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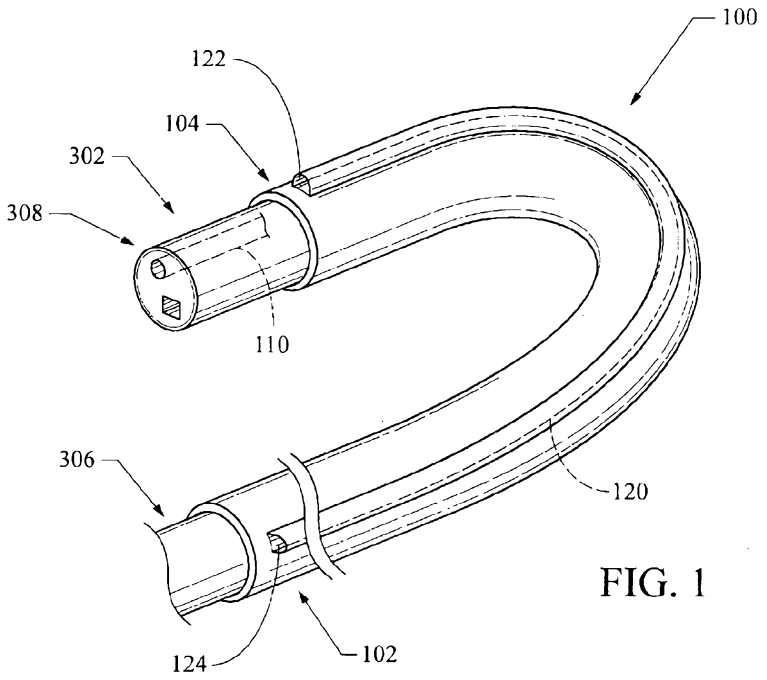


FIG. 1

[Continued on next page]

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(57) Abstract: An endoscope sheath is provided for advancing medical devices into the anatomy of a patient. The endoscope sheath includes at least one lumen that may be used to advance devices alongside an endoscope. The endoscope sheath may include an endoscope cap configured to mate with the lumen. The endoscope may include one or more coupling members configured to mate with the openings of the lumen.

ENDOSCOPE SHEATH

TECHNICAL FIELD

[0001] The present invention relates to medical devices, and more particularly to an endoscope sheath.

BACKGROUND OF THE INVENTION

[0002] Physicians use endoscopes during minimally invasive procedures to visualize the patient anatomy, diagnose various conditions, and deliver instrumentation to the treatment site. Devices are typically delivered via a working channel of the endoscope, which generally ranges from about 2.0 to 3.5 mm in diameter, and may be used to introduce catheters and other elongate devices, including forceps, scissors, brushes, snares, and baskets. Larger working channels of 5.0 mm in diameter are available in certain specialized endoscopes, and may be used to pass relatively large devices or provide capability for improved aspiration or decompression. Some devices, however, are simply too large to pass through available endoscopes. Moreover, the specialized endoscopes with larger working channels can be expensive, as well as difficult to intubate due to increased rigidity and outer diameter.

[0003] Devices too large for the endoscope working channel must be introduced through an alternate, and often more invasive procedure, such as laparoscopy or open surgery. Laparoscopic surgery involves creating 0.5-1.5 cm incisions in a patient's abdominal wall so that a laparoscope and other instruments can be introduced into the abdominal and pelvic cavities. Open surgery generally involves creating one or more long incisions in a patient, followed by extensive muscle stripping, prolonged retraction of tissues, denervation and devascularization of tissue. While effective at introducing larger devices, laparoscopic and open surgical procedures can increase the risk of complications and trauma to the patient, as well as extend recovery time and hospital stays.

[0004] What is needed are devices and methods for endoscopic introduction of medical devices too large for the endoscope working channel without necessitating the use of invasive procedures. Specifically, devices and methods are needed for introduction of medical devices alongside and external to an endoscope.

SUMMARY

[0005] The present disclosure generally provides an endoscope sheath. The sheath may be used to aid in the delivery of devices to a selected target area in the anatomy of a patient. Preferably, the sheath is used in conjunction with a system for advancing devices alongside an endoscope. In one embodiment, the sheath can be used with a tether system used for pulling devices down alongside an endoscope. The tether system may include a guiding member for advancing devices beyond a distal portion of the endoscope. In another embodiment, the sheath may be used in conjunction with an endoscope cap used for deflecting devices into a selected target anatomy. In another embodiment, the sheath, the tether system, and the endoscope cap may be used in combination.

[0006] In one aspect, an endoscope sheath is provided. The endoscope sheath includes a first proximal end, a first distal end, and a first lumen extending from the first proximal end to the first distal end. The first lumen is configured to receive an endoscope. The endoscope sheath further includes a second lumen having a second proximal end and second distal end, wherein the second lumen is configured to receive a medical device. The endoscope sheath further includes a first aperture and a second aperture, wherein the first aperture is disposed at the second proximal end and wherein the second aperture is disposed at the second distal end. Preferably, the first aperture is located distal to the first proximal end, and the second aperture is located proximal to the first distal end.

[0007] In one embodiment, the endoscope sheath may include an endoscope cap. The cap may be integral with the sheath, or alternatively, may be detachable. The endoscope cap may include a first coupling member mated with the second lumen of the endoscope sheath at the second distal end. The first coupling member may include a first coupling member proximal portion and a first coupling member distal portion. The first coupling member may further include a first coupling member lumen extending from the first coupling member proximal portion to the first coupling member distal portion, with the lumen open at both ends. The first coupling member lumen preferably is configured to receive the medical device delivered through the second lumen. In one embodiment, the first coupling member proximal portion includes an outer surface configured to frictionally engage an inner surface of the endoscope sheath second lumen. Preferably, the first coupling member is comprised of a rigid material.

[0008] In another embodiment, the endoscope sheath may include a first coupling member mated with the second lumen at the second distal end. The endoscope sheath may

include a second coupling member mated with the second lumen at the second proximal end. The first coupling member may include a body and a first coupling member lumen extending from a first coupling member proximal portion to a first coupling member distal portion. Preferably, the first coupling member lumen is open at both ends. The first coupling member may be comprised of a rigid material. Likewise, the second coupling member may include a body and a second coupling member lumen extending from a second coupling member proximal portion to a second coupling member distal portion. Preferably, the second coupling member lumen is open at both ends. The second coupling member may be comprised of a rigid material.

[0009] In another embodiment, the endoscope sheath includes a first proximal end, a first distal end, and a first lumen extending from the first proximal end to the first distal end. The first lumen may be configured to receive an endoscope. The endoscope sheath includes a second lumen having a second proximal end and a second distal end, wherein the second lumen is configured to receive a medical device. The endoscope sheath further includes a first aperture and a second aperture, wherein the first aperture is disposed at the second proximal end and wherein the second aperture is disposed at the second distal end. The first aperture is located distal to the first proximal end, and the second aperture is located proximal to the first distal end. The endoscope sheath further includes a first coupling member mated with the second lumen at the second distal end, and a second coupling member mated with the second lumen at the second proximal end.

[0010] In another aspect, a method is provided for delivering a medical device to an internal site of treatment. The method uses an endoscope and an endoscope sheath. The endoscope sheath includes a first proximal end, a first distal end, and a first lumen extending from the first proximal end to the first distal end. The first lumen is configured to receive the endoscope. The endoscope sheath further includes a second lumen having a second proximal end and second distal end, wherein the second lumen is configured to receive the medical device. The endoscope sheath further includes a first aperture and a second aperture, wherein the first aperture is disposed at the second proximal end and wherein the second aperture is disposed at the second distal end. The method includes advancing the medical device into the first aperture, advancing the medical device through the second lumen, and advancing the medical device to and out of the second aperture. In one embodiment, the medical device is advanced through the second lumen by pushing the device therethrough.

[0011] Other systems, methods, features and advantages will be apparent to one with skill in the art upon examination of the following figures and detailed description. It is intended

that all such additional systems, methods, features and advantages be included within this description, be within the scope of the invention, and be protected by the following claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] The system may be better understood with reference to the following drawings and description. The components in the figures are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the invention. Moreover, in the figures, like referenced numerals designate corresponding parts throughout the different views.

[0013] FIG. **1** depicts endoscope sheath **100**.

[0014] FIG. **2** depicts medical device **320**.

[0015] FIG. **3** depicts endoscope cap **130**.

[0016] FIG. **4A** depicts endoscope cap **130** with coupling member **140**.

[0017] FIG. **4B** depicts endoscope sheath **100** and endoscope cap **130**.

[0018] FIG. **5** depicts endoscope sheath **100** with coupling member **150**.

[0019] FIGS. **6A-6C** depict endoscope cap **130** with ramp **205**.

[0020] FIG. **6D** depicts device **320** delivered through endoscope sheath **100**.

[0021] FIG. **7** depicts endoscope sheath **100** and a tether system.

[0022] FIG. **8** depicts device **320** delivered through endoscope sheath **100**.

[0023] FIGS. **9A-9C** depict guiding device **400**.

[0024] FIG. **9D** depicts loading of guiding device **400** onto a tether and a wire guide.

[0025] FIG. **9E** depicts endoscope sheath **100** and guiding device **400**.

[0026] FIGS. **10A-10F** depict delivery of a large plastic biliary stent into the common bile duct using endoscope sheath **100**.

DEFINITIONS

[0027] Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention pertains. In case of conflict, the present document, including definitions, will control. Preferred methods and materials are described below, although methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention. The materials, methods, and examples disclosed herein are illustrative only and not intended to be limiting.

[0028] The terms "comprise(s)," "include(s)," "having," "has," "can," "contain(s)," and variants thereof, as used herein, are intended to be open-ended transitional phrases, terms, or words that do not preclude the possibility of additional acts or structures. The present invention also contemplates other embodiments "comprising," "consisting of" and "consisting essentially of," the embodiments or elements presented herein, whether explicitly set forth or not.

[0029] The term "biocompatible," as used herein, refers to a material that is substantially non-toxic in the in vivo environment of its intended use, and that is not substantially rejected by the patient's physiological system. A biocompatible structure or material, when introduced into a majority of patients, will not cause an undesirably adverse, long-lived or escalating biological reaction or response. Such a response is distinguished from a mild, transient inflammation which typically accompanies surgery or implantation of foreign objects into a living organism.

[0030] The term "distal," as used herein, refers to a direction that is generally towards a target site within a patient's anatomy during a medical procedure.

[0031] The term "proximal," as used herein, refers to a direction that is generally towards a physician during a medical procedure.

[0032] The term "stricture," as used herein, refers to any narrowing of a bodily lumen in relation to an adjacent lumen portion.

DETAILED DESCRIPTION

[0033] FIG. **1** depicts endoscope sheath **100** disposed over an endoscope **302**, the endoscope having a proximal portion **306** and a distal portion **308**. Sheath **100** includes a proximal portion **102** and a distal portion **104**. The sheath extends from the endoscope proximal portion to the endoscope distal portion. The sheath includes a first lumen **110** for the endoscope and a second lumen **120** for delivering devices alongside the endoscope. In some embodiments, the sheath may include a plurality of lumens for delivering devices alongside the endoscope. Lumen **120** extends from proximal portion **102** to distal portion **104** and has a distally located aperture **122**, and a proximally located aperture **124**.

[0034] The sheath may have a range of widths and lengths depending on the size of the endoscope to be used. In general, the sheath length ranges from about 100 cm to about 200 cm; and the sheath has a wall thickness of between about 0.1 mm to about 8 mm. The maximum diameter of lumen **120** generally ranges from about 2 mm to about 30 mm,

preferably about 4 mm to about 25 mm, more preferably about 6 mm to about 20 mm, most preferably 8 to about 15 mm. In some embodiments, the sheath is comprised of an elastic material wherein lumen **120** may have a unexpanded diameter and an expanded diameter, with the expanded diameter being greater than the unexpanded diameter. In other embodiments, the sheath may be comprised of an inelastic material such that the diameter of the sheath lumen in the unexpanded diameter and the expanded diameter are about the same.

[0035] The sheath may be constructed from any suitable biocompatible material. Preferably, the sheath comprises a polymeric material. In one embodiment, the sheath may be comprised of an elastomeric material. Suitable elastomeric materials include, but are not limited to, polyurethane-based elastomer, polyester-based elastomer, polyolefin-based elastomer, polyamide-based elastomer, polystyrene-based elastomer, fluorine-based elastomer, silicone rubber, fluororubber, and latex rubber. In another embodiment, the sheath may be comprised of a substantially inelastic material. In a preferred embodiment, the sheath may be comprised of an inelastic material such that length of the sheath may not change substantially as lumen **120** contracts and expands as devices are delivered therethrough. In one preferred embodiment, the sheath may comprise expanded polytetrafluoroethylene (ePTFE). In some embodiments, the sheath can be coated with one or more materials as needed. For example, the sheath may be coated with a hydrophilic or lubricous material to facilitate advancement of the endoscope and sheath through the patient anatomy.

[0036] FIG. **2** depicts a device **320** that may be delivered to a selected target anatomy using sheath **100**. As shown, device **320** is intended to be a generic representation of any device that may advanced down sheath lumen **120**. The device may be pushed down the sheath lumen, optionally with the aid of a pushing catheter or other similar device; the device may be pulled down; or the device may be both pushed and pulled down the lumen. Device **320** may be a device adapted to provide therapy or diagnosis to the selected target anatomy, or alternatively, a device configured to deliver another therapeutic or diagnostic device to the selected target anatomy. Device **320** may be, for example, a nasoenteric tube, a J portion of a PEG-J tube, a colon decompression tube, a biliary stent, a delivery catheter, an overtube, an introducer sheath, or another device. Device **320** includes a proximal end **324** and a distal end **326**. In some embodiments, as will be explained in greater detail below, device **320** may have a coupling element **322** complimentary to and configured to couple with another coupling element. In other embodiments, coupling element **322** may be absent from device **320**.

[0037] FIG. **3** depicts an endoscope cap **130** that may be configured to engage the distal end of the sheath. Cap **130** may be detachable from the sheath, or alternatively, may be integral therewith. The cap may be a tubular structure including a body **131** having a proximal end **132**, a distal end **134**, and an aperture **135** configured to receive the distal end of an endoscope. The distal end **134** may have apertures **136** and **138** configured to align with an endoscope working channel and visualization device, respectively.

[0038] In some embodiments, the cap may be configured to fit over the distal end of sheath **100**. For example, the cap may be configured to a diameter such that the cap tightly fits over the distal end of the endoscope and sheath. A cap comprised of a thermoplastic elastomer may be particularly suited to such embodiments. Cap **130** may include a frictional inner diameter surface configured to further secure the cap to the endoscope and sheath. In another embodiment, the cap may be fixedly attached to the distal end of the sheath. For example, the cap may be attached to the distal end of the sheath via an ultrasonic welding process. In other embodiments, the cap may include adhesive, magnets, a detent structure, or other suitable structures and materials configured to fixedly or temporarily attach cap **130** to sheath **100**.

[0039] In some embodiments, the cap **130** may include an engagement portion **137** configured to secure the cap to the endoscope and sheath. The engagement portion may be integral with or attached to proximal end **132** of the cap. The engagement portion, which preferably extends proximally from body **131**, may be constructed from a flexible material that provides a frictional inner diameter surface. For example, the engagement portion may be constructed of a polyurethane that is molded to body **131**. In other embodiments, it may be constructed from, for example, silicone or another soft polymer that will provide an ability to mount and frictionally (but removably) attach cap **130** to the endoscope and sheath.

[0040] Body **131** may be constructed of rigid material(s). In some embodiments, all or a portion of the body may be generally transparent. For example, the body may be constructed of a clear polycarbonate polymer. Alternatively, it may be constructed of another clear, translucent, or opaque polymer such as polyurethane, acrylic, or nylon. Body **131** preferably is dimensioned such that its outer diameter is about the same as the outer diameter of the endoscope on which cap **130** is to be used. For example, body **131** may have an outer diameter of about 8.5 mm to about 12 mm for use with endoscopes having those outer diameters. The skilled artisan will appreciate that body **131** may be dimensioned appropriately for use with endoscopes having greater or lesser diameters, and it may also have a cross-section configured for use with a similarly-shaped endoscope.

[0041] FIG. **4A** depicts endoscope cap **130** further including a coupling member **140** configured to mate with lumen **120** at aperture **122**. The coupling member may provide stress relief in the sheath lumen, and thus prevent the sheath from tearing during delivery of devices therethrough. In particular, as a device is advanced down lumen **120**, with coupling member **140** in place, the device advances from lumen **120** into lumen **146**, and thereafter exits into the patient anatomy. The coupling member includes a proximal end **142**, a distal end **144**, and a lumen **146** extending from proximal end **142** to distal end **144**. Coupling member **140** may be configured to frictionally engage the inner surface of lumen **120** near aperture **122**. Alternatively, where the endoscope cap is fixedly attached to the sheath, coupling member **140** may be fixedly mated with lumen **120**. For example, proximal end **142** may be attached to the lumen **120** at aperture **122** with adhesive, with ultrasonic welding, or another suitable material or method as is known in the art. FIG. **4B** depicts endoscope cap **130** mated with sheath **100**, wherein coupling member **140** is mated with lumen **120**.

[0042] Optionally, the sheath may include another coupling member **150** mated or configured to mate with lumen **120** at aperture **124**. FIG. **5** depicts coupling member **150** mated with proximal portion **102** and lumen **120** at aperture **124**. Coupling member **150** includes a body **151** having a lumen **153** for the endoscope, and a lumen **152** through which a device may be inserted and thereafter advanced through lumen **120** toward the distal portion of the endoscope. Similarly to endoscope cap **130**, coupling member **150** may be configured to be detachable from the sheath or may be integral therewith. The coupling member may include suitable structural elements to secure the member to the endoscope and sheath, such as those already described herein. For example, in one embodiment, coupling member **150** may be integral with the proximal end of the sheath, and may be configured to frictionally engage a proximal portion of the endoscope. Optionally, where cap **130** is absent from the endoscope sheath, the sheath may include a coupling member **150** mated or configured to mate with lumen **120** at aperture **122** wherein a device advanced down lumen **120** may enter lumen **153** and thereafter exit into the patient anatomy.

[0043] FIGS. **6A-6C** depict endoscope cap **130** configured for a duodenoscope wherein the cap includes a ramp **205** that can be used to deflect medical devices toward a selected target anatomy. The cap also includes a side aperture **207** configured to accommodate the endoscope's visualization devices (e.g., camera, CCD, or fiber-optic element) and working channel(s). The cap may also include coupling member **140** as described above and depicted in FIG. **6C**. As an illustrative example, FIG. **6D** depicts use of sheath **100** and endoscope cap

130 to deliver a grasping device **320** to the distal end of an endoscope. As shown, device **320** has been pushed down lumen **120** and thereafter deflected by ramp **205**.

[0044] The ramp **205** may be configured to a variety of angles of elevation relative to the body **131**. In general, however, the ramp presents an angle of elevation ranging from about 1 degree to about 90 degrees relative to body **131**, preferably about 5 degrees to about 75 degrees, more preferably about 10 degrees to about 60 degrees, and most preferably about 20 degrees to about 45 degrees. The ramp incline surface may be a uniform planar surface, or alternatively, may be a curvilinear surface. Preferably, the ramp surface is atraumatically shaped. For example, ramp **205** as shown in FIG. **6A** presents an atraumatic profile with rounded edges along the ramp surfaces. In some embodiments, the ramp may comprise surface structures configured to receive a device delivered down the sheath. For example, ramp **205** may comprise a grasping slot configured to grasp a device delivered through lumen **120**. The grasping slot may take on any suitable shape or form for grasping device **320**. Suitable grasping configurations are disclosed in U.S. Patent Application Publication No. 2007/0208219, and may be applied to the presently disclosed ramps.

[0045] The ramp may be comprised of any suitable biocompatible material(s). In some embodiments, the ramp may be comprised of the same material as body **131**. In other embodiments, the ramp may be comprised of a different material from body **131** or a combination thereof. Preferably, the ramp is comprised of a polymeric material. Properties of the ramp, such as flexibility/rigidity, may be adjusted by selection of an appropriate polymer as is known in the art. For example, polymers with a low coefficient of friction may be particularly suitable for various embodiments, while polymers with a high coefficient of friction may be suitable in other embodiments, such as for ramps configured to grasp a delivered device. Suitable polymeric materials include, but are not limited to, polytetrafluorethylene, polyethylene, ultra-high molecular weight polyethylene, polypropylene, perfluoroelastomer, fluoroelastomer, nitrile, neoprene, polyurethane, silicone, styrene-butadiene, rubber, polycarbonate, acrylic, nylon, or combinations thereof.

[0046] FIG. **7** shows sheath **100** disposed on endoscope **302** wherein the endoscope includes a tether system. The tether system may be used to pull devices down alongside the endoscope from proximal portion **306** to distal portion **308**. Endoscope **302** has a working channel **310** extending from proximal portion **306** to distal portion **308**. The working channel connects to an aperture **312** disposed at distal portion **308**. Tether **304** extends alongside the endoscope through lumen **120** from the proximal portion **306** to the distal portion **308** and enters working channel **310** via aperture **312**. The tether extends back through the working

channel to proximal portion **306** and exits at port **314**. The tether includes a first end **305** and a second end **307**. The tether may include a coupling element **316**, preferably located at second end **307**. The coupling element may be attached to or integrally formed with tether **304**. The coupling element may be attached to the tether by glue, adhesive, or suture, for example. Once endoscope **302** has reached a selected target anatomy and device **320** has been coupled to the tether, device **320** may be advanced to the distal portion of the endoscope by pulling the tether back through working channel **310** from port **314**. Preferably, device **320** can be pushed from its proximal end **324** while the tether is used to pull from its distal end **326**.

[0047] In one exemplary embodiment, FIG. **8** shows a grasping device **320** that has been advanced down lumen **120** using the tether system. Grasping device **320** includes a coupling element **322** integral with the device. The grasping device extends from proximal portion **306** to aperture **124**, through lumen **120**, and exits aperture **122**. After delivery to distal portion **308**, as will be explained in greater detail below, device **320** may be decoupled from the tether and the tether can be pulled back into working channel **310**. The grasping device may then be used to perform various functions in the patient anatomy as is known in the art. Introducing device **320** with sheath **100** minimizes mucosal trauma to tissue surrounding the path of introduction.

[0048] Tether **304** may be a strap, a wire, a suture, a thread, or any other device capable of functioning as a tether suitable for the intended use. Preferably, the tether is configured to bend without kinking. In cases where additional instruments will be introduced through the endoscope working channel or where the working channel will be used to provide aspiration or decompression, preferably the tether occupies minimal space therein and does not substantially interfere with the procedure. In one embodiment, the tether may be a wire having a 0.035 millimeter diameter, and can be used with an endoscope having a lumen diameter of 4.8 millimeters, for example. In another embodiment, the tether may be a flexible strap, such as a nylon strap, configured to conform to an inner surface of the endoscope working channel. The tether may be fabricated from a variety of biocompatible materials, including metal alloys and polymeric materials. Suitable polymeric materials include, for example, nylon, polyester, polyethylene, ultra-high molecular weight polyethylene, or polypropylene. Suitable metal alloys include, for example, nickel-titanium alloys. The tether can be coated with one or more materials. Preferably, at least a portion of the tether is coated with a hydrophilic or other lubricious material that can facilitate

advancement of the tether through the anatomy of the patient. The tether may be coated with, for example, SLIP-COAT® Biopolymer, STS Biopolymers, Inc., Henrietta N.Y.

[0049] The coupling elements **316** and **322** may include any suitable structures configured to temporarily couple two medical devices. For example, the coupling elements may include a closed loop structure as depicted in FIGS. **2** and **7**. The coupling elements may include releasable or breakable sutures, temporary or dissolvable bonds or adhesives, magnets, or a combination thereof. The coupling elements may include a biocompatible ball which is crimped, glued, or otherwise designed to slide off or break apart with the application of sufficient amount of pull force (e.g., 3 pounds), and can thereafter be safely passed through the gastrointestinal system or be absorbed thereby. Optionally, device **320** may be coupled directly to the tether, with for example, breakable or dissolvable sutures.

[0050] The tether system may further include a guiding device used to advance devices beyond the distal portion of the endoscope (FIGS. **9A-9E**). Guiding device **400** includes a flexible or semi-flexible elongate member **402**, a fulcrum **404**, and a variable stiffness cable **406**. The elongate member **402** includes a distal portion **410** and a proximal portion **412**. The elongate member may have a range of lengths and diameters depending on the size of the working channel of the endoscope to be used and the procedure to be performed. In general, the length of elongate member **402** ranges from about 100 cm to about 300 cm. The cross-sectional diameter generally ranges from about 1 mm to about 3 mm, and is preferably configured for advancement through the working channel of the endoscope. The skilled artisan will appreciate that all dimensions provided herein are intended as examples only, and guiding devices having different dimensions may be substituted for a particular use.

[0051] Elongate member **402** includes a biocompatible material that encases variable stiffness cable **406**, shielding it from direct exposure to the patient anatomy. The material may be, for example, expanded polytetrafluoroethylene, polytetrafluoroethylene, polyethylene, or polyurethane. In one exemplary embodiment, elongate member **402** may be fabricated by placing heat shrink tubing, such as heat shrink polytetrafluoroethylene tubing, over the variable stiffness cable **406** and thereafter heat shrinking the tubing in place. The elongate shaft may comprise one or more materials providing the shaft with properties of sufficient strength, flexibility, and resistance to compression in order to traverse tortuous areas of the anatomy. Such materials include nylon, polyether block amides, polyethylene terephthalate, polytetrafluoroethylene, polyetheretherketone, or combinations thereof. The skilled artisan will appreciate, however, that the elongate member may be constructed from other biocompatible materials as is known in the art to provide the desired properties.

[0052] Fulcrum **404** is attached to or integrally formed with distal portion **410** of elongate member **402**. The fulcrum may be any suitable structure configured to receive tether **304** and provide a point at which the tether can be advanced through or around. Fulcrum **404** may be, for example, a single loop structure (FIG. **9A**), a double loop structure (FIG. **9B**), or a cylindrical structure having a lumen **405** extending therethrough (FIG. **9C**). The fulcrum has a diameter ***d*** preferably ranging from about 1 mm to about 3 mm. In some embodiments, the fulcrum may be constructed of wire, suture, or thread. In other embodiments, the fulcrum may be constructed of a more rigid material. In general, however, fulcrum **404** may comprise any material suitable for the intended use. The fulcrum may include, for example, polymeric materials such as nylon, and/or metallic materials such as nickel-titanium alloys.

[0053] Portions of the guiding device can be coated with one or more materials. Preferably, at least a portion of elongate member **402** is coated with a hydrophilic or other lubricious material. Hydrophilic or other lubricious coatings are known to facilitate advancement of devices through patient anatomy or introducer devices. In some embodiments, fulcrum **404** may be comprised of and/or coated with a material that facilitates smooth advancement of the tether therethrough. Preferred materials include polytetrafluoroethylene, ultra-high molecular weight polyethylene (UHMWPE), nylon, and polyoxymethylene.

[0054] Variable stiffness cable **406** is disposed through elongate member **402** and includes a helical spring **442** extending from proximal portion **412** to distal portion **410** near fulcrum **404**. The spring includes a small pitch between the adjacent turns. A wire **444**, such as a stainless steel wire, extends through the central bore of spring **442** and is affixed to the distal end thereof. Alternatively, the wire and the spring may both be affixed to a distal tip. Wire **444** is operatively connected to a hand assembly **413** located proximal to proximal portion **412**. Hand assembly **413** includes an actuator **414** that can be used to compress or decompress spring **442**. For example, in some embodiments, retraction of the actuator in the proximal direction retracts wire **444**. This retraction of the wire reduces the distance between the turns in spring **442**, and thereby reduces the spring's flexibility. Additional examples of variable stiffness cables are disclosed in U.S. Patent Nos. 4,215,703 and 3,854,473, the disclosures of which are herein incorporated by reference in their entirety.

[0055] Guiding device **400** may be loaded onto tether **304** at the proximal portion of the endoscope by passing first end **305** of tether **304** through fulcrum **404**. Preferably, the guiding device is also loaded onto the proximal end of a wire guide **450** that exits port **314** and has been used to cannulate the target anatomy. The tether and the wire guide may be

passed, for example, through the double loop fulcrum **404**, as depicted in FIG. **9D**. The elongate member **402** can then be advanced into the working channel **310** via port **314**. Thereafter, the elongate member may be advanced through the working channel, out apertures **312**, and to a selected target anatomy beyond distal portion **308**. In some embodiments, an endoscopic elevator apparatus may be used to aid in advancement of elongate member **402** into the selected target area. As the elongate member advances beyond the distal portion of the endoscope, preferably the tether becomes looped around the fulcrum and is pulled into the target anatomy.

[0056] Once distal portion **410** of elongate member **402** reaches a target anatomy **480**, the variable stiffness cable **406** may be used to stiffen and anchor the elongate member in place (FIG. **9E**). The tether can then be pulled back through working channel **310** from port **314**, thereby advancing a coupled device **320** through lumen **120** toward distal portion **308**. Upon reaching the distal portion of the endoscope, device **320** may advanced toward the target anatomy.

[0057] During introduction of the endoscope and extension of the guiding device into the target anatomy, the tether can be held secure as needed. Preferably, the tether is long enough so that control can be maintained at both ends while the endoscope and guiding device are advanced to the target anatomy. In other words, preferably the tether is greater than two times the length of the endoscope. In embodiments using the guiding device, preferably the tether is greater than two times the additive length of the endoscope and the length of the portion of elongate member **402** that extends out of aperture **312** and to the target anatomy. The portion of tether exiting port **314** can be held secure at the port by, for example, a locking device (e.g., Fusion® Wire Guide Locking Device, Cook Endoscopy Inc., Winston-Salem, N.C.), or by holding the tether. Likewise, the other end of the tether, specifically the portion of tether extending through lumen **120** back to proximal portion **306**, can be held secure by a locking mechanism or similar device, or by holding the tether. As elongate member **402** or device **320** is advanced into the target anatomy, the tether can be unlocked as needed.

[0058] FIGS. **10A-10F** demonstrate a method by which a medical device can be introduced alongside the endoscope to a selected target anatomy. In one exemplary embodiment, endoscope sheath **100** can be used with Endoscopic Retrograde Cholangiopancreatography (ERCP). ERCP involves inserting a duodenoscope into a patient's mouth and through the esophagus, stomach, and duodenum until it reaches the area where the ducts of the biliary tree and the pancreas open into the duodenum. Devices delivered through the endoscope's working channel may then traverse the Papilla of Vater for

access to the ductal system. Therein, these devices can be used to perform diagnostic and therapeutic procedures. Examples of such devices include wire guides, baskets, snares, stents, extraction balloons, introducer brushes, catheters, and baby endoscopes usually of 0.8 mm to 4 mm in diameter.

[0059] One ERCP procedure includes delivery of a plastic biliary stent into an area of the bile or pancreatic duct where a stricture is blocking drainage of fluid. The blockage may be caused by a tumor in the bile or pancreatic duct. Typically, by the time symptoms appear in the patient, the tumor is at an advanced stage and is deemed inoperable. As a result, management of the cancer usually focuses on palliation of the symptoms. As an alternative to surgical bypass procedures for palliation, a stent may be delivered by ERCP and positioned through the obstructed area so as to maintain a pathway for fluid to flow across. However, the maximum diameter of a plastic biliary stent generally depends on the diameter of the endoscope's working channel. As a result, in some instances multiple stents must be placed within the stricture to allow for sufficient drainage. Using the presently disclosed endoscope sheath, plastic biliary stents having diameters larger than the endoscope's working channel can be delivered to the bile or pancreatic ducts. These larger tubes may facilitate more efficient drainage of the duct and may be less prone to clogging compared to their smaller counterparts.

[0060] FIGS. **10A-10F** illustrate delivery of a large plastic biliary stent **610** into the common bile duct using sheath **100**. The tether **304**, guiding device **400**, and cap **130** with ramp **205** are also used to deliver the stent. The procedure begins with the tether disposed through lumen **120** and back through lumen **310**, as depicted in FIG. **10A**. The endoscope may then be advanced into the patient and positioned in the duodenum **602** to allow viewing of the Sphincter of Oddi and the Papilla of Vater **604**, which lie at the opening to the common bile duct **606** and the pancreatic duct. Next, the wire guide **450** may be extended out of apertures **207** and **312**, through the Ampulla of Vater and into the ductal system (FIG. **10B**). Preferably, the wire guide is advanced past the stricture **608**. A dilator catheter may be used as needed to facilitate cannulation of the duct. A more detailed description of cannulation of the common bile duct with the assistance of a dilator catheter is disclosed in U.S. Patent Application Publication No. 2005/0059890, the disclosure of which is herein incorporated by reference in its entirety. The guiding device **400** can be loaded over the wire guide and the tether **304** at the proximal portion of the endoscope. Elongate member **402** of the guiding device may be advanced through the endoscope's working channel and thereafter extended out of apertures **207** and **312** and into the ductal system, all the while advancing over the wire

guide via fulcrum **404** (FIG. **10C**). The endoscope may include an elevator apparatus that may be used to deflect the guiding device toward the ductal system. As elongate member **402** advances into the ductal system, the tether will also be advanced by virtue of its contact with fulcrum **404**. Preferably, fulcrum **404** is advanced past stricture **608** so that the biliary stent can be pulled into place when advanced into the target anatomy. Once elongate member **402** is advanced to the desired location, variable stiffness cable **406** may be engaged by manipulation of actuator **414**, thereby causing stiffening of the elongate member **402**. Stiffening anchors the elongate member in position and provides rigidity which can prevent buckling during delivery of device **320**.

[0061] Next, the biliary stent may be coupled to the tether at the proximal portion of the endoscope. Preferably, the stent is loaded into and delivered via a delivery catheter that is configured to couple to the tether. The delivery catheter, as device **320**, includes a coupling element **322** for coupling to the tether, and preferably includes a stiffening element or a partially rigid portion so that the catheter can be pushed from its proximal end **324**. Pushing the stent or the delivery catheter can reduce tension on the tether during introduction and may reduce the incidence of mucosal trauma. Once coupled, device **320** may be advanced into lumen **120** at aperture **124**. Device **320** may then be advanced through lumen **120** and thereafter to the distal portion of the endoscope. Upon exiting lumen **120** at aperture **122**, preferably device **320** is deflected by ramp **205** toward the Papilla of Vater **604** (FIG. **10D**).

[0062] The delivery catheter may be advanced along elongate member **402** of guiding device **400** by continuing to push from the proximal end while pulling with tether **304**. Preferably, the delivery catheter is advanced to distal portion **410**, and thus, the target anatomy (FIG. **10E**). Once the delivery catheter reaches the target site (i.e., the stricture), it may then be decoupled from the tether. For example, the delivery catheter may be held at the proximal end while the tether is pulled back at port **314** with sufficient force to detach coupling element **316** from coupling element **322**, thereby decoupling the delivery catheter from the tether. The tether may then be pulled out of the ductal system and back into the endoscope working channel **310**. The guiding member **400** and subsequently the wire guide **450** may be advanced out of the ductal system and back into the endoscope. Next, the biliary stent **610** may be delivered to the site of the stricture **608** by pushing the stent out of the delivery catheter using an internal pushing catheter (FIG. **10F**). The delivery catheter may then be removed from the patient anatomy. The skilled artisan will appreciate that the steps of accessing, delivering, decoupling, and removal of devices from the target anatomy may be

varied as necessary. For example, if additional procedures are to be performed using the wire guide, it may be preferable to only partially retract the wire guide from the bile duct.

[0063] While various embodiments of the invention have been described, it will be apparent to those of ordinary skill in the art that many more embodiments and implementations are possible within the scope of the invention. Accordingly, the invention is not to be restricted except in light of the attached claims and their equivalents.

CLAIMS

1. An advancing system, comprising:

an endoscope having a proximal portion, a distal portion, a working channel extending from the proximal portion to the distal portion, an endoscope aperture disposed at the distal portion and in communication with the working channel, and a port disposed at the proximal portion and in communication with the working channel; and

an endoscope sheath having a first lumen extending from a first proximal end to a first distal end, wherein the endoscope is disposed through the first lumen, a second lumen extending from a second proximal end to a second distal end and configured to receive an elongate medical device, and a first aperture and a second aperture in fluid communication with the second lumen,

wherein the first aperture is disposed at the second proximal end of the second lumen, wherein the second aperture is disposed at the second distal end of the second lumen, and wherein the second aperture is spaced proximally of a distal end of the endoscope; and

further comprising an endoscope cap coupled to the endoscope sheath, the endoscope cap enclosing the distal end portion of the endoscope there within and having a distal end that is spaced distally of the endoscope aperture, the endoscope cap comprising a non-movable ramp disposed on an outer surface thereof, the ramp being configured to deflect an elongate medical device delivered through the second lumen along an angled pathway that extends outwardly and away from a longitudinal axis of the endoscope.

2. The advancing system of claim 1 wherein the first aperture is located distal to the first proximal end, and wherein the second aperture is located proximal to the first distal end.

3. The advancing system of claim 1 wherein the endoscope sheath comprises expanded polytetrafluroethylene.

4. The advancing system of claim 1 wherein the second lumen has a diameter ranging from about 2 mm to about 30 mm.

5. The advancing system of claim 1 wherein the endoscope cap is fixedly attached to the endoscope sheath at the first distal end.

6. The advancing system of claim 1 wherein the endoscope cap is detachable from the endoscope sheath.

7. The advancing system of claim 1 wherein the endoscope cap comprises a first coupling member mated with the second lumen at the second distal end.

8. The advancing system of claim 7 wherein the first coupling member comprises:

a first coupling member proximal portion and a first coupling member distal portion; and

a first coupling member lumen extending from the first coupling member proximal portion to the first coupling member distal portion, the first coupling member lumen open at both ends, wherein the first coupling member lumen is configured to receive the elongate medical device.

9. The advancing system of claim 8 wherein the first coupling member proximal portion comprises an outer surface configured to frictionally engage an inner surface of the second lumen.

10. The advancing system of claim 7 wherein the first coupling member is comprised of a rigid material.

11. The advancing system of claim 1 wherein the endoscope sheath comprises a first coupling member mated with the second lumen at the second distal end.

12. The advancing system of claim 11 wherein the first coupling member comprises:

a body; and

a first coupling member lumen extending through the body from a first coupling member proximal portion to a first coupling member distal portion, wherein the first coupling member is comprised of a rigid material.

13. The advancing system of claim 1 wherein the endoscope sheath comprises a second coupling member mated with the second lumen at the second proximal end.

14. The advancing system of claim 13 wherein the second coupling member comprises:

a body; and

a second coupling member lumen extending through the body from a second coupling member proximal portion to a second coupling member distal portion, wherein the second coupling member is comprised of a rigid material.

15. An advancing system configured for an endoscope having a proximal portion, a distal portion, a working channel extending from the proximal portion to the distal portion, an endoscope aperture disposed at the distal portion and in communication with the working channel, and a port disposed at

the proximal portion and in communication with the working channel, the advancing system comprising:

an endoscope sheath having a first lumen extending along a first length from a first proximal end to a first distal end and configured to receive the endoscope, a second lumen extending along a second length from a second proximal end to a second distal end and configured to receive an elongate medical device, the second lumen being coupled to the first lumen along the second length of the second lumen, and a first aperture and a second aperture wherein the first aperture is disposed at the second proximal end and wherein the second aperture is disposed at the second distal end and wherein the first aperture is located distal to the first proximal end, and wherein the second aperture is located proximal to the first distal end; and

an endoscope cap having a non-movable ramp, wherein the ramp comprises a concave surface that is configured to engage and deflect an elongate medical device delivered through the second lumen along an angled pathway and away from a longitudinal axis of the endoscope, and wherein the endoscope cap is configured to receive the distal portion of the endoscope.

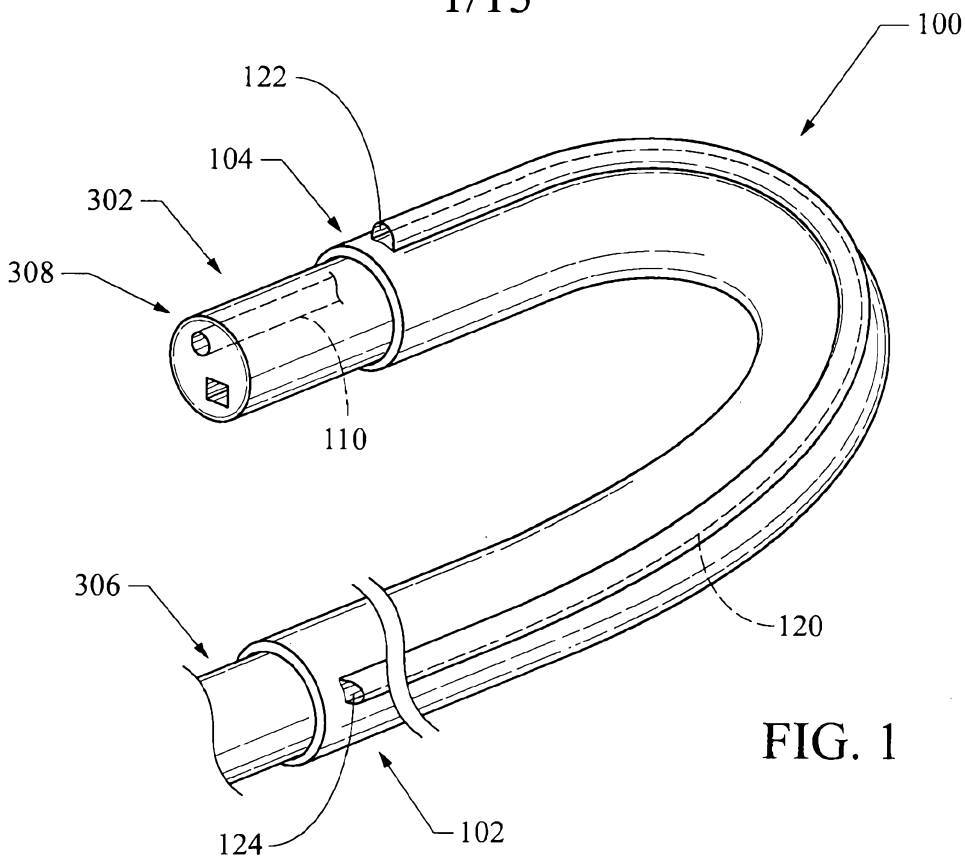


FIG. 1

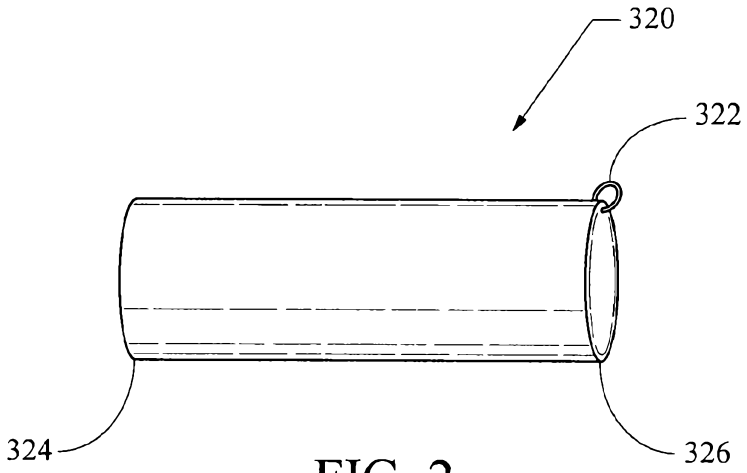


FIG. 2

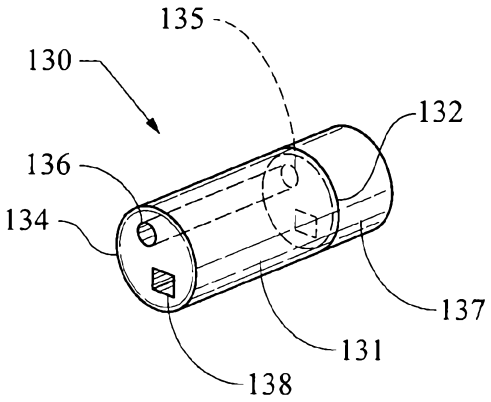


FIG. 3

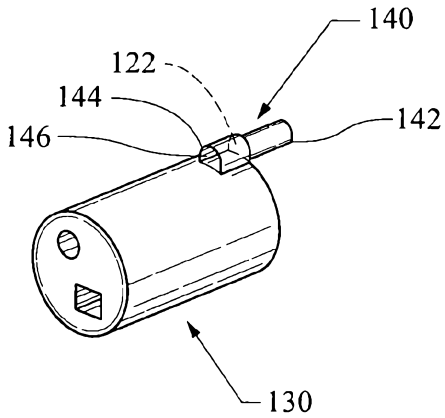


FIG. 4A

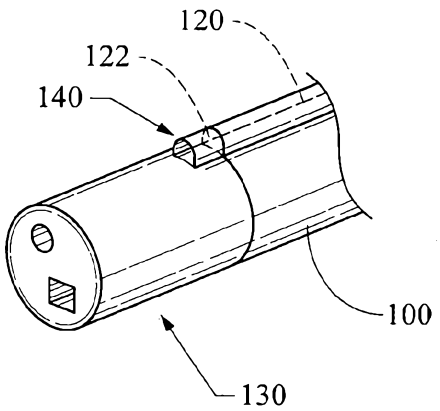


FIG. 4B

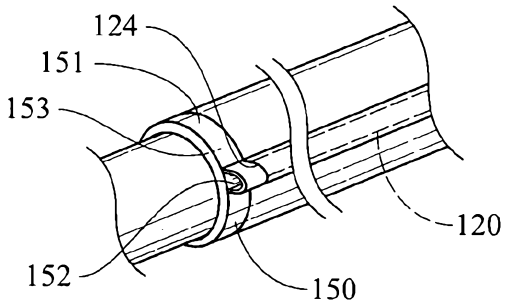


FIG. 5

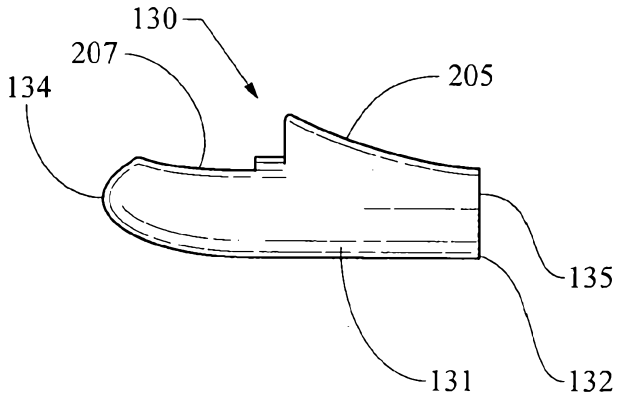


FIG. 6A

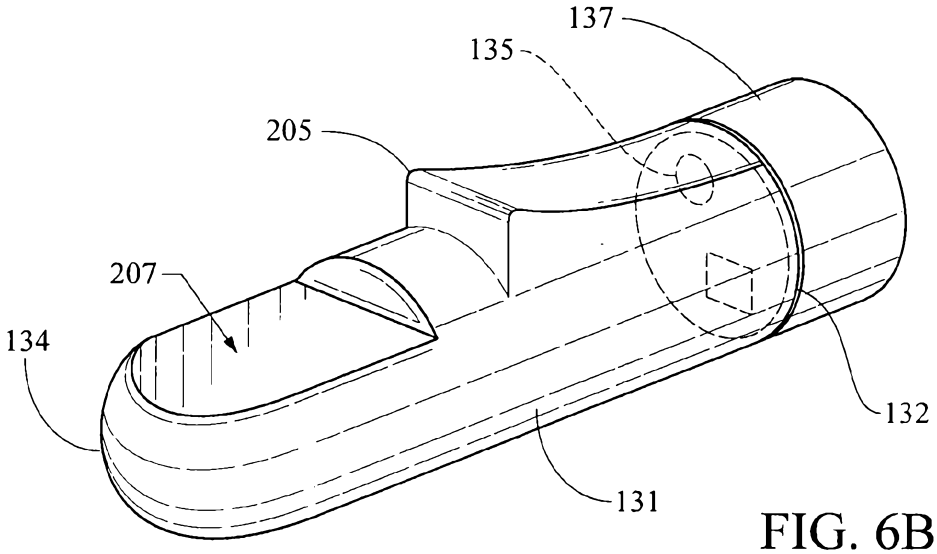


FIG. 6B

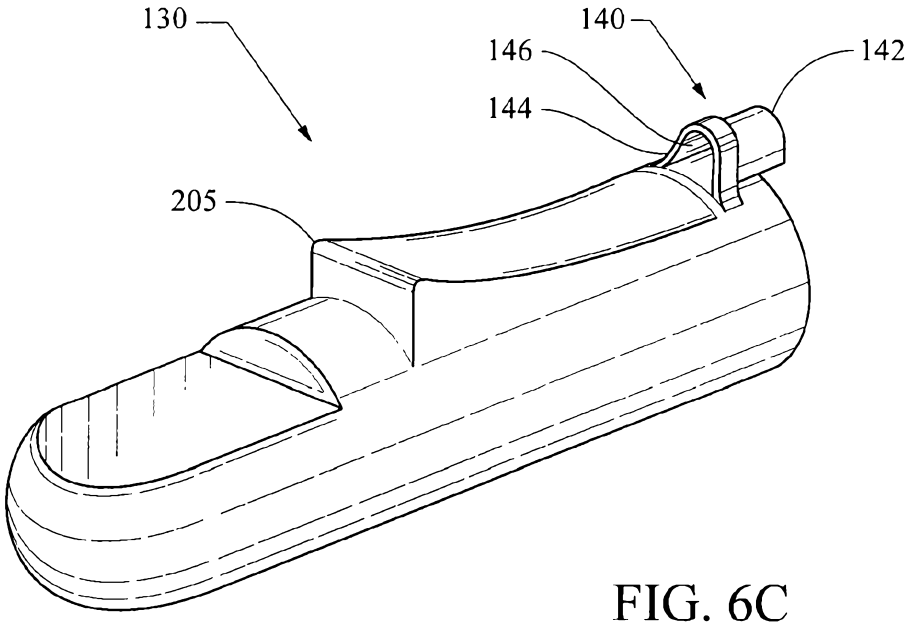


FIG. 6C

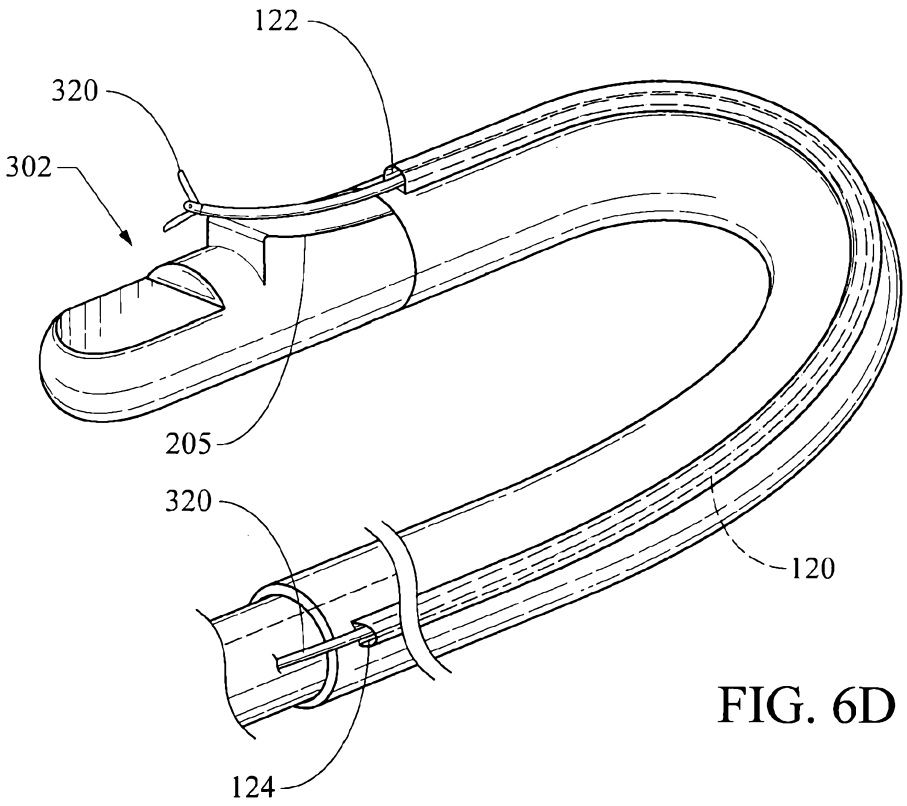


FIG. 6D

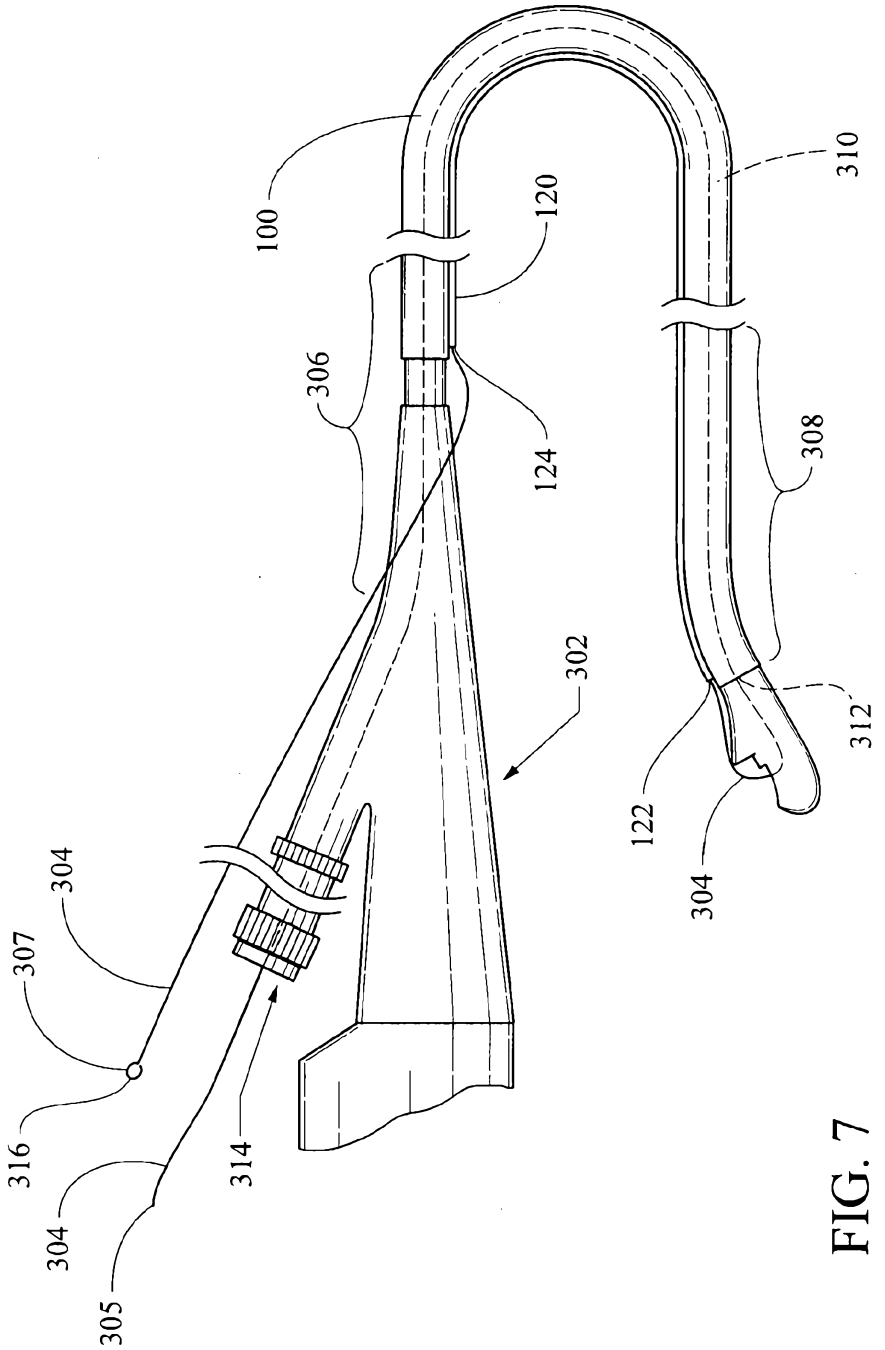


FIG. 7

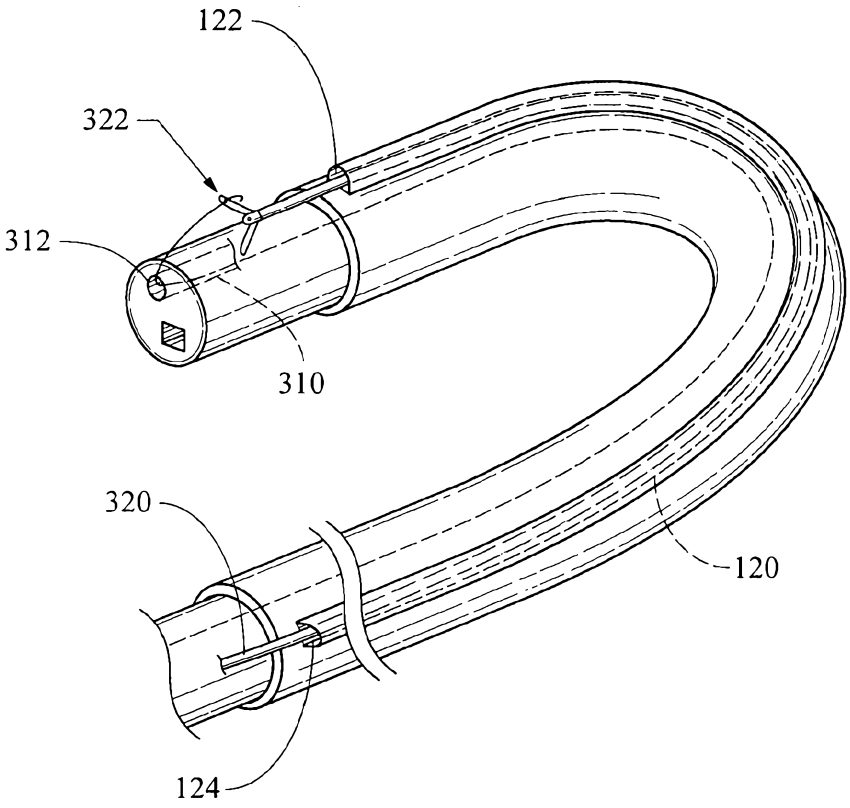


FIG. 8

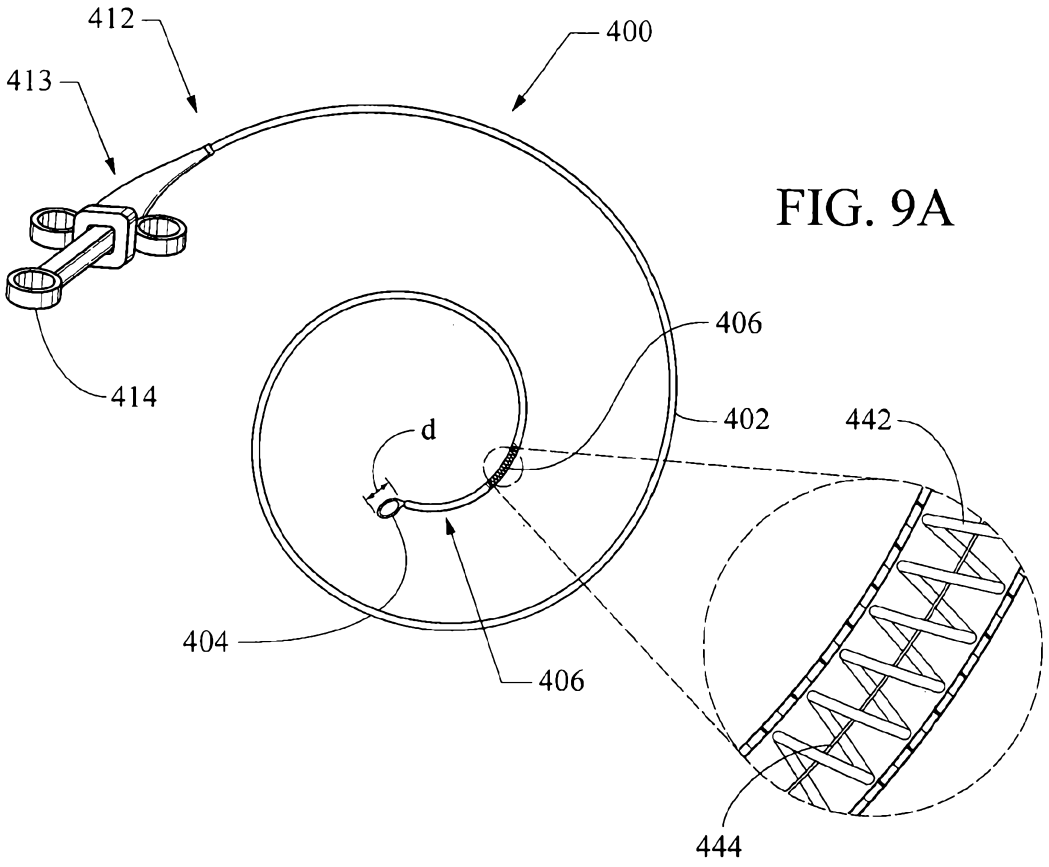


FIG. 9A

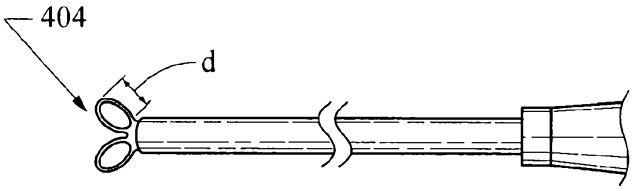


FIG. 9B

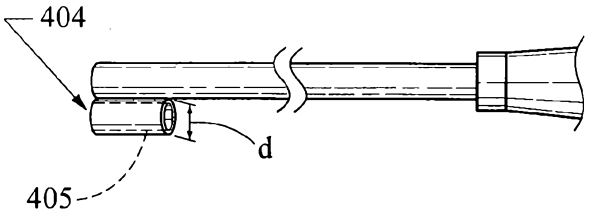


FIG. 9C

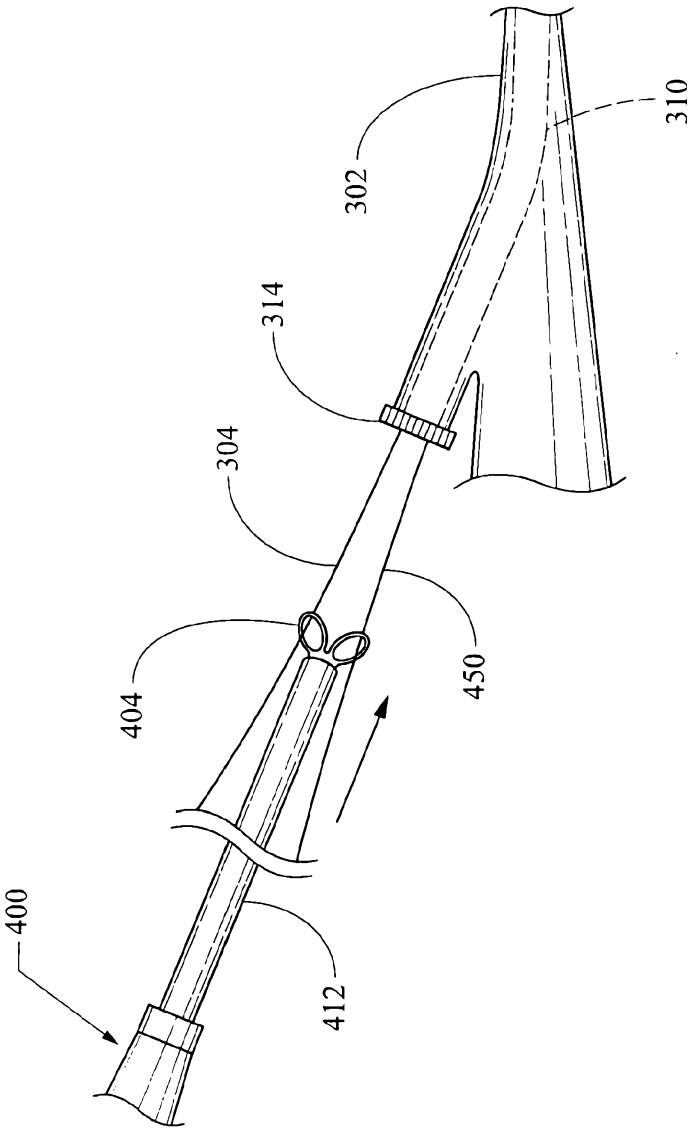


FIG. 9D

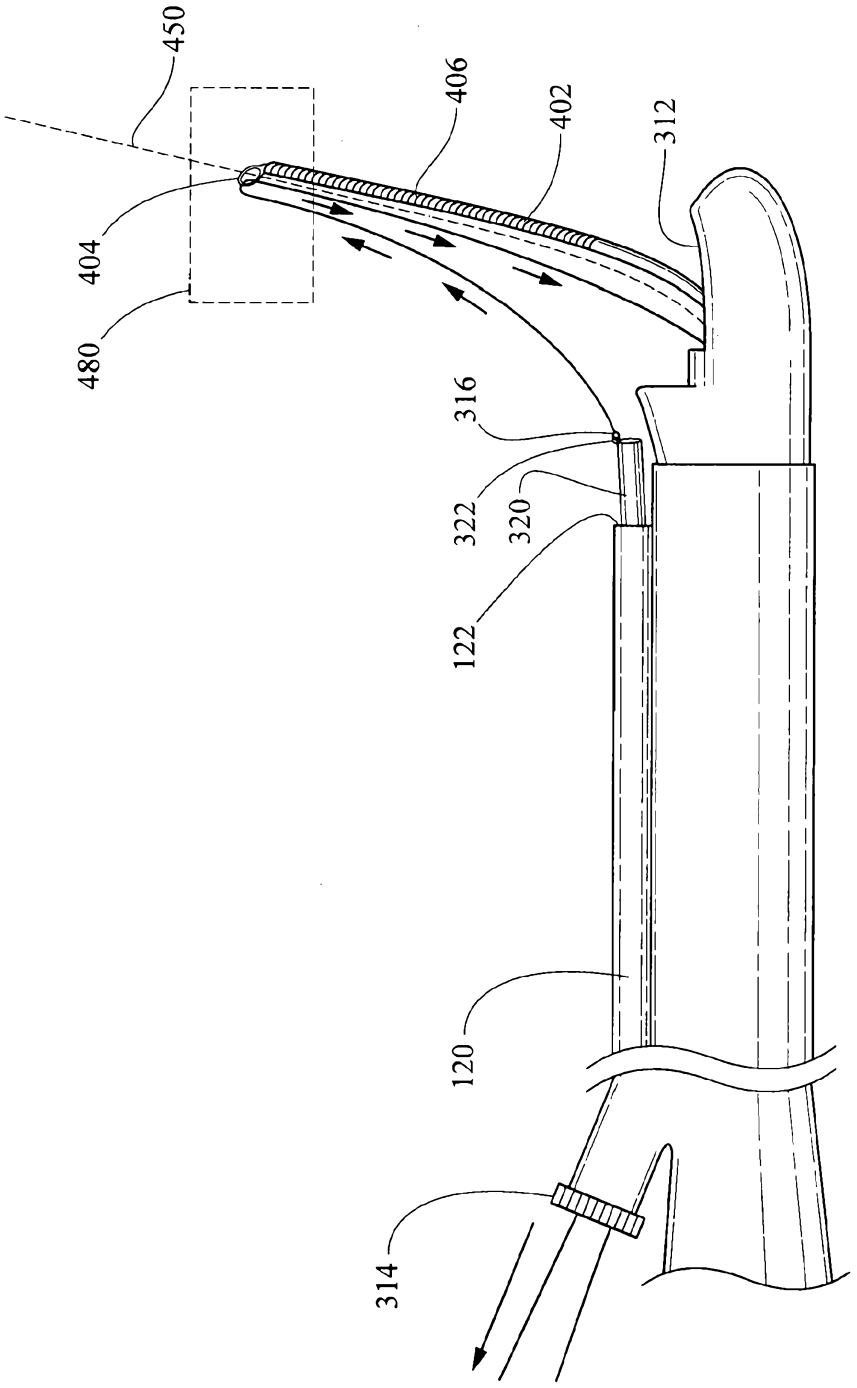


FIG. 9E

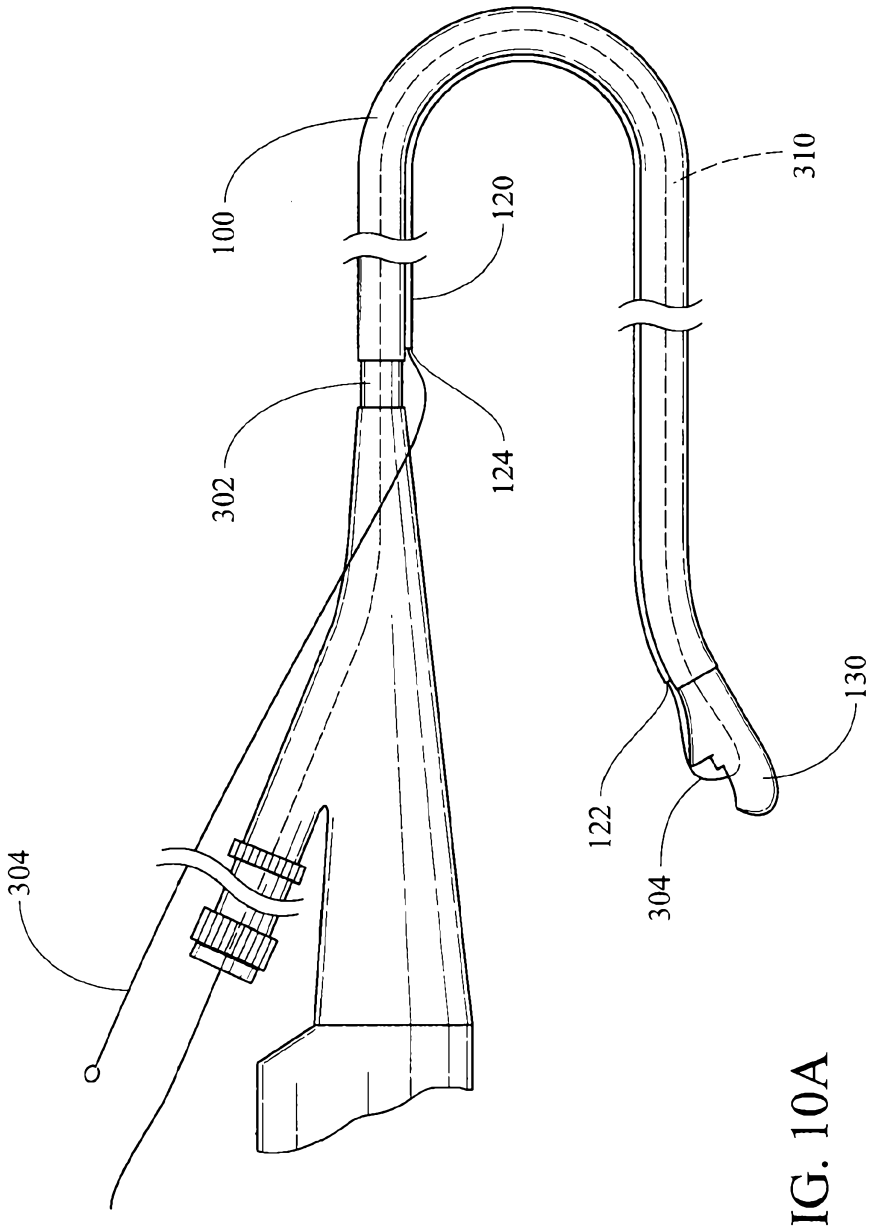


FIG. 10A

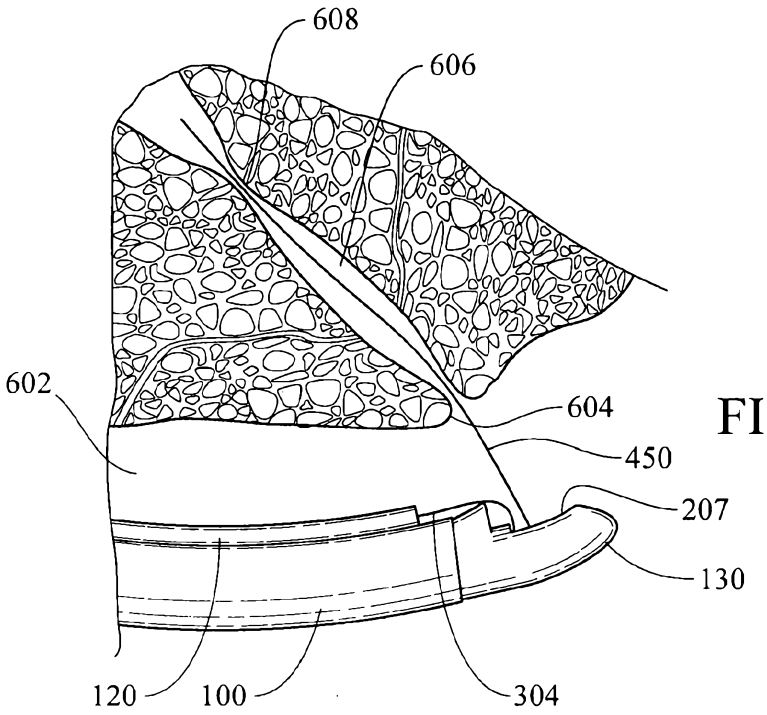


FIG. 10B

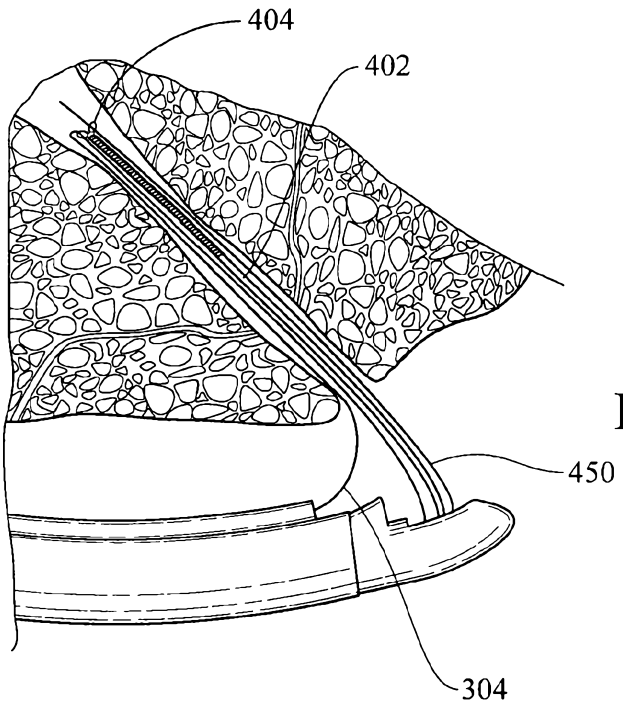


FIG. 10C

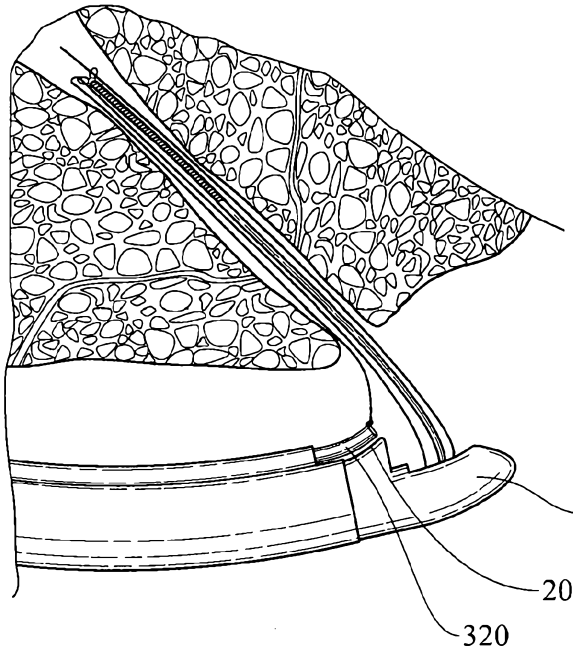


FIG. 10D

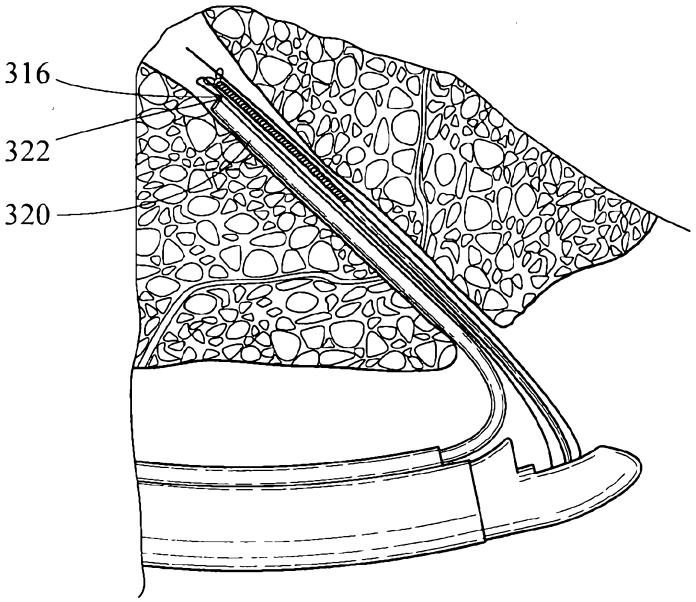


FIG. 10E

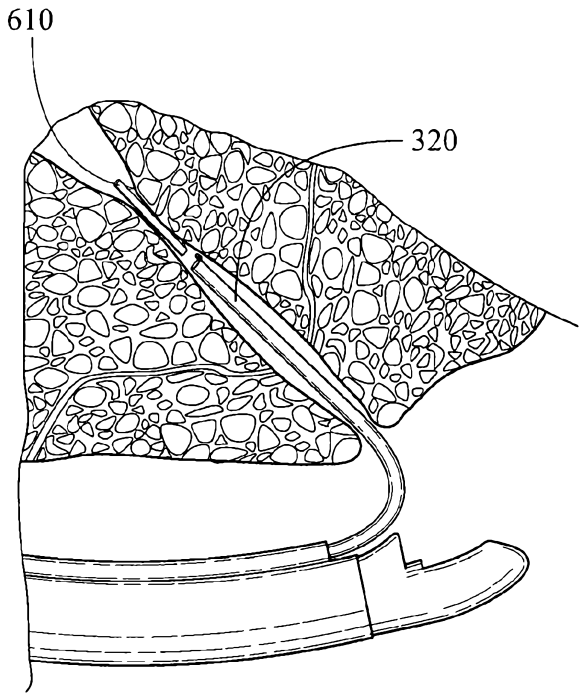


FIG. 10F