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(54) METHOD, APPARATUS AND KIT FOR BILE OR PANCREATIC DUCT ENDOSCOPY

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(57) **ABSTRACT**

A method, apparatus and kit for performing bile or pancreatic duct endoscopy. In some embodiments, the kit includes a wire adapted to be navigated perorally or pernasally to a position within the biliary tree or the pancreatic duct. The kit can further include an endoscope having a generally tubular body movable along the wire to and within the biliary tree or pancreatic duct. The kit can further include a tool dimensioned to be received within and movable along the tubular body of the endoscope. In some embodiments, the apparatus includes the wire, the endoscope and an overtube positioned over the endoscope and movable along the wire. Also, in some embodiments the method includes navigating the wire to within the biliary tree or pancreatic duct, and installing the endoscope over the wire to a position within the biliary tree or pancreatic duct.

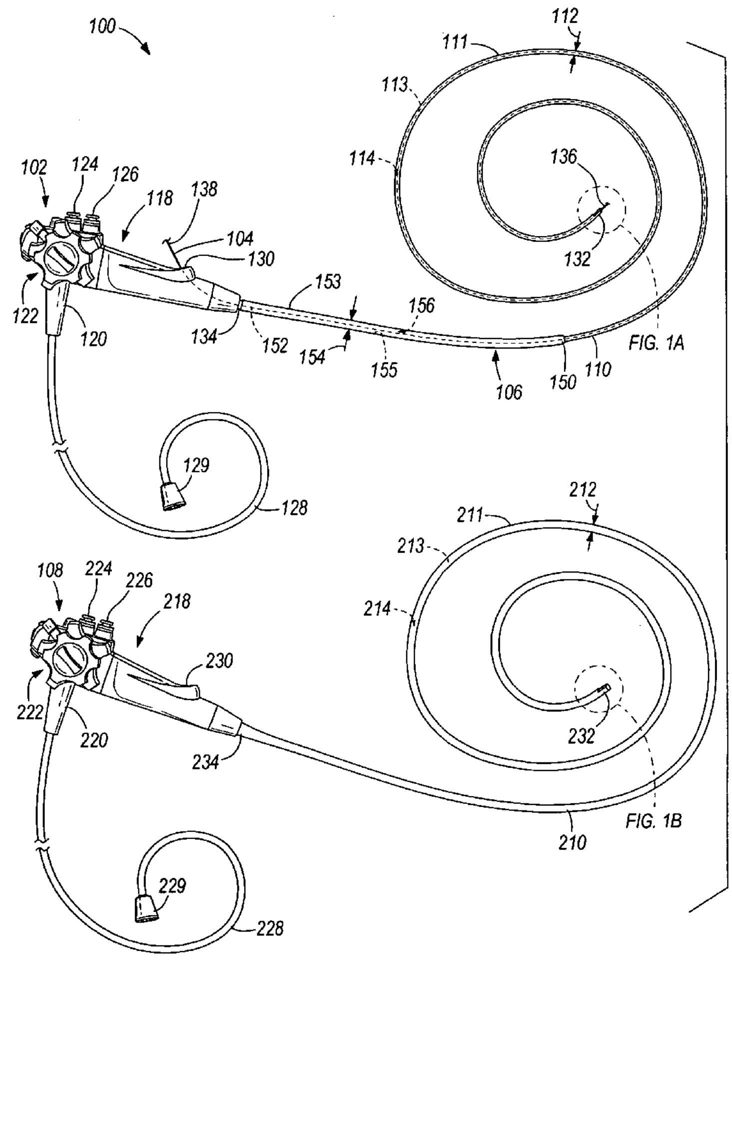

FIG. 1A

FIG. 1B

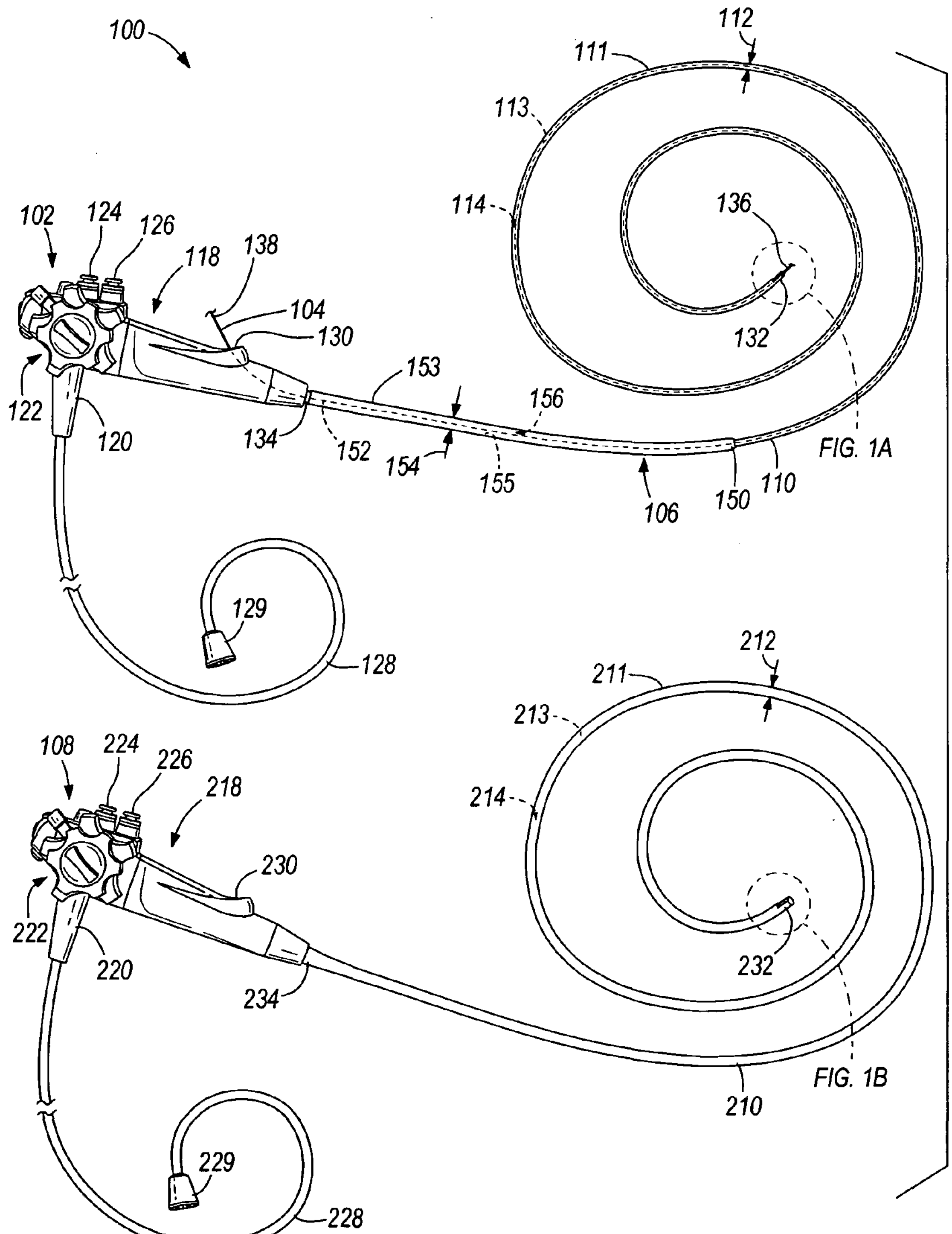
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FIG. 1A
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FIG. 1B

FIG. 1

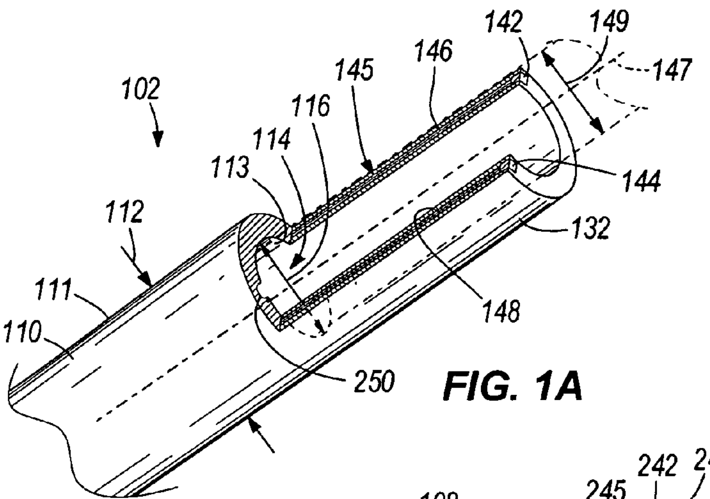

FIG. 1A

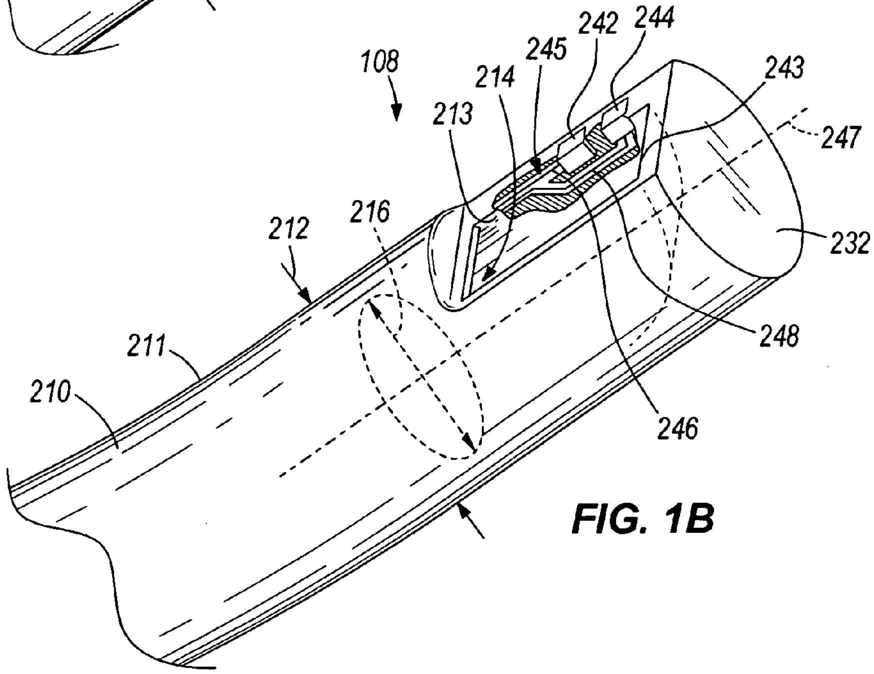

FIG. 1B

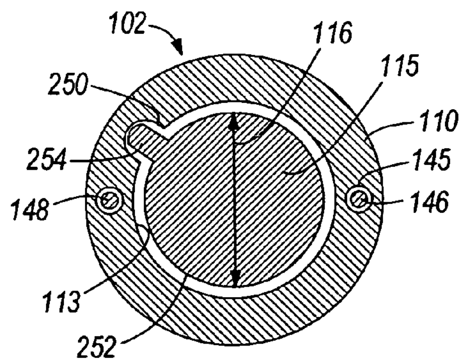

FIG. 7B

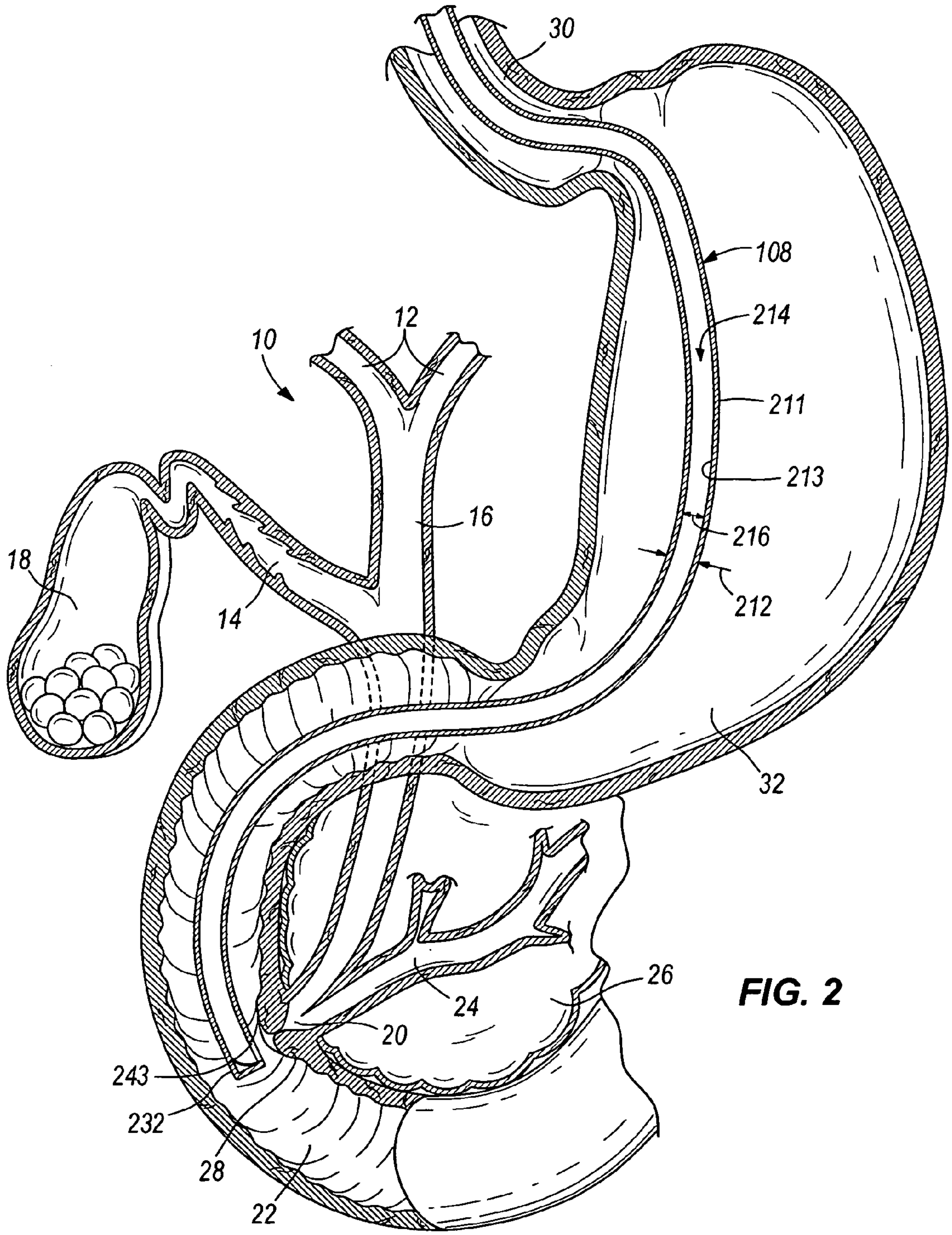

FIG. 2

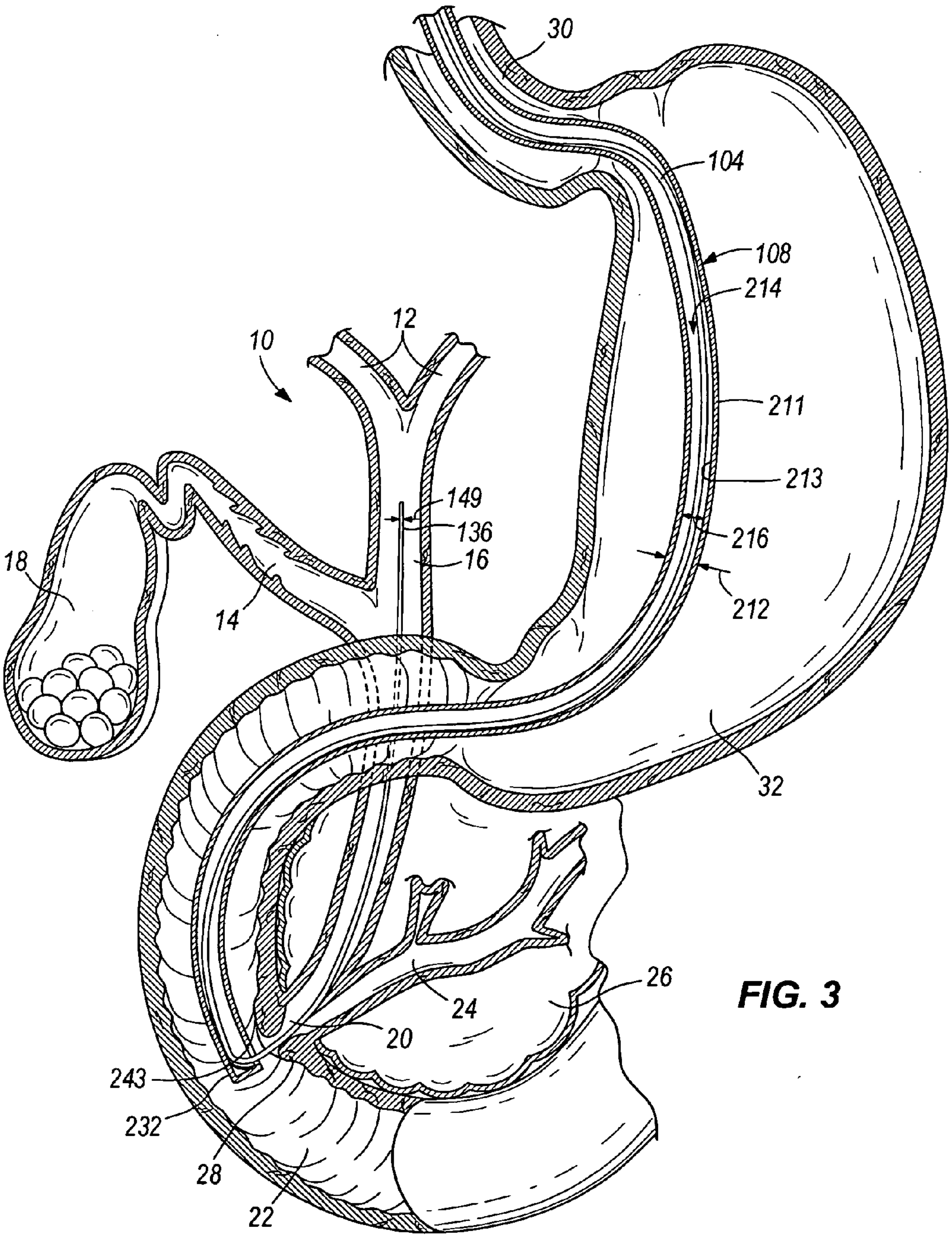
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FIG. 3

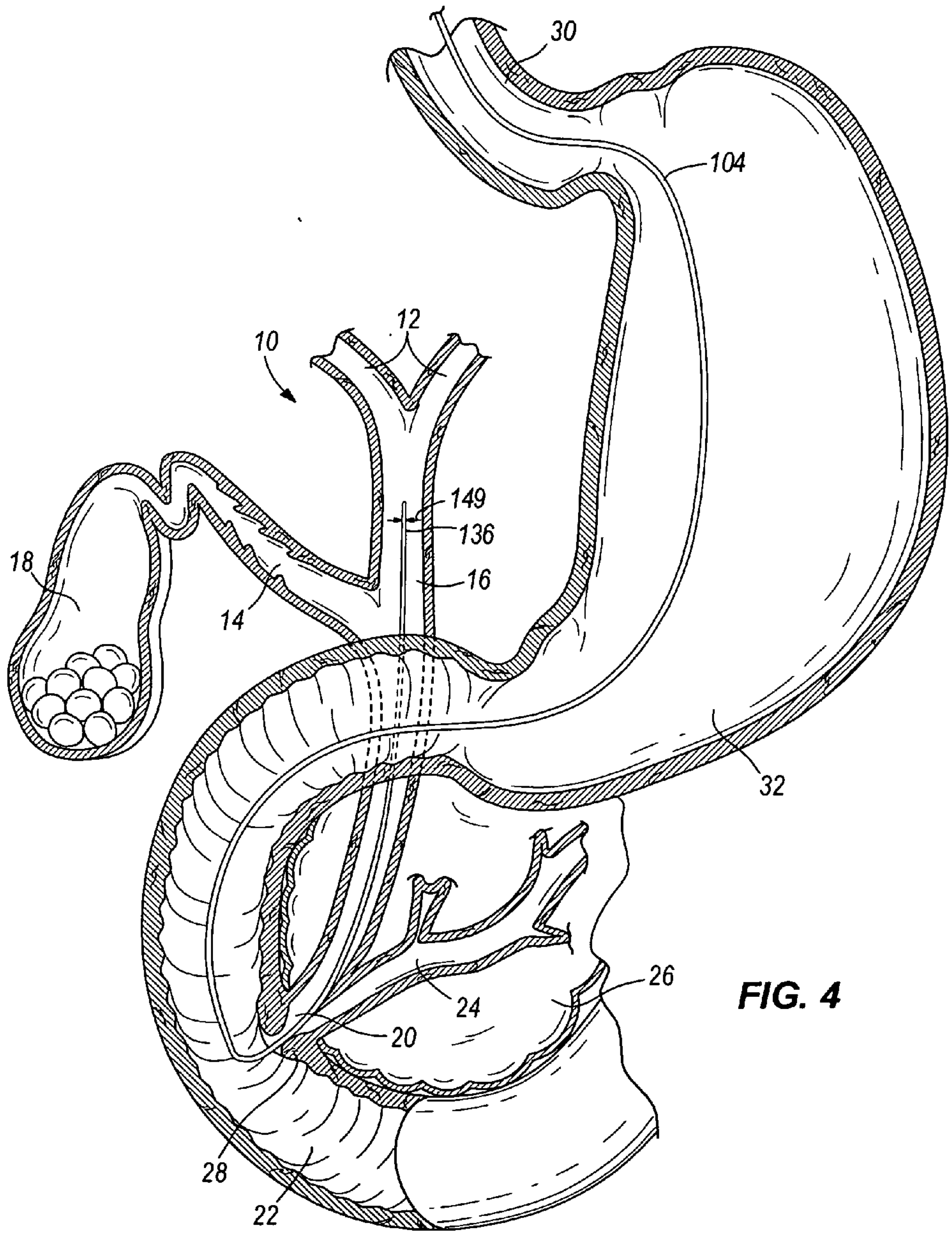

FIG. 4

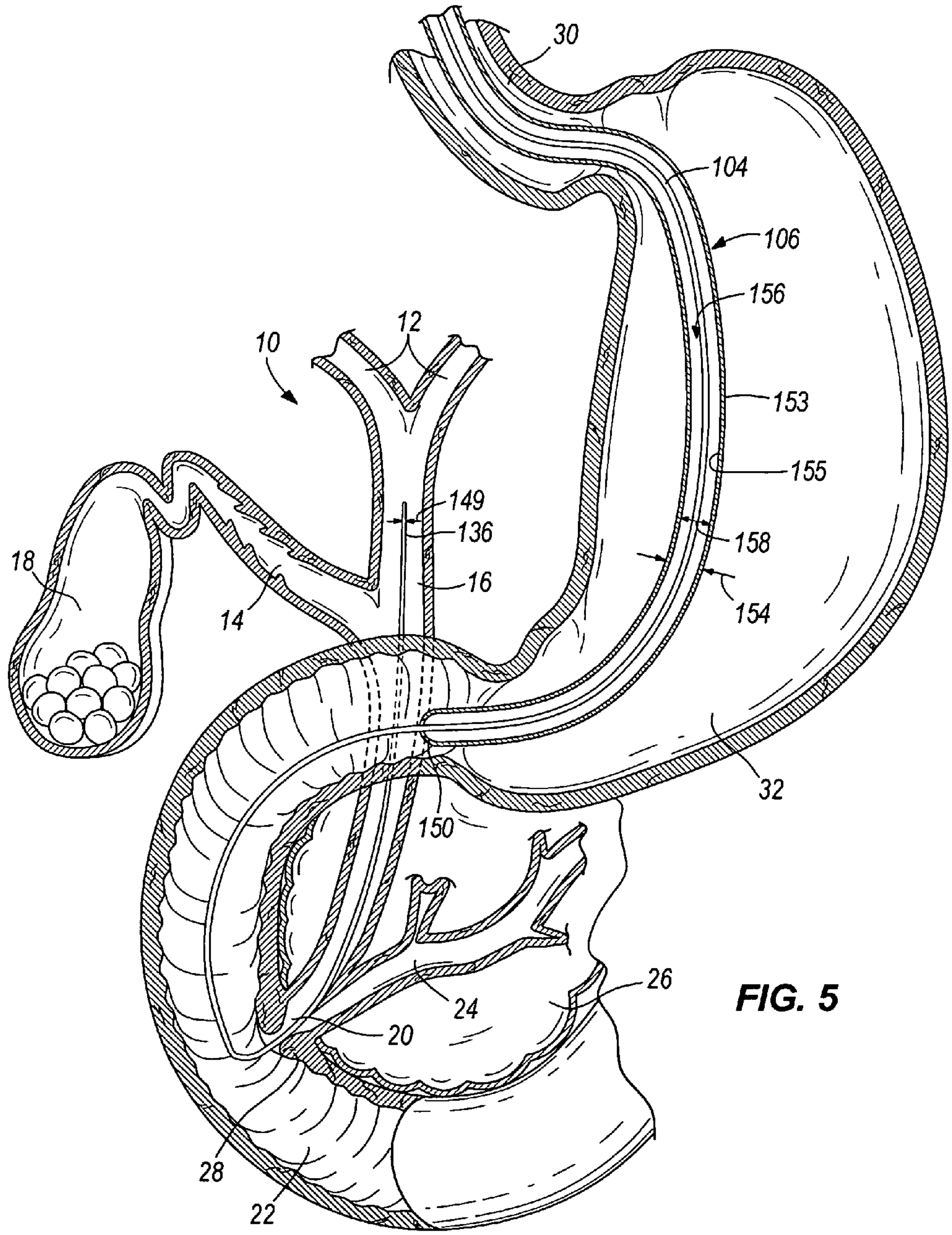
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FIG. 5

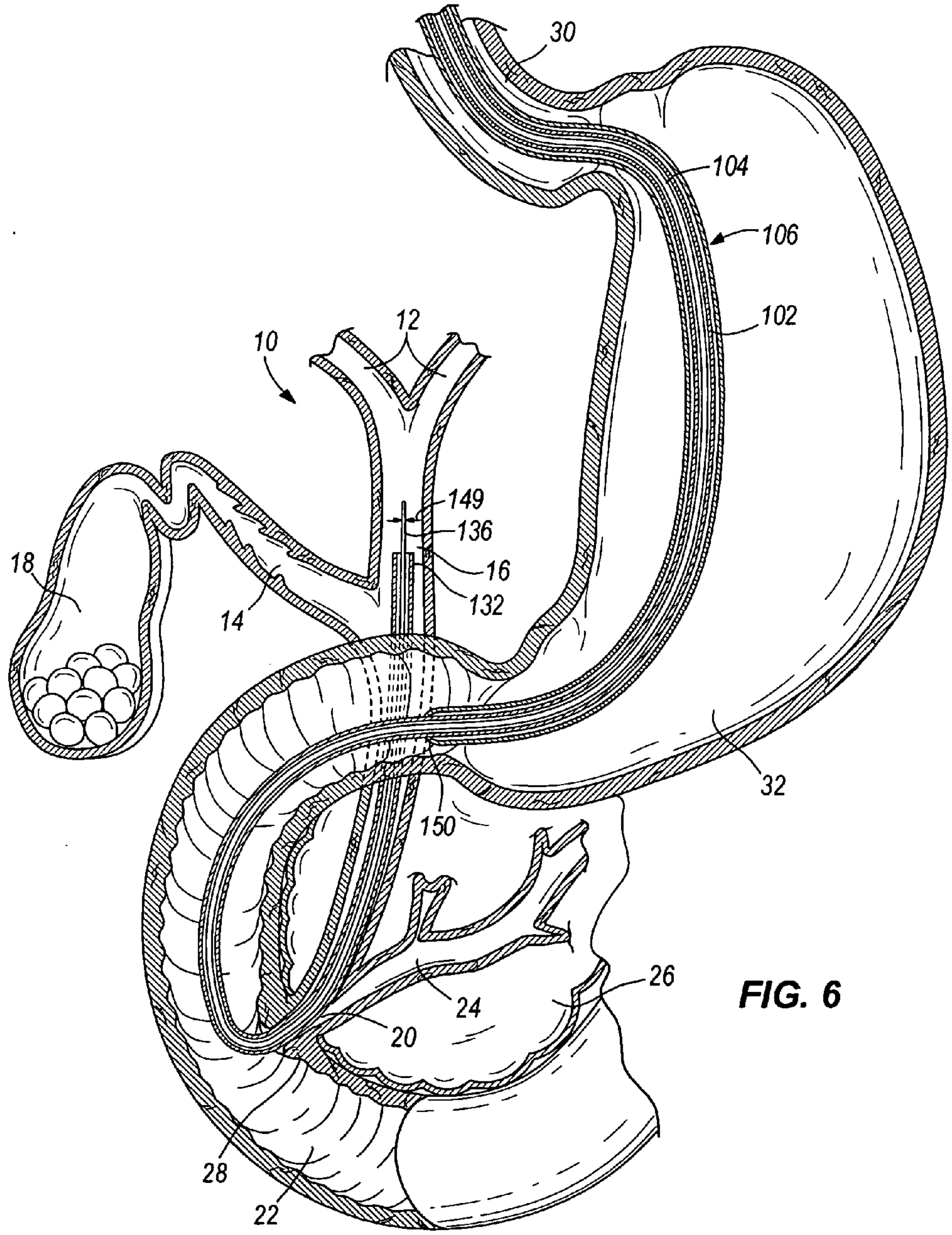


FIG. 6

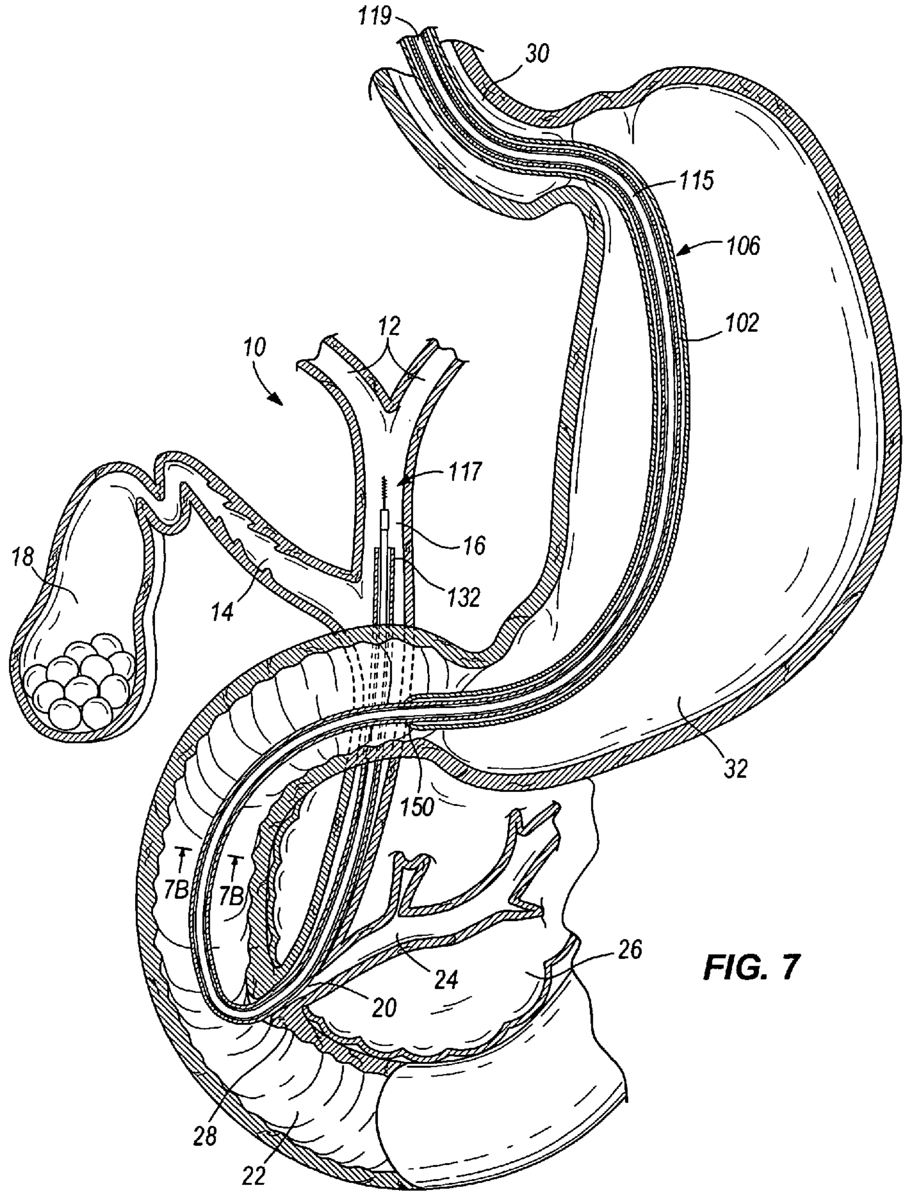
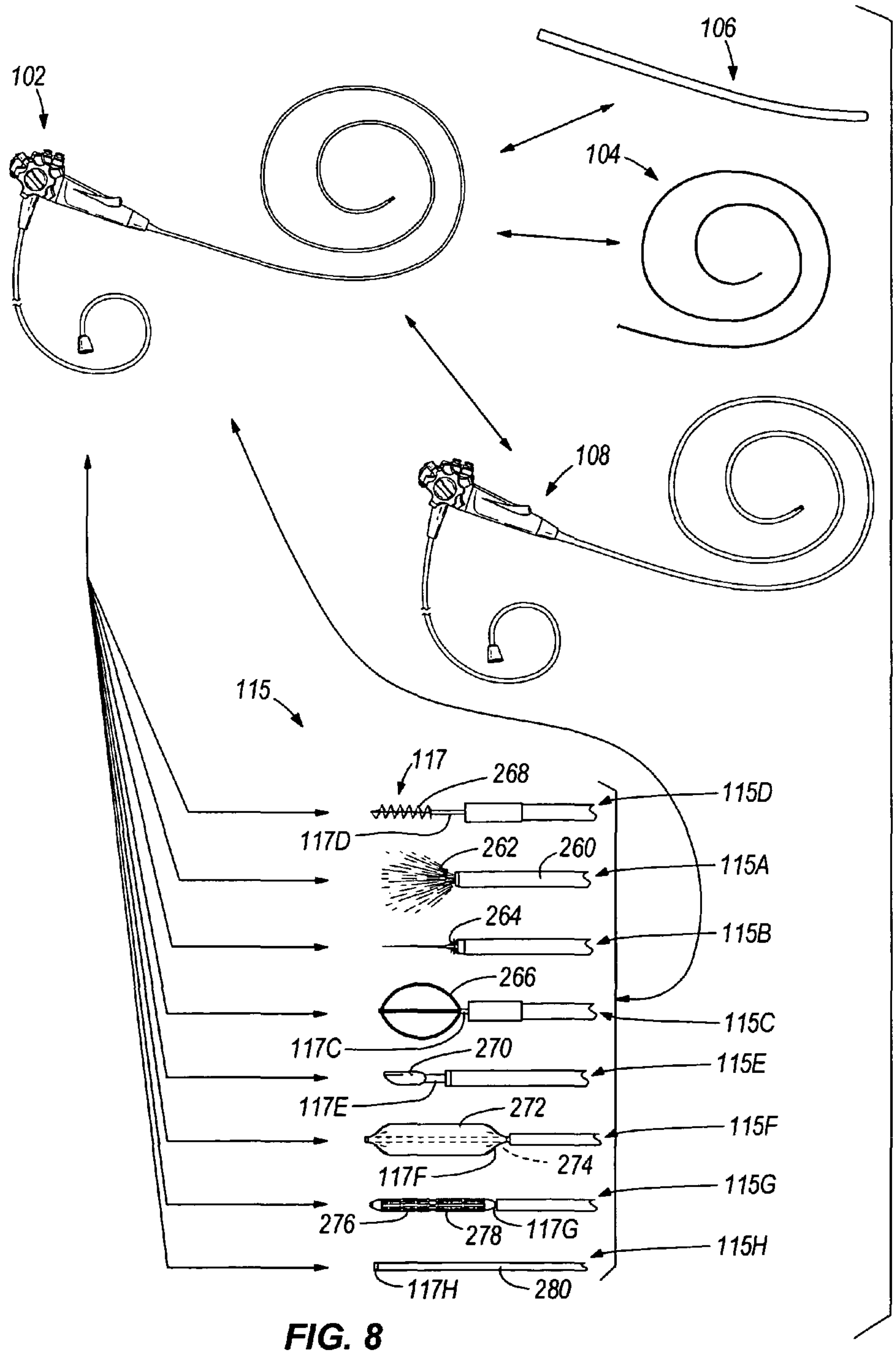


FIG. 7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108
115
117
268
115D
117D
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115A
264
115B
266
115C
117C
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115E
117E
272
115F
274
117F
115G
276
278
117G
115H
117H
280

FIG. 8

METHOD, APPARATUS AND KIT FOR BILE OR PANCREATIC DUCT ENDOSCOPY

BACKGROUND

[0001] Peroral cholangioscopy and percutaneous transhepatic cholangioscopy (PTCS) are existing nonsurgical procedures that permit direct visualization of the biliary tree and target biopsies of pathological findings. In peroral cholangioscopy, a small caliber (e.g., about 3 mm) scope (often referred to as a "baby" scope) is typically fed through the channel of a duodenoscope ("mother" scope) and is then advanced into the common bile duct (CBD). Overall, the procedure can be safer and faster than PTCS. However, such conventional peroral cholangioscopy procedures are generally expensive, time consuming, cumbersome, and require two experienced endoscopists: one to operate the mother scope, the other to operate the baby scope. Also, the lack of dedicated water and/or air channels compromises visibility and requires the assembly and use of a cumbersome water irrigation system, which can add time and effort to such procedures. Additional limitations include the extreme fragility of the baby scope (resulting in a short useful life of the baby scope and high repair costs), and the small caliber (e.g., less than about 2 mm) of the working channel that only permits passage of small biopsy forceps able to obtain very small and, in many cases, inadequate tissue samples. In light of these drawbacks, the popularity of peroral bile or pancreatic duct endoscopy has remained limited.

SUMMARY

[0002] Some embodiments of the present invention provide a kit for bile or pancreatic duct endoscopy, wherein the kit comprises a wire adapted to be navigated perorally or pernasally to the ampulla of Vater; and an endoscope comprising a generally tubular body, the tubular body having a lumen and an outer diameter, the outer diameter being less than about 7 mm, the lumen dimensioned to receive the wire, the endoscope movable along the wire via relative movement between the lumen and the wire within the lumen for navigation of the endoscope along the wire to and within the ampulla of Vater.

[0003] In some embodiments, a kit for bile or pancreatic duct endoscopy is provided, and comprises an endoscope adapted to be navigated perorally or pernasally to at least one of the ampulla of Vater, the common bile duct, the pancreatic duct, the cystic duct, and the hepatic ducts, the endoscope comprising a generally tubular body, the tubular body including a lumen and an outer diameter, the outer diameter being less than approximately 7 mm; and a tool dimensioned to be received within the lumen of the tubular body of the endoscope, the tool adapted to perform at least one of diagnosis and therapy in at least one of the ampulla of Vater, the common bile duct, the pancreatic duct, the cystic duct, and the hepatic ducts.

[0004] Some embodiments of the present invention provide an apparatus for performing bile or pancreatic duct endoscopy upon a patient having a mouth and an ampulla of Vater, wherein the apparatus comprises a wire adapted to extend from the patient's mouth to the patient's ampulla of Vater; an endoscope comprising a generally tubular body, the tubular body including a lumen and an outer diameter, the outer diameter being less than about 7 mm, the lumen dimensioned to receive the wire such that the endoscope is positioned over and is movable along the wire; and an overtube having a lumen dimensioned to receive the endoscope, the overtube being positioned over the endoscope and movable along the wire.

[0005] In some embodiments, a method for performing endoscopy of a bile or pancreatic duct of a patient is provided and comprises navigating a wire perorally or pernasally to and within at least one of the ampulla of Vater, the common bile duct, the pancreatic duct, the cystic duct, and the hepatic ducts of the patient; providing an endoscope, the endoscope comprising a generally tubular body, the tubular body including a lumen and an outer diameter, the outer diameter being less than about 7 mm; installing the endoscope over the wire while the wire is in place within at least one of the ampulla of Vater, the common bile duct, the pancreatic duct, the cystic duct, and the hepatic ducts of the patient such that the wire is received within the lumen of the tubular body of the endoscope; navigating the endoscope along the wire to a position within at least one of the ampulla of Vater, the common bile duct, the pancreatic duct, the cystic duct, and the hepatic ducts; and viewing the at least one of the ampulla of Vater, the common bile duct, the pancreatic duct, the cystic duct, and the hepatic ducts with the endoscope.

[0006] Other features and aspects of the invention will become apparent by consideration of the detailed description and accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] **FIG. 1** is a view of a bile or pancreatic duct endoscopy apparatus according to an embodiment of the present invention;

[0008] **FIG. 1A** is a close-up cut-away view of a portion of the bile or pancreatic duct endoscopy apparatus of **FIG. 1**;

[0009] **FIG. 1B** is a close-up cut-away view of another portion of the bile or pancreatic duct endoscopy apparatus of **FIG. 1**;

[0010] **FIGS. 2-7** are schematic illustrations of various portions of the bile or pancreatic duct endoscopy apparatus of **FIGS. 1, 1A** and 1B, shown at various points in a method for performing bile or pancreatic duct endoscopy according to an embodiment of the present invention;

[0011] **FIG. 7B** is a schematic cross-sectional illustration of a portion of the bile or pancreatic duct endoscopy apparatus illustrated in **FIG. 7**.

[0012] **FIG. 8** illustrates component parts of a plurality of kits for performing bile or pancreatic duct endoscopy according to several embodiments of the present invention.

DETAILED DESCRIPTION

[0013] Before any embodiments of the invention are explained in detail, it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of components set forth in the following description or illustrated in the following drawings. The invention is capable of other embodiments and of being practiced or of being carried out in various ways. Also, it is to be understood that the phraseology and terminology used herein is for the purpose of description and should not be regarded as limiting. The use of "including,""comprising," or "having" and variations thereof herein is meant to encompass the items listed thereafter and equivalents thereof as well as additional items. Unless specified or limited otherwise, the terms "mounted,""connected,""supported," and "coupled" and variations thereof are used broadly and encompass both direct and indirect mountings, connections, supports, and couplings. Further, "connected" and "coupled" are not restricted to physical or mechanical connections or couplings.

[0014] Also, as used herein and in the appended claims, the term "biliary tree"**10** (see **FIGS. 2-7**) collectively refers to the gallbladder **18** and the ducts through which bile travels, including the hepatic ducts **12** that carry bile from the liver, the cystic duct **14** that carries bile between the common bile duct **16** and the gallbladder **18**, the common bile duct **16** that carries bile from the hepatic ducts **12** and/or the cystic duct **14**, and the ampulla of Vater **20** (or the hepatopancreatic duct **20**) that carries bile from the common bile duct **16** to the duodenum **22**.

[0015] In some patients, the ampulla of Vater **20** also serves as the junction between the common bile duct **16** and the main pancreatic duct **24** (see **FIGS. 2-7**), as shown in **FIGS. 2-7**, and is therefore sometimes referred to as the "hepatopancreatic duct"**20**. However, in some patients, the ampulla of Vater **20** serves merely as a termination of the common bile duct **16**, and the pancreatic duct **24** enters the duodenum separately, next to the ampulla of Vater **20**. Therefore, as used herein and in the appended claims, the term "ampulla of Vater"**20** is intended to encompass the common duct or swelling extending from the juncture of the common bile and pancreatic ducts (in some patients) as well as to either or both ducts extending from the common bile duct and pancreas, respectively. Although the ampulla of Vater **20** illustrated in the accompanying figures serves to carry bile and pancreatic juice to the duodenum **22**, it should be understood that this structure need not carry pancreatic juice to the duodenum **22**. Furthermore, the endoscopy methods, apparatuses and kits disclosed herein can be used to investigate the pancreatic duct separately by accessing the pancreatic duct **24** directly from the duodenum **22**.

[0016] As used herein and in the appended claims, the term "bile duct endoscopy" refers to endoscopy of any portion of the biliary tree **10** of a patient. Similarly, as used herein and in the appended claims, the term "pancreatic duct endoscopy" refers to endoscopy of the main pancreatic duct **24** or smaller pancreatic ducts that feed the main pancreatic duct **24** (collectively referred to herein as "the pancreatic duct **24**"). The main pancreatic duct **24** connects the pancreas **26** to the duodenum **22** directly or indirectly (e.g., via the ampulla of Vater **20** as described above). Accordingly, as used herein and in the appended claims, the term "bile or pancreatic duct endoscopy" refers to endoscopy of at least a portion of any one or more of the following: the ampulla of Vater **20**, the pancreatic duct **24** (whether accessed indirectly via the ampulla of Vater **20** or directly via the duodenum **22**), the common bile duct **16**, the cystic duct **14**, and the hepatic ducts **12**.

[0017] Also, as used herein and in the appended claims, the terms "upstream" and "downstream" refer generally to the overall direction of fluid movement for a given, non-pathological biological process. That is, the term "upstream" is used to describe any location, element or process that occurs prior to the point or area being referred to relative to the direction of fluid movement, whereas the term "downstream" is used to describe any location, element or process that occurs subsequent to the point or area of reference with respect to fluid movement. For example, and with reference to **FIGS. 2-7**, bile flows from the liver via hepatic ducts **12** to the common bile duct **16**, and to the ampulla of Vater **20**. Accordingly, the hepatic ducts **12** are upstream of the common bile duct **16**, and the common bile duct **16** is upstream of the ampulla of Vater **20**; whereas, the ampulla of Vater **20** is downstream of the common bile duct **16**, and the common bile duct **16** is downstream of the hepatic ducts **12**.

[0018] In addition, as used herein and in the appended claims, the terms "proximal" and "distal" are used to refer to relative locations or positions with respect to an origin. That is, the term "proximal" is used to describe any location or position that is situated nearer the origin, whereas the term "distal" is used to describe any location or position that is situated farther from the origin. In the present invention, the origin is generally defined as the location or position of entry into an internal cavity of a patient (i.e., the position of the physician), and the terms "proximal" and "distal" are used to describe locations or positions relative to that entry point. For example, an endoscope has a proximal end that can be grasped by a physician, and a distal end that can be positioned within an internal cavity of a patient. The distal end of the endoscope can be moved distally in the internal cavity. For example, the distal end of the endoscope can enter the mouth, and then be moved distally into the esophagus, the stomach, and so forth, to capture images of the areas of interest within the patient.

[0019] Furthermore, as used herein and in the appended claims, the term "retrograde" refers to movement in a direction generally opposite the usual direction of movement or flow. For example, endoscopic retrograde cholangiography (ERC) includes navigating an endoscope from the duodenum **22** (see **FIGS. 2-7**), to the ampulla of Vater **20**, to the common bile duct **16**, and so forth, because the endoscope is being navigated opposite the direction that bile normally moves in these structures.

[0020] **FIGS. 1, 1A** and 1B illustrate a bile or pancreatic duct endoscopy apparatus **100** (also referred to herein as "endoscopy apparatus"**100**) according to an embodiment of the present invention. In some embodiments, the endoscopy apparatus **100** includes a first endoscope **102**, a wire **104**, an overtube **106**, and a second endoscope **108**.

[0021] The first endoscope **102** can include a generally tubular body **110** shaped and dimensioned to be received in an internal cavity of a patient's body, and specifically, in the biliary tree **10** and/or pancreatic duct **24** of the patient. The tubular body **110** of the first endoscope **102** in the illustrated embodiment has an outer surface **111** that defines an outer diameter **112** and an inner surface **113** that defines a lumen **114** through the tubular body **110** and an inner diameter **116**. As used herein and in the appended claims, the term "diameter" is employed to refer to a thickest dimension of an element's cross-sectional shape, and does not alone indicate or imply the shape of the element.

[0022] The lumen **114** is sometimes referred to herein as a "working channel"**114**. The outer diameter **112** can be sized to access a variety of locations within the biliary tree **10** and the pancreatic duct **24**. In some embodiments, the outer diameter **112** is less than about 7 mm, which allows the tubular body **110** of the endoscope **102** to access the ampulla of Vater **20** and various regions within the biliary tree **10** or pancreatic duct **24**. The entrance to the ampulla of Vater **20** is defined by the major duodenal papilla **28** and the sphincter of Oddi, a muscle that encircles the entrance to the ampulla of Vater **20**. For many applications, the sphincter of Oddi will need to be cut (e.g., a 5-10 mm incision can be made) or dilated to allow the wire **104** and/or the tubular body **110** to access the ampulla of Vater **20**.

[0023] In some embodiments, the outer diameter **112** of the tubular body **110** is less than about 6 mm, which can allow the tubular body **110** to access the common bile duct **16**, and hepatic ducts **12** in normal or diseased conditions. Also, in some embodiments, the outer diameter **112** of the tubular body **110** is less than about 5 mm, which can allow the tubular body **110** to access the common bile duct **16**, the hepatic ducts **12**, and in some cases, the cystic duct **14** and the pancreatic duct **24** in normal or conditions. For example, in some embodiments, the outer diameter **112** of the tubular body **110** is between about 5 mm and about 6 mm (e.g., such as a 5.6 mm GIF-XP **160** ultra-slim upper endoscope, available from Olympus America, Inc., Melville, N.Y.). In some embodiments, the outer diameter **112** of the tubular body **110** is at least about 3 mm. Also, in some embodiments, the outer diameter **112** is at least about 4 mm. For example, in some embodiments the outer diameter **112** is greater than about 3.4 mm. The smaller the outer diameter **112**, the further upstream the tubular body **110** will be allowed to navigate.

[0024] The above description relating outer diameter **112** of the tubular body **110** to accessible sites is given as a general approximation of the anatomical structures that may be accessed under normal or diseased conditions with an outer diameter **112** of these sizes. However, patient variability can affect which ducts are accessible by various sizes of tubular bodies **110**. In addition, diseased or pathological conditions can affect which ducts are accessible by various sizes of tubular bodies **110**. For example, under some pathological conditions, the pancreatic duct **24** may be accessible by a tubular body **110** having an outer diameter **112** of about 6 mm, and under some pathological conditions, the cystic duct **14** may be accessible by a tubular body **110** having an outer diameter of about 5 mm.

[0025] The inner diameter **116** of the tubular body **110** can be large enough to allow the wire **104** and/or one or more types of tools **115** (see **FIGS. 7 and 8**) to be received within and moved relative to the lumen **114**. Each tool **115** can include a distal end **117** and a proximal end **119**. In addition, the inner diameter **116** of the tubular body **110** can be sized to allow the tools **115** to be navigated within and along the lumen **114** to a variety of sites in the biliary tree **10** for a variety of diagnostic and therapeutic procedures, as described in greater detail below with reference to **FIGS. 7 and 8**, including sphincterotomy, lithotripsy, stone removal, stone reduction, tissue removal, stenting, cauterization, biopsy, surgery, and the like. In some embodiments, the inner diameter **116** is at least about 1.2 mm to allow a variety of diagnostic and therapeutic tools to fit within the lumen **114** of the tubular body **110**, and be moved along the lumen **114**. In some embodiments, the inner diameter **116** is at least about 2 mm. For example, a tubular body **110** having an inner diameter **116** no less than about 2 mm and no greater than about 6 mm can be utilized for tool insertion and movement, as well as for wire insertion and movement as described in greater detail below.

[0026] In some embodiments, the first endoscope **102** also includes a control portion **118**. The control portion **118** can include a handle **120**, a plurality of controls (e.g., dials **122** in the illustrated embodiment) for controlling the first endoscope **102** (e.g., for controlling flexion of the tubular body **110**), an irrigation valve **124**, a suction valve **126**, and/or a cable **128** that houses power connection wiring, fiber optics wiring, and the like. The cable **128** can include a connector **129** allowing the cable **128** to be connected to a power supply, a computer or computer peripheral device (which in some embodiments can run cholangiography software or other instructions, can be microprocessor-based, and/or can include a database or other information repository), a monitor, dedicated video processing and/or viewing equipment, a fluid supply, a suction device, and/or other devices and systems for operation of the first endoscope **102**. The control portion **118** can further include a lumen port **130** permitting access to the lumen **114** of the tubular body **110** of the first endoscope **102**. In some embodiments, the lumen port **130** can allow other devices (e.g., the wire **104**, one or more tools **115**, and the like) to be moved into and along the lumen **114** and to be manipulated by the physician.

[0027] As shown in **FIG. 1**, the tubular body **110** includes a distal end **132** and a proximal end **134** in fluid communication with the lumen port **130**. In addition, the wire **104** includes a distal end **136** and a proximal end **138**. As also shown in **FIG. 1**, the tubular body **110** of the first endoscope **102** includes a length. The length can be dimensioned to allow the tubular body **110** to reach desired anatomical structures.

[0028] As described in greater detail below with reference to **FIGS. 2-7**, the wire **104** can be positioned within the internal cavities that are desired to be investigated, and the first endoscope **102** can be installed over the wire **104**. In other words, when the distal end **136** of the wire **104** has been positioned within the desired internal cavity, the distal end **132** of the tubular body **110** can be slid over the proximal end **138** of the wire **104** and moved relative to the wire **104** to navigate the distal end **132** of the tubular body **110** to the desired location (e.g., adjacent the distal end **136** of the wire **104**, in some embodiments), as shown in **FIGS. 1 and** 1A.

[0029] With continued reference to the illustrated embodiment, the distal end **132** of the tubular body **110** and the distal end **136** of the wire **104** are shown in greater detail in FIG. IA. The distal end **132** of the tubular body **110** of the first endoscope **102** can include a light **142** positioned to illuminate anatomical structures to be investigated as the distal end **132** is moved within an internal cavity of a patient. The distal end **132** can also include a camera **144** for viewing and/or recording images of anatomical structures as the distal end **132** is moved along the internal cavity of a patient.

[0030] The light **142** and the camera **144** are shown in the illustrated embodiment as being positioned in a space **145** defined between the outer surface **111** and the inner surface **113** of the tubular body **110**. The light **142** and the camera

144 are also illustrated as being substantially flush with the distal end **132** of the tubular body **110**. However, the light **142** and/or the camera **144** can be recessed or protrude with respect to the surrounding portions of the tubular body **110**, in other embodiments. Also with reference to the illustrated embodiment, the lumen **114** can extend through the distal end **132** of the tubular body **110** in a direction substantially parallel to a longitudinal axis **147** of the tubular body **110**. In addition, the light **142** and the camera **144** in the illustrated embodiment are positioned to direct light and retrieve images, respectively, in a direction substantially parallel to the longitudinal axis **147** of the tubular body **110**. Accordingly, the illustrated embodiment of the first endoscope **102** is an end-viewing endoscope. In other embodiments, the lumen can be in fluid communication with the exterior of the tubular body **110** via one or more apertures in any other portion of the distal end **132** of the tubular body **110**. In this regard, any other type of endoscope can be used (e.g., side-viewing endoscopes, and the like) without departing from the present invention.

[**0031**] Power supply wiring **146** and fiber optics wiring **148** can be connected to the light **142** and the camera **144** and can extend through the space **145** of the tubular body **110** along at least a portion of the length of the tubular body **110**. The locations, orientations and configurations of the light **142**, camera **144**, power supply wiring **146**, and fiber optics wiring **148** are shown in **FIG. 1A** by way of example only. Any other arrangement, configuration and relative orientation of these elements can be employed as desired without departing from the spirit and scope of the present invention.

[**0032**] In some embodiments, the wire **104** includes appropriate dimensions and properties (e.g., length, outer diameter **149**, shape, degree of taper (if any), stiffness, flexibility, elasticity, biocompatibility, and the like) that allow the wire **104** to be navigated perorally or pernasally to the biliary tree **10** or pancreatic duct **24**. A variety of wires **104** can be used for this purpose. For example, in some embodiments, the wire **104** includes a 0.035-inch JAGWIRE® Super Stiff guidewire available from Boston Scientific, Natick, Mass. As shown in **FIG. 1**, in some embodiments the outer diameter **149** of the wire **104** gradually tapers from the proximal end **138** to the distal end **136**. In other embodiments, this taper can be more or less pronounced, and can extend along any portion of the length of the wire **104**. Also, in some embodiments the distal end **136** of the wire **104** has an outer diameter **149** of less than or equal to about 0.035 inches (0.889 mm) to allow the wire **104** to readily navigate past the major duodenal papilla **28** to the ampulla of Vater **20**.

[**0033**] In some embodiments, the wire **104** is stiffer than the 0.035-inch JAGWIRE® Super Stiff guidewire. In some embodiments, the wire **104** includes a lumen through which a removable core can be positioned and moved relative to the wire **104** to provide greater stiffness to at least a portion of the length of the wire **104**. In some embodiments, the distal end **136** (e.g., the distal 3-5 cm of the wire **104**) has different properties (e.g., reduced stiffness) than the remainder of the length of the wire **104**, because different material properties are needed for navigating into tiny, fragile structures than are needed for supporting an endoscope or for navigating through large anatomical structures. For example, navigating the first endoscope **102** through the stomach **32** can cause the first endoscope **102** to curl up, wind, tangle or loop in the stomach **32**, instead of continuing on a substantially straight and direct path through the stomach **32**. The wire **104** can assist in tracking the first endoscope **102** through the stomach **32**, and can minimize looping of the first endoscope **102** in the stomach **32** by allowing the first endoscope **102** to be navigated over the wire **104**.

[**0034**] The overtube **106** can be used to assist in navigating the first endoscope **102** along the wire **104** to reach desired locations within the patient. Overtubes **106** that can be used in conjunction with the present invention include overtubes supplied by Fujinon Photo. The overtube **106** includes a distal end **150** and a proximal end **152**. The overtube **106** can also include an outer surface **153** that defines an outer diameter **154** sized to allow the overtube **106** to be inserted perorally or pernasally. The overtube **106** can also include an inner surface **155** that defines a lumen **156** through the overtube **106** and an inner diameter **158**. As shown in **FIG. 1**, the inner diameter **158** can be dimensioned to allow the first endoscope **102** to be received within and navigated along the lumen **156** of the overtube **106**, and in some embodiments to allow the first endoscope **102** to pass through the overtube **106**. That is, the inner diameter **158** of the overtube **106** is greater than the outer diameter **112** of the first endoscope **102**, in some embodiments. In order to reduce the opportunity for interference between the overtube **106** and internal cavities of the patient, the distal end **150** of the overtube **106** can be rounded or chamfered, or can otherwise be shaped without sharp edges or corners.

[**0035**] As shown in **FIGS. 2-7**, in some applications the wire **104** can be inserted perorally or pernasally into a patient's esophagus **30** and can be navigated via the stomach **32** to the duodenum **22** and biliary tree **10** or pancreatic duct **24**, such as by another endoscope that can then be removed from the patient (as described in greater detail below). As mentioned above, the first endoscope **102** can loop in the stomach **32**, and the wire **104** can minimize looping of the first endoscope **102** in the stomach **32**. In addition, because the wire **104** is small relative to the volume of the stomach **32**, installing the first endoscope **102** over the wire **104** in the stomach **32** can be difficult and can cause the wire **104** and/or the first endoscope **102** to loop in the stomach **32** as the first endoscope **102** is advanced along the wire **104** in the stomach **32**. Accordingly, in some embodiments, the overtube **106** can be installed over the wire **104** (e.g., by backloading the overtube **106** over the wire **104** prior to installing the first endoscope **102** over the wire **104**) and positioned within the stomach **32** to guide the first endoscope **102** and to substantially prevent the wire **104** and/or the first endoscope **102** from looping as the first endoscope **102** is moved along the wire **104** in the stomach **32**.

[**0036**] The overtube **106** illustrated in **FIGS. 1-8** has a length that is less than the length of the tubular body **110** of the first endoscope **102**. Specifically, as shown in **FIGS. 2-7**, the length of the overtube **106** allows the overtube **106** to be navigated to a position adjacent a distal portion of the stomach **32** and a proximal portion of the duodenum **22** (e.g., the duodenal bulb). However, in some embodiments, the length of the overtube **106** is sized to allow the overtube **106** to be navigated further through the duodenum **22** to a position adjacent the entrance to the ampulla of Vater **20** (and the entrance to the pancreatic duct **24**, in some patients). The overtube can have a number of different lengths and diameters for receiving the first endoscope **102** and for assisting in navigating the first endoscope **102** along the wire **104** in relatively large internal cavities. In some embodiments, the overtube **106** includes an inner diameter **158** that is greater than the outer diameter **112** of the tubular body **110** of the first endoscope **102**, and that allows the tubular body **110** to move relative to the lumen **156** of the overtube **106** without friction. For example, in some embodiments, the overtube **106** includes an inner diameter of at least about 8 mm. In some embodiments, the overtube **106** includes an outer diameter of less than about 1 cm. In some embodiments, the overtube **106** includes a length of at least about 50 cm to readily access a distal portion of the stomach **32** or a proximal portion of the duodenum **22**.

[0037] With continued reference to **FIG. 1**, the second endoscope **108** in the illustrated embodiment shares many of the same elements and features described above with reference to the first endoscope **102**, wherein like numerals represent like elements. Accordingly, elements and features of the second endoscope **108** corresponding to elements and features of first endoscope **102** are provided with the same reference numerals in the **200** series. Reference is made to the description of the first endoscope **102** above for a more complete description of the features and elements (and alternatives to such features and elements) of the second endoscope **108**.

[0038] In some embodiments, the second endoscope **108** includes a tubular body **210** having an outer surface **211** that defines an outer diameter **212**, an inner surface **213** that defines a lumen **214** and an inner diameter **216**, and a control portion **218**. The tubular body **210** can include a length that extends from a distal end **232** to a proximal end **234**, and can have a lumen port **230** in fluid communication with the lumen **214**.

[0039] The outer and inner diameters **212**, **216** and the cross-sectional lumen size of the tubular body **210** of the second endoscope **108** can be generally larger than outer and inner diameters **112**, **116** and the cross-sectional lumen size of the tubular body **110** of the first endoscope **102**. As shown in **FIG. 2**, the second endoscope **108** is adapted to be navigated perorally or pernasally into the esophagus **30**, the stomach **32** and the duodenum **22** to a position adjacent the entrance to the ampulla of Vater **20** (and the pancreatic duct **24**, in some patients). The second endoscope **108** in the illustrated embodiment is adapted to be navigated to such a position without requiring the assistance or guidance of the wire **104** or the overtube **106**. However, the inner diameter **216** and the lumen **214** can be sized to allow the wire **104** to be received within and moved along the lumen **214** of the tubular body **210**.

[0040] The distal end **232** of the tubular body **210** according to an embodiment of the present invention is shown in greater detail in **FIG. 1B**. As shown in **FIG. 1B**, the distal end **232** can include a light **242** positioned to illuminate anatomical structures to be investigated as the distal end **232** is moved along an internal cavity within a patient. The distal end **232** can further include a camera **244** for viewing and/or recording images of anatomical structures as the distal end **232** is moved along the internal cavity of the patient.

[0041] The light **242** and the camera **244** of the second endoscope **108** are shown by way of example in **FIG. 1B** as being positioned in a space **245** defined between the outer surface **211** and the inner surface **213** of the tubular body **210**. The tubular body **210** can include an aperture **243** defined therein in fluid communication with the lumen **214** of the tubular body **110** to allow fluid and/or devices to be passed into and out of the lumen **214** via the aperture **243**. The aperture **243** can be oriented in any manner with respect to a longitudinal axis **247** of the tubular body **210**, and in the illustrated embodiment is oriented substantially orthogonally to the longitudinal axis **247** of the tubular body **210**.

[0042] The light **242** and the camera **244** can be positioned adjacent the aperture **243**, or in any other locations suitable for illuminating and capturing images of an area of interest within the patient's body. The light **242** and camera **244** are substantially flush with the outer surface **211** of the tubular body **110** in the illustrated embodiment, but could instead be recessed or protrude with respect to surrounding portions of the tubular body **210**. With continued reference to the illustrated embodiment, the light **242** and the camera **244** are directed substantially orthogonally to the longitudinal axis **247** of the tubular body **210**. Accordingly, the second endoscope **108** is a side-viewing endoscope. Employing a side-viewing endoscope can permit the second endoscope **108** to be navigated through the duodenum **22** to a position adjacent the ampulla of Vater **20** without tortuous twisting or turning of the distal end **232** of the tubular body **210** to locate the entrance to the ampulla of Vater **20**. The location of the aperture **243** also allows for side access to the lumen **214** of the tubular body **210**. It should be understood, however, that the second endoscope **108** can include an end-viewing endoscope without departing from the spirit and scope of the present invention.

[0043] In the illustrated embodiment (see **FIG. 1B**), the distal end **232** of the tubular body **210** is closed, and the lumen **214** of the second endoscope **108** does not extend through the distal end **232**. However, in other embodiments, the lumen **214** does extend through the distal end **232** of the tubular body **210**. Furthermore, in the embodiment shown in **FIG. 1B**, the aperture **243** is positioned at the distal end **232** of the tubular body **210**. However, in other embodiments, the aperture **243** can be positioned anywhere along the length of the tubular body **210**, and need not be located at or proximate the distal end **232**. In addition, although the aperture **243** in the illustrated embodiment is positioned substantially orthogonally with respect to the longitudinal axis **247** of the tubular body **210** (to allow the lumen **214** to be accessed from a side of the tubular body **210**), the aperture **243** can be positioned at a variety of angles or orientations relative to the longitudinal axis **247** of the tubular body **210** while still allowing fluid and/or devices to be moved into or out of a side of the lumen **214**.

[0044] Power supply wiring **246** and fiber optics wiring **248** can be connected to the light **242** and the camera **244**, and can extend through the space **245** of the tubular body **210** along any portion of the length of the tubular body **210**. The locations, orientations and configuration of the light **242**, camera **244**, power supply wiring **246** and fiber optics wiring **248** are shown in **FIG. 1B** by way of example only. Any other arrangement, configuration and relative orientation of these elements can be employed as desired without departing from the spirit and scope of the present invention.

[0045] In some embodiments, the second endoscope **108** includes a duodenoscope, such as the TJF-160 duodenoscope, available from Olympus America, Melville, N.Y.

[0046] A bile or pancreatic duct endoscopy method (referred to herein as "the method") according to an embodiment of the present invention is illustrated in **FIGS. 2-7**, and is presented by way of example only.

[0047] With reference first to **FIG. 2**, the method can include navigating the distal end **232** of the tubular body **210** of the second endoscope **108** perorally or pernasally into the esophagus **30** of a patient, into the stomach **32**, and into the duodenum **22** to a position adjacent the entrance to the ampulla of Vater **20**. The distal end **232** can be properly positioned by using the light **242** and the camera **244** of the second endoscope **108** to image the inner wall of the duodenum **22** to locate the entrance to the ampulla of Vater **20**. When the entrance to the ampulla of Vater **20** is located, the aperture **243** of the second endoscope **108** can be positioned adjacent (e.g., at least partially in line) with the entrance to the ampulla of Vater **20**.

[0048] As mentioned above, after the second endoscope **108** has been properly positioned within the duodenum **22**, the sphincter of Oddi can be cut or dilated to allow or enhance access to the ampulla of Vater **20**.

[0049] As shown in **FIG. 3**, after the second endoscope **108** has been properly positioned within the duodenum **22**, the distal end **136** of the wire **104** can be navigated into the lumen port **230** of the second endoscope **108** and into the lumen **214** of the tubular body **210** of the second endoscope **108**. The wire **104** can be moved along the lumen **214** of the tubular body **210** until the distal end **136** of the wire **104** reaches the aperture **243** in the tubular body **210**. In other embodiments, the wire **104** can be placed in this position with respect to the second endoscope prior to insertion and navigation of the second endoscope **108** within the patient as described above. The distal end **136** of the wire **104** can then be navigated out of lumen **214** via the aperture **243**, past the major duodenal papilla **28**, and into the ampulla of Vater **20** (or into the entrance to the pancreatic duct **24**, in some patients). The distal end **136** of the wire **104** can be further navigated upstream (i.e., in a retrograde manner) to at least one of the common bile duct **16**, the pancreatic duct **24**, the cystic duct **14**, and the hepatic ducts **12**. By way of example only, the distal end **136** of the wire **104** is illustrated in **FIG. 3** as being positioned within the common bile duct **16**.

[0050] As shown in **FIG. 4**, the second endoscope **108** can be removed after the wire **104** has been positioned in the desired location within the biliary tree **10** or the pancreatic duct **24**. The second endoscope **108** can be removed by moving the second endoscope **108** proximally relative to the wire **104** so that the lumen **214** of the second endoscope **108** moves relative to the wire **104**, and the wire **104** remains positioned in the biliary tree **10** or pancreatic duct **24**.

[0051] As shown in **FIG. 5**, in some embodiments the overtube **106** can be installed over the wire **104** by backloading the overtube **106** onto the wire **104**. In other words, the rounded distal end **150** of the overtube **106** in the illustrated embodiment can be positioned over the proximal end **138** of the wire **104** and moved distally along and over the wire **104** such that the lumen **156** of the overtube **106** is moved relative to the wire **104**. In the embodiment illustrated in **FIG. 5**, the length of the overtube **106** is less than that of the wire **104**. Therefore, the overtube **106** is installed over a portion of the wire **104**, and extends to a location adjacent a distal portion of the stomach **32**, or a proximal portion of the duodenum **22**. As mentioned above, in some embodiments, the length of the overtube **106** can be greater than that illustrated in **FIG. 5**, and/or the overtube **106** can be positioned to extend further distally than what is illustrated in **FIG. 5**. It should also be noted that the overtube **106** can be shorter than that shown in the illustrated embodiment.

[0052] As shown in **FIG. 6**, in some embodiments the first endoscope **102** can be installed over the wire **104** by backloading the tubular body **110** of the first endoscope **102** over the wire **104**. That is, the distal end **132** of the tubular body **110** can be positioned over the proximal end **138** of the wire **104** and can be moved distally along and over the wire **104** such that the lumen **114** of the tubular body **110** is moved relative to the wire **104**. In some embodiments, the inner diameter **158** of the overtube **106** can be sized to allow the tubular body **110** of the first endoscope **102** to be received within and moved relative to the lumen **156** of the overtube **106**, at least for a portion of the length of the wire **104** as shown in **FIG. 6**. Specifically, in the embodiment illustrated in **FIG. 6**, the tubular body **110** of the first endoscope **102** is navigated within and along the lumen **156** of the overtube **106** through the stomach **32**. After the distal end **132** of the tubular body **110** reaches the rounded distal end **150** of the overtube **106** (i.e., in some embodiments, adjacent a distal portion of the stomach **32**), the distal end **132** of the tubular body **110** exits the lumen **156** of the overtube **106** and continues along and over the wire **104** to the biliary tree **10** or the pancreatic duct **24**. The distal end **132** of the tubular body **110** can be navigated to a position adjacent the distal end **136** of the wire **104**. As illustrated in **FIG. 6**, for example, the distal end **132** of the tubular body **110** is navigated to a position within the common bile duct **16**.

[0053] As shown in **FIG. 7**, in some embodiments the wire **104** can be removed from the lumen **114** of the tubular body **110** of the first endoscope **102**. In some embodiments, removing the wire **104** can increase the amount of space within the lumen **114** available for other devices or tools **115**. As shown in **FIG. 7**, one or more tools **115** can be positioned within the lumen **114** of the tubular body **110** by, for example, inserting the distal end **117** of the tool **115** into the lumen port **130** of the first endoscope **102**. The distal end **117** of the tool **115** can then be moved along and relative to the lumen **114** of the tubular body **110** until it reaches the distal end **132** of the tubular body **110**. In the embodiment shown in **FIG. 7**, for example, the distal end **117** is navigated to a position within the common bile duct **16**.

[0054] In some embodiments, the overtube **106** (if employed) can be removed after the first endoscope **102** has been navigated to a desired location in the patient, or at least after the first endoscope **102** has passed through the overtube **106** and the location of the patient's body in which the overtube **106** is located.

[0055] As shown in **FIG. 7B**, the inner surface **113** of the tubular body **110** can include a recess **250** defined therein that extends along at least a portion of the tubular body **110**, and in some embodiments extends along substantially the entire length of the tubular body **110**. One or more tools **115** can be provided with at least one protrusion on an outer surface **252** thereof. The protrusion **254** can be shaped and dimensioned to be received within the recess **250** of the tubular body **110** such that movement of the tubular body **110** in a substantially circumferential direction (e.g., twisting of the tubular body **110**) generates rotational movement of the tool **115**. In the embodiment illustrated in **FIG. 7B**, the outer surface **252** of the tool **115** does not fit tightly within the lumen **114** of the tubular body **110**. Rather, there is an amount of clearance between the outer surface **252** of the tool **115** and the inner surface **113** of the tubular body **110** in order to allow the tool **115** to be moved along and relative to the tubular body **110**. In some embodiments, the first endoscope **102** can be adapted to receive at least one tool **115** within the lumen **114** of the tubular body **110** as just described. In such embodiments, the distal end **117** of the tool **115** can be moved into position by moving the tool **115** into the lumen **114** and along the tubular body **110** when the tool **115** is needed.

[**0056**] **FIG. 7B** illustrates the recess **250** as being defined in the inner surface **113** of the tubular body **110**, and the protrusion **254** as extending from the outer surface **252** of the tool **115** by way of example only. It should be understood that the inner surface **113** can instead include a protrusion, and the outer surface **252** of the tool **115** can instead include a recess. Furthermore, only one mating recess **250** and protrusion **254** are illustrated in **FIG. 7B**. However, it will be appreciated that any number of additional mating features of the tool **115** and tubular body **110** can be utilized as desired. Furthermore, the protrusion **254** and recess **250** illustrated in **FIG. 7B** represent only one type of engagement between the tool **115** and tubular body **250**.

[**0057**] A variety of other types of engagement can be established between the outer surface **252** of the tool **115** and the inner surface **113** of the tubular body **110** to allow the tool **115** to be manipulated by manipulating the tubular body **110** without departing from the spirit and scope of the present invention.

[**0058**] **FIG. 8** illustrates a plurality of kits for performing bile or pancreatic duct endoscopy according to several embodiments of the present invention. The bile or pancreatic duct endoscopy apparatus **100** illustrated in **FIG. 1** includes several component parts that can be combined in a variety of different manners for being packaged, marketed, and/or sold as kits. For example, as shown in **FIG. 8**, the first endoscope **102** can be combined with at least one of the overtube **106**, the wire **104**, the second endoscope **108**, and one or more tools **115** to form a kit according to different embodiments of the present invention.

[**0059**] As further illustrated in **FIG. 8**, a variety of tools **115** can be used with the present invention to perform a variety of diagnostic and therapeutic procedures. The first endoscope **102** can be combined with one or more of these tools **115** to form different kits for performing a variety of diagnostic and therapeutic procedures. A variety of tools **115** (each including a unique distal end **117**) is illustrated in **FIG. 8** by way of example only. In this regard, it should be understood that a number of other tools can be used with the present invention, as known to those of ordinary skill in the art.

[**0060**] Packaging component parts of the bile or pancreatic duct endoscopy apparatus **100** in any of the kits disclosed herein can enable manufacturers to have increased control over the use of their products by physicians and others. In this regard, a manufacturer can encourage and provide instructions regarding the use of various combinations of products produced by the manufacturer and/or regarding the intended manner in which such products are to be used. With such control, the performance of products produced and sold by the manufacturer can increase significantly based at least upon the performance predictability of such products produced by the manufacturer.

[**0061**] By providing a manufacturer with increased control over which products are used in conjunction with other products, the likelihood of products being misused or mishandled (e.g., combined with unknown or untested third-party products, operated in unpredictable ways, and the like) or failing and/or resulting in injury or equipment damage can be reduced significantly. For example, a user may otherwise use a manufacturer's product in conjunction with an incompatible product manufactured by another party. Such use may cause the product to break or fail, may void the warranty of the manufacturer's product and/or the third-party product, and may result in unexpected problems during medical procedures. By packaging various products intended to be used together in a kit, the manufacturer can reduce the likelihood of these unfortunate events.

[**0062**] Furthermore, the kits disclosed herein can reduce the likelihood that poorly-founded warranty claims or other liability claims will be brought against the manufacturer, particularly in situations where a user has inappropriately used a manufacturer's product in a manner in which it was not intended (e.g., with incompatible products manufactured by others).

[**0063**] As shown in **FIG. 8**, a first tool **115**A includes a fluid delivery or removal device **260**. In some embodiments, the fluid delivery or removal device **260** can include a fluid passage **262** that can be connected to an irrigation and/or suction system to allow at least one of a liquid (e.g., water), gas (e.g., oxygen), or a combination of gases (e.g., air) to be delivered to and/or removed from a site of interest within the biliary tree **10** or the pancreatic duct **24**. For example, following lithotripsy of a gallstone, the fragments or pieces of the gallstone should be removed to avoid blockage of any portion of the biliary tree **10** by the gallstone fragments or pieces. If the fragments or pieces are small enough, they can be removed by suction via the fluid delivery or removal device **260**. As another example, during an endoscopic procedure, the area within the biliary tree **10** to be investigated may need to be flushed with water to better visualize the area (e.g., in order to clear bile covering surfaces of the area and inhibiting visualization of anatomical structures under investigation).

[**0064**] Also with reference to **FIG. 8**, a second tool **115**B includes a laser **264**, which can be operated at a particular wavelength and power for performing one or more types of treatments. For example, the laser **264** can be used to destroy tissue (e.g., endoscopic cauterization) or break up stones (e.g., lithotripsy). The laser **264** can include an Nd-YAG laser, a holmium laser, a tunable-dye laser, and combinations thereof.

[**0065**] As shown in **FIG. 8**, a third tool **115**C includes a basket **266** positioned at its distal end **117**C (e.g., a Dormia basket, available from Olympus America, Melville, N.Y.).

The basket **266** can be used in therapeutic procedures, including, without limitation, procedures to entrap and remove stones (e.g., gallstones) or fragments of stones. The basket **266** can also be used in diagnostic procedures, including, without limitation, intraductal biopsy, where a portion of a stone, build-up, plaque, or other material within the biliary tree **10** can be removed and analyzed (e.g., for cancerous cells). Baskets **266** are well-known in the art and therefore not described further herein.

[0066] As shown in **FIG. 8**, a fourth tool **115**D includes a brush **268** positioned at its distal end **117**D (e.g., at least one of a cleaning brush, a cytology brush, and the like). The brush **268** can be used to clear out occluded areas within the biliary tree **10** or the pancreatic duct **24** either as a treatment or to better visualize an area of interest. The brush **268** can further be used for cell and/or tissue remove, or to obtain cytology samples (e.g., for identifying/distinguishing malignant tissue).

[0067] As shown in **FIG. 8**, a fifth tool **115**E includes a blade **270** positioned at its distal end **117**E. The blade **270** can be used for sphincterotomy (e.g., of the sphincter of Oddi), for biopsy, or for surgery. In addition, the blade **270** can be used to cut through an occlusion in the biliary tree **10** or pancreatic duct **24**, to remove cells and/or tissue, or the blade **270** can be used in combination with a basket **266** or a balloon **272** (described below) to cut and remove an infected or suspicious portion of the biliary tree **10** or pancreatic duct **24** for further analysis and diagnosis.

[0068] As shown in **FIG. 8**, a sixth tool **115**F includes a balloon **272** positioned at its distal end **117**F (e.g., at least one of an extraction balloon for removing stones or stone fragments, a balloon dilator for stretching, thinning and/or narrowing stones or other occlusions, and combinations thereof). In some embodiments, for example, the balloon **272** can be positioned on a catheter **274** and in fluid communication with a lumen of the catheter **274**. The lumen of the catheter **274** can be in fluid communication with a balloon inflating device external to the patient, as known in the art. The balloon **272** can be positioned within an occluded area of the biliary tree **10** or the pancreatic duct **24**, and can be inflated to widen any portion of the biliary tree **10** or pancreatic duct **24** and/or to reduce the size of a stone, or force out plaque or other build-up within any portion of the biliary tree **10** or pancreatic duct **24**. Furthermore, in some embodiments, the balloon **272** can be positioned upstream of a gallstone, inflated, and then moved downstream to pull the gallstone out of the biliary tree and into the duodenum **22**.

[0069] A seventh tool **115**G can be used alone or in combination with the sixth tool **115**F described above. The seventh tool **115**G includes a stent **276** positioned at its distal end **117**G. In some embodiments, the stent **276** can be positioned on a catheter **278** in a reduced-diameter configuration. As known in the art, the stent **276** can be a balloon-expandable stent or a self-expanding stent **276**. The stent **276** can be positioned in an occluded area within the biliary tree **10** or the pancreatic duct **24**, and the diameter of the stent **276** can be increased to approximately an inner diameter of the duct to be treated. The stent **276** can thereby hold plaque or other build-up against an inner surface of the duct to remove blockage and increase the flow of fluid in the duct. In some embodiments, the stent **276** is placed after treatment with the balloon **272**.

[0070] As shown in **FIG. 8**, an eighth tool **115**H includes a fiber optic viewing device **280** at its distal end **117**H. The fiber optic viewing device **280** can be used to view and/or obtain images of ducts that are too small to be navigated with the first endoscope **102**. In such cases, the smaller fiber optic viewing device **280** can be extended distally from the distal end **132** of the tubular body **110** of the first endoscope **102** into narrow structures that the distal end **132** of the tubular body **110** cannot access.

[0071] The above description of tools **115** and the corresponding illustrations in **FIG. 8** are meant to be illustrative of tools **115** that can be used with the present invention, and are not meant to be limiting. Other tools **115** can be used in accordance with the present invention, including, without limitation, at least one of biopsy forceps, retrieval forceps, retrieval loops, washing pipes, and the like.

[0072] Working examples of the present invention will now be described, are meant to be illustrative of the present invention, and do not indicate or imply a limitation upon the present invention.

[0073] In a first example, the second endoscope **108** included a standard side-viewing therapeutic duodenoscope (TJF-160, Olympus America, Inc., Melville, N.Y.); the wire **104** included a 0.035-inch diameter super stiff Jagwire (Boston Scientific Corp., Natick, Mass.); and the first endoscope **102** included an ultra-slim upper endoscope (GIF-XP 160, Olympus America). An overtube **106** was not used.

[0074] Endoscopic retrograde cholangiography (ERC) were performed upon patients using the standard side-viewing therapeutic duodenoscope. Following completion of the ERC procedure, a 0.035-inch diameter super stiff Jagwire **104** (Boston Scientific Corp., Natick, Mass.) was placed in the CBD **16**. Using the wire **104** to maintain access, the duodenoscope **108** was removed and the wire **104** was back loaded on to an ultra-slim upper endoscope **102** (GIF-XP 160, Olympus America), which was advanced over the guidewire **104** under fluoroscopic and endoscopic control into the duodenum **22** and then across the ampulla of Vater **20** into the CBD **16** and upstream.

[0075] Direct cholangioscopy was attempted and successfully performed in 3 patients, as will now be described.

[0076] Patient No. 1 was a 79-year old male with a history of a para-ampullary choledocho-duodenal fistula and persistent/recurrent choledocholithiasis requiring multiple ERC in the past. This patient presented with cholangitis six weeks after the last ERC, during which a pigtail stent was left in place. An ERC was initially performed, and showed the presence of a pigtail stent across the para-ampullary fistula and purulent draining material. The stent was removed, and the CBD **16** cannulated through the orifice of the fistula. Contrast injection demonstrated an extremely dilated CBD **16** (20 mm) with upstream biliary dilatation and numerous filling defects in the CBD **16**, CHD, and left hepatic duct **12**. Multiple large and small muddy brown stones were extracted using a combination of an 18 mm extractor balloon **115**F (Wilson-Cook) and a Dormia basket **115**C (Olympus). Direct cholangioscopy as described above revealed the persistence of large amounts of sludge and stones, and an extremely dilated biliary system. Based upon these findings, surgical consultation to evaluate the possibility of performing an hepaticojejunostomy was recommended.

[0077] Patient No. 2 was a 91-year old female with a history of a large stone (about 1.5 cm) removed 6 weeks earlier, and presented for a follow-up ERC performed to remove the previously-placed biliary stent and evaluate the completeness of stones clearance. After removal of the biliary stent, the CBD **16** was cannulated and swept with a 15 mm extractor balloon **115**F, resulting in retrieval of some sludge. With the wire **104** in place, the duodenoscope **108** was exchanged for the pediatric upper endoscope **108**, which was advanced through the previously performed sphincterotomy site into the CBD **16**. Cholangioscopy of the CBD **16**, CHD, and left and right main biliary ducts was then performed and revealed a limited amount of sludge in the left biliary system, which was completely suctioned through the endoscope **108**, obviating the need for repeat stent placement.

[0078] Patient No. 3 was a 79-year old female who presented with jaundice in the setting of choledocholithiasis, which was seen on abdominal computed tomography performed at admission. Using a sphincterotome (Boston Scientific), the major papilla was successfully cannulated, and contrast injection showed the presence of a single large stone in the distal CBD **16**. A sphincterotomy was then performed, and an attempt at stone extraction with a Dormia basket **115**C was made but failed. A mechanical lithotripsy basket was subsequently used to break the stone, and the resulting stone fragments were extracted using a 11.5 mm extractor balloon **115**F. Using the same technique, cholangioscopy was performed, and revealed complete clearance of the CBD **16**, CHD, and left and right biliary ducts.

[0079] The embodiments described above and illustrated in the figures are presented by way of example only and are not intended as a limitation upon the concepts and principles of the present invention. As such, it will be appreciated by one having ordinary skill in the art that various changes in the elements and their configuration and arrangement are possible without departing from the spirit and scope of the present invention as set forth in the appended claims.

What is claimed is:

1. A kit for bile or pancreatic duct endoscopy, the kit comprising:

a wire adapted to be navigated perorally or pernasally to the ampulla of Vater; and

an endoscope comprising a generally tubular body, the tubular body having a lumen and an outer diameter, the outer diameter being less than about 7 mm, the lumen dimensioned to receive the wire, the endoscope movable along the wire via relative movement between the lumen and the wire within the lumen for navigation of the endoscope along the wire to and within the ampulla of Vater.

2. The kit of claim 1, wherein the lumen of the endoscope is defined by an inner diameter, and wherein the inner diameter is at least about 2 mm.

3. The kit of claim 1, wherein the endoscope is further adapted to be navigated via movement with respect to the wire from the ampulla of Vater to at least one of the pancreatic duct, the common bile duct, the cystic duct, and the hepatic ducts.

4. The kit of claim 1, further comprising an overtube having a lumen dimensioned to receive the endoscope.

5. The kit of claim 4, wherein the overtube is adapted to be positioned over the endoscope adjacent a portion of the wire.

6. The kit of claim 1, further comprising a tool dimensioned to be received within the lumen of the tubular body of the endoscope.

7. The kit of claim 6, wherein the tool includes at least one of a fluid delivery device, a fluid removal device, a laser, a basket, a brush, a blade, a balloon dilator, a balloon, a catheter, a stent, a fiber optic viewing device, and combinations thereof.

8. The kit of claim 1, wherein the endoscope is a first endoscope, the kit further comprising a second endoscope having a generally tubular body, the tubular body of the second endoscope having a second lumen having a cross-sectional area greater than that of the lumen of the tubular body of the first endoscope, the second lumen dimensioned to receive the wire to allow relative movement between the second lumen and the wire.

9. The kit of claim 1, wherein the outer diameter of the tubular body of the endoscope is greater than about 3.4 mm.

10. A kit for bile or pancreatic duct endoscopy, the kit comprising:

an endoscope adapted to be navigated perorally or pernasally to at least one of the ampulla of Vater, the common bile duct, the pancreatic duct, the cystic duct, and the hepatic ducts, the endoscope comprising a generally tubular body, the tubular body including a lumen and an outer diameter, the outer diameter being less than approximately 7 mm; and

a tool dimensioned to be received within the lumen of the tubular body of the endoscope, the tool adapted to perform at least one of diagnosis and therapy in at least one of the ampulla of Vater, the common bile duct, the pancreatic duct, the cystic duct, and the hepatic ducts.

11. The kit of claim 10, wherein the tool includes at least one of a fluid delivery device, a fluid removal device, a laser, a basket, a brush, a blade, a balloon dilator, a balloon, a catheter, a stent, a fiber optic viewing device, and combinations thereof.

12. The kit of claim 10, wherein the tool is movable along the lumen of the tubular body of the endoscope.

13. The kit of claim 10, wherein the tool includes at least one of a groove and a protrusion such that the tool is engageable with and movable along the lumen of the tubular body of the endoscope.

14. The kit of claim 10, wherein the lumen of the tubular body of the endoscope includes at least one of a groove and a protrusion to engage at least a portion of the tool and to allow the tool to be manipulated by manipulation of the endoscope.

15. An apparatus for performing bile or pancreatic duct endoscopy upon a patient having a mouth and an ampulla of Vater, the apparatus comprising:

a wire adapted to extend from the patient's mouth to the patient's ampulla of Vater;

an endoscope comprising a generally tubular body, the tubular body including a lumen and an outer diameter, the outer diameter being less than about 7 mm, the lumen dimensioned to receive the wire such that the endoscope is positioned over and is movable along the wire; and an overtube having a lumen dimensioned to receive the endoscope, the overtube being positioned over the endoscope and movable along the wire.

16. The apparatus of claim 15, wherein the outer diameter of the tubular body of the endoscope is greater than about 3.4 mm.

17. The apparatus of claim 15, wherein the overtube has an inner diameter sufficiently large to permit movement of the endoscope through the overtube and along the wire.

18. The apparatus of claim 15, wherein:

the patient has a stomach;

the endoscope is adapted to be positioned at least as distally as the patient's ampulla of Vater; and

the overtube is movable into a position proximate the patient's stomach.

19. The apparatus of claim 15, wherein the overtube is positioned at least partially within the patient's stomach to facilitate movement of the endoscope along the wire within the patient's stomach.

20. The apparatus of claim 15, further comprising a tool dimensioned to be positioned within and movable along the lumen of the tubular body of the endoscope, the tool adapted to perform at least one of diagnosis and therapy in at least one of the ampulla of Vater, the common bile duct, the pancreatic duct, the cystic duct, and the hepatic ducts.

21. The apparatus of claim 20, wherein the tool includes at least one of a fluid delivery device, a fluid removal device, a laser, a basket, a brush, a blade, a balloon dilator, a balloon, a catheter, a stent, a fiber optic viewing device, and combinations thereof.

22. A method for performing endoscopy of a bile or pancreatic duct of a patient, the method comprising:

navigating a wire perorally or pernasally to and within at least one of the ampulla of Vater, the common bile duct, the pancreatic duct, the cystic duct, and the hepatic ducts of the patient;

providing an endoscope, the endoscope comprising a generally tubular body, the tubular body including a lumen and an outer diameter, the outer diameter being less than about 7 mm;

installing the endoscope over the wire while the wire is in place within at least one of the ampulla of Vater, the common bile duct, the pancreatic duct, the cystic duct, and the hepatic ducts of the patient such that the wire is received within the lumen of the tubular body of the endoscope;

navigating the endoscope along the wire to a position within at least one of the ampulla of Vater, the common bile duct, the pancreatic duct, the cystic duct, and the hepatic ducts; and

viewing the at least one of the ampulla of Vater, the common bile duct, the pancreatic duct, the cystic duct, and the hepatic ducts with the endoscope.

23. The method of claim 22, wherein the endoscope is a first endoscope, the method further comprising navigating a second endoscope perorally or pernasally to the ampulla of Vater, the second endoscope comprising a generally tubular body having a larger diameter than that of the first endoscope.

24. The method of claim 23, wherein:

the wire is dimensioned to be received within and movable along a lumen of the second endoscope; and

navigating the wire includes navigating the wire along the second lumen.

25. The method of claim 22, further comprising removing the wire from the at least one of the ampulla of Vater, the common bile duct, the pancreatic duct, the cystic duct, and the hepatic ducts of the patient by moving the wire relative to the lumen of the tubular body of the endoscope.

26. The method of claim 22, further comprising navigating a tool along the lumen of the endoscope to a position within at least one of the ampulla of Vater, the common bile duct, the pancreatic duct, the cystic duct, and the hepatic ducts.

27. The method of claim 26, further comprising performing at least one of diagnosis and therapy with the tool.

28. The method of claim 26, further comprising performing at least one of fluid delivery, fluid removal, cauterization, lithotripsy, tissue removal, stone removal, biopsy, surgery, stenting, stone reduction, and combinations thereof with the tool.

29. The method of claim 22, further comprising:

providing an overtube having a lumen dimensioned to receive the endoscope and the wire; and

moving the overtube along the wire to position the overtube within the patient.

30. The method of claim 29, wherein navigating the endoscope along the wire includes navigating the endoscope within the lumen of the overtube.

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