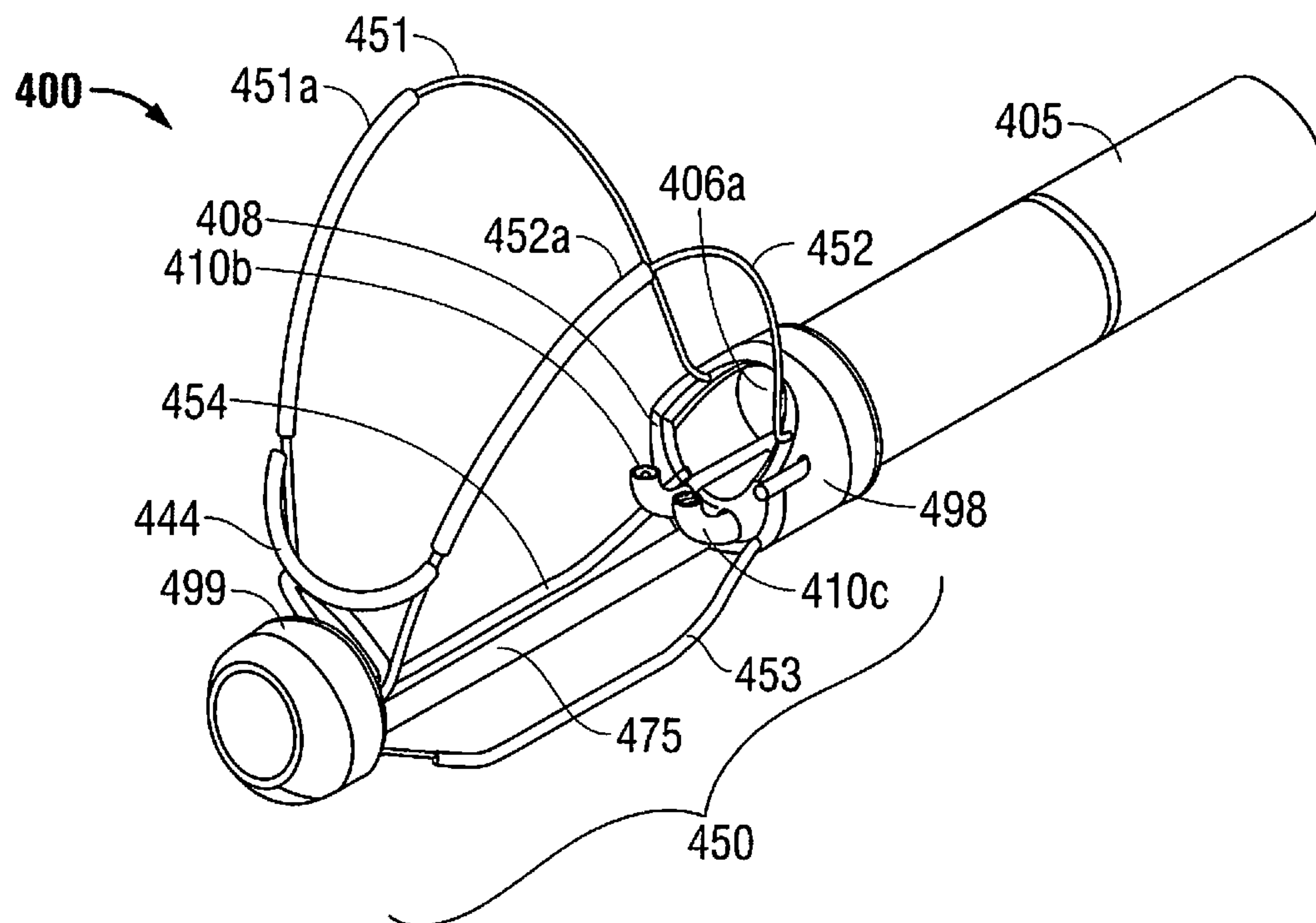


FIG. 4E

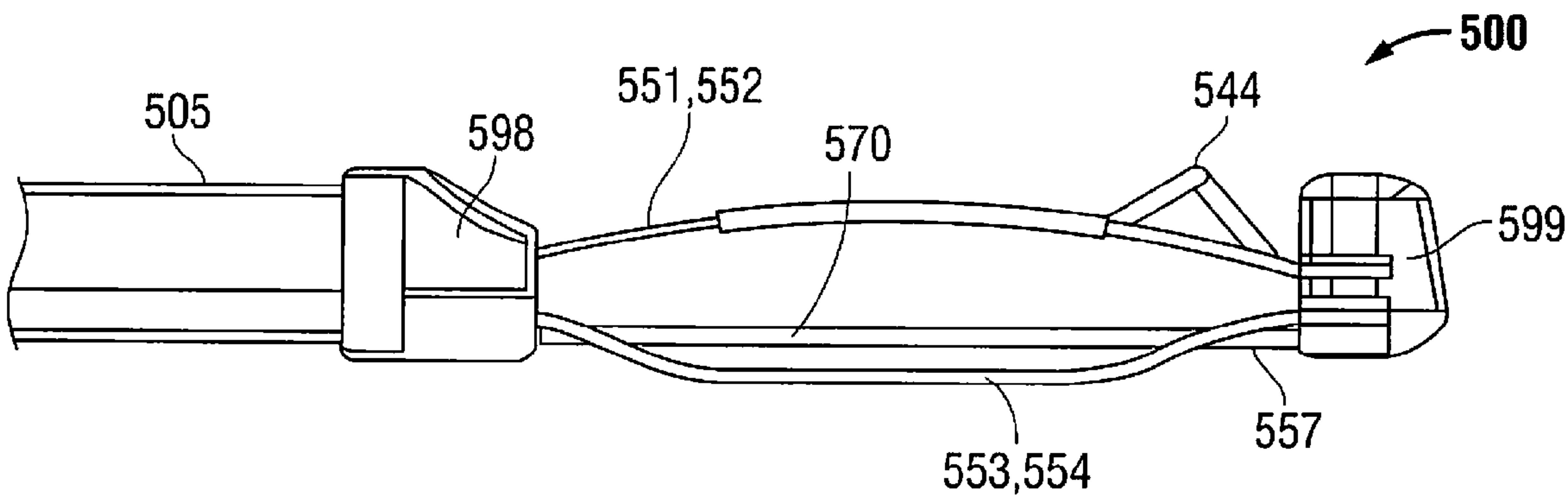


FIG. 5A

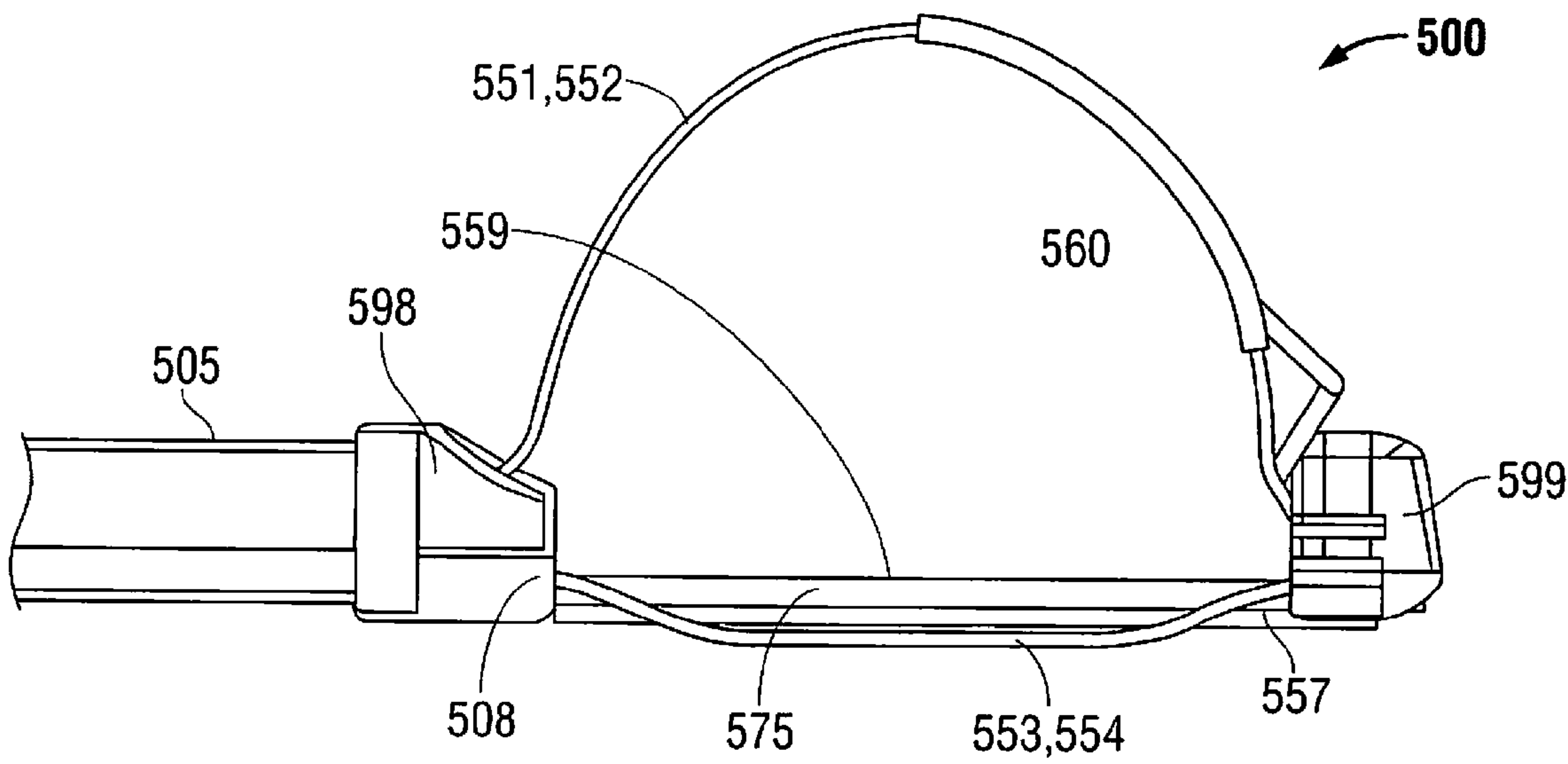


FIG. 5B

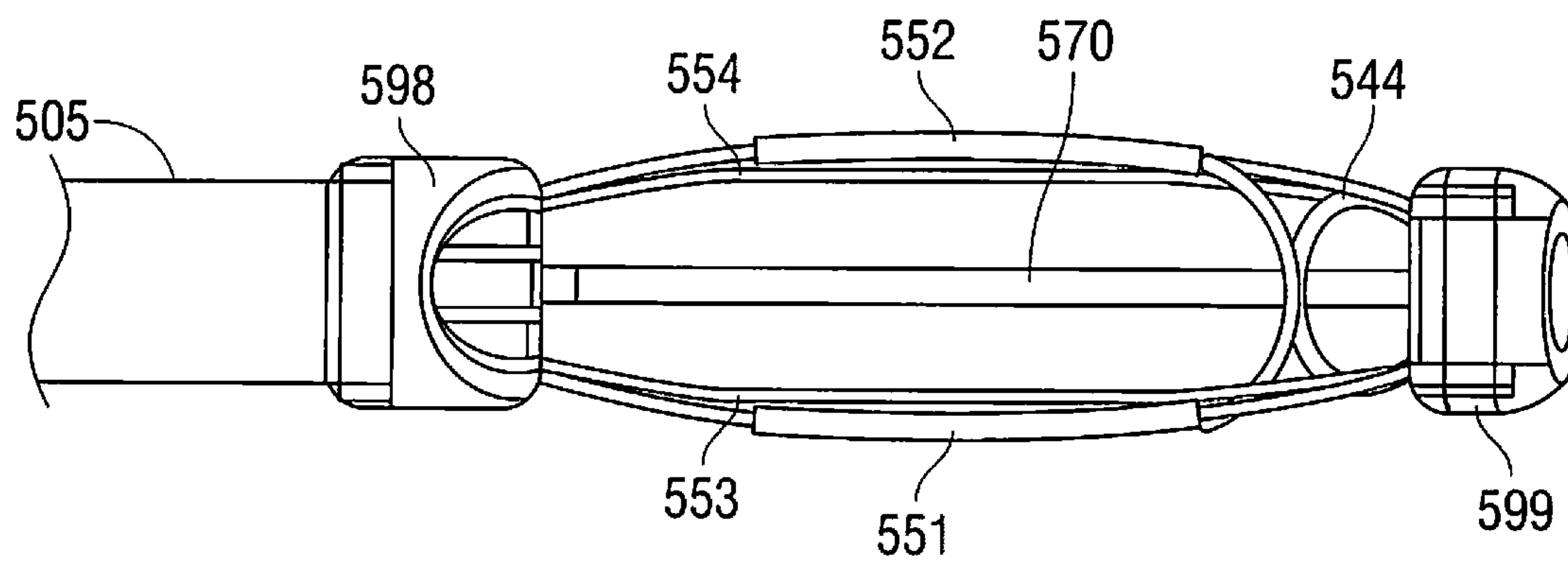


FIG. 5C

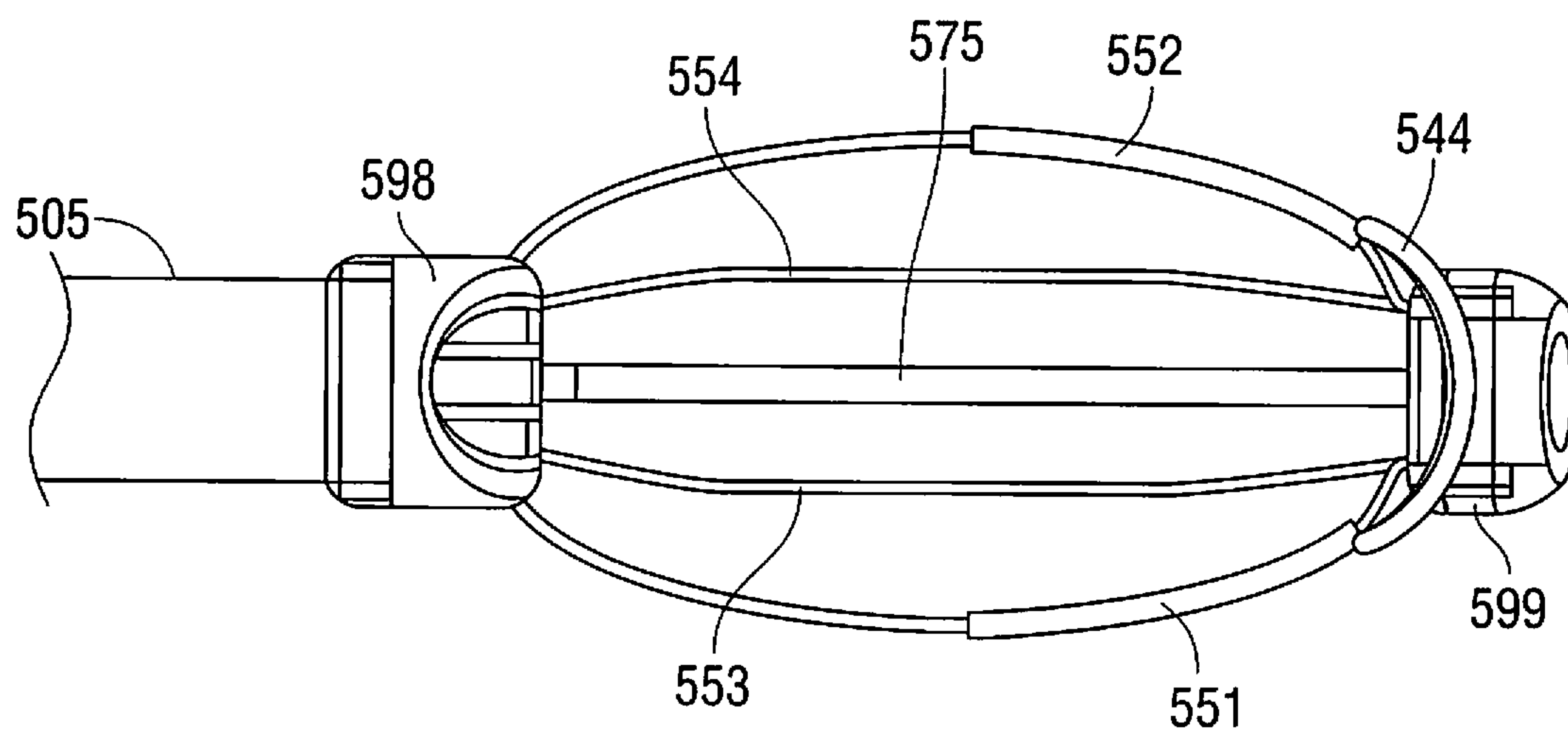


FIG. 5D

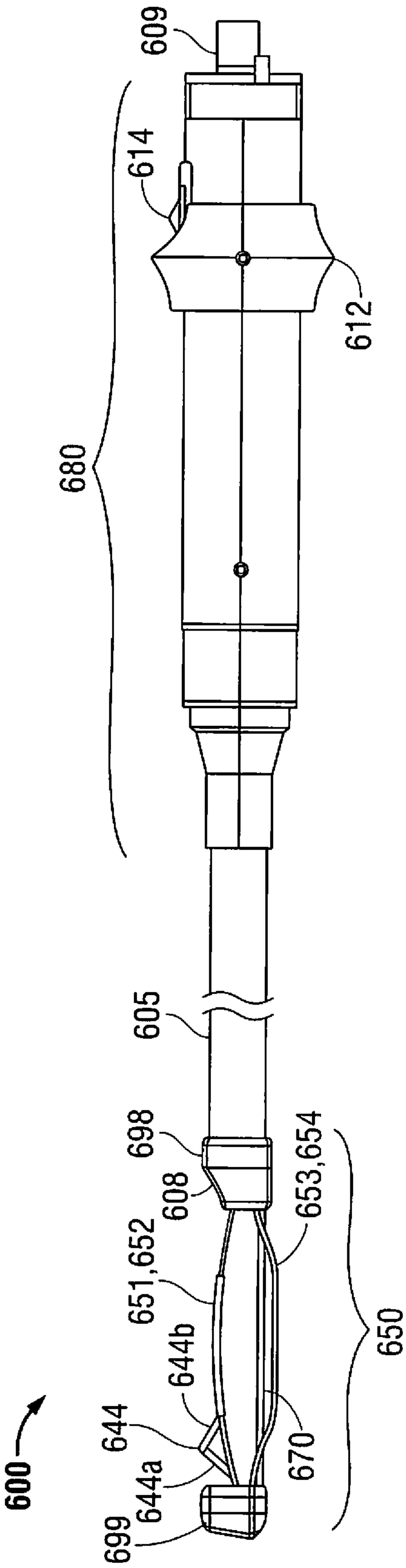


FIG. 6A

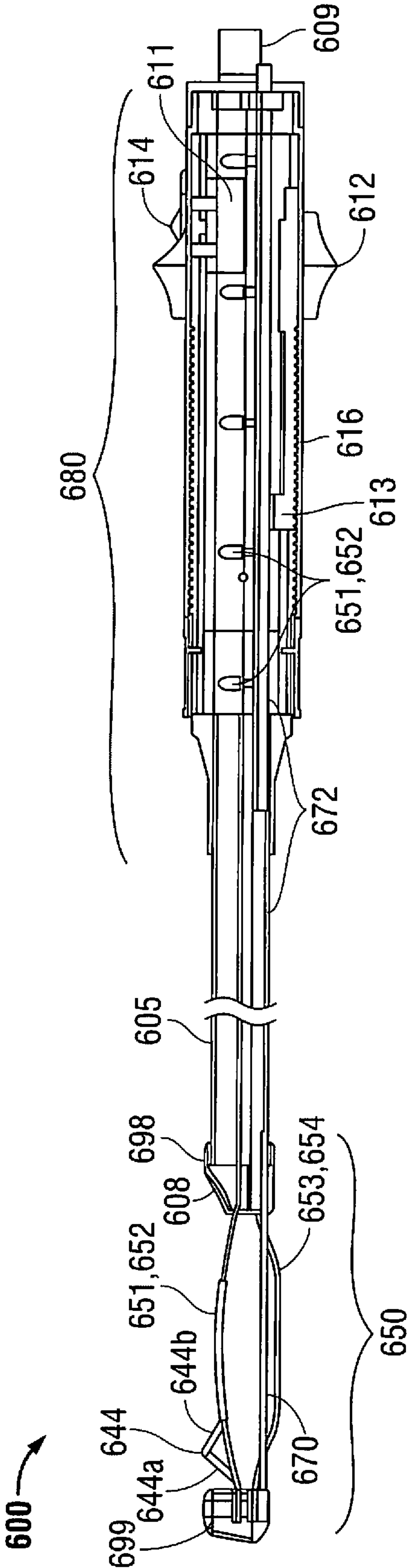


FIG. 6B

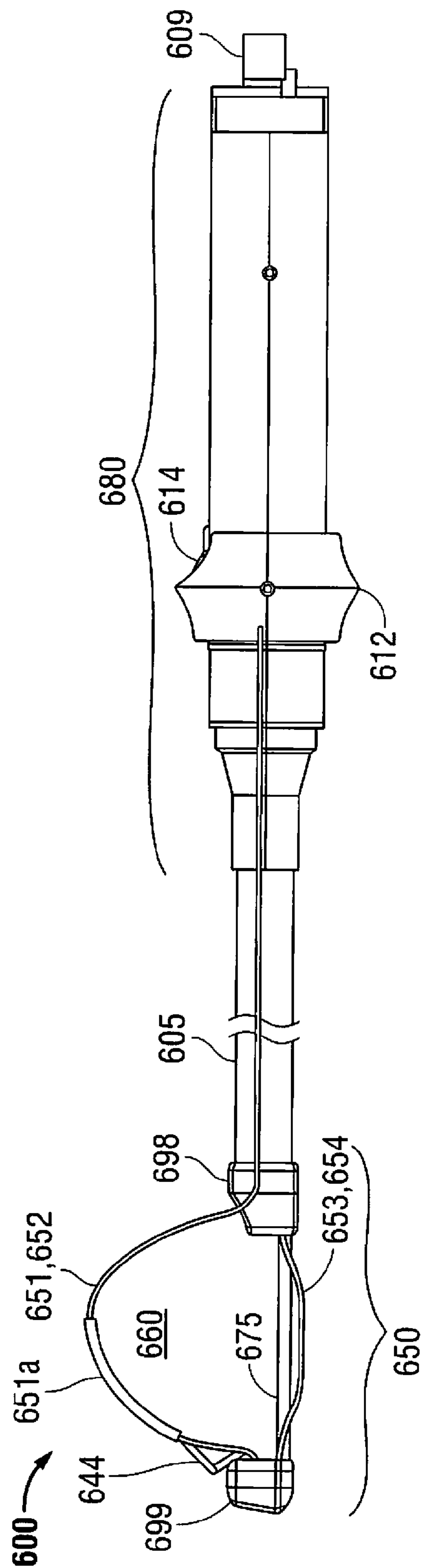


FIG. 6C

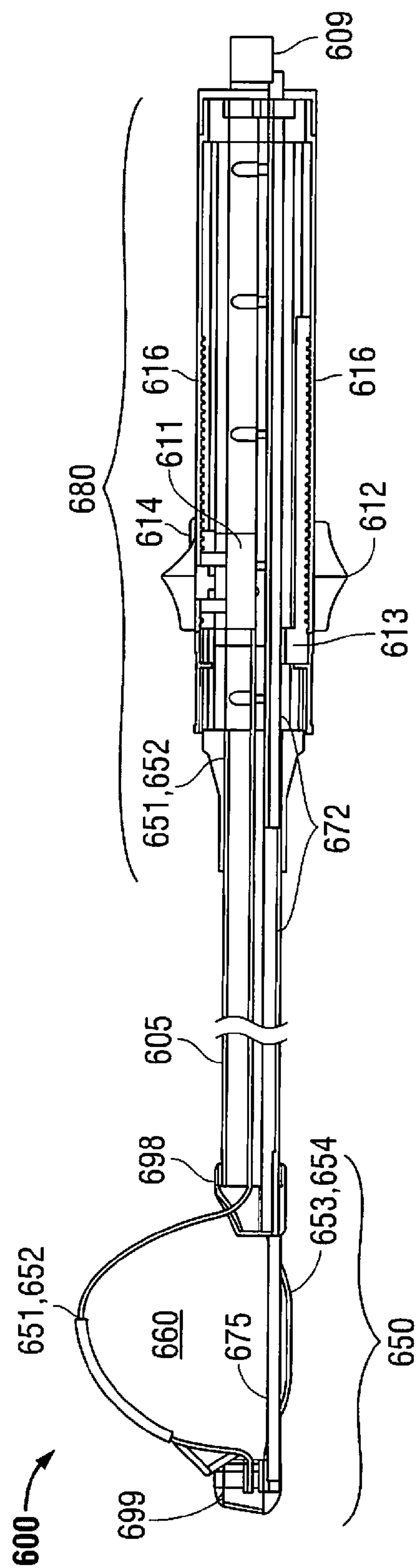


FIG. 6D

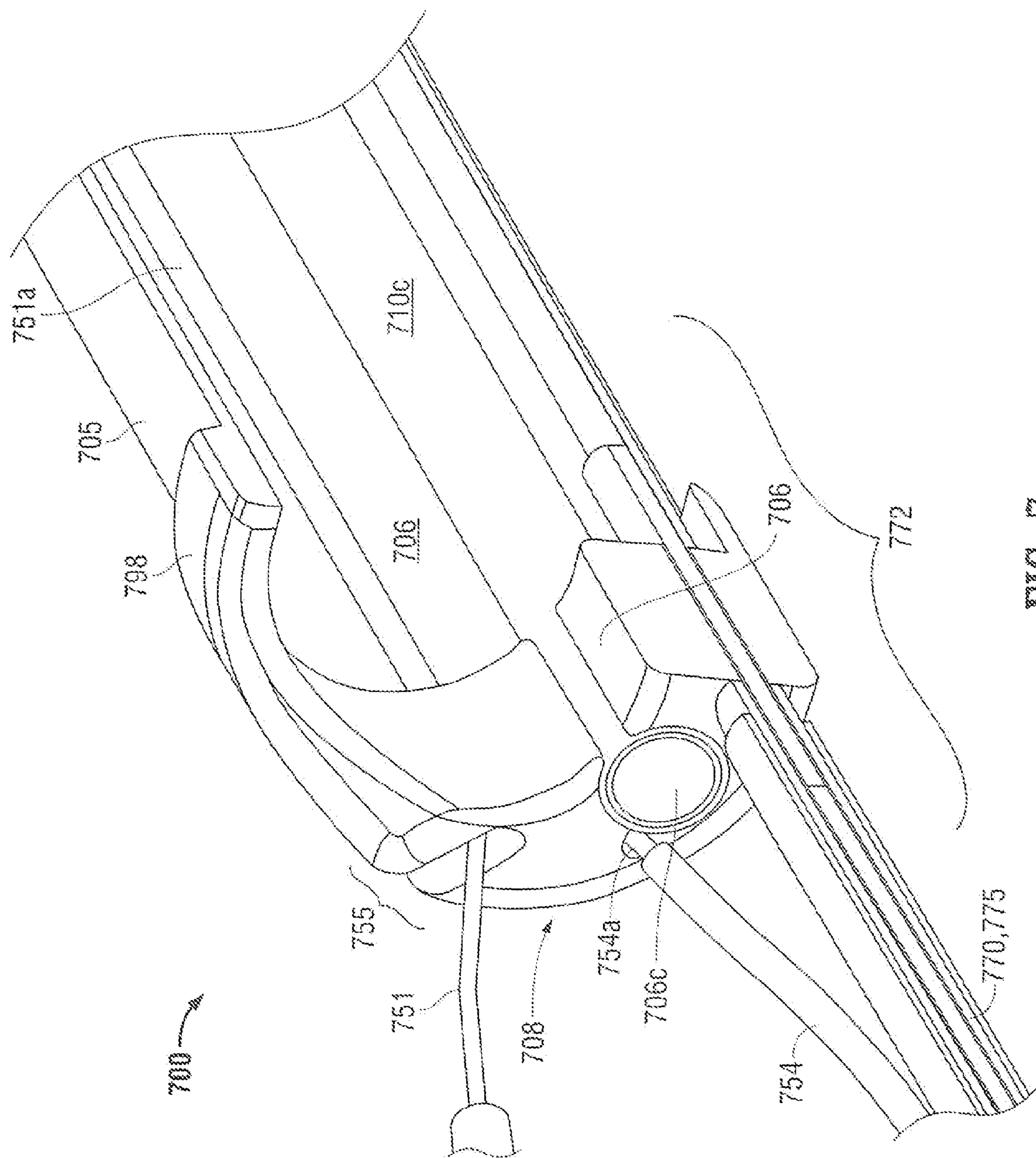


FIG. 7

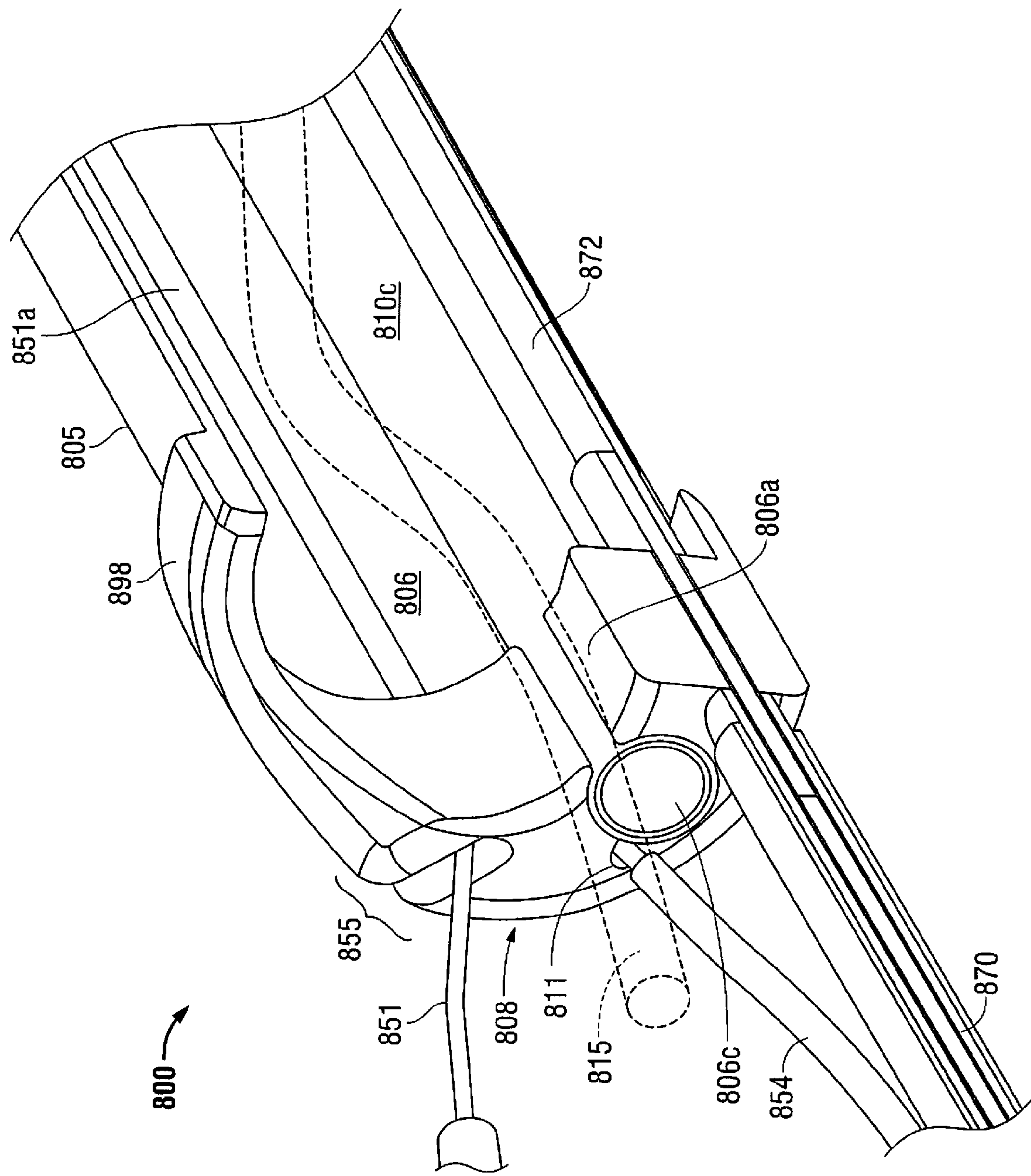


FIG. 8

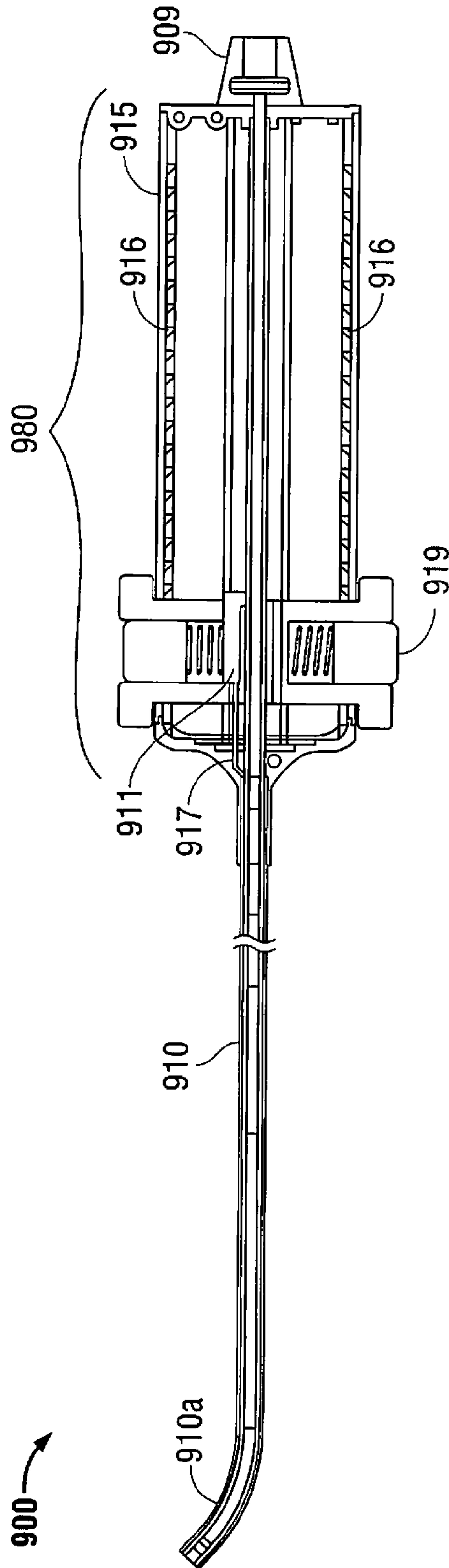


FIG. 9A

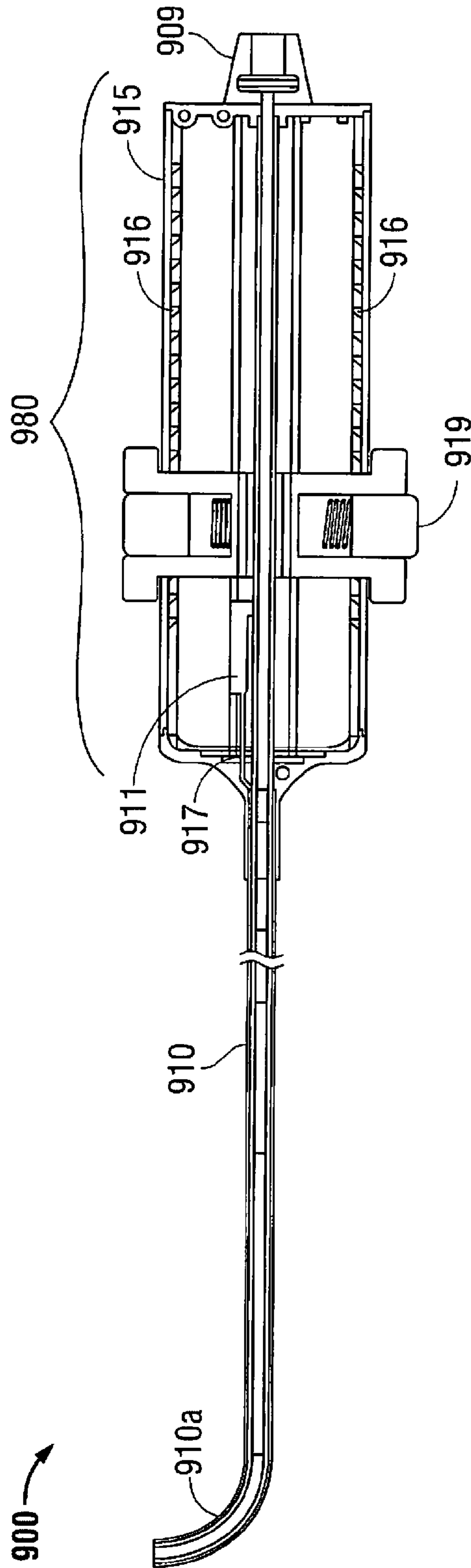


FIG. 9B

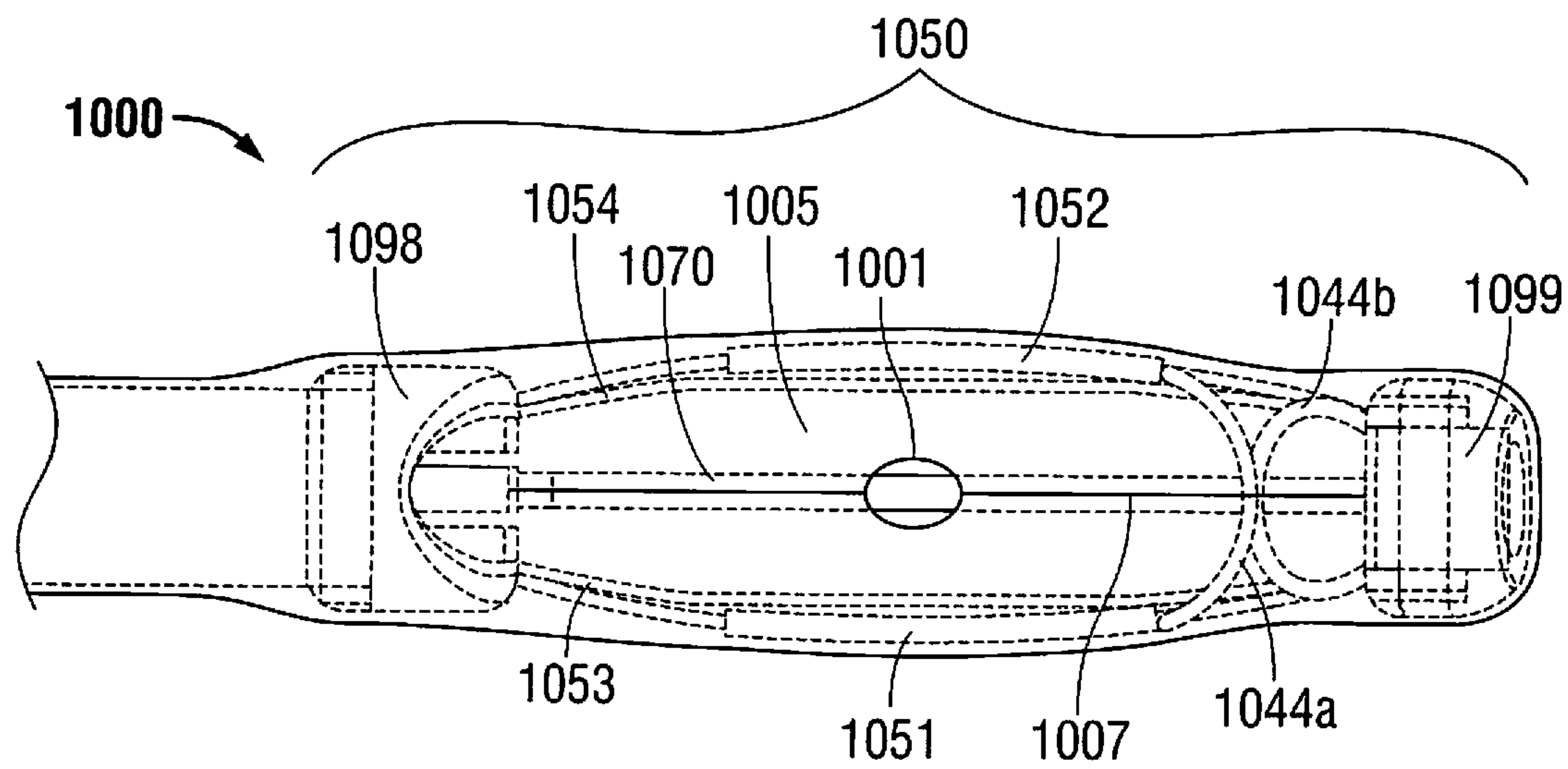


FIG. 10A

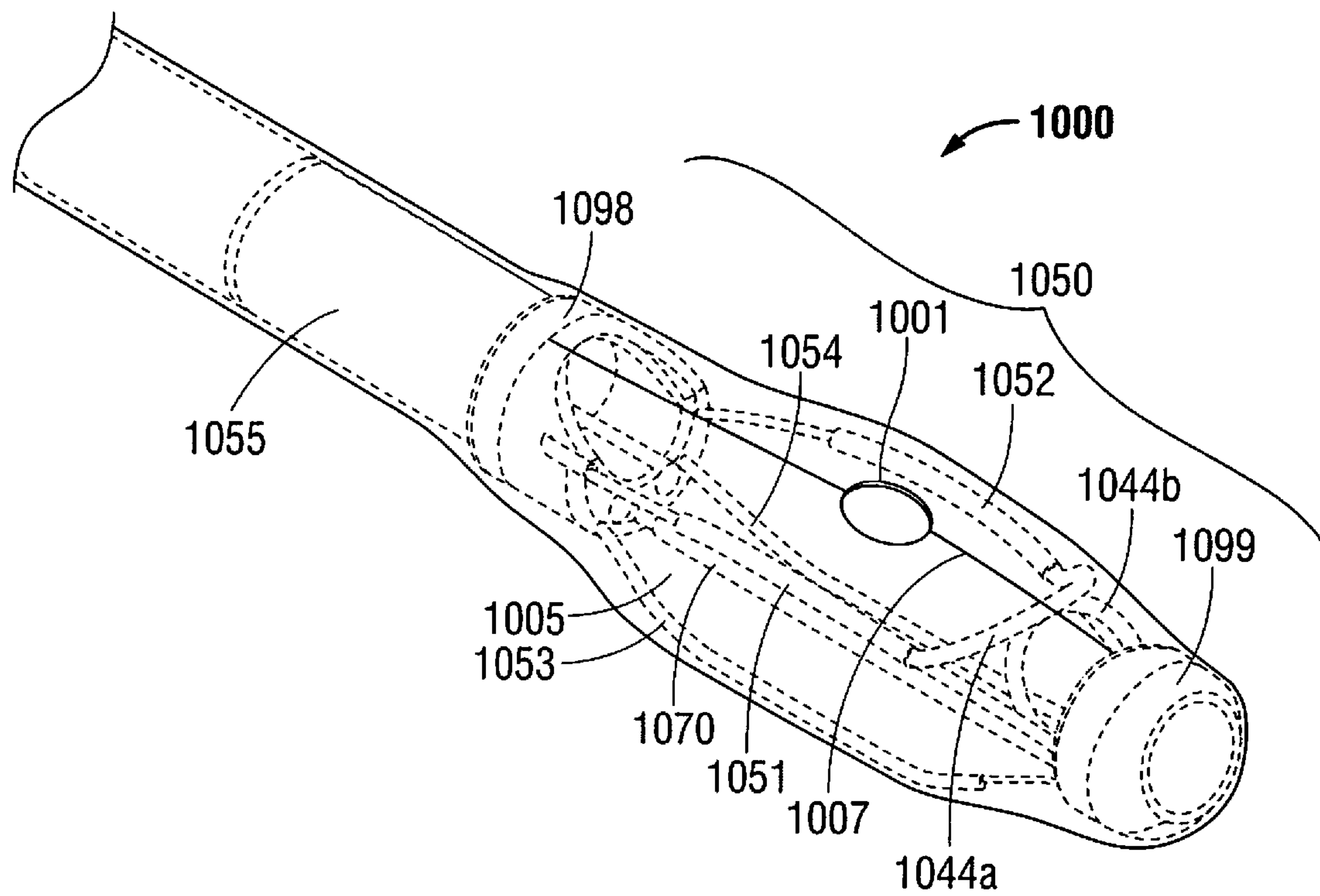


FIG. 10B

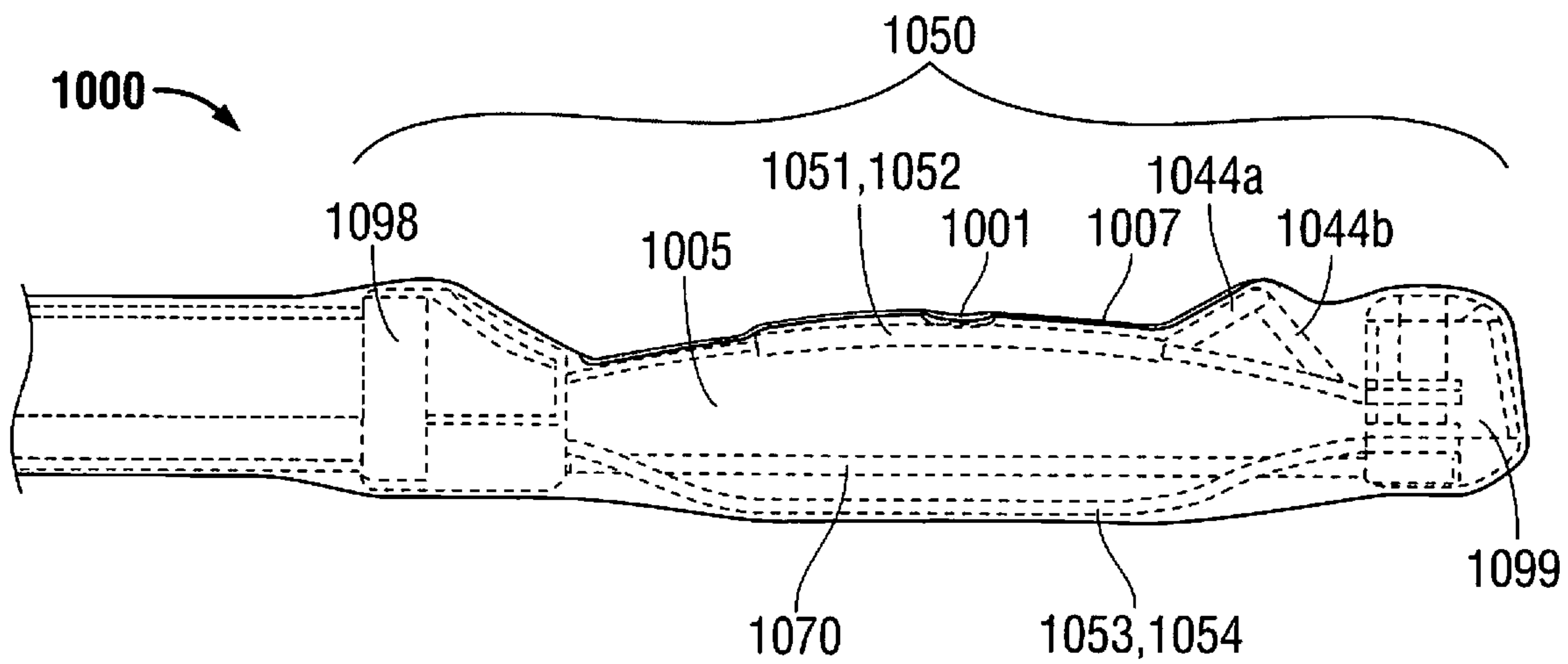


FIG. 10C

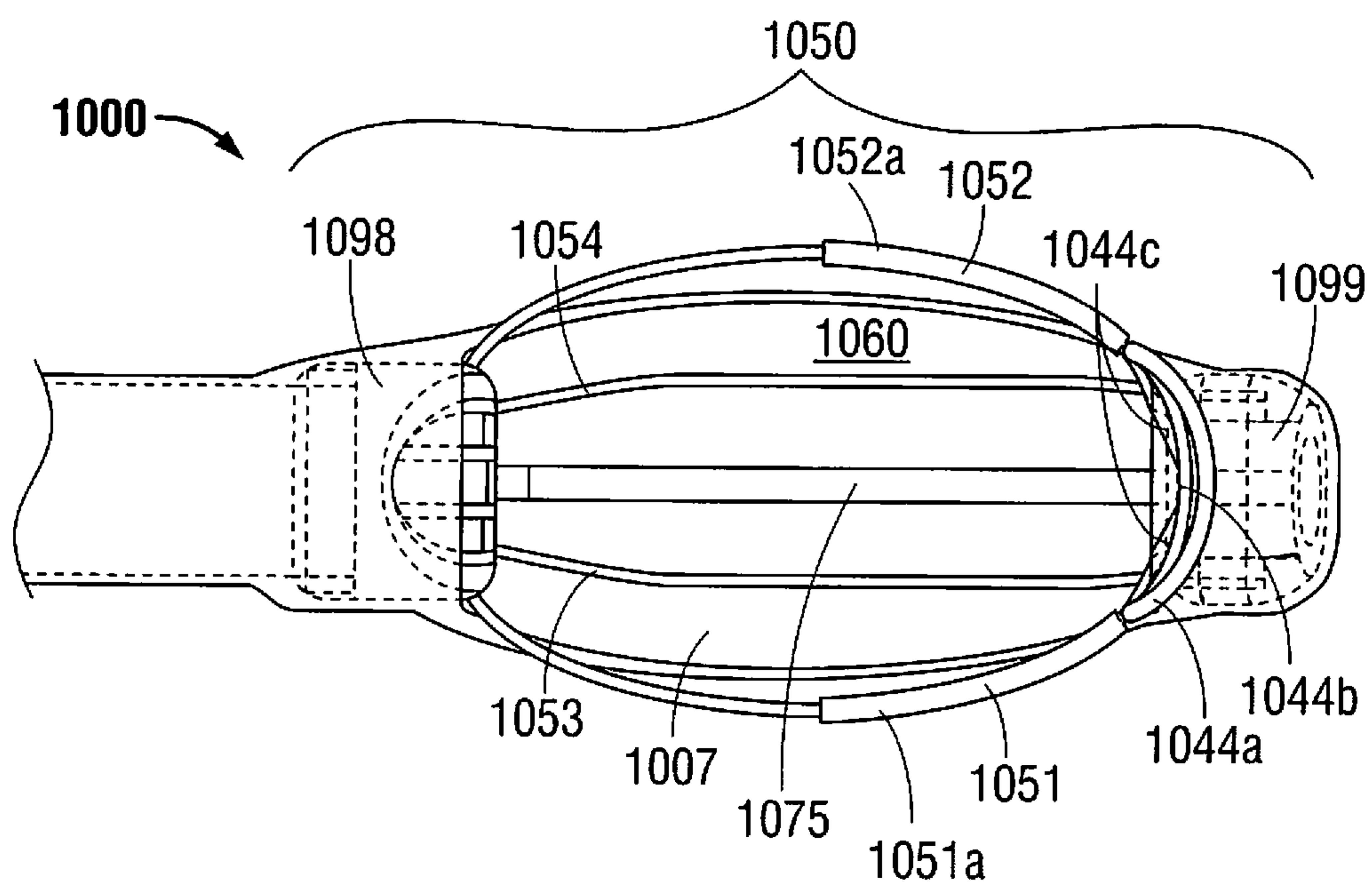


FIG. 10D

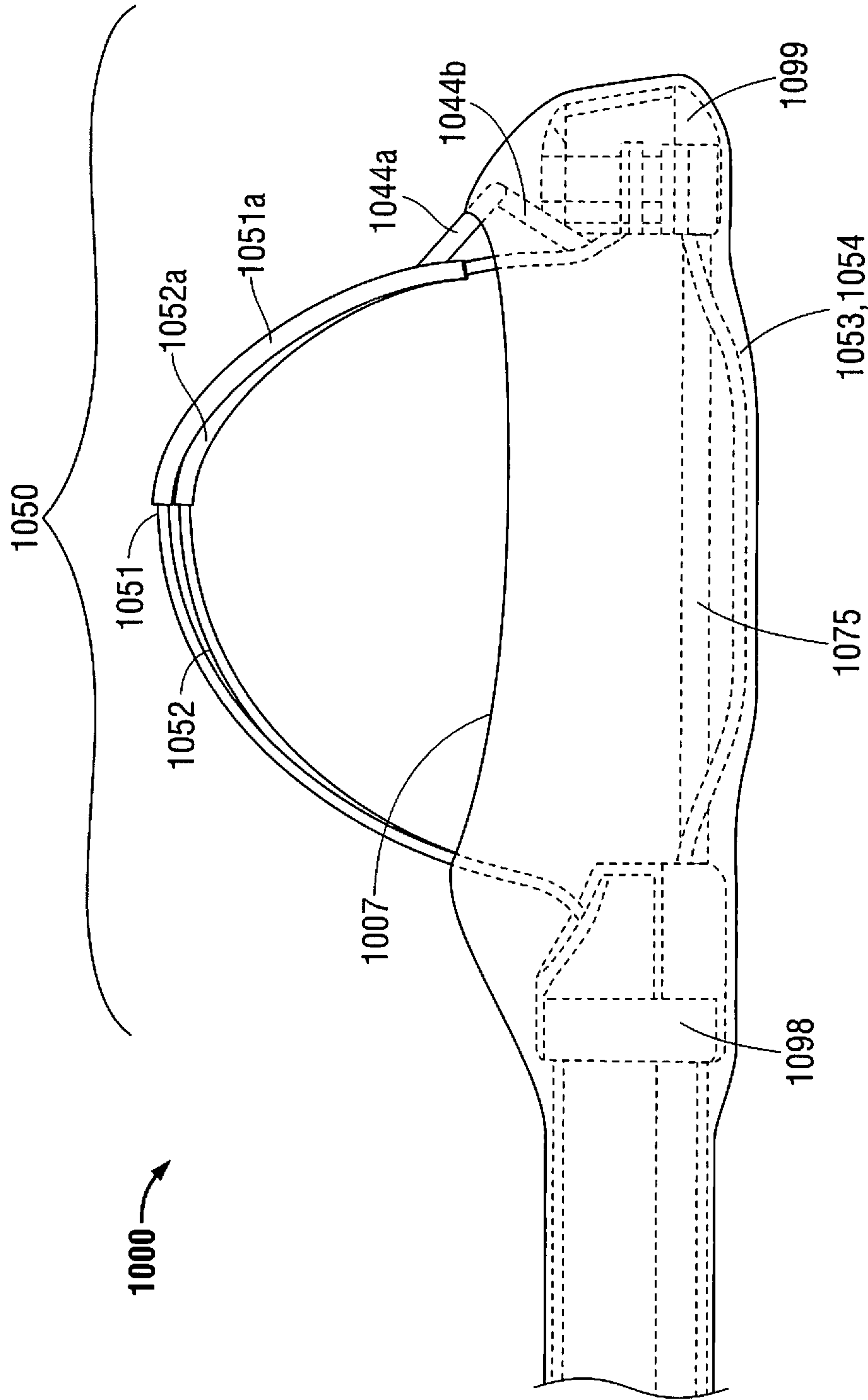
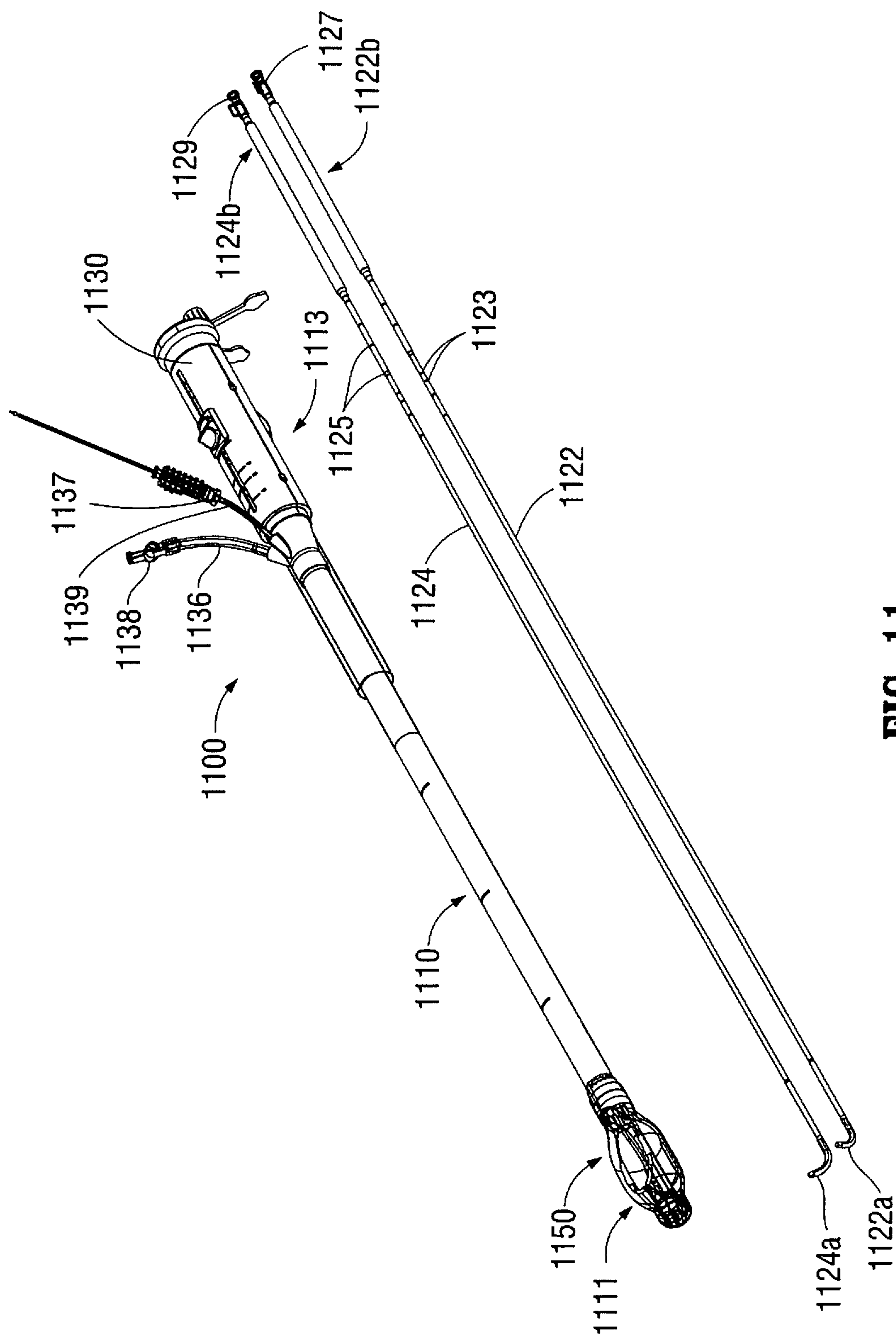


FIG. 10E



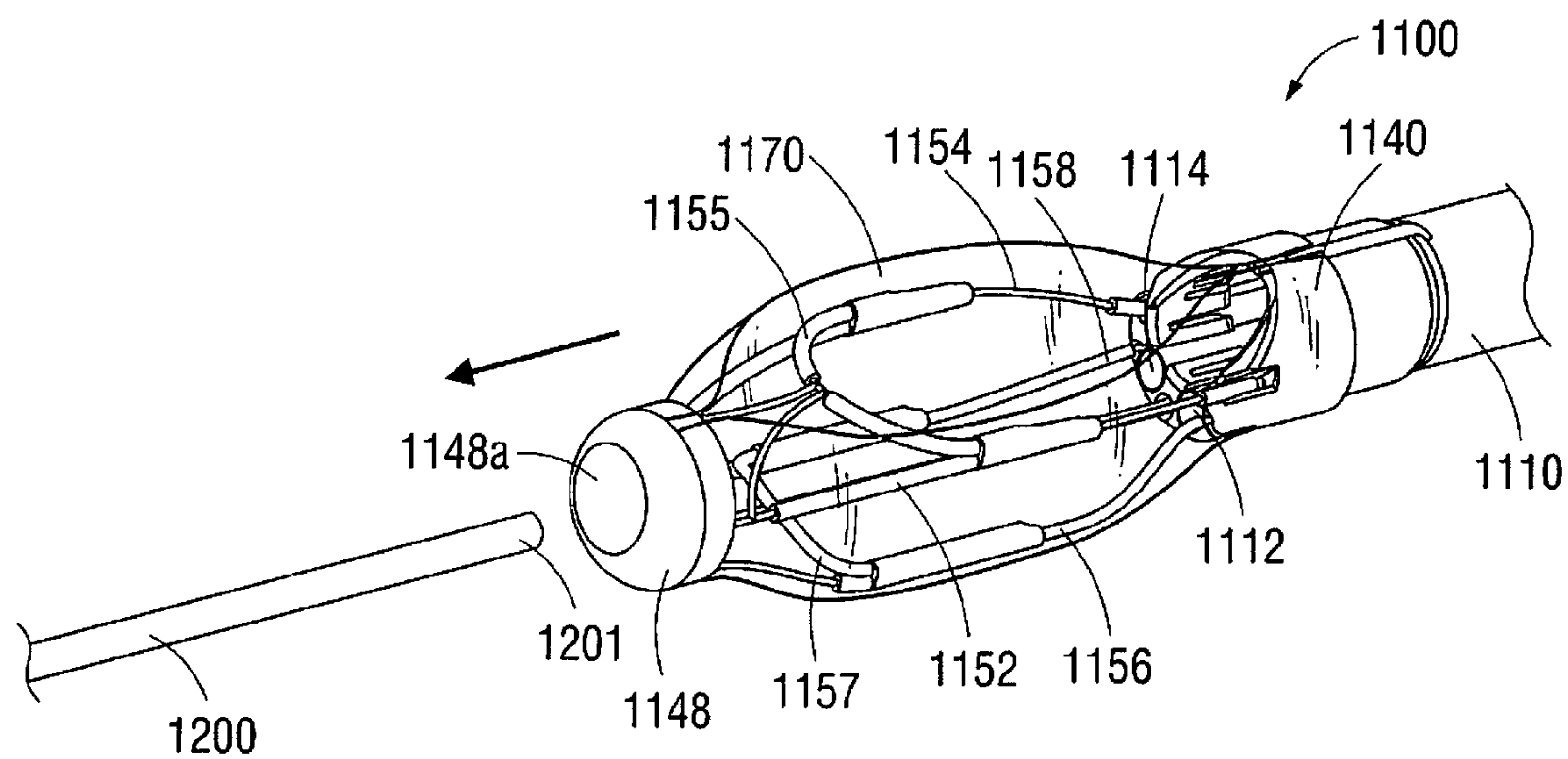


FIG. 12

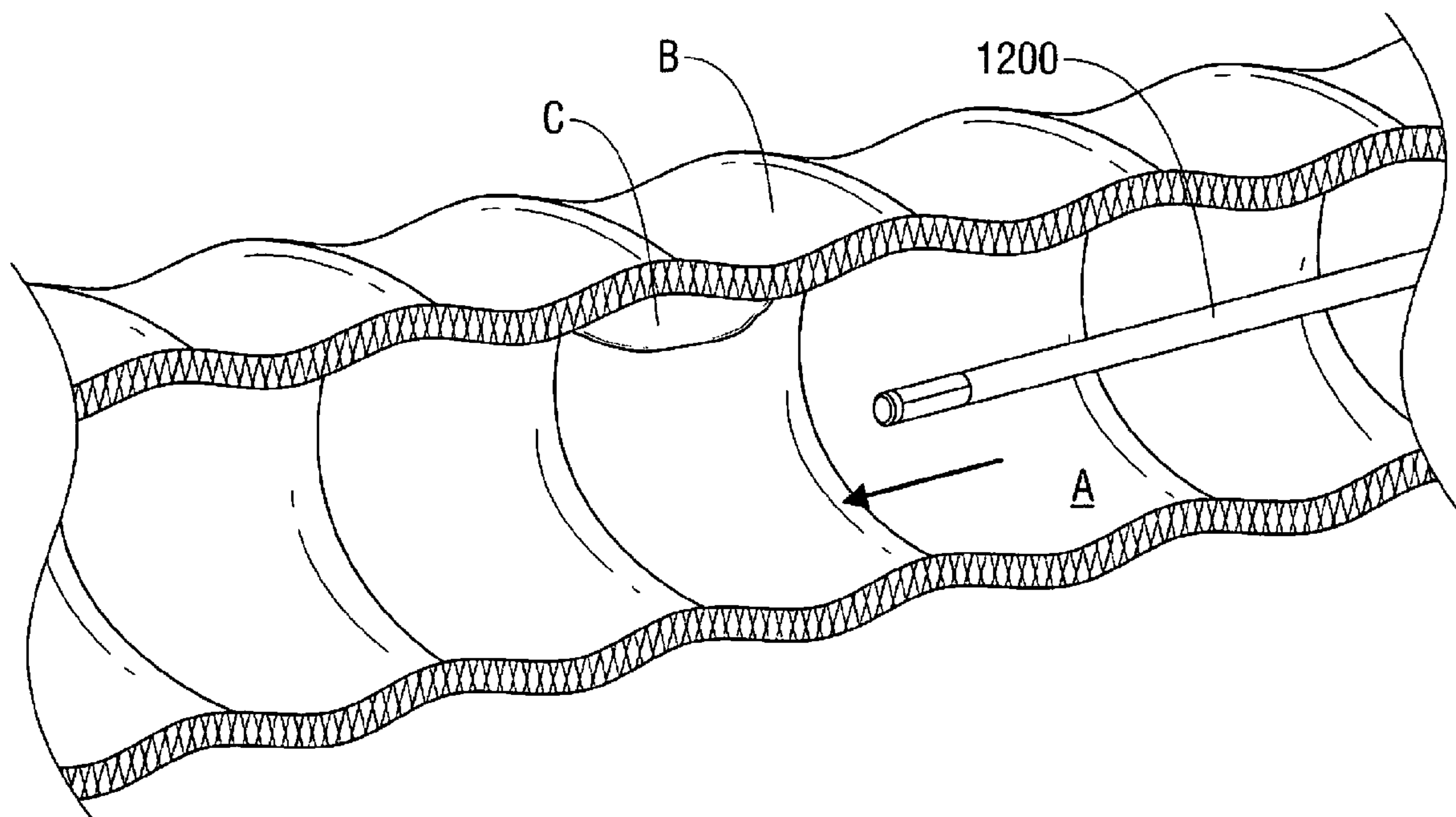


FIG. 13

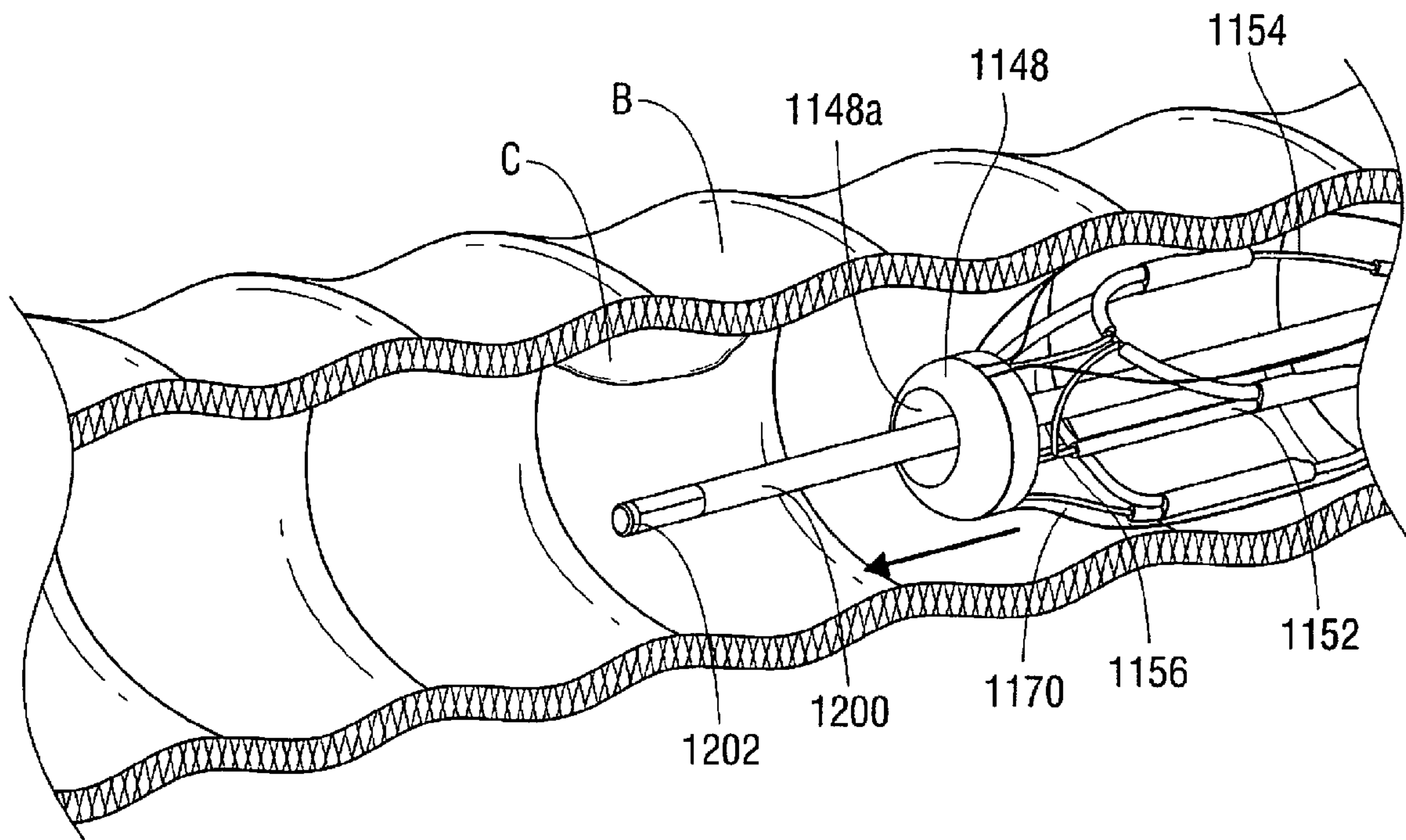


FIG. 14

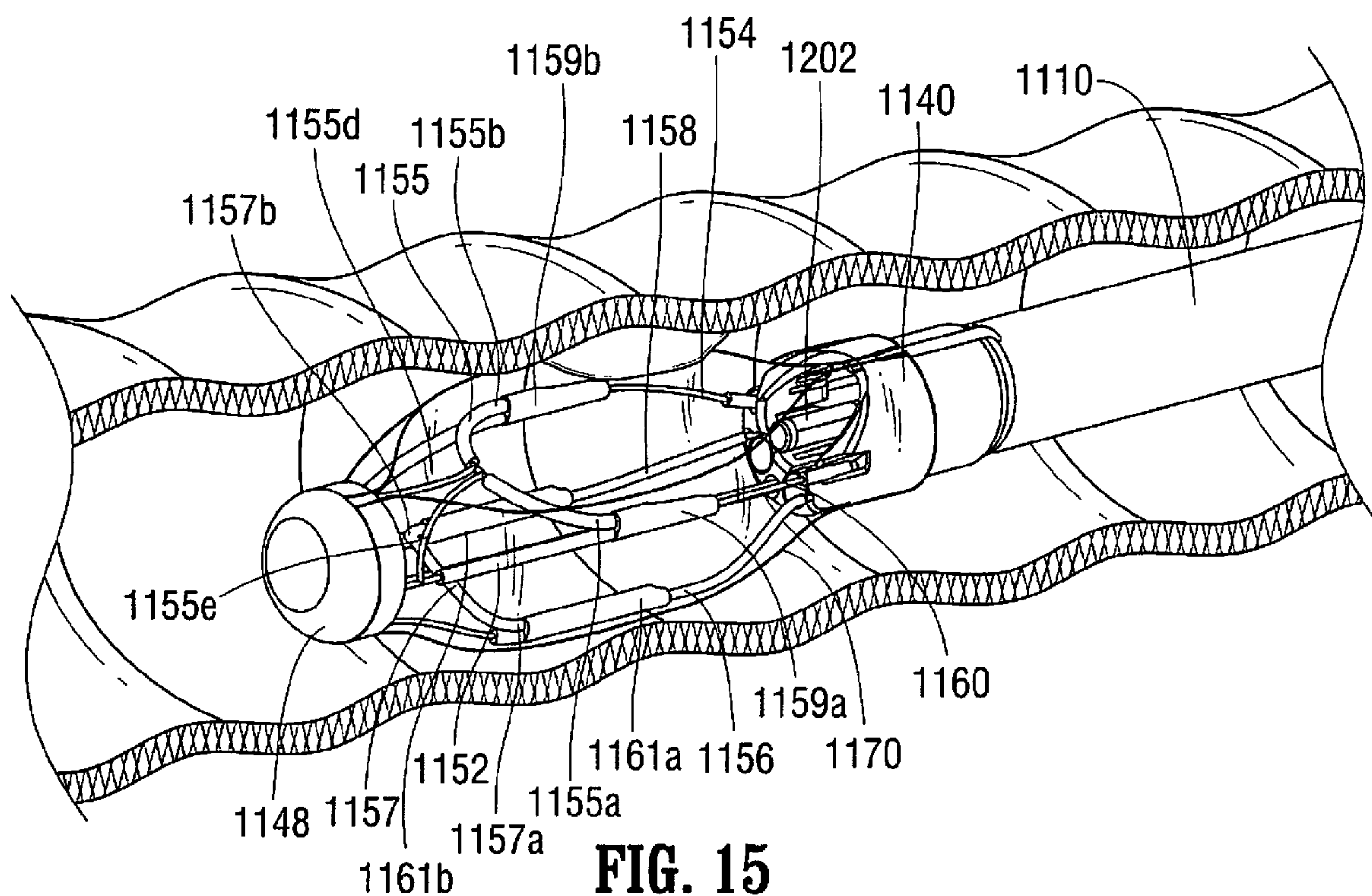


FIG. 15

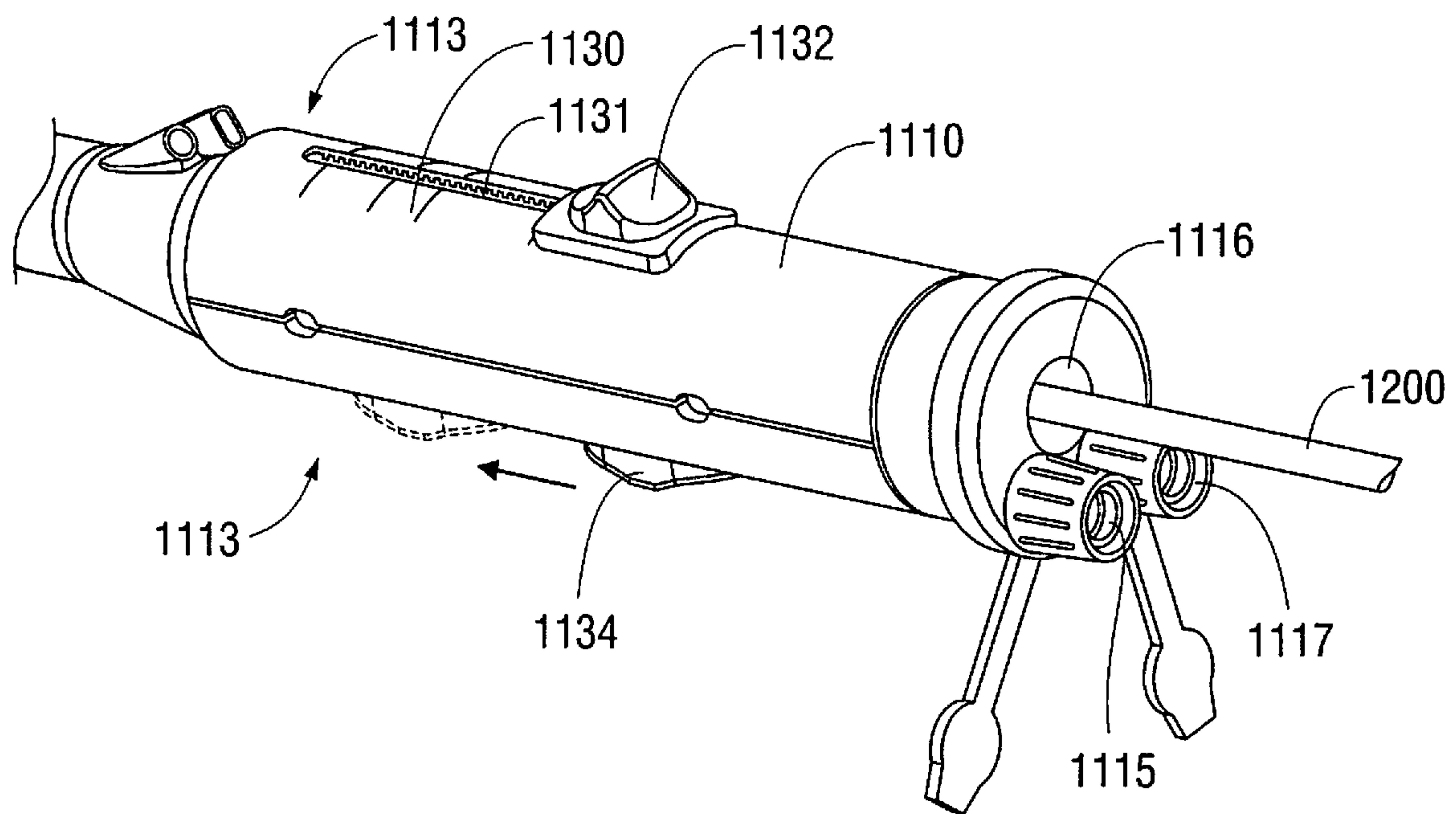


FIG. 16

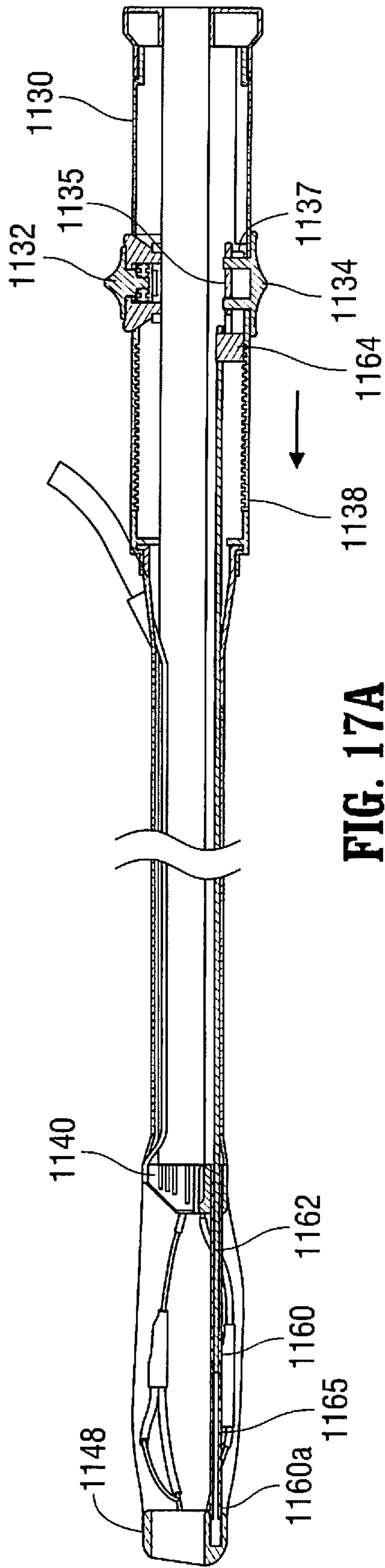


FIG. 17A

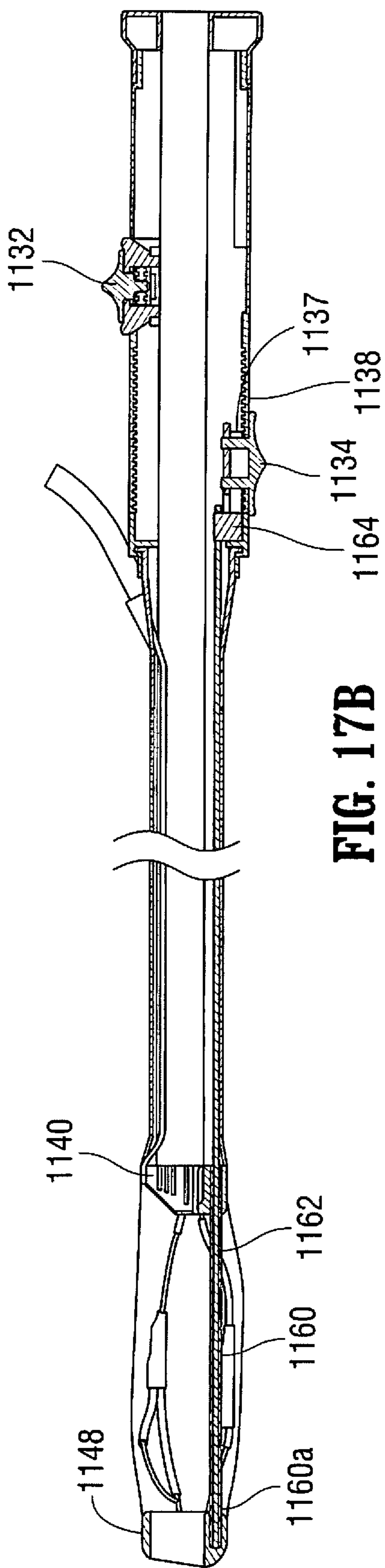


FIG. 17B

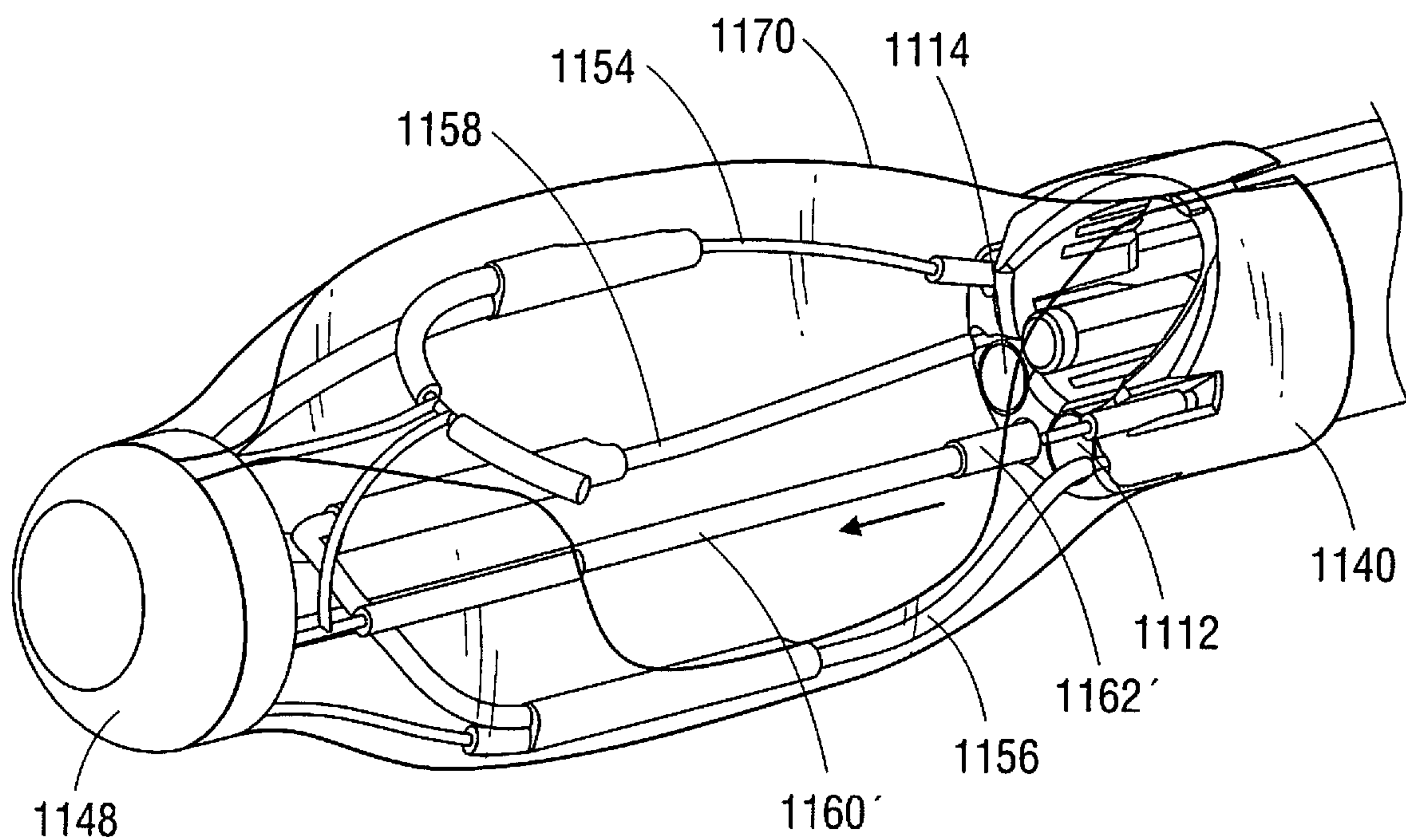


FIG. 17C

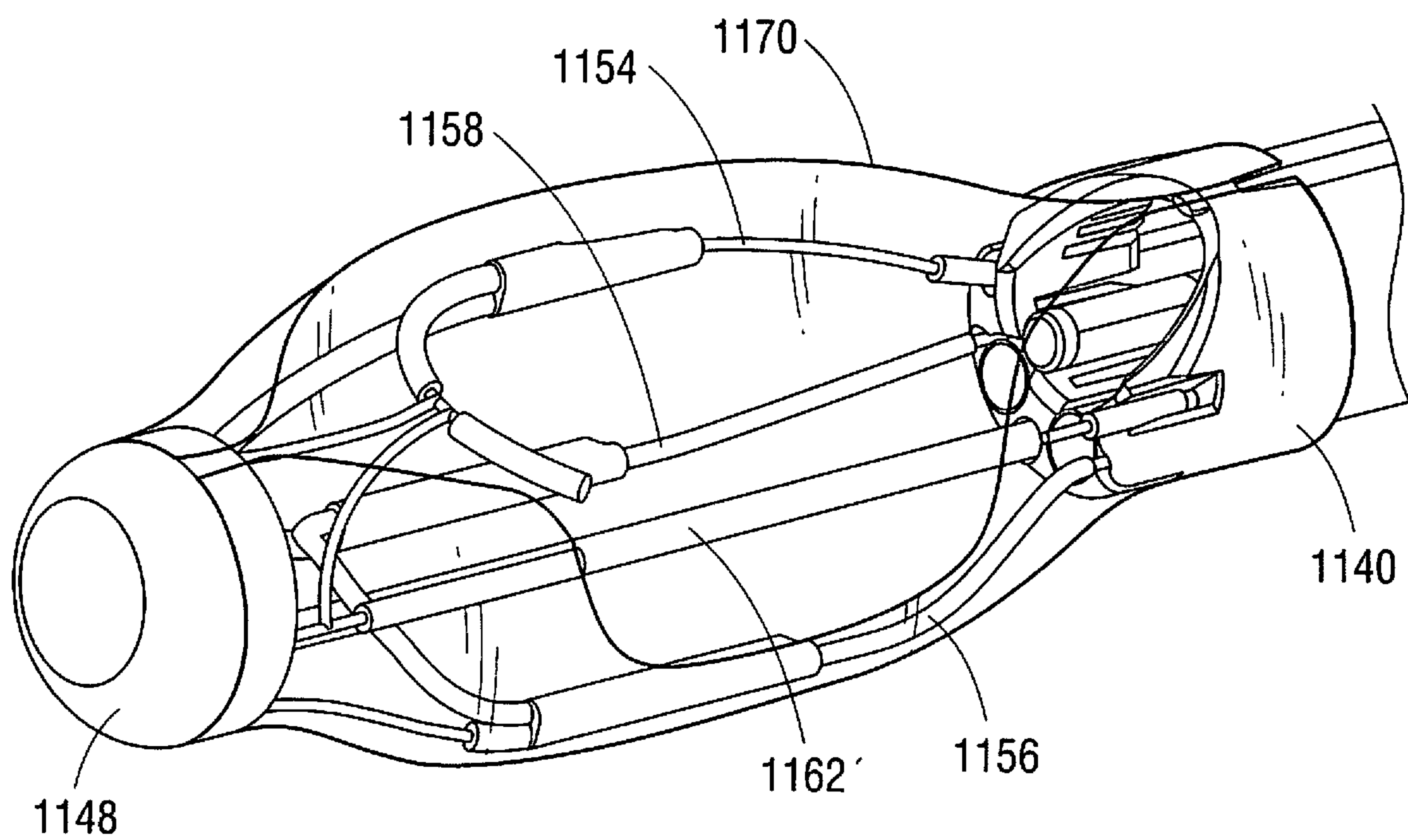


FIG. 17D

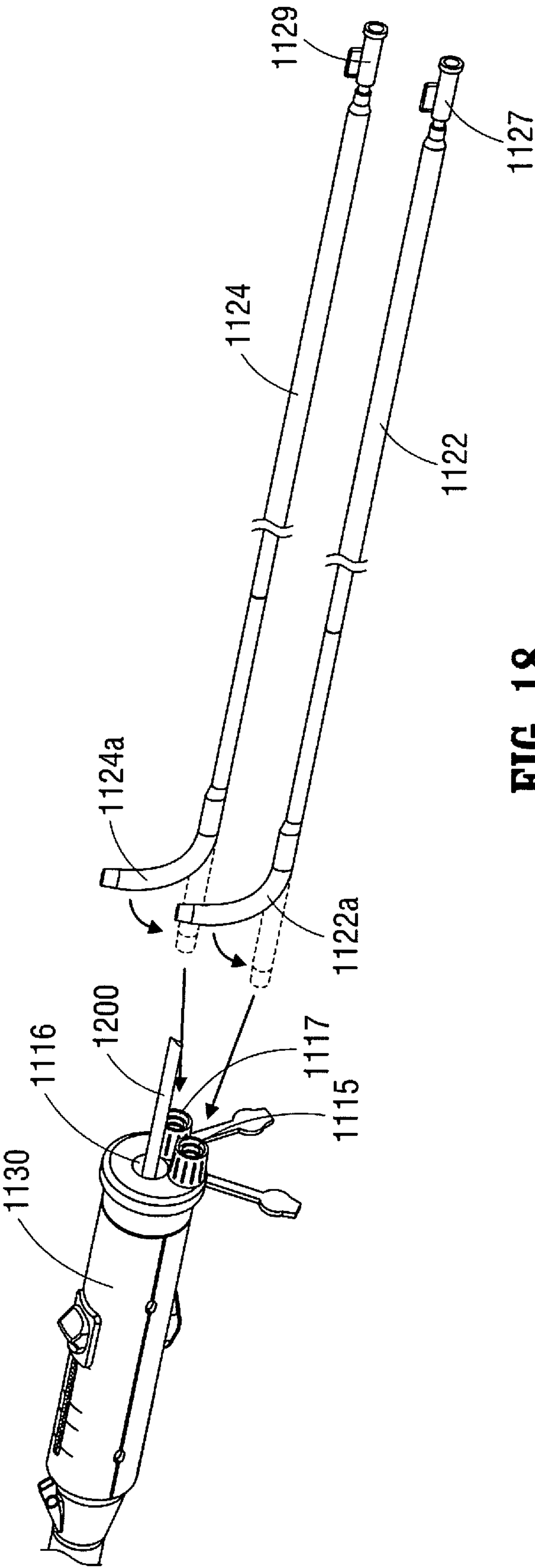


FIG. 18

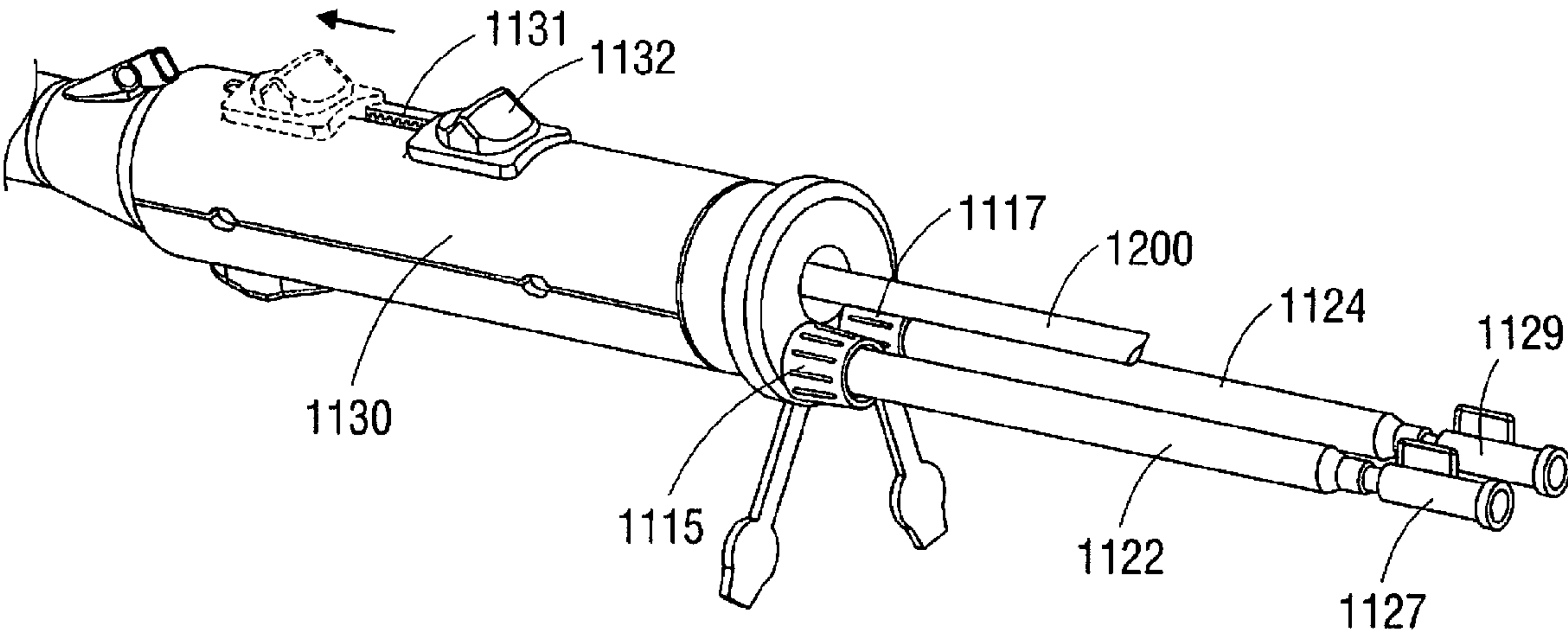


FIG. 19A

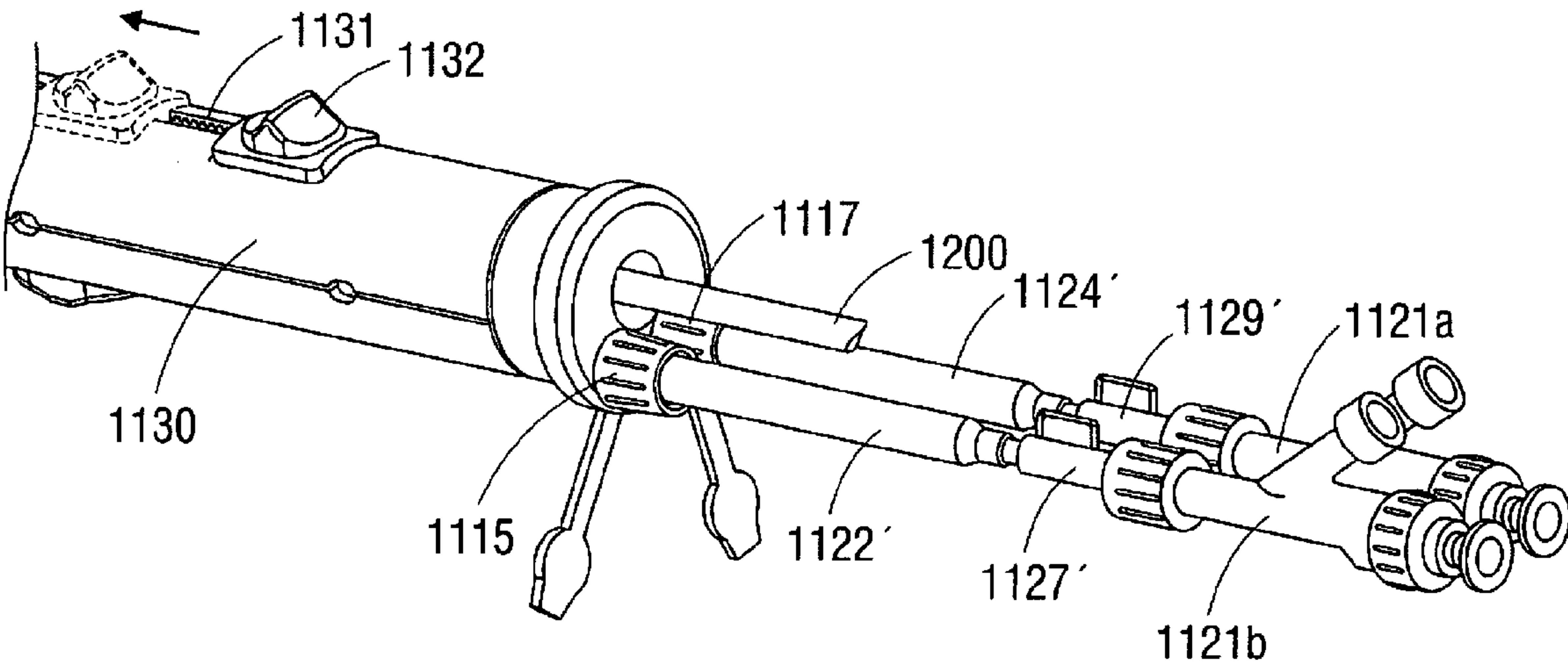


FIG. 19B

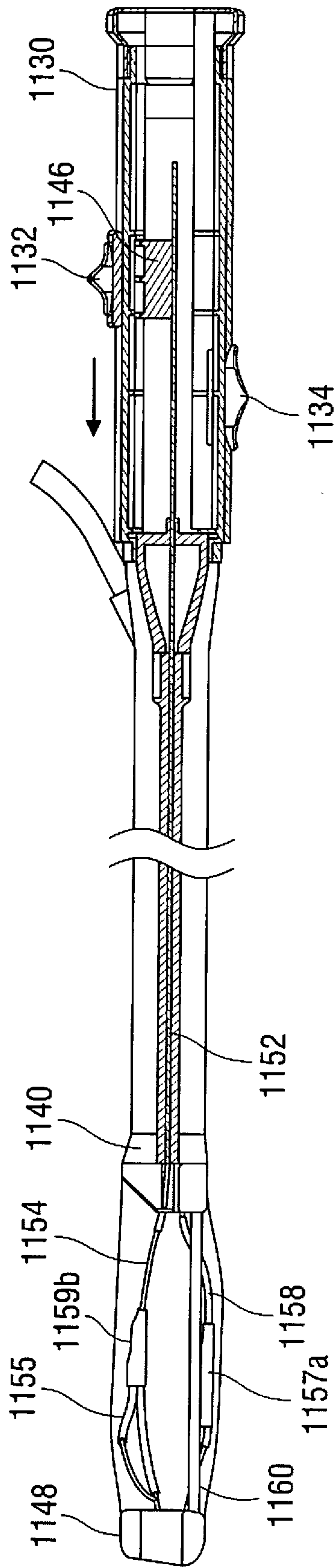


FIG. 20A

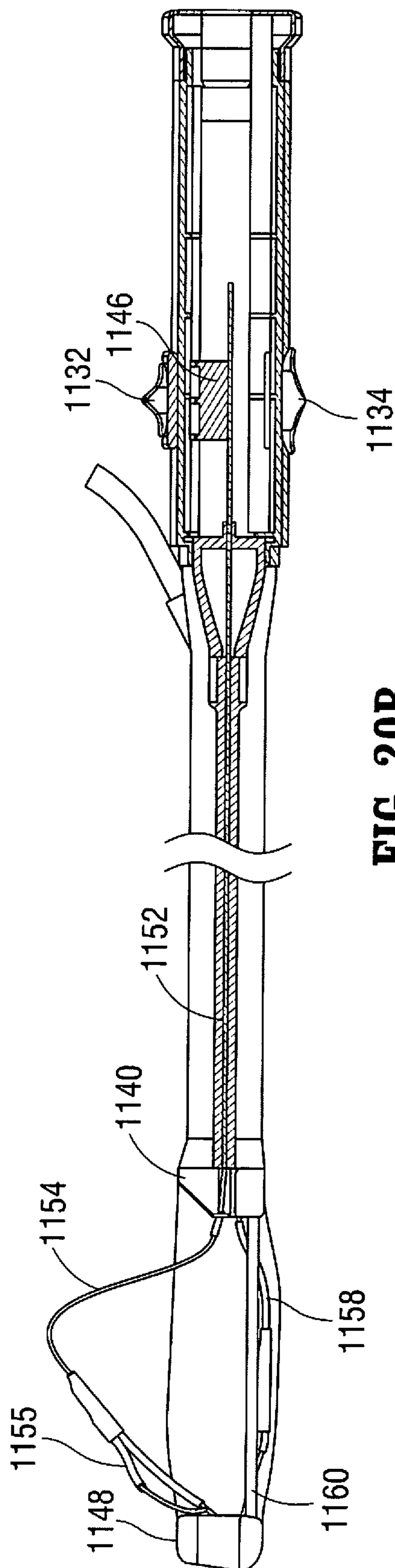


FIG. 20B

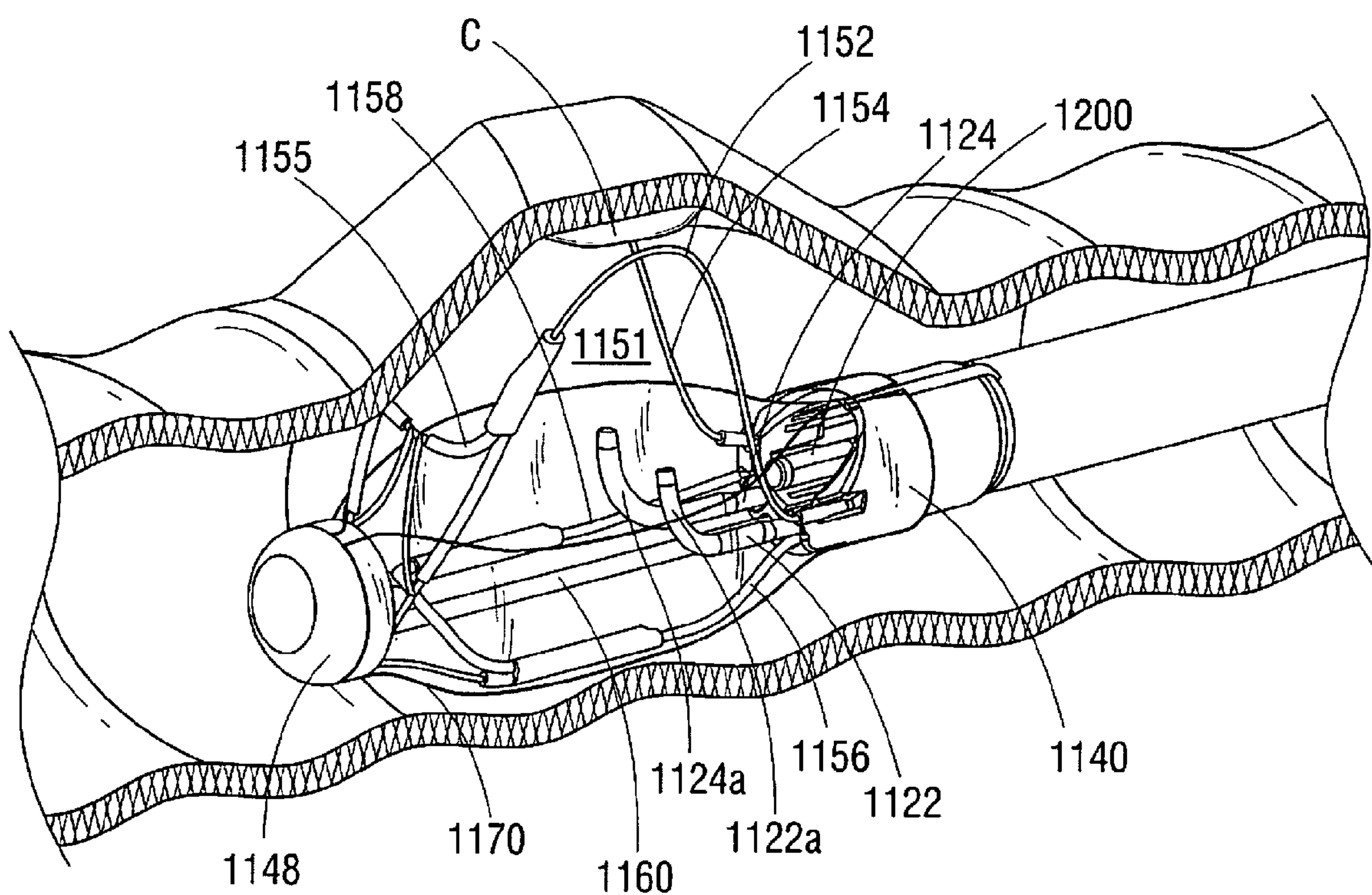


FIG. 21A

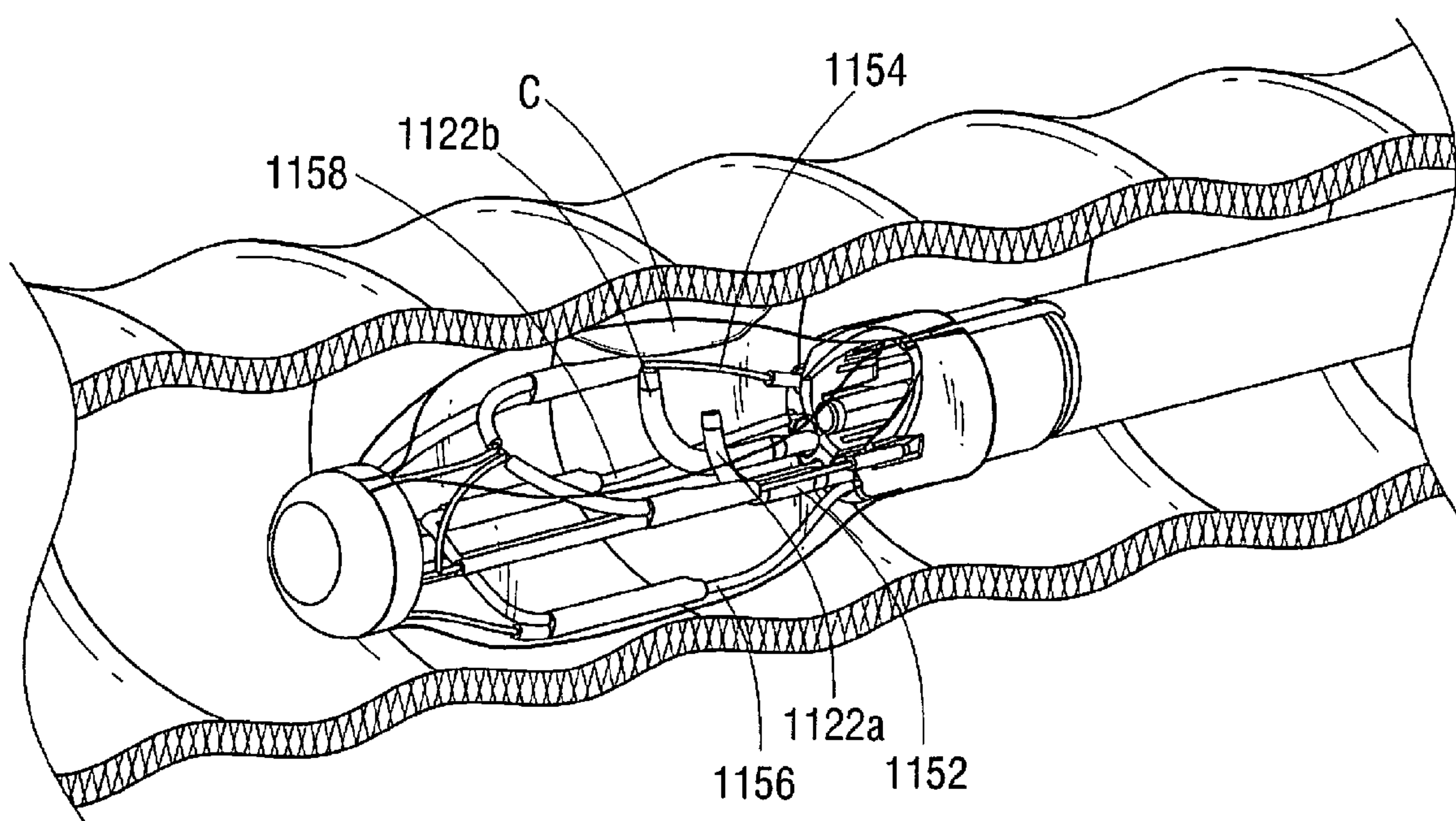


FIG. 21B

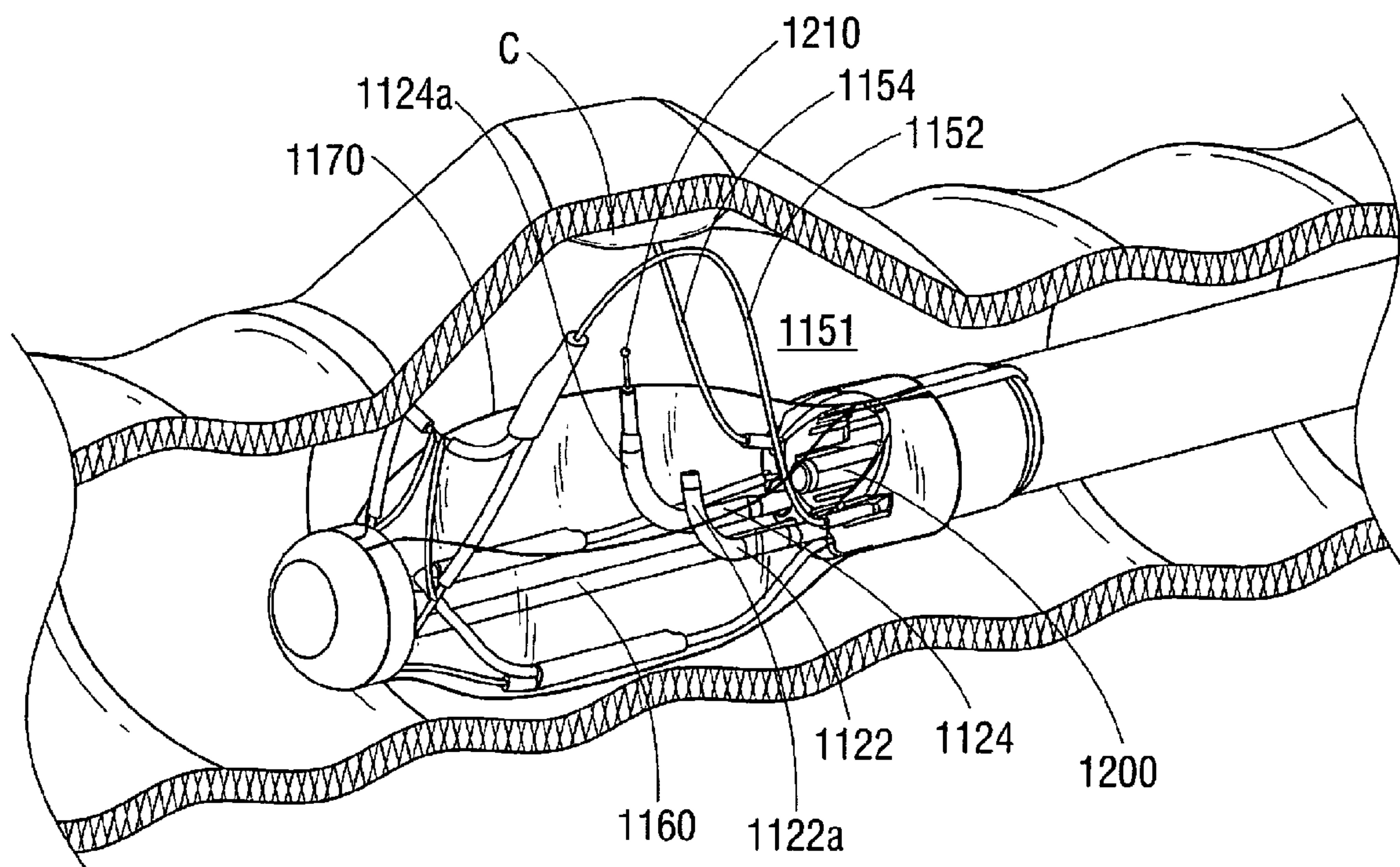


FIG. 22

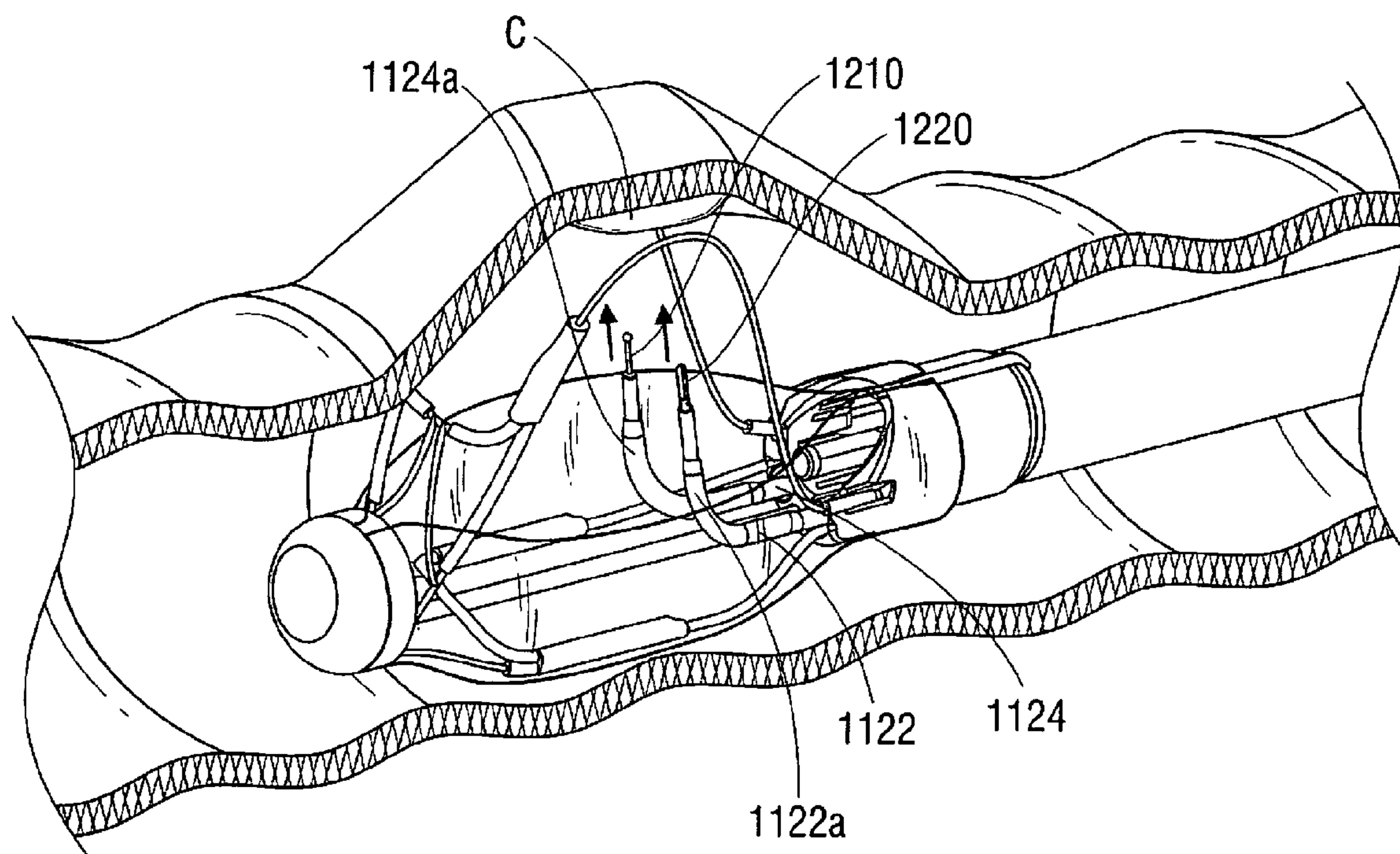


FIG. 23

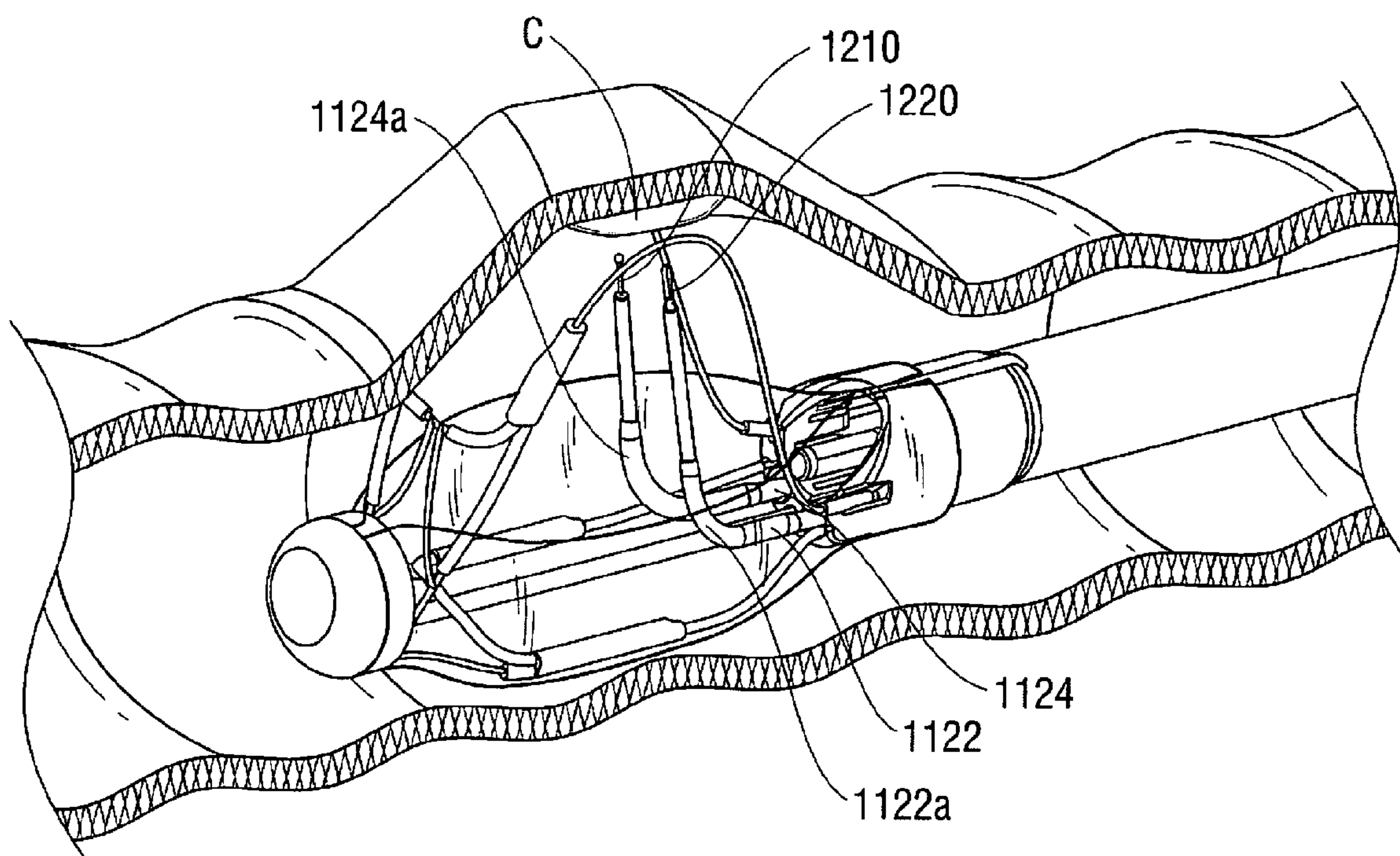


FIG. 24

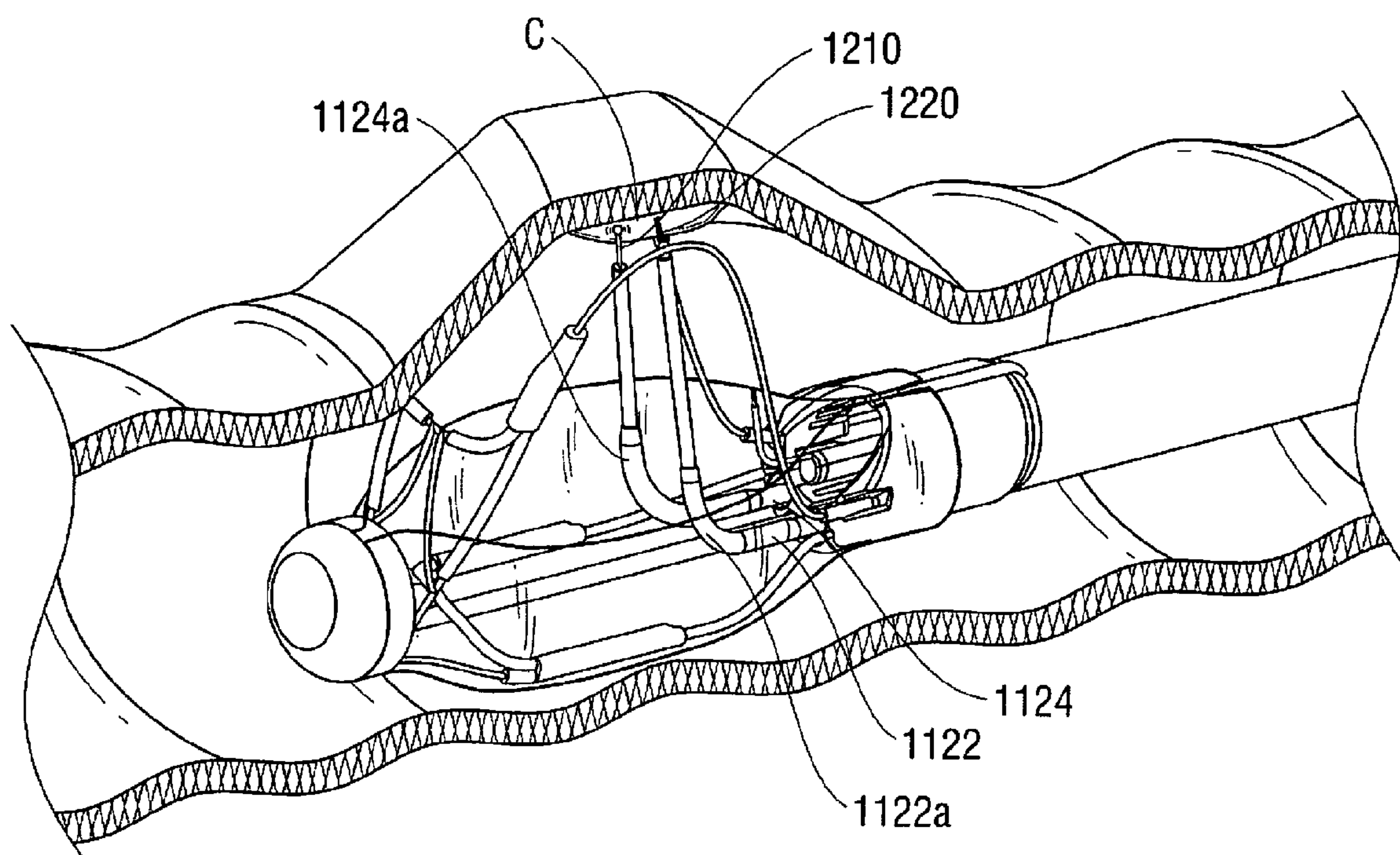


FIG. 25

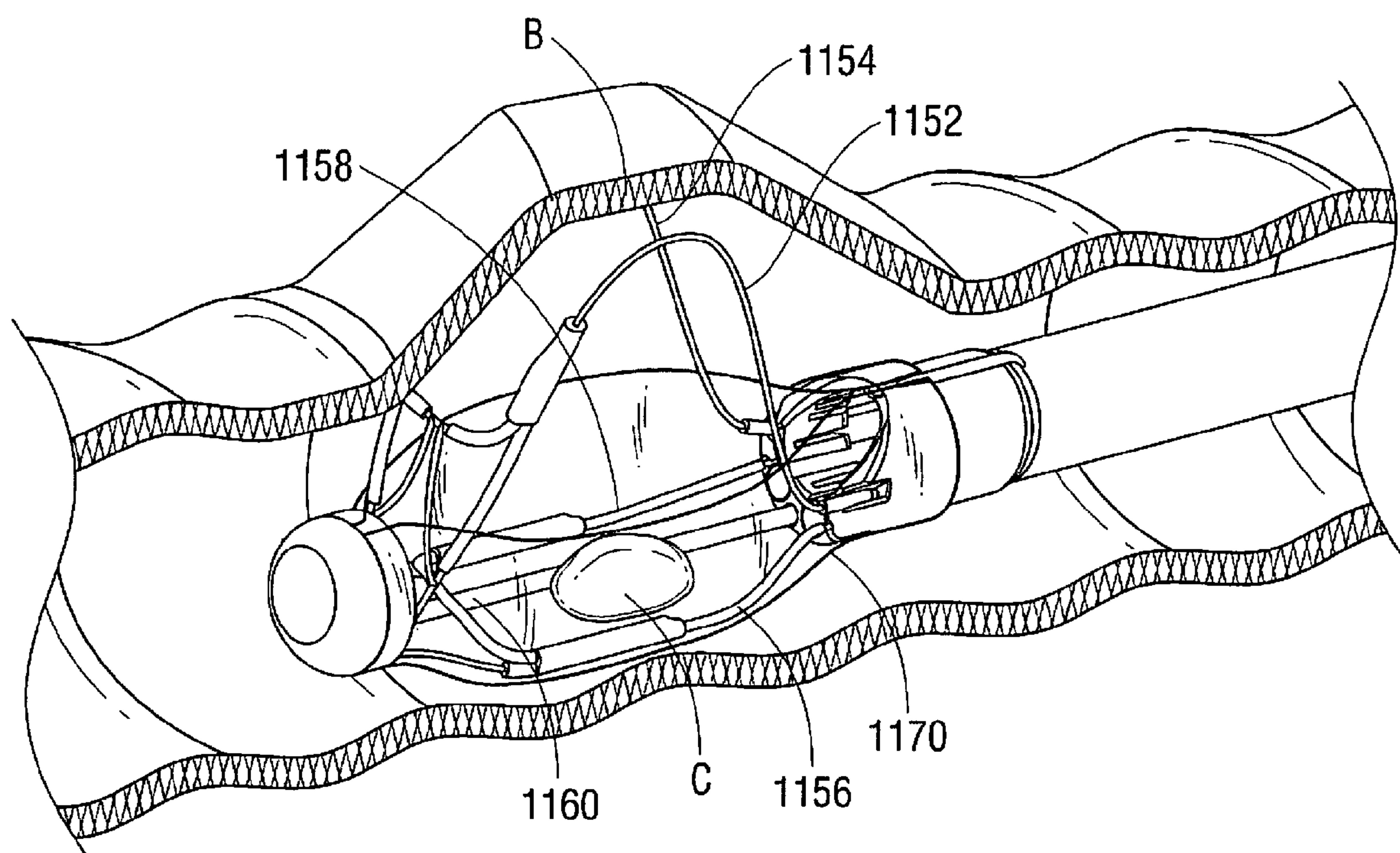


FIG. 26

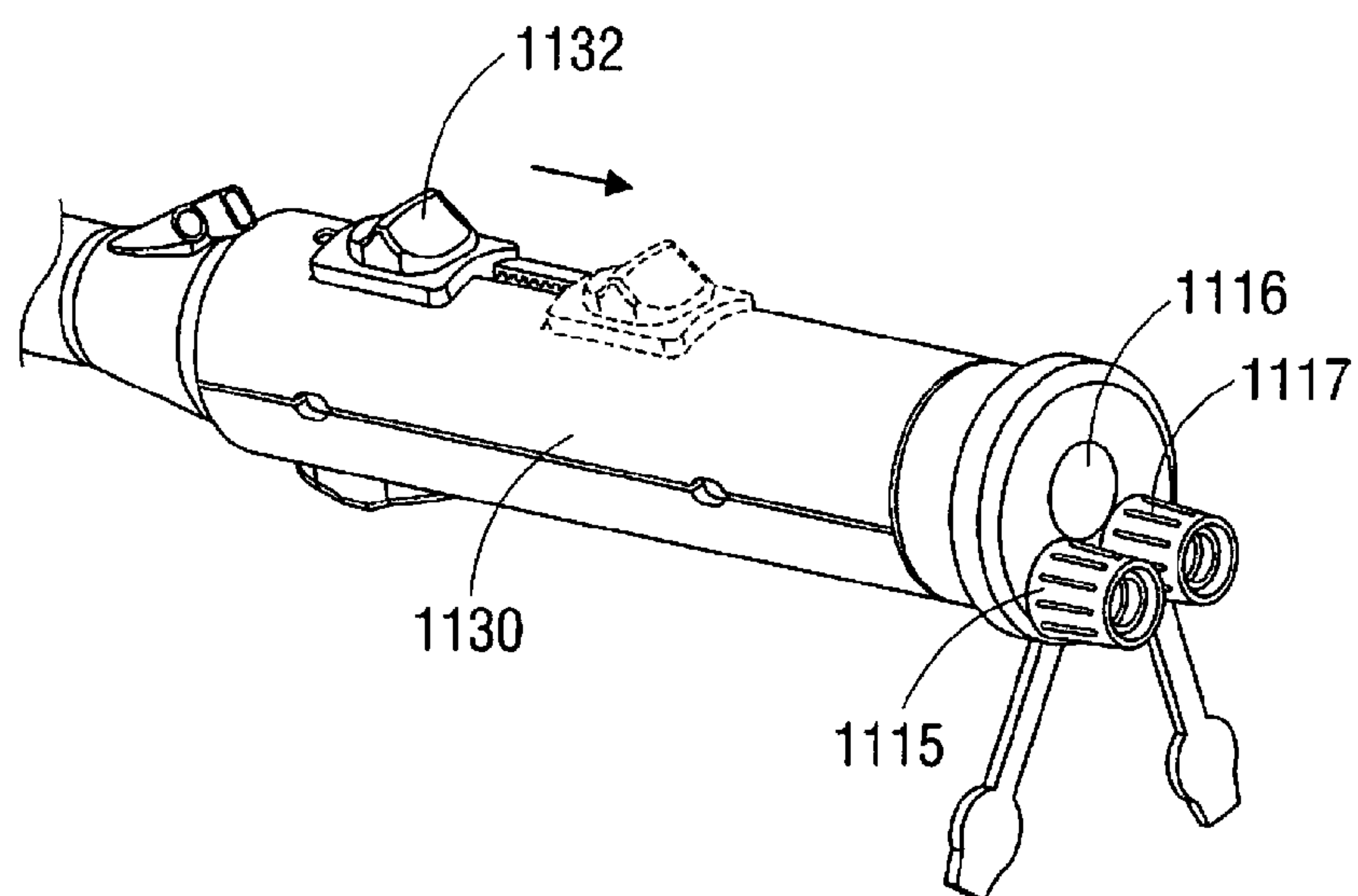


FIG. 27

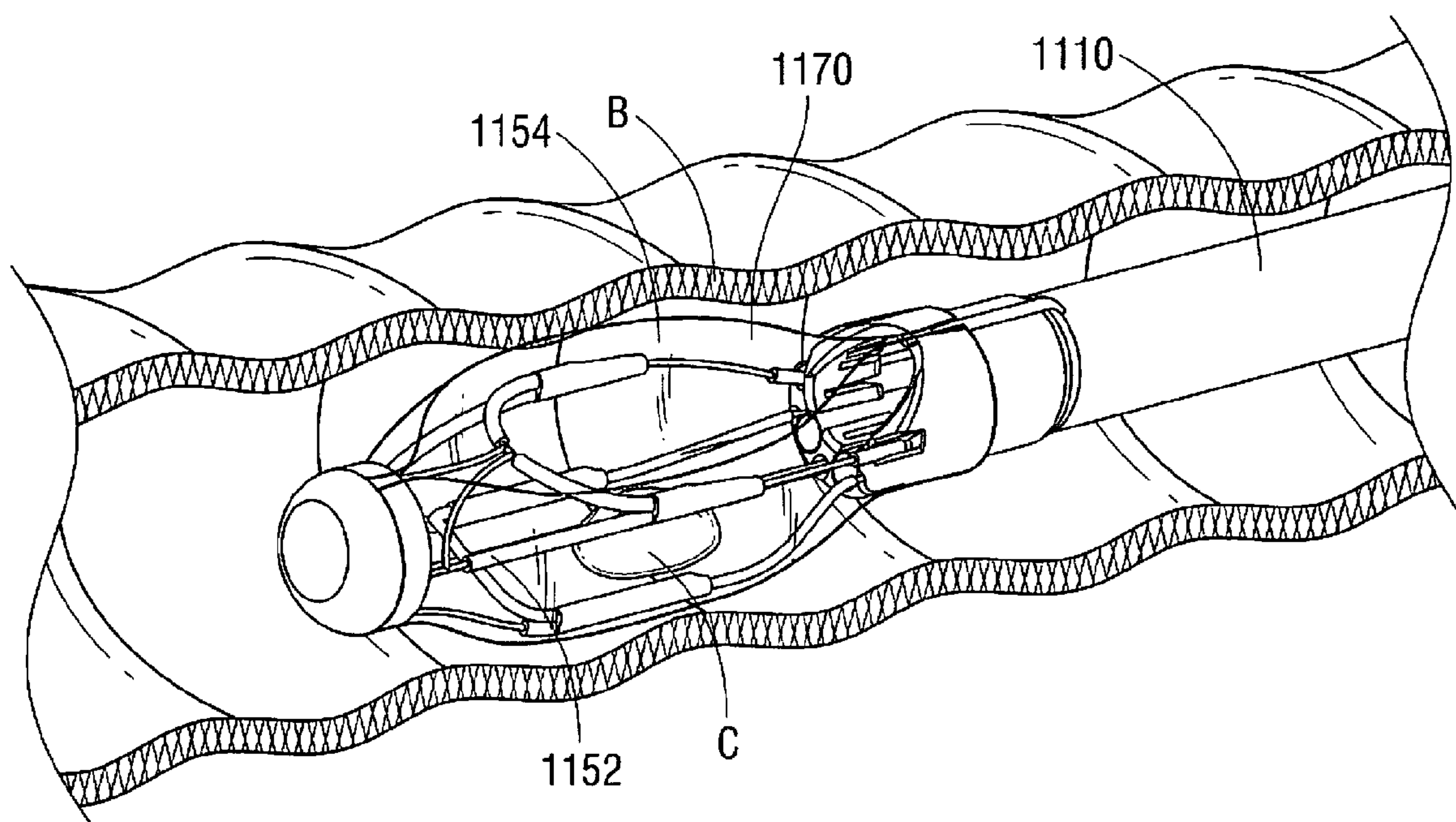


FIG. 28

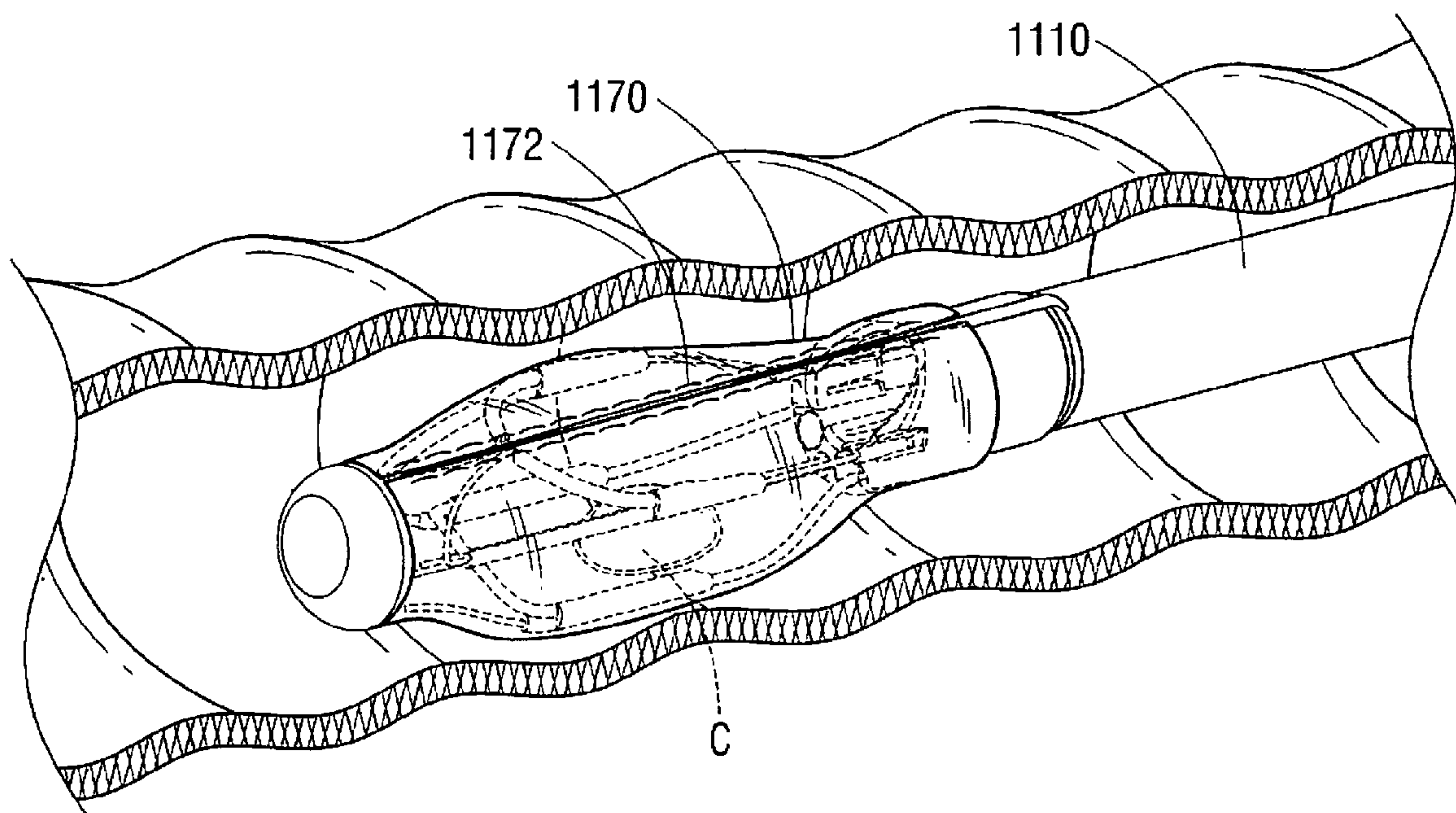


FIG. 29

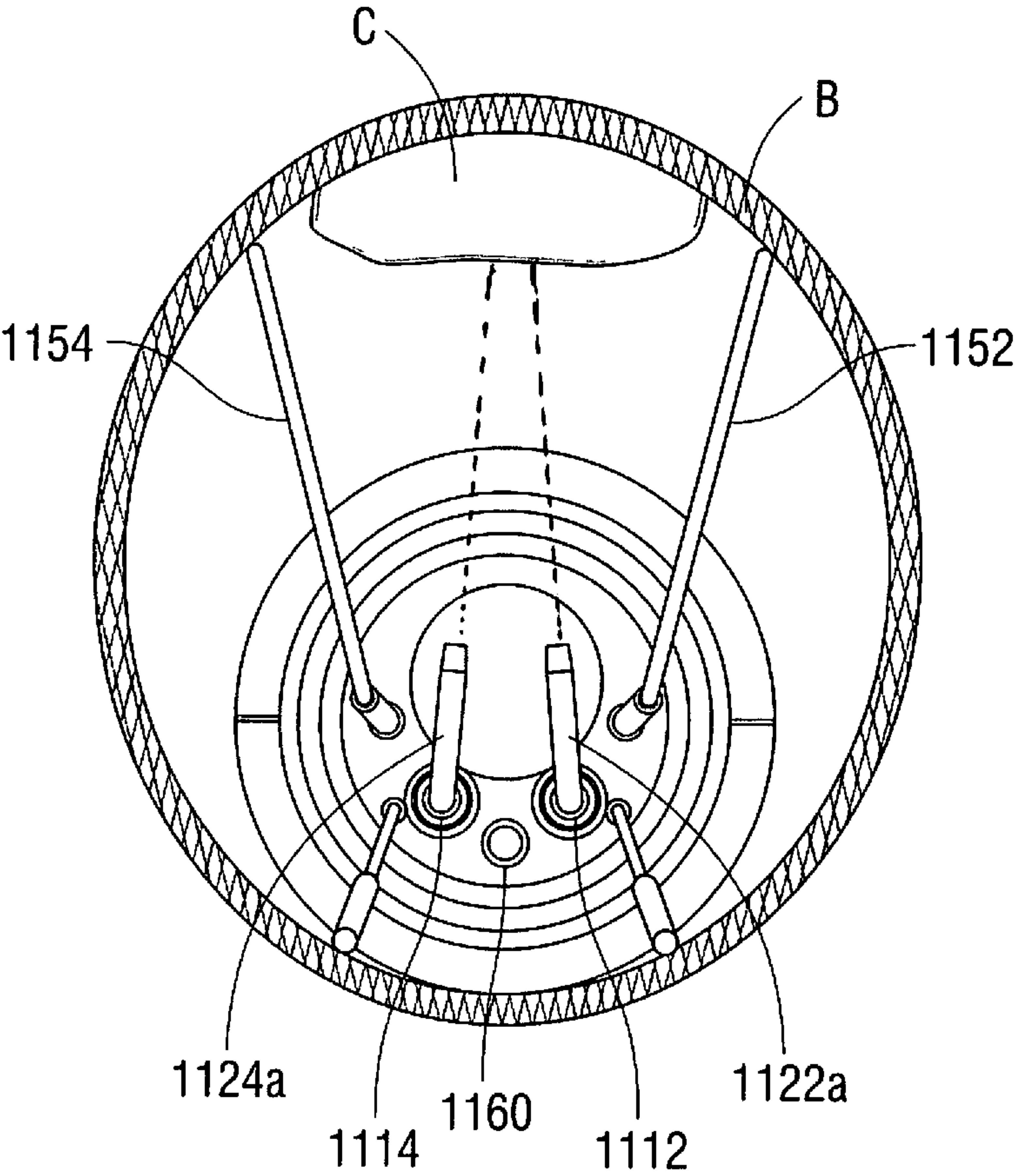


FIG. 30

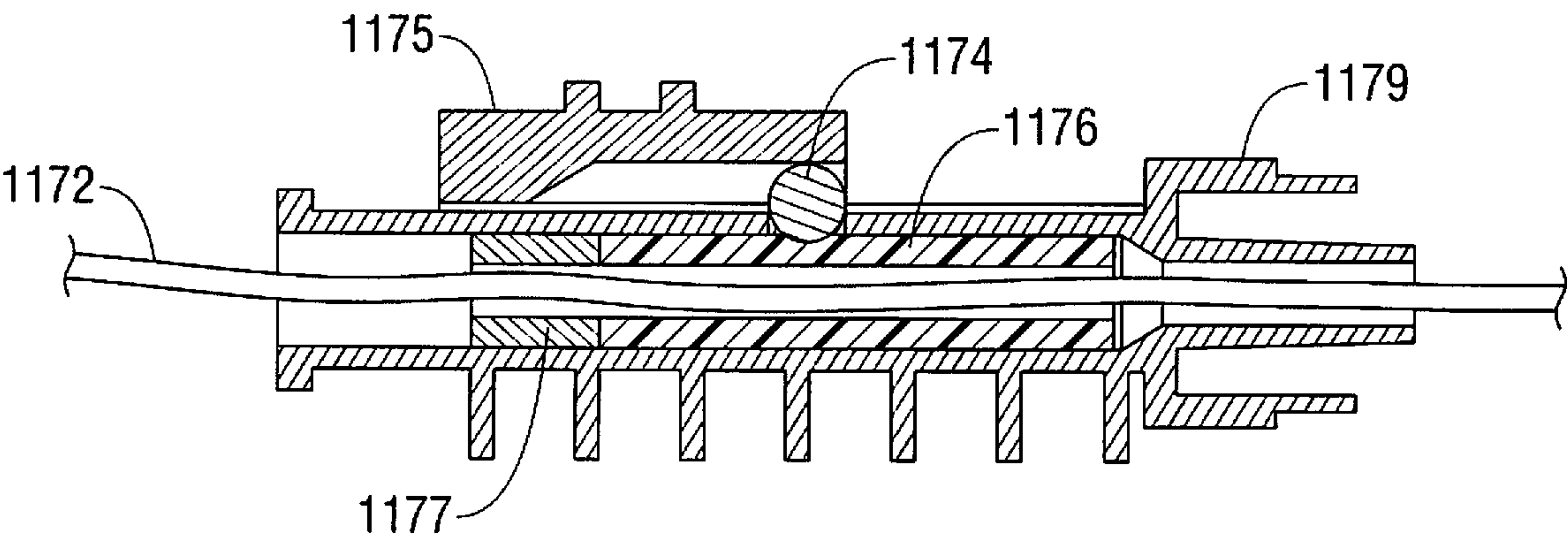


FIG. 31A

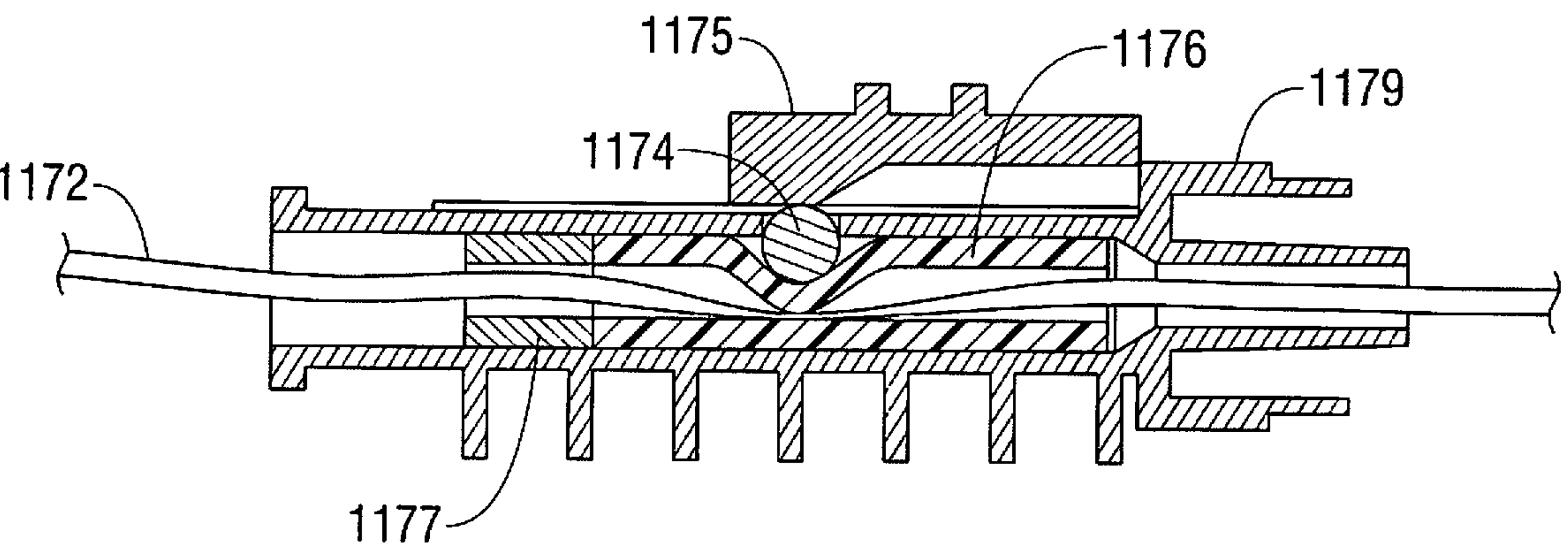


FIG. 31B

**MULTI-LUMEN-CATHETER RETRACTOR
SYSTEM FOR A MINIMALLY-INVASIVE,
OPERATIVE GASTROINTESTINAL
TREATMENT**

Matter enclosed in heavy brackets [] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue; a claim printed with strikethrough indicates that the claim was canceled, disclaimed, or held invalid by a prior post-patent action or proceeding.

This application is a continuation in part of application Ser. No. 12/970,604, filed Dec. 16, 2010, which claims priority from provisional application 61/287,077, filed Dec. 16, 2009, and is a continuation in part of application Ser. No. 13/531,477, filed Jun. 22, 2012. The entire contents of each of these applications are incorporated herein by reference.

BACKGROUND

1. Field of the Invention

The teachings provided herein are generally directed to improved methods and devices for operatively treating gastrointestinal disorders endoscopically in a stable, yet dynamic operative environment, and in a minimally-invasive manner.

2. Description of the Related Art

Endoscopic procedures involving the gastrointestinal system offer advantages over conventional surgery in that they are less invasive and may provide visualization. These procedures continue to evolve to address problems and provide new methods of treatment identified by those skilled in the art.

One current problem includes a lack of technology for an optimal minimally-invasive expansion of a stable, working space adjacent to the target tissues that could otherwise collapse around the target lesion or defect during an operative treatment. Having the ability to effectively expand and optimally reconfigure (reshape) the working space could markedly facilitate an intra-luminal operation. A better expanded, stable and optimally configured working space allows the instruments and endoscope to be independently manipulated and properly visualized around the target tissue. One of skill would appreciate having the ability to see and approach both the target tissue and the surrounding anatomy for reference, orientation, and surgical maneuvering.

Another current problem includes a lack of an endoscopic technology for not only expanding, but also affixing and reshaping, both the target tissue and surrounding tissue. In a bowel, for example, such a stable operative space could include a space that is non or less collapsible, with limited peristalsis or aperistaltic, and/or affixed at a particular point in the abdominal cavity. The fixed point can be considered fixed in relation to, for example, a fixed body point in the patient, such as the patient's hip. Significant bowel movement is considered to be highly undesirable during an intra-luminal operation on the bowel, for example, since it may create a challenging, unstable operative environment. Such bowel movement is normal, of course, even in a sedated patient and can be caused, for example, by bowel collapse from an air leak, peristalsis, breathing, and movement of the scope and instruments. Having a technology to

overcome this problem would help provide a stable operative space, which is clinically desired by one of skill in the operative environment.

Another current problem includes a lack of an endoscopic technology for retracting the tissue dynamically, for example, through an adjustable tissue retraction structure allowing for a controlled degree of expansion or collapse of the structure, to further configure the working space as desired around the instruments and target tissue. Such control can effectively provide for a method of adjusting the retractor, as well as tissue placement, in-and-around the working space. By increasing and releasing the tension on the retractor, the amount of tissue to be placed in the working space, for example, can be better-gauged and controlled during a procedure. Moreover, the tissue retraction and, particularly, traction-contraction can be facilitated to help create a desired dissecting plane or position the tissue more optimally during an operation. Having a technology to overcome this problem would help create an operative environment that is more desirable for tissue dissection, retraction, cutting and a removal of tissue.

Another current problem includes a lack of an endoscopic technology for organizing the endoscope, instruments, and working space in a manner that can maximize the working space for the treatment. The larger working space can improve the ability to manipulate the instruments and endoscope in a minimally-invasive manner from outside the body. Namely, one of skill would like to have a working space that has a point of entry for the instruments that is as far as practical from the target tissue to provide additional flexibility in approaching and visualizing the target tissue, perhaps providing more operating room for selecting a trajectory of the instruments toward the target tissue that is, for example, at least substantially perpendicular to the plane of dissection of the target tissue. Having a technology to overcome this problem would provide the person of skill with a system and procedure that is more desirable for a removal of tissue.

In view of at least the above, one of skill in the art of endoscopic, gastrointestinal surgical treatments would appreciate the technology taught herein which provides (i) a minimally-invasive expansion of the intra-luminal working space; (ii) an affixing, particularly an affixing that includes a reconfiguring without stretching or reconfiguring with stretching, of both the target tissue and surrounding tissue to help provide a stable, operative space; (iii) a retracting of the tissue dynamically, allowing for a partial or complete expansion or collapse, to further configure the working space between the instruments and the target tissue; and (iv) an organization of the endoscope instruments, such as the retractor and tools to maximize the working space and maneuverability, allowing for a maximum flexibility in approaching and visualizing the target tissue. It should be appreciated that having such improvements would reduce the technical complexity, and increase the efficacy and safety of, otherwise complex endoscopic operations. Moreover, doing so at a low cost, while using an affordable system that is introduced in the subject atraumatically and in a manner that does not substantially disrupt the conventional colonoscopy workflow, would be seen by those of skill as a very substantial advancement in the field of endoscopic surgical procedures.

SUMMARY

The teachings provided herein are generally directed to improved methods and devices for operatively treating gas-

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gastrointestinal disorders endoscopically in a stable, yet dynamic operative environment, and in a minimally-invasive manner. The systems, for example, include an endoscopic surgical suite. The surgical suite can have a reversibly-expandable retractor that expands to provide a stable, operative environment within a subject. The expansion can be asymmetric around a stabilizer subsystem to maximize space for a tool and an endoscope to each be maneuvered independently to visualize a target tissue and treat the target tissue from outside the patient in a minimally invasive manner. Embodiments taught herein provide, among other improvements, an increase in distance between tool ports and the target tissue to improve maneuverability and triangulation of the tools with respect to the target tissue, as well as a larger field of view.

In one aspect of the present disclosure, a system for performing minimally invasive procedures in a body lumen of a patient, such as a gastrointestinal tract, is provided comprising a flexible catheter having a first lumen configured and dimensioned to receive an endoscope therethrough and a second lumen configured and dimensioned to receive a first flexible tube therethrough. The first flexible tube is slidable axially through the second lumen and has a first channel (lumen) extending therethrough dimensioned and configured to receive a first endoscopic tool (instrument) for axial movement therein, the first flexible tube having a longitudinal axis and a tube distal portion movable to an angled position with respect to the longitudinal axis. A body lumen reshaping (reconfiguring) system is positioned at a distal portion of the catheter, the reshaping system including first and second flexible elements movable from a non-expanded insertion position to an expanded position forming an expanded cage to reshape the body lumen to an asymmetric shape to form an asymmetric working space, the distal portion of the first flexible tube movable within the expanded cage. A covering can be provided for at least a portion of the reshaping system, the covering having an opening to receive body tissue.

In some embodiments, the catheter has a third lumen configured and dimensioned to receive a second flexible tube, the second flexible tube having a second channel (lumen) extending therethrough configured and dimensioned to receive a second endoscopic tool (instrument) for axial movement therein. The second flexible tube can have a longitudinal axis and a tube distal portion movable to an angled position with respect to the longitudinal axis. The second flexible tube can be slidable axially within the third lumen and the distal portion of the second flexible tube can be movable within the expanded cage.

In some embodiments, the first flexible tube and/or second flexible tube are unattached to the catheter. In some embodiments, the distal tips of the flexible tubes can be substantially aligned with the longitudinal axis when positioned within the lumens of the catheter and return to the angled position when exposed from the second and third lumens.

In some embodiments, the cage further comprises third and fourth elements, wherein upon expansion of the reshaping system to the expanded position the first and second elements move from their collapsed insertion position outwardly away from a longitudinal axis of the catheter to the expanded position and the third and fourth elements remain substantially in a non-expanded insertion position.

The system in some embodiments can include a stabilizer movable from a first position to a second position to increase the stability and rigidity of the cage (reshaping system). In some embodiments, the cage includes a fifth flexible ele-

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ment, and the stabilizer comprises a stabilizing element movable within a lumen of the fifth element.

In some embodiments, the first and second flexible elements expand to only one side of the catheter to form the asymmetric working space and asymmetric cage to asymmetrically reshape (reconfigure) the body lumen.

The system can include a first and/or second actuator. The first actuator can be positioned at a proximal region of the catheter and operably coupled to the stabilizing element to move the stabilizing element between a first position and a second position to increase the stability and rigidity of the cage. The second actuator can be positioned at a proximal region of the catheter and operably coupled to the first and second flexible elements to move the first and second elements between the non-expanded and expanded positions.

In some embodiments, a retaining (locking) mechanism is provided to maintain the second actuator in one of several positions to retain (lock) the first and second elements in a desired expanded position. A release mechanism can be provided for releasing the retaining mechanism.

The system in some embodiments includes a proximal coupler to retain a proximal portion of the first and second elements and a distal coupler to retain a distal portion of the first and second elements, wherein the proximal and distal couplers can include an opening dimensioned to receive the endoscope therethrough when the catheter is backloaded over the endoscope. In some embodiments, a distal portion of the covering is attached to the distal coupler and a proximal portion of the covering is attached to the proximal coupler.

The covering can be closable to encapsulate tissue therein for removal. A flexible closing member such as a suture can be attached to the covering, wherein the flexible closing member is pulled to close the covering.

In some embodiments, a first and/or second transverse bridge member can be provided. The first transverse bridge member can be provided to join the first and second flexible elements to increase the rigidity of the reshaping system. The second transverse bridge member can be provided to join the third and fourth elements to increase the rigidity of the reshaping system.

In accordance with another aspect of the present disclosure, a method for performing a minimally invasive procedure in a body lumen of a patient, such as a gastrointestinal tract, is provided. The method preferably comprises the steps of inserting a flexible catheter over a proximal region of a flexible endoscope, inserting the flexible endoscope in the body lumen to visualize target tissue, and advancing the catheter over the endoscope, expanding a body lumen reshaping (re-configuring) system from a non-expanded insertion position to an expanded position to reshape the body lumen to create an asymmetric working space, and maneuvering a first flexible tube within the catheter, the first flexible tube having a distal curved tip and being axially movable and rotatable within the catheter to locate and orient the distal curved tip. The method preferably further comprises the step of maneuvering a first endoscopic instrument (tool) within the first flexible tube, wherein the first flexible tube can be located at a selected position to define a fixed curve and the endoscopic tool can be movable axially to adjust a distance between a distal tip of the endoscopic tool and target tissue without changing the selected position or curvature of the fixed curve.

In some embodiments, the method can include the steps of a) maneuvering a second flexible tube within the catheter, the second flexible tube having a distal curved tip and being

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axially movable and rotatable within the catheter to locate and orient its distal curved tip; and b) maneuvering a second endoscopic tool within the second flexible tube, wherein the second flexible tube can be located at a selected position to define a fixed curve and the second endoscopic tool can be

movable axially to adjust a distance between a distal tip of the second endoscopic tool and the target tissue without changing the selected position or curvature of the fixed curve.

In some embodiments, the distal tip of the first flexible tube and/or the distal tip of the second flexible tube is normally curved and is in a substantially straightened position when in the confines of the catheter during insertion and automatically assumes a curved position when exposed from the confines of the catheter.

In some embodiments, the first and second flexible tubes are independently axially movable and independently rotatable and are removably insertable through the catheter and remain unattached to the catheter.

In some embodiments, the first and second endoscopic tools are angled toward the target tissue to achieve triangulation with the target tissue.

The method can further include the step of inserting a working instrument through a working channel of the endoscope and into the asymmetric working space created by the reshaping system.

The reshaping system can include a covering, and the method can further include the step of closing the covering to encapsulate target tissue for removal.

The method can further comprise the step of rigidifying the reshaping system. In some embodiments, a control is actuated to distally advance rigidifying structure with respect to the reshaping system to rigidify and stabilize the reshaping system.

The teachings in another aspect include a floating, multi-lumen-catheter retractor system for ease of positioning in a subject. These systems are designed to provide a minimally invasive treatment of the subject. In some embodiments, the systems comprise a highly flexible outer tube configured for guiding a floating channel and a floating endoscope in an at least substantially floating arrangement within the system. This flexible outer tube can have a lumen, a proximal end, and a distal end. And, during a use of the system, the floating channel can serve as a guide through which a tool is manipulated in a treatment of a target tissue in a subject. In some embodiments, the tool can include a grasper, a forceps, a snare, a clamp, a scissor, a knife, a dissector, an endoscopic stapler, a tissue loop, a clip applier, a suture-delivering instrument, or an energy-based tissue coagulator or cutter. And, in some embodiments, the floating channel can have an elevator component for moving a bendable section to manipulate the tool.

The system in some aspects can also comprise a stable, yet dynamic operative environment in that it can include a reversibly-expandable retractor that expands to form a treatment space in the subject. The retractor can be configured, for example, for the expansion to occur distal to the distal end of the outer tube and at least substantially render the target tissue aperistaltic for the treatment. During the use of the system, in the embodiments utilizing a floating channel, the floating channel can be at least substantially attached to the lumen of the outer tube at a first proximal location and a first distal location, and be at least substantially floating in the lumen of the outer tube between the first proximal location and the first distal location. Likewise, during the use of such system, in some embodiments, the floating endoscope can be at least slidably-attached to the lumen of the

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outer tube at a second proximal location and a second distal location, and be at least substantially floating in the lumen of the outer tube between the second proximal location and second distal location. And, during the use of the system, the at least substantially floating arrangement can at least substantially increase the flexibility of the system over a second such system, the second such system having a lumen for a tool and an endoscope affixed to the lumen throughout the length of the outer tube between the proximal end and the distal end of the outer tube. The increased flexibility of the at least substantially floating arrangement can facilitate an ease of positioning the system in the subject for the treatment of the target tissue.

In some embodiments, the retractor can be a reversibly-stabilized and reversibly-expandable retractor, the retractor forming an asymmetrical treatment space upon the expansion. And, the retractor can be configured to reversibly stiffen an otherwise flexible arrangement of the retractor, the flexible arrangement designed to facilitate the ease of positioning of the system in the subject and to reversibly stiffen for the expansion of the retractor.

The teachings in another aspect also include a multi-lumen catheter system having a reversibly-stabilized and reversibly-expandable retractor for a minimally invasive treatment of a subject. The system can comprise a flexible outer tube for guiding a channel and an endoscope within the system, the flexible outer tube having a lumen, a proximal end, and a distal end. The channel can serve as a guide through which a tool is manipulated in a treatment of a target tissue in a subject. In some embodiments, the retractor can be a reversibly-stabilized and reversibly-expandable retractor forming a treatment space upon expansion and configured for the expansion to occur distal to the distal end of the outer tube. The retractor can be designed to reversibly-stiffen an otherwise flexible arrangement of the retractor, the flexible arrangement designed to facilitate the positioning of the system in the subject and to reversibly stiffen for the expansion of the retractor. In these embodiments, the reversibly-stiffened arrangement of the retractor can form an at least substantially rigid beam as a structural support for the expansion.

During a use of the some embodiments of the system which utilize the floating system, the channel (guide) can be a floating channel that is (i) at least substantially attached to the lumen of the outer tube at a first proximal location and a first distal location and (ii) at least substantially floating in the lumen of the outer tube between the first proximal location and the first distal location. Likewise, during the use of such system, the endoscope can be a floating endoscope that is (iii) at least slidably-attached to the lumen of the outer tube at a second proximal location and a second distal location and (iv) at least substantially floating in the lumen of the outer tube between the second proximal location and second distal location. And, during the use of such floating system in some embodiments, the channel (guide) and the endoscope form an at least substantially floating arrangement that (v) at least substantially increases the flexibility of the system over a second such system having separate lumens for a tool and an endoscope, the separate lumens affixed to the lumen throughout the length of the outer tube between the proximal end and the distal end of the outer tube, the increased flexibility facilitating an ease of positioning the system in the subject for the treatment of the target tissue.

The teachings also include in some embodiments a surgical suite with a floating, multi-lumen-catheter retractor system having a reversibly-stabilized and reversibly-ex-

pandable retractor for a minimally invasive treatment of a subject. In some of these floating embodiments, the system can comprise a highly flexible outer tube for guiding a floating channel and a floating endoscope in an at least substantially floating arrangement within the system. The flexible outer tube can have a lumen, a proximal end, and a distal end; and, the floating channel can serve as a guide through which a tool is manipulated in a treatment of a target tissue in a subject. The retractor can be a reversibly-stabilized and reversibly-expandable retractor forming a treatment space upon expansion. The retractor can be configured, for example, for the expansion to occur distal to the distal end of the outer tube and to reversibly stiffen an otherwise flexible arrangement of the retractor, the flexible arrangement designed to facilitate the positioning of the system in the subject and to reversibly stiffen for the expansion of the retractor.

During a use of the floating system in some embodiments, the floating channel (guide) can be (i) at least slidably-attached to the lumen of the outer tube at a first proximal location and a first distal location and (ii) at least substantially floating in the lumen of the outer tube between the first proximal location and the first distal location. Likewise, during the use of the floating system in some embodiments, the floating endoscope can be (iii) at least slidably-attached to the lumen of the outer tube at a second proximal location and a second distal location; and, (iv) at least substantially floating in the lumen of the outer tube between the second proximal location and second distal location. And, during the use of the floating system in some embodiments, the at least substantially floating arrangement can (v) at least substantially increase the flexibility of the system over a second such system having lumens for a tool and an endoscope, the lumens affixed to the lumen of the outer tube throughout the length between the proximal end and the distal end of the outer tube. The increased flexibility can facilitate an ease of positioning of the system in the subject; and, the reversibly-stiffened arrangement of the retractor can form an at least substantially rigid beam as a structural support for the expansion in the subject for the treatment of the target tissue.

In some embodiments, the retractor can comprise at least two expandable retractor elements, each of the members having a proximal end and a distal end, the proximal end slidably engaged with the outer tube, and each of the members configured such that an increase in the amount of sliding of the proximal end toward the distal end compresses the member and expands the retractor. These embodiments can also include a distal nexus located distal to the distal end of the outer tube and at which the distal end of each of the at least two retractor elements is affixed; and, a stabilizer subsystem connecting the distal nexus to the distal end of the outer tube and having an at least substantially rigid component configured to reversibly stiffen an otherwise flexible portion of the retractor for an asymmetric expansion of the retractor.

In some embodiments, the retractor comprises four expandable retractor elements, each of the members having a proximal end and a distal end, the proximal end slidably engaged with the outer tube, and each of the members configured such that an increase in the amount of sliding of the proximal end toward the distal end compresses the member and expands the retractor. These embodiments can also include a proximal coupler attached to the distal end of the outer tube, the proximal coupler having four retractor ports for the slidable engagement with the four retractor elements, the four retractor ports positioned circumferen-

tially around the proximal coupler and configured to facilitate a reversible, axial sliding of the retractor elements for the asymmetric expansion of the retractor. These embodiments can also include a distal nexus or coupler located distal to the distal end of the outer tube and at which the distal ends of each of the four retractor elements are affixed; and, a stabilizer subsystem connecting the distal nexus to the distal end of the outer tube and having (i) a flexible component that extends from the proximal coupler to the distal nexus and (ii) an at least substantially rigid component that is slidably engaged with the proximal coupler and reversibly extends from the proximal coupler to the distal nexus to reversibly-stiffen the retractor in an asymmetric expansion of the retractor.

The flexible component and the rigid component can in some embodiments have central axes that are each at least substantially parallel to the central axis of the distal end of the shaft, the rigid component forming an at least substantially rigid beam as a structural support for the asymmetric expansion, the rigid beam having a luminal side and an abluminal side. And, the expansion can occur in a disproportionately greater amount on the luminal side of the rigid beam to increase the treatment space, the treatment space having a volume that is asymmetrically distributed around the rigid beam. In some embodiments, the expansion can occur in an amount that is at least 5× greater on the luminal side of the beam than the abluminal side of the beam.

In some embodiments, the system can include a bridge member configured to maintain a desired orientation of the retractor elements during the expansion, the bridge member operably stabilizing at least two of the four retractor elements. Moreover, in some embodiments, the outer tube can be wire-reinforced to provide kink resistance and torqueability to the system to further facilitate a positioning of the system in the subject.

The systems provided herein can be used in several different methods of treatment. For example, the systems can be used in a method of treating a gastrointestinal lesion using a multidirectional and multi-angular approach to the lesion. The method can include positioning the system in a subject's gastrointestinal tract, the positioning including placing the retractor in proximity to a target lesion for a treatment; expanding the retractor to create the treatment space for use of the tool; improving visualization, for example, some lesions can be seen much better when tissue is retracted and stabilized; optimally positioning the target tissue in relation to the tool, for example, by optimizing the position of the duodenal papilla, facilitating its cannulation during a procedure; treating the target tissue with the tool; collapsing the retractor; and, withdrawing the system from the subject. The lesion can include, for example, a perforation, a tissue pathology a polyp, a tumor, a bleed, a diverticuli, an ulcer, a cancerous tissue, an abnormal vessel, or an appendix.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 illustrates a system for operatively treating gastrointestinal disorders endoscopically in a stable, yet dynamic operative environment, and in a minimally-invasive manner, according to some embodiments.

FIGS. 2A and 2B illustrate how a system as taught herein can be positioned for treating a lesion in the ascending colon, according to some alternate embodiments.

FIGS. 3A-3L illustrate how a system as taught herein can be used in removing a lesion in a colon, according to some embodiments, the colon shown in a cutaway view to show

the system in perspective, wherein FIG. 3A illustrates the system being inserted into the colon and having a sheath covering the retractor, FIG. 3B illustrates the retractor in the non-expanded position, FIG. 3C illustrates the retractor in the expanded position to create an asymmetric working space and further showing the endoscope in an articulated position, FIG. 3D is a view similar to FIG. 3C showing two endoscopic instruments extending from respective tool channels, FIG. 3E illustrates the tool channels and the endoscopic instruments bent toward the target lesion, FIG. 3F illustrates the lesion being removed from the wall of the colon by the endoscopic instruments, FIG. 3G illustrates the lesion removed from the wall of the colon and positioned within the retractor, FIG. 3H illustrates endoscopic instruments extending from the tool channels and bent toward the colon wall to repair the defect in the colon wall resulting from removal of the lesion, FIG. 3I illustrates placement of clamps to close the tissue defect in the colon wall, FIG. 3J illustrates the retractor in the collapsed position to capture the lesion for removal from the colon; FIG. 3K illustrates the retractor encapsulated within the sheath for removal from the colon, and FIG. 3L illustrates the closed tissue defect after completion of the surgical procedure.

FIGS. 4A-4E illustrate details of a system as taught herein, in side, axial, and oblique views of expanded and collapsed configurations, and including a stabilizer subsystem, according to some alternate embodiments, wherein FIG. 4A is a side view of the system with the retractor in the non-expanded (collapsed) position, FIG. 4B is an axial view of the system with the retractor in the non-expanded position, FIG. 4C is an axial view of the system with the retractor in the expanded position, FIG. 4D is a perspective view of the system in the position of FIG. 4A, and FIG. 4E is a view similar to FIG. 4D showing the retractor in the expanded position.

FIGS. 5A-5D illustrate side and top views of a system as taught herein, having side views and top views of expanded and collapsed configurations, according to some alternate embodiments, wherein FIG. 5A is a side view of the system with the retractor in the non-expanded (collapsed) position, FIG. 5B is a side view similar to FIG. 5A showing the retractor in the expanded position; FIG. 5C is a top view of the system with the retractor in the non-expanded position of FIG. 5A, and FIG. 5D is a top view of the system with the retractor in the expanded position of FIG. 5B.

FIGS. 6A-6D illustrate side views of a system as taught herein, having side views and cross-sections of expanded and collapsed configurations of the system, according to some other alternate embodiments, wherein FIG. 6A is a side view of the system with the retractor in a non-expanded (collapsed) position; FIG. 6B is a side view similar to FIG. 6A with a housing half removed to show internal components of the system, FIG. 6C is a side view similar to FIG. 6A showing the retractor in an expanded position, and FIG. 6D is a side view similar to FIG. 6B showing the retractor in the expanded position.

FIG. 7 illustrates a cutaway view of the distal end of the outer tube of a system as taught herein, showing components of the expansion and collapse of the retractor, according to some embodiments.

FIG. 8 illustrates the cutaway view of FIG. 7, showing the distal end of the outer tube of a system as taught herein, in which components of the system can be floating in the outer tube to enhance flexibility for positioning the system in a subject, according to some embodiments.

FIGS. 9A and 9B illustrate side views of working, and/or floating, channels that can be used to guide tools as taught herein, according to some embodiments.

FIGS. 10A-10E illustrate an alternate embodiment of the system wherein a retractor sheath covers a retractor of a system as taught herein, according to some embodiments, wherein FIG. 10A is a top view of the system with the retractor in a non-expanded (collapsed) position, FIG. 10B is a perspective view of the system in a non-expanded position, FIG. 10C is a side view of the system with the retractor in a non-expanded position, FIG. 10D is a top view of the system showing the retractor in an expanded position, and FIG. 10E is a side view of the system showing the retractor in the expanded position.

FIG. 11 is a perspective view of an alternate embodiment of the system showing the catheter and two tool channels.

FIG. 12 is a perspective view of the catheter of FIG. 11 being inserted over the proximal end of the endoscope of FIG. 13 (prior to insertion of the endoscope into the colon), the retractor system shown in the collapsed position.

FIG. 13 illustrates insertion of the endoscope through the colon.

FIG. 14 is a perspective view showing the catheter of FIG. 11 being further advanced over the endoscope of FIG. 13, the retractor system shown in the collapsed position.

FIG. 15 is a perspective view showing the catheter fully advanced over the endoscope to the desired position adjacent the target tissue, the retractor system shown in the collapsed position.

FIG. 16 is a perspective view of the proximal end of the catheter of FIG. 11.

FIGS. 17A and 17B are side views in partial cross-section showing movement of the actuator from a proximal position to a distal position to advance the rigidifying structure to stiffen the retractor system.

FIG. 17C is a perspective view similar to FIG. 15 showing an alternate embodiment of the rigidifying structure.

FIG. 17D is a perspective view similar to FIG. 17C showing the rigidifying structure of FIG. 17C advanced over the flexible element.

FIG. 18 is a perspective view showing the two tool channels (guides) adjacent the proximal end of the catheter of FIG. 11 for insertion therethrough.

FIG. 19A is a perspective view illustrating the tool channels inserted into the catheter of FIG. 11 and FIG. 19B is a perspective view illustrating an alternative embodiment of the tool channels.

FIGS. 20A and 20B are side views in partial cross-section showing movement of the actuator from a proximal position to a distal position to move the retractor system to the expanded position.

FIG. 21A is a view similar to FIG. 15 showing the retractor system in the expanded position and further illustrating the tool channels being advanced into the working space (chamber) created by the expansion of the retractor system.

FIG. 21B is a view similar to FIG. 21A illustrating an alternate embodiment wherein the tool channels are advanced from the catheter prior to expansion of the retractor system.

FIG. 22 is a view similar to FIG. 21A showing a first endoscopic instrument (tool) advanced from a first tool channel.

FIG. 23 is a view similar to FIG. 22 showing a second endoscopic instrument (tool) advanced from a second tool channel.

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FIG. 24 is a view similar to FIG. 23 showing both endoscopic instruments further advanced from the tool channels.

FIG. 25 is a view similar to FIG. 24 showing the endoscopic instruments further advanced from the tool channels to dissect the lesion on the colon wall.

FIG. 26 is a view similar to FIG. 25 showing the lesion which has been removed from the colon wall by the dissecting instrument placed within the retractor system.

FIG. 27 is a perspective view of the proximal end of the catheter showing proximal movement of the actuator to return the retractor system to the collapsed position for removal from the colon.

FIG. 28 is a view similar to FIG. 26 showing the retractor system in the collapsed position.

FIG. 29 is a view similar to FIG. 28 showing the covering member closed to encapsulate the lesion for removal.

FIG. 30 is a front view of the system in the expanded position of the retractor system and showing two channels extending from the catheter.

FIGS. 31A and 31B are cross-sectional views illustrating the switch for retaining the suture for closing the covering (bag).

DETAILED DESCRIPTION

The teachings provided herein are generally directed to improved methods and devices for operatively treating gastrointestinal disorders endoscopically in a stable, yet dynamic operative environment, and in a minimally-invasive manner. The systems, for example, include an endoscopic surgical suite that is created by the systems disclosed herein. The surgical suite can have a reversibly-expandable retractor that expands to provide a stable, operative environment within a subject. In some embodiments, the expansion can be asymmetric around a stabilizer subsystem to maximize space for a tool and an endoscope to each be maneuvered independently to visualize a target tissue and treat the target tissue from outside the patient in a minimally invasive manner. Embodiments taught herein can provide, among other improvements, an increase in distance between tool ports and the target tissue to enhance the independent maneuverability and triangulation of each of the tools with respect to the target tissue. This increase in distance can also provide a way of obtaining a larger field of view. The systems taught herein, for example, can (i) enable a working space to be dynamically configured around the target tissue in tortuous body lumens and orifices such as the gastrointestinal tract using controls from outside the body; (ii) provide a flexible, passageway for multiple surgical tools and instruments, such as endoscope and graspers to be passed from outside the body towards the target tissues; (iii) organize and/or constrain tools in the working space; (iv) at least substantially immobilize and/or stabilize the target tissue and surrounding tissue for a treatment; and/or (v) enable control over the geometry position, and orientation of the instruments such as the grasper in the working space from outside the body.

In some embodiments disclosed herein, an articulating endoscope is inserted through a channel of the catheter; in other embodiments the system is backloaded over a flexible endoscope, such as a conventional colonoscope, then the endoscope is inserted to a position adjacent the target tissue and then the catheter is advanced over the flexible endoscope so the reshaping system (cage) is next to the target tissue.

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In some embodiments disclosed herein, the endoscopic working instruments (tools) for treating the target tissue are inserted directly through a respective lumen or channel of the multi-lumen catheter. In these embodiments where the instruments (tools) are inserted directly into the lumen of channel of the catheter, the working instruments can have a curve at a distal end which automatically assumes the curved position when exposed from the catheter so it can curve toward the target tissue, or alternatively, the working instruments can have a mechanism actively controlled by the user to articulate/angle the distal tip. In other embodiments, instead of the endoscopic working instruments (tools) being inserted directly into the channel or lumen of the catheter, a flexible tube is inserted through the lumen or channel of the catheter and acts as a guide for the instrument. That is, the flexible tube is first inserted into the lumen or channel of the catheter and then the endoscopic instrument is inserted through the respective flexible tube. The flexible tube can have a curve at a distal end which automatically assumes the curved position when exposed from the catheter so it can curve toward the target tissue, or alternatively, the flexible tube can have a mechanism actively controlled by the user to articulate/angle the distal tip. In these embodiments utilizing the flexible tubes, the curving and maneuverability of the flexible tubes controls the positioning and orientation of the endoscopic instruments, and therefore the endoscopic instruments need not be provided with a pre-curved tip or articulating mechanisms.

In preferred embodiments, the systems disclosed herein include a retractor which creates an asymmetric working space within the body lumen. More particularly, when working in a confined body lumen, such as the colon, expansion of the lumen is limited because it is undesirable to over-expand which could stretch the lumen beyond its ability to return to its normal state or more dangerously could rupture the lumen. The asymmetric working spaces disclosed herein are designed to reconfigure or reshape the body lumen-transform the cylindrical space within the body lumen to a non-cylindrical asymmetrical space (i.e., changing the geometry) to shift the space around the target tissue to create more working space around the target tissue to provide both visual and mechanical improvements. Stated another way, in a cylindrical working space, there is a lot of area of unused space while in the reshaping of the embodiments disclosed herein the space is moved or shifted to reduce the unused space and create a larger area for tissue access and treatment.

The terms "treat," "treatment", and "treating" used herein include, for example, the therapeutic and/or prophylactic uses in the prevention of a disease or disorder, inhibition of a disease or disorder, and/or amelioration of symptoms of disease or disorder. The term "subject" and "patient" can be used interchangeably and refer to an animal such as a mammal including, but not limited to, non-primates such as, for example, a cow, pig, horse, cat, dog, rat, and mouse; and, primates such as, for example, a monkey or a human.

In some embodiments, the systems taught herein can include dynamically reconfigurable, asymmetric retractor structures on the distal end of a flexible and torque-able multi-channel shaft having a handle that allows for control over both the stiffness and geometry of the working space formed by the expansion of the retractor. In some embodiments, the retractor can include a stabilizer subsystem having 2-8, 3-5, 4-6, or any range therein, flexible retractor elements. In some embodiments, the retractor elements can be aligned at least substantially parallel to each other when fully collapsed for positioning in the patient. In some

embodiments, the retractor elements are aligned on planes that are within about 5-30 degrees, about 10-25 degrees, about 15-20 degrees, about 15 degrees, or any range therein, of each other. In some embodiments, the retractor elements form a frame that has a length ranging from about 4-12 cm. 6-10 cm, 7-9 cm, 5-11 cm, or any range therein. In some embodiments, the frame is about 8 cm long. In some embodiments, the retractor elements form a frame that has a width ranging from about 1-5 cm. 2-4 cm, or any range therein. In some embodiments, the frame is about 3 cm wide. In some embodiments, the retractor elements form a frame that has a height ranging from about 1-5 cm. 2-4 cm, or any range therein. In some embodiments, the frame is about 3 cm high. One of skill will appreciate that there are a number of suitable materials that can be used to make the retractor elements for the purposes set-forth herein. In some embodiments, the retractor elements can be made from NITINOL. In some embodiments, the retractor element can comprise multifilament steel wires or polymer cords. The polymer materials can include polyetheretherketone (PEEK), nylon, polyester, polycarbonate, polyurethane, or polyethylene. The gauge of the retractor elements can vary, depending on material. In some embodiments, the retractor elements can comprise wires that range from about 0.020"-0.40" in diameter. In some embodiments, the retractor elements are about 0.030" in diameter.

The term "about" is used in the teachings herein to describe possible variations in amounts or ranges that can be used in embodiments. It can be used in embodiments, for example, to include the exact amount or range specified, as well as a variation of which that would not create a substantial difference in function. A difference in function can be insubstantial, for example, where it is less than 20% in some embodiments, less than 15% in other embodiments, less than 10% in yet other embodiments, or perhaps even less than 5% in yet other embodiments. One of skill will appreciate that the percentage difference in function required for to be substantial will depend on the function of the embodiment itself that is under comparison.

The methods, devices, and systems taught herein can be used for minimally-invasive procedures. A non-invasive procedure, in contrast, can be defined as a procedure that includes no violation of the skin or the mucosa, and no appreciable damage to any other tissues of the body. A minimally-invasive surgical operation, on the other hand, involves minimal access trauma and minimal collateral tissue damage during a surgical operation. The terms "minimal," "minimize," "minimizing," "minimized," "avoid," "avoiding," "avoided," can be used interchangeably in some embodiments. Minimally-invasive surgery is desirable, for example, to reduce trauma to the patient, speed the healing process, reduce risk and, thus, reduce the length and expense of a hospital stay by minimizing or avoiding tissue damage, or risk of tissue damage. Tissue damage, or the risk thereof, can be minimized or avoided, for example, where a procedure is designed to minimize or avoid unnecessary tissue contact that may otherwise be associated with a procedure. The gentle procedures taught herein, for example, are directed to preserving tissue during a gastrointestinal surgery.

The systems taught herein can be dynamic in some embodiments, for example, such that the tissue retraction can include partial or complete expansion or collapse of a retractor to facilitate an increase or decrease in the distance between instruments and the target tissue, which is useful in reconfiguring the work space and aiding in axial movements of the tools. By increasing and releasing the tension, the

amount of tissue to be placed in the working space can also be better-gauged during a procedure, for example, and tissue traction-contraction can be facilitated to help in creating a dissecting plane during a removal of tissue. One of skill will appreciate having the ability to dynamically reconfigure the working space and optimize traction-contraction on the target tissue, as this can facilitate surgical manipulations.

The systems disclosed herein also enable triangulation to be achieved. Tissue triangulation, wherein the tissue is triangulated between two endoscopic instruments, enhances access and maneuverability.

FIG. 1 illustrates a system for operatively treating gastrointestinal disorders endoscopically in a stable, yet dynamic operative environment, and in a minimally-invasive manner, according to some embodiments. The system **100** can include a multi-lumen-catheter retractor system for ease of positioning in a subject, and such systems can be designed to provide a minimally invasive treatment of the subject. The system **100** can have a flexible outer tube **105** configured for guiding one or more channels **110** and an endoscope **115** within the system **100**. The flexible outer tube **105** can have a lumen (not shown), a proximal end (not shown), and a distal end **108** to house, for example, the channel(s) and the endoscope during use of the system **100**. The lumen can extend from the proximal to the distal end so the tool channels **110** can be manipulated at a proximal end by the user. The outer tube **105** can alternatively be a multi-luminal tube, so a separate lumen accommodates the endoscope and the individual tool channels, and during the use of the system **100**, the channel **110** can serve as a guide through which a tool **120,125** can be inserted and manipulated in a treatment of a target tissue **190** in the gastrointestinal tract **195** (or other areas) of the subject. The channel **110** can, for example, be in operable contact with an independently manipulable-and-articulable tool, the channel having an elevator component for moving a bendable section. Thus, the length of the channel in some embodiments is sufficient so it can extend out the proximal end of the outer tube **105** for manipulation by the user. The tool channels are bendable or articulable at a distal end so they angle away from the longitudinal axis and toward the target tissue **190**. Such bendability can be achieved by providing tool channels (guides) **110** of shape memory material with a shape memorized bent position as shown in FIG. 1. When contained within the lumen of the outer tube **105** for insertion, the tool channels **110** would have a substantially straightened position, and when advanced from the distal end of the outer tube **105**, would return to the bent position of FIG. 1. Other materials could also be utilized. In alternate embodiments, the tool channel **110** can have a mechanism such as an elevator component or a control wire attached to a distal end which can be pulled by the user or pulled by an actuator to move the tool channel to the bent position. These different ways to achieve bendability (articulation) of the tool channels can be used for the various embodiments of the systems described herein.

In some embodiments, the tool inserted through the tool channel can be any tool known to one of skill. For example, the tool **120,125** can include a grasper, a forceps, a snare, a scissor, a knife, a dissector, a clamp, an endoscopic stapler, a tissue loop, a clip applier, a suture-delivering instrument, or an energy-based tissue coagulator or cutter. The bendability of the channel **110** for moving a bendable section, often a distal end of the channel **110**, manipulates, i.e., bends, the tool **120,125** positioned therein. In some embodiments, at least one channel **110** and/or the endoscope **115** can have at least substantial freedom to move within the

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outer tube **105** during operation, or "float," such that the system **100** can be considered to be a floating, multi-lumen-catheter retractor system. It should be appreciated that the terms "tool" and "instrument" can be used interchangeably in some embodiments taught herein. As can be appreciated, the tool **120,125** can be flexible, at least at a distal end such that when the tool channel **110** bends in a manner described above, it also bends the tool which is positioned therein. Alternatively, it is also contemplated that the tool **120,125** can be articulable or controllably bendable or composed of shape memory or other material so it bends without reliance on the bendability of the tool channels **110**.

Although two tool channels **110** are illustrated, it should also be appreciated that a system with more than two tool channels or with only one tool channel can also be utilized. Additionally, the endoscope can have a working channel for insertion of a working instrument such as a grasper or dissector.

It is also contemplated that the tools can be provided with bendability characteristics so that they can be inserted directly through the lumen of the outer tube **105** without the need for tool channels. In these embodiments, the tools themselves have the bendable or articulable feature so as not to rely on the tool channels for bending/angling toward the target tissue.

In some embodiments, the system can comprise a stable, yet dynamic operative environment in that it can include a reversibly-expandable retractor **150**, as shown in FIG. 1, that expands to form a treatment space or working chamber **160** in the subject. The retractor **150** can be configured, for example, for the expansion to occur distal to the distal end **108** of the outer tube **105**. In some embodiments, the retractor can at least substantially render the target tissue **190** aperistaltic for the treatment. The retractor **150** can have a variety of configurations to serve, for example, as a scaffolding within the gastrointestinal tract **195**. For example, the retractor **150** can include retractor elements **151,152,153,154**, along with a proximal coupler **198** operably connected to the retractor elements **151,152,153,154**, whether at least substantially attached and/or at least slidably-engaged to the retractor elements **151,152,153,154**, and a distal nexus or hub (or coupler) **199** for a distal point of an operable connection with the retractor elements **151,152,153,154**.

In the embodiment of FIG. 1, retractor element **151** is a flexible element having a proximal portion **151a** extending from the proximal coupler **198** at a first angle, a distal portion **151b** extending from the distal hub or coupler **199** at a second angle preferably different from the first angle, and an engaging portion **151c**, which engages the tissue, extending between the proximal and distal portions **151a, 151b**. As shown, portion **151a** extends at a greater angle to the longitudinal axis than distal portion **151c** providing an asymmetric expansion of the retractor element itself. Thus, the length of the distal portion **151b** exceeds the length of proximal portion **151a**. Retractor element **152** can be similarly configured and angled as retractor element **151**, or alternatively of a different configuration and angle. Retractor elements **151** and/or **152** can alternatively be configured so the proximal and distal portions are of the same length and angles. Note the retractor elements **151, 152** expand in a direction to one side of the longitudinal axis. This asymmetric expansion creates an asymmetric chamber described below.

The retractor **150** can be a reversibly-stabilized and reversibly-expandable retractor, the retractor **150** forming an asymmetrical treatment space **160** upon the expansion. And, the retractor **150** can be configured to reversibly stiffen an

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otherwise flexible arrangement of the retractor **150**, the arrangement designed to facilitate ease of positioning of the system **100** in the subject and to reversibly stiffen for the expansion of the retractor **150**. The stabilization of the retractor **150** can, in some embodiments, include a means for stabilizing the retractor **150** through a stabilizer subsystem as taught herein, the stabilizer having, for example, an at least substantially-rigid beam **175** to support the expanded retractor **150**.

Rigidifying the retractor systems as disclosed in the various embodiments herein, i.e., by utilizing a substantially rigid beam, advantageously stabilizes the retractor system, i.e., limits bending of the distal tip which could otherwise occur due to the opposing force of the tissue during expansion. Thus, the stabilizer carries the load and works to create a more stabilized chamber. In some embodiments, beam **175** can be substantially rectangular in cross-section, substantially circular in cross-section or of other cross-sectional shapes. It can be provided of a stiffer material than the retractor elements. In some embodiments, the beam can have a cross sectional dimension larger than a cross sectional dimension of the retractor element. As shown in FIG. 1, the beam **175** is at the base of the chamber formed by the retractor elements, with the retractor elements extending radially (laterally) away from the beam **175**. The beam **175** can be formed by the more rigid element exposed when the retractor elements are exposed from the outer tube for expansion, or alternatively, can be advanced independently from within the outer tube as in some of the embodiments described in more detail below.

In some embodiments, the outer tube can have any dimensions believed to be useful to one of skill for the purposes taught herein. For example, the outer tube can have an outer diameter ranging from about 3 mm to about 30 mm, about 5 mm to about 25 mm, about 7 mm to about 22 mm, from about 9 mm to about 20 mm, from about 11 mm to about 18 mm, from about 8 mm to about 15 mm, from about 10 mm to about 16 mm, or any range therein in increments of 1 mm. The length of the outer tube can range, for example, from about 30" to about 72", from about 31" to about 36", from about 28" to about 80", from about 32" to about 40", from about 34" to about 38", or any range therein in increments of 1".

The outer tube can be manufactured from any materials known to be useful to one of skill for the purposes taught herein. For example, the outer tube can comprise a polymer, or perhaps a polymer having an embedded wire reinforcement. The wire reinforcement can be a mesh, a braid, a helical coil or any combination thereof. The wire reinforcement can include any material believed by one of skill to be useful for the purposes set forth herein. For example, wire reinforcement can comprise a material having an elastic modulus that is about 1-3 orders of magnitude higher than the polymer tube. The wire material can comprise, for example, a stainless steel having a diameter ranging from about 0.003" to about 0.017", about 0.005" to about 0.015", about 0.010" to about 0.012", or any range therein in increments of about 0.001". The tube hardness, or durometer, can be any of that which one of skill will find useful for the purposes set forth herein. For example, the hardness can range, for example, from about 50 Shore A to about 60 Shore A, about 40 Shore A to about 80 Shore A, about 45 Shore A to about 70 Shore A, or any range therein in increments of 1 Shore A. One of skill will appreciate that the outer tube should be flexible, elastically bendable, but sufficiently stiff torsionally to transmit torque from the handle or proximal end of the system to the retractor or distal end of the system.

The outer tube can be connected to at a distal end to a ring, referred to herein as the proximal coupler in some embodiments, which can have portals formed therein for retractor elements to slide through, as well as a desired orientation and positioning of the channels for the endoscope and at least one tool, such that the retractor elements, endoscope, and at least one tool are organized relative to each other in a predetermined manner to achieve a particular function, such as an increase in working space, a better view of a plane of dissection, or any other procedural variable deemed of interest to one of skill. For example, in the embodiment shown in FIG. 1, the portals for the retractor elements are spaced radially outwardly from the portals for the endoscope and the tool channels.

In some embodiments, the retractor structures taught herein are each a means for substantially immobilizing the lesion to the extent desired for the treatment. For example, the current use of loops and a piece-meal removal of flat or wide-based polyps, such as those having a base of about 1 cm or wider, may not provide clear surgical margins, whereas the systems taught herein can, in some embodiments, immobilize or affix the entire circumference of the bowel wall around the treatment area and facilitate the production of clear surgical margins. One of skill will appreciate having a working space that can be provided by the systems taught herein, the working space being (i) at least substantially non-collapsible, (ii) at least substantially aperistaltic; and, (iii) at least substantially affixed at a particular point in the abdominal cavity in relation to any fixed body point, like a hip, for example. This is a significant improvement over existing systems, as existing systems have not addressed many existing problems including, for example, bowel collapse that can result from an air leak from the working space; peristalsis that is normal, even in a sedated patient; and, additional undesired bowel movements caused by the patient's breathing, movement of the scope or other instrument manipulation, or perhaps even by a surrounding peristalsis causing movement at a treatment area. Such problems are addressed by systems taught herein. As such, systems taught herein can offer a rigid, stable structure having at least substantial resistance to a variety of moving forces in the abdomen that are typically present during a gastrointestinal endoscopic procedure. One of skill will appreciate decreasing the effects of these moving forces on the working space to help reduce otherwise inherent technical complexities, limited efficacies, and decreased safety during endoscopic procedures.

In addition to creating the working space with the above advantages, the working space is formed to create a sufficient working distance for the tools for treatment, e.g., polyp dissection, to enhance maneuvering and manipulating the individual tools, enabling tissue triangulation. Working space distance is also advantageously formed to enhance visibility of the target tissue.

In some embodiments, the systems taught herein can be slidably positioned over an endoscope during use. In these embodiments, the endoscope would first be inserted to a position adjacent the target tissue and then the multi-lumen tube or catheter advanced over the endoscope, with the endoscope sliding over the endoscope receiving lumen (channel) of the outer tube or catheter. In fact, it should be appreciated that there are a variety of methods of using systems taught herein that are already used by one of skill in current state-of-the-art procedures. For example, the method can include inserting the multi-luminal tube into an over-tube, cover, or sheath. And, in some embodiments, the endoscope can be a colonoscope. In many embodiments,

regardless of the method of use, the retractor structures can mechanically retract one side of the colonic wall in an asymmetric manner to increase the distance between the target lesion and the opposite wall, as well as between the lesion and the instruments in their most retracted, but visualized, position to increase the effective work space.

In some embodiments, the systems can include a multi-lumen catheter having at least 2 working channels for manipulating tools and an endoscope, each of the two working channels having 6 degrees of freedom that are independent from each other and the endoscope. The ability to independently manipulate the endoscope and tools allows, for example, one instrument to retract the tissue or lesion away or substantially perpendicular to another instrument, for example, the dissecting instrument, while independently optimizing the endoscope's position and, hence, the view of the treatment area. This would facilitate the removal of tissue with clear margins. The channels can manipulate the tools with several degrees of freedom, 6 degrees of freedom in some embodiments, providing a greatly enhanced maneuverability in the working area when compared to current state-of-the-art systems. In some embodiments, the at least one independently manipulable-and-articulable tool can be independently rotatable to an angle of up to about 360 degrees, about 315 degrees, about 270, about 225 degrees, about 180 degrees, about 135 degrees, or about 90 degrees in the working area. In addition the tools can be independently bendable to an angle of up to about 180 degrees, about 135 degrees, about 90 degrees, or about 45 degrees in at least one direction in the working area.

The systems taught herein can have a means for organizing the orientation of the floating channels, in order to further facilitate improving the flexibility of the system. In some embodiments, for example, the proximal coupler, the ring that can be attached to the distal end of the outer tube, can be used to organize the tools and endoscope in a particular arrangement to facilitate a particular positioning of the tools as they emerge from the shaft into the working space created by the retractor. In some embodiments, the tool channels can be placed further than the endoscope from the retractor elements that expand the most. Likewise, the proximal end of the outer tube can also have respective openings for each of the channels, and these openings can be, for example, a part of a handle coupler, or the handle itself, operably connecting one or more of the channels to the outer tube. The operable connection between the outer tube and channels can provide a means for controlling the endoscope and tools, for example, from outside the patient. The rings can be made of any material believed by one of skill to be suitable for the purposes discussed herein. For example, the rings can be made of stainless steel, or perhaps a plastic such as polycarbonate or acrylonitrile butadiene styrene (ABS).

It should be appreciated that, in some embodiments, the systems taught herein can include any combination of components, the selected combination of which is designed to be operable with components that are obtained separate from the system. For example, the system can include an outer tube and a retractor component, the outer tube being operable with at least one channel obtained separately and an endoscope obtained separately. Likewise, the system can include an outer tube, a retractor, and an endoscope, and the channels are obtained separately; or an outer tube, a retractor, and a channel, the endoscope obtained separately. Moreover, the system can include an outer tube, a retractor, an

endoscope, and at least one channel; or, a handle, an outer tube, a retractor, an endoscope, at least one channel, and at least one tool.

The terms “substantial,” and “substantially” can be used, for example, to refer to a relative measure for a parameter. It can be used in some embodiments, for example, to refer to a degree of change or function that relates to an amount, a performance, or some other characteristic. The following are for purposes of example in describing general embodiments: As described, the systems can be considered to be floating systems, can have a floating channel, a floating endoscope, multiple floating channels, or a combination thereof, in some embodiments. For example, the phrase, “an at least substantially floating arrangement within the system”, can refer to an arrangement, for example a channel or endoscope arrangement, that can have some attachment that restricts movement in at least one direction, a minimal attachment to minimize such restriction of movement, or perhaps no attachment at all, to another system component. For example, a channel or endoscope can be arranged to be at least substantially floating in the outer tube relative to a second such system that does not use a floating-type arrangement to increase flexibility, or inherently achieve an increase in flexibility, of the second such system. As such, in many embodiments, the endoscope and/or channel can have a substantial portion of its arrangement unattached within the system, allowing the substantial portion to “float” or move substantially freely within the outer tube. The “substantial portion” can be, for example, a percentage of the arrangement that must remain unattached within the system to provide a performance characteristic, such as an increased flexibility of the system when compared to the second such system that does not use a floating-type arrangement to increase flexibility, or inherently achieve an increase in flexibility, of the second such system.

The phrase, “at least substantially render the target tissue aperistaltic for the treatment”, for example, can refer to the target tissue having some minimal peristalsis, or perhaps no peristalsis, under the conditions of normal use to provide a performance characteristic, such as controlling movement of the target tissue to facilitate treatment. The phrase, “at least substantially attached”, for example, “at least substantially attached to the lumen of the outer tube”, for example, can refer to a component having a fixed attachment or moveable attachment. In some embodiments, the attachment can be between the component and the lumen, such that there is a loss of at least one degree of freedom of movement of the component. For example, the component can slide and/or rotate in relation to the lumen of the outer tube, as long as the sliding and/or rotating occur in relation to a particular fixed point on the lumen. Likewise, “at least substantially attached” can, of course, mean “fixed”, “reversibly fixed,” or the like, in some embodiments. Likewise, “at least slidably-attached” can refer to an attachment between components that allows for at least sliding motion between components such as, for example, a sliding motion between a port and a tube. In some embodiments, an endoscope can be at least slidably-attached, for example, where the scope is allowed to slide in the direction of the scope’s central axis in and out of a port, such that the distance that the scope extends beyond the port is adjustable. And, in some embodiments, a component can be “at least slidably-attached” where it can slide as well as move in other directions. For example, the port can be substantially larger than the scope, in some embodiments, such that the scope can slide axially, as well as move side-to-side, align its central axis parallel to the

central axis of the outer tube, or perhaps, misalign its central axis to not be parallel to the central axis of the outer tube.

The phrase, “at least substantially increases the flexibility” can refer to an orientation of components that enhances the flexibility of a system when compared to another orientation and design of the components. For example the phrase “at least substantially increases the flexibility of the system over a second such system” can refer to a comparison of flexibility of the claimed system over the second system not having the floating arrangement under the conditions of normal use, such that the flexibility of the system has increased to a minimal amount that improves the ease of positioning the system in the subject for the treatment of the target tissue.

The phrase, “at least substantially rigid component,” can refer to a component that is rigid, or sufficiently rigid, such that the desired function is obtained, under the forces that are created with normal use. For example, a desired function may be to prevent or inhibit the occurrence of a bending moment of the rigid component at one or more points along the length of a retractor upon expansion of the retractor in the subject. In some embodiments, the systems taught herein can have a retractor with four retractor elements, at least two of which are expandable in the subject to create a working space for a treatment. In this example, the expansion of the at least two retractor elements toward the target tissue to create the working space requires a force sufficient to retract the tissue and, creates an opposing force in the opposite direction that can create the bending moment in the rigid component. One of skill should appreciate that such a bending moment can be problematic, for example, where it contributes to an instability that affects the user’s control over the position of the retractor during a treatment of the target tissue. In such embodiments, a component that prevents or inhibits the bending moment can be “at least substantially rigid,” for example, where the user retains a desired level of control, or at least sufficient control, over the position of the retractor during the retraction of the target tissue. In some embodiments, a component that prevents or inhibits a bending moment, whether in or out of the subject, can be at least substantially rigid where the bending of the component due to the expansion of the retractor creates a deflection that ranges from 0.0 to about 5 degrees, about 1.0 degree to about 10 degrees, about 2.0 degrees to about 12 degrees, about 3.0 degree to about 10 degrees, about 1.0 degree to about 15 degrees, about 1.0 degree to about 9.0 degrees, about 1.0 degree to about 8.0 degrees, about 1.0 degree to about 7.0 degrees, about 1.0 degree to about 6.0 degrees, about 1.0 degree to about 5.0 degrees, about 1.0 degree to about 4.0 degrees, or any range therein in increments of about 0.1 degree. In some embodiments, the deflection of the rigid component cannot exceed about 1.0 degree, about 2.0 degrees, about 3.0 degrees, about 4.0 degrees, about 5.0 degrees, about 6.0 degrees, about 7.0 degrees, about 8.0 degrees, about 9.0 degrees, about 10.0 degrees, or any 0.1 degree increment therein. The bending can be measured, for example, as a point of deflection from the original position of the rigid component’s axis from force created on the rigid component through the expansion.

The terms “substantial” or “substantially” can be used interchangeably in some embodiments, and can be described using any relative measures acceptable by one of skill. For example, relative percentages can be used to indicate a substantial amount, substantial change, substantial difference, substantial function, or the like. In some embodiments, the percentage can be greater than 10%, greater than 20%, greater than 30%, greater than 40%, or greater than 50%. In

some embodiments, the percentage can be greater than 60%, greater than 70%, or greater than 80%. And, in some embodiments, the percentage can be greater than 90%, greater than 95%, or in some embodiments, even greater than 99%. For example, a substantial [amount]" or a "substantial [change]", can include any amount or change relative to a reference parameter. The amount or change, for example, can include an increase or decrease relative to the reference parameter, can be compared to a reference point for the parameter. The deviation from the reference point can be, for example, in an amount of at least 1%, at least 2%, at least 3%, at least 5%, at least 10%, at least 15%, at least 20%, at least 25%, at least 30%, at least 35%, at least 40%, at least 45%, or any 1% increment therein. Also, for example, a "substantial [function]" or "substantially [functioning]" limitation can serve as a comparison to a reference function parameter, to indicate a deviation that will still provide the intended function. Reference functions can include, for example, floating, aperistalsis, attaching, flexing, rigidity, a position or positioning relative to another object, and the like. The deviation from the reference point can be, for example, in an amount of less than 1%, less than 3%, less than 5%, less than 10%, less than 15%, less than 20%, less than 25%, less than 30%, less than 35%, less than 40%, less than 45%, or any 0.1% increment therein. For example, a component can have an acceptable, substantial [function] when it deviates from the reference by less than the acceptable deviation.

As such, the system can include a floating, multi-lumen-catheter retractor system for ease of positioning in a subject, and such systems can be designed to provide a minimally invasive treatment of the subject. In some embodiments, the systems comprise a highly flexible outer tube configured for guiding a floating channel and a floating endoscope in an at least substantially floating arrangement within the system. This flexible outer tube can have a lumen, a proximal end, and a distal end. And, during a use of the system, the floating channel can serve as a guide through which a tool is manipulated in a treatment of a target tissue in a subject. In some embodiments, the tool can include a grasper, a forceps, a scissor, a knife, a dissector, an endoscopic stapler, a tissue loop, a clip applicator, a suture-delivering instrument, or an energy-based tissue coagulator or cutter. And, in some embodiments, the floating channel can have an elevator component for moving a bendable section to manipulate the tool. In some embodiments, at least one channel and/or the endoscope can have at least substantial freedom to move within the outer tube during operation, or "float," such that the system can be considered to be a floating, multi-lumen-catheter retractor system as taught herein.

Likewise, the system can also comprise a stable, yet dynamic operative environment in that it can include a reversibly-expandable retractor that expands to form a treatment space in the subject. The retractor can be configured, for example, for the expansion to occur distal to the distal end of the outer tube and at least substantially render the target tissue aperistaltic for the treatment; wherein, during a use of the system in a subject, the floating channel can be at least substantially attached to the lumen of the outer tube at a first proximal location and a first distal location, and be at least substantially floating in the lumen of the outer tube between the first proximal location and the first distal location. Likewise, during the use of the system, the floating endoscope can be at least slidably-attached to the lumen of the outer tube at a second proximal location and a second distal location, and be at least substantially floating in the lumen of the outer tube between the second proximal

location and second distal location. And, during the use of the system, the at least substantially floating arrangement can at least substantially increase the flexibility of the system over a second such system, the second such system having a lumen for a tool and an endoscope affixed to the lumen throughout the length of the outer tube between the proximal end and the distal end of the outer tube. The increased flexibility of the at least substantially floating arrangement can facilitate an ease of positioning the system in the subject for the treatment of the target tissue. Moreover, the retractor can be a reversibly-stabilized and reversibly-expandable retractor, the retractor forming an asymmetrical treatment space upon the expansion. And, the retractor can be configured to reversibly stiffen an otherwise flexible arrangement of the retractor, the flexible arrangement designed to facilitate the ease of positioning of the system in the subject and to reversibly stiffen for the expansion of the retractor.

FIGS. 2A and 2B illustrate how a system as taught herein can be positioned for treating a lesion in the ascending colon, according to some embodiments. It should be appreciated that any series of steps and methods known to one of skill to be useful in the positioning **200** can be used with systems taught herein. FIG. 2A illustrates how an endoscope **215** can be used to locate the lesion, a target tissue **290** in a portion of the ascending colon **295**. FIG. 2B illustrates how the multi-lumen-catheter retractor system **201** can be guided to the target tissue **290** using the endoscope **215** as a guide for the positioning **200** of the system in the treatment of the target tissue **290**. As can be appreciated, the multi-lumen catheter is advanced over the endoscope **215** as shown in FIG. 2B.

FIGS. 3A-3L illustrate how a system as taught herein can be used in removing a lesion in a colon, according to some embodiments. As noted above, the system can also be used in other areas of the patient's body and to treat other target tissue. The description herein regarding removal of a polyp from the wall of the colon is shown and described by way of example as the system (as well as the other systems disclosed herein) can be used for other surgical applications and in other body spaces. The system can be positioned as in FIGS. 2A and 2B in the treatment **300** of a gastrointestinal lesion **390**, and a multidirectional and multi-angular approach to the lesion can be used. As in FIGS. 2A and 2B, for example, the approach can include identifying a lesion in a gastrointestinal lumen of a subject using an endoscope **315**; and, forming a substantially rigid and stable endoluminal working area for treating a target tissue, the gastrointestinal lesion **390**. In FIG. 3A, the system is positioned at the lesion **390**, and in FIG. 3B, the expandable retractor **350** is exposed for subsequent expansion to create an asymmetrical working space **360** (FIG. 3C). In FIG. 3A, a sheath or cover **355** is positioned over the retractor elements to facilitate insertion, with the distal end of the sheath **355** abutting the distal coupler **399** or alternatively overlying the distal coupler. After insertion to the target site, the sheath **355** is removed to expose the retractor elements for subsequent expansion as shown in FIG. 3B. It should also be appreciated that alternatively, the retractor elements can be biased to an expanded position and retained in a collapsed delivery position by the sheath **355**. In such embodiments, removal of the sheath **355** to expose the retractor elements would enable the retractor elements to automatically expand to their expanded position of FIG. 3C.

FIGS. 3C and 3D illustrate the creation of the working space **360**, and manipulation of the endoscope **315** and tools **320,325**. After positioning the retractor **350** in proximity to

the lesion 390, the retractor 350 is expanded to form the asymmetrical working space 360 for the treating of the lesion 390. The retractor 350 in some embodiments can be expanded by moving distal coupler 399 and proximal coupler 398 relative to one another, wherein as the distance between the couplers 399, 398, shortens, the retractor elements are forced more laterally with respect to the longitudinal axis of the outer tube (catheter) 305. In alternate embodiments, the retractor elements can be operably connected to an actuator such that the actuator is moved to bow the retractor elements such as in the embodiment of FIG. 11 discussed in detail below. In still other alternative embodiments, the retractor elements can be composed of a shape memory or other material such that when exposed from the outer tube or from a sheath covering the outer, they automatically return to their expanded configuration, e.g., their shape memorized expanded configuration. When such shape memorized retractor elements are utilized, once exposed they would automatically move from the position of FIG. 3B to the position of FIG. 3C.

The system can have any configuration taught herein, such as (i) at least one independently manipulable-and-articulable scope 315 to be used in viewing the lesion 390, (ii) at least one tool channel 310 for at least one independently manipulable-and-articulable tool 320,325 to be used in the treating of the lesion 390, and (iii) the retractor 350, which can be an asymmetrically expandable structure. In some embodiments, the retractor 350 can be expanded asymmetrically toward the lesion 390, the expanding including a portion of the retractor 350 pushing on tissue surrounding the lesion 390 to increase the working area by providing an asymmetrical working area and thus facilitate an entry of the lesion 390 into the working area 360 for the treating. The retractor 350 can be located distal to the distal end of the outer tube 305 and the asymmetrical working area 360 can be substantially rigid and stable relative to the independently manipulable-and-articulable scope 315 and the at least one tool 320,325 to facilitate treating the lesion 390. The treating of the lesion 390 can include, for example, (i) viewing the lesion 390 with the articulating scope 315 and (ii) using the at least one tool 320,325 in the treatment of the lesion 390 with a multidirectional and multi-angular approach to the lesion 390 in the asymmetrical working area 360.

In the embodiment of FIGS. 3A-3J, four retractor elements are provided. Two retractor elements 353, 354 are at the base of the retractor system and have an outwardly bowed or arcuate shape. Two retractor elements 351, 352 expand more radially outwardly to apply a force against the wall of the colon on which the lesion is found. These retractor elements are described in more detail below.

In some embodiments, the independently manipulable-and-articulable scope 315 and the at least one tool 320,325 can be independently movable axially in the working area 360, independently rotatable in the working area 360, and independently bendable in at least one direction in the working area 360. Accordingly, in some embodiments, the portion of the retractor 350 pushing on the tissue surrounding the lesion 390, e.g. retractor elements 351, 352, can be expanded further from the central axis 307 of the distal end of the outer tube 305 than other portions of the retractor to provide an even larger working area 360 for the treating of the lesion 390 when compared to a second such structure that merely expands symmetrically around the central axis 307 of the distal end of the outer tube 305. This is due to the fact that it is desirable to create the largest working distance from the instrument tips to the target tissue, achieved by

changing the configuration of the colon in the target area, but without overstretching, damaging or rupturing the colon.

Note that after the retractor system is expanded as shown in FIG. 3C, the endoscope 315 can be articulated in the working space 360 toward the target lesion 390 to improve visibility.

FIG. 3E illustrates a multidirectional and multi-angular approach to the lesion 390, showing the step of positioning the work area 360, endoscope 315, and tools 320,325 in relation to the lesion 390. After the retractor 350 is expanded as shown in FIG. 3C, the user of the system can view and approach the lesion 390 with the tools 320,325 from nearly any desired angle within the working space 360. The tool channels 310 are advanced through the respective lumens in the multi-lumen catheter or tube and the endoscopic tools or instruments are inserted through the tool channels 310, with the distal ends of the tools extending distally of the tool channel 310 as shown in FIG. 3D. The advantages of the tool channels are described below in more detail in conjunction with the embodiment of FIG. 11, and such advantages are applicable to this and other embodiments utilizing the tool channels. As noted above, it is also contemplated that in alternative embodiments, the endoscopic tools can be inserted directly into the lumens of the catheter or tube, without the use of tool channels, provided they have the bending/articulating characteristics described above which enable their manipulation without the use of bendable/articulatable tool channels.

FIG. 3F illustrates the versatility of the system, showing the step of removing the lesion 390 using tool 320 to excise the lesion 390 from an independently chosen first angle, while tool 325 can be used to grasp the lesion 390 from an independently chosen second angle and endoscope 315 can be used to view the lesion 390 from an independently chosen third angle. As shown, the different angling of the tools 320, 325 advantageously achieve tissue triangulation to facilitate access, maneuverability and removal of the lesion. After the excision of the lesion 390 from the gastrointestinal tract 395 by the dissection tool 320, a tissue defect 397 remains. Note the dissection tool 320 can in some embodiments be in the form of an electrosurgical instrument, although other dissecting/excising tools can also be utilized. FIG. 3G illustrates the step of releasing the excised lesion 390 into the retractor assembly in preparation for completion of the procedure. FIGS. 3H and 3I illustrate the step of closing the tissue defect 397, showing that tool 320 for excision of the lesion 390 has been replaced by tool 322 for closure of the lesion. The lesion can be closed by various methods such as mechanical (e.g., clips staples or structures), glue, electrosurgical energy, etc. FIGS. 3J and 3K illustrate the steps of capturing the lesion 390 for removal using tool 323 and collapsing the retractor 350 to capture and contain the lesion 390 within the collapsed retractor elements 351, 352, 353, 354 in preparation for removal of the system from the subject, including the use of an optional retractor cover 355 which can be slid over the catheter to further encapsulate the lesion retained within the collapsed retractor elements. FIG. 3L is a view of the closed tissue defect following completion of the treatment.

In some embodiments, as shown for example in FIGS. 3B-3J, the system can comprise a stable, yet dynamic operative environment in that it can include a reversibly-expandable retractor 350 that expands to form a treatment space 360 in the subject. The retractor 350 can be configured, for example, for the expansion to occur distal to the distal end 308 of the outer tube (catheter) 305. In some embodiments, the retractor can at least substantially render

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the target tissue **390** aperistaltic for the treatment. The retractor **350** can have a variety of configurations to serve, for example, as a scaffolding within the gastrointestinal tract **395**. For example, the retractor **350** can include retractor elements **351,352,353,354**, along with a proximal coupler or hub **398** operably connected to the retractor elements **351,352,353,354**, whether at least substantially attached and/or at least slidably-engaged to the retractor elements **351,352,353,354**, and a distal nexus or coupler **399** for a distal point of an operable connection with the retractor elements **351,352,353,354**. The distal nexus or hub **399** is shown in the shape of a ring, although it can be virtually any shape desirable to one of skill, such as a cone, hemisphere, sphere, and the like, and it may or may not include a port for passage of the endoscope beyond the distal end of the system. As noted above, in some embodiments, the proximal coupler **398** can be moved toward the distal coupler **399**, the distal coupler moved toward the proximal coupler **398**, or both couplers moved toward each other to reduce their distance to force the retractor elements radially outwardly. The extent of outward expansion of the retractor elements can be controlled by controlling the distance between the proximal and distal couplers **398,399**. The retractor can be repeatedly moved between expanded and retracted positions as desired by adjusting the distance between the coupler **398,399**. Such controlled expansion of the retractor elements can also be achieved by operatively coupling the proximal end of the retractor elements to an actuator as in the embodiment of FIG. 11. Alternatively, as noted above, the retractor elements can be composed of a material, e.g., shape memory material, to automatically expand when exposed from a catheter or sheath.

In the expanded position of the retractor elements as shown, retractor element **351** is a flexible element having a proximal portion **351a** extending from the proximal coupler **398** at a first angle, a distal portion **351b** extending from the distal hub or coupler **399** preferably at a second angle different from the first angle, and an engaging portion **351c**, which engages the tissue, extending between the proximal and distal portions **351a,351b**. As shown, portion **351a** extends at a greater angle to the longitudinal axis than distal portion **351b** providing an asymmetric expansion of the retractor element itself. Thus, the length of the distal portion **351b** exceeds the length of portion **351a**. Retractor element **352** can be similarly configured and angled as retractor element **351**, or alternatively of a different configuration and angle. Retractor elements **351** and/or **352** can alternatively be configured so the proximal and distal portions are of the same length and angles. Note the retractor elements **351,352** expand in a direction to one side of the longitudinal axis. This asymmetric expansion creates an asymmetric chamber (working space). Retractor elements **351,352** extend in an arcuate or bowed manner as mentioned above. In some embodiments, the retractor elements **351,352** only expand in one direction with respect to the longitudinal axis of the catheter so they remain above (as viewed in the orientation of FIG. 3D) a longitudinal plane containing the longitudinal axis. In some embodiments, only elements **351,352** expand while elements **353,354**, which form the base of the retractor (cage) remain in substantially the same position in the insertion (collapsed) and expanded position of the retractor. Note as with the retractor elements of FIG. 1, the elements **351,352,353,354** can be covered with a plastic or other material to create a covered chamber as in the embodiment of FIG. 10A described below.

The retractor **350** can be a reversibly-stabilized and reversibly-expandable retractor, the retractor **350** forming an

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asymmetrical treatment space **360** upon the expansion. And, the retractor **350** can be configured to reversibly stiffen an otherwise flexible arrangement of the retractor **350**, the arrangement designed to facilitate ease of positioning of the system **300** in the subject and to reversibly stiffen for the expansion of the retractor **350**. The stabilization of the retractor **350** can, in some embodiments, include a means for stabilizing the retractor **350** through a stabilizer subsystem as taught herein, the stabilizer having, for example, an at least substantially-rigid beam **375** to support the expanded retractor **350**. The substantially rigid beam **375** can be substantially rectangular in cross-section, substantially circular in cross-section or of other cross-sectional shapes. It can be provided of the same or of a stiffer material than the retractor elements. It helps to create a more stabilized chamber as described herein. As shown, the beam **375** is at the base of the chamber formed by the retractor elements, with the retractor elements extending radially (laterally) away from the beam **375**. The beam **375** can be formed by the more rigid element exposed when the retractor elements are exposed from the outer tube for expansion, or alternatively, can be advanced independently from the outer tube or formed by advancement of a rigidifying structure as in some of the embodiments described in more detail below.

FIGS. 4A-4E illustrate details of an alternate system as taught herein, in side, axial, and oblique views of expanded and collapsed configurations, and including a stabilizer sub-system, according to some embodiments. The figures illustrate an example of a multi-lumen catheter system which is similar to the system of FIGS. 3A-3K in that it has a reversibly-stabilized and reversibly-expandable retractor for a minimally invasive treatment of a subject. FIGS. 4A-4C illustrate side and axial views that show that the system **400** can comprise a flexible outer tube (or catheter) **405** for guiding a tool channel (not shown) and an endoscope (not shown) within the system **400** in the same manner as system **300**. The flexible outer tube **405** has a lumen, a proximal end (not shown), and a distal end **408**. The one or more tool channels (not shown) serves as a guide through which an endoscopic tool (not shown) can be manipulated in a treatment of a target tissue in a subject in the same manner as tool channels **310** of FIG. 3G manipulate tools **320,325**. In some embodiments, the retractor **450** can be a reversibly-stabilized and reversibly-expandable retractor **450** forming a treatment space upon expansion and configured for the expansion to occur distal to the distal end **408** of the outer tube **405**. The retractor **450** can be designed to reversibly-stiffen an otherwise flexible arrangement of the retractor **450**, the flexible arrangement designed to facilitate the positioning of the system in the subject and to reversibly-stiffen for the expansion of the retractor **450**. In these embodiments, the reversibly-stiffened arrangement of the retractor **450** can form an at least substantially-rigid beam **475** from an otherwise flexible beam **470** as a structural support for the expansion of the retractor **450**. In some embodiments, the stabilizer subsystem can include the flexible beam **470**, which may comprise a flexible tube, and a means for creating the at least substantially-rigid beam **475**. The means, as taught herein, can include all embodiments taught herein, including the mechanisms for slidably-engaging an at least substantially-rigid rod or beam, for example, within the flexible rod or beam **470** prior to expanding the retractor. In some embodiments, the terms "rod" and "beam" can be used interchangeably and, in some embodiments, the terms "beam" and "tube" can be used interchangeably. The

beam **475** can be configured and function in the same manner as described above for beam **375**, including the alternatives described herein.

In some embodiments, the flexible beams taught herein in each of the embodiments disclosed can comprise a polymer, such as polyimide, polyether block amides (PEBAX), nylon, polyethylene, polyurethane, polyvinylchloride (PVC), PEEK, or polytetrafluoroethylene (TEFLON). One of skill will appreciate that the flexible beams can be reinforced tubes made from components and designs known to the art. The flexible beam can be, for example, a flexible tube that is reinforced with metal wires, braids, or coils that include, for example, a metal such as a stainless steel or NITINOL. In some embodiments, the flexible tube can be kink resistant and transmit torque. And, in some embodiments, the flexible tube can comprise a combination of both flexible sections and rigid sections. In these embodiments, a flexible section can lie-between rigid sections, for example. Such flexible tubes can include composites of overlapping tubes joined using any method known to one of skill, including bonding using epoxy or cyanoacrylates, in some embodiments.

In some embodiments, any of the systems taught herein can include a bridge member to add stability to the retractor. For example, the retractor system **450** can include a bridge member **444** configured to maintain a desired orientation of the retractor elements **451, 452, 453, 454** during the expansion, the bridge member **444** operably stabilizing at least two **451, 452** of the four retractor elements **451, 452, 453, 454**. That is, in the embodiment of FIG. 4A, the bridge member **444** is attached to the two retractor elements **451, 452** which are configured to expand laterally outwardly to expand or reconfigure the tissue wall. The bridge member **444** creates a transverse structure for the elements **451, 452**, limiting side-to-side movement. As shown, bridge member **444** can also include a second bridge section **444a** connected to bridge **444** and to retractor elements **452** and **453** thereby connecting all four retractor elements **451, 452, 453, 454**. The upper surface (as viewed in the orientation of FIG. 4B) can be arcuate as shown. The bridge member **444** can be a separate component or alternately integrally formed with one both of the retractor elements **451, 452**. The bridge member can be composed of a material similar to the elements **451, 452** or can be composed of a different material.

Additional bridge members can be provided on the retractor elements **451, 452** to increase stability. Note that one or more bridge members can be used with the other retractor embodiments disclosed herein. Note that the bridge member **444** can, in some embodiments, in the collapsed position, angle radially outwardly from the longitudinal axis such as in FIGS. 4B and 4D, but change to angle more radially inwardly in the expanded position of FIGS. 4C and 4E.

Additionally, an additional bridge member (or multiple bridge members) can extend between the two lower (as view in orientation of FIG. 4C) retractor elements **453, 454** independent of bridge member **444**. These elements **453, 454** can help open up the lower section of the retractor system, and the bridge member(s), whether independent or connected to bridge **444**, can help to stabilize these elements, e.g., limit side to side movement. Such bridge members on the lower retractor elements can be used with the other retractor embodiments disclosed herein.

In some embodiments, each of the systems taught herein can have an outer tube that is wire-reinforced, such as mesh, braided, or the like, to provide kink resistance and torque-ability to the system, as well as to further facilitate a positioning of the system in the subject.

FIGS. 4D and 4E illustrate oblique views of the system **400** in collapsed and expanded configurations. The multi-lumen concept is presented with clarity in these figures, showing multiple lumens **406a, 406b, 406c** in the catheter **405** in system **400**. Lumen **406a** can contain an endoscope (not shown) such as endoscope **315** described above, lumen **406b** can contain a first working channel **410b** for a first endoscopic tool (not shown), and lumen **406c** can contain a second working channel **410c** for a second endoscopic tool (not shown). The working channels **410b, 410c** can receive the first and second tools directly therein, or alternatively, receive tool channels (tool guides) like tool channels **310** described above for angling the endoscopic tools slidably positioned therein. FIG. 4D illustrates the system in the collapsed configuration and FIG. 4E illustrates the system in the expanded configuration. In FIG. 4E, the tool channels **410b** and **410c** are shown exposed from the catheter **405** so their distal ends are in a curved position. The tool channels can be further advanced axially to align the curved distal ends with the target tissue.

The system **400** also includes retractor elements **451, 452, 453** and **454**. The retractor system further includes a flexible tube or beam **470** in the collapsed configuration, whereas in the expanded configuration, the retractor system has a rigid beam **475** that was formed from the flexible beam **470**. A rigid beam can be formed from a flexible beam, in some embodiments, by slidably inserting a rigid rod into a flexible tube that composes the flexible beam. More specifically, in this embodiment, the flexible beam **470** slidably receives there-over a stabilizing or rigidifying structure such as a rigid rod. The rigidifying (stabilizing) structure can be independently actuated by the user by actuating a control, such as a slidable lever, operably connected to the rigidifying structure, such that movement of the actuator distally advances the rigidifying structure over the flexible beam **470** to thereby stiffen the beam. Alternatively, the flexible beam **470** can have a lumen to slidably receive therein a rigidifying structure such as a rigid rod. The structure in either version can optionally be retracted from the flexible beam **470** to return the system back to the original more flexible state to aid collapsing of the retractor system. The beam **470** can be substantially circular in cross-section, although other cross-sectional shapes are also contemplated. As in the aforescribed embodiments, the rigid beam limits deflection of the distal end of the catheter which could otherwise occur by pressure exerted on the distal end by the body lumen wall.

In many embodiments, the term "tool channel" can be used interchangeably with the term "working channel" or "tool guide." And, in some embodiments, a channel can be a separate component placed inside the outer tube, or it can be a space remaining in the lumen of the outer tube between separate components that were placed in the outer tube, the separate components including, for example, an endoscope, a working channel, an instrument, a guide, and the like.

In some embodiments, as shown for example in FIGS. 4A-4E, the system can comprise a stable, yet dynamic operative environment in that it can include a reversibly-expandable retractor **450** that expands to form a treatment space **460** in the subject. The retractor **450** can be configured, for example, for the expansion to occur distal to the distal end **408** of the outer tube **405**. In some embodiments, the retractor can at least substantially render the target tissue **490** aperistaltic for the treatment. The retractor **450** can have a variety of configurations to serve, for example, as a scaffolding within the gastrointestinal tract **495**. For example, the retractor **450** can include retractor elements

451,452,453,454, along with a proximal coupler 498 operably connected to the retractor elements 451,452,453,454, whether at least substantially attached and/or at least slidably-engaged to the retractor elements 451,452,453,454, and a distal nexus or coupler 499 for a distal point of an operable connection with the retractor elements 451,452,453,454. Relative movement of the couplers 498, 499 can expand the retractor elements as described above. Alternatively, as described above, the retractor elements can be operably attached to a proximal actuator which moves the proximal portions relative to the fixed distal portions to bow the retractor elements outwardly, which in preferred embodiments can be made of superelastic material (although other materials are contemplated), or shape memorized retractor elements can be utilized.

The retractor elements 451 and 452 can have a covering 451a, 452a, respectively, which add bulk to the retractor elements 451, 452 by increasing its cross-sectional diameter. This is described in more detail below in conjunction with the embodiment of FIGS. 6A-6D.

Moreover, the retractor 450 can be a reversibly-stabilized and reversibly-expandable retractor, the retractor 450 forming an asymmetrical treatment space 460 upon the expansion. And, the retractor 450 can be configured to reversibly stiffen an otherwise flexible arrangement of the retractor 450, the arrangement designed to facilitate ease of positioning of the system 400 in the subject and to reversibly stiffen for the expansion of the retractor 450. The stabilization of the retractor 450 can, in some embodiments, include a means for stabilizing the retractor 450 through a stabilizer subsystem as taught herein, the stabilizer having, for example, an at least substantially-rigid beam 475 to support the expanded retractor 450.

FIGS. 5A-5D illustrate side and top views of a system as taught herein, having side views and top views of expanded and collapsed configurations, according to some embodiments. The tool channels and tools are omitted for clarity, being similar to those described herein. FIGS. 5A and 5B illustrates side views of system 500 in collapsed and expanded configurations showing an example of an asymmetric work space that can be formed during an endoscopic procedure using the system 500. And, as shown in FIG. 5B, as with the previously described embodiments, the expansion can occur in a disproportionally greater amount on the luminal side 559 of the rigid beam 575 than the abluminal side 557 of the rigid beam 575 to increase the treatment, or working, space 560, the treatment space 560 having a volume that is asymmetrically distributed around the rigid beam 575. In some embodiments, the expansion of the various retractors systems disclosed herein can occur in an amount that is at least 5× greater on the luminal side 559 of the rigid beam 575 than the abluminal side 557 of the rigid beam 575. And in some embodiments, the expansion can be at least 1.1× greater, at least 1.3× greater, at least 1.5× greater, at least 2.0× greater, at least 2.5× greater, at least 3.0× greater, at least 3.5× greater, at least 4.0× greater, at least 4.5× greater, at least 5.0× greater, at least 5.5× greater, at least 6.0× greater, at least 6.5× greater, at least 7.0× greater, at least 7.5× greater, at least 8.0× greater, at least 8.5× greater, at least 9.0× greater, at least 9.5× greater, at least 10.0× greater, or any 0.1× increment within this range, on the luminal side of the beam than the abluminal side of the beam.

In some embodiments, as shown for example in FIGS. 5A-5D, the system can comprise a stable, yet dynamic operative environment in that it can include a reversibly-expandable retractor 550 that expands to form a treatment

space 560 in the subject. The retractor 550 can be configured, for example, for the expansion to occur distal to the distal end 508 of the outer tube 505. In some embodiments, the retractor can at least substantially render the target tissue aperistaltic for the treatment. The retractor 550 can have a variety of configurations to serve, for example, as a scaffolding within the gastrointestinal tract 595. For example, the retractor 550 can include retractor elements 551,552,553,554, along with a proximal coupler 598 operably connected to the retractor elements 551,552,553,554, whether at least substantially attached and/or at least slidably-engaged to the retractor elements 551,552,553,554, and a distal nexus or coupler 599 for a distal point of an operable connection with the retractor elements 551,552,553,554. The couplers 588, 599 can be relatively movable to expand the retractor elements 551, 552 (and optionally elements 553, 554) in the same manner as the couplers described above, e.g., couplers 198, 199. The retractor elements can alternatively be fixedly attached at their distal ends, e.g., to distal coupler 599, and operatively connected at proximal ends to an actuator or made of self-expanding material such as shape memory material as in the alternative embodiments described herein. Each retractor element 551, 552 in the embodiment of FIG. 5B expands to a substantially uniform (symmetric) arcuate shape, although alternatively they each can be configured to expand to a non-uniform (non-symmetric) shape as in the embodiments described above. Note that in this embodiment where the retractor elements 551, 552 individually expand to a substantially symmetric shape, there expansion is on one side of the multi lumen outer tube 505, i.e., to only one side of a longitudinal plane through which the central longitudinal axis passes. Therefore, their expansion with respect to the retractor system is asymmetric while their individual expanded shape might be symmetric. Retractor elements 553, 554 have a slightly bowed configuration similar to retractor elements 353, 354. Retractor elements 553, 554, positioned as the lower elements of the cage as viewed in the orientation of FIG. 5A, can have limited expansion or can be provided so they do not expand when the retractor system expands but instead remain substantially in the same position. In such embodiments, the expanding retractor elements 553, 554 can be operably connected to an actuator and the lower elements 553, 554 can be fixedly (non-movably) attached to the catheter, e.g., to fixed proximal and distal couplers. Such attachment alternative is also applicable to the other embodiments disclosed herein wherein it is disclosed that the lower retractor elements maintain substantially the same position in the collapsed and expanded positions of the retractor system.

Moreover, as with the retractors described hereinabove, the retractor 550 can be a reversibly-stabilized and reversibly-expandable retractor, the retractor 550 forming an asymmetrical treatment space 560 upon the expansion. And, the retractor 550 can be configured to reversibly stiffen an otherwise flexible arrangement of the retractor 550, the arrangement designed to facilitate ease of positioning of the system 500 in the subject and to reversibly stiffen for the expansion of the retractor 550. The stabilization of the retractor 550 can, in some embodiments, include a means for stabilizing the retractor 550 through a stabilizer subsystem as taught herein, the stabilizer having, for example, an at least substantially-rigid beam 575 to support the expanded retractor 550. In the embodiment of FIGS. 5A-5D, the rigid beam 575 can be provided in a permanently stiffened condition as beam 175 of FIG. 1, or alternatively can be formed by advancement of a rigidifying (stabilizing) structure over

a flexible element or into the lumen of the flexible tubular member by an actuator as described above. In either case, the beam rigidifies the retractor system in the asymmetrical configuration creating the stable asymmetrical working space to facilitate access and manipulation of the target tissue.

FIGS. 6A-6D illustrate side views of a system as taught herein having side views and cross-sections of expanded and collapsed configurations of the system, according to some embodiments. The figures illustrate an example of a multi-lumen catheter system having a reversibly-stabilized and reversibly-expandable retractor for a minimally invasive treatment of a subject. FIGS. 6A and 6B illustrates a side view that shows that the system 600 can comprise a flexible outer tube 605 for guiding one or more tool channels (not shown) similar to the tool channels described above and an endoscope (not shown) similar to the endoscope described above within the system 600. The flexible outer tube 605 has a lumen, a proximal end extending into the handle 680, and a distal end 608. Each tool channel (serves as a guide through which a tool (not shown) can be manipulated in a treatment of a target tissue in a subject. That is, the tool channels are configured to receive and reorient the tools inserted therethrough as in the embodiments described above. In some embodiments, the retractor 650 can be a reversibly-stabilized and reversibly-expandable retractor 650 forming a treatment space 660 upon expansion and configured for the expansion to occur distal to the distal end 608 of the outer tube 605. The retractor 650 can be designed to reversibly-stiffen an otherwise flexible arrangement of the retractor 650, the flexible arrangement designed to facilitate the positioning of the system in the subject and to reversibly-stiffen for the expansion of the retractor 650. In these embodiments, the reversibly-stiffened arrangement of the retractor 650 can form an at least substantially-rigid beam 675 from an otherwise flexible beam 670 as a structural support for the expansion of the retractor 650.

Handle 680 at the proximal end includes entry ports for operatively combining the system with external components, such as an entry port 609 for an endoscope (not shown) and/or a tool (not shown). The handle 680 is also operatively connected to the proximal end of the outer tube 605 and can have exit ports from the handle 680 into the outer tube 605. The system can include a stabilizer subsystem, in some embodiments. For example, a stabilizer actuator 612 can be included on the handle 680 to reversibly-stiffen the flexible beam 670 to create the at least substantially-rigid beam 675 for the expansion of the retractor 650. A retractor actuator 614 can be included on the handle 680 to reversibly expand the retractor 650. The retractor 650 is shown in FIGS. 6A and 6B in the collapsed (non-expanded) condition.

FIGS. 6C and 6D illustrate oblique views of the system 600 in expanded configurations. The expanded configurations have a rigid beam 675 that was formed from the flexible beam that is typically present in the collapsed state for positioning in the subject. The rigid beam 675 can be formed from a flexible beam, in some embodiments, by slidably inserting a rigid member (e.g., a rod) either over or alternatively into a flexible member that composes the flexible beam to transform the flexible beam into a stiffer, more rigid beam. As shown in FIGS. 6B and 6D, the stabilizer actuator 612 is operably connected to the rigid member (stabilizing structure) such as rigid rod 672 through a rod coupler 613. Consequently, movement of the actuator 612 in a first direction, e.g., a distal direction from a proximal position, will cause the stabilizing structure 672 to

advance over the flexible beam 670 to rigidify it (forming beam 675) to stabilize the retractor system, and movement of the actuator 612 in a reverse, e.g., a proximal direction back to its proximal position, will retract the stabilizing structure 672 from the flexible beam 670 to return the flexible beam 670 to its more flexible condition.

The retractor actuator 614 is operably connected to retractor elements 651,652 through an element coupler 611. The stabilizer actuator 612 and/or the retractor actuator 614 can be reversibly engageable with the handle 680, in some embodiments, such that the stabilizer actuator 612 and/or the retractor actuator 614 can be reversibly-fixed in position relative to the handle 680. In some embodiments, the stabilizer actuator 612 and/or the retractor actuator 614 can be multi-positional, having at least three positions for expansion and/or collapse of the retractor. In some embodiments, the stabilizer actuator 612 and/or the retractor actuator 614 can have a plurality of ratchet teeth 616 to provide a plurality of positions for reversibly-fixing the stabilizer and/or for reversibly fixing the retractor in position during expansion or collapse of the retractor. As shown in FIG. 6B, in the proximal position of the retractor actuator 614, coupler 611 is in the proximal position and the retractor elements are in the non-expanded position. To expand the retractor elements, retractor actuator 614 is slid distally to move the attached coupler 611 distally, as shown in FIG. 6D, thereby causing the attached elements 651, 652 to bend outwardly due to their fixed connection at their distal end to the distal coupler 699.

One of skill will appreciate that the handle can be any of a variety of shapes to provide a desired or ergonomic position for operation of the system. By way of example, the retractor actuator can be configured as a finger-activated button on the handle 680 that slides back and forth through a slot in the handle 680 to expand or collapse the retractor elements. A means for dynamically adjusting or ratcheting the retractor position can be provided along the handle slot to lock the position of the retractor elements in place when the retractor actuator button is not pressed. A button on the opposite side of the handle can be operatively connected to the stabilizer subsystem to convert the flexible beam into a rigid beam, or convert the rigid beam into a flexible beam. The handle can have inner channels routed axially, for example, within the body of the handle and in communication with ports for tools and endoscope introduction into the outer tube. In some embodiments, the handle can be configured to require that the stabilizer actuator is activated before the retractor actuator can be activated, serving as a "safety" mechanism in the operation of the system.

As such, in some embodiments, as shown for example in FIGS. 6A-6D, the system can comprise a stable, yet dynamic operative environment in that it can include a reversibly-expandable retractor 650 that expands to form a treatment space or working chamber 660 in the subject. The retractor 650 can be configured, for example, for the expansion to occur distal to the distal end 608 of the outer tube 605. In some embodiments, the retractor can at least substantially render the target tissue 690 aperistaltic for the treatment. The retractor 650 can have a variety of configurations to serve, for example, as a scaffolding within the gastrointestinal tract 695. For example, the retractor 650 can include retractor elements 651,652,653,654, along with a proximal coupler 698 operably connected to the retractor elements 651,652, 653,654, whether at least substantially attached and/or at least slidably-engaged to the retractor elements 651,652, 653,654, and a distal nexus or coupler 699 for a distal point of an operable connection with the retractor elements 651,

652, 653, 654. More specifically, the distal end of the retractor elements **651, 652** are attached within slots or openings in the proximal end of the distal coupler **699**. The proximal ends of the retractor elements **651, 652** extend proximally through lumens in the catheter to attach to movable coupler **611**. In this manner, with the distal ends of the retractor elements **651, 652** fixed, distal movement of the coupler **611** forces retractor elements to bow outwardly as shown. Retractor elements **653, 654** can be attached to the distal coupler **699** and in some embodiments attached to movable coupler **611** if some expansion of these retractor elements **653, 654** is desired, or alternatively, fixedly attached to the catheter if expansion is not desired and expansion is limited to the retractor elements **651, 652**.

It should be appreciated, that such couplers for retraction element expansion disclosed in FIGS. **6A-6D** can be utilized with the other embodiments of the retractor systems disclosed herein. Additionally, it should be appreciated that alternative ways to expand the retractor elements can be utilized, including for example providing relatively movable couplers **698, 699** to expand the retractor elements **651, 652**, (and optionally **653, 654**) in the same manner as the couplers described above, e.g., couplers **198, 199**. The retractor elements can also alternatively be made of self-expanding material such as shape memory material.

Each of the retractor elements **651, 652** in the embodiment of FIGS. **6A-6D** expand to a substantially symmetric arcuate shape, although alternatively they can be configured to expand to an asymmetric shape as in the embodiments described above. Note that in this embodiment where the retractor elements **651, 652** expand to a substantially symmetric shape, their expansion is on one side of the longitudinal axis of the multi lumen tube outer tube (catheter) **605**. Therefore, the expansion of the retractor system is asymmetric while their individual expanded shape is substantially symmetric. Retractor elements **653, 654** can optionally expand slightly outwardly in a bowed configuration. The retractor element **651** can have a covering **651** thereon. Similarly, retractor element **652** can have a covering thereon. The covering extends over an intermediate portion of the elements **651, 652** and can be in the form of a heat shrink tubing. The covering helps control expansion by providing a less flexible region. This covering is similar to covering **451a** and **452a** of the embodiment of FIGS. **4D, 4E**.

As described herein, the retractor **650** can be a reversibly-stabilized and reversibly-expandable retractor, the retractor **650** forming an asymmetrical treatment space **660** upon the expansion. And, the retractor **650** can be configured to reversibly stiffen an otherwise flexible arrangement of the retractor **650**, the arrangement designed to facilitate ease of positioning of the system **600** in the subject and to reversibly stiffen for the expansion of the retractor **650**. The stabilization of the retractor **650** can, in some embodiments, include a means for stabilizing the retractor **650** through a stabilizer subsystem as taught herein, the stabilizer having, for example, an at least substantially-rigid beam **675** to support the expanded retractor **650**.

The rigid rod can be a straight component comprising a rigid material, for example stainless steel or another metal or alloy, that is slidable in and out of the inner diameter (lumen) of the flexible tube. As such, the stabilizer subsystem can have a flexible beam or rigid beam by sliding the rigid rod proximal (i.e., anally) to the flexible tube by pulling back on the rigid rod through a mechanism operably connected to the handle. The rigid rod can be pushed forward (i.e., orally) into the flexible tube to stiffen and straighten the flexible tube as in the embodiments described above. By pushing the

rigid rod across the length of the flexible tube, the flexible tube, or flexible beam, becomes rigid and straight, and in effect renders the whole retractor structure at least substantially rigid and straight to stabilize the retractor system. One of skill in the art will appreciate that any mechanism of reversibly stiffening a flexible component in vivo may be used in some embodiments. For example, the flexible tube, or flexible beam, may also comprise a series of rigid tubes having a flexible, non-stretchable cable passing through the lumens of the tubes. When the cable is relaxed, the series of rigid tubes can be separated using, for example, a compressible component such as a spring between each of the series of rigid tubes to provide a flexible non-overlapping configuration. When the cable is tensioned, the compressible components compress, and the rigid tubes overlap, converting the flexible beam into a rigid beam. Such alternative mechanisms can be utilized with any of the embodiments described herein.

The reversibly-stabilized retractor, as described herein, is useful in positioning the working space at the site of treatment of the target tissue as it can be rendered flexible for positioning and later rendered rigid for expansion of the retractor. During introduction of a system taught herein into a tortuous body lumen, for example a colon, the retractor can be unexpanded and flexible. This flexibility allows the retractor to bend to conform to the bends in the tortuous body lumen, so that it can be advanced with ease and not cause trauma to the lumen. The rings which hold the retractor elements together can also have lumens that allow passage of a guide such as an endoscope. In such embodiments, when the retractor is in the flexible mode for introduction, for example, the rings can be free to slide over the guide as the system is advanced forward. In some embodiments, the lumens of the rings can be large enough relative to the diameter of the guide to allow for tilting and translation of the system on the guide, helping the system conform to the bends of the guide during advancement of the system orally or anally. Once the retractor is advanced to the target location in the lumen, the flexible beam of the retractor can be straightened and stiffened as described herein. Since the system can be flexible and torsionally stiff, the proximal shaft or the handle can be easily rotated as desired relative to the location of the target lesion.

The retractor elements can have at least one pair that is pre-shaped having peaks pointing outwards at a desired angle. In some embodiments, the angle can range from about 45 degrees to about 135 degrees, about 60 degrees to about 120 degrees from each other on one side of the rigid beam, the vertex of the angle being the central axis of the rigid beam, as can be seen in the figures provided herein. In some embodiments, the angle is about 90 degrees between retractor elements. Upon expansion, the retractor elements bulge outwards on one side disproportionately more than the other retractor elements, resulting in an asymmetrical expansion of the retractor. The at least substantially rigid beam prevents or inhibits deformation of the retractor during creation of forces on the retractor in the expansion and prevents or inhibits bending of the catheter tip. The forces include forces from expanding tissue outwards asymmetrically, as well as the initial forces applied on the retractor elements to create an asymmetrical working space.

In some embodiments, the target lesion can be located on the side of the most expanded retractor elements so to facilitate maximizing or increasing the distance between the lesion to be treated and the portals at which the endoscope and tools are introduced into the working space. The endoscope and tools can be maneuvered independently, for

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example, to access the lesion at a greater range of angles than is currently clinically obtainable using state-of-the-art systems. This increased maneuverability can improve the view of the lesion and ability to manipulate and dissect the lesion. For example, a grasper can be advanced out of the instrument channel into the working space and flexed towards the polyp, grasp the polyp and retract the tissue to expose the base of the polyp for dissection by a dissection tool through the multi-channel systems taught herein. Sometimes, it can also be desired to reduce the distance between the lesion to be treated and the portals at which the endoscope and tools are introduced into the working space. For example, it can be desired to locate the lesion on the side of the least expanded retractor elements to better align the lesion with the endoscope channel substantially parallel to the lumen wall. Such a configuration may be clinically optimal while the polyp is retracted by a grasper towards the most expanded side. In such embodiments, a dissection tool can be advanced through a channel at the base of the polyp and dissect the polyp's base where it attaches to the lumen wall, while the position of the endoscope provides a close view of the base of the polyp to help identify the desired margin for dissection.

Any of the systems taught herein can include a bridge member, which provides structural support to add stability to the retractor. The bridge member can include any configuration conceivable by one of skill to provide additional support, such as a scaffolding means, for enhancing or buttressing the stability and rigidity of the expanded retractor. For example, bridge member 644 is configured to maintain a desired orientation of the retractor elements 651, 652, 653, 654 during the expansion, the bridge member 644 operably stabilizing at least two 651, 652 of the four retractor elements 651, 652, 653, 654. As shown, the bridge member outer portion in the collapsed position of the retractor 650 extends radially outwardly and in the expanded position extends more distally (see. FIG. 6D). Although only one bridge member 644 is shown, it is also contemplated that more than one bridge member could be provided to connect retractor elements 651, 652. Additionally, one or more bridge members can be provided to connect retractor elements 653, 654 to stabilize and limit side to side movement of these elements as well. Moreover, in some embodiments, each of the systems taught herein can have an outer tube, for example outer tube 605, that is wire-reinforced, such as mesh, braided, or the like, to provide kink resistance and torqueability to the system, as well as to further facilitate a positioning of the system in the subject. In some embodiments, the bridge member 644 can be configured to reduce drag from surrounding tissue during use. For example, as shown in FIGS. 6A and 6B, the bridge member 644 can be configured to facilitate a movement of the system in a gastrointestinal tract by designing the bridge member 644 to include a forward component 644a that is inclined to facilitate forward movement orally, and a reverse component 644b that is inclined to facilitate reverse movement anally.

The bridge member can be connected to the retractor elements, for example, to maintain a desired orientation of the retractor elements as they expand against a gastrointestinal tissue, for example. As the retractor is expanded, the bridge member is also expanded outward. In some embodiments, the bridge member is operably connected only to the retractor elements that expand the most, for example the retractor elements 651, 652 in FIG. 6, which can be the members that incur the most induced forces on the retractor due to the disproportionate pressure applied to create the asymmetrical working space in the expansion. In some

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embodiments, the bridge can be designed to flex to prevent the retractor elements from collapsing towards each other or bending away from each other, while also providing some spring or elasticity to the system to comply gently with the tissue. One of skill will appreciate that the bridge can comprise any suitable material that provides the material characteristics desired. For example, the bridge can be formed from a curved nitinol wire in some embodiments. The ends of the nitinol wires can be connected to the retractor elements using any manufacturing process deemed suitable by one of skill for the in vivo uses taught herein, such process including, for example, tubing connectors, adhesives, or solder.

FIG. 7 illustrates a cutaway view of the distal end of the outer tube of a system 700 as taught herein, showing components of the expansion and collapse of the retractor, according to some embodiments. The figure illustrates the distal end 708 of outer tube 705. The distal end 708 includes a slot guide 755 to control the orientation of an expanding retractor element 751, as well as a port 754a for operably receiving/supporting a lower retractor element 754. Another slot guide (not shown) can be provided to control the orientation of another retractor element. A lumen 706c can be provided to contain a working channel 710c for insertion of a tool channel as described above for insertion of working instruments or alternatively for direct insertion of working instruments without a tool channel. The lumen 706 of the outer tube 705 can also be used to guide an endoscope (not shown) through an exit port in distal end 708. Only a portion of retractor components 751, 754, 770, is shown to partially describe the relation between the outer tube 705 and the retractor in some embodiments. The retractor can be configured, for example, for the expansion to occur distal to the distal end 708 of the outer tube 705. For example, the retractor can include four retractor elements as in the embodiments described above, with retractor elements 751 and 754 shown and the two other retractor elements not shown because of the cutaway view. A proximal coupler 798 is operably connected to the four retractor elements, whether at least substantially attached and/or at least slidably-engaged to the retractor elements. The retractor can be configured to reversibly stiffen an otherwise flexible arrangement of the retractor, the arrangement designed to facilitate ease of positioning of the system 700 in a subject and to reversibly stiffen for the expansion of the retractor in the subject. The stabilization of the retractor can, in some embodiments, include a means for stabilizing the retractor through a stabilizer subsystem as taught herein, the stabilizer having, for example, a flexible beam 770 that can be converted to an at least substantially-rigid beam 775, using a means for slidably engaging a rigid, or substantially rigid, component 772 as taught herein in operable connection with the flexible beam 770, to support the expanded retractor. The flexible beam 770 can be stiffened in the manners described herein with respect to the flexible beams of the other embodiments.

FIG. 8 illustrates a cutaway view similar to FIG. 7, except in this embodiment, a floating channel system is provided. That is, FIG. 8 shows the distal end of the outer tube of a system as taught herein, in which components of the system can be floating in the outer tube to enhance flexibility for positioning the system in a subject, according to some embodiments. The figure illustrates the distal end 808 of outer tube 805. The distal end 808 includes a slot guide 855 to control the orientation of an expanding retractor element 851 and an opening 811 for lower retractor element 854. A second slot guide and a second opening (not shown) are

provided to receive respectively another upper and lower retractor element. A lumen **806c** can be provided to contain a working channel **810c** which receives a tool channel to guide a working instrument or alternatively directly receives a working instrument. The lumen **806** of the outer tube **805** is used to guide an endoscope **815**. Only a portion of the retractor components **851**, **854** are shown to partially describe an embodiment of the relation between the outer tube **805** and the retractor. The retractor can be configured, for example, for the expansion to occur distal to the distal end **808** of the outer tube **805**. For example, the retractor can include four retractor elements in the same manner as described above, only two of which are shown (elements **851** and **854**). A proximal coupler **898** is operably connected to the retractor elements, whether at least substantially attached and/or at least slidably-engaged to the retractor elements. The retractor can be configured to reversibly stiffen an otherwise flexible arrangement of the retractor, the arrangement designed to facilitate ease of positioning of the system **800** in a subject and to reversibly stiffen for the expansion of the retractor in the subject. The stabilization of the retractor can, in some embodiments, include a means for stabilizing the retractor through a stabilizer subsystem as taught herein, the stabilizer having, for example, a flexible beam **870** that can be converted to an at least substantially-rigid beam **875** in any of the manners described herein with respect to the rigidifying of the flexible beam, e.g., using a means for slidably engaging a rigid, or substantially rigid, component **872** as taught herein in operable connection with the flexible beam **870**, to support the expanded retractor. As in the other embodiments described herein, an actuator can be utilized which is operably coupled to the rigidifying structure to advance and retract it with respect to the flexible beam **870**.

The retractor elements are movable between a collapsed insertion position and an expanded position to form an asymmetric working chamber as in the embodiments described above.

During a use of the system **800**, the working channel **810c** can be a floating channel that is (i) at least substantially attached to the lumen of the outer tube at a first proximal location (not shown) and a first distal location **806c** and (ii) at least substantially floating in the lumen **806** of the outer tube **805** between the first proximal location (not shown) and the first distal location **806c**. Likewise, during the use of the system **800**, the endoscope **815** can be a floating endoscope **815** that is (iii) at least slidably-attached to the lumen **806** of the outer tube **805** at a second proximal location (not shown) and a second distal location **806a** and (iv) at least substantially floating in the lumen **806** of the outer tube **805** between the second proximal location (not shown) and second distal location (**806a**). And, during the use of the system **800**, the working channel **810c** and the endoscope **815** also form separate floating components of a floating arrangement that (v) at least substantially increases the flexibility of the system **800** over a second such system having separate lumens for a tool and an endoscope, the separate lumens affixed to the lumen throughout the length of the outer tube between the proximal end and the distal end of the outer tube, the increased flexibility facilitating an ease of positioning the system **800** in the subject for the treatment of the target tissue. In some embodiments, the endoscope **815** can be at least slidably-attached to the distal end **808** of the outer tube **805** by inserting the endoscope **815** through a dedicated port (not shown) for the endoscope **815**, such that the system **800** is configured to be substantially limited to a sliding movement in and out of the distal end **808** of the outer tube

805. And, in some embodiments, the endoscope **815** can be allowed to also float in a port **806a** that is substantially larger than the endoscope **815**, providing a sliding motion for the endoscope as well as room for side-to-side movements as well.

FIGS. **9A** and **9B** illustrate side views of working, and/or floating, channels that can be used to guide tools as taught herein, according to some embodiments. As discussed herein, the working channels can have at least a portion of which floats in the lumen of the outer tube in a manner that is the same or similar to FIG. **8** to further enhance the flexibility of the outer tube during position of the system in a subject. In some embodiments, the terms “channel,” “floating channel”, and “tool channel” can be used interchangeably. Each tool channel can be operatively connected to a handle **980** in a manner that is the same or similar to the operable connections taught herein for the retractor actuator and/or the stabilizer actuator. FIG. **9A** shows the tip **910a** of the tool channel **910** in a substantially extended position, whereas FIG. **9B** shows the tip **910a** of the tool channel **910** in a substantially bent position, such that the distal tip **910a** is deflected substantially normal to the central axis of the tool channel **910**. A system **900** consistent with other systems taught herein, for example, can include an entry port **909**, a tool channel **91** inserted through entry port **909**, a wire coupler **911**, ratchet teeth **916**, a pull wire **917** for flexing or extending the tip **910a** of the working channel **910**, and wire actuator **919**. The ability to flex the tip **910a** of the tool channel **910** facilitates independent positioning of a tool (not shown) in the treatment of a target tissue in a subject. In some embodiments, the wire actuator **919** can be multi-positional, having at least three positions for bending tip **910a** of tool channel **910**. In some embodiments, the wire actuator **919** can have tooth engageable with one of a plurality of ratchet teeth **916** in handle housing **915** to provide a plurality of positions for reversibly-fixing the bent tip **910a** in position during use of the tool (not shown) in the treatment of the target tissue in the subject. More specifically, when the wire actuator **919** is moved from its distal position of FIG. **9A** to a more proximal position, it pulls pull wire **917**, which is attached to the tip **910a** of tool channel **910**, proximally to tension the tip **910a**, causing it to bend to the configuration of FIG. **9B**. Engagement of the tooth of actuator **919** with the teeth **916** maintains the position of actuator **919** and thus maintains the bent position of the tip **910a**. Note although the tip is shown bent at substantially 90 degrees to the longitudinal axis of the tool channel **910**, bending to other angles is also contemplated. Also, in some embodiments, actuator **919** is provided to control the angle of tip **910a** by controlling the degree of proximal retraction of the pull wire **917**, with further retraction further bending the tip **910a** and less retraction bending the tip **910a** to a lesser degree. More than one tool channel can be provided, and the multiple tool channels can be controlled by actuator **919**, or alternatively, a separate actuator **919** can be provided for each tool channel. Also, various mechanisms can be utilized to lock the actuator(s) **919** in position to maintain the bent position of the tip of the tool channels.

Other mechanisms can also be utilized to control the tool channels. Alternatively, one or more of the tool channels can have a pre-bent (pre-curved) tip which is substantially straight when in the insertion position within the confines of the multi-lumen tube (catheter) and returns to the pre-bent position when exposed from the confines of the catheter.

As described herein, the channels can be configured to control the trajectory and position of instruments such as forceps in the working space created by the retractor. In

some embodiments, a channel can be removed from, or inserted through, the outer tube of the system, alone or inside an additional channel that may be used as a guide. The channels can be virtually any size considered by one of skill to be useful in the systems described herein. For example, a channel can have an inner diameter ranging from about 1 mm to about 5 mm, from about 2 mm to about 4 mm, from about 1 mm to about 3 mm, or any range therein. The length of the channel should, of course, complement the length of the system. For example, the channel can have a length ranging from about 40" to about 72", from about 48" to about 60", from about 42" to about 70", from about 44" to about 68", or any range therein in increments of 1".

The channels can also comprise any material or configuration known to one of skill to be suitable for the uses described herein. For example, the channels can comprise a single polymer layer, multiple polymer layers, a wire reinforced layer, or a combination thereof. In some embodiments, a channel can comprise (i) an inner layer of a polymer such as, for example TEFLON or polyethylene for slippery luminal surface on the inner diameter of the channel; (ii) a metal such as, for example, a stainless steel, nitinol, or cobalt chromium as a wire reinforcement in the configuration of a braid, mesh, or helical coil layer covering the inner layer; and, (iii) an outer layer of a polymer such as, for example, PEBAX, polyurethane, polyethylene, silicone, PVC, or nylon.

In some embodiments, the channels can be configured such that the outer layer (iv) is the most rigid in the proximal section of the channel (i.e., the first about 12" to about 24" of the channel), having a hardness of about 60 Shore D to about 80 Shore D; (v) has a medium stiffness in the middle section (i.e., the next about 12" to about 36" of the channel), having a hardness of about 50 Shore D to about 72 Shore D; and, (vi) is the most flexible in the distal section (i.e., the next about 0.5" to about 2" of the channel), having a hardness of about 20 Shore D to about 50 Shore D). The distal section of the channel can be the section that flexes and can be the distal about 1" of the channel, in some embodiments. In some embodiments, the channels can have a rigid section just proximal to the distal section to keep this flexible section straight when there is a bending moment on the tip such as when the instrument which is inserted through the channel is grasping a tissue during a gastrointestinal treatment, for example. The length of the rigid section of the channels can range, for example, from about 1 cm to about 10 cm, from about 2 cm to about 8 cm, from about 3 cm to about 7 cm, from about 4 cm to about 6 cm, about 6 cm, or any range therein in 1 cm increments. The rigid section can include a rigid tube comprising a reinforcement material such as, for example, stainless steel or NITINOL, or a polymer such as PEEK or a polyimide embedded between the outer polymer layer and the inner polymer layer. The rigid section can have any suitable length to perform its function in the system. In some embodiments, the rigid section can have a length ranging from about 0.001" to about 0.005".

The thickness of the inner layer of the channels can range from about 0.0005" to about 0.005", from about 0.001" to about 0.004", from about 0.002" to about 0.003", about 0.001", or any range therein in 0.0005" increments. The thickness of the reinforcement layer can range from about 0.001" to about 0.006", from about 0.002" to about 0.005", from about 0.003" to about 0.005", from about 0.001" to about 0.003", about 0.002", or any range therein in increments of 0.0005". The thickness of the outer layer can range from about 0.003" to about 0.012", from about 0.004" to

about 0.010", from about 0.005" to about 0.009", from about 0.005" to about 0.008", about 0.010", or any range therein in increments of 0.001".

For flexing the distal end of the channel, there can be a side lumen with a pull wire embedded between the inner layer and the outer layer. In some embodiments, the side lumen can be located between the inner layer and the reinforcement layer, or the side lumen can be a part of the inner layer. The side lumen can be made of any material considered by one of skill to be useful in the systems taught herein. For example, the material can include a flexible tube of polymer such as, for example, TEFLON or polyethylene. In some embodiments, the side lumen runs parallel to the length of the channel in the distal section of the channel and then helical proximal to the distal section of the channel. The pitch of the helix can vary, for example, from about 1.0" to about 6.0", from about 2.0" to about 5.0", from about 1.0" to about 4.0", from about 3.0" to about 5.0", about 4.0", or any range therein in 0.1" increments. By routing the side lumen helically, the wire tension can be distributed all around the shaft so that the shaft can be rotated in any orientation smoothly and remain at least substantially stable. In some embodiments, the pull wire can run from the wire actuator in the handle into the side lumen, out of the distal end of the side lumen, and looped around a rigid ring. The rigid ring (stainless steel, 0.002-0.005" thick, 0.040"-0.25" long) at the distal end and back into the side lumen and out into the handle and attached to the wire actuator. The handle can be operatively connected to the channel, the handle having a housing, and a lumen in communication with the channel. The wire actuator is operatively attached to the pull-wire inside the housing with a button on the outside of the handle allowing the wire actuator to slide back (proximal) and forth (distal) on the handle to pull and push the pull-wire. Pulling the wire makes the tip flex and become rigid, whereas pushing the wire can make the tip relax and straighten. The slide has a means for locking the wire actuator in place, for example, using complementary ratchet teeth on the housing and wire actuator mechanism. When the wire actuator button is pressed, the ratchet teeth can disengage and unlock the pull-wire. In some embodiments, the tip can flex from about 0 degrees to about 150 degrees. In another embodiment, the tip can flexed from about 45 degrees to about 100 degrees. The can be designed to be flexible in bending but stiff in torsion, allowing the channel to follow the curvatures of the anatomy and allow for a rotation of the handle from outside the body during use, transmitting torque to rotate the tip to a desired direction.

The tool (working) channels positioned inside the outer tube provide a multi-lumen catheter having manipulable passages for independently manipulating tools from outside the body into the working space inside created by expansion of the retractor. In some embodiments, from 1 to 3 flexible tubes run inside of the outer tube and can be detached from the outer tube, as described herein, which facilitates the flexibility of the system. In some embodiments, these flexible tubes can be attached at two points: (i) the proximal coupler of the retractor, which can be a ring-type structure having ports at the distal end of the outer tube, and (ii) at the proximal end of the shaft, such as at the handle. This can provide a floating arrangement in the outer tube that is unique, constraining the ends of the flexible tubes while allowing for a substantially free-floating movement of the flexible tubes in the outer tube to enhance the flexibility of the system.

In some embodiments, 2 inner tubes can be positioned adjacent to the inner surface of the outer tube to provide,

effectively, 3 separate channels. The 2 inner tubes can function as 2 independent tool channels while the space between these first 2 channels and the outer tube functions as a third channel. The third channel can be substantially larger than the other 2 channels. Each of the first 2 tool channels can have, for example, an inner diameter ranging from about 2 mm to about 6 mm, about 3 mm to about 5 mm, or any range therein. In some embodiments, the diameter of the first 2 tool channels can be about 4 mm. Each of the channels can be designed to accommodate an endoscope such as a colonoscope, as well as endoscopic tools that include, for example, forceps, graspers, clip applicator, dissectors, snares, electrical surgical probes, or loops. In some embodiments, the largest diameter channel can be the channel for the endoscope.

The channel for accommodating the endoscope can be designed to have an inner diameter, for example, ranging from about 5 mm to about 15 mm, from about 6 mm to about 12 mm, from about 11 mm to about 14 mm, from about 5 mm to about 10 mm, from about 8 mm to about 13 mm, or any range therein in 1 mm increments. The inner tubes can comprise any suitable material known to one of skill to be useful for the purposes set-forth herein, as well as composites thereof. For example, the inner tubes can comprise a fluoropolymer such as TEFLON for lubricity to ease tool or endoscope passage and movements. Other materials that may be used include, for example, polyethylene, polypropylene, PEBAX, nylon, polyurethane, silicone, and composites thereof, each of which may also be used with a lubricant coating. The tubes may also comprise a metallic wire reinforcement such as a braid, mesh or helical coil, each of which may be embedded in the tube.

One of skill should appreciate that the systems taught herein can be used as a surgical suite with a floating, multi-lumen-catheter retractor system having a reversibly-stabilized and reversibly-expandable retractor for a minimally invasive treatment of a subject. In these embodiments, the system can comprise a flexible outer tube for guiding a floating channel and a floating endoscope in a substantially floating arrangement within the system. Due to the construction of the floating system, the system is highly flexible, such that the flexible outer tube can be highly flexible and have a lumen, a proximal end, and a distal end; and, the floating channel can serve as a guide through which a tool is manipulated in a treatment of a target tissue in a subject. The retractor can be a reversibly-stabilized and reversibly-expandable retractor forming a treatment space upon expansion. The retractor can be configured, for example, for the expansion to occur distal to the distal end of the outer tube and to reversibly stiffen an otherwise flexible arrangement of the retractor, the flexible arrangement designed to facilitate the positioning of the system in the subject and to reversibly stiffen for the expansion of the retractor. That is, the system can include a stabilizing/rigidifying structure as in the embodiments described above, which can be slidable to rigidify the element and retractor system.

During a use of the system, the floating channel can be (i) at least slidably-attached to the lumen of the outer tube at a first proximal location and a first distal location and (ii) at least substantially floating in the lumen of the outer tube between the first proximal location and the first distal location. Likewise, during the use of the system, the floating endoscope can be (iii) at least slidably-attached to the lumen of the outer tube at a second proximal location and a second distal location; and, (iv) at least substantially floating in the lumen of the outer tube between the second proximal location and second distal location. And, during the use of

the system, the floating arrangement can (v) at least substantially increase the flexibility of the system over a second such system having lumens for a tool and an endoscope, the lumens affixed to the lumen of the outer tube throughout the length between the proximal end and the distal end of the outer tube. The increased flexibility can facilitate an ease of positioning of the system in the subject; and, the reversibly-stiffened arrangement of the retractor can form an at least substantially rigid beam as a structural support for the expansion in the subject for the treatment of the target tissue.

In some embodiments, the retractor comprises at least two expandable retractor elements, each of the members having a proximal end and a distal end, the proximal end slidably engaged with the outer tube, and each of the members configured such that an increase in the amount of sliding of the proximal end toward the distal end compresses the member and expands the retractor. These embodiments can also include a distal nexus or coupler located distal to the distal end of the outer tube and at which the distal end of each of the at least two retractor elements is affixed; and, a stabilizer subsystem connecting the distal nexus to the distal end of the outer tube and having an at least substantially rigid component configured to reversibly stiffen an otherwise flexible portion of the retractor for an asymmetric expansion of the retractor.

In some embodiments, the retractor comprises four expandable retractor elements, each of the members having a proximal end and a distal end, the proximal end slidably engaged with the outer tube, and each of the members configured such that an increase in the amount of sliding of the proximal end toward the distal end compresses the member and expands the retractor. These embodiments can also include a proximal coupler attached to the distal end of the outer tube, the proximal coupler having four retractor ports for the slidable engagement with the four retractor elements, the four retractor ports positioned circumferentially around the proximal coupler and configured to facilitate a reversible, axial sliding of the retractor elements for the asymmetric expansion of the retractor. These embodiments can also include a distal nexus or coupler located distal to the distal end of the outer tube and at which the distal ends of each of the four retractor elements are affixed; and, a stabilizer subsystem connecting the distal nexus to the distal end of the outer tube and having (i) a flexible component that extends from the proximal coupler to the distal nexus and (ii) an at least substantially rigid component that is slidably engaged with the proximal coupler and reversibly extends from the proximal coupler to the distal nexus to reversibly-stiffen the retractor in an asymmetric expansion of the retractor. The retractor elements can be moved to the expanded position in any of the ways discussed above. Also, if desired, only two of the retractor elements expand as in the embodiments described above.

The flexible component and the rigid component can have central axes that are each at least substantially parallel to the central axis of the distal end of the shaft, the rigid component forming an at least substantially rigid beam as a structural support for the asymmetric expansion, the rigid beam having a luminal side and an abluminal side.

The systems provided herein can be used in several different methods of treatment. For example, the systems can be used in a method of treating a gastrointestinal lesion using a multidirectional and multi-angular approach to the lesion. The method can include positioning the system in a subject's gastrointestinal tract, the positioning including placing the retractor in proximity to a target lesion for a treatment; expanding the retractor to create the treatment

space for use of the tool; treating the lesion with the tool; collapsing the retractor; and, withdrawing the system from the subject. The lesion can include, for example, a perforation, a tissue pathology a polyp, a tumor, a cancerous tissue, a bleed, a diverticuli, an ulcer, an abnormal vessel, or an appendix.

It should be appreciated that there are a number of procedures and variations, in addition to those taught above, that can be used readily by one of skill in the implementation of the systems taught herein. In some embodiments, one of skill can insert the endoscope through the endoscope channel of the system and extend the distal end of the endoscope distal to the distal end of the retractor to form an assembly. The assembly can then be inserted into a body lumen or orifice, such as the colon, and advanced orally until the distal end of the scope or the lens is in proximity to the target tissue (lesion or defect) to be treated. The system is advanced forward over the scope until the retractor is positioned over the distal end of the endoscope while observing the image from the endoscope. The system is advanced until the target tissue is located between the proximal coupler and distal nexus of the retractor while observing the image from the endoscope. The handle or outer tube can be rotated to rotate the retractor so that the target tissue is at the desired position relative to the retractor members while observing the image from the endoscope. The retractor can then be straightened and stabilized by converting the flexible beam to a rigid beam. The retractor can then be expanded by moving the retraction actuator forward on the handle while observing the image from the endoscope. This action pushes the tissue outwards, creates a working space around the target tissue, and anchors and stabilizes the target tissue. Optionally, while the retractor is expanded, the system can be pulled back to shift the peak of the most expanded members distally to improve working distance between the endoscope and the peak of the asymmetric work space, wherein the peak is generally recommended to be located around the target tissue. With the instruments inserted into the working (tool) channels, insert the working channels into the proximal ports of the system and advance the instruments and channels distally until the tips of the working channels are distal to proximal coupler of the retractor while observing the image from the endoscope. At this time, the tips of the working channels can be flexed to the appropriate angulation for the tools to approach the lesion to be treated. The working channels can be rotated and moved axially as needed to the desired position for the tools. Likewise, the instruments/tools can be advanced relative to the distal end of the working channels as needed to extend the instruments as needed to reach the target tissue. Various instruments can be inserted through the working channels as desired, and both the endoscope and the instruments can be advanced and positioned independently into the working area to further manipulate and visualize the target tissue at closer proximities or angulations. This is because, in some embodiments, the endoscope can also flex within the working space.

In some embodiments, it's desirable to provide for delivering a system taught herein with an optional cover, or sheath that covers a portion of the system, including the retractor during delivery of the retractor to a target site, during a treatment of a target tissue at the target site, during a removal of the target tissue, and/or during a removal of the system from the subject, or a combination thereof. Recall that some embodiments of such an optional cover 355 have been illustrated herein, for example, in FIGS. 3A and 3K. One of skill will appreciate that the retractor has elements that can catch, snag, or otherwise disturb or contact tissue

during delivery, or removal, of the retractor to or from the target site. Also, the treatment of the target tissue may include, for example a dissection of tissue that can be performed within the cover without or intermingling the target tissue with the surrounding tissues. Moreover, the dissected tissue may be a cancerous or other tissue that is desirable to contain during treatment or removal by encapsulating it within the cover. The terms "cover" and "sheath" can be used interchangeably in many embodiments, and one of skill can appreciate that such embodiments are open to improvements, as taught herein.

FIGS. 10A-10E illustrate a retractor sheath covering a retractor of a system as taught herein, according to some embodiments. FIGS. 10A-10C show top, oblique, and side-views showing a flexible, clear sheath 1000 that covers a collapsed configuration of the retractor 1050 to render an at least substantially smooth and/or atraumatic surface 1005 for a delivery of the retractor 1050 to a target site (not shown) for a treatment of a target tissue (not shown). In FIGS. 10A-10C, the cover is in a closed configuration that can be sustained until the expansion of the retractor 1050 for the treatment, or it can be reversibly-obtained following the treatment. FIGS. 10D and 10E show a top-view and side-view of an expanded configuration of the retractor with the cover in an open configuration for the treatment.

The sheath 1000 can be designed to prevent or inhibit the retractor elements 1051, 1052, 1053, 1054 and bridge members 1044a, 1044b from catching, snagging, or otherwise disturbing or contacting tissue during a delivery or removal of the retractor 1050 to or from the target site. The sheath 1000 is attached at one end to the distal hub or coupler 1099 and extends proximally past the proximal coupler or hub 1098 and is attached to the outer surface of the catheter 1055. Alternatively, the sheath 1000 can be attached at a proximal end to proximal coupler 1098. Such retainers can be used at any position around the retractor to facilitate a retention of the configuration of the working space 1060, for example, to retain the configuration under forces of the expansion of the retractor 1050. During the procedure the sheath 1000 can also prevent or inhibit tissue from entering the retractor 1050 until desired. The sheath 1000 can also act as a collection means for entrapping and/or pulling out a resected tissue, which can be particularly desirable in the resection of cancerous tissue in some embodiments. The sheath 1000 can be at least substantially closed around the retractor 1050 during delivery, and can be designed to open as the retractor 1050 is expanded to create the working space 1060 for the treatment. Alternatively, the expansion of the retractor elements and the sheath can be independent.

A flexible beam 1070 can be converted to the at least substantially rigid beam 1075 using the methods and structure of conversion as described above in conjunction with the other embodiments. For example, an actuator can be operably connected to the beam (rigidifying structure) 1075 to advance it into a lumen of the flexible beam 1070, or alternatively advance it over the flexible beam 1070 (as shown in FIG. 10D), to stiffen (make more rigid) the flexible beam 1070. The bridge member 1044a can connect the expandable retractor elements 1051, 1052 and bridge member 1044b can connect elements 1053, 1054 to restrict lateral movement and stabilize the retractor as in the other bridge members described herein. In alternate embodiments, bridge member 1044b extends from bridge member 1044a and connects to elements 1053, 1054 such that all four elements 1051, 1052, 1053 and 1054 are connected by the bridge elements 1044a, 1044b. Bridge member 1044c can connect elements 1053, 1054. Coverings 1051a and 1052a can be

applied to the retractor elements **1051**, **1052**, respectively, to control expansion as described in the embodiment of FIG. **11** below.

In some embodiments, the sheath **1000** can be perforated longitudinally (not shown), designed such that the sheath **1000** opens upon expansion of the retractor **1050** through tearing of the perforation at the target site. In some embodiments, a tongue-and-groove mechanism, for example a ZIPLOCK mechanism, can be used to at least substantially close a slit **1007** at the top of the retractor **1050** which can also open upon the expansion of the retractor **1050** at the target site. In some embodiments, a larger perforation, or unclosed portion **1001**, can remain in the sheath **1000** to facilitate the tearing or opening of the sheath at the target site upon the expansion of the retractor **1050**. In some embodiments, the terms "slit" and "opening" can be used interchangeably.

In some embodiments, the sheath can be reversibly opened, such that the sheath can be re-closable. For example, a drawstring, cable, or wire, can be operably positioned in communication with the opening for the re-closing of the opening by pulling or pushing the drawstring, cable, or wire from outside the patient during the treatment. In some embodiments, the edges of the opening can form longitudinal pockets or channels for pulling or pushing the drawstring, cable, or wire as desired from outside the patient during the treatment, such as by routing the drawstring, cable, or wire through the system and, perhaps, through the handle as with the other actuation means. In some embodiments, a drawstring is used to re-close the sheath, wherein the strings can be tensioned at the handle to close the slit, or loosened to allow the retractor to expand. In some embodiments, the sheath has a stiffening strip running transversely around the mid portion of the cage to facilitate the cage wires expanding without catching on the surrounding sheath. The stiffening strip can be another layer of the sheath welded or glued onto the existing sheath. It can also be formed as a thickened area. Alternatively, a stiffer material can be inserted in the pocket running transversely. The stiffening material may be the same as that of the sheath or it may be a stiffer material.

One of skill will appreciate that any of the known materials and/or methods of covering the sheath may be useful for the purposes taught herein. For example, the sheath can range from about 10 mm to about 30 mm at the ends that are attached to the proximal coupler and distal nexus, each of which can be used to define the ends of the retractor **1050**. Moreover, the sheath can be heat welded, glued, or heat-shrunk to the proximal coupler and/or distal nexus, or perhaps substantially proximal or distal to these components, to fasten the sheath to the retractor. In some embodiments, the sheath may even cover the system as a sterilizing, or clean, cover, such that the sheath is an extension of a disposable and/or replaceable component that may be applied, for example, in a sterilization process. And, in some embodiments, the sheath can be larger at the mid portion where the diameter can range, for example, from about 20 mm to about 40 mm in a closed configuration. The sheath can be, for example, opaque, translucent, or clear, and the material composing the sheath can be, for example, a polyethylene, nylon, fluorinated ethylene propylene (FEP), TEFLON, polyethylene terephthalate (PET), or polycarbonate. And, in some embodiments, the sheath material can range, for example, from about 0.0010" to about 0.0060" thick, from about 0.0020 to about 0.0080" thick, from about 0.0030" to about 0.0050" thick, from about 0.0010" to about

0.0030" thick, from about 0.0005" to about 0.0100" thick, about 0.0020" thick, or any range therein in about 0.0005" increments.

In use, when the retractor system **1050** is moved from the collapsed insertion position of FIG. **10B** to the expanded position of FIG. **10E**, the expandable retractor elements are expanded away from the sheath **1000**. The sheath **1000** can remain open at a surface facing the target tissue to be treated, e.g., removed, from the patient's body. Alternatively, the sheath **1000** can remain closed and be opened by an endoscopic tool to receive the removed lesion. Note as shown in FIG. **10E**, in the expanded position, the sheath **1000** is covering the retractor elements **1053**, **1054** and rigid beam **1075** and is spaced from expanded elements **1051**, **1052**. In alternate embodiments, the sheath can also cover elements **1051**, **1052** in their expanded configuration.

FIGS. **11-30** illustrate alternative embodiments of the system, designated generally by reference numeral **1100**. System **1100** includes a multi-lumen catheter or tubular member **1110** configured to receive one or more tool channels or instrument guides. FIG. **11** shows two tool channels **1122** and **1124**, it being understood that in some embodiments, only one tool channel can be utilized and in other embodiments more than two tool channels can be utilized, with the catheter provided with a sufficient number of lumens. The tool channels **1122**, **1124** can be packaged as a kit with the catheter **1110** as shown in FIG. **11**. Alternatively, the tool channels **1122**, **1124** can be packaged separately. In other embodiments, the tool channels are packaged already inside the lumens of the catheter **1110**. Each tool channel **1122**, **1124** has a lumen (channel) to receive an endoscopic instrument (tool) therethrough.

The tool channels (flexible tubes or guides) **1122** and **1124** **65** are inserted through the proximal end of the catheter **1110** and advanced through respective lumens **1112**, **1114** in the catheter **1110** (see FIG. **12**). As shown in FIG. **16**, which illustrates a proximal portion **1113** of catheter **1110**, the catheter **1110** can include ports **1115**, **1117**, cooperating with the lumens **1112**, **1114**, respectively (see e.g. FIG. **13**), which can include valves to maintain insufflation when the tool channels **1122**, **1124** are inserted therethrough and translated axially therein. Tool channel (tube) **1122** preferably has a pre-bent tip **1122a**, best shown in FIGS. **11** and **18**, to provide a curved distal end. Tool channel (tube) **1124** also preferably has a pre-bent tip **1124a**, providing a curved distal end. When the tool channels **1122**, **1124** are inserted into the lumens **1112**, **1114** of catheter **1110**, the tips **1122a**, **1124a** are preferably substantially straightened to facilitate advancement through the lumens. When the tool channels **1122**, **1124** are advanced sufficiently distally so the distal tips **1122a**, **1124a** are exposed from the confines of the walls of the catheter lumens **1112**, **1114**, the tips **1122a**, **1124a**, return to the pre-set curved position. This can be understood with reference to FIG. **18** which illustrates in phantom the straightened position of the tool channels **1122**, **1124** for movement within the catheter **1110**. As in the other embodiments disclosed herein, the tool channels **1122**, **1124** can be composed of superelastic material, although other materials to provide the curved tip which returns from a substantially straight insertion shape to a curved shape when exposed can also be used, such as stainless steel. Also, as in the other embodiments disclosed herein, shape memory properties of material such as Nitinol can be used with a memorized curved tip shape. In alternative embodiments as described above, the tool channels **1122**, **1124** can have a mechanism such as a pull wire which is actuated to bend its distal end. The tool channels **1122**, **1124** in the embodiments of FIGS.

11-30 are unattached to the catheter 1110 so that the user can freely control their axial movement from a proximal end portion 1122b, 1124b, during use. However, it is also contemplated that in alternate embodiments the tool channels can be attached to the catheter.

The tool channels 1122, 1124 can optionally include markings 1123, 1125, respectively, at a region proximal to the catheter 1110 to provide a visual indicator to the user of the depth of insertion of the tool channels 1122, 1124 through the catheter lumens 1112, 1114. The tool channels 1122, 1124 can have a luer fitting 1127, 1129, respectively, (FIGS. 11 and 19A) with a valve, at the proximal end which can close off backflow of insufflation gas from the body. This maintains insufflation when the endoscopic tool is inserted through the tool channels 1122, 1124 as described below. The tool channels in an alternate embodiment shown in FIG. 19B have a hemostatic valve 1121A, 1121B connected at a proximal end of tool channels 1122', 1124', respectively, to maintain insufflation during tool insertion. As shown, valves 1121A, 1121B are proximal of luer fittings 1127', 1129'. The tool channels 1124', 1126' are identical to tool channels 1124, 1126 in all other respects.

In one embodiment, the tool channels 1122, 1124 can be composed of a flexible soft material, such as Pebax. A super-elastic nitinol backbone can in some embodiments be embedded in the wall of the Pebax material, e.g., within the curved portion. Other materials are also contemplated.

Catheter 1110 also preferably has a lumen 1116 (see e.g., FIG. 16) configured and dimensioned to receive an endoscope 1200. In some embodiments, the lumen 1116 is dimensioned to receive a conventional endoscope, e.g., a conventional colonoscope, and the catheter 1110 is back-loaded over the endoscope. This is described in more detail below in conjunction with the method of use. In alternate embodiments, the lumen 1116 can receive an articulating endoscope. Moreover, in alternate embodiments, the endoscope can be inserted into the catheter and inserted into the body lumen.

With reference to FIGS. 11 and 16, catheter 1110 includes a handle housing 1130 at the proximal portion 1113 which contains two actuators: actuator 1132 for controlling movement of the retractor system 1150 and actuator 1134 for controlling movement of the rigidifying (stabilizing) structure. These are discussed in more detail below. Catheter 1110 also includes tubing 1139 having a luer coupling 1137 and a control switch 1175 (see FIGS. 31A, 31B) for closing off an internal gasket 1176. The suture 1172 for closing covering 1170 is secured by the elastomeric gasket 1176 as the switch 1174 is moved from the position of FIG. 31A to the position of FIG. 31B. More particularly, in the initial position of FIG. 31A, the ball valve 1174, seated in a slot in the housing 1179, does not apply a force to the gasket 1176. This enables the suture 1172 to freely move within the lumen of the catheter. When it is desired to lock the suture 1172 in position, i.e., after the suture 1172 is tensioned to close the covering 1170, the switch 1175 is slid forward, thereby camming the ball 1174 downwardly (as viewed in the orientation of FIG. 31B) to collapse the lumen in the gasket 1176 against the suture 1172 to thereby secure the suture 1172. This locks the suture 1172 against movement which thereby maintains the covering (bag) in the closed position encapsulating the target tissue as described herein. Note that the reverse movement of the switch 1175 unlocks the suture 1172 to enable free movement of the suture 1172. Catheter 1110 also has tubing 1136 having a one-way stopcock 1038 to provide an insufflation port. This port can be used to supplement the insufflation gas provided by the endoscope

1200. The insufflation gas flows through lumen 1116 in the area around the endoscope 1200 since the cross sectional dimension of the lumen 1116 exceeds the cross-sectional dimension of the endoscope 1200 to leave a sufficient gap.

As shown, the tubings 1139, 1136 are positioned distal of the actuators 1132, 1134,

Turning now to the retractor system 1150, which forms a body lumen reshaping or reconfiguring system, and with initial reference to FIG. 13, the retractor system 1150 is positioned at the distal portion 1111 of the catheter 1110 (distal of proximal hub 1140) and includes flexible retractor elements 1152 and 1154. Retractor system also includes retractor elements 1156 and 1158. Retractor elements 1152, 1154 form the expandable elements which create the working chamber (space) within the body lumen and form an asymmetric cage. Retractor elements 1156, 1158 form the base of the retractor system, thus helping to define the retractor cage along with elements 1152, 1154. In some embodiments, retractor elements 1156, 1158 do not undergo any change when the retractor system 1150 moves from the collapsed insertion position to the expanded position; in other embodiments, retractor elements 1156, 1158 undergo a slight change in position, i.e., slight expansion or bowing, when the retractor system 1150 is expanded. Retractor elements 1152, 1154, are expandable to form an asymmetric working chamber to improve visibility and working space as described in detail above with respect to the other systems forming asymmetrical working spaces.

As shown by comparing FIGS. 15 and 21A, retractor elements 1152 and 1154 move from a collapsed insertion position wherein they preferably do not extend beyond the transverse dimension of the catheter 1110 to an expanded position wherein they bow laterally outwardly and have a transverse dimension extending beyond the transverse dimension of the catheter 1110. Also by comparing FIGS. 15 and 21A, it can be seen that lower (as viewed in the orientation of these figures) elements 1156, 1158 in the collapsed position do not extend beyond, or significantly beyond, the transverse dimension of the catheter 1110 and when the retractor is expanded, remain substantially in the same position so they still do not extend beyond, or significantly beyond, the transverse dimension of the catheter 1110. In some embodiments, the elements 1156, 1158 do not extend at all beyond the transverse dimension of the catheter 1110. As in the embodiments described above, the retractor system 1150, i.e., the retractor elements 1152, 1154, expand to only one side of a plane passing through the longitudinal axis of the catheter 1110, thereby creating the asymmetric working space 1151 (and asymmetric cage), with its attendant advantages described herein.

Retractor elements 1152, 1154 have a bridge member 1155 to add stability to the retractor and maintain a desired orientation of the retractor elements during the expansion. The bridge member 1155 is attached to the two retractor elements 1152, 1154, preferably at an intermediate portion, to create a transverse structure for the elements 1152, 1154, limiting side-to-side movement. As shown, bridge member 1155 has a first arm 1155a connected to retractor element 1152 and a second arm 1155b attached to retractor element 1154. The upper surface (as viewed in the orientation of FIG. 15) can be arcuate as shown. The bridge member 1155 can be a separate component attached to the retractor elements by tubular elements 1159a, 1159b, which are attached to retractor elements 1152, 1154, respectively. In this version, the tubular element 1159a, 1159b has a first opening to receive the retractor element and a second opening to receive an arm of the bridge member. Note the tubular

elements **1159a**, **1159b** also bulk up the diameter of the retractor elements **1152**, **1154** since in some embodiments the retractor elements **1152**, **1154** are about 0.035 inches in diameter (although other dimensions are contemplated). Other methods of attachment of the bridge members are also contemplated. Alternately, the bridge member **1155** can be integrally formed with one both of the retractor elements **1152**, **1154**. The bridge member **1155** can be composed of a material similar to the elements **1152**, **1154** or can be composed of a different material. The bridge member **1155** can also include legs **1155d** and **1155e** which are connected to lower elements **1158**, **1156**, respectively, to attach the bridge member to lower elements **1158**, **1156**, respectively, to add to the stability of the retractor system. These leg members are preferably composed of soft elastomeric material such as polyurethane tubing to add more structure to the cage and facilitate expansion of the cage in a more predictable fashion.

Additional bridge members (not shown) can be provided on the retractor elements **1052**, **1054** to increase stability. The bridge member **1055** can, in some embodiments, in the collapsed position, extend substantially axially as in FIGS. **15** and **17A**, but change to angle inwardly (downwardly) toward the longitudinal axis of the catheter **1010** in the expanded position of the retractor elements **1052**, **1054** such as in FIG. **21A**.

An additional bridge member **1157** (or alternatively multiple bridge members) extends between the two lower (as viewed in orientation of FIG. **15**) retractor elements **1156**, **1158**. These elements **1156**, **1158** can help open up the lower section of the retractor system **1150**, and help form the cage for the working space, and the bridge member(s) **1157** can help to stabilize these elements **1156**, **1158**, e.g., limit side to side movement. The bridge member **1157** as shown has arms **1157a**, **1157b** connecting to elements **1156**, **1158**, respectively. The bridge member **1057** can be a separate component attached to the retractor elements by tubular elements **1161a**, **1161b** which are attached to retractor elements **1156**, **1158**, respectively. The tubular elements **1161a**, **1161b** can have a first opening to receive the element **1156** or **1158** and a second opening to receive an arm of the bridge member **1157**. Other ways of attaching the bridge member(s) are also contemplated. Alternatively, the bridge member **1157** can be integrally formed with one or both of the retractor elements **1156**, **1158**. The bridge member **1157** can be composed of a material similar to the elements **1156**, **1158** or can be composed of a different material.

Additional bridge members (not shown) can be provided on the retractor elements **1156**, **1158** to increase stability. The bridge member **1157** can, in some embodiments, in the collapsed position, be substantially parallel with a longitudinal axis of the catheter **1110** or extend substantially axially such as in FIG. **15**, and substantially remain in this position in the expanded position of the retractor elements **1152**, **1154** as in FIG. **21A** since in this embodiment, the retractor elements **1156**, **1158** remain in substantially the same position when the retractor system **1150** is expanded.

The catheter **1110** includes a proximal coupler (cap) **1140** through which the retractor elements extend. Handle housing **1130** includes a longitudinally extending slot **1131** (FIG. **16**) along which retractor actuator **1132** axially slides. The retractor elements **1152**, **1154** are coupled to the actuator **1132** via block **1146**, shown in FIGS. **20A** and **20B**. That is, each retractor element **1152**, **1152** has a proximal extension that extends through the respective lumen **1112**, **1114** in the catheter **1150** and is connected at its proximal end to the block **1146**. In this manner, when the actuator **1132** is moved

along axial slot **1131** from its proximal position of FIG. **20A** to its distal position of FIG. **20B**, the block **1146** is moved distally, thereby forcing the retractor elements **1152**, **1154** laterally outwardly since the elements **1152**, **1154** are fixedly attached to the distal coupler **1148** at their distal ends. Elements **1156**, **1158** in this embodiment, are fixedly attached to the distal coupler **1148** at their distal ends, and fixedly attached to the proximal coupler **1140** (or other portion of the catheter **1110**) at their proximal ends such that movement of actuator **1132** does not effect movement of these elements **1156**, **1158**. It should be appreciated, however, that if it is desired to have the elements **1156**, **1158** move, e.g., flex slightly outwardly when the retractor **1150** is expanded, these elements **1156**, **1158** can be attached to the block **1146** so they would be moved when actuator **1132** is advanced, or alternatively attached to a separate actuator. In one embodiment, the elements **1152**, **1154**, **1156** and **1158** can be fixed within slots formed in the distal coupler **1148**. Note the proximal and distal couplers **1140**, **1148** can have openings dimensioned to receive an endoscope when the catheter **1110** is backloaded over the endoscope as described below. Housing **1130** can include a plurality of teeth (not shown) similar to the teeth of FIGS. **6A-6D** for engagement by a tooth coupled to the actuator **1132**, thereby forming a retaining or locking mechanism to retain the retractor elements in one of several select positions. A release mechanism for the retaining or locking mechanism can be provided.

Additionally, it should be appreciated that alternative ways to expand the retractor elements can be utilized, including for example providing relatively movable couplers **1140**, **1148** to expand the retractor elements **1152**, **1154** (and optionally **1156**, **1158**) in the same manner as the couplers described above, e.g., couplers **198**, **199**. The retractor elements can also alternatively be made of self-expanding material, such as shape memory material, which expand when exposed from the catheter or sheath.

Retractor elements **1152**, **1154** can optionally have a small crimp forming a flattened position at a distal end adjacent where they are anchored to the distal coupler **1148**. This reduces the bending stiffness at the point so it acts like a hinge to create a more predictable direction of expansion, e.g., to deflect upwardly and slightly outwardly. This also decreases the amount of force required to initiate the bending. Such flattened portion can also be used with the retractor elements of the other embodiments disclosed herein.

The retractor system **1150** can be configured to reversibly stiffen an otherwise flexible arrangement of the retractor **1150**. In this regard, retractor system **1150** can include a substantially-rigid beam to support the expanded retractor **1150** which helps to create a more stabilized chamber (or cage) as described herein. With reference to FIGS. **15** and **17A**, a flexible tube or beam **1160** is provided in the collapsed configuration, whereas in FIG. **17B**, the retractor system has a rigid beam that is formed from the flexible beam **1160**. More specifically, in this embodiment, the flexible beam **1160** is in the form of a rod or tube **1165** having a lumen to slidably receive a stabilizing or rigidifying structure such as a rigid tube or rod (beam) **1162**. The rigidifying (stabilizing) structure **1162** is independently actuated by the user by movement of actuator **1134**. Actuator **1134** is slidably mounted within a longitudinally extending slot of housing **1130**. In the initial position of FIG. **17A**, rigidifying structure **1162** is retracted within a lumen of the catheter and either not engaged, or only partially engaged, with flexible tube (or rod) **1160**. Rigidifying structure **1162**

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is attached at its proximal end to sliding block **1164** which is operably connected to actuator **1134**. To rigidify tube **1160**, actuator **1134** is slid distally to the position of FIG. **17B**, thereby advancing sliding block **1164** and the attached stabilizing structure **1162** distally. Such movement advances the rigidifying structure **1162** through the lumen **1165** of the flexible tube **1160** to the distal end **1160a** to thereby stiffen the beam. The rigidifying structure **1162** can optionally be removed from the flexible beam **1060** to return the system back to the original more flexible state to aid collapsing of the retractor system **1050** by sliding the actuator **1134** in the reverse direction (proximally) within the axial slot, thereby withdrawing rigidifying structure **1162** from the advanced position within flexible tube **1160**. In one embodiment, the rigidifying structure **1164** is in the form of a structure having a proximal and distal metal tubular structure joined by a flexible braid polyimide tube. However, it should be appreciated that other structures are also contemplated. Note the structures **1160**, **1162** can be substantially circular in cross-section, although other cross-sectional shapes are also contemplated. As in the aforescribed embodiments, the rigid beam limits deflection of the distal end **1111** of the catheter **1110** which could otherwise occur by pressure exerted on the distal end by the body lumen wall.

As shown in FIGS. **17A** and **17B**, the actuator can include a connector **1135** having a tooth or pawl **1137** to engage a tooth on the rack **1138** positioned within housing **1130** to retain the rigidifying structure **1164** in one of several selected positions.

In the alternate embodiment of FIGS. **17C** and **17D**, instead of advancing a rigidifying structure within the lumen of the flexible element, the rigidifying structure is advanced over the flexible element. More specifically, flexible beam **1160'** is rigidified by movement of a rigidifying structure, e.g., tubular member **1162'**, over the flexible beam **1160'**. That is, rigidifying member **1162'** has a lumen configured and dimensioned to receive flexible beam **1160'** as it is passed thereover in the direction of the arrow of FIG. **17C**. Note that flexible element **1152** has been removed from FIGS. **17C** and **17D** for clarity. Actuator **1134**, as well as alternative methods, can be utilized for such movement

A covering or cover **1170** is preferably provided at a distal end of the catheter **1110**. Covering **1170** in the illustrated embodiment is mounted around the perimeter of the proximal coupler **1140** and the distal coupler **1148**. In some embodiments, the cover **1170** is pleated and sealed around the couplers (caps) **1140**, **1148** by a heat shrink wrap. The cover **1170** is positioned around the elements **1152**, **1154**, **1156**, **1158** in the collapsed insertion position, with an opening in the cover **1170** facing toward the target tissue, e.g., the lesion to be removed. That is, in the orientation of FIG. **15**, the opening in cover **1170** faces upwardly. The cover **1170** can be configured to have an opening in the collapsed position, or, alternatively, it can be provided with a slit which can be opened due to stretching when the retractor elements **1152**, **1154** are moved to the expanded position. When the retractor elements **1152**, **1154** are expanded, they move past the cover **1170** toward the target tissue. Alternatively, the edges of the cover **1170** can be attached to the retractor elements **1152**, **1154** and thereby move with the retractor elements. When the target tissue is removed by the endoscopic instruments described herein, the removed tissue is placed within the cover **1170**, and the cover **1170** is closed, e.g., by a suture or string **1172** shown in FIG. **29** to encapsulate the tissue and prevent leakage and seeding during removal from the body lumen. The suture **1172** can be embedded in a wall of the cover **1170** or in pockets or

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channels formed in the cover **1170**, where it is permanently fixed at a distal anchor point, and pulled proximally to tension the suture **1172** and close the cover **1170**.

As with the cover (sheath) **1000** of FIG. **10**, the cover **1170** by covering the retractor elements **1152**, **1154**, **1156**, **1158** can provide a smooth and atraumatic surface for the delivery of the retractor system to the target site. The cover **1170**, like cover **1000**, also helps to prevent tissue, e.g. the luminal walls, from entering through the spaces between the beam **1160** and elements **1156**, **1158** during the surgical procedure.

In a preferred embodiment, the two ends of suture **1172** extend out of tubing **1139**. Their proximal ends can be covered by a length of tubing to facilitate grasping by the user. The suture **1172** extends through switch **1137** and tubing **1139**, through a dedicated lumen (channel) in the catheter, through the covering **1170**, and is looped at the distal cap **1148** where it is attached (anchored). During the procedure, the suture **1172** remains untensioned. After the tissue is placed within the cover (bag) **1170**, the two proximal ends of the looped suture **1172** are pulled proximally to tension the suture **1172** to close the cover **1170**. The switch can then be moved to frictionally engage to the suture **1172** to secure it so it locks in the tensioned position to maintain closure of the cover **1170**.

The use of the system of FIG. **11** will now be described with reference to removing a lesion, such as a polyp, from a colon wall, it being understood, however, that the system **1100** can be used for other procedures within the colon or the gastrointestinal tract, as well as used for other procedures in other body lumens or body spaces of a patient.

Turning first to FIGS. **12** and **13**, a distal viewing endoscope **1200**, in which the system **1100** has been backloaded over the proximal end **1201** as shown in FIG. **12**, is inserted through lumen A in the colon B in a procedure to remove the target polyp C from the wall of the colon B. The endoscope **1200** in this embodiment is a distal viewing scope with a wide distal viewing area of about 150-170 degree range so the polyp C and surrounding area can be visualized. After placement of the scope **1200** adjacent the target issue, i.e., slightly proximal of the target polyp C, the system **1100** is further advanced over the endoscope **1200**. Distal coupler (cap) **1148** has an opening **1148a**, and proximal coupler (cap) **1140** has an opening communicating with the lumen **1116** (FIG. **16**) of the catheter **1110** to enable such backloading of the endoscope **1200** and advancement of the system **1100** thereover. The catheter **1110** is advanced over the endoscope **1200** as shown in FIG. **14** until it reaches the target site as shown in FIG. **15**, with the retractor system **1050** aligned with the polyp C. As can be appreciated, in this insertion position of the catheter **1110**, the retractor system **1150** is in the non-expanded (or collapsed) position, with retractor elements **1152**, **1154**, preferably not exceeding, or only slightly exceeding, the transverse dimension of the catheter **1110**. In this position, the retractor elements, or at least retractor elements **1156**, **1158**, are covered by the covering **1170**. As shown, in this position, the distal end **1202** of the endoscope **1200** is preferably positioned at the end of proximal coupler **1140** and does not extend into the working space **1151** to thereby leave more room for maneuvering of the endoscopic instruments within the working space. Other positions, however, are also contemplated, e.g., in some versions the endoscope can extend into the working space **1151**. Note also in this insertion position, actuators **1134** and **1132** are in their retracted position as shown in FIG. **16**.

Next, to rigidify the retractor system **1150**, the actuator **1134** is moved distally from the position of FIG. 17A to the position of FIG. 17B (see also the arrow in FIG. 16) to advance rigidifying structure **1162** from the retracted position to an advanced position within lumen **1165** of flexible tube **1160**. This stiffens/stabilizes the retractor system **1150** as discussed above. Note, as discussed above, the retractor system **1150** can alternatively be stiffened/stabilized by advancement of a rigidifying structure over the flexible element as shown in FIGS. 17C and 17D.

The retractor system **1150** is now expanded. Actuator **1132** is advanced distally from the position of FIG. 20A to the position of FIG. 20B (see also FIG. 19). This advances block **1146** (which is operably coupled to retractor elements **1152** and **1154** as discussed above) which forces retractor elements **1152**, **1154** laterally outwardly to the position of FIG. 20B, thereby creating the asymmetric working space (chamber) as described in detail above.

Next, tool channels **1122**, **1124** are inserted through the ports **1115**, **1117** in the proximal region of the catheter **1110** (see FIG. 19A) and advanced by the user through the catheter lumens **1112**, **1114** so they extend out the distal openings of the lumens **1112**, **1114** and into the chamber **1151** as shown in FIG. 21A. Note as they emerge from the lumens **1112**, **1114**, and out of the confines of the lumen walls of the catheter **1110**, their distal tips **1122a**, **1124a** return to their curved (bent) position, curving upwardly (as viewed in the orientation of FIG. 21A) toward the polyp C. Note in FIG. 21A, the retractor elements are first expanded, followed by insertion of the tool channels **1122**, **1124** out of the catheter lumens **1112**, **1114** and into the working space **1151**. However, it is also contemplated that in an alternative embodiment, the tool channels **1122**, **1124** can be inserted through the catheter lumens **1112**, **1114** and into the working space **1151** prior to expansion of the retractor elements **1152**, **1154**. This alternate method is shown in FIG. 21B, with the tool channel tips **1122a**, **1122b** exposed, but the retractor system **1150** still in the non-expanded position. Note the tool channels **1122**, **1124** can be independently rotated and/or moved axially to adjust their position with respect to the polyp C. As can be appreciated, the terms upwardly and downwardly as used herein refer to the orientation of the system in the referenced Figures. If the position of the system (and target tissue) changes, the orientation and terms would also change.

After insertion of the tool channels **1122**, **1124**, endoscopic instrument (tool) **1210** is inserted through the luer fitting **1129** (FIG. 19A) of the tool channel **1124** and advanced through the lumen (channel) of the tool channel. As shown in FIG. 22, a first endoscopic instrument **1210** extends from tool channel **1124** and follows the curve of the tool channel **1124**. A second endoscopic instrument (tool) **1220** is inserted through the luer fitting **1127** of tool channel **1122** and advanced through the lumen of the tool channel **1122**. As shown in FIG. 23, the second endoscopic instrument follows the curve of the tool channel **1122**. As noted above, the tool channels can valve, such as the hemostatic valves as shown in FIG. 19B, so insufflation is not lost during insertion and removal of the endoscopic instruments from the tool channels. The endoscopic instruments **1210**, **1220** can be moved further axially as shown in FIGS. 24 and 25 to extend further from the tool channels **1122**, **1124** to contact and treat, e.g., remove, the polyp C. This movement of the endoscopic instruments shown by comparing FIGS. 23-25 shows the advantage of the tool channels **1122**, **1124**. As can be seen, once the tool channels **1122**, **1124** are in the desired position with respect to the polyp C, they can be

considered as defining a fixed curve. This means that when the endoscopic instruments **1210**, **1220** are axially advanced, they move closer to the target polyp C, without a change in curvature and without a change in their axial position with respect to the polyp C, thus providing an extra degree of freedom. The endoscopic instrument **1210**, which in the illustrated embodiment is a grasper, applies tension on the polyp C while the electrosurgical dissector **1180** dissects/severs the polyp C from the colon wall B. Other endoscopic instruments for polyp removal can also be utilized. Additionally, in some embodiments, a single tool channel can be utilized and another endoscopic instrument, e.g., a grasper or a dissector, can be inserted through a working channel (lumen) of the endoscope. Such instrumentation inserted through an endoscope can also be utilized with the embodiments having two or more tool channels.

Also note that due to the angles of the tool channels **1122**, **1124** and thus the endoscopic instruments inserted there-through, tissue triangulation can be achieved as depicted by the dotted lines in FIG. 30.

After removal of the polyp C from the colon wall B, it is placed within the cover **1170** as shown in FIG. 26, ready for removal from the body. Actuator **1134** can be moved proximally to return the retractor system to the more flexible condition if desired. Actuator **1132** is moved proximally in the direction of the arrow of FIG. 27 to return the expanded retractor elements **1152**, **1154** to their collapsed position of FIG. 28 for removal of the catheter **1110**. The string or suture **1172** is then tensioned to close the cover (bag) **1170** as shown in FIG. 29, forming a bag to encapsulate the polyp C. The switch **1175** can then be moved to the position of FIG. 31B to lock the string **1172** and thereby maintain the cover **1170** in the closed position. Catheter **1110** is then removed from the colon B with the polyp C protected (encapsulated) within the cover **1170**. Note that the cover **1170** is preferably transparent so that the drawings illustrate the retractor elements, bridge members, beam, etc. However, to facilitate understanding of the cover **1170**, FIG. 29 shows the retractor elements, bridge elements, beam etc. in phantom inside the bag/cover **1170**.

Note the endoscopic instruments can be used for partial tissue resection, for example, submucosal or subserosal resection. The endoscopic instruments could also be utilized for full thickness tissue resection. The instruments enable removal of the lesion with healthy tissue margins, thereby providing a complete, en-block removal of the pathological lesion.

Without intending to be limited to any theory or mechanism of action, the above teachings were provided to illustrate a sampling of all possible embodiments rather than a listing of the only possible embodiments. As such, it should be appreciated that there are several variations contemplated within the skill in the art that will also fall into the scope of the claims.

We claim:

1. A system for performing minimally invasive procedures in a body lumen of a patient, the system comprising:
 - a flexible catheter having a first lumen configured and dimensioned to receive an endoscope therethrough and a second lumen configured and dimensioned to receive a first flexible tube therethrough;
 - a first flexible tube movable through the second lumen, the first flexible tube having a first channel extending therethrough configured and dimensioned to receive a first endoscopic tool for axial movement therein, the first flexible tube having a longitudinal axis and a tube distal portion movable to an angled position with

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respect to the longitudinal axis, the first flexible tube slidable axially within the second [lumen];

a body lumen reshaping system positioned at a distal portion of the catheter, the reshaping system including first and second flexible elements movable from a non-expanded insertion position to an expanded position forming an expanded cage to reshape the body lumen to an asymmetric shape to form an asymmetric working space, the distal portion of the first flexible tube movable within the expanded cage; and

a proximal coupler to retain a proximal portion of the first and second flexible elements and a distal coupler to retain a distal portion of the first and second flexible elements, wherein the proximal and distal couplers include a lumen dimensioned to receive the endoscope therethrough when the catheter is backloaded over the endoscope;

an actuator positioned at a proximal region of the catheter and operably coupled to the first and second flexible elements to move the first and second flexible elements between the non-expanded and expanded positions; and

a retaining mechanism to maintain the actuator in one of several positions to retain the first and second flexible elements in a desired expanded position.

2. The system of claim 1, further comprising a covering for the body lumen reshaping system, the covering having an opening to receive body tissue.

3. The system of claim 2, wherein the covering is closable to encapsulate body tissue for removal.

4. The system of claim 3, further comprising a flexible closing member attached to the covering, wherein the flexible closing member is pulled to close the covering.

5. The system of claim 4, further comprising a mechanism for retaining the flexible closing member in position to maintain the covering in a closed configuration.

6. The system of claim 1, wherein the first flexible tube is unattached to the catheter.

7. The system of claim 1, wherein the catheter has a third lumen configured and dimensioned to receive a second flexible tube, the second flexible tube having a second channel extending therethrough configured and dimensioned to receive a second endoscopic tool for axial movement therein, the second flexible tube having a longitudinal axis and a tube distal portion movable to an angled position with respect to the longitudinal axis, the second flexible tube slidable axially within the second lumen and the distal portion of the second flexible tube movable within the expanded cage.

8. The system of claim 1, wherein the reshaping system further comprises third and fourth elements, wherein upon expansion of the reshaping system to the expanded position the first and second elements move from their collapsed insertion position outwardly away from a longitudinal axis of the catheter to the expanded position and the third and fourth elements remain substantially in a non-expanded insertion position.

9. The system of claim 8, wherein the first and second flexible elements expand to only one side of the catheter to form the asymmetric working space and asymmetric cage to asymmetrically reshape the body lumen.

[10. The system of claim 1, further comprising an actuator positioned at a proximal region of the catheter and operably coupled to the first and second flexible elements to move the first and second flexible elements between the non-expanded and expanded positions.]

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11. The system of claim 1, wherein the first flexible tube includes a valve at a proximal portion to accommodate the first endoscopic tool without losing insufflation.

12. The system of claim 1, wherein the first and second flexible elements have a flattened portion at a distal region to form a hinge.

[13. The system of claim 10, further comprising a retaining mechanism to maintain the actuator in one of several positions to retain the first and second flexible elements in a desired expanded position.]

14. The system of claim 1, further comprising a covering for the body lumen reshaping system, wherein a distal portion of the covering is attached to the distal coupler and a proximal portion of the covering is attached to the proximal coupler.

15. The system of claim 1, wherein the distal portion of the first flexible tube is substantially aligned with the longitudinal axis when positioned within the second lumen of the catheter and returns to the angled position when exposed from the second lumen.

16. A system for performing minimally invasive procedures in a body lumen of a patient, the system comprising: a flexible catheter having a first lumen configured and dimensioned to receive an endoscope therethrough and a second lumen configured and dimensioned to receive a first flexible tube therethrough;

a first flexible tube movable through the second lumen, the first flexible tube having a first channel extending therethrough configured and dimensioned to receive a first endoscopic tool for axial movement therein, the first flexible tube having a longitudinal axis and a tube distal portion movable to an angled position with respect to the longitudinal axis, the first flexible tube slidable axially within the second lumen;

a body lumen reshaping system positioned at a distal portion of the catheter, the reshaping system including first and second flexible elements movable from a non-expanded insertion position to an expanded position forming an expanded cage to reshape the body lumen to an asymmetric shape to form an asymmetric working space, the distal portion of the first flexible tube movable within the expanded cage; and

a stabilizer, the stabilizer movable from a first position to a second position to increase the stability and rigidity of the cage, wherein the reshaping system includes a flexible stabilizer receiving element, and the stabilizer comprises a stabilizing element movable within a lumen of the flexible stabilizing receiving element.

17. The system of claim 16, further comprising a first actuator positioned at a proximal region of the catheter and operably coupled to the stabilizing element to move the stabilizing element between a first position and a second position to increase the stability and rigidity of the cage.

18. The system of claim 17, further comprising a second actuator positioned at a proximal region of the catheter and operably coupled to the first and second flexible elements to move the first and second flexible elements between the non-expanded and expanded positions.

19. The system of claim 18, further comprising a retaining mechanism to maintain the second actuator in one of several positions to retain the first and second flexible elements in a desired expanded position.

20. The system of claim 17, wherein the first actuator slides the stabilizing element in an axial direction from a position proximal of the body lumen reshaping system to a distal position to move the stabilizing element into the lumen of stabilizing receiving element.

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21. The system of claim 16, wherein the first and second flexible elements expand to only one side of the catheter to form the asymmetric working space to asymmetrically reshape the body lumen.

22. The system of claim 16, further comprising a covering for the body lumen reshaping system, the covering having an opening to receive body tissue.

23. The system of claim 16, wherein the stabilizing element is composed of a stiffer material than the stabilizing receiving element.

24. A system for performing minimally invasive procedures in a body lumen of a patient, the system comprising:

a flexible catheter having a first lumen configured and dimensioned to receive an endoscope therethrough and a second lumen configured and dimensioned to receive a first flexible tube therethrough;

a first flexible tube movable through the second lumen, the first flexible tube having a first channel extending therethrough configured and dimensioned to receive a first endoscopic tool for axial movement therein, the first flexible tube having a longitudinal axis and a tube distal portion movable to an angled position with respect to the longitudinal axis, the first flexible tube slidable axially within the second lumen;

a body lumen reshaping system positioned at a distal portion of the catheter, the reshaping system including first and second flexible elements movable from a non-expanded insertion position to an expanded position forming an expanded cage to reshape the body lumen to an asymmetric shape to form an asymmetric working space, the distal portion of the first flexible tube movable within the expanded cage;

wherein the first and second flexible elements have a tubing on an intermediate portion to increase the diameter of the flexible elements.

25. The system of claim 24, wherein the first and second flexible elements expand to only one side of the catheter to form the asymmetric working space to asymmetrically reshape the body lumen.

26. The system of claim 24, further comprising a covering for the body lumen reshaping system, the covering having an opening to receive body tissue.

27. A system for performing minimally invasive procedures in a body lumen of a patient, the system comprising:

a flexible catheter having a first lumen configured and dimensioned to receive an endoscope therethrough and

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a second lumen configured and dimensioned to receive a first flexible tube therethrough;

a first flexible tube movable through the second lumen, the first flexible tube having a first channel extending therethrough configured and dimensioned to receive a first endoscopic tool for axial movement therein, the first flexible tube having a longitudinal axis and a tube distal portion movable to an angled position with respect to the longitudinal axis, the first flexible tube slidable axially within the second lumen;

a body lumen reshaping system positioned at a distal portion of the catheter, the reshaping system including first and second flexible elements movable from a non-expanded insertion position to an expanded position forming an expanded cage to reshape the body lumen to an asymmetric shape to form an asymmetric working space, the distal portion of the first flexible tube movable within the expanded cage; and

a first transverse bridge member joining the first and second flexible elements to increase the rigidity of the reshaping system;

wherein the reshaping system further comprises third and fourth elements, wherein upon expansion of the reshaping system to the expanded position the first and second elements move from their collapsed insertion position outwardly away from a longitudinal axis of the catheter to the expanded position and the third and fourth elements remain substantially in a non-expanded insertion position, the system further comprising a second transverse bridge member joining the third and fourth elements to increase the rigidity of the reshaping system.

[28. The system of claim 27, further comprising a second transverse bridge member joining the third and fourth elements to increase the rigidity of the reshaping system.]

29. The system of claim 27, further comprising a stabilizer, the stabilizer movable from a first position to a second position to increase the stability and rigidity of the cage.

30. The system of claim 27, wherein the first and second flexible elements have a tubing on an intermediate portion to increase the diameter of the flexible elements.

31. The system of claim 27, wherein the first bridge member is attached to the first flexible element by a tubular element having a first opening to receive the flexible element and a second opening to receive the first bridge member.

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