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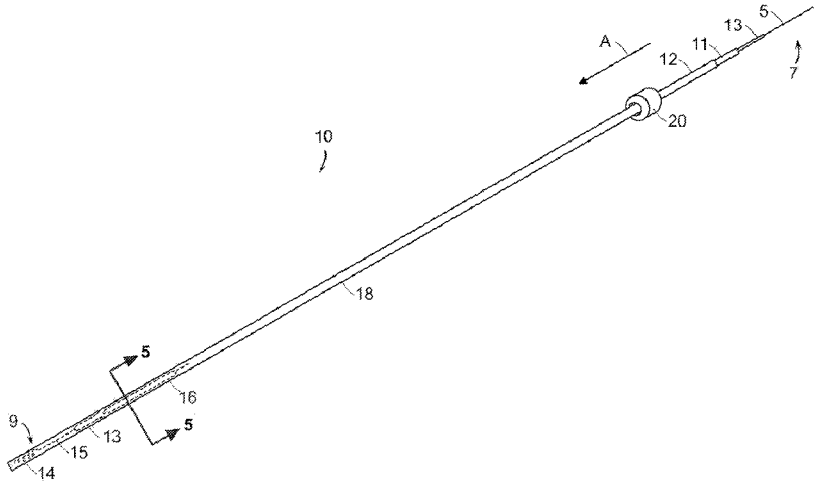


FIG. 1

(57) Abstract: A surgical device comprises a guide tube having a proximal end, a distal end, and an inside diameter. A needle has a proximal end and a distal end. The needle comprises a longitudinal portion having a diameter suitable to be slidably received within the inside diameter of the guide tube. The needle comprises a helical element disposed at the distal end of the needle.

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SURGICAL DEVICE

BACKGROUND

[0001] Endoscopy refers to looking inside a human body for medical reasons using an instrument called an endoscope. Endoscopy is a minimally invasive diagnostic medical procedure used to evaluate interior surfaces of an organ or other tissue by inserting a small tube into the body, often, but not necessarily, through a natural body opening of a patient or through a relatively small incision. Using the endoscope, a surgeon may view surface conditions of the organs or other tissue, including abnormal or diseased tissue such as lesions and other various surface conditions. The endoscope may have a rigid or a flexible tube and, in addition to providing an image for visual inspection and photography, the endoscope may be adapted and configured for taking biopsies, retrieving foreign objects, and introducing medical instruments to a tissue treatment region, referred to generally herein as a surgical site.

[0002] Laparoscopic surgery is a minimally invasive surgical technique in which operations are performed through small incisions (usually 0.5cm to 1.5cm) or keyholes, as compared to the larger incisions required in traditional open-type surgical procedures. Laparoscopic surgery includes operations within the abdominal or pelvic cavities, whereas keyhole surgery performed on the thoracic or chest cavity is called thoracoscopic surgery. Laparoscopic and thoracoscopic surgery belong to the broader field of endoscopy.

[0003] A key element in laparoscopic surgery is the use of a laparoscope: a telescopic rod lens system that is usually connected to a video camera (single-chip or three-chip). Also attached is a fiber-optic cable system connected to a "cold" light source (halogen or xenon) to illuminate the operative field and configured to be inserted through a 5mm or 10mm cannula to view the surgical site. The abdomen is usually insufflated with carbon dioxide gas to create a working and viewing space for a surgeon. Stated another way, the abdomen is essentially blown up like a

balloon (i.e., insufflated) thereby elevating the abdominal wall above the internal organs like a dome. Carbon dioxide gas can be used for the insufflation because it is common to the patient's body and can be removed by the respiratory system if it is absorbed through tissue.

[0004] Minimally invasive therapeutic procedures used to treat diseased tissue by introducing medical instruments to the surgical site through a natural opening of a patient are known as Natural Orifice Translumenal Endoscopic Surgery (NOTES™). In general, there are a variety of systems for inserting an endoscope through a natural opening in the human body, dissecting a lumen, and then, treating the inside of the abdominal cavity. For example, in U.S. Pat. No. 5,297,536 to Wilk, issued on March 29, 1994, which is hereby incorporated by reference in its entirety, a sample treatment system is disclosed. This system is comprised of a dissecting device for perforating a lumen wall, an endoscope insert member for inserting an endoscope, a tube, an endoscope, and a pneumoperitoneum device for deflating the abdominal cavity, and a closing device.

[0005] When transluminal endoscopic surgery is carried out using the above-referenced system, an overtube can first be inserted through a natural opening in the patient's body (e.g., mouth, anus, or vagina). A distal end of the overtube may be attached to an organ wall or other tissue by vacuum pressure, thus being temporarily fixed thereon such that the organ wall or other tissue can be punctured. An incising instrument, such as a needle, for example, may be passed through the overtube from a proximal end of the overtube to a distal end of the overtube, and/or through a working channel of the endoscope, and used to puncture and create an opening through the organ wall or other tissue. An inflatable member, such as a medical balloon, for example, may be positioned in the opening and then inflated to enlarge the opening. Once the opening has been enlarged by the inflatable member, the inflatable member can be at least partially deflated and removed from the body and the overtube may then be inserted into and partially through the opening to serve as a working channel for the endoscope and/or other surgical instruments or devices to the surgical site. After surgery of the inside of the organ or other tissue is complete, the overtube may be removed from the enlarged opening so that the opening can be closed by an

O-ring or other suitable closure device and then the endoscope and the overtube may be withdrawn from the body.

[0006] The peritoneum may be accessed through the stomach wall or wall of other hollow body organs or internal body lumens, to achieve surgical therapy or diagnostic procedures therein. To minimize the potential for inadvertent damage to underlying organs or tissues, the piercing process required in the translumenal access of the peritoneum needs to be safe and controllable at the distal tip of an endoscope. Accordingly, in the field of endoscopy, there remains a need for improved methods and devices for translumenal access of internal body cavities using a needle and an inflatable member, to pierce the internal body lumens during an endoscopic surgical procedure.

FIGURES

[0007] The novel features of the various embodiments are set forth with particularity in the appended claims. The various embodiments, however, both as to organization and methods of operation may best be understood by reference to the following description, taken in conjunction with the accompanying figures as follows.

[0008] Fig. 1 illustrates a perspective view of one embodiment of a surgical device comprising a needle, an elongated guide wire, a conduit, an inflation conduit, an inflatable member, and a protective sleeve, which is shown in an extended or a first position.

[0009] Fig. 2 illustrates a perspective view of one embodiment of the surgical device of Fig. 1 with the protective sleeve shown partially retracted to expose the needle and a tapered segment.

[0010] Fig. 3 illustrates a perspective view of one embodiment of the surgical device of Fig. 1 with the protective sleeve shown retracted to a second position to expose the needle, the tapered segment, and the inflatable member.

[0011] Fig. 4 illustrates an exploded view of one embodiment of an inflatable member of the surgical device of Fig. 1.

[0012] Fig. 5 illustrates a cross-sectional view of one embodiment of the surgical device taken along line 5—5 of Fig. 1.

[0013] Fig. 6 is a perspective view of a distal portion of one embodiment of a needle of the surgical device of Fig. 1 showing a partial cross-sectional view of a guide tube to receive the needle.

[0014] Fig. 7 illustrates a perspective view of one embodiment of a protective sleeve for the surgical device of Fig. 1.

[0015] Fig. 8 illustrates a perspective view of one embodiment of the surgical device of Fig. 1 showing a protective sleeve in a retracted or second position exposing the needle, the tapered segment, and the inflatable member in an inflated state.

[0016] Fig. 9 illustrates a perspective close-up view of one embodiment of the surgical device of Fig. 1 showing a close-up view of a distal end of the surgical device showing the protective sleeve in a retracted or second position exposing the needle, the tapered segment, and the inflatable member with the inflatable member in an inflated state.

[0017] Fig. 10 illustrates a perspective close-up view of one embodiment of the surgical device of Fig. 1 in fluid communication with a fluid source showing the protective sleeve in a retracted or second position exposing the needle, the tapered segment, and the inflatable member with the inflatable member in an inflated state.

[0018] Fig. 11 is a cross-sectional view of one embodiment of the surgical device of Fig. 1.

[0019] Fig. 12 illustrates a cross-sectional view of a distal portion of one embodiment of the surgical device of Fig. 1 extending through a working channel of an endoscope and creating an opening in tissue to allow access to a surgical site.

[0020] Fig. 13 illustrates a cross-sectional view of the distal portion of one embodiment of the surgical device of Fig. 1 with the protective sleeve in a first position and being advanced through the opening in the tissue.

[0021] Fig. 14 illustrates a cross-sectional view of the distal portion of one embodiment of the surgical device of Fig. 1 after the protective sleeve has been retracted into the second position to expose the inflatable member to the opening in the tissue.

[0022] Fig. 15 illustrates a cross-sectional view of the distal portion of the surgical device of Fig. 1 after the protective sleeve has been retracted into the second position and with the inflatable member sufficiently inflated to expand the opening in accordance with one non-limiting embodiment

[0023] Fig. 16 illustrates a cross-sectional view of the distal portion of one embodiment of the surgical device of Fig. 1 after the protective sleeve has been retracted into the second position and with the inflatable member inflated to expand the opening in the tissue.

[0024] Fig. 17 illustrates one embodiment of the surgical device of Fig. 1 being used in conjunction with an overtube, an endoscope, and various other components and inserted into the upper gastrointestinal tract of a patient.

[0025] Fig. 18 illustrates a perspective view of the distal portion of one embodiment of the surgical device of Fig. 1 extending from a working channel of a distal end of the endoscope of Fig. 17.

DESCRIPTION

[0026] It will be appreciated that the terms "proximal" and "distal" are used herein with reference to a clinician, a surgeon, or a user ("surgeon") manipulating one end of an instrument or device that protrudes out of a patient (i.e., a natural orifice). The term "proximal" refers to a portion of the instrument or device closest to the surgeon and the term "distal" refers to a portion of the instrument located furthest from the surgeon. It will be further appreciated that for conciseness and clarity, spatial terms such as "vertical," "horizontal," "up," and "down" may be used herein with respect to the figures. Surgical instruments or devices, however, may be used in many orientations and positions and, as such, these terms are not intended to be limiting and absolute.

[0027] During the course of various surgical procedures, such as in intralumenal and translumenal access procedures, for example, there often exists a need to pierce the wall of hollow body organs or internal body lumens ("lumen" or "access lumen" hereinafter) with a needle to access a cavity, organ, or other lumen. From inside the lumen, a target exit is selected and after suctioning the target exit site of the lumen onto the distal end of an endoscope, using a distal tip of an over-the-scope overtube/endotrocar conduit, or an end cap, an elongated guide wire with a needle formed integrally at the distal end may be introduced through a conduit, such as a catheter, to the target exit site. The wall of the lumen may be pierced with a needle, a needle knife, or other cutting, piercing, incising, or puncturing member ("needle") in accordance with the described embodiments. In various embodiments, the needle may be solid or hollow such that the most distal end of the needle can puncture tissue. In one embodiment, the needle comprises an elongated member referred herein as a guide wire, a spiral, helical, or corkscrew shaped portion with a sharp metallic point or tip for piercing at a distal end ("helical portion" hereinafter), and in one embodiment, a tapered segment at the proximal end of the helical portion. Due to the nature of the helical portion, in one embodiment, the wall of the lumen may be pierced using a twisting motion (e.g., clockwise or counterclockwise) of the helical portion, of the needle, for example, which may be imparted by twisting the distal end of the guide wire, which extends outside the patient's body. The needle, including the guide wire, tapered segment, and helical portion, may be constructed of any suitable metals or alloys such as stainless steel, alloys of stainless steel, shape memory alloys such as nickel titanium (NiTi) commercially known as NITINOL, or any other materials suitable for piercing the walls of hollow organs or lumens.

[0028] As previously discussed, in one embodiment, a portion or segment of the elongated guide wire portion of the needle proximal to the helical portion may be tapered (necked down) to a smaller diameter to reduce the column strength of the guide wire, limiting the likelihood of damage to unintended anatomical structures once the guide wire is advanced through a catheter (e.g., a flexible or rigid hollow tube or conduit). This may allow a length of the guide wire to be

fed into the peritoneum, or other hollow body cavity or lumen, outside the access lumen and left in place as a future path for repeated ingress/egress with an endoscope. In other embodiments, the helical portion may be formed separately from the guide wire portion and attached thereto using any known attachment technique. Once the helical portion and the guide wire are attached or formed integrally on a distal end thereof, the entire assembly may be referred to as a "needle" and/or guide wire, for example.

[0029] Once the wall of the access lumen is pierced with the helical needle, an inflatable member, such as a medical balloon, for example, may be used to enlarge the opening or incision in the wall or other tissue ("opening") formed with the helical portion of the needle. The opening is enlarged to create surgical space for advancing overtubes and surgical instruments or devices and/or for allowing a surgeon to access the translumenal surgical site. These inflatable members are commercially available from Boston Scientific Corporation, C. R. Bard, Inc., and Cook Medical Inc., for example. The inflatable member is then pushed behind the helical needle and dilated to stretch the exit site in preparation for an over-the-scope overtube/endotrocar entry, providing an atraumatic ingress/egress path for the endoscope.

[0030] In various embodiments, an overtube comprising a hollow conduit, different from a guide tube or guide wire conduit, can be introduced into a natural opening in a patient's body. In one embodiment, a guide tube or guide wire conduit can be inserted into the overtube which has been inserted into the natural opening in the patient's body. In one embodiment, an endoscope can be inserted into the overtube through the proximal end of the overtube and extend through or near the distal end of the overtube. In such an embodiment, the conduit can be positioned within a working channel of the endoscope and can extend from a distal end thereof to allow the conduit and the needle to gain access to the tissue proximal to a surgical site or surgical access site.

[0031] In various embodiments, an inflatable member, such as a medical balloon, for example, can be attached to, positioned on, surround, or can be integrally formed on or with an outer surface of a distal portion of the guide wire conduit, for example, and can be introduced into the opening in the tissue created by advancing the needle distally through the tissue. The inflatable

member can then be transitioned from an uninflated or a collapsed state to an inflated or an expanded state thereby radially or otherwise displacing side walls of the opening to create a larger opening or surgical space in the tissue such that the enlarged opening can receive a portion of the endoscope, a portion of the overtube, and/or portions of other surgical instruments or devices, for example, therethrough.

[0032] In various embodiments, an inflation conduit can surround a portion of a conduit and can extend from a fluid source to a proximal portion of the inflatable member such that the inflatable member can be expanded with fluid from the fluid source. In one embodiment, the inflation conduit can comprise an inner diameter or perimeter larger than the outer diameter or perimeter of the conduit to allow the fluid from the fluid source to flow or be pumped into and out of the inflatable member. The fluid from the fluid source can flow or be pumped through a void created between the outer diameter or perimeter of the conduit and the inner diameter or perimeter of the inflation conduit, for example. As such, a distal portion of the inflation conduit can be attached to and in fluid communication with the proximal portion of the inflatable member with a distal portion of the inflatable member sealed to a portion of the conduit or member positioned on the conduit such that the inflatable member can be inflated. In other various embodiments, the inflation conduit can be eliminated and end portions of the inflatable member can be sealed to the conduit. The conduit can be in fluid communication with the fluid source at its proximal portion and be in fluid communication with the inflatable member at its distal portion through an opening, aperture, slot, or perforation (not illustrated) in the conduit. As a result, the fluid from the fluid source can be flowed or pumped into the conduit and through the opening, aperture, slot, or perforation, which can be in fluid communication with an internal area of the inflatable member to inflate the inflatable member.

[0033] Because the inflatable member is made of a very thin material, such as polyethylene terephthalate glycol, polyurethane, plastic, nylon, or combinations thereof, for example, it can be somewhat susceptible to tearing or puncturing while it is being fed through the overtube, the working channel of the endoscope, and while it is being advanced through the opening in the

tissue. Further, the inflatable member can sometimes at least partially inflate prior to being positioned within the opening in the tissue owing to subatmospheric pressure conditions within the overtube. These subatmospheric pressure conditions can cause the inflatable member to prematurely inflate if the inflatable member is in fluid communication with atmospheric pressure or with a space having a higher pressure than the subatmospheric pressure conditions within the overtube. Even if a valve is supplied between the inflatable member and an atmospheric pressure space external to the patient, any fluid within the conduit and/or the inflation conduit may cause the inflatable member to at least partially inflate owing to the fluid remaining within the conduit and/or the inflation conduit intermediate the valve and the inflatable member. Such premature inflation can cause delays during a surgical procedure as a partially inflated inflatable member may not fit properly into the opening in the tissue. To at least partially alleviate or eliminate the above-referenced difficulties, a surgical device is provided with a protective sleeve which can, in some circumstances, at least partially cover the inflatable member at appropriate times during a surgical procedure to prevent, inhibit, or at least minimize opportunities for tearing, puncturing, or premature inflation of the inflatable member. The protective sleeve also may be provided to protect the endoscope channel from sharp points, and to keep the inflatable member properly pleated during initial insertion as described in accordance with the disclosed embodiments.

[0034] With reference now to Figs. 1-5, illustrates a one embodiment of a surgical device 10 comprising a needle 5, an elongated guide tube 13, a conduit 11, an inflation conduit 12, and an inflatable member 16 covered by a protective sleeve 18 in an extended or a first position. A distal end 9 of the surgical device 10 comprises, the needle 5 comprises a helical element 14, a tapered element 15 located proximally relative to the helical element 14, and an elongated portion that is accessible at a proximal end 7 of the surgical device 10. In the embodiment, illustrated in Figs. 3 and 5, the inflatable member 16 comprises a plurality of longitudinal pleats 35. The inflatable member 16 is disposed on an outside surface of the conduit 11, is in fluid communication with the inflation conduit 12, and is slidably received within the protective

sleeve 18, to keep the inflatable member 16 properly pleated during initial insertion. In one embodiment, the surgical device 10 can be inserted into and extend through a distal end of a working channel of an endoscope positioned within an overtube, as described in further detail below. In various embodiments, the surgical device 10, via its various components such as the helical element 14, can be used to puncture tissue to create an opening therein and then expand the opening using the inflatable member 16, such that an overtube, the endoscope, and/or another surgical instrument or device can be advanced distally through the opening to gain access to a surgical site.

[0035] The protective sleeve 18 optionally comprises a handle or handle 20 on its proximal portion to slidably located the protective sleeve 18 in one or more desired positions. The protective sleeve 18 is configured to be positioned at least partially over (i.e., cover) the helical element 14 and the inflatable member 16 to protect and shield the inflatable member 16 from tearing, puncturing, and/or premature inflation, for example, and to prevent or minimize opportunities for the helical element 14 to puncture undesired tissue or damage any of the instruments during deployment. As previously discussed, the protective sleeve 18 keeps the inflatable member 16 properly pleated during initial insertion. Using the handle 20, a clinician can be push the protective sleeve 18 distally in the direction indicated by arrow "A" to deploy the protective sleeve 18 as shown in Fig. 1. The protective sleeve 18 can be pulled proximally in the direction indicated by arrow "B" to expose the distal end 9 of the needle 5, the helical element 14 and the tapered element 14, as shown in FIG. 2, where the protective sleeve 18 is in a partially retracted first position exposing the helical element 14 and the tapered element 15. The protective sleeve 18 can be pulled proximally further in the direction indicated by arrow "B" to also expose inflatable member 16, as shown in Figs. 3 and 4, for example, where the protective sleeve 18 is shown in a further retracted second position exposing the helical element 14, the tapered element 15, and the inflatable member 16.

[0036] In various embodiments, the needle 5 may be formed in a variety of configurations. In one embodiment, the helical element 14, the tapered element 15, and the elongated portion of the

needle may be formed integrally or as separate attachable elements. For example, the helical element 14 may be attachable to the tapered element 15, which may be attachable to the elongated portion of the needle 5. These elements may be attached using any suitable techniques, such as, for example, bolting, screwing, welding, crimping, gluing, epoxying, bonding, brazing, soldering, press fitting, snap fitting, riveting, heat shrinking, ultrasonic welding or any other suitable method. In other embodiments, the helical element 14 and/or the tapered element 15 may be attached to the distal end of the guide tube 13, thus eliminating the need for the elongated portion of the needle 5. In this respect, the terms guide tube 13 and needle 5 may be used interchangeably and the guide tube 13 may take the form of a solid or stranded wire and hence may be referred to as a guide wire, without limitation. In other embodiments, the helical element 14 and/or the tapered element 15 may be formed integrally on a distal end of the guide tube 13. Therefore, the term "needle" may encompass the guide tube 13 with an attached helical element 14 and/or tapered element 15 or the guide tube 13 with an integrally formed helical element 14 and/or tapered element 15, without limitation.

[0037] The helical element 14 portion of the needle 5 may be employed to penetrate, pierce, cut, incise, grasp, or puncture tissue in accordance with the described embodiments. In one embodiment, the helical element 14 comprises a spiral, helical, or corkscrew ("helical" hereinafter) shape with a sharp metallic point or tip at the distal end that is suitable for penetrating tissue. The helical element 14 can be formed with a wire or tube having an outside diameter suitable for penetrating, piercing, cutting, incising, grasping, or puncturing tissue. Accordingly, the wall of an internal body lumen may be pierced using a twisting motion of the helical element 14, for example. In the illustrated embodiment, an internal body lumen may be pierced by threading or twisting the helical element 14 in a clockwise direction as illustrated by arrow "CW," in Figs. 2-4, for example. In other embodiments, however, to pierce the lumen the helical element 14 may be threaded or twisted in a counterclockwise direction. Once an initial opening is formed in the lumen using the helical element 14, the tapered element 15 portion and the guide tube 13 may be fed into the peritoneum, or other hollow body cavity or lumen, outside

the access lumen, and left in place as a future path for repeated ingress/egress with an endoscope. The helical element 14 may be constructed of any suitable metals or alloys such as stainless steel, alloys of stainless steel, shape memory alloys such as nickel titanium (NiTi) commercially known as NITINOL, or any other materials suitable for piercing the walls of hollow organs or lumens. When formed of a shape memory alloy, the helical element 14 may be pulled in direction "B" through the opening defined by the guide tube 13.

[0038] For additional clarity, Fig. 5 illustrates a cross-sectional view of the embodiment of the surgical device 10 taken along line 5—5 of Fig. 1 to illustrate the relative positions of the protective sleeve 18, the inflation conduit 12, the conduit 11, the guide tube 13, and the needle 5 and one embodiment of how these elements can be situated. The protective sleeve 18 can have an inner diameter or perimeter which is larger than a respective outer diameter or perimeter of the inflatable inflation conduit 12, the conduit 11, and the inflatable member 16 to enable the protective sleeve 18 to at least partially or fully surround a portion of the inflatable inflation conduit 12 and/or the inflatable member 16.

[0039] An enlarged view of the tapered element 15 is shown in Fig. 6. In one embodiment, a distal portion of the needle 5 proximal the helical element 14 may be tapered (necked down) to a smaller diameter to define the tapered element 15. The tapered element 15 comprises a middle segment 23 having a diameter d_1 that is less than the outside diameter d_1 of the elongated portion of the needle 5. A first tapered segment 25 reduces the outside diameter OD_5 of the needle 5 to the diameter d_2 of the middle segment 23 and a second tapered segment 27 reduces the diameter d_3 of the helical element 14 to the diameter d_2 of the middle segment 23. In one embodiment the diameter d_1 of the needle 5 is substantially the same as the diameter d_3 of the helical element 14, however, in other embodiments the diameters d_1 and d_3 may be different. The middle segment 23 portion of the tapered element 15 makes middle segment 23 slightly bendable or collapsible under an applied longitudinal force, which may result when pushing on the needle 5 in direction "A," for example. Thus, the tapered element 15 reduces the column strength of the needle 5 to minimize or limit the likelihood of unintentionally damaging anatomical structures when the

needle 5 is advanced translumenally through layers of tissue. The bendability or collapsibility of the tapered segment 23 prevents a build up of pressure against the tissue to be pierced and allows a more controlled advancement of the distal portion of the needle 5 though the tissue.

[0040] Fig. 7 illustrates a perspective view of the embodiment of the protective sleeve 18 of the surgical device of Fig. 1. As previously discussed, the protective sleeve 18 can be movable by way of the handle 20, for example, between the first position (see e.g., Fig. 1), to cover, or at least partially cover, the helical element 14, the tapered element 15, and the inflatable member 16, and a second position (see e.g., Fig. 3), where it can expose the helical element 14, the tapered element 15, and the inflatable member 16 for inflation. In one embodiment, using the handle 20, a clinician (e.g., surgeon) can slide the protective sleeve 18 between the first position and the second position (or into any other suitable intermediate position) by applying a proximal-to-distal force, in direction A (i.e., pushing, as shown in Figs. 1 and 3), or by applying a distal-to-proximal force, in direction B (i.e., pulling, as shown in Figs. 2 and 3). The optional handle 20 may be integrally formed with or on or attached to a proximal portion of the protective sleeve 18 to facilitate slidable movement of the protective sleeve 18 relative to the inflation conduit 12. It will be appreciated by those of ordinary skill in the art that any suitable handle or gripping device can be used with the surgical device 10. Further, the handle 20 can be eliminated and the surgeon can instead grasp the proximal portion of the protective sleeve 18 to move the protective sleeve 18 between the first and the second positions and any other suitable positions. In one embodiment, the protective sleeve 18 may be frictionally coupled or engaged to the inflation conduit 12 in any suitable manner. It will be appreciated by those of ordinary skill in the art that any other suitable mechanical members can be used to advanced and/or retract the protective sleeve 18 relative to the inflation conduit 12. In other various embodiments, the advancement and retraction of the protective sleeve 18 can be automated through the use of at least one actuator, for example.

[0041] In one embodiment, the protective sleeve 18 and the handle 20 may be attached using any suitable techniques, such as, for example, bolting, screwing, welding, crimping, gluing,

epoxying, bonding, brazing, soldering, press fitting, snap fitting, riveting, heat shrinking, ultrasonic welding or any other suitable method. In one embodiment, the protective sleeve 18 and the handle 20 may be threadably connected, for example. The handle 20 can have female threads formed on an inner surface thereof and the protective sleeve 18 can have male threads formed on an outer surface thereof such that the threads on the outer surface of the protective sleeve 18 engage the threads on the inner surface of the handle 20. In another embodiment, the protective sleeve 18 and the inflation conduit 12 may be threadably connected, for example. The inflation conduit 12 can have male threads formed on an outer surface thereof and the protective sleeve 18 can have female threads formed on an inner surface thereof such that the threads on the inner surface of the protective sleeve 18 engage the threads on the outer surface of the inflation conduit 12.

[0042] With reference now to Figs. 1-7, generally, the inflation conduit 12 may define a longitudinal opening therethrough long enough to extend from a proximal end of the inflatable member 16 to a proximal end 7 of the surgical device 10. The inflation conduit 12 may be formed of or may comprise a flexible material to allow at least its distal portion to travel through the tortuous path within the patient's body to and at least partially through the opening in the tissue. In one embodiment, the needle 5 can be sized and configured to be slidably disposed within the guide tube 13. The guide tube 13 and the needle 5 may sized and configured to be slidably disposed within the conduit 11, which extends from a distal portion of the inflatable member 16 to a proximal end 7 of the surgical device 10.

[0043] In one embodiment, the various components of the surgical device 10 may have the following dimensions selected such that the various internal components are slidably movable within certain defined openings of the external components. Accordingly, in one embodiment, the protective sleeve 18 has an inside diameter ID_1 of about 2.4mm and an outside diameter OD_1 of about 2.6mm. The outside diameter OD_1 of the protective sleeve 18 is selected such that it is slidably movable within a typical working channel of an endoscope, which typically may vary from about 2.8mm to about 3.7mm. The inflation conduit 12 has an inside diameter ID_2 of about

1.8mm and an outside diameter OD_2 of about 2.3mm. The outside diameter OD_2 of the inflation conduit 12 is less than the inside diameter ID_1 of the protective sleeve 18 such that the protective sleeve 18 can slidably move over the inflation conduit 12. The conduit 11 has an outside diameter OD_3 of about 1.5mm and an inside diameter ID_3 of about 1.0mm. The outside diameter OD_3 of the conduit 11 is less than an inside diameter ID_2 of the inflation conduit 12 such that the conduit 11 can be slidably received within the longitudinal opening defined by the inflation conduit 12. The guide tube 13 has an outside diameter OD_4 of about 0.9mm and an inside diameter ID_4 of about 0.7mm, which is less than the inside diameter ID_3 of the conduit 11 such that the guide tube 13 can slidably move within the conduit 11. The needle 5 has an outside diameter OD_5 ranging from about 0.4mm to about 0.5mm, which is less than the inside diameter ID_4 of the guide tube 13 such that the needle 5 is slidably movable within the longitudinal opening defined by the guide tube 13. In one embodiment, the inflation conduit 12 and the conduit 11 are fixed and the needle 5 is configured to be slidably movable within the longitudinal opening defined by the guide tube 13. In another embodiment, the guide tube 13 may be slidably movable within the longitudinal opening defined by the conduit 11 and/or the inflation conduit 12. These dimensions are provided merely as examples and are not limited in this context.

[0044] In various embodiments, apertures, cut-outs, slots, and/or joints (not shown) may be formed on the protective sleeve 18 to make the device lighter and/or for various surgical reasons, such as, for example, to add flexibility to the protective sleeve 18 and/or to facilitate the steerability of the protective sleeve 18. Also, the protective sleeve 18 can be formed of or comprise a transparent or semi-transparent material. In one embodiment, the protective sleeve 18 may be formed of or may comprise a lubricious, low coefficient of friction material, such as polyethylene, polyetheretherketone (PEEK®), polytetrafluoroethylene (TEFLON®), plastic, nylon, ethylene, and/or a combination thereof, for example, to enable easy sliding movement of the protective sleeve 18 over the inflation conduit 12 and/or the inflatable member 16. In such an embodiment, the lubricious, low coefficient material can also help prevent, inhibit, or at least minimize any opportunities for the protective sleeve 18 from tearing or puncturing the inflatable

member 16 when sliding over the inflatable member 16 and/or when sliding between the first position and the second position. In various embodiments, the protective sleeve 18 can be flexible as required for traveling along the tortuous path inside the patient's body to the surgical site. In other various embodiments, portions of the protective sleeve 18 can be flexible while other portions can be rigid or semi-rigid, for example. As previously discussed, the protective sleeve 18 may comprise additional features to enhance its flexibility and/or steerability.

[0045] With reference now to Figs. 8-11, the surgical device 10 is shown with the protective sleeve 18 in a retracted or second position and the inflatable member 16 exposed and inflated through the use of a fluid source 22 (e.g., liquid or gas). In the embodiment illustrated in Figs. 8-11, the inflatable member 16 is in fluid communication with the fluid source 22, which is configured to supply a fluid for filling or inflating the inflatable member 16 at an appropriate time during the surgical procedure. The fluid source 22 can be in fluid communication with the inflatable member 16 through the inflation conduit 12. In one embodiment, fluid source 22 can be in fluid communication with the inflatable member 16 through a tube 21 connecting the fluid source 22 and the inflatable member 16 through the inflation conduit 12. The fluid source 22 can be in fluid communication with the inflatable member 16 through the inflation conduit 12 and an optional tube 21 connecting the fluid source 22 and the inflation conduit 12. A proximal handle 29 (Fig. 11) may be provided to apply a torque to the guide tube 13.

[0046] As previously discussed, the inflation conduit 12 can extend at least from the proximal portion of the inflatable member 16 to the tube 21 (or the inflatable member 12 can extend directly to the fluid source 22) and can have an inner diameter or perimeter larger than the outer diameter or perimeter of the conduit 11. As such, a void can be formed intermediate the inner surface of the inflation conduit 12 and the outer surface of the conduit 11. The inflatable member 16 can also be sealed with the conduit 11 or other member on the conduit 11 at its distal portion and can be in fluid communication with the inflation conduit 12 on its proximal portion such that the inflatable member 16 can be inflated by the fluid source 22. The fluid from the fluid source 22 can then be flowed or pumped through the tube 21, through the void, and then

into the inflatable member 16. In one embodiment, the inflatable member 16 may be inflated by controlling a control unit (not illustrated) external to the patient that can be operated by the surgeon. In other embodiments, the inflatable member 16 may be inflated by the surgeon activating a manual pump or another suitable inflation device, for example.

[0047] In various embodiments, the inflatable member 16 can be filled with a fluid, in liquid or gas form, such as saline or carbon dioxide, for example, as such fluids are common to the patient's body and can be easily absorbed and/or exhausted by the body. In various embodiments, as the inflatable member 16 is filled with the fluid, the inflatable member 16 can expand radially outward from the inflation conduit 12 to enlarge the size of the opening in the tissue. It will be appreciated that the inflatable member 16 can expand in any suitable fashion depending on the configuration of the inflatable member 16 and the particular surgical need.

[0048] As shown in more detail in Fig. 9, the conduit 11 may be disposed within the inflation conduit 12. The conduit 11 provides a channel for the guide tube 13. The conduit 11 is attached to the distal end of the inflatable member 16 and extends therefrom to the proximal end 7 of the surgical device 10. The inflation conduit 12 is attached to the proximal end of the inflatable member 16 and extends therefrom to the proximal end 7 of the surgical device 10. The proximal end of the inflatable member 16 is in fluid communication with the inflation conduit 12 and the inflation source 22. The distal end of the inflatable member 16 is sealed between the outside diameter surface of the conduit 11 and the inside diameter surface of a tapered tip 17.

[0049] In various embodiments, the proximal end of the inflatable member 16 can be integrally formed with, integrally formed on, positioned on, or attached to an outer surface of the distal portion of the inflation conduit 12. In various embodiments, the proximal end of the inflatable member 16 partially surrounds the distal portion of the inflation conduit 12. As the inflatable member 16 can surround the distal portion of the inflation conduit 12, it may have a larger, or slightly larger, outer perimeter or diameter than the outer perimeter or diameter of the inflation conduit 12 in its uninflated state. Likewise, as the inflation conduit 12 can surround a portion of the conduit 11, it can have a larger, or slightly larger, outer perimeter or diameter than the outer

perimeter or diameter of the conduit 11. It will be appreciated that more than one inflatable member can be used with the surgical device 10 as is recognized by those of ordinary skill in the art. Further, the inflatable member 16 may comprise any suitable inflatable member known to those of ordinary skill in the art.

[0050] Figs. 12-16 illustrate the surgical device 10 at various stages of deployment through a cross-section of tissue 32. In use, the surgical device 10 can be configured to be slidably received within an overtube 24 and an endoscope 26 comprising at least one working channel 28. The endoscope 26 can be any suitable endoscope known to those of ordinary skill in the art. In various embodiments, the overtube 24 can first be inserted into a natural orifice of a patient's body. In at least one embodiment, the endoscope 26 can then be positioned within and extend at least partially through the overtube 24 or extend to or from a distal end 30 of the overtube 24. In at least one embodiment, the distal end 30 of the overtube 24 can engage the tissue 32 and can apply suction to the tissue 32 owing to the subatmospheric pressure conditions created within the overtube 24. The overtube 24 can be in fluid communication with any suitable suction source such as a vacuum pump, for example, (not illustrated) or other suitable vacuum producing device. Appropriate end seals (not illustrated) may be provided to maintain the subatmospheric pressure conditions within the overtube 24. These subatmospheric pressure conditions within the overtube 24 can cause a portion of the tissue 32 proximal to a surgical access site to be pulled or drawn into the overtube 24 to locate the tissue 32 for puncturing with the helical element 14 of the guide tube 13 of the surgical device 10. The suction applied to the tissue 32 at the distal end 30 of the overtube 24 can at least partially offset any proximal-to-distal (i.e., pushing) force, in direction "A" (as shown in Figs. 1 and 3), being applied to the tissue 32. The helical element 14 of the needle 5 is advanced until it contacts the tissue 32. As previously discussed, the tissue 32 may be pierced by threading the helical element 14 in a clockwise rotation "CW."

[0051] As previously referenced, if the proximal end of the inflation conduit 12 and/or the conduit 11 is open to atmospheric pressure (i.e., not sealed), or even if the inflation conduit 12 and/or the conduit 11 has a valve at its proximal end, the inflatable member 16 could still, at least

partially, prematurely inflate owing to the subatmospheric pressure conditions within the overtube 24. As previously discussed, premature inflation of the inflatable member 16 can cause the inflatable member 16 to be enlarged such that it may not fit within the opening in the tissue 32. To address this issue, the protective sleeve 18 may be located in the first position to prevent, inhibit, or at least minimize such premature inflation from occurring by containing the inflatable member 16 within the inflation conduit 12 and thus inhibiting, for example, the inflatable member from expanding outwardly relative to the inflation conduit 12 and/or the conduit 11 prior to an appropriate time during a surgical procedure. Stated another way, the protective sleeve 18 can surround the inflatable member 16 closely enough to at least inhibit the inflatable member 16 from prematurely inflating. Furthermore, to any extent that the inflatable member 16 may partially inflate due to the tolerances of manufacturing, the inflatable member 16 can be contained within the hollow elongate opening defined by the protective sleeve 18 and, thus, can be inhibited from inflation by the protective sleeve 18, for example.

[0052] With reference to Figs. 12 and 13, while the suction is applied to the tissue 32, the helical element 14 is advanced into the tissue 32 by threading the helical element 14 in a clockwise rotation "CW" to puncture or pierce the tissue 32 and create an initial "helical needle sized" opening 34 therein. Once the helical element 14 has punctured or pierced through the tissue 32 and has created the opening 34, the distal end 9 of the surgical instrument is advanced through the opening 34. The tapered tip 17 at the distal end of the inflatable member 16 is then advanced through the opening 34, stretching it to advance the inflatable member 16 to a position within the opening 34. Owing to the position of the inflatable member 16 on or attachment to, for example, the distal portion of the inflation conduit 12 and the relative stretchability of the tissue 32, the inflatable member 16 can be advanced distally toward, into, and at least partially through the opening 34 in the tissue 32. This advancement can be accomplished by the surgeon applying a proximal-to-distal (i.e., pushing) force to the proximal portion of the inflation conduit 12 in direction "A." While advancing the inflation conduit 12, the protective sleeve 18 can also be advanced by the surgeon again applying a proximal-to-distal (i.e., pushing) force to the

proximal portion of the protective sleeve 18 and/or to the handle 20, in direction "A," to maintain the inflatable member 16 in a shielded or protected state (i.e., the first position) until it is ready to be inflated.

[0053] Fig. 13 illustrates one stage of deployment of the surgical device 10 through the cross-section of tissue 32. As illustrated, the protective sleeve 18, along with the inflation conduit 12 and the inflatable member 16, can be advanced at least partially through the opening 34 in the tissue 32 with the protective sleeve 18 in the first position to cover the inflatable member 16. In this manner, the protective sleeve 18 shields the inflatable member 16 and protects it from puncturing or tearing during the advancement stage of deployment. The protective sleeve 18 generally should be advanced through the opening 34 in the tissue 32 while in the first position, although the inflation conduit 12 and the inflatable member 16 could be advanced through the opening 34 when the protective sleeve 18 is in the second position or in any other suitable intermediate position.

[0054] Referring to Fig. 14, once the protective sleeve 18, the inflation conduit 12, and the inflatable member 16 are advanced through the opening 34 in the tissue 32, the protective sleeve 18 can be retracted into the second position. This retraction can be accomplished by the surgeon applying a distal-to-proximal (i.e., pulling or retracting) force, in the direction "B," to the proximal portion of the protective sleeve 18 and/or to the optional handle 20. As illustrated in Fig. 14, when the protective sleeve 18 is retracted into the second position, the inflatable member 16 can be exposed such that it can be inflated via the inflation conduit 12 and the fluid source 22 to expand the opening 34 in the tissue 32.

[0055] As shown in Fig. 15, before the inflatable member 16 is inflated, the distal end 30 of the overtube 24 can be partially withdrawn from contact with the tissue 32 to alleviate or eliminate the suction being applied to the tissue 32. Alternatively, the vacuum source could be powered off, for example, while maintaining the distal end 30 of the overtube 24 in contact with the tissue 32. The fluid source 22 (see Fig. 7) can then flow a fluid into the inflatable member 16 through the inflation conduit 12 to inflate the inflatable member 16. Alternatively, the conduit 11 may be

configured such that the fluid can be flowed through the conduit 11 to inflate the inflatable member 16.

[0056] As shown in FIG. 15, as the inflatable member 16 is filled with the fluid, the inflatable member 16 can apply a force to the sidewalls 36 of the opening 34 created in the tissue 32 to radially or otherwise expand the opening 34 given the relatively elastic properties of the tissue 32. This expansion can continue until the opening 34 is large enough to accommodate the distal end 30 of the overtube 24 and/or the distal end of the endoscope 26 therethrough, for example. Once the opening 34 is expanded to a suitable size by the inflatable member 16, the fluid can be withdrawn, pumped, or otherwise removed from the inflatable member 16 and flowed back into the fluid source 22 through the inflation conduit 12 or the conduit 11, for example. After a sufficient amount of the fluid, or substantially all of the fluid, is withdrawn from the inflatable member 16, the surgical device 10, comprising the inflation conduit 12, the helical element 14, the tapered element 15, the inflatable member 16, the conduit 11, and the protective sleeve 18, can be withdrawn from the working channel 28 of the endoscope 26. Withdrawal of the surgical device 10 from the working channel 28 allows other surgical instruments or devices to be inserted into the working channel 28 and extended from the distal end of the working channel 28 to obtain access to the surgical site through the opening 34 in the tissue 32. It will be appreciated that endoscopes may comprise more than one working channel. Accordingly, other surgical instruments may be inserted through any of these additional working channels enabling the surgical device 10 to remain in-situ, for example, during a surgical procedure.

[0057] As illustrated in Fig. 16, this expansion can continue until the opening 34 is large enough to accommodate the distal end 30 of the overtube 24 and/or the distal end of the endoscope 26 therethrough, for example. Once the inflatable member 16 is inflated it fills the inside diameter of the distal end of the overtube 24, making it substantially contiguous with the overtube 24. The inflated inflatable member 16 acts as a tip for leading in and pushing the entire overtube 24 and endoscope 26 assembly through the opening 34 formed in the tissue 32 (e.g., stomach or other hollow organ wall). Once the opening 34 is expanded to a suitable size by the

inflatable member 16, the fluid can be withdrawn, pumped, or otherwise removed from the inflatable member 16 and flowed back into the fluid supply 22 through inflation conduit 15 or the conduit 12. After a sufficient amount of the fluid, or substantially all of the fluid, is withdrawn from the inflatable member 16, the surgical access device 10, comprising the conduit 12, the needle 14, the inflatable member 16, the inflation conduit 15, and the protective sleeve 18, can be withdrawn from the working channel 28 of the endoscope 26. Withdrawal of the surgical access device 10 from the working channel 28 allows other surgical instruments or devices to be inserted into the working channel 28 and extended from the distal end of the working channel 28 to obtain access to the surgical site through the opening 34 in the tissue 32. It will be appreciated that endoscopes may comprise more than one working channel. Accordingly, other surgical instruments may be inserted through any of these additional working channels enabling the surgical access device 10 to remain in-situ, for example, during a surgical procedure. It will be appreciated that the overtube 24 can remain inserted through the opening 34 and the endoscope 26 withdrawn such that other instruments can be advanced through the overtube 24 to the surgical site.

[0058] In various embodiments, the overtube 24 can generally be flexible so as to allow navigation through the tortuous pathway of a body lumen during an endoscopic procedure. The size of the overtube 24 can vary but, in various embodiments, it can have a length that allows it to be inserted translumenally through a patient's esophagus and an inner diameter or perimeter suitable to receive the endoscope 26 therein. The overtube 24 can be made flexible using various techniques. For example, the overtube 24 can be formed from a flexible material and/or it can include one or more features formed therein to facilitate flexibility, such as a plurality of cut-outs or slots, for example. In other embodiments, the overtube 24 can be formed from a plurality of linkages that are movably coupled to one another. The overtube 24 can also include regions that vary in flexibility. For example, certain portions of the overtube 24, such as the distal portion, can be more rigid than other portions of the overtube 24, such as the proximal portion, to correspond to the shape of a body lumen through which the overtube 24 is being inserted. This

can be achieved by forming the overtube 24 from different materials, varying the diameter or thickness of the overtube 24, and/or using various other suitable techniques known to those of ordinary skill in the art. A person skilled in the art will appreciate that the overtube 24 can have virtually any configuration that allows the overtube 24 to flex as it is inserted through a tortuous body lumen. The overtube 24 can also include other features to facilitate use, such as one or more spiral wires embedded therein in a configuration to prevent kinking of the overtube 24 during flexure, for example. In various embodiments, the protective sleeve 18, the inflation conduit 12, and/or the conduit 11 may include any suitable features discussed above with respect to the overtube 24, for example.

[0059] The surgical device 10 as described herein can have many uses. A non-limiting example of one particular use is described below with reference to Figs. 17 and 18. In various embodiments, a flexible endoscopic portion 131 of an endoscope 160 (e.g., gastroscope) is inserted into an upper gastrointestinal tract of a patient. Fig. 17 illustrates the surgical device 10 inserted through a natural orifice such as the mouth 110 and esophagus 112 into the stomach 114 to establish an opening in the stomach 114 for performing a surgical operation such as a gall bladder removal or a cholecystectomy, for example. Fig. 18 illustrates a distal portion 132 of the endoscope 160. As shown in Figs. 17 and 18, the endoscope 160 may comprise the distal portion 132 and a proximal portion140. In at least one embodiment, an overtube 130, configured to receive at least the endoscopic portion 131 of the endoscope 160, can be inserted into the mouth 110 and can extend towards and/or into the stomach 114. The overtube 130 can create a working channel for insertion of the endoscopic portion 131 of the endoscope 160. In various embodiments, the overtube 130 may be fabricated from nylon or high-density polyethylene plastic, for example. In various embodiments, the endoscopic portion 131 can define various working channels 138 that extend at least from the natural orifice 110 to the surgical site. In addition, the endoscopic portion 131 may define a viewing port 136, for example. As such, the endoscope 160 may be used for viewing the surgical site within the patient's body. Various

cameras and/or lighting apparatuses may be inserted into the viewing port 136 of the endoscope 160 to provide the surgeon with a view of the surgical site.

[0060] In the embodiment illustrated in Fig. 17, one of the tools, devices, or surgical instruments that can be accommodated in the working channels 138 is a hollow vacuum/air tube 150 that may be in fluid communication with a fluid source such as at least one of a vacuum source 152 and a pressurized air source 154. In one embodiment, the vacuum/air tube 150 can be sized to receive therein another surgical instrument in the form of the endoscope 160. A variety of different types of endoscopes are known and, therefore, their specific construction and operation will not be discussed in great detail herein. In various embodiments, the endoscope 160 may operably support a video camera that communicates with a video display unit 164 that can be viewed by the surgeon during the surgical procedure. In addition, the endoscope 160 may further comprise a fluid-supply lumen therethrough that is coupled to a source of water 172, saline solution, and/or any other suitable fluid and/or an air supply lumen that is coupled to a source of air 178.

[0061] In use, the surgical device 10 can be inserted into one of the working channels 138 through either working channel port 141 or 143 and then through either working channel tube 146 or 147 to working channel 138 and used to puncture, pierce, create, or incise an opening in tissue "T" proximal to the surgical site. As illustrated in Figs. 17 and 18, a portion of the surgical device 10 can extend from the distal end of the working channel 138 to enable access to the tissue "T." In various embodiments, the surgical device 10 can function as explained herein.

[0062] In various embodiments, again referring generally to the various stages of deployment illustrated in Figs. 12-16, a method of using the surgical device 10 is provided. First, the surgeon can insert an overtube 24 into a natural opening of a patient, such as the mouth, for example. The surgeon can then either insert a portion of the endoscope 26 into the overtube 24 or can simply insert the surgical device 10 into the overtube 24. In many instances, the surgeon may insert the portion of the endoscope 26 before inserting the surgical device 10 to allow the surgeon to view the surgical site via a viewing port of the endoscope 26. In such an instance, the

surgeon can position the surgical device 10 within and at least partially through the working channel 28 of the endoscope 26. As the surgical device 10 is inserted into the working channel 28 or the overtube 24, the protective sleeve 18 can be in the first position where it at least partially covers, shields, and protects the inflatable member 16 to prevent, inhibit, or at least minimize tearing or puncturing the inflatable member 16 during insertion. Once a distal end of the surgical device 10 reaches the surgical site, the surgeon can then turn on a vacuum producing device to create negative pressure conditions or subatmospheric pressure conditions within the overtube 24. These conditions within the overtube 24 can cause a portion of the tissue 32 near the surgical access site or surgical site to be at least partially drawn into the distal end of the overtube 24 such that the portion of the tissue 32 can be punctured by the helical element 14 of the surgical device 10.

[0063] To puncture the portion of the tissue 32, the surgeon can advance the distal end of the helical element 14 into and insert it into the tissue 32 by applying a proximal-to-distal (i.e., pushing) force, in the direction indicated by arrow "A," to the proximal portion of the helical element 14. The helical element 14 is then threaded in a clockwise direction "CW" to pierce and penetrate the tissue 32 and create the opening 34. After the helical element 14 has created the opening 34 in the tissue 32, the surgeon can then advance the distal end of the inflation conduit 12 into and through the opening 34 by applying a proximal-to-distal (i.e., pushing) force, in direction "B," to the proximal portion of the inflation conduit 12. In such an embodiment, the surgeon can also apply a proximal-to-distal (i.e., pushing) force to the handle 20 or proximal portion of the protective sleeve 18 to ensure that the protective sleeve 18 remains in the first position during insertion of the distal end of the inflation conduit 12 into and at least partially through the opening 34 in the tissue 32. In other various embodiments, a portion of the protective sleeve 18 can be releasably engaged with a portion of the inflation conduit 12 or a portion of the inflation conduit 12 to prevent, inhibit, or at least minimize sliding of the protective sleeve 18 at inappropriate times during the surgical procedure. As discussed previously, by maintaining the protective sleeve 18 in the first position during insertion into the

opening 34 in the tissue 32, the inflatable member 16 can be substantially protected from puncturing, tearing, and/or premature inflation under subatmospheric pressure conditions within the overtube 24. Next, the surgeon can move and/or retract the protective sleeve 18 from the first position to a second position thereby exposing the inflatable member 16 to the sidewalls 36 of the opening 34. As previously discussed, the protective sleeve 18 can be moved using the handle 20 or by pushing or pulling the proximal portion of the protective sleeve 18, for example. Also, as discussed above, this movement of the protective sleeve 18 can be accomplished through the use of other mechanical members, such as threads, for example, or through suitable automated members, for example.

[0064] Once the protective sleeve 18 has been retracted into the second position, the surgeon can then activate the fluid source 22 to begin filling the inflatable member 16 via the inflation conduit 12 or the conduit 11. Filling the inflatable member 16 can cause the opening 34 in the tissue 32 to be enlarged as the inflatable member 16 applies a force to the sidewalls 36 of the opening 34 during expansion. Once the opening 34 has been sufficiently expanded, the overtube 24 and the endoscope 26 can be pushed or advanced through the opening 34 in the tissue 32. Subsequently, the inflatable member 16 can be deflated and the surgeon can remove the surgical device 10 from the overtube 24 or working channel 28 and insert appropriate surgical instruments or devices to begin or continue a surgical procedure.

[0065] The devices disclosed herein can be designed to be disposed of after a single use, or they can be designed to be used multiple times. In either case, however, the devices can be reconditioned for reuse after at least one use. Reconditioning can include any combination of the steps of disassembly of the devices, followed by the cleaning or replacement of particular pieces, and subsequent reassembly. In particular, the devices can be disassembled, and any number of the particular pieces or parts of the devices can be selectively replaced or removed in any combination. Upon the cleaning and/or replacement of particular parts, the devices can be reassembled for subsequent use either at a reconditioning facility or by a surgical team immediately prior to a surgical procedure. Those skilled in the art will appreciate that the

reconditioning of the devices can utilize a variety of techniques for disassembly, cleaning/replacement, and reassembly. The use of such techniques, and the resulting reconditioned devices, are all within the scope of the present application.

[0066] Preferably, the various embodiments described herein will be processed before surgery. First, a new or used device is obtained and, if necessary, cleaned. The device can then be sterilized. In one sterilization technique, the device is placed in a closed and sealed container, such as a plastic or TYVEK® bag. The container and device are then placed in a field of radiation that can penetrate the container, such as gamma radiation, x-rays, or high-energy electrons. The radiation kills bacteria on the device and in the container. The sterilized device can then be stored in the sterile container. The sealed container keeps the device sterile until it is opened in the medical facility. It is preferred that the device is sterilized. This can be done by any number of ways known to those skilled in the art, including beta or gamma radiation, ethylene oxide, or steam.

[0067] Although the various embodiments have been described herein in connection with certain disclosed embodiments, many modifications and variations to those embodiments may be implemented. Also, where materials are disclosed for certain components, other materials may be used. The foregoing description and following claims are intended to cover all such modifications and variations.

[0068] Any patent, publication, or other disclosure material, in whole or in part, that is said to be incorporated by reference herein is incorporated herein only to the extent that the incorporated material does not conflict with existing definitions, statements, or other disclosure material set forth in this disclosure. As such, and to the extent necessary, the disclosure as explicitly set forth herein supersedes any conflicting material incorporated herein by reference. Any material, or portion thereof, that is said to be incorporated by reference herein, but which conflicts with existing definitions, statements, or other disclosure material set forth herein will only be incorporated to the extent that no conflict arises between that incorporated material and the existing disclosure material.

CLAIMS

What is claimed is:

1. A surgical device, comprising:

a guide tube having a proximal end, a distal end, and an inside diameter; and

a needle having a proximal end and a distal end, the needle comprising:

a longitudinal portion having a diameter suitable to be slidably received within the inside diameter of the guide tube; and

a helical element disposed at the distal end of the needle.

2. The surgical device of claim 1, comprising a tapered element located proximally relative to the helical element.

3. The surgical device of claim 2, wherein the tapered element comprises:

a first tapered segment;

a second tapered segment; and

a middle segment located between the first and second tapered segments, the middle segment having a diameter which is less than any one of the diameter of the longitudinal portion and a diameter of the helical element.

4. The surgical device of claim 3, wherein the first tapered segment reduces the diameter of the longitudinal portion of the needle to a reduced diameter of the middle segment; and wherein the second tapered segment reduces the diameter of the helical element to the reduced diameter of the middle segment.

5. The surgical device of claim 4, wherein the diameter of the longitudinal portion of the needle is substantially the same as the diameter of the helical element.

6. The surgical device of claim 4, wherein the diameter of the longitudinal portion of the needle is different from the diameter of the helical element.

7. The surgical device of claim 1, wherein the helical element is formed of a shape memory alloy.

8. The surgical device of claim 1, wherein the helical element is integrally formed with the longitudinal portion of the needle.

9. The surgical device of claim 1, wherein the helical element is rotatable by rotating the distal end of the needle.

10. The surgical device of claim 1, comprising a conduit to slidably receive the guide tube.

11. A method of claim 1, comprising:

inserting the surgical device of claim 1 into a natural orifice of a patient;

advancing the helical element until it contacts a wall of inner body lumen; and

piercing the inner body lumen by rotating the helical element.

12. A surgical device, comprising:

a guide tube having a proximal end and a distal end; and

a needle having a proximal end and a distal end, wherein the proximal end of the needle is attached to the distal end of the guide tube; and

a helical element disposed at the distal end of the needle.

13. The surgical device of claim 12, comprising a tapered element located proximally relative to the helical element.

14. The surgical device of claim 13, wherein the tapered element comprises:

a first tapered segment;

a second tapered segment; and

a middle segment located between the first and second tapered segments, the middle segment having a diameter which is less than any one of the diameter of the guide tube and a diameter of the helical element.

15. The surgical device of claim 14, wherein the first tapered segment reduces the diameter of the guide tube to a reduced diameter of the middle segment; and wherein the second tapered segment reduces the diameter of the helical element to the reduced diameter of the middle segment.

16. The surgical device of claim 15, wherein the diameter of the guide tube is substantially the same as the diameter of the helical element.

17. The surgical device of claim 15, wherein the diameter of the guide tube is different from the diameter of the helical element.

18. The surgical device of claim 12, wherein the helical element is formed of a shape memory alloy.

19. A surgical device, comprising:

a guide tube comprising a proximal end and a distal end;

an inflatable member at least partially surrounding a portion of the conduit and positioned proximal to the distal end of the guide tube, the inflatable member comprising an outer perimeter;

a sleeve at least partially surrounding a portion of the guide tube, the sleeve comprising an elongate channel comprising an inner diameter larger than an outer diameter of the guide tube, the sleeve moveable at least between a first position and a second position, the sleeve configured to shield the inflatable member when the sleeve is in the first position, and the sleeve configured to expose the inflatable member for inflation when the sleeve is in the second position; and

a needle configured to be slidably disposed within the guide tube, the needle comprising:

a longitudinal portion slidably disposed within the inside diameter of the guide tube;

a helical element having disposed at the distal end of the needle; and

a tapered element located proximally relative to the helical element;

wherein the tapered element comprises:

a first tapered segment;

a second tapered segment; and

a middle segment located between the first and second tapered segments, the middle segment having a diameter which is less than a diameter of any one of the longitudinal portion of the needle and the helical element.

20. The surgical device of claim 19, wherein the sleeve is configured to cover the inflatable member when the sleeve is in the first position to at least inhibit the inflatable member from inflating under subatmospheric pressure conditions.

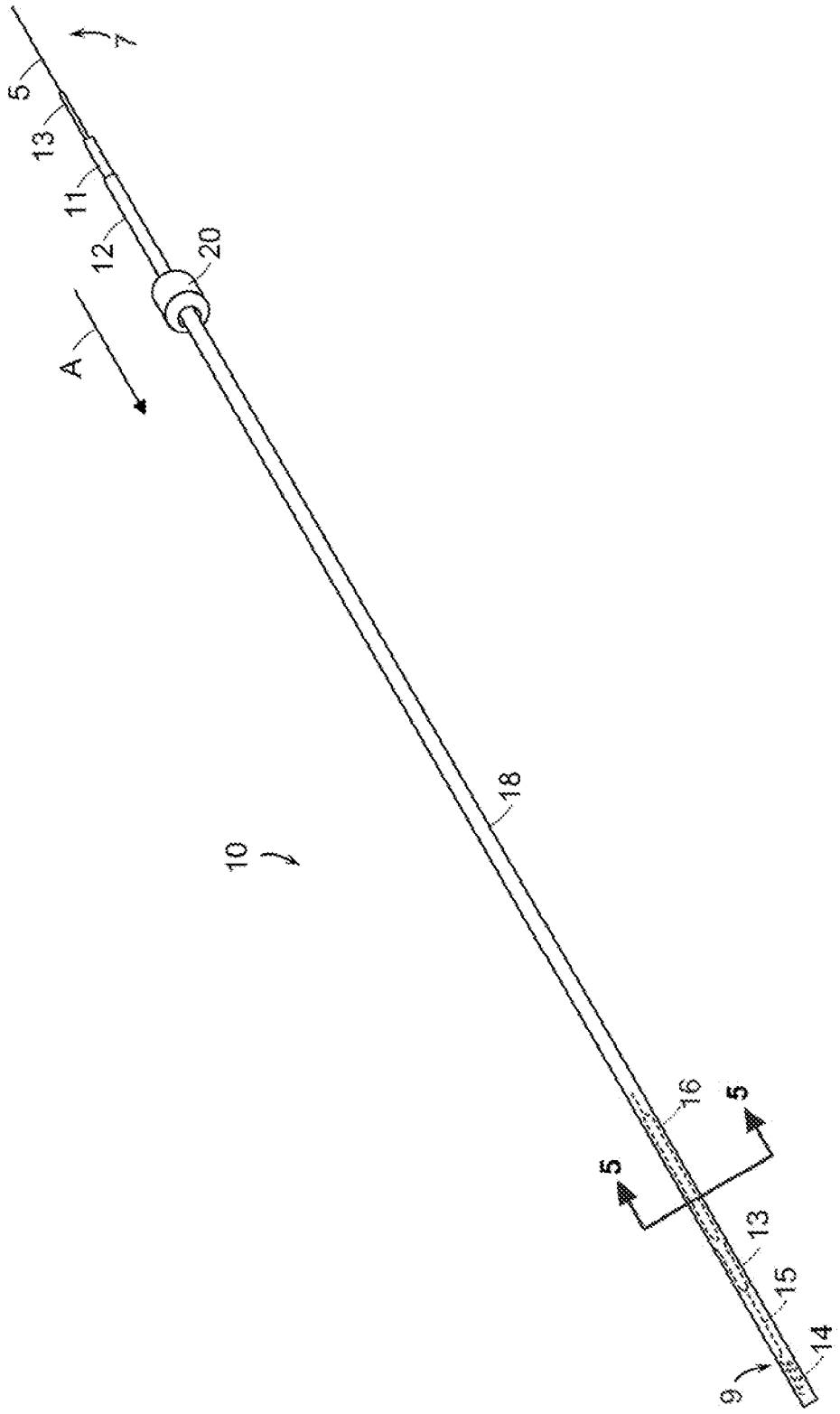


FIG. 1

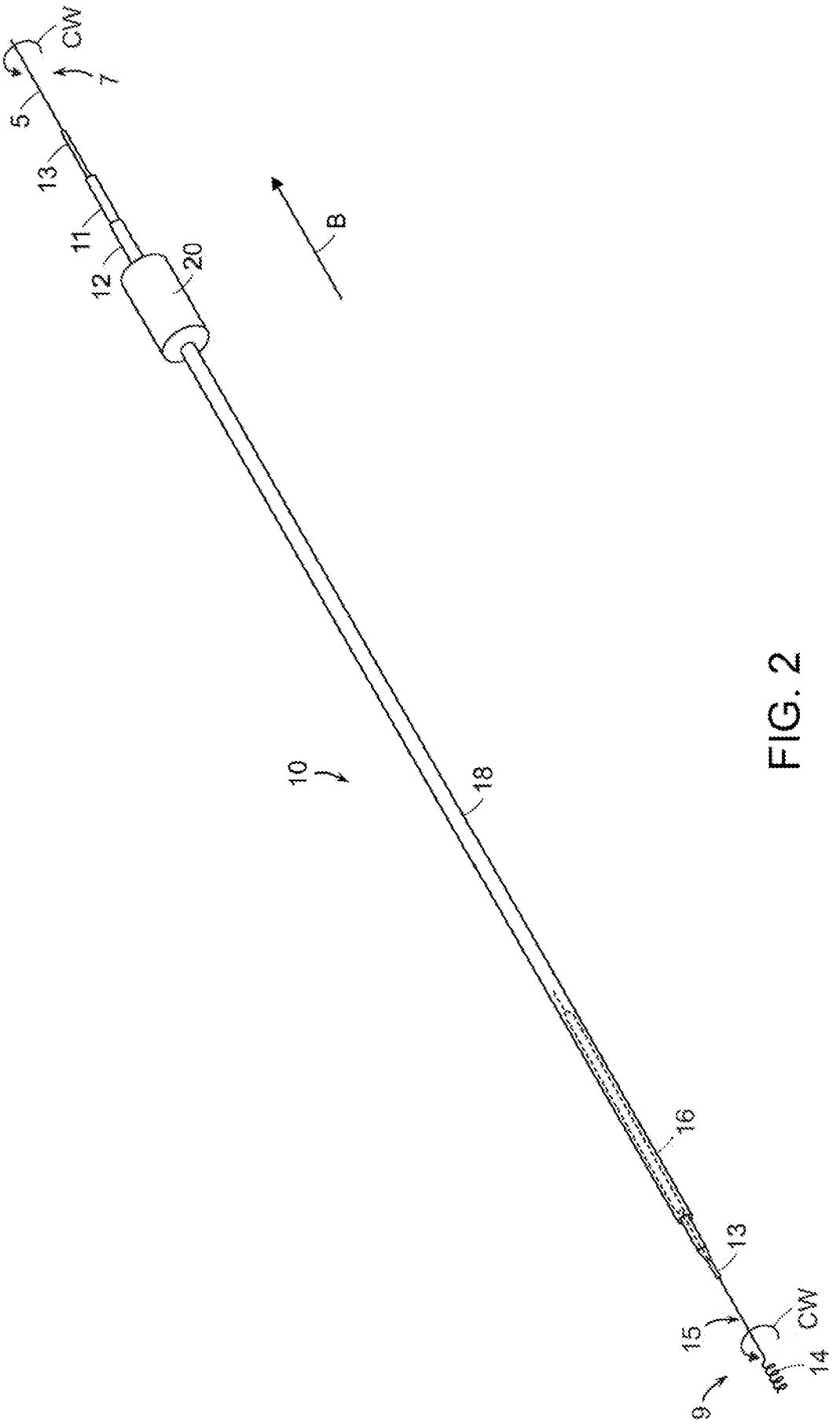


FIG. 2

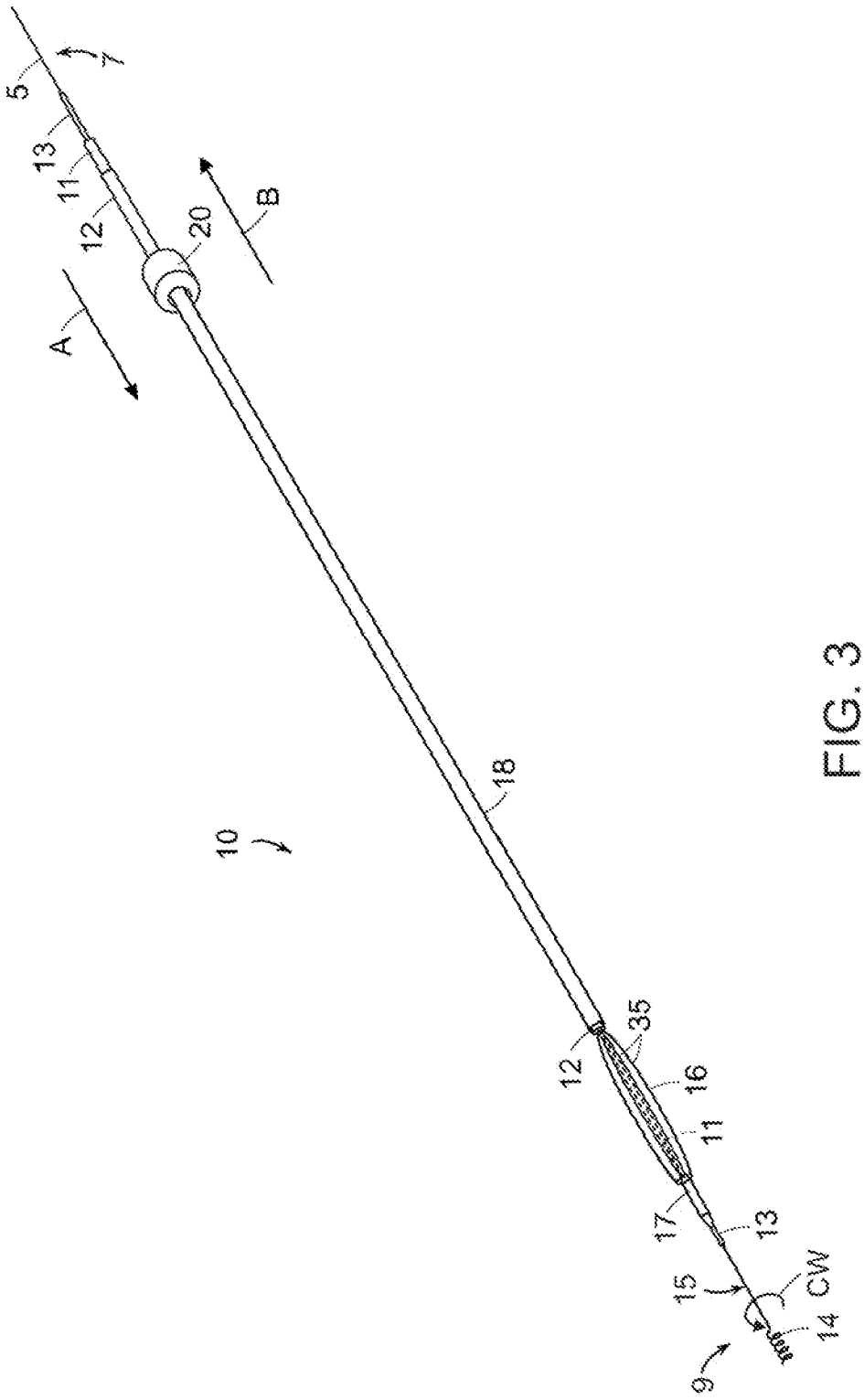


FIG. 3

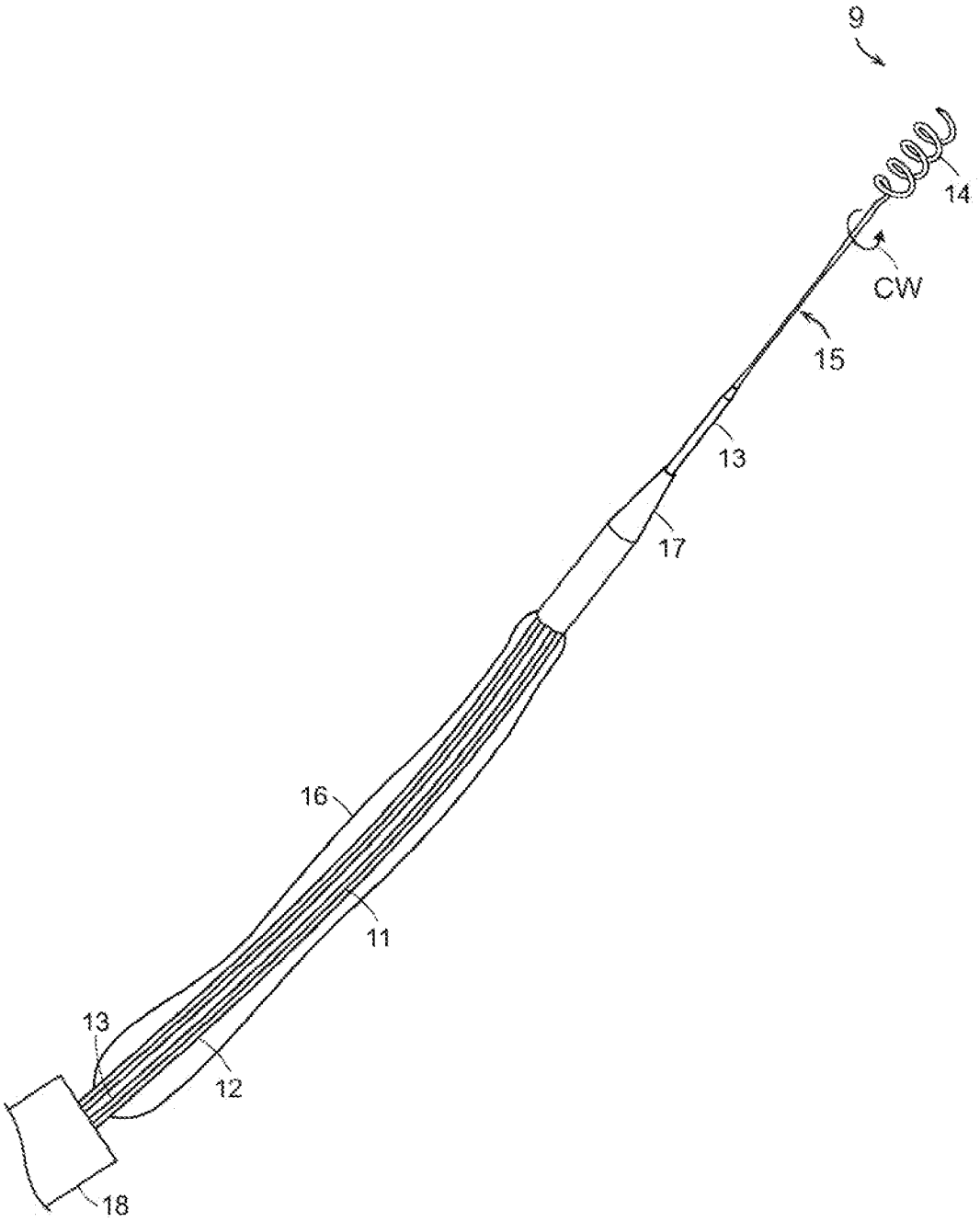


FIG. 4

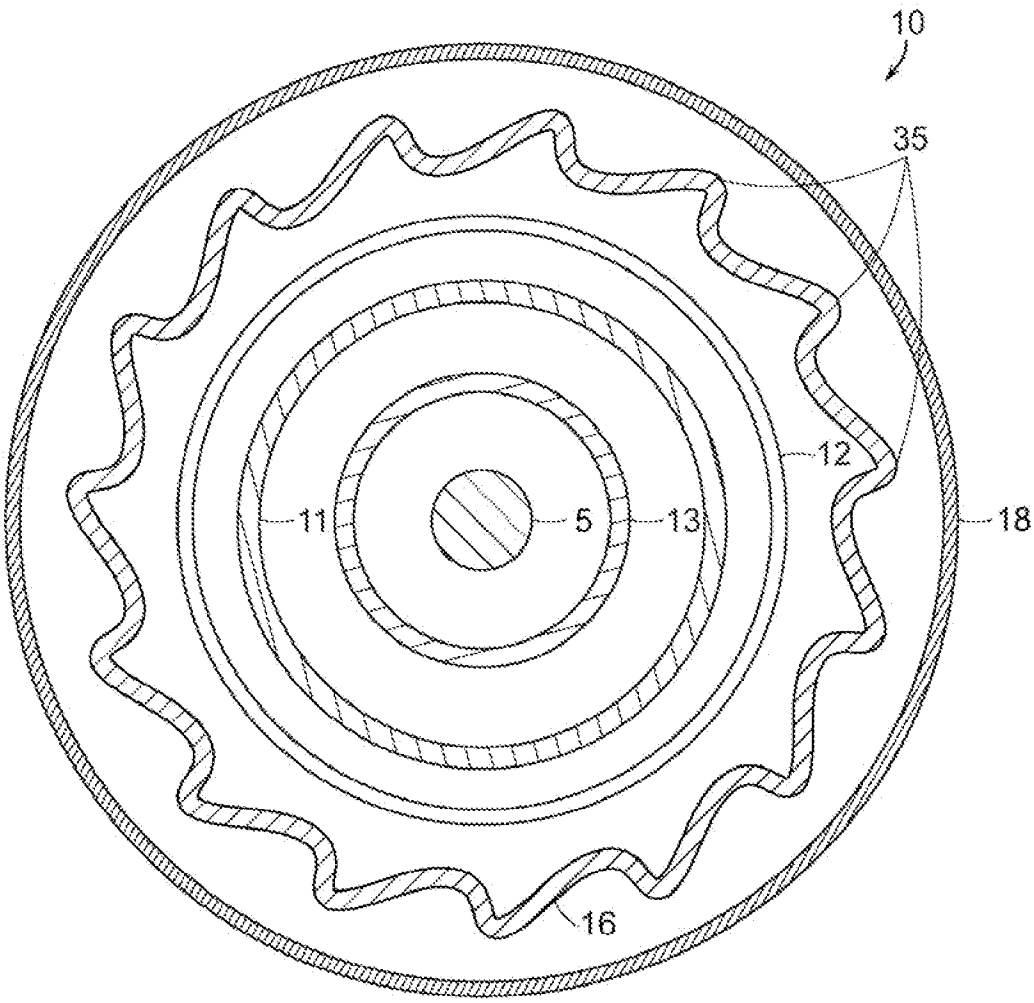


FIG. 5

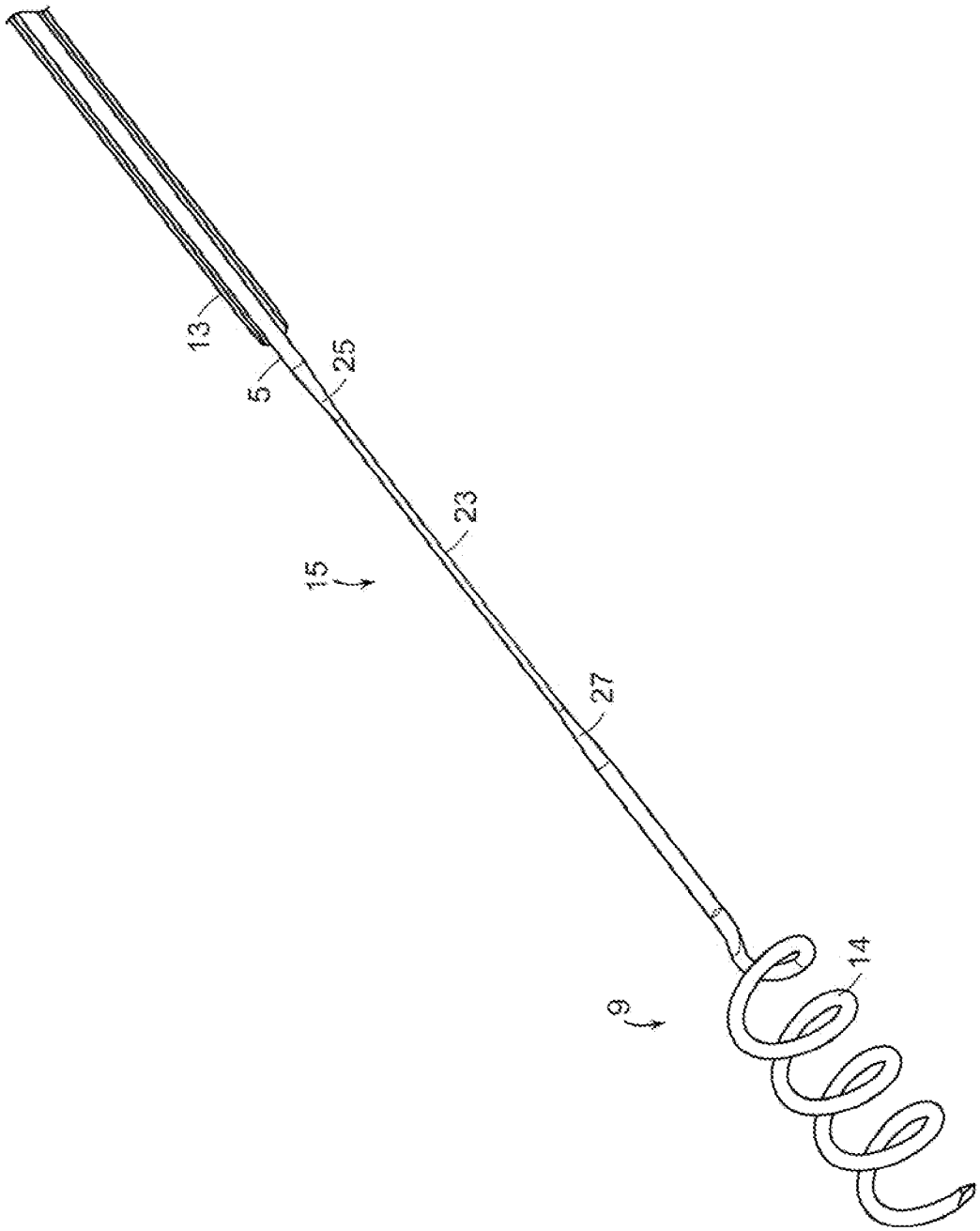


FIG. 6

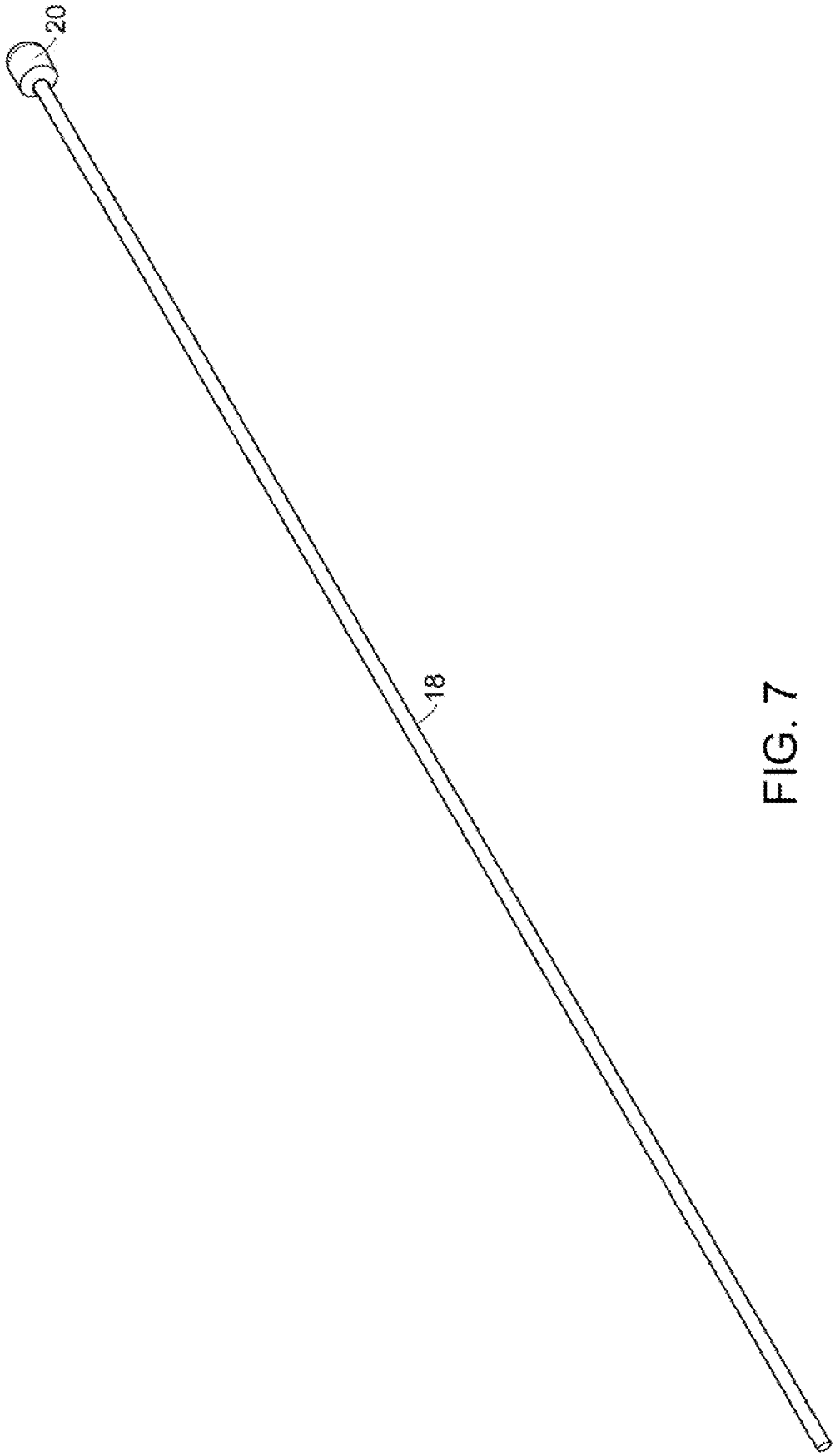


FIG. 7

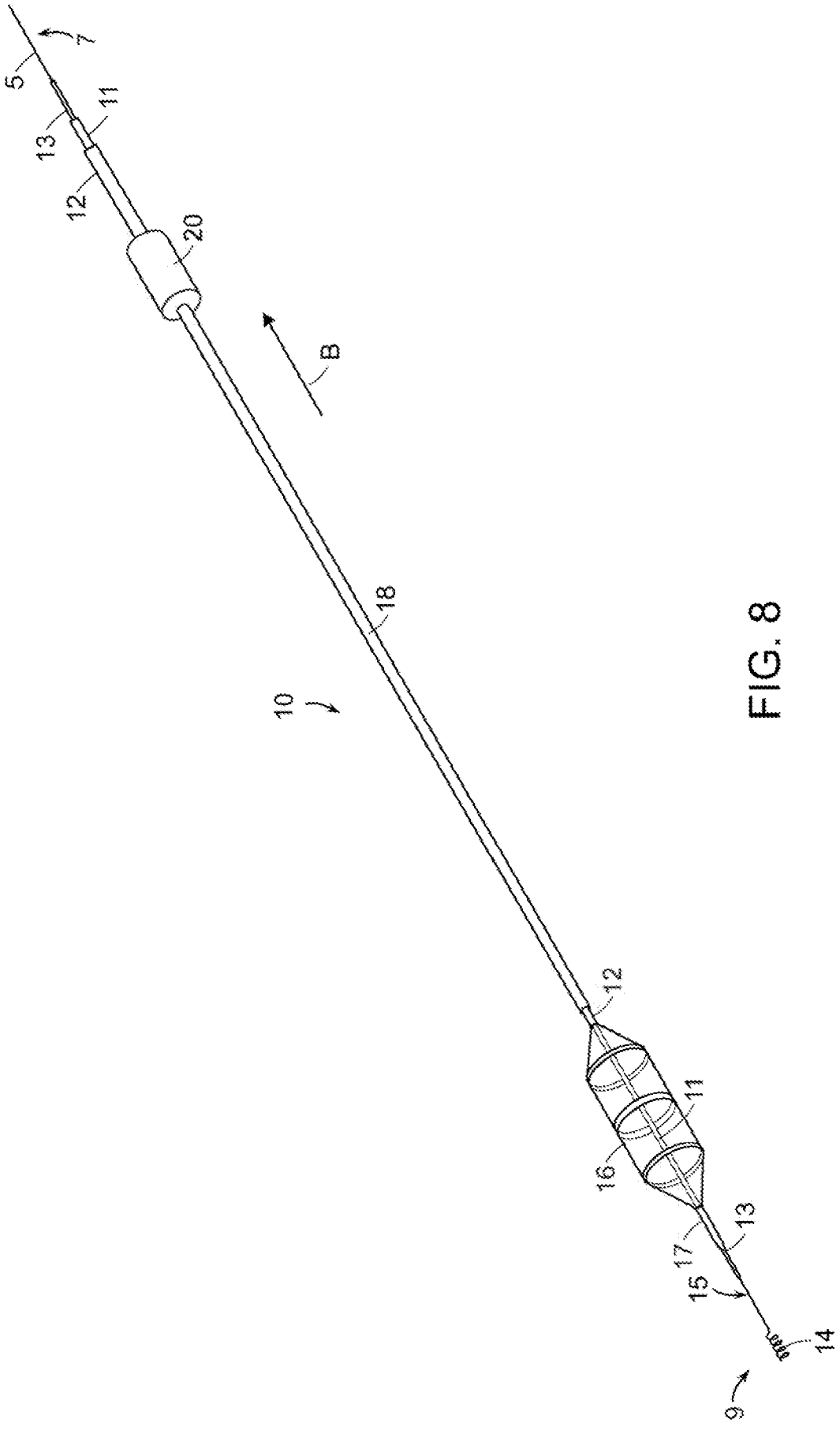


FIG. 8

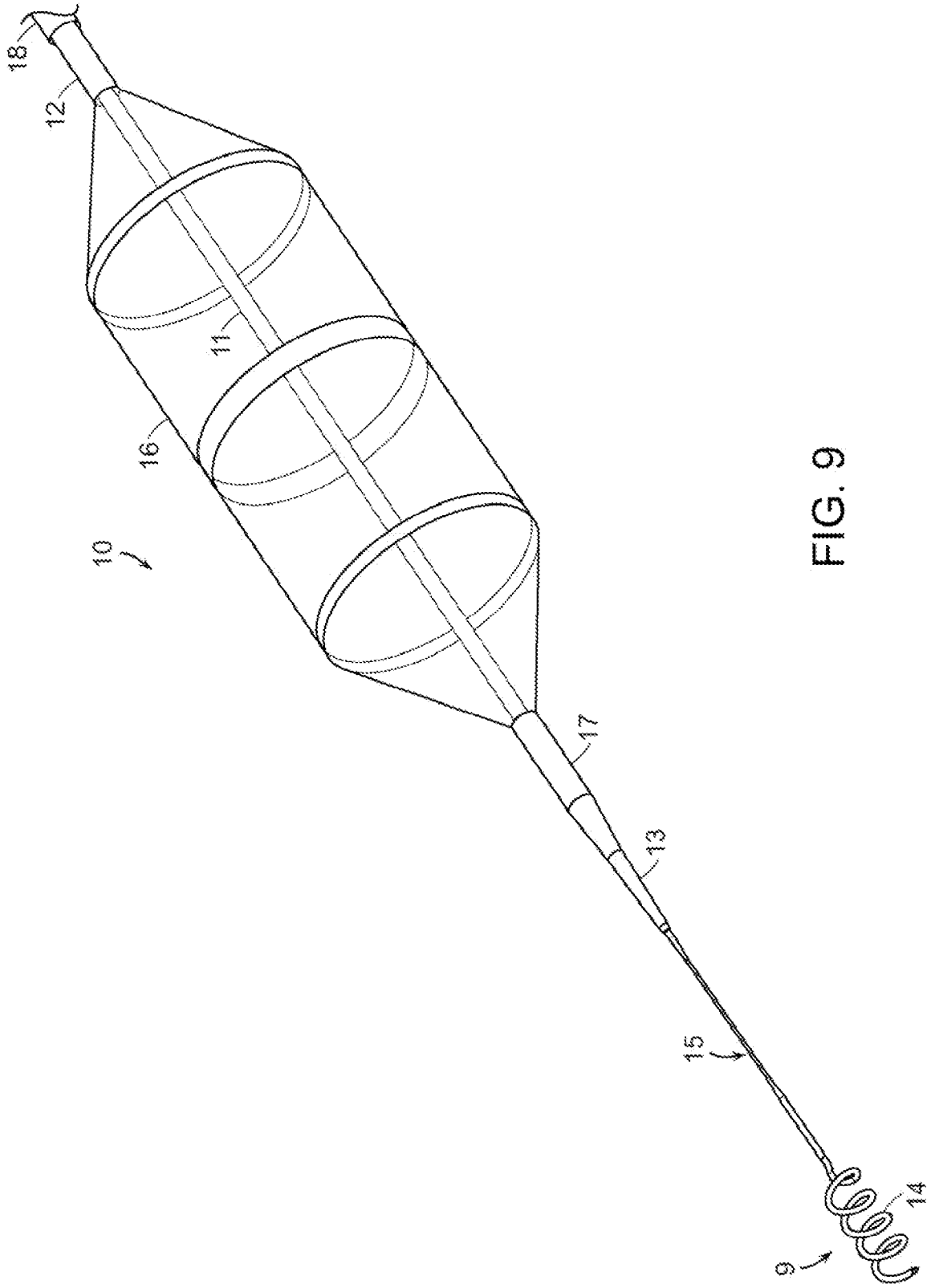


FIG. 9

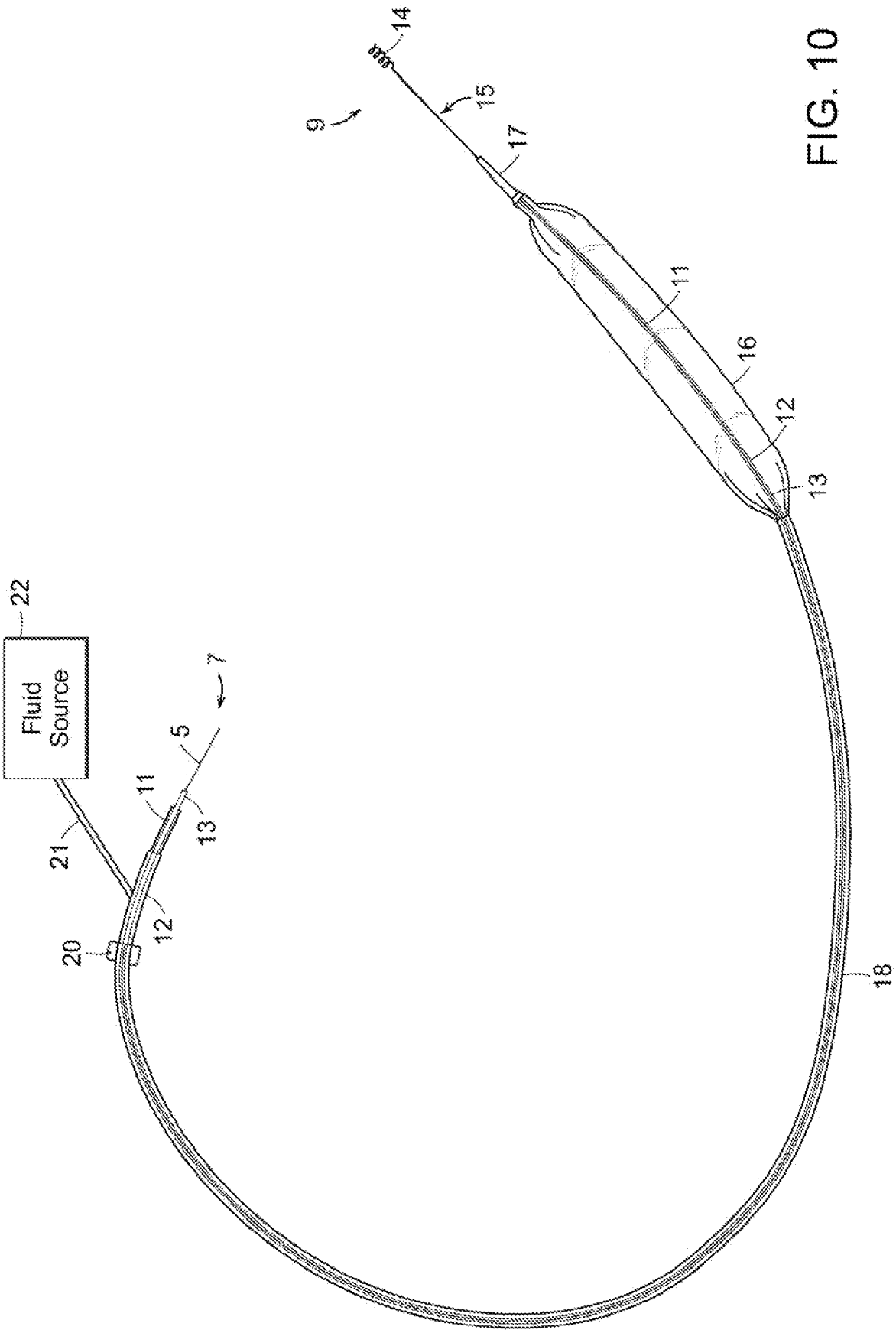


FIG. 10

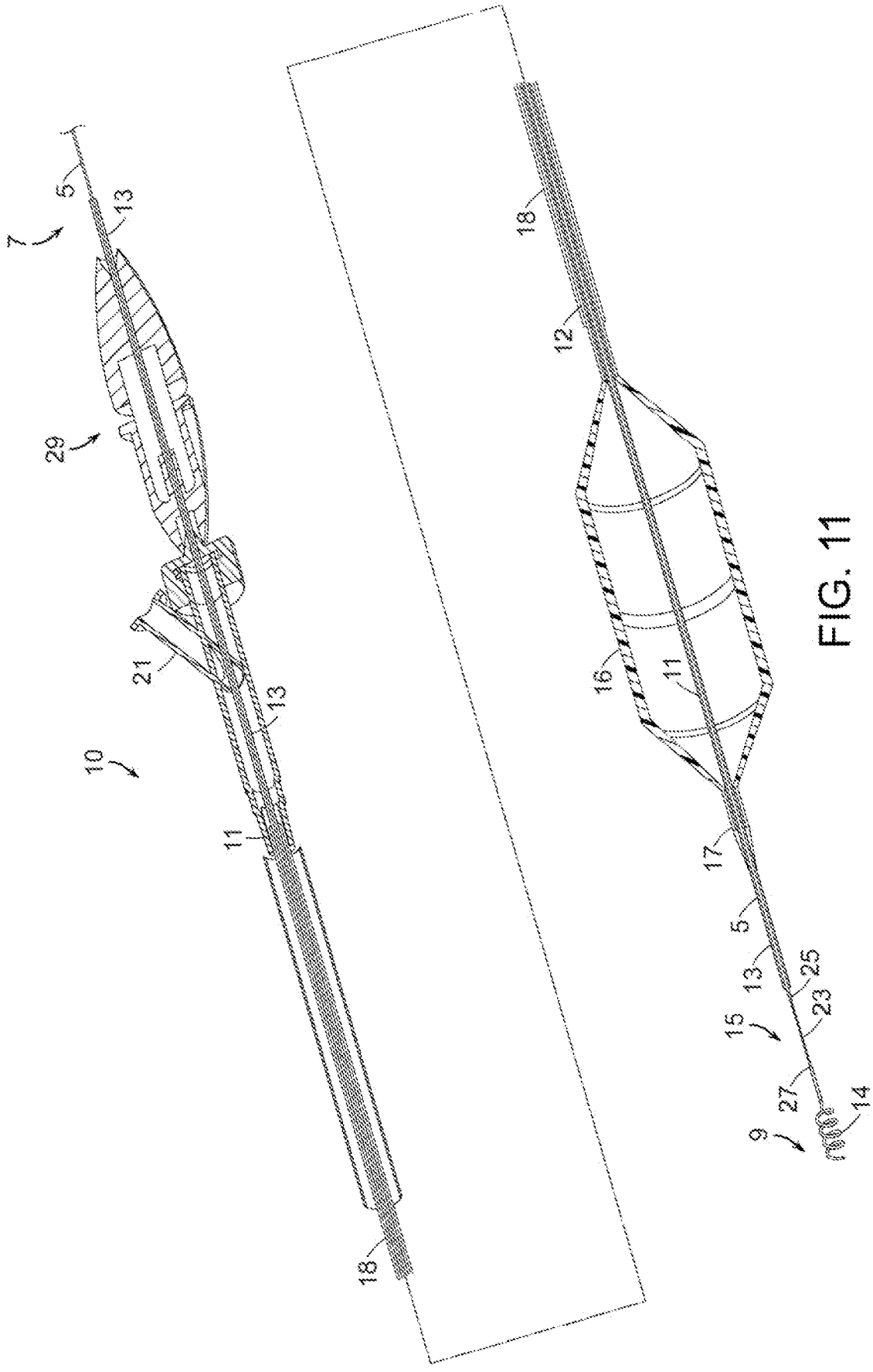


FIG. 11

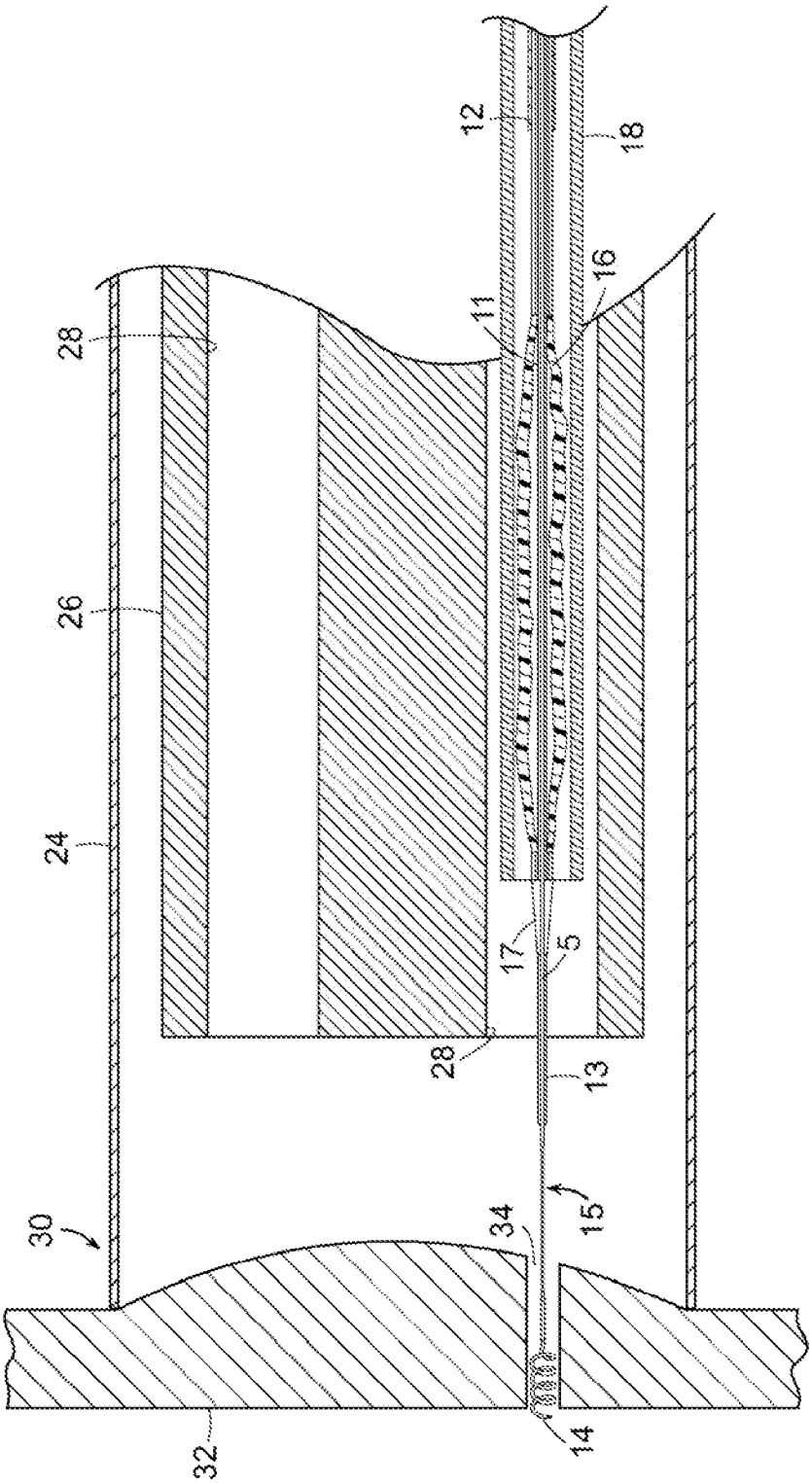


FIG. 12

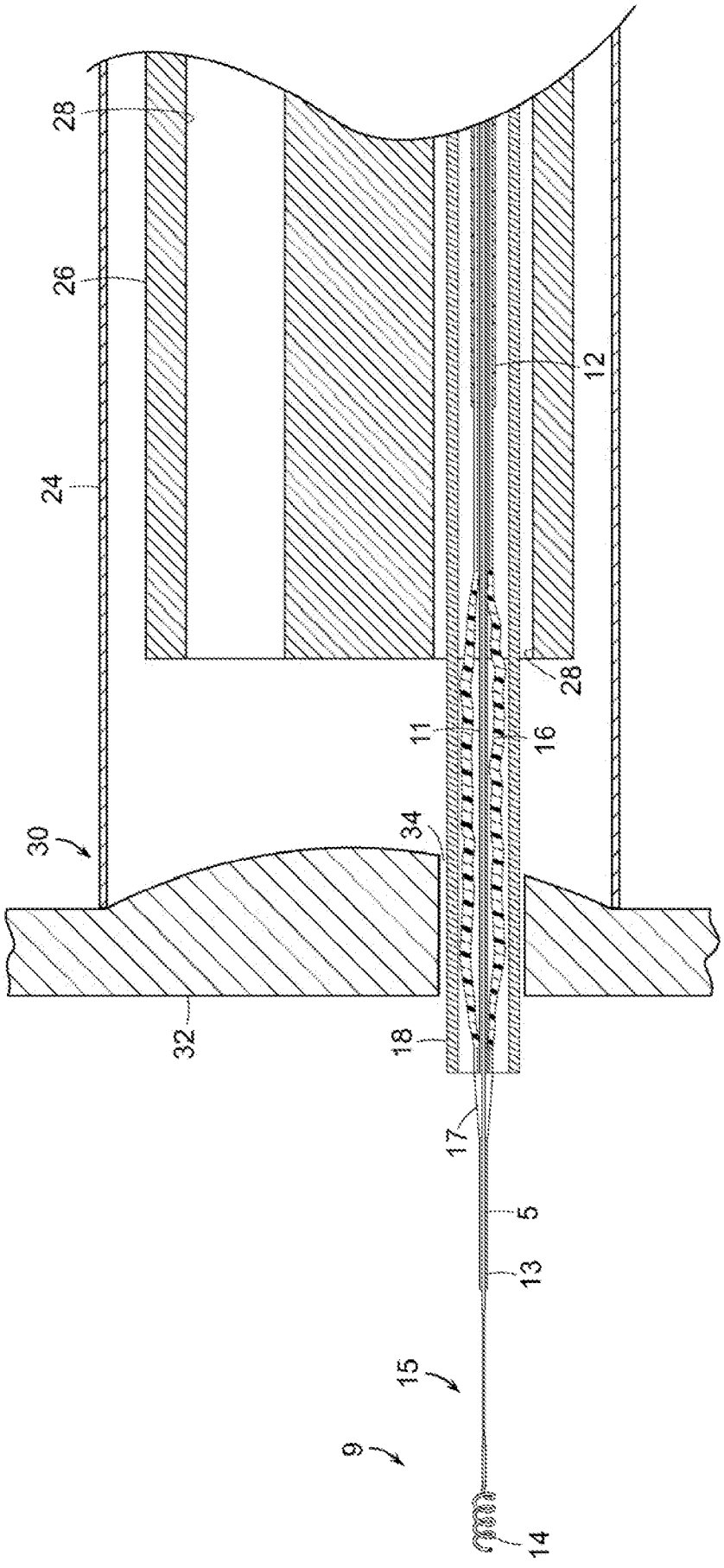


FIG. 13

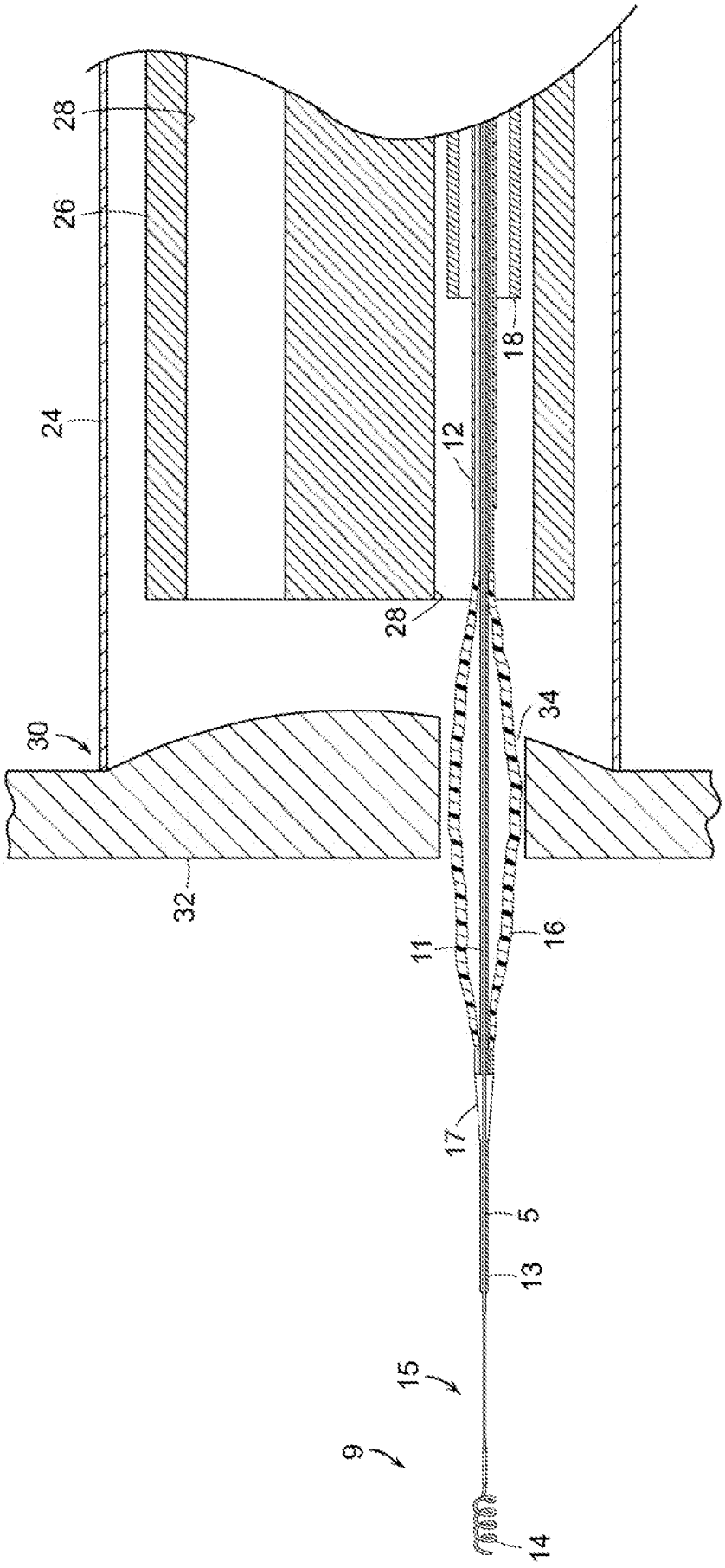


FIG. 14

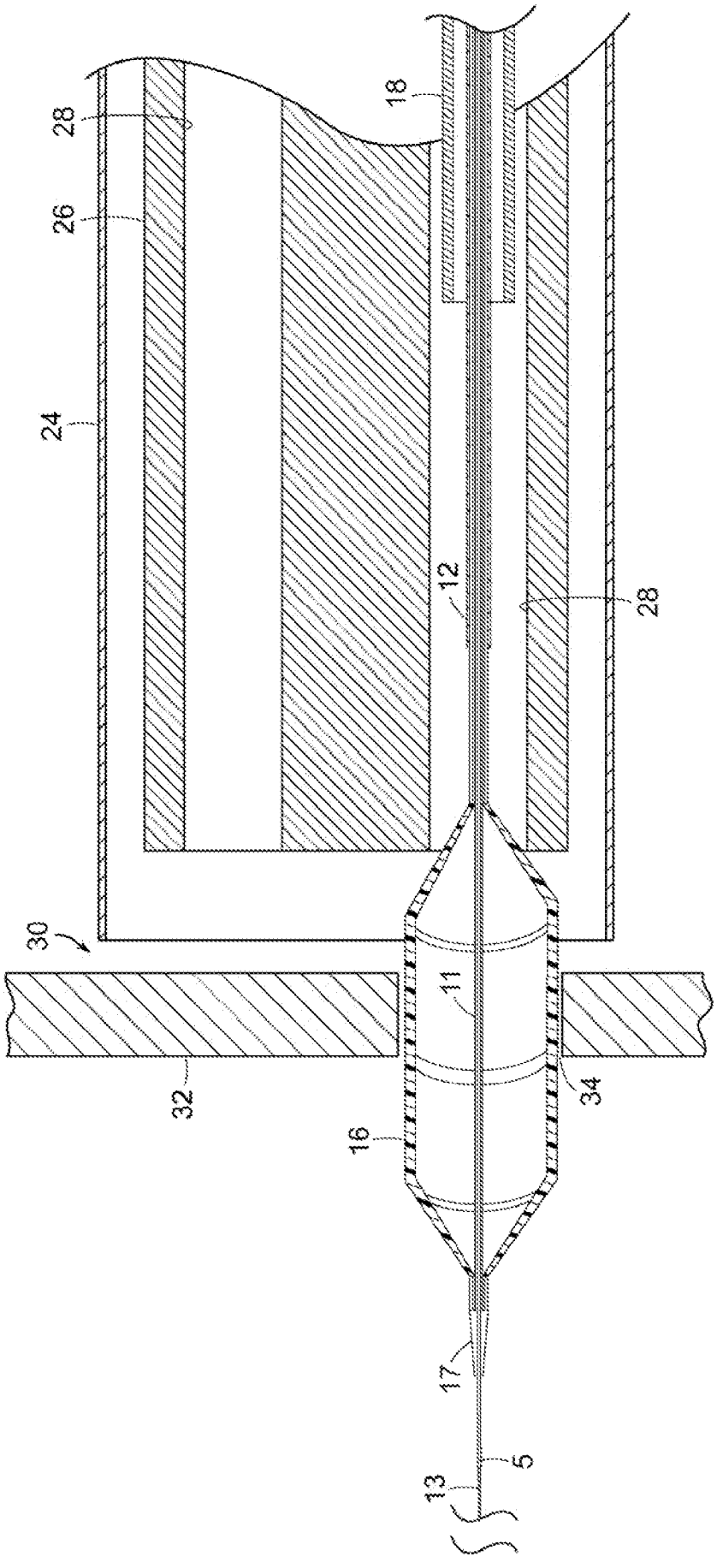


FIG. 15

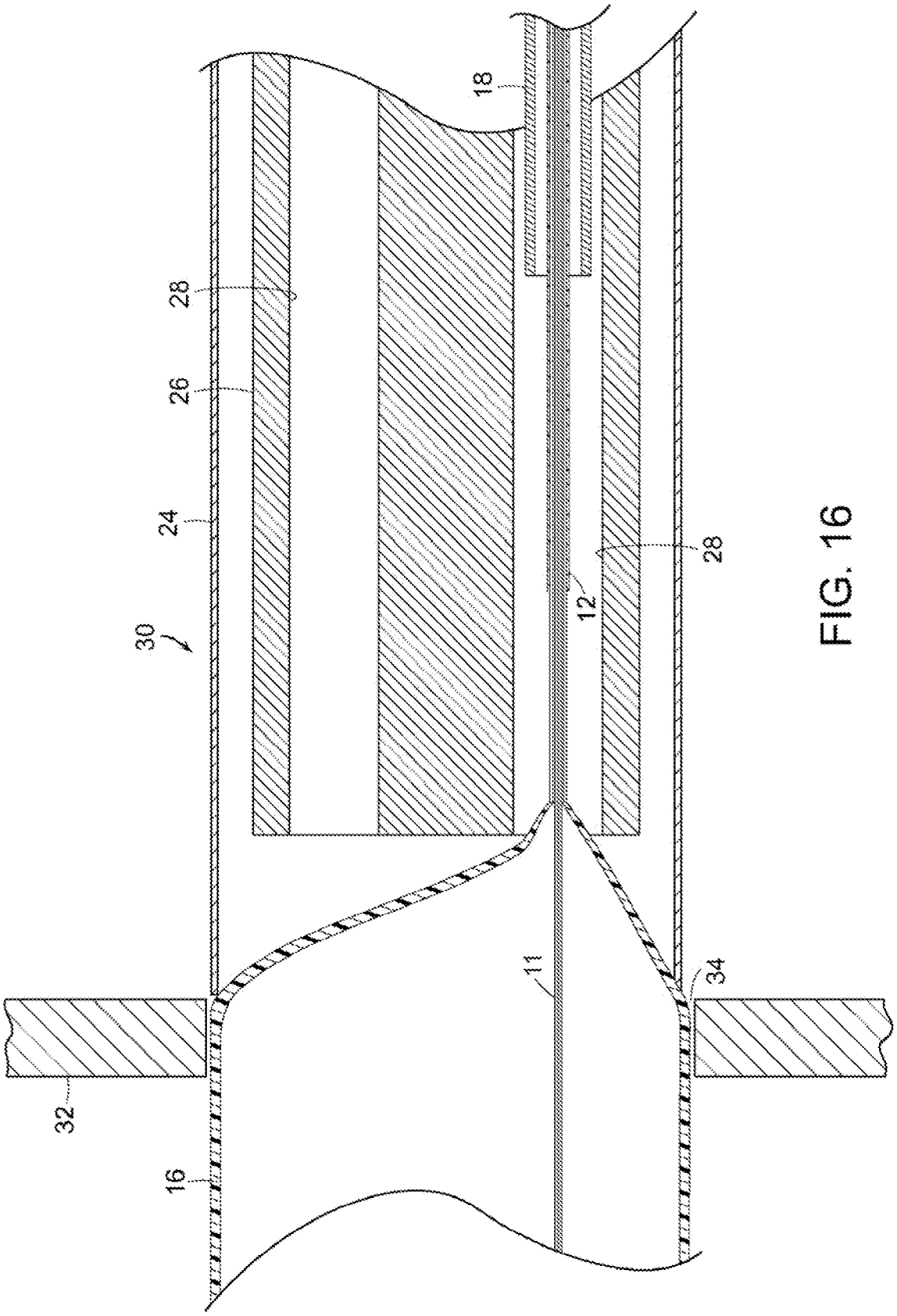


FIG. 16

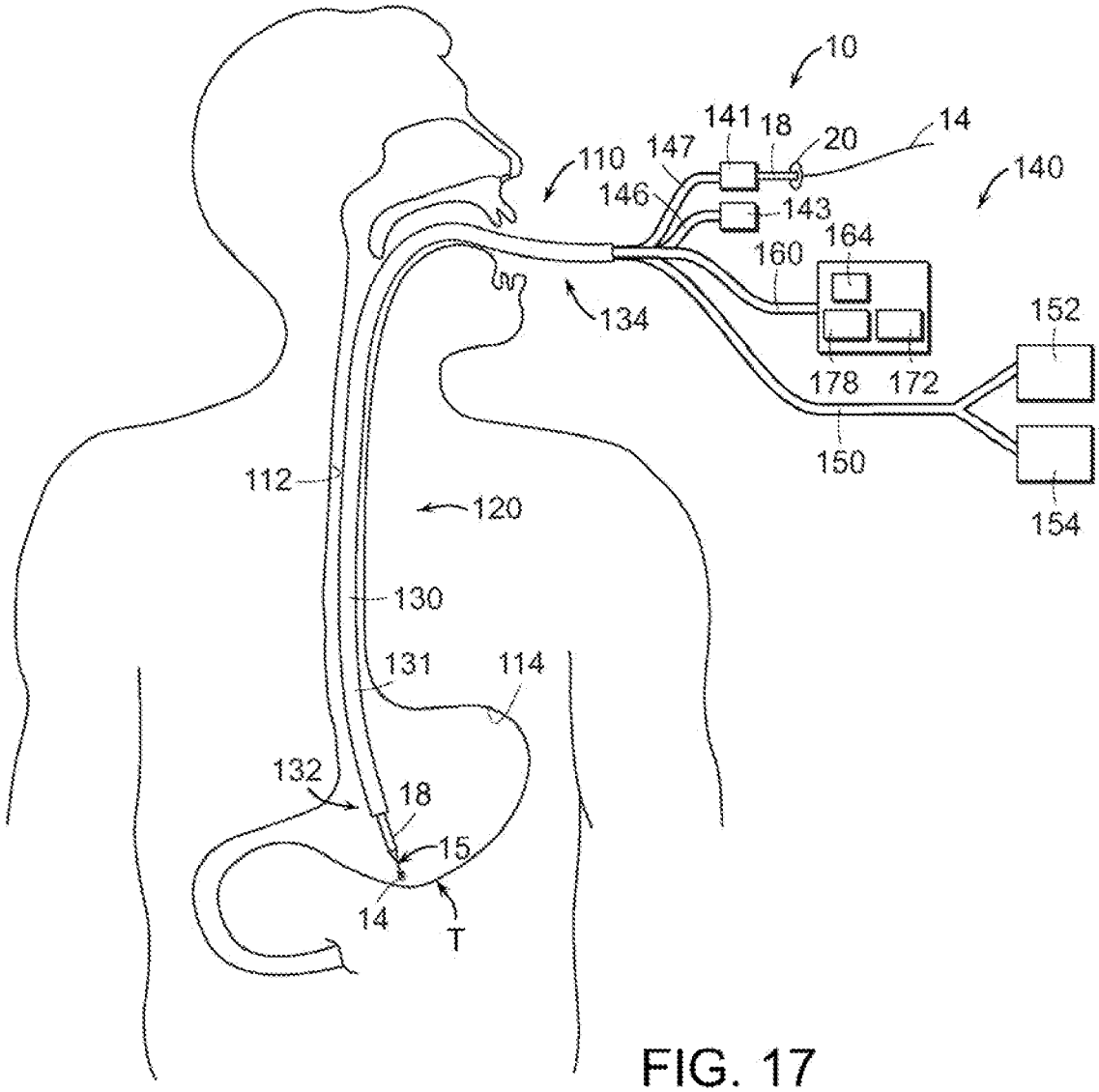

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FIG. 17

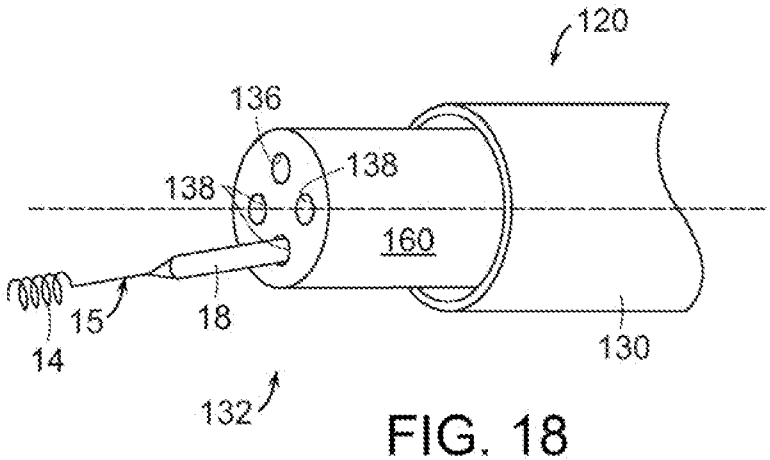

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FIG. 18

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/022177

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/34 A61M29/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61M

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2007/123840 A1 (COX JOHN A [US]) 31 May 2007 (2007-05-31) figures 19B-E	1,7-10, 18
X	US 2005/251166 A1 (VAUGHAN ROBERT A [US] ET AL) 10 November 2005 (2005-11-10) figures 7,8	1,7-10, 12,18
A	US 2007/255306 A1 (CONLON SEAN P [US] ET AL) 1 November 2007 (2007-11-01) the whole document	1-10, 12-20

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 April 2010	11/05/2010

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Held, Günter

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/022177

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 11
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2010/022177

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2007123840 A1	31-05-2007	NONE	
US 2005251166 A1	10-11-2005	NONE	
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		EP 1867291 A2	19-12-2007
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