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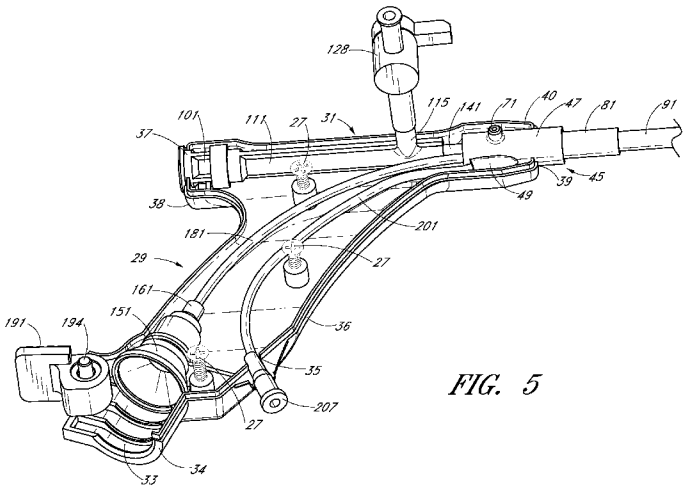

FIG. 5

(57) Abstract: A system for performing a medical procedure and an introducer device suitable for use in the system. The system may be used, for example, to examine and/or to treat the uterus. According to one embodiment, the system includes an introducer, a morcellator, a flexible hysteroscope, and a fluid-containing syringe. The introducer is suitable for transcervical insertion into the uterus and includes a gun-shaped housing and a rigid sheath extending distally from the housing. The sheath is shaped to include an instrument lumen, a visualization lumen, and a pair of fluid lumens. The introducer also includes a first assembly within the housing for receiving the morcellator and for guiding the distal end of the morcellator into the instrument lumen and a second assembly within the housing for guiding the hysteroscope into the visualization channel. In addition, the introducer further includes an assembly for fluidly connecting the syringe to the fluid lumens.

WO 2008/124649 A2

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SYSTEM FOR USE IN PERFORMING A MEDICAL PROCEDURE AND INTRODUCER DEVICE SUITABLE FOR USE IN SAID SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims the benefit under 35 U.S.C. 119(e) of U.S. Provisional Patent Application Serial No. 60/910,618, filed April 6, 2007, and U.S. Provisional Patent Application Serial No. 60/910,625, filed April 6, 2007, both of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] The present invention relates generally to systems for use in performing medical procedures and relates more particularly to a new system for use in performing a medical procedure and to an introducer device suitable for use in said system.

[0003] There are many types of situations in which it is desirable for a medical procedure to be performed on a patient. Such a procedure may be diagnostic and/or therapeutic in nature. For example, in the field of gynecology, one may wish to examine and/or treat a uterus for various abnormal conditions including, but not limited to, the presence of fibroids, polyps, tumors, adhesions, or other abnormalities within a uterus; endometriosis or other abnormal bleeding; uterine prolapse; ectopic pregnancy; and fertility issues (both the inability to conceive and the desire to avoid pregnancy).

[0004] The uterus is a pear-shaped organ made up two distinct anatomical regions: the cervix and the corpus. The cervix is a narrow cylindrical passage (about 1.5-4.0 mm in diameter) which connects at its lower end with the vagina. The corpus, which is the portion of the uterus that grows during pregnancy to carry a fetus, is shaped to include two portions: the lower uterine segment and the fundus. The cervix widens at its upper end to form the lower uterine segment of the corpus. The lower uterine segment, in turn, widens at its upper end into the fundus of the corpus. When in a relaxed state, the uterus is a flaccid

organ, and the opposing walls of the corpus are typically in contact with one another. Dimensionally, the length of the uterus, measured from the cervix to the fundus, is approximately 8-10 cm, and the maximum width of the uterus, which is near the fundus, is about 4-5 cm. Extending from the fundus of the uterus on either side are fallopian tubes. The fallopian tubes are continuous with the uterine cavity and allow the passage of an egg from an ovary to the uterus where the egg may implant if fertilized.

[0005] Conventionally, the examination and/or treatment of the uterus is typically performed as follows: First, obturators of increasing diameter are serially inserted into and then removed from the cervix to gradually dilate the cervix to about 5 mm so that a hysteroscope may be safely inserted into the cervix. (Some physicians omit this step of using obturators to dilate the cervix prior to insertion of a hysteroscope.) Then, the distal end of a hysteroscope is inserted through the cervix, and a fluid, such as a saline solution or a sugar-based aqueous solution, is transmitted through a fluid inlet channel in the hysteroscope to wash the uterus of mucus, blood and other debris that may be present, the washing fluid and debris thereafter exiting the uterus through a fluid outlet channel in the hysteroscope. Then, once the washing of the uterus is complete, the fluid outlet channel is closed and additional fluid is conducted through the fluid inlet channel into the uterus until the uterus becomes distended, i.e., the walls of the corpus are moved away from each other. Once the uterus is distended sufficiently, the fluid outlet channel is re-opened, with maintenance of the distended uterus being achieved by controlling the respective fluid inlet and outlet flow rates.

[0006] With the uterus thus distended, examination of the uterus is performed using the visualization channel of the hysteroscope. If fibroids (i.e., benign tumors), polyps or other abnormalities are detected, such abnormalities may be removed, for example, by resection. Such resection may be achieved using an electromechanical cutting device inserted through a working channel in the hysteroscope. Tissue is then removed by contacting the cutter, which typically has a rotating cutting instrument, with the part of the uterus wall of interest. Examples of such electromechanical cutting devices, which are commonly referred to in the art as morcellators, are disclosed in, for example, U.S. Patent No. 7,226,459, inventors Cesarini et al., issued June 5, 2007; U.S. Patent No. 6,032,673, inventors Savage et al., issued March 7, 2000; U.S. Patent No. 5,730,752, inventors Alden et al., issued March

24, 1998; U.S. Patent Application Publication No. US 2006/0047185 A1, inventors Shener et al., published March 2, 2006; and PCT International Publication No. WO 99/11184, published March 11, 1999, all of which are incorporated herein by reference.

[0007] One shortcoming with the above procedure is that it typically requires that anesthesia be administered to the patient. This is because conventional hysteroscopes of the type through which an electromechanical cutting device may be inserted typically have a diameter of about 9 mm. By contrast, the cervix typically cannot be dilated to a diameter greater than about 5.5 mm without causing considerable discomfort to the patient. As a result, due to the need for anesthesia, the above procedure is typically performed in a hospital operating room and, as a result, bears a large cost due to the setting and the support personnel required.

SUMMARY OF THE INVENTION

[0008] It is an object of the present invention to provide a novel system for use in performing a medical procedure.

[0009] It is another object of the present invention to provide a system as described above that may be used, for example, in the examination and/or treatment of the uterus.

[0010] It is still another object of the present invention to provide a novel introducer device for use in the above system.

[0011] Additional objects, as well as aspects, features and advantages, of the present invention will be set forth in part in the description which follows, and in part will be obvious from the description or may be learned by practice of the invention. In the description, reference is made to the accompanying drawings which form a part thereof and in which is shown by way of illustration various embodiments for practicing the invention. The embodiments will be described in sufficient detail to enable those skilled in the art to practice the invention, and it is to be understood that other embodiments may be utilized and that structural changes may be made without departing from the scope of the invention. The following detailed description is, therefore, not to be taken in a limiting sense, and the scope of the present invention is best defined by the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] The accompanying drawings, which are hereby incorporated into and constitute a part of this specification, illustrate various embodiments of the invention and, together with the description, serve to explain the principles of the invention. In the drawings wherein like reference numerals represent like parts:

[0013] Fig. 1 is a right side view of a first embodiment of a system for use in diagnosing and/or treating a body cavity, the system being constructed according to the teachings of the present invention and being shown in a partially disassembled state;

[0014] Fig. 2 is a right side view of the system of Fig. 1, the system being shown in an assembled state;

[0015] Fig. 3 is a perspective view of the introducer device shown in Fig. 1;

[0016] Figs. 4(a) and 4(b) are exploded perspective views of the introducer device of Fig. 1;

[0017] Fig. 5 is a right perspective view of the introducer device of Fig. 1, with the right half of the housing removed;

[0018] Fig. 6 is a longitudinal section view of the introducer device of Fig. 1;

[0019] Fig. 7 is an enlarged fragmentary perspective view, shown in section, of the introducer device of Fig. 1, with only the manifold, strain relief and sheath being shown;

[0020] Fig. 8 is an enlarged distal end view of the multi-lumen sheath of the introducer device shown in Fig. 1;

[0021] Fig. 9 is an enlarged fragmentary view of the instrument guide assembly of the introducer device shown in Fig. 1;

[0022] Fig. 10 is a perspective view, broken away in part, of an alternate embodiment of an introducer device constructed according to the teachings of the present invention;

[0023] Fig. 11 is a fragmentary perspective view of the introducer device shown in Fig. 10;

[0024] Fig. 12 is an enlarged fragmentary view of the distal end of the introducer device shown in Fig. 10;

[0025] Fig. 13 is a perspective view of a further alternate embodiment of an introducer device constructed according to the teachings of the present invention;

[0026] Fig. 14 is an enlarged perspective view of the distal end of the introducer device shown in Fig. 13;

[0027] Fig. 15 is a fragmentary perspective view, partly in section, of the proximal end of the introducer device shown in Fig. 13;

[0028] Fig. 16 is a perspective view of a further alternate embodiment of an introducer device constructed according to the teachings of the present invention, with the scope cover being shown in a rolled-up state;

[0029] Fig. 17 is an enlarged fragmentary perspective view of the proximal end of the introducer device of Fig. 16;

[0030] Fig. 18 is an enlarged fragmentary perspective view of the distal end of the introducer device of Fig. 16;

[0031] Fig. 19 is an enlarged fragmentary side view of the distal end of the introducer device of Fig. 16;

[0032] Fig. 20 is a section view of the introducer device of Fig. 19 taken line 1-1;

[0033] Fig. 21 is a fragmentary side view of the introducer device shown in Fig. 16, with the scope cover being shown in an unrolled state;

[0034] Fig. 22 is a perspective view of an alternate sheath cap that may be used with the introducer device of Fig. 16;

[0035] Fig. 23 is a perspective view of a further alternate sheath cap that may be used with the introducer device of Fig. 16;

[0036] Fig. 24 is a perspective view of a further alternate embodiment of an introducer device constructed according to the teachings of the present invention;

[0037] Fig. 25 is a fragmentary side view, broken away in part, of the introducer device shown in Fig. 24;

[0038] Fig. 26 is an enlarged fragmentary perspective view of the distal end of the introducer device shown in Fig. 24;

[0039] Fig. 27 is an enlarged fragmentary perspective view of the proximal end of the introducer device shown in Fig. 24;

[0040] Fig. 28 is a perspective view of one embodiment of a protective cover for a visualization device;

[0041] Figs. 29(a) and 29(b) are side and fragmentary end views, respectively, of a further alternate embodiment of an introducer device constructed according to the teachings of the present invention;

[0042] Fig. 30 is an end view of a further alternate embodiment of an introducer device constructed according to the teachings of the present invention;

[0043] Fig. 31 is a partly schematic, perspective view of a further alternate embodiment of an introducer device constructed according to the teachings of the present invention;

[0044] Fig. 32 is a distal end view of a further alternate embodiment of an introducer device constructed according to the teachings of the present invention;

[0045] Fig. 33 is a fragmentary longitudinal section view of a further alternate embodiment of an introducer device constructed according to the teachings of the present invention; and

[0046] Fig. 34 is a fragmentary side view, partly in section, of a further alternate embodiment of an introducer device constructed according to the teachings of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0047] Referring now to Figs. 1 and 2, there are shown various views of a first embodiment of a system that may be used in the diagnosis and/or treatment of a body cavity, the system being constructed according to the teachings of the present invention and being represented generally by reference numeral 11.

[0048] System 11 may comprise an introducer device 13, a visualization device 15, a fluid supply device 17, and a tissue modifying device 19.

[0049] Referring now to Figs. 3 through 7, introducer 13 may comprise a housing 21. Housing 21, in turn, may comprise a left handle half 23 and a right handle half 25. Left handle half 23 and right handle half 25, which may be molded or otherwise fabricated from a rigid polymer or other suitable material, may be joined by a plurality of screws 27. Instead of

being joined by screws 27, left handle half 23 and right handle half 25 may be joined using a suitable adhesive, crush pins, or may be welded together ultrasonically or otherwise. Left handle half 23 and right handle half 25 jointly define a hollow, gun-shaped structure comprising a handle portion 29 and a barrel portion 31. Handle portion 29 may be shaped to include an opening 33 provided at its bottom end 34 and an opening 35 provided along its distal face 36 near bottom end 34. A slot 33-1 may be provided in right handle half 25, slot 33-1 extending from opening 33 towards barrel portion 31 for a short distance. Barrel portion 31 may be shaped to include an opening 37 provided at its proximal end 38 and an opening 39 provided at its distal end 40. In addition, barrel portion 31 may be shaped to include a transverse opening 41 provided in right handle half 25 at a location intermediate to proximal end 38 and distal end 40.

[0050] The interior surfaces of left handle half 23 and right handle half 25 may shaped to include complementary sets of ribs (not shown). Such ribs may provide structural reinforcement to left handle half 23 and right handle half 25 and may help to maintain the correct positioning and alignment of the components positioned within housing 21.

[0051] Introducer 13 may further comprise a manifold 45. Manifold 45, which may be molded or otherwise fabricated from a rigid polymer or other suitable material, may be a unitary, branched structure shaped to include a main tubular member 47 and a side tubular member 49. Main member 47 may comprise a proximal end 51, an open distal end 53, a side wall 55, and a longitudinal lumen 57. Proximal end 51 of main member 47 may be shaped to include a top opening 59 of comparatively greater diameter and a bottom opening 61 of comparatively smaller diameter. Side member 49 may comprise an open proximal end 63, an open distal end 65, a side wall 67, and a longitudinal lumen 69. Lumen 69 of side member 49 may be in fluid communication with lumen 57 of main member 47 through open distal end 65.

[0052] Manifold 45 may be coupled to housing 21 using a pair of pins 71 and 73 that may extend from side wall 55 and that may be received within hollow embossments 75 and 77, respectively, provided on the interior faces of left handle half 23 and right handle half 25, respectively. With manifold 45 thus coupled to housing 21, proximal end 51 of manifold 45 may be positioned in barrel portion 31, with side wall 55 tightly fitting within opening 39

and with distal end 53 of manifold 45 extending distally a short distance beyond distal end 40.

[0053] Introducer 13 may further comprise a strain relief member 81. Strain relief member 81, which may be molded or otherwise fabricated from a rigid polymer or other suitable material, may be a unitary tubular structure shaped to include an open proximal end 83, an open distal end 85, a side wall 87, and a longitudinal lumen 89. Strain relief member 81 may be partially inserted into lumen 57 of manifold 45 and may be tightly fitted within lumen 57 and fixedly secured thereto using a suitable adhesive or the like, with proximal end 83 of strain relief member 81 being positioned just distal to open distal end 65 of side member 49 and with distal end 85 of strain relief member 81 extending distally a short distance beyond distal end 53 of main member 47.

[0054] Introducer 13 may further comprise a sheath 91, which is also shown separately in Fig. 8. Sheath 91, which may be extruded or otherwise fabricated from a suitable polymer, such as nylon 12, may be a rigid, unitary structure shaped to include a proximal end 92, a distal end 93, and a side wall 94. Sheath 91 may be further shaped to include a plurality of longitudinal lumens of fixed shape and size, such lumens including a top lumen 96, a bottom lumen 97, and a pair of side lumens 98-1 and 98-2. As will be discussed further below, top lumen 96 may be used as an instrument lumen, bottom lumen 97 may be used as a visualization lumen, and side lumens 98-1 and 98-2 may be used as fluid lumens. Proximal end 92 of sheath 91 may be partially inserted into lumen 89 of strain relief member 81 and may be tightly fitted within lumen 89 and fixedly secured thereto using a suitable adhesive or the like, with proximal end 92 of sheath 91 flush with proximal end 83 of strain relief member 81 and with distal end 93 of sheath 91 extending distally beyond distal end 85 of strain relief member 81 for several inches.

[0055] Sheath 91, which is preferably the only component of introducer 13 that is to be inserted into a patient, may be dimensioned to have an outer diameter of about 5.5 mm, with lumen 96 having a diameter of about 3 mm, lumen 97 having a diameter of about 2 mm, and lumens 98-1 and 98-2 each having a diameter of about 1.33 mm. By thus dimensioning sheath 91, if sheath 91 is inserted through the cervix of a patient, the risk of injury to the patient and the need for anesthesia to be administered to the patient may be minimized.

However, it should be understood that the above dimensions for sheath 91 are merely exemplary and may be varied depending upon how system 11 is to be used.

[0056] In another embodiment (not shown), instead of making sheath 91 entirely of a rigid material, sheath 91 may include a proximal portion made of a rigid material and a distal portion made of a flexible and/or softer material.

[0057] Introducer 13 may further comprise an instrument guide assembly mounted within housing 21 for providing a continuous channel aligned with lumen 96 into which tissue modifying device 19 may be inserted. The instrument guide assembly may comprise a guide body 101. Body 101, which may be molded or otherwise fabricated from a rigid polymer or other suitable material, may be a unitary tubular structure shaped to include a proximal portion 103, a distal portion 105 and an intermediate portion 107. Intermediate portion 107 may be reduced in inner diameter and in outer diameter relative to proximal portion 103 and distal portion 105 so that an annular seat 108 is formed within body 101 at the juncture of intermediate portion 107 and distal portion 105. The interior surface of body 101 may taper inwardly from proximal portion 103 to intermediate portion 107 to facilitate insertion of device 19 into intermediate portion 107 and to delimit the extent to which device 19 may be inserted into body 101.

[0058] Body 101 may be tightly fitted within opening 37 of housing 21 and fixedly secured thereto using a suitable adhesive or the like, with distal portion 105 and intermediate portion 107 of body 101 being positioned within barrel portion 31 of housing 21 and with proximal portion 103 of body 101 extending through opening 37 and continuing proximally for a short distance beyond proximal end 38 of housing 21.

[0059] The instrument guide assembly may further comprise a sleeve 111. Sleeve 111, which may be molded or otherwise fabricated from a rigid polymer or other suitable material, may be a unitary, branched structure shaped to include a main tubular member 113 and a side tubular member 115. Main member 113 may comprise an open proximal end 116, an open distal end 117, and a longitudinal lumen 119. Proximal end 116 of main member 113 may be shaped to be tightly fitted within distal portion 105 of body 101 and may be bonded thereto using a suitable adhesive. Side member 115 may comprise an open proximal end 120, an open distal end 121 and a longitudinal lumen 123. Lumen 123 of side member

115 may be in fluid communication with lumen 119 of main member 113 through open proximal end 120. Distal end 121 of side member 115 may extend through opening 41 provided in right handle half 25 of housing 21 and may be coupled to a valve 128. Valve 128 may be an actively-controlled valve, such as a stopcock valve, or a passively-controlled valve, such as a spring-activated ball valve. Valve 128 may be connected at its output end to a length of tubing (not shown), as well as to a fluid receptacle (not shown), for conducting, as well as collecting, outflow fluid passing through valve 128.

[0060] The instrument guide assembly may further comprise the combination of a seal 131 and a valve 133. Seal 131 and valve 133 may be elastomeric members securely positioned between seat 108 of body 101 and proximal end 116 of sleeve 111 (see Fig. 9). Seal 131, which may be located proximally relative to valve 133, may include a central opening 135. Opening 135 may be appropriately dimensioned so that, when tissue modifying device 19 is inserted therethrough, fluid may not readily pass proximally through seal 131 around the outside of device 19. Valve 133, which may be shaped to include a dome having a cross-slit at its top, may be designed so that, in the absence of device 19 being inserted therethrough, fluid may not readily pass proximally therethrough.

[0061] The instrument guide assembly may further comprise a tube 141. Tube 141, which may be a rigid hypotube made of stainless steel or the like, may comprise a proximal end 143 and a distal end 145. Proximal end 143 may be fixedly mounted within lumen 119 of sleeve 111 using a suitable adhesive or the like. Distal end 145 of tube 141 may be tightly fitted within lumen 96 of sheath 91 and may be secured therewithin using a suitable adhesive or the like.

[0062] Introducer 13 may further comprise a visualization guide assembly mounted within housing 21 for providing a continuous channel aligned with lumen 97 into which visualization device 15 may be inserted. The visualization guide assembly may comprise a guide body 151. Body 151, which may be molded or otherwise fabricated from a rigid polymer or other suitable material, may be a unitary tubular structure shaped to include a proximal portion 153 of comparatively greater diameter, a distal portion 155 of comparatively smaller diameter, and an intermediate portion 157 tapering in diameter from proximal portion 153 to distal portion 155. Body 151 may be disposed within handle portion

29 of housing 21, with proximal portion 153 spaced inwardly a short distance from opening 33 and with distal portion 155 facing towards barrel portion 31. Proximal portion 153 may be tightly fitted between and fixedly secured to left handle half 23 and right handle half 25 of housing 21 using adhesive or other suitable means. As will be discussed further below, proximal portion 153 may be appropriately dimensioned to receive the proximal portion of visualization device 15, with intermediate portion 157 of body 151 being appropriately dimensioned to serve as a stop to limit the extent to which visualization device 15 may be inserted into body 151. An annular seat 158 may be provided within distal portion 155 and may be spaced proximally relative to distal end 159 of distal portion 155.

[0063] The visualization guide assembly may further comprise a guide connector 161. Guide connector 161, which may be molded or otherwise fabricated from a rigid polymer or other suitable material, may be a unitary tubular structure shaped to include a proximal portion 163 of comparatively greater diameter, a distal portion 165 of comparatively smaller diameter, and an intermediate portion 167 tapering in diameter from proximal portion 163 to distal portion 165. Proximal portion 163 may be shaped to be tightly fitted within distal portion 155 of body 151 and may be bonded thereto using a suitable adhesive.

[0064] The visualization guide assembly may further comprise the combination of a seal 171 and a valve 173. Seal 171 and valve 173 may be elastomeric members securely positioned between seat 158 of body 151 and proximal portion 163 of connector 161. Seal 171, which may be located proximally relative to valve 173, may include a central opening appropriately dimensioned so that, when visualization device 15 is inserted therethrough, fluid may not readily pass proximally through seal 171 around the outside of device 15. Valve 173, which may be shaped to include a dome having a cross-slit at its top, may be designed so that, in the absence of device 15 being inserted therethrough, fluid may not readily pass proximally therethrough.

[0065] The visualization guide assembly may further comprise a tube 181. Tube 181, which may be a flexible unitary member fabricated from a suitable polymer or other material, may comprise a proximal end 183, a distal end 185, and a lumen 186. Proximal end 183 may be fixedly mounted within distal portion 165 of connector 161 using a suitable

adhesive or the like. Distal end 185 of tube 181 may be tightly fitted within lumen 97 of sheath 91 and may be secured therewithin using a suitable adhesive or the like. Lumen 186 may be appropriately dimensioned so that the distal portion of visualization device 15 may be inserted thereinto and, in this manner, guided by tube 181 to lumen 97.

[0066] Introducer 13 may further comprise a mechanism for reversibly coupling visualization device 15 to the visualization guide assembly. This mechanism may comprise a cam lock 191. Lock 191, which may be fabricated from a rigid polymer or other suitable material, may be a unitary structure shaped to comprise a lever 192 and a fulcrum 193. The fulcrum 193 may be pivotally mounted on housing 21 using a pivot pin 194 inserted through a transverse opening 195 in fulcrum 193 and securely received at its opposite ends in openings 196 and 197 provided in left handle half 23 and right handle half 25, respectively. Fulcrum 193 may comprise a face 198 adapted to frictionally engage the proximal portion of device 15 when lever 192 is pivoted towards handle portion 29.

[0067] Introducer 13 may further comprise a tube 201. Tube 201, which may be fabricated from a suitable polymer or other material, may be a flexible unitary structure shaped to include a proximal end 203 and a distal end 205. Proximal end 203 may be secured to the distal end of a luer fitting 207 securely mounted within opening 35 of housing 21. Distal end 205 may be positioned within lumen 69 of manifold 45 and may be secured in place using an adhesive or other suitable means. As will be discussed further below, luer fitting 207 may be connected to the output of fluid supply device 17. In this manner, fluid dispensed through fitting 207 and into tube 201 may be conducted by tube 201 to manifold 45. Thereafter, the fluid in manifold 45 may flow distally through lumens 98-1 and 98-2 of sheath 91.

[0068] Referring back now to Figs. 1 and 2, visualization device 15, which may be, for example, a conventional flexible hysteroscope, may comprise a proximal portion 211 and a distal portion 213. Proximal portion 211, which may be comparatively rigid, compact in length, and wide in diameter, may comprise an input port 215, an output port 217, and a distal end 218. Distal portion 213, which may be comparatively flexible, elongated in length, and narrow in diameter, may comprise a distal end 219. Device 15 may be appropriately dimensioned so that distal end 218 of proximal portion 211 may be received in body 151,

with distal portion 213 extending distally through seal 171, valve 173, connector 161, tube 181 and lumen 97 and with distal end 219 positioned at or a short distance beyond distal end 93 of sheath 91. Although not present in the embodiment shown, proximal portion 211 of device 15 may be provided with notches or other physical features that may be used to mate with or otherwise engage cam lock 191. Distal end 219 of device 15 may be constructed to permit the viewing of objects at an angle, such as at a 15 degree angle, relative to the longitudinal axis of distal portion 213. In this manner, by placing device 15 in a particular angular orientation, device 15 may be used to view the operation of the distal end of tissue modifying device 15. Such an angular orientation may be ensured by orienting device 15 so that input port 215 is aligned with and extends through slot 33-1.

[0069] Fluid supply device 17 may comprise a fluid-containing syringe (or another suitable fluid-dispensing device) having an output end 221 that may be coupled to luer fitting 207. Fluid supply device 17 may comprise automated means (not shown) for dispensing fluid therefrom at a desired rate.

[0070] Tissue modifying device 19 may comprise a morcellator designed to remove fibroids, polyps, and other abnormalities from a uterus. Device 19 may be appropriately dimensioned to be received within the instrument channel of introducer 13, with the distal end 231 of device 19 inserted through lumen 96 of sheath 91 and extending distally beyond distal end 93 of sheath 91. Examples of morcellators suitable for use in the present invention are disclosed in, for example, U.S. Patent No. 7,226,459, inventors Cesarini et al., issued June 5, 2007; U.S. Patent No. 6,032,673, inventors Savage et al., issued March 7, 2000; U.S. Patent No. 5,730,752, inventors Alden et al., issued March 24, 1998; U.S. Patent Application Publication No. US 2006/0047185 A1, inventors Shener et al., published March 2, 2006; and PCT International Publication No. WO 99/11184, published March 11, 1999, all of which are incorporated herein by reference. An additional example of a morcellator suitable for use in the present invention is disclosed in U.S. Patent Application No. 12/098,250, inventors Gruber et al., filed on even date herewith, which application is incorporated herein by reference.

[0071] To prepare system 11 for use, distal end 219 of visualization device 15 may be inserted first through the visualization guide channel of introducer 13, next through

manifold 45, and then through lumen 97 of sheath 91. With device 15 thus inserted into introducer 13, cam lock 191 may be used to secure proximal portion 211 of device 15 to introducer 13. Input end 215 and output end 217 of device 15 may then be coupled to a light source and to a camera, respectively. If desired, the camera may be omitted, and output end 217 may be observed directly with the unaided eye. Fluid supply device 17 may then be coupled to luer fitting 207 of introducer 13. Distal end 93 of sheath 91 may then be inserted transcervically, i.e., through the vagina and the cervix, into the uterus of the patient. Prior to introducing distal end 93 of sheath 91 into the patient, the cervix may be gradually dilated in the conventional manner using obturators of increasing diameter. The uterus may then be washed of blood and other debris that may be present by dispensing fluid from fluid supply device 17 into introducer 13, which fluid may then exit introducer 13 distally through lumens 98-1 and 98-2. Valve 128 may be opened during this washing procedure so that fluid and any debris present in the uterus may exit the uterus proximally through lumen 96 of sheath 91 and, thereafter, may exit introducer 13 by passing proximally through tube 141, into main member 113 of sleeve 111, through side member 115 of sleeve 111, and through valve 128. When the washing procedure is complete, valve 128 may be closed while fluid may continue to be dispensed into the uterus through lumens 98-1 and 98-2, thereby causing the uterus to become distended by the fluid. When the uterus becomes sufficiently distended by such fluid, valve 128 may be opened while fluid may continue to be dispensed into the uterus. In this manner, the uterus may be maintained at a desired degree of distension while fluid is continuously circulated through the uterus. With the uterus thus distended with fluid, device 15 may be used to examine the interior of the uterus. If abnormalities are detected that one wishes to remove, such abnormalities may be removed by inserting tissue modifying device 19 distally through the instrument channel guide of introducer 13 and then through channel 96 of sheath 91 and then by resecting the abnormalities using device 19. When treatment is complete, device 19 may be withdrawn from introducer 13, and introducer 13 and device 15 may be withdrawn from the patient.

[0072] Although system 11 has been discussed above in connection with the diagnosis and/or treatment of the uterus of a female patient, it should be understood that

system 11 is not limited to such a use and may be used in the diagnosis and/or treatment of other anatomies that may be apparent to those of ordinary skill in the art.

[0073] Referring now to Figs. 10 through 12, there are shown various view of an alternate embodiment of an introducer device constructed according to the teachings of the present invention, the introducer device being represented generally by reference numeral 301.

[0074] Introducer device 301, which may be used, for example, with visualization device 15, fluid supply device 17 and tissue modifying device 19, may comprise a hub 303. Hub 303, which may be fabricated from a rigid polymer or other suitable material, may be shaped to comprise a proximal end 305, a distal end 307 and a side wall 309. Hub 303 may additionally be shaped to comprise a plurality of lumens of fixed shape and size, such lumens including a first lumen 311, a second lumen 313, and a third lumen 315. First lumen 311 and second lumen 313 may extend from proximal end 305 to distal end 307. Third lumen 315 may extend from side wall 309 to distal end 307, with third lumen 315 being positioned below first lumen 311 and with second lumen 313 being positioned to the side of first lumen 311 and third lumen 315. As will be discussed further below, first lumen 311 may be used as a scope lumen, second lumen 313 may be used as an instrument lumen, and third lumen 315 may be used as a fluid lumen.

[0075] Hub 303 may be further shaped to include a thumb ring 318 and a pair of finger rests 319-1 and 319-2 so that introducer device 301 may be operated using the thumb, forefinger and middle finger of one hand.

[0076] Device 301 may further comprise a first Touhy-Borst valve 321 and a second Touhy-Borst valve 323, the distal end of valve 321 being inserted into the proximal end of first lumen 311 and fixedly mounted therewithin, the distal end of valve 323 being inserted into the proximal end of second lumen 313 and fixedly mounted therewithin. Valve 321 may be appropriately dimensioned for visualization device 15, and valve 323 may be appropriately dimensioned for tissue modifying device 19.

[0077] Device 301 may further comprise a length of flexible tubing 331. Tubing 331, in turn, may comprise a proximal end 335 and a distal end 337. Proximal end 335 of tubing 331 may be fixed to the distal end of a luer-activated check valve 339, and distal end

337 of tubing 331 may be coupled to the proximal end of lumen 315. Valve 339 may be adapted for connection to fluid supply device 17 and may be constructed so as to permit fluid to flow through valve 339 only when connected to fluid supply device 17.

[0078] Device 301 may further comprise a flexible sheath 341. Sheath 341, which may be a unitary silicone extrusion or other suitable structure, may be shaped to include a right side 342 and a left side 343. Right side 342 and left side 343 may jointly define a proximal end 344, proximal end 344 being secured within distal end 307 of hub 303. Right side 342 may be shaped to include a distal end 345, a top longitudinal lumen 346 and a bottom longitudinal lumen 347. The proximal end of lumen 346 may be aligned with the distal end of lumen 311, and the proximal end of lumen 347 may be aligned with the distal end of lumen 315. Left side 343 may be shaped to include a distal end 348 and a longitudinal lumen 349. Distal end 348 of left side 343 may terminate a short distance proximal to distal end 345 of right side 342. The proximal end of lumen 349 may be aligned with the distal end of lumen 313.

[0079] Sheath 341 may be dimensioned to have an outer diameter of about 5.5 mm, with lumen 349 having a diameter of about 3 mm, lumen 346 having a diameter of about 2 mm, and lumen 347 having a diameter of about 1.33 mm. By thus dimensioning sheath 341, if sheath 341 is inserted through the cervix of a patient, the risk of injury to the patient and the need for anesthesia to be administered to the patient may be minimized. However, it should be understood that the above dimensions for sheath 341 are merely exemplary and may be varied depending upon how introducer 301 is to be used.

[0080] Device 301 may further comprise a sheath cap 351. Cap 351, which may be a rigid, unitary, transparent structure made of polycarbonate or a similarly suitable material, may be shaped to comprise a proximal end 353, a distal end 355, a top lumen 357 and a bottom lumen 359. Proximal end 353 may have a transverse profile similar to right side 342 and may be fixed to distal end 345 of right side 342, with top lumen 357 aligned with lumen 346 and with bottom lumen 359 aligned with lumen 347. The distal end of top lumen 357 may be sealed with a protective lens 360 to keep fluid and other matter from entering lumen 357 and from coming into contact with visualization device 15. As can be appreciated, instead of being mounted within cap 351, lens 360 could be integrally formed

with cap 351. In this manner, visualization device 15 may not need to be cleaned between uses. Distal end 355 may be shaped to include a deflector 361 for deflecting the flow of fluid from lumen 359 upwardly. In this manner, some of the deflected fluid may be used to wash lens 360, thereby keeping clear the field of view for device 15.

[0081] In use, distal end 219 of visualization device 15 may be inserted first through valve 321, next through lumen 311, and then into lumen 357 up to lens 360. Input end 215 and output end 217 of device 15 may then be coupled to a light source and to a camera, respectively. If desired, the camera may be omitted, and output end 217 may be observed directly with the unaided eye. Fluid supply device 17 may then be coupled to valve 339. Cap 351 and sheath 341 may then be inserted transcervically into the uterus of the patient. (Prior to introducing cap 351 and sheath 341 into the patient, the cervix may be gradually dilated in the conventional manner using obturators of increasing diameter.) The uterus may then be washed of blood and other debris that may be present by dispensing fluid from fluid supply device 17 into the uterus through lumen 359. Fluid and debris may exit the uterus by moving proximally through lumens 349 and 313 and valve 323. When the washing procedure is complete, additional fluid may be dispensed into the uterus through lumen 359 to cause the uterus to become distended. With the uterus thus distended with fluid, device 15 may be used to examine the interior of the uterus. If abnormalities are detected that one wishes to remove, such abnormalities may be removed by inserting tissue modifying device 19 distally first through valve 323, next through lumen 313, and then through lumen 349 and then by resecting the abnormalities using device 19. When treatment is complete, device 19 may be withdrawn from introducer 301, and introducer 301 and device 15 may be withdrawn from the patient.

[0082] Referring now to Figs. 13 through 15, there are shown various views of a further alternate embodiment of an introducer device constructed according to the teachings of the present invention, the introducer device being represented generally by reference numeral 401.

[0083] Introducer device 401, which may be used, for example, with visualization device 15, fluid supply device 17 and tissue modifying device 19, may comprise a flexible sheath 403. Sheath 403, which may be a unitary silicone extrusion or other suitable structure,

may be shaped to include a proximal end 405, a distal end 407 and a side wall 408. In addition, sheath 403 may further comprise a top longitudinal lumen 409, a middle longitudinal lumen 411, and a bottom longitudinal lumen 413. As will be discussed further below, top lumen 409 may receive device 15, middle lumen 411 may receive device 19, and bottom lumen 413 may be used as a fluid lumen. In order to minimize the diameter of sheath 401, lumen 411 may be molded in a collapsed state and may expand when device 19 is inserted thereinto.

[0084] Device 401 may further comprise a first Touhy-Borst valve 421. The distal end of valve 421 may be inserted into the proximal end of middle lumen 411 and may be fixedly mounted therewithin. Valve 421, which may be appropriately dimensioned to receive tissue modifying device 19, may include a cross-slit check valve 425 for preventing the proximal flow of fluid from a patient therethrough.

[0085] Device 401 may further comprise a second Touhy-Borst valve 423 and a length of tubing 427. Valve 423 may be appropriately dimensioned to receive visualization device 15. The proximal end of tubing 427 may be inserted into the distal end of valve 423 and may be fixedly mounted therewithin. The distal end of tubing 427 may be inserted through side wall 408 of sheath 401 and may be spliced into top lumen 409.

[0086] Device 401 may further comprise a length of flexible tubing 431. The distal end of tubing 431 may be inserted through side wall 408 of sheath 403 and may be spliced into bottom lumen 413. The proximal end of tubing 431 may be coupled to the distal end of a balloon-type pressure indicator 433, which may be designed to expand in response to elevated fluid pressure within the patient. Indicator 433 may, in turn, be coupled to the distal end of a luer-activated check valve 435.

[0087] Device 401 may further comprise a scope cap 451. Cap 451, which may be a rigid, unitary, transparent structure made of polycarbonate or a similarly suitable material, may be a tubular member shaped to comprise a proximal end 453, a distal end 455, and a lumen 457. Proximal end 453 of cap 451 may be fixed by an adhesive or other suitable means to distal end 407 of sheath 403, with lumen 457 aligned with top lumen 409 and similar in profile thereto. Distal end of lumen 457 may be sealed with a protective lens 460 to keep fluid and other matter from entering lumen 457 and from coming into contact with

visualization device 15. (As can be appreciated, instead of being mounted within cap 451, lens 460 could be integrally formed with cap 451. In addition, cap 451 and lens 460 could be reduced in size and mounted within the distal end of top lumen 409.)

[0088] Device 401 may be used in a fashion similar to that described above for device 301.

[0089] Referring now to Figs. 16 through 21, there are shown various views of a further alternate embodiment of an introducer device constructed according to the teachings of the present invention, the introducer device being represented generally by reference numeral 501.

[0090] Introducer device 501, which may be used, for example, with visualization device 15, fluid supply device 17 and tissue modifying device 19, may comprise a flexible sheath 503. In the present embodiment, sheath 503 may be transparent. Sheath 503, which may be a unitary polyurethane extrusion or other suitable structure, may be shaped to include a proximal end 505, a distal end 507 and a side wall 508. Side wall 508 may have a generally oval shape in transverse cross-section, with one side of side wall 508 being shaped to include a longitudinal groove 511. Sheath 503 may further comprise a top longitudinal lumen 513 and a bottom longitudinal lumen 515. As will be discussed further below, top lumen 513 may receive device 15, and bottom lumen 515 may be used as a fluid lumen.

[0091] Introducer device 501 may further comprise a first Touhy-Borst valve 521. Valve 521 may comprise a pair of pegs 523 and 525 extending distally from its distal end 527. Peg 523 may be fixedly mounted within top lumen 513 of sheath 503, and peg 525 may be fixedly mounted within bottom lumen 515 of sheath 503.

[0092] Device 501 may further comprise a second Touhy-Borst valve 531 and a length of tubing 533. Valve 531 may be appropriately dimensioned to receive visualization device 15. The proximal end of tubing 533 may be inserted into the distal end of valve 531 and may be fixedly mounted therewithin. The distal end of tubing 533 may be inserted through side wall 508 of sheath 503 and may be spliced into top lumen 513. A scope cover 535, which may be used to protect the proximal end of device 15, may be mounted at its distal end to valve 531. Cover 535, which may be made of a polyurethane film or other suitable material, may be packaged in a compact state (see Fig. 16) and may, thereafter, be

unrolled to an expanded state (see Fig. 21). In the present embodiment, cover 535 may be transparent.

[0093] Device 501 may further comprise a length of flexible tubing 541. The distal end of tubing 541 may be inserted through side wall 508 of sheath 503 and may be spliced into bottom lumen 515. The proximal end of tubing 541 may be coupled to the distal end of a balloon-type pressure indicator 543 (similar to indicator 433), which, in turn, may be coupled to the distal end of a luer-activated check valve 545.

[0094] Device 501 may further comprise a sheath cap 551. Cap 551, which may be a rigid, unitary, transparent structure made of polycarbonate or a similarly suitable material, may be shaped to comprise a proximal end 553, a distal end 555, a top lumen 557 and a bottom lumen 559. Proximal end 553 may have a transverse profile generally similar to sheath 503 (with cap 551 additionally being shaped to include protrusions 558-1 and 558-2) and may be fixed to distal end 507 of sheath 503 using a suitable adhesive (and, optionally, interlocking parts (not shown)), with top lumen 557 aligned with lumen 513 and with bottom lumen 559 aligned with lumen 515. The distal end of top lumen 557 may be sealed with a protective lens 560 to keep fluid and other matter from entering lumen 557. (As can be appreciated, instead of being mounted within cap 551, lens 560 could be integrally formed with cap 551.) Distal end 555 may be shaped to include a deflector 561 for deflecting the flow of fluid from lumen 559 upwardly to wash lens 560.

[0095] Device 501 may further comprise a stretchable sleeve 571. Sleeve 571, which may be made of a polyurethane film or a similarly suitable material, may comprise a proximal end and a distal end 575. The proximal end may be positioned proximate to the distal end of the opening in valve 521. Distal end 575 may be positioned between distal end 507 of sheath 503 and distal end of cap 551. The side wall 577 of sleeve 571 conforms generally to the shape of sheath 503; however, because of groove 511 and protrusions 512-1 and 512-2, an instrument lumen 581 is formed between sleeve 571 and sheath 503. Lumen 581 is aligned with the opening in valve 521 and may be used to receive tissue modifying device 19. Because sleeve 571 is stretchable, lumen 581 may expand to accommodate device 19.

[0096] Device 501 may be used in a fashion similar to that described above for device 301.

[0097] Alternate embodiments of a sheath cap that may be used in place of sheath cap 551 are shown in Figs. 22 and 23 and are represented generally by reference numerals 561 and 563, respectively.

[0098] Referring now to Figs. 24 through 27, there are shown various views of a further alternate embodiment of an introducer device constructed according to the teachings of the present invention, the introducer device being represented generally by reference numeral 601.

[0099] Introducer device 601, which may be used, for example, with visualization device 15, fluid supply device 17 and tissue modifying device 19, may comprise a hub 603. Hub 603, which may be fabricated from a rigid polymer or other suitable material, may be shaped to comprise a proximal end 605, a distal end 607 and a side wall 609. Hub 603 may additionally be shaped to comprise a plurality of lumens of fixed shape and size, such lumens including a first lumen 611, a second lumen 613, and a third lumen 615. First lumen 611, second lumen 613 and third lumen 615 may extend from proximal end 605 to distal end 607, with third lumen 615 being positioned below first lumen 611 and with second lumen 613 being positioned to the side of first lumen 611 and third lumen 615. As will be discussed further below, first lumen 611 may be used as a scope lumen, second lumen 613 may be used as an instrument lumen, and third lumen 615 may be used as a fluid lumen.

[0100] Device 601 may also include an elongated handle 617 having an end 618 secured to hub 603.

[0101] Device 601 may further comprise a first Touhy-Borst valve 621 and a second Touhy-Borst valve 623, the distal end of valve 621 being inserted into the proximal end of first lumen 611 and fixedly mounted therewithin, the distal end of valve 623 being inserted into the proximal end of second lumen 613 and fixedly mounted therewithin. Valve 621 may be appropriately dimensioned for visualization device 15, and valve 623 may be appropriately dimensioned for tissue modifying device 19.

[0102] Device 601 may further comprise a length of flexible tubing 631. Tubing 631, in turn, may comprise a proximal end 635 and a distal end 637. Proximal end 635 of

tubing 631 may be fixed to the distal end of a luer connector 639, and distal end 637 of tubing 631 may be coupled to the proximal end of lumen 615. Connector 639 may be adapted for connection to fluid supply device 17.

[0103] Device 601 may further comprise a flexible sheath 641. Sheath 641, which may be a unitary polyurethane extrusion or other suitable structure, may have the shape of an "8" and may comprise a top portion 643 having a longitudinal lumen 644 and a bottom portion 645 having a longitudinal lumen 646. Sheath 641 may be bifurcated at its proximal end, with the proximal end of top portion 643 being fixedly mounted within lumen 611 and with the proximal end of bottom portion 645 being fixedly mounted within lumen 615.

[0104] Device 601 may further comprise a flexible sleeve 651. Sleeve 651, which may be made of a polyurethane film or other suitable material, may be secured along one side thereof to sheath 641, with the proximal end 652 of sleeve 651 being coupled to lumen 613 with a tube 653. Sleeve 651 may include a lumen 656 adapted to receive device 19 or the like. Sleeve 651 may assume a collapsed state when unoccupied and an expanded state when occupied by device 19 or the like.

[0105] Device 601 may be used in a fashion similar to that described above for device 301.

[0106] Because lumen 644 of sheath 641 may have an open distal end, a hysteroscope or other visualization device 15 positioned within lumen 644 may be exposed to contaminants from a patient. To guard against the possibility of such contamination, it may be desirable to insert visualization device 15 in a protective device prior to its insertion into introducer 601. An example of such a protective device is shown in Fig. 28 and is represented generally by reference numeral 671. As can be seen, device 671 may comprise a tubular body conforming generally to the shape of a flexible hysteroscope. The tubular body, which may be made of polyurethane or a similar material, may include a proximal portion 673 of comparatively greater diameter and a distal portion 675 of comparatively lesser diameter. A seal or lens cover 677, which may be made of polycarbonate or a similar material, may be mounted at the distal end of distal portion 675.

[0107] Referring now to Figs. 29(a) and 29(b), there are shown side and fragmentary end views of a further alternate embodiment of an introducer device constructed according to the teachings of the present invention, the introducer device being represented generally by reference numeral 701.

[0108] Device 701 may comprise one or more sheets of a thin film that are welded or otherwise joined together to define a top lumen 703 and a bottom lumen 705. Top lumen 703 may be used to receive a scope within a sterile sleeve and may have diametrical clearance to permit the conduction of fluid, such as a saline flush, therethrough. Bottom lumen 705 may be used to receive an instrument, such as a morcellator. The film may have a thickness of less than about 0.0025 inch so that lumens 703 and 705 are easily collapsible when unoccupied. Top lumen 703 and bottom lumen 705 may be interconnected by a seam 707 extending from the distal ends 703-1 and 705-1 of lumens 703 and 705, respectively, to an intermediate point 709 distal to proximal ends 703-2 and 705-2 of lumens 703 and 705, respectively. Point 709 may be, for example, approximately 25 cm from distal ends 703-1 and 705-1. In this manner, device 701 may be shaped to include a unitary distal portion 711 and a bifurcated proximal portion 713. A stabilizer 715 may be inserted over bifurcated proximal portion 713. The overall height h_1 of device 701 at its distal end may be no greater than about 5.5 mm to minimize the risk of injury to the patient and the need for anesthesia.

[0109] Referring now to Fig. 30, there is shown an end view of a further alternate embodiment of an introducer device constructed according to the teachings of the present invention, the introducer device being represented generally by reference numeral 721.

[0110] Device 721 may comprise a unitary flexible sheath, which may be an extruded member made of a polymer or another suitable material. Device 721 may be shaped to include a top longitudinal lumen 723 and a bottom longitudinal lumen 725. Lumen 723 may have a relatively fixed size and shape and may be dimensioned to receive a centrally placed scope, as well as fluid delivery tubes on opposite sides of said scope. Lumen 725 may have an expandable size and shape and may be adapted to receive an instrument, such as a morcellator. When lumens 723 and 725 are unoccupied, device 721 may have a diameter of about 3 mm, and lumen 723 may have a diameter of about 1.5 mm.

[0111] Referring now to Fig. 31, there is shown a partly schematic, perspective view of a further alternate embodiment of an introducer device constructed according to the teachings of the present invention, the introducer device being represented generally by reference numeral 751.

[0112] Device 751, which may be used in hysteroscopic examinations, may comprise a flexible sheath 753. Sheath 753, which may be a unitary extruded member or other suitable structure, may be shaped to include a first longitudinal lumen 755, a second longitudinal lumen 757, and a third longitudinal lumen 759. Lumen 755 may be adapted to serve as a scope channel, lumen 757 may be adapted to serve as fluid delivery channel, and lumen 759 may be adapted to serve as a fluid removal channel.

[0113] Device 751 may further comprise a length of tubing 761 and a valve 763. The distal end of tubing 761 may be inserted into the proximal end of lumen 759 and may be fixed therewithin. The proximal end of tubing 761 may be coupled to an inlet of valve 763. Valve 763 may be a pressure-actuated valve that is constructed so that fluid from tubing 761 will flow therethrough only when a threshold fluid pressure within the patient has been reached. In this manner, the outflow of fluid from the patient and, hence, the fluid pressure within the patient and the degree of uterine distension may be regulated. Fluid pressures of 30 mmHg to 100 mmHg are commonly used to distend the uterus during hysteroscopic gynecology exams. Therefore, valve 763 may be designed for a pressure somewhere in this range. Valve 763 may be a passively-controlled valve, such as a duckbill valve or a ball valve, or may be a valve whose actuating threshold pressure is adjustable.

[0114] Because device 751 is designed specifically solely for observation and does not include a dedicated instrument channel, device 751 may have a sufficiently small transverse cross-sectional profile to permit its insertion into a patient without requiring anesthesia.

[0115] In many of the devices described above, a conventional flexible hysteroscope may be used for observation. Such a hysteroscope typically includes a plurality of light delivery fibers surrounding one or more optic fibers. When using such a hysteroscope in devices like device 301, which may include a lens cap at the distal end of the observation lumen, there may be some undesired reflection of the illuminating light off the

lens cap towards the optic fibers. Several of the embodiments discussed below may ameliorate this phenomenon by removing the light delivery fibers from the observation lumen with its lens cap and, instead, positioning these fibers in a separate lumen.

[0116] Referring now to Fig. 32, there is shown a distal end view of one such embodiment of an introducer device constructed according to the above-described precepts, the introducer device being represented generally by reference numeral 801.

[0117] Device 801 may comprise a unitary flexible sheath 803, which may be an extruded member made of a polymer or another suitable material. Sheath 803, which may have a "tear-drop"-shape in transverse cross-section, may be shaped to include an observation lumen 805, a pair of fluid delivery lumens 806-1 and 806-2, a pair of light delivery lumens 807-1 and 807-2, and an instrument lumen 809. As can be appreciated, the sizes, shapes and relative locations of lumens 805, 806-1 and 806, 807-1 and 807-2, and 809 may be modified as desired. In addition, the transverse cross-section of sheath 803 may be modified as desired.

[0118] Device 801 may additionally comprise a transparent lens cap 811, which may be mounted at the distal end of observation lumen 805 to provide a fluid seal to protect the optic fibers (not shown) disposed within lumen 805.

[0119] Device 801 may further comprise a first light fiber bundle 813 fixedly mounted within light delivery lumen 807-1 and a second light fiber bundle 813 fixedly mounted within light delivery lumen 807-2. The distal ends of bundles 813 may lie flush with the distal end 815 of sheath 803, and the proximal ends of bundles 813 may be coupled to a light source (not shown).

[0120] As can be appreciated, because light fiber bundles 813 are not positioned within observation lumen 805, the above-described phenomenon of reflection off lens cap 811 is amerliorated.

[0121] Referring now to Fig. 33, there is shown a fragmentary longitudinal section view of the distal end of an alternate embodiment of an introducer device constructed in accordance with the teachings of the present invention, the introducer device being represented generally by reference numeral 851.

[0122] Device 851, which may be used for hysteroscopic examinations, may comprise an elongated tube 853, which may be made of stainless steel or a similarly suitable material. A light fiber bundle 855 may be fixedly mounted within tube 853. (For simplicity, the individual fibers of bundle 855 are not shown in Fig. 33.) Bundle 855 may comprise a distal end 857 extending distally a short distance from tube 853. End 857 may be rounded to facilitate its insertion through the cervix of a patient. (End 857 may alternatively be shaped to other desired geometries.) Bundle 855 may further comprise a central lumen 859 extending longitudinally from distal end 857. An optic fiber 861, which may be encapsulated within in a protective cover 862 having a lens cap 863 at its distal end, may be positioned within lumen 859. An annular space 865 may be formed between bundle 855 and cover 862, with space 865 being adapted for fluid inflow to a patient. A tube 866, which may be made of plastic or another suitable material, may be inserted coaxially around tube 853, with an annular space 867 being formed between tube 866 and tube 853, space 867 being adapted for fluid outflow. Side holes 869 may be provided in tube 866 near its distal end 871 for passage of fluid outflow therethrough in the event that the distal end of space 867 becomes clogged.

[0123] Referring now to Fig. 34, there is shown a fragmentary side view, partly in section, of an alternate embodiment of an introducer device constructed in accordance with the teachings of the present invention, the introducer device being represented generally by reference numeral 901.

[0124] Device 901, which may be used for hysteroscopic examinations, may comprise an elongated rigid outer tube 903. Tube 903 may comprise an open proximal end 905, an open distal end 907, a side wall 909, and a longitudinal lumen 911. Distal end 907 may be reduced in diameter relative to proximal end 905. Side wall 909 may be shaped to include a first port 913 and a second port 915, first port 913 being located proximally relative to second port 915. Side wall 909 may also be shaped to include a plurality of transverse openings 917 located proximate to distal end 907.

[0125] Device 901 may further comprise an elongated rigid inner tube 921. Tube 921 may comprise an open proximal end 923, an open distal end 925, a side wall 927, and a longitudinal lumen 929. Proximal end 923 may be outwardly flared relative to the remainder of tube 921 and may be fixed to the interior surface of wall 909 of tube 903 at a location

between first port 913 and second port 915. Distal end 925 of tube may be fixed to distal end 907 of tube 921. In this manner, first port 913 may be used for fluid inflow, which may then pass distally through tube 921, whereas second port 915 may be used for fluid outflow that has entered tube 903 through openings 917. The distal end 931 of a scope 933 may be passed through open proximal end 905 of tube 903 and then through lumen 929.

[0126] The embodiments of the present invention described above are intended to be merely exemplary and those skilled in the art shall be able to make numerous variations and modifications to it without departing from the spirit of the present invention. All such variations and modifications are intended to be within the scope of the present invention as defined in the appended claims.

WHAT IS CLAIMED IS:

1. A surgical access device for providing at least one auxiliary lumen for the insertion of a surgical instrument or other therapeutic device into a patients body, said surgical access device comprising:

a first channel providing a first lumen for the insertion of a surgical instrument with a rigid shaft;

a second channel providing a second lumen for the insertion of a flexible or semi-rigid visualization device; and

at least one other lumen for the installation of a distension media.

2. An access device as in Claim 1 wherein a distal tip comprises a flexible bumper tip to enable easy passage through a cervical os.

3. An access device as in Claim 1 wherein the visualization device comprises independent members for visualization and illumination.

4. An access device as in Claim 1 wherein the instrument channel is capable of sealing on an inserted instrument when inserted or providing an outflow channel without the instrument inserted.

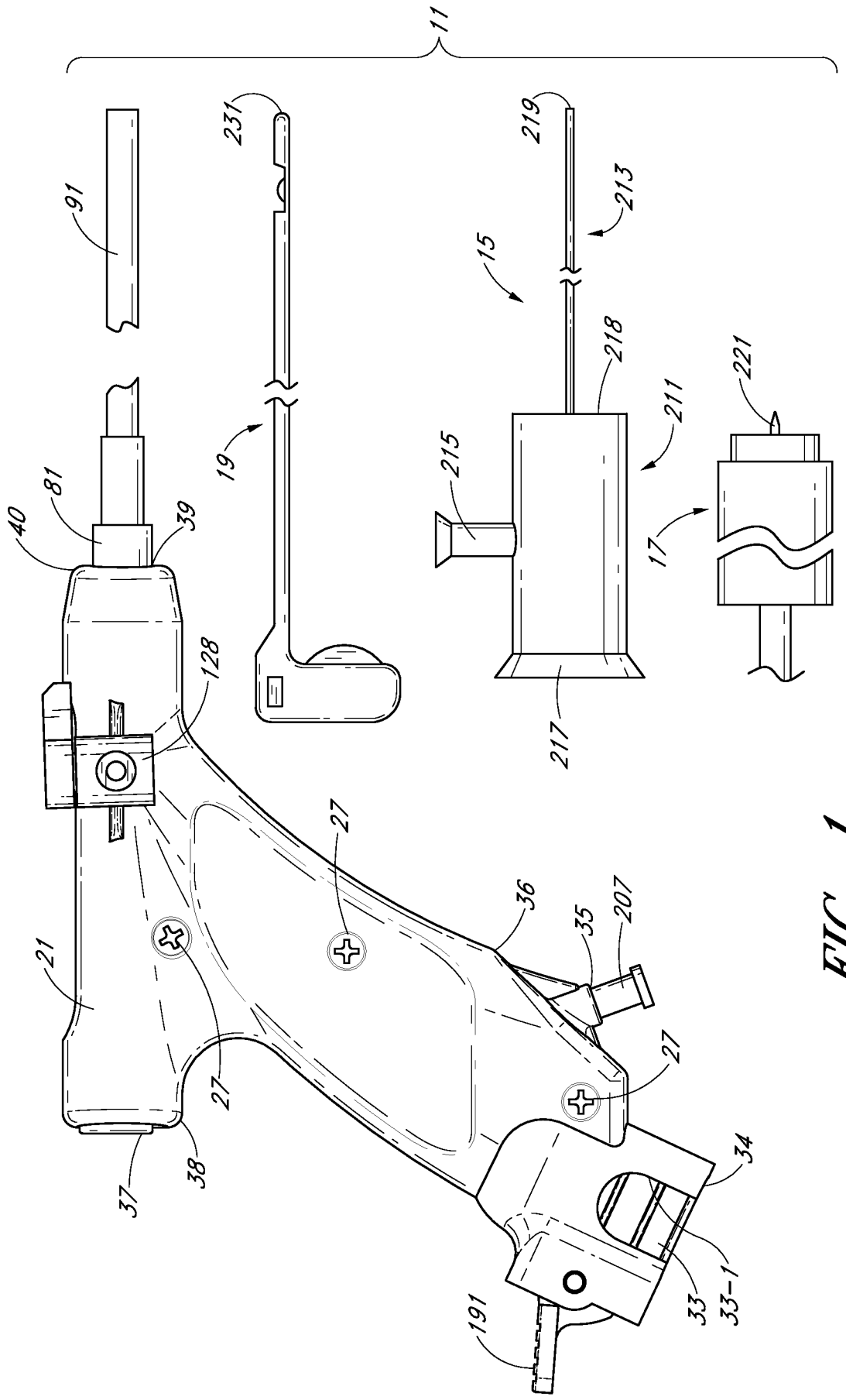
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FIG. 1

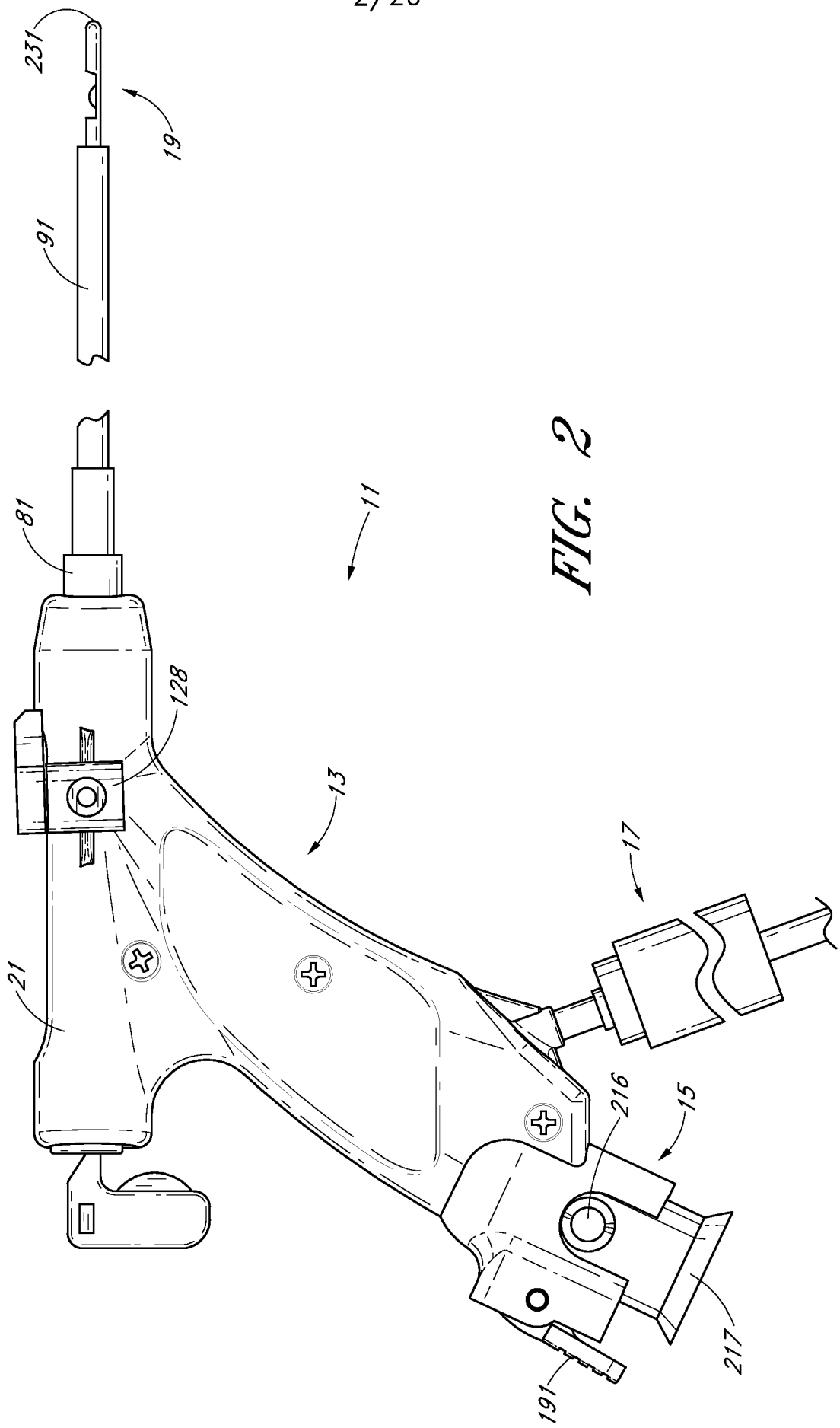

FIG. 2

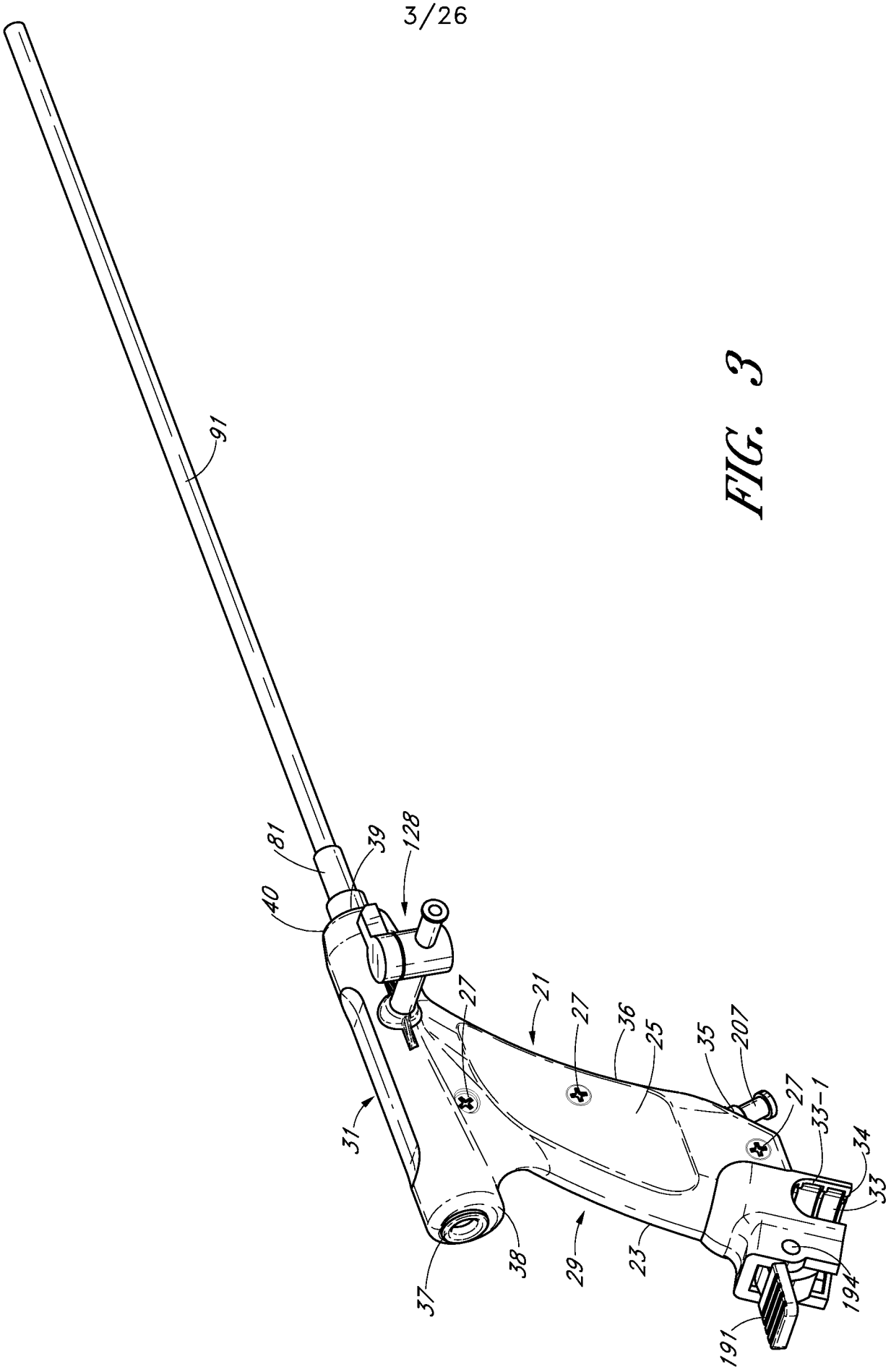
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FIG. 3

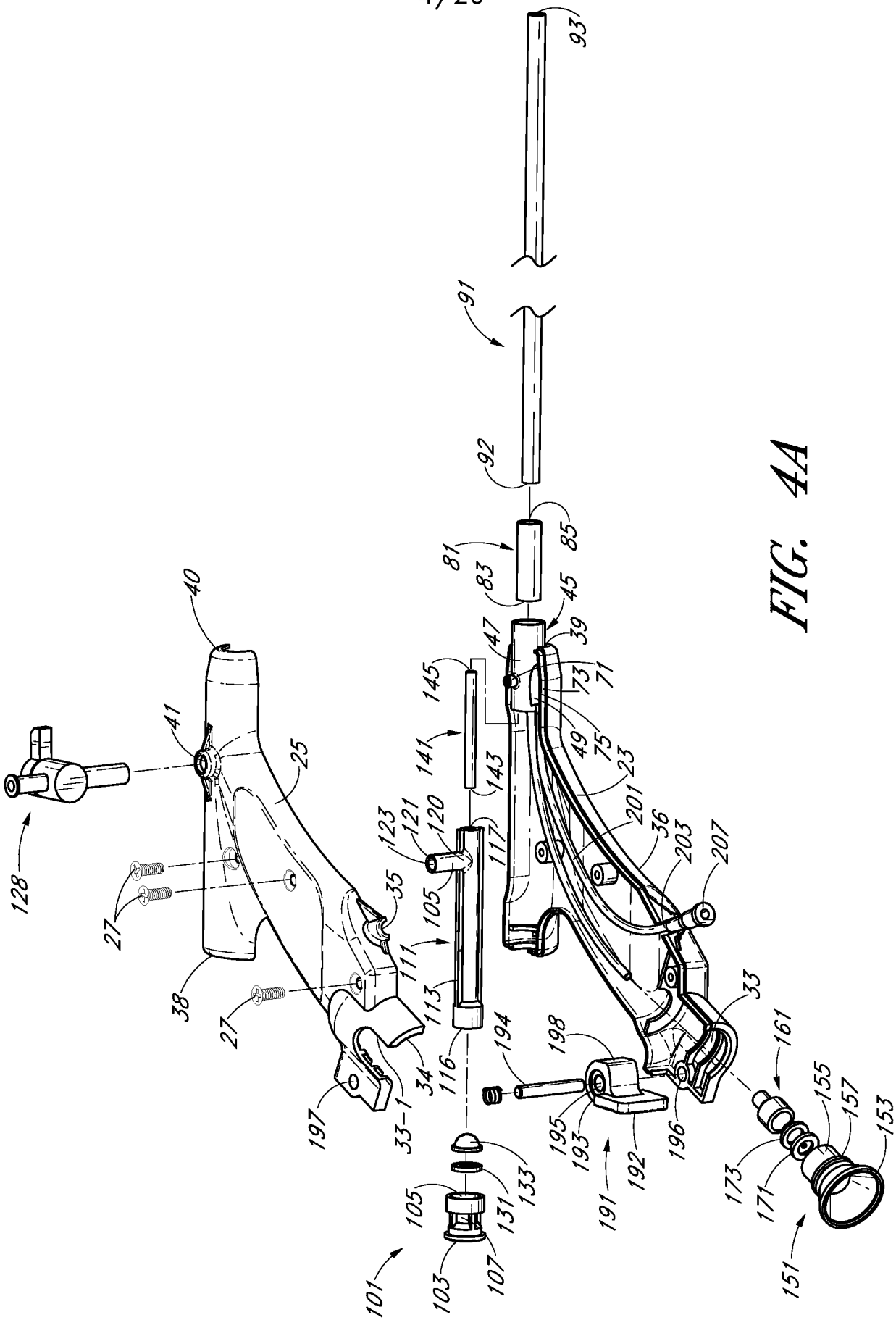
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FIG. 4A

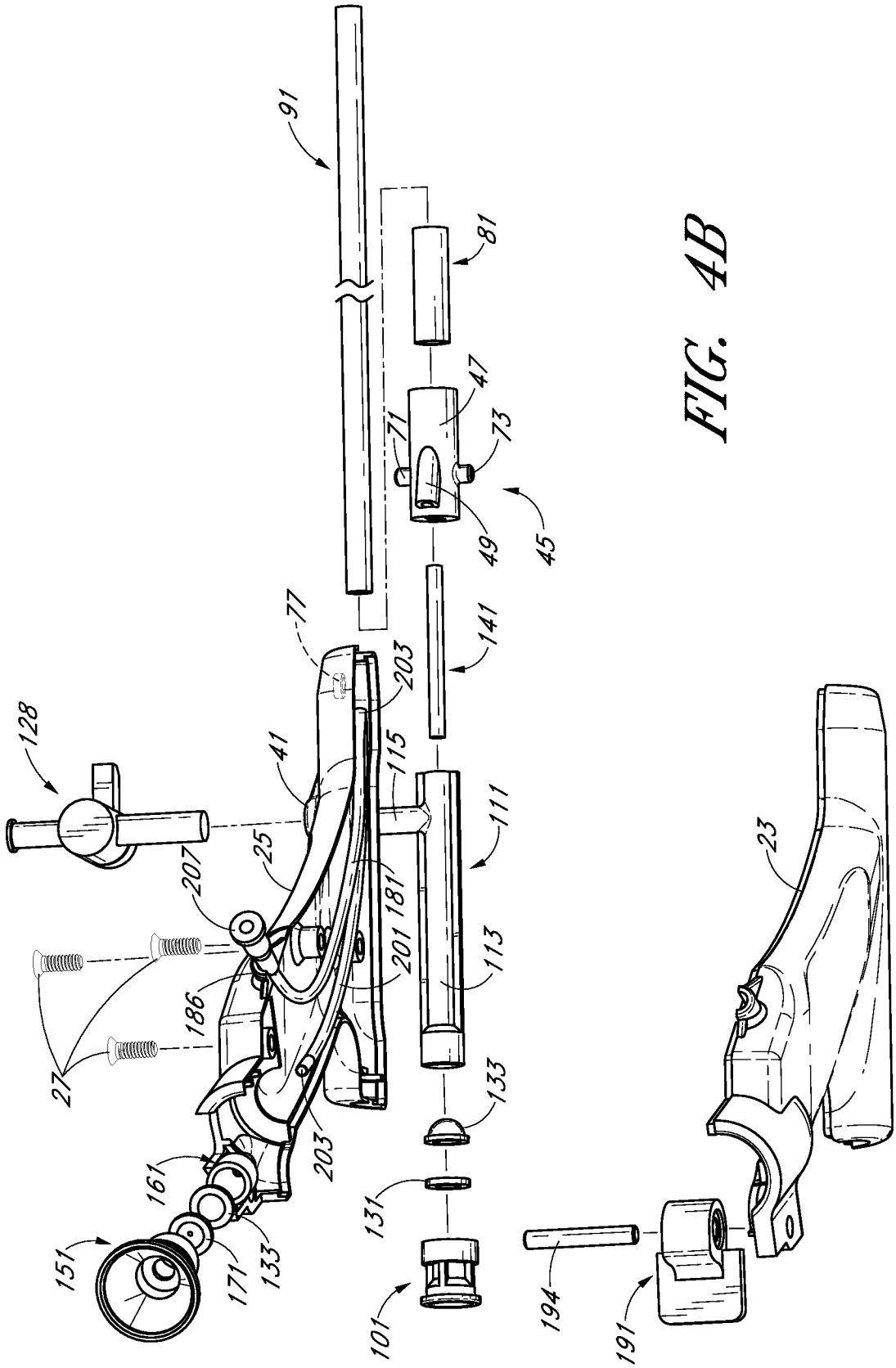
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FIG. 4B

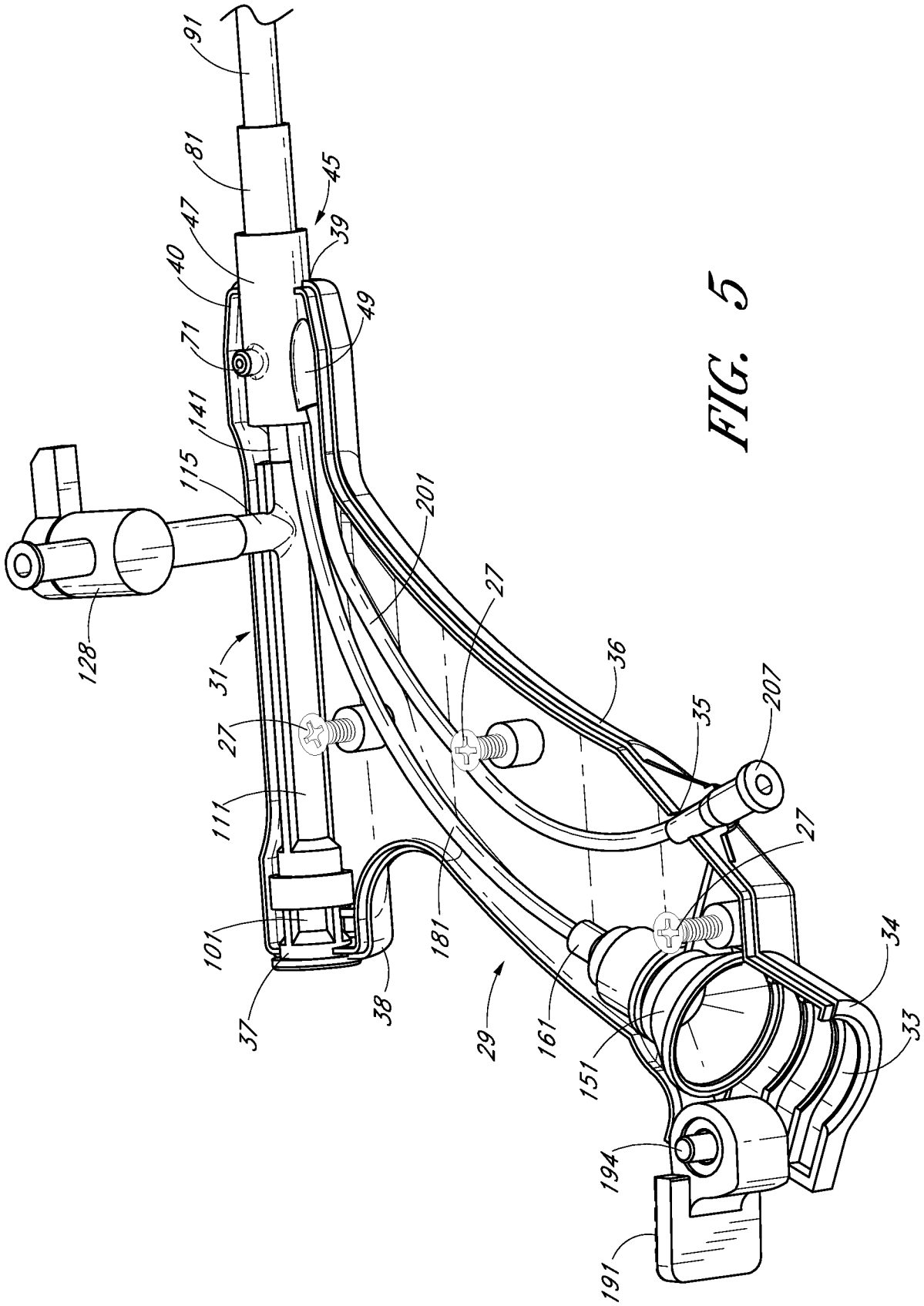
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FIG. 5

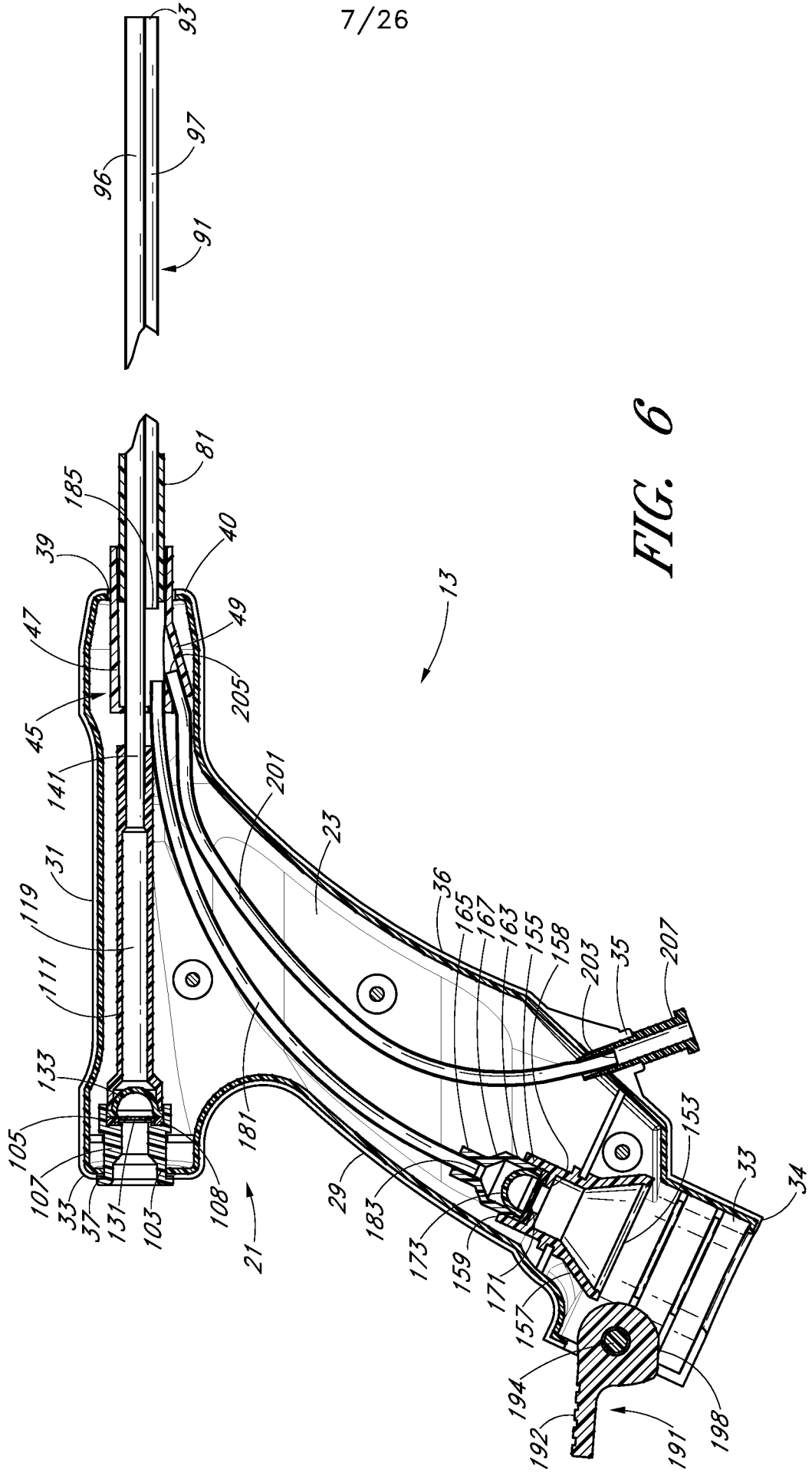
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FIG. 6

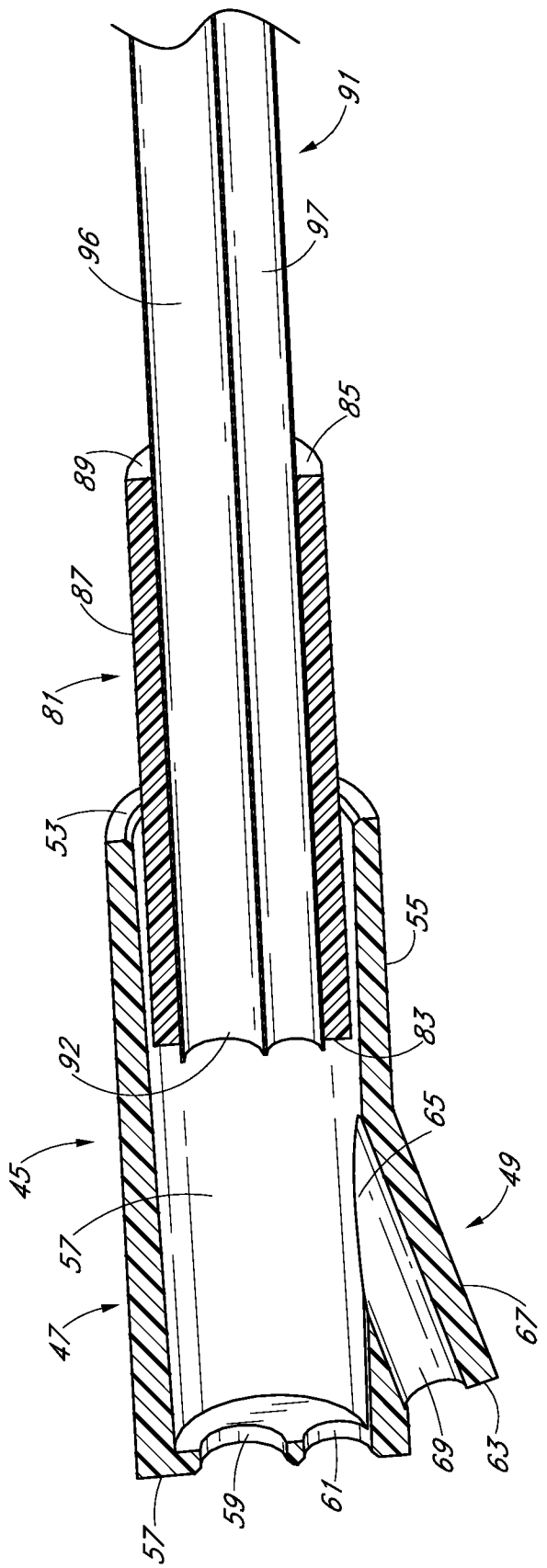

FIG. 7

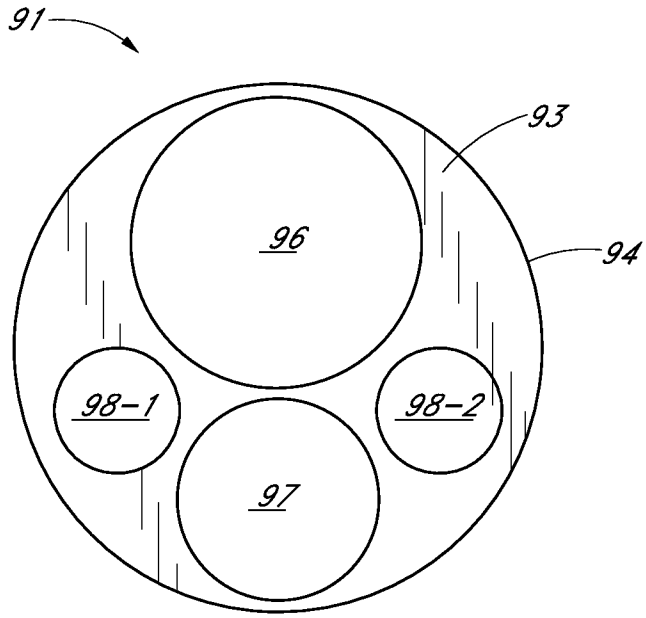

FIG. 8

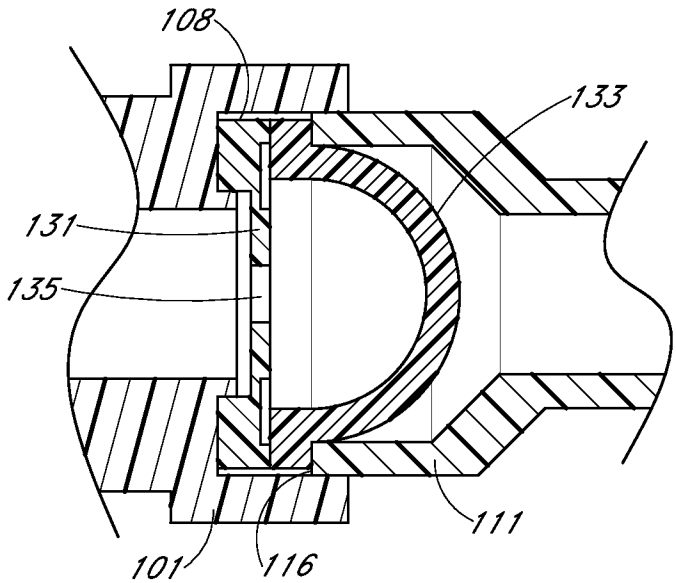

FIG. 9

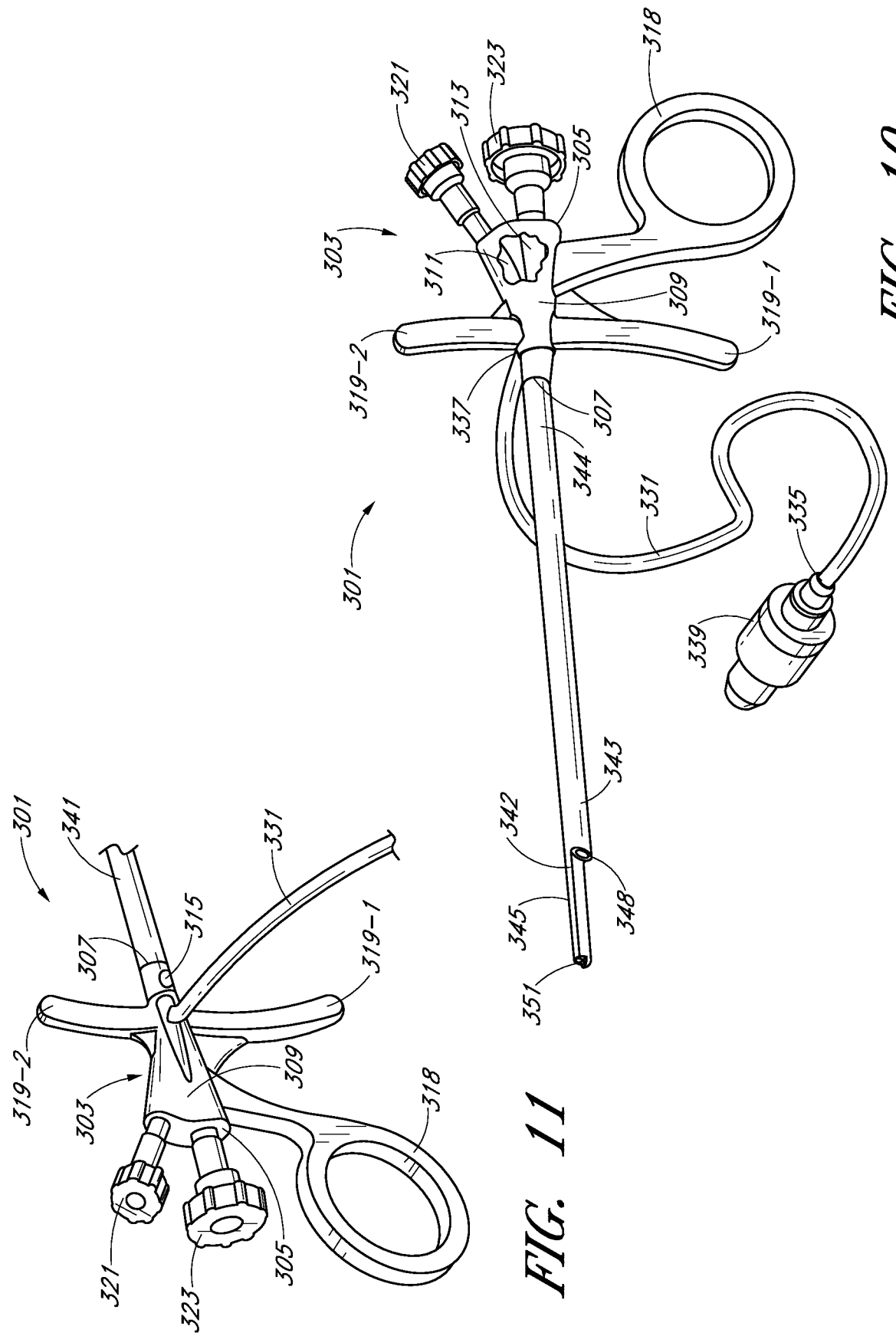
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FIG. 11

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FIG. 10

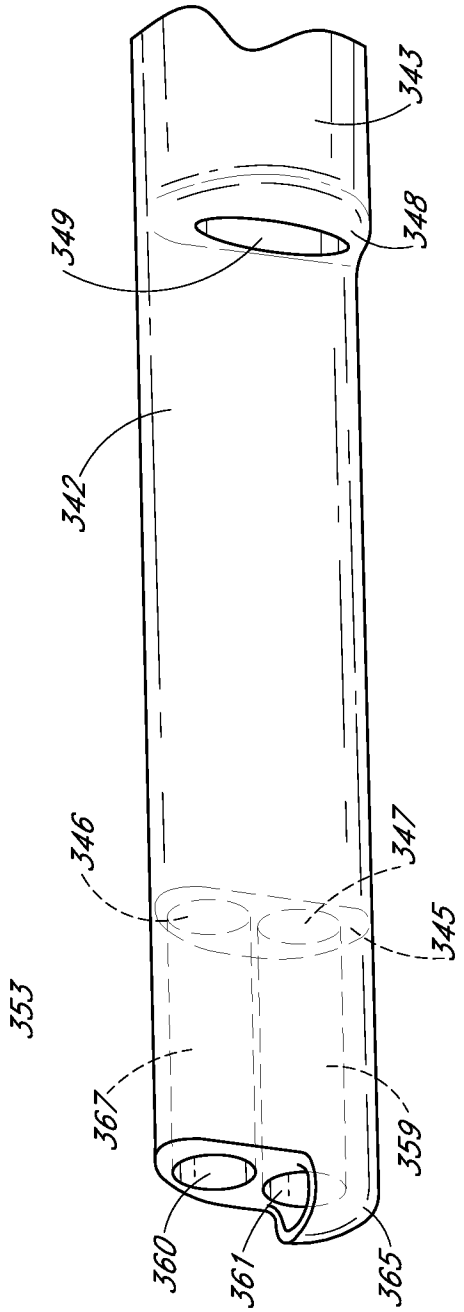

FIG. 12

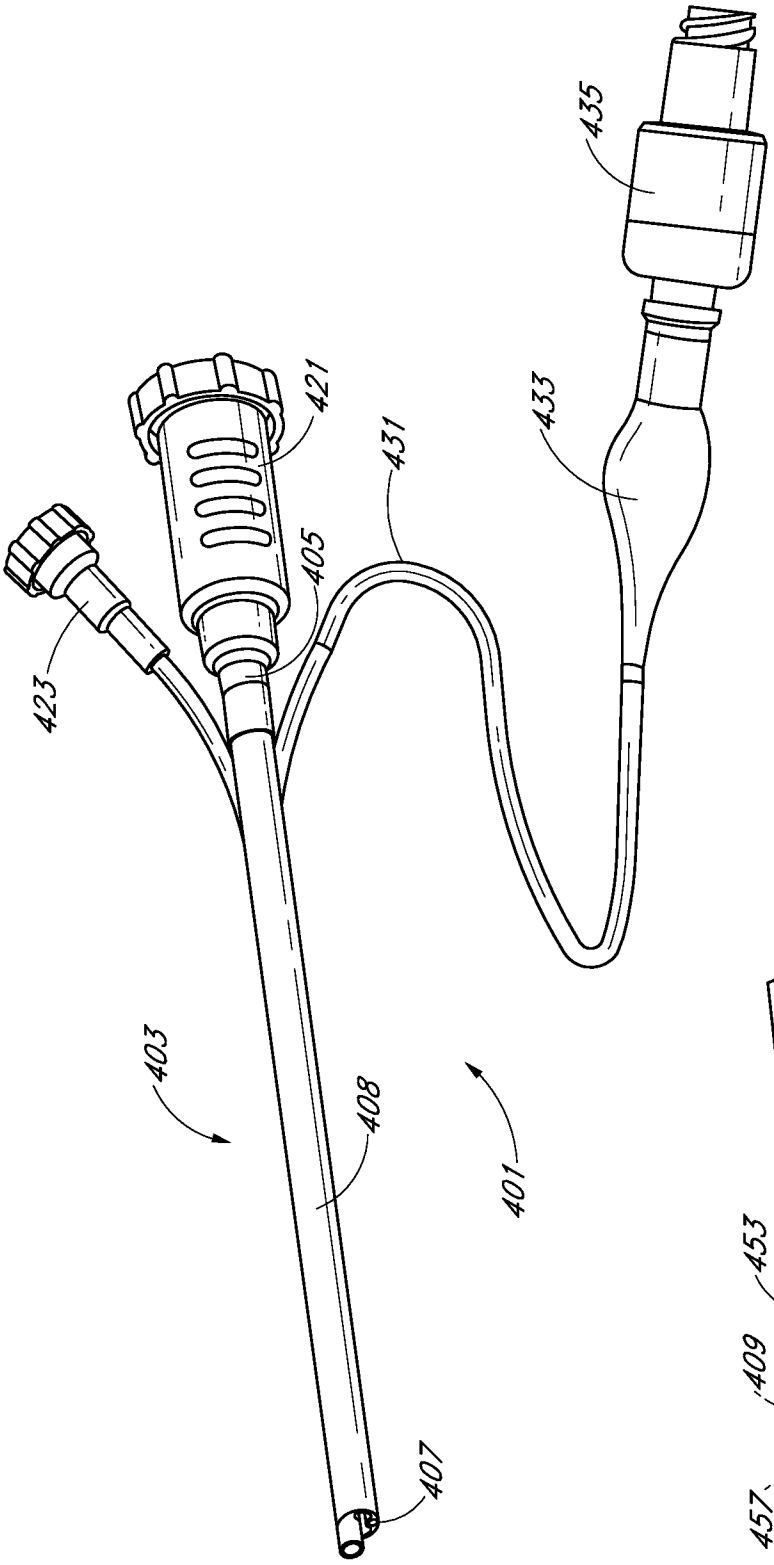
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FIG. 13

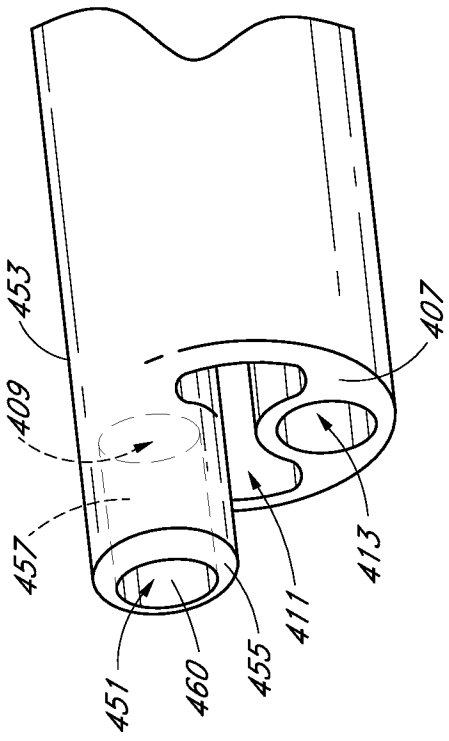
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FIG. 14

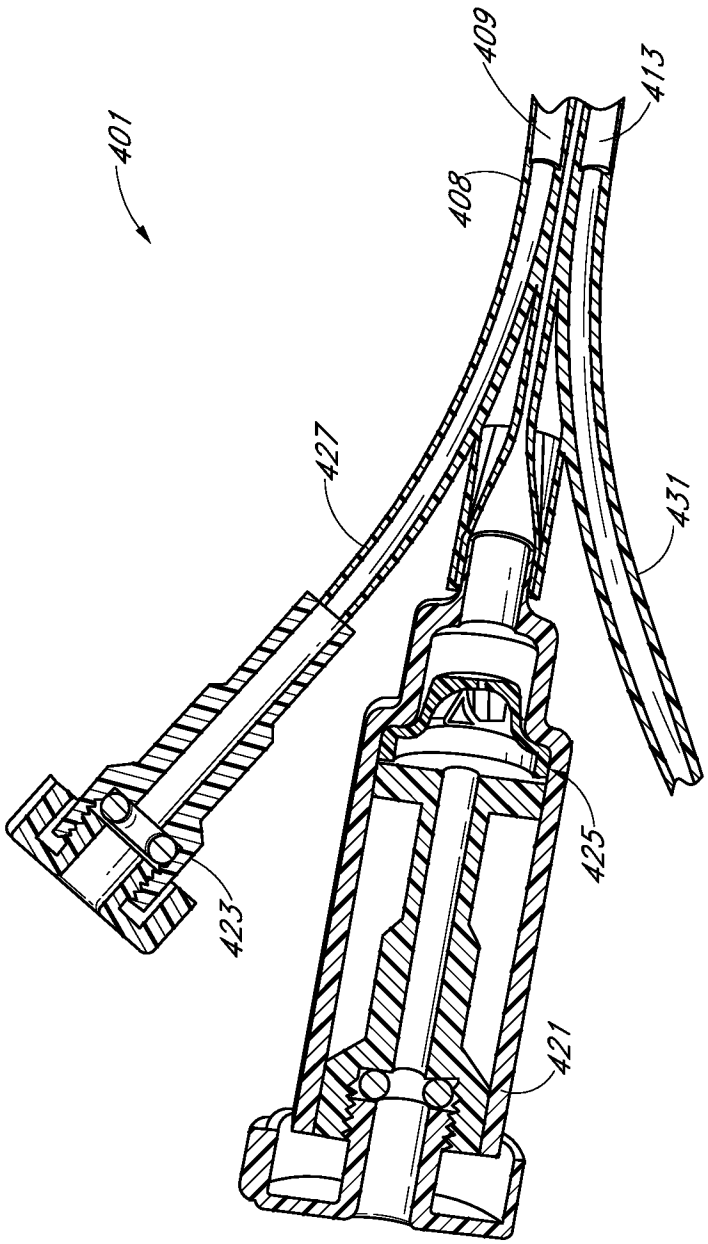

FIG. 15

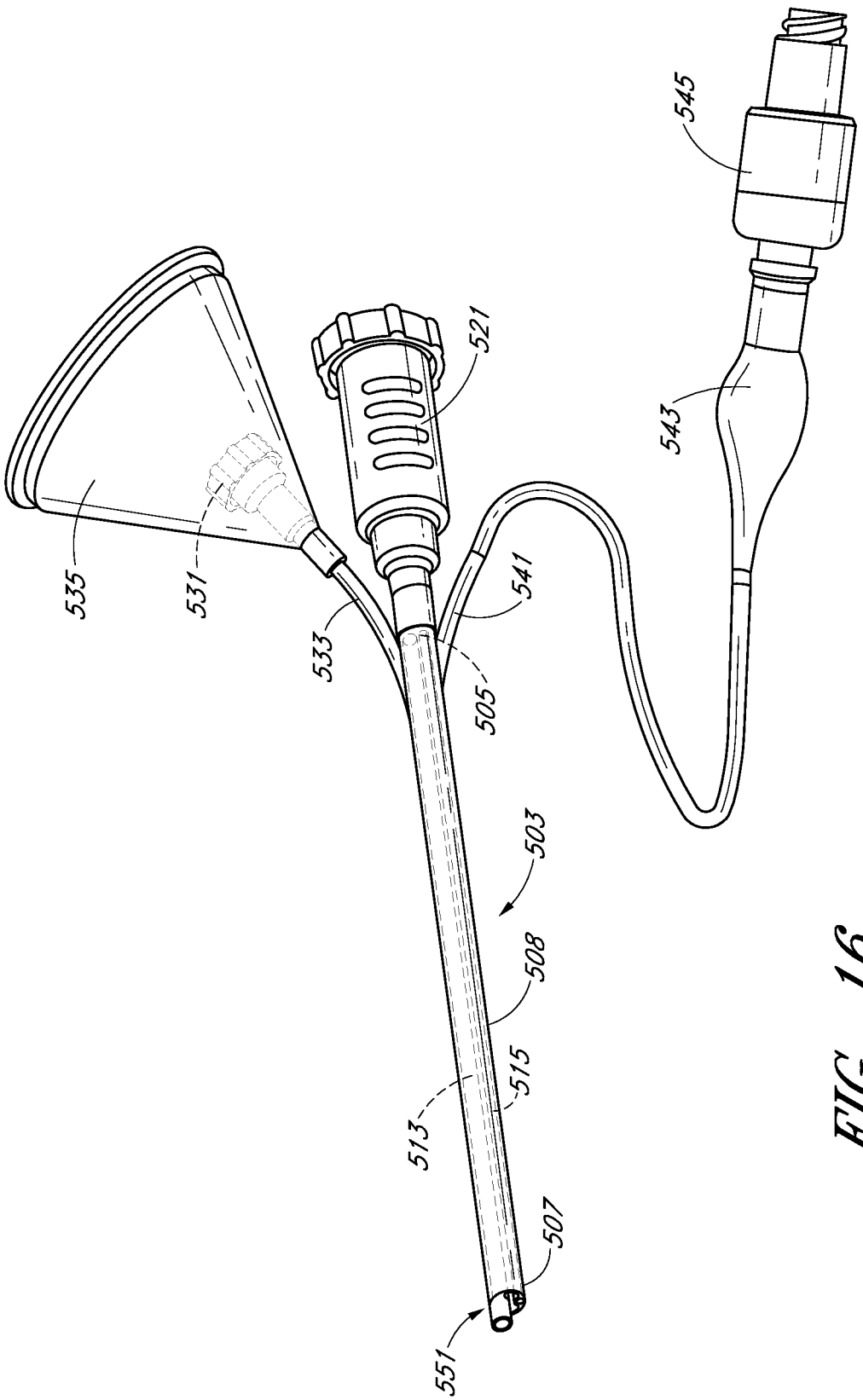

FIG. 16

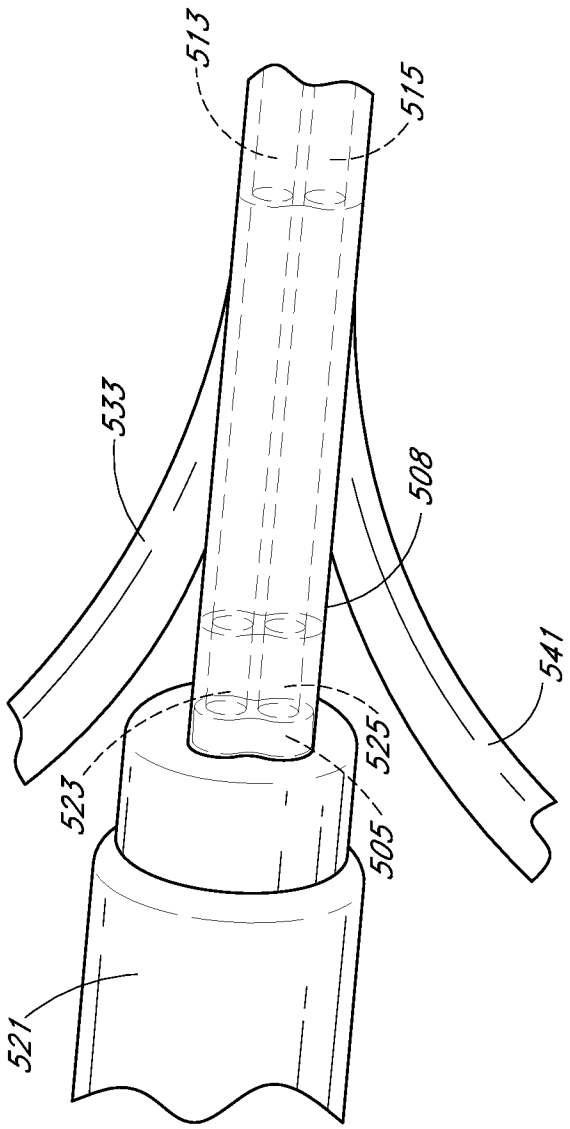

FIG. 17

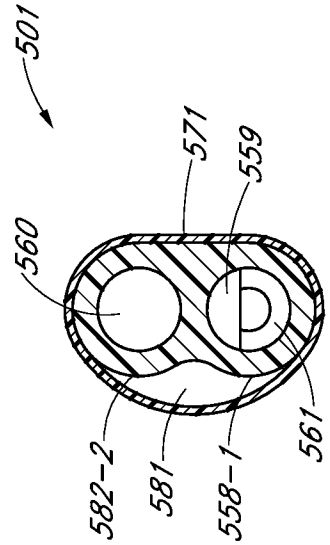

FIG. 20

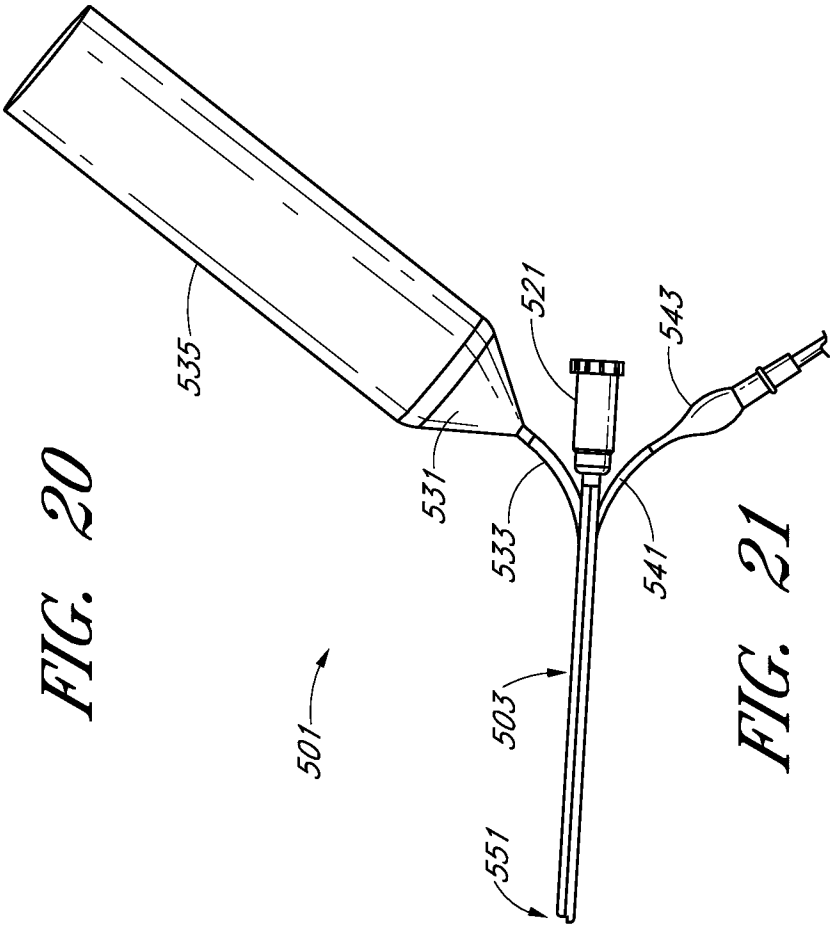

FIG. 21

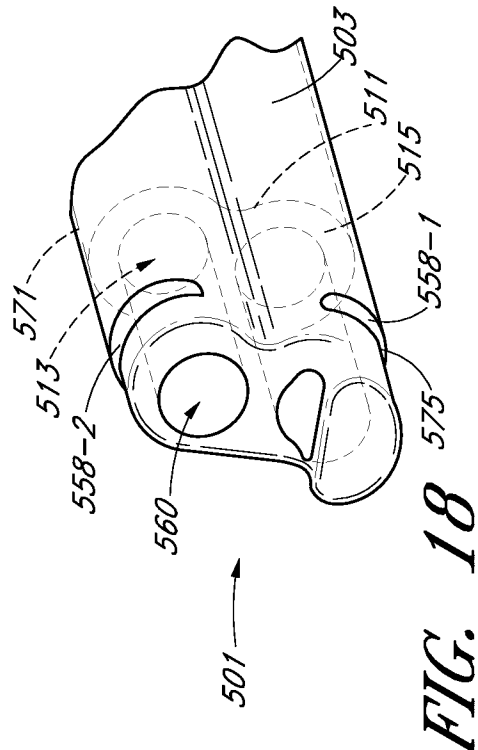

FIG. 18

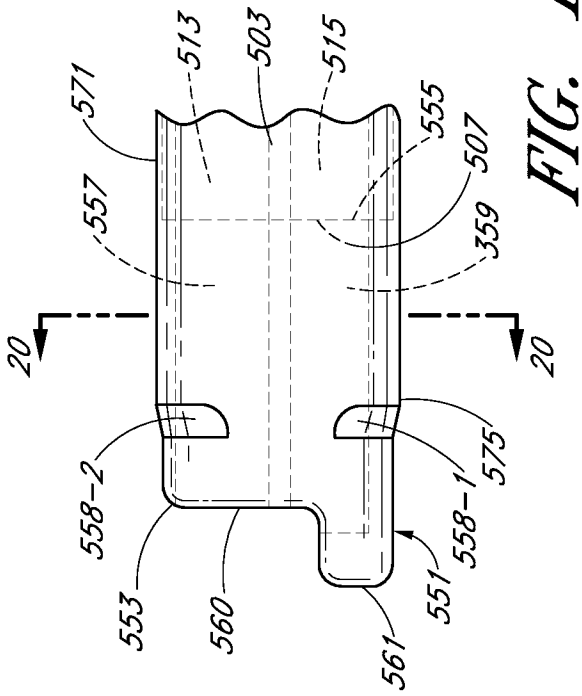

FIG. 19

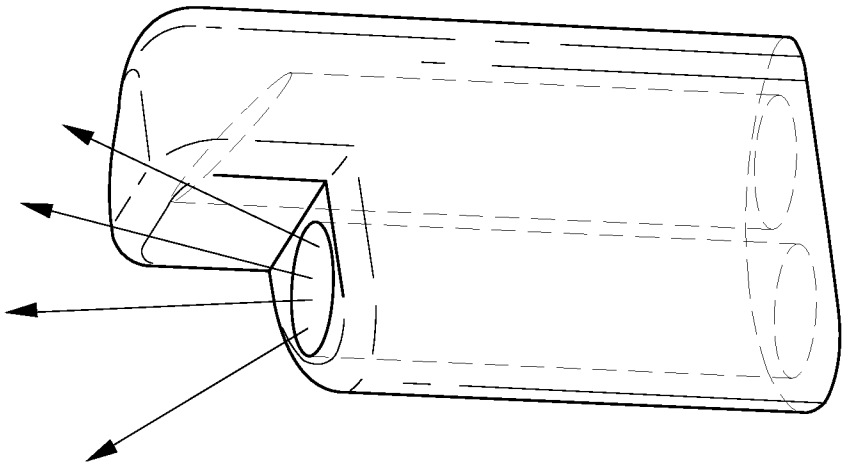

FIG. 23

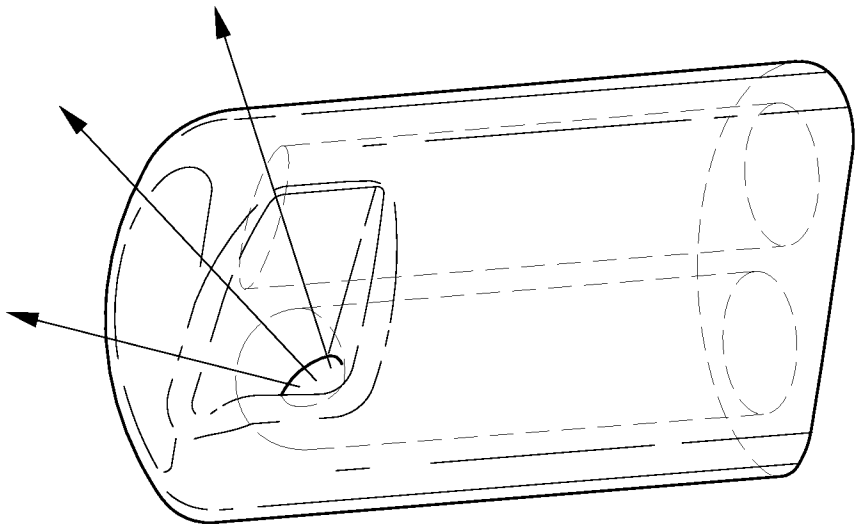

FIG. 22

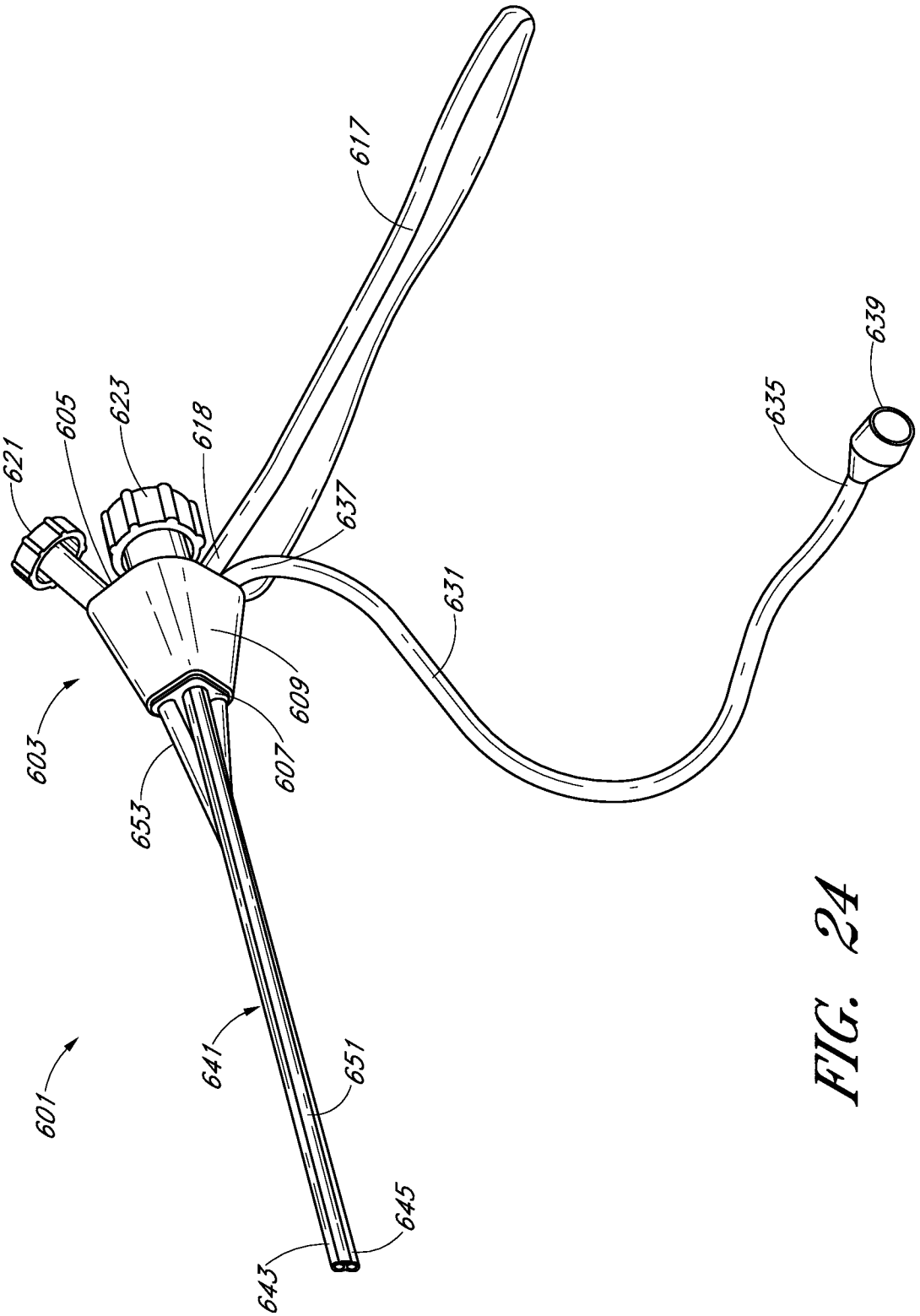
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FIG. 24

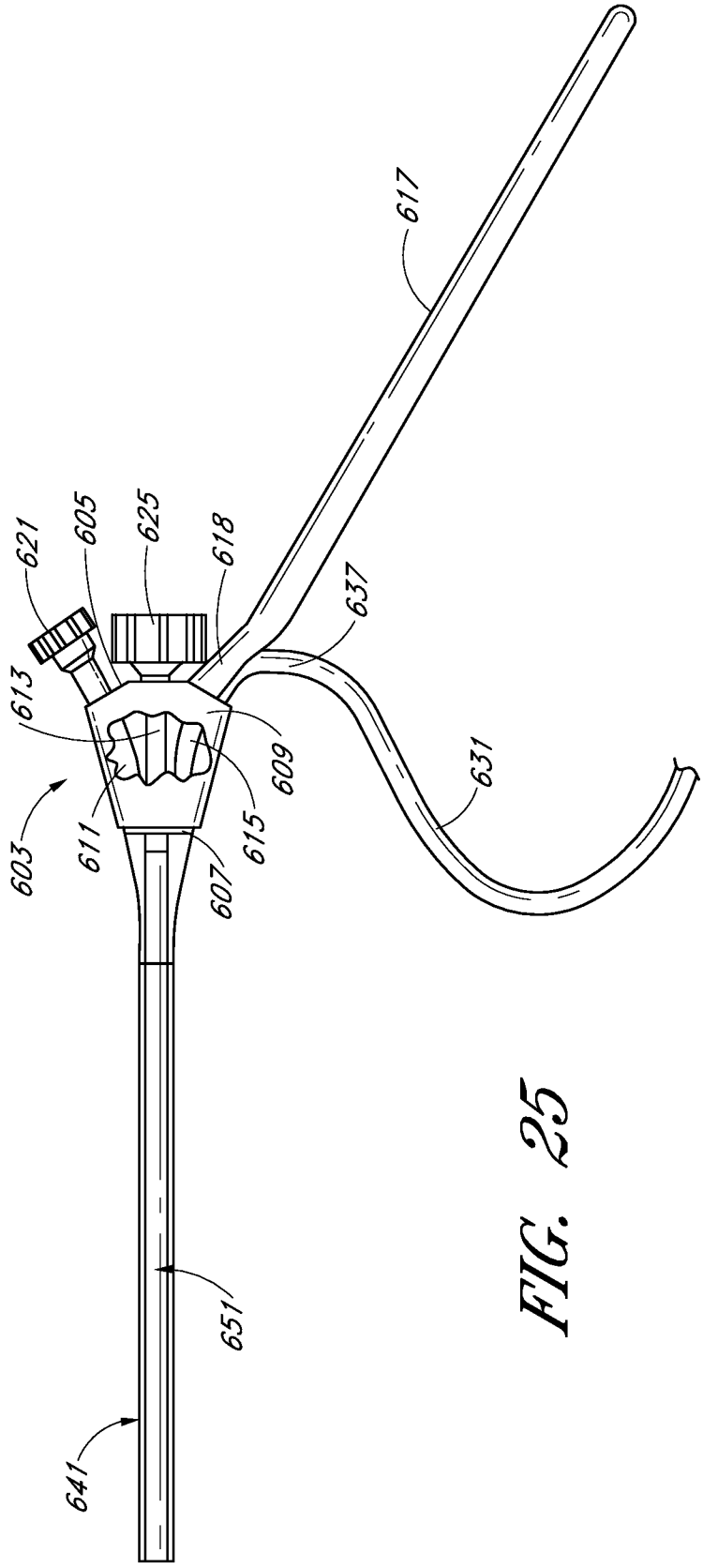
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FIG. 25

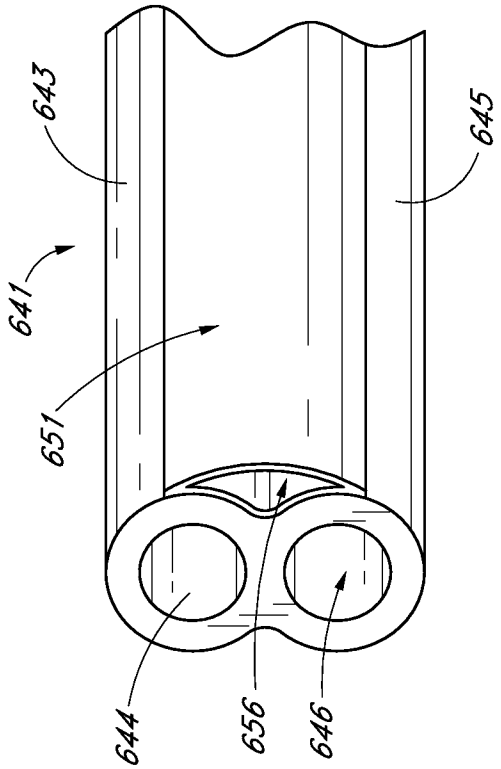
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FIG. 26

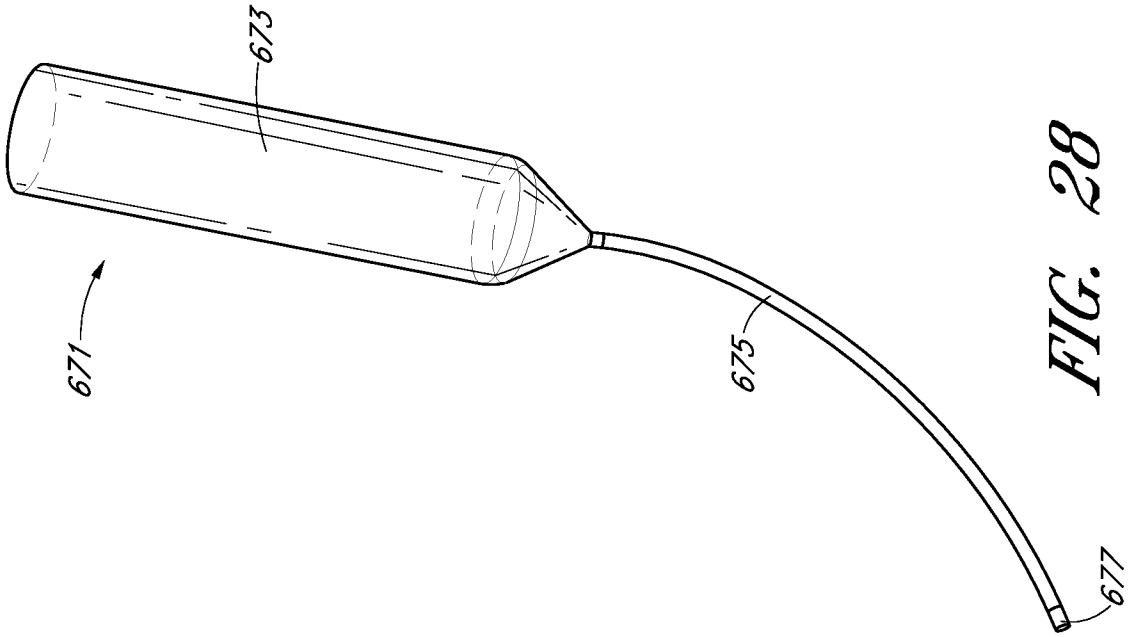
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FIG. 28

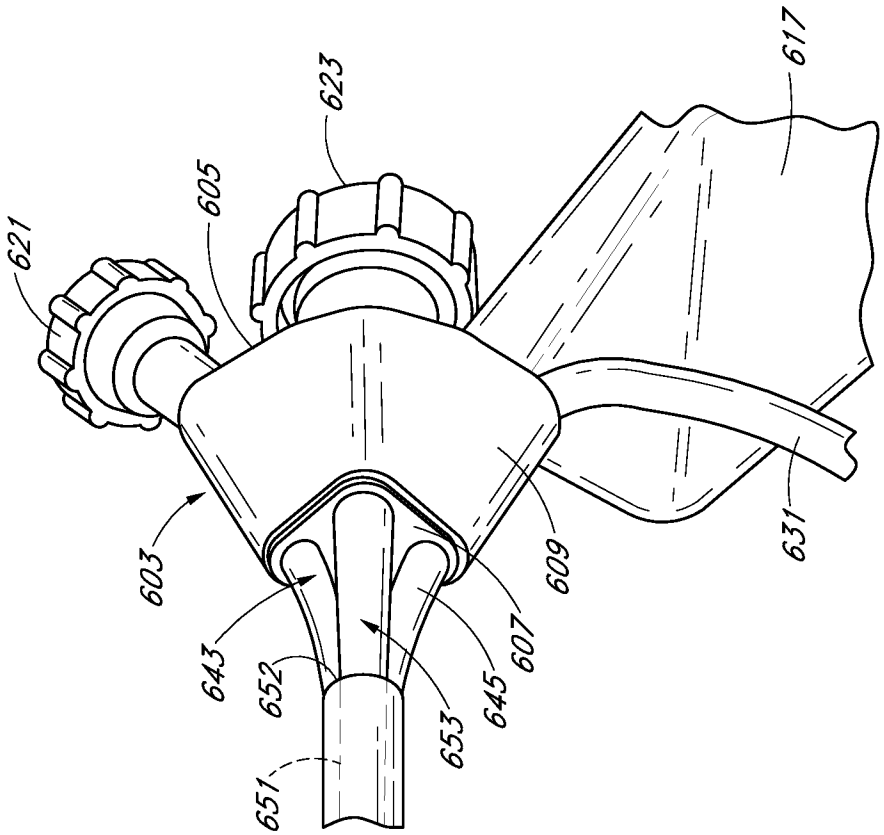
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FIG. 27

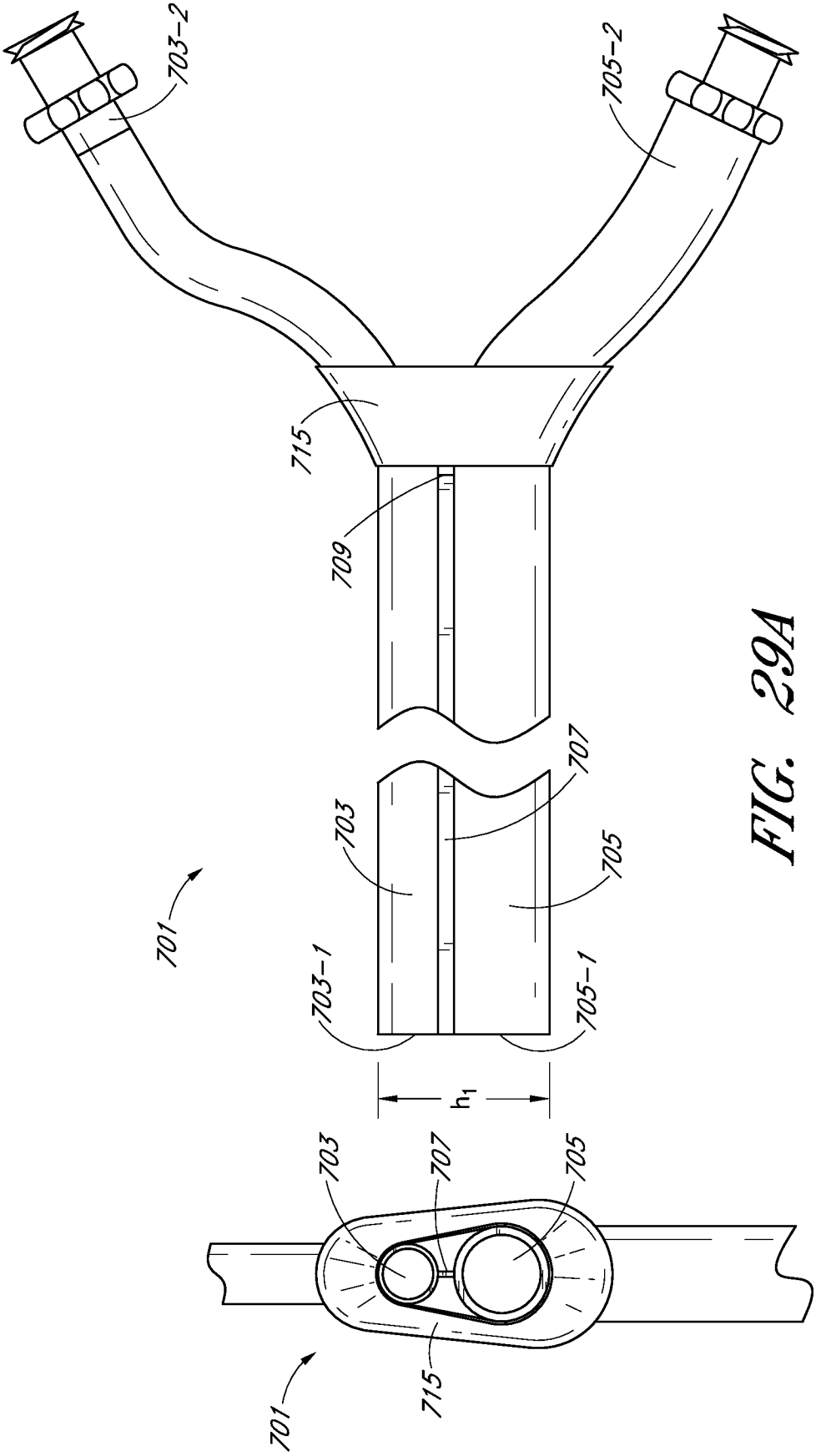

FIG. 29A

FIG. 29B

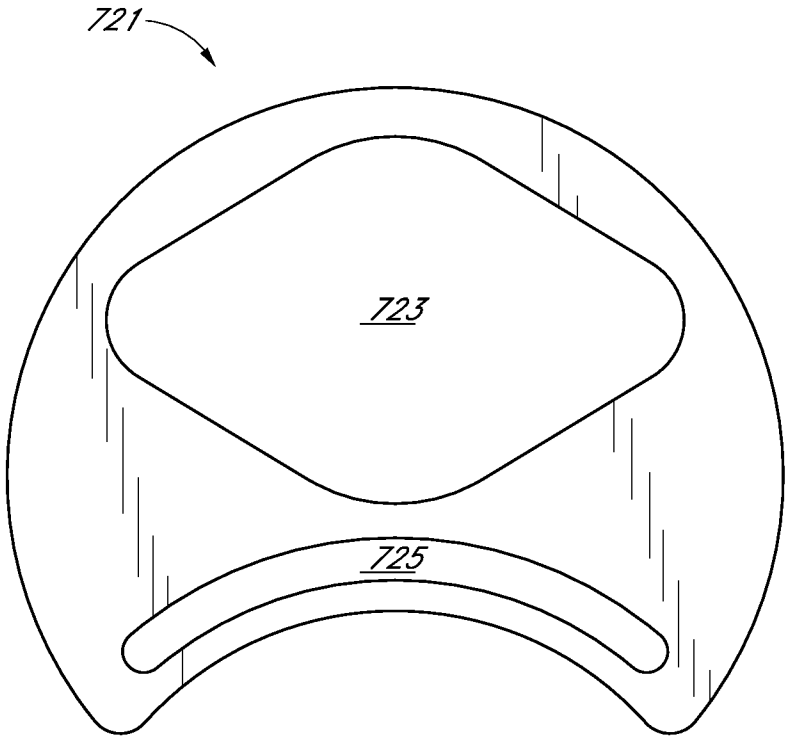

FIG. 30

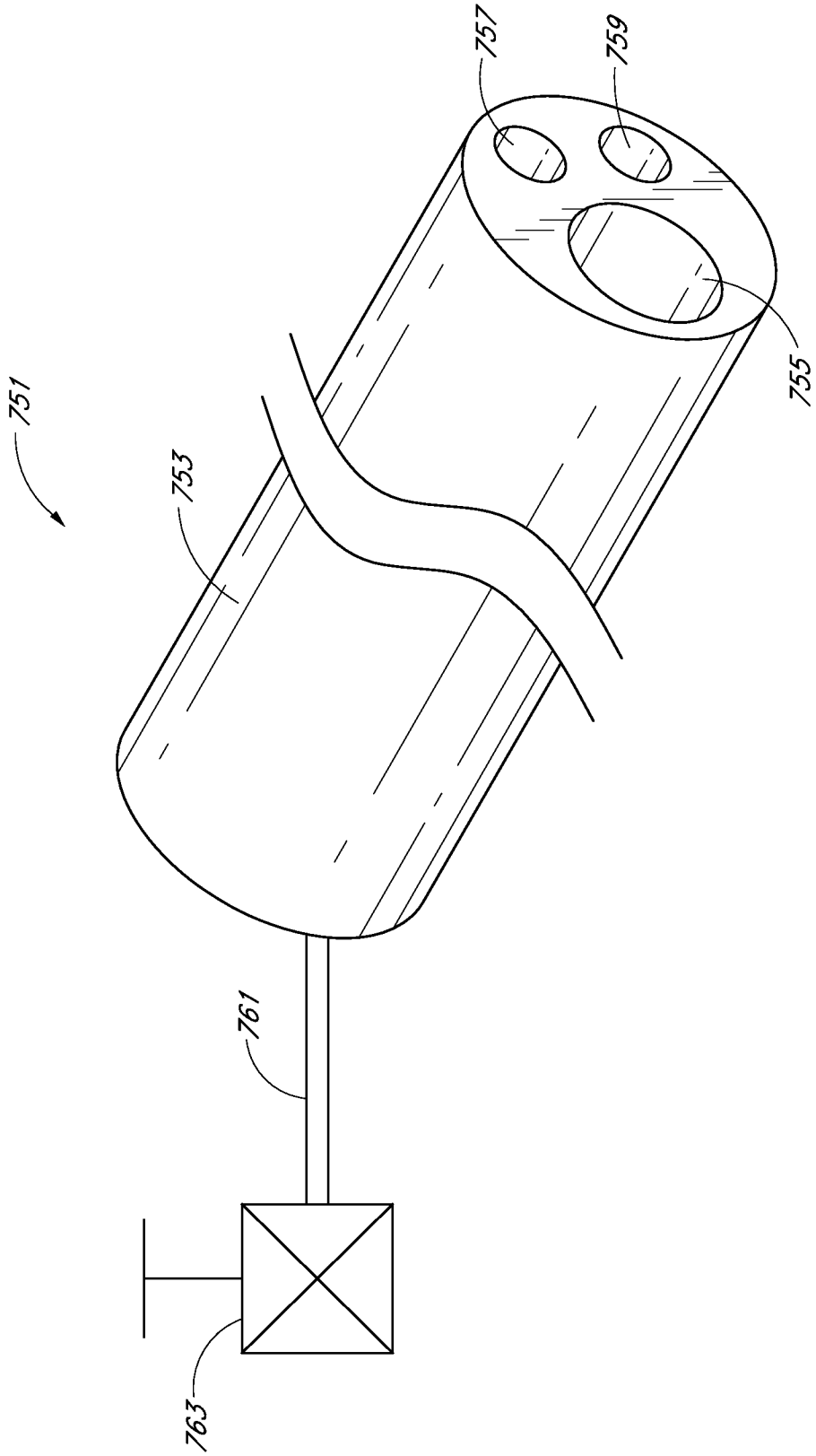

FIG. 31

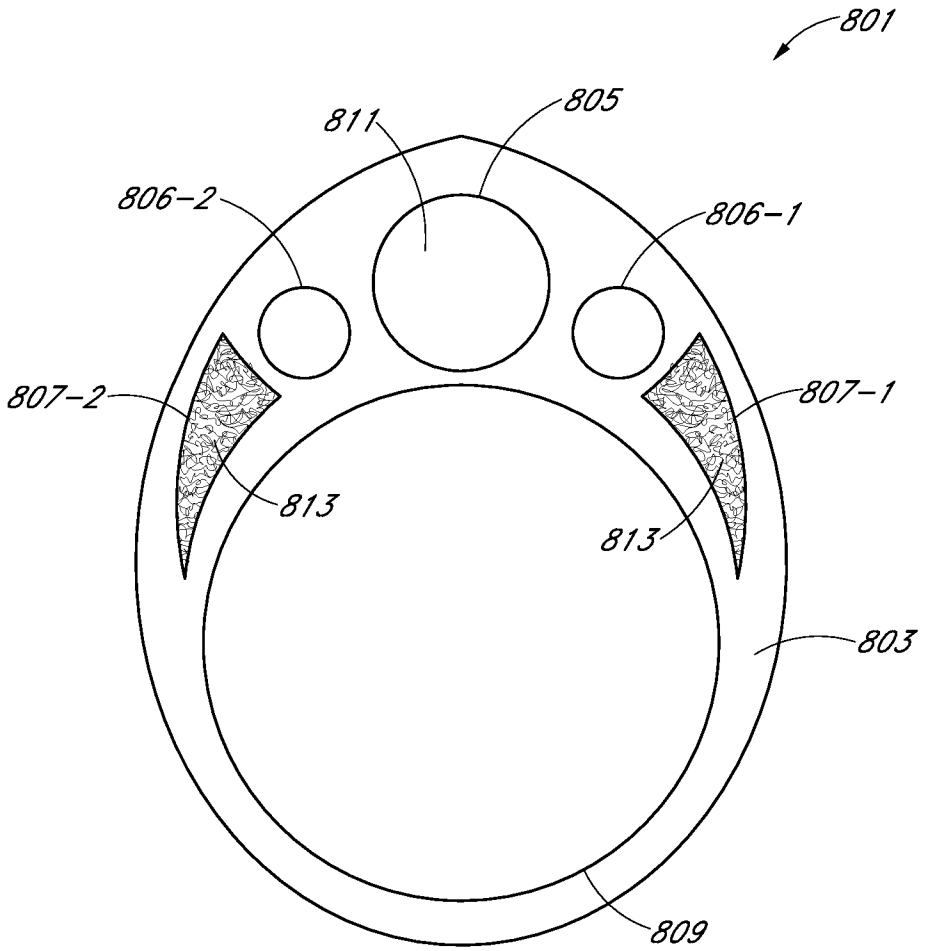

FIG. 32

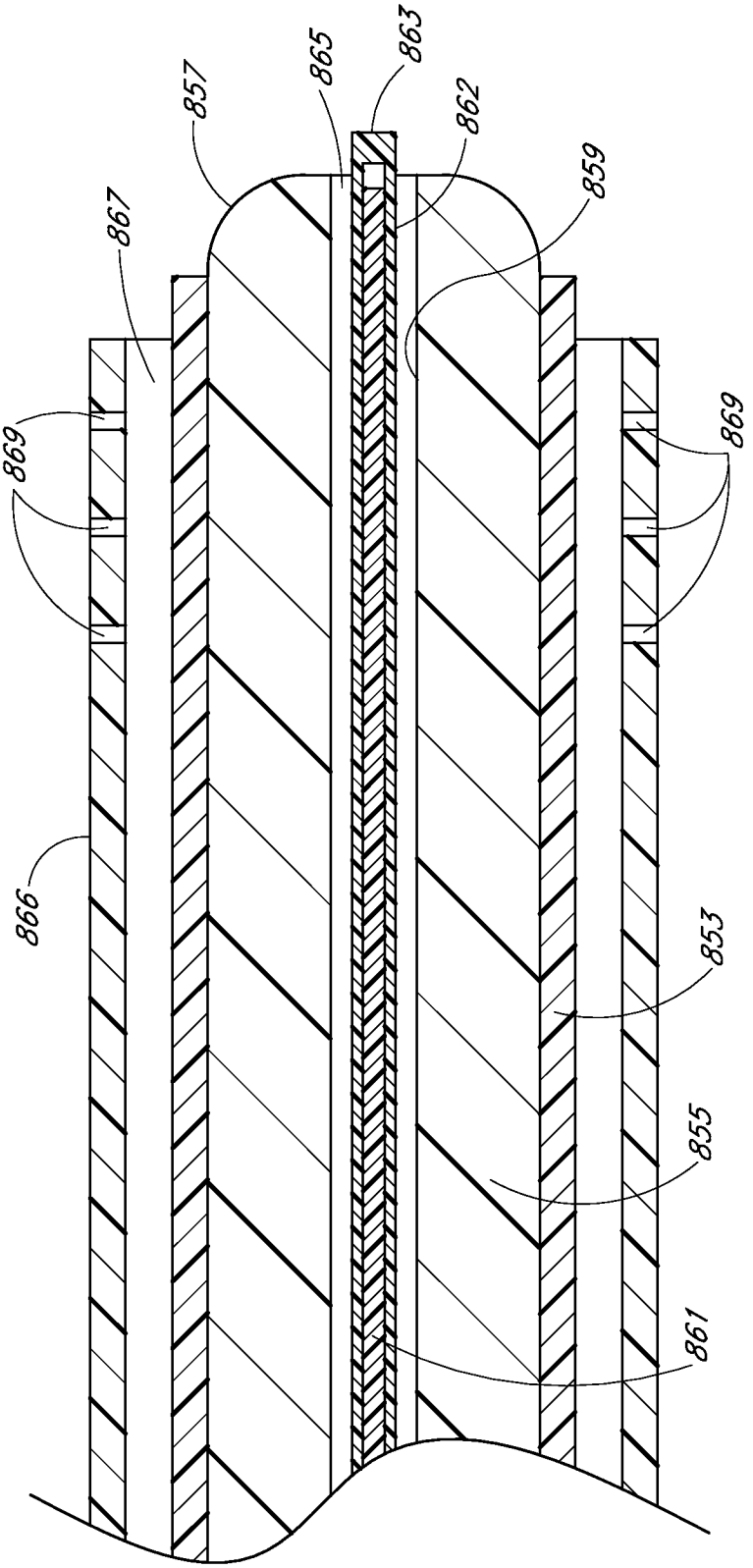

FIG. 33

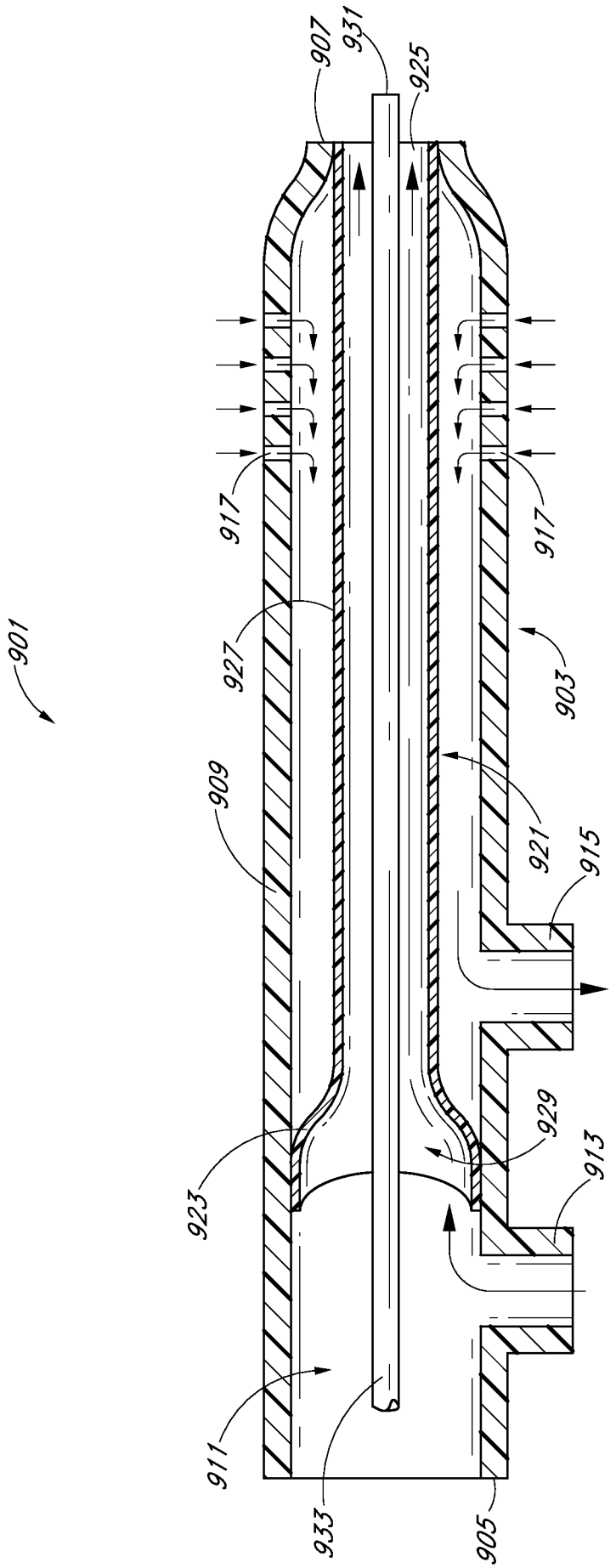
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FIG. 34