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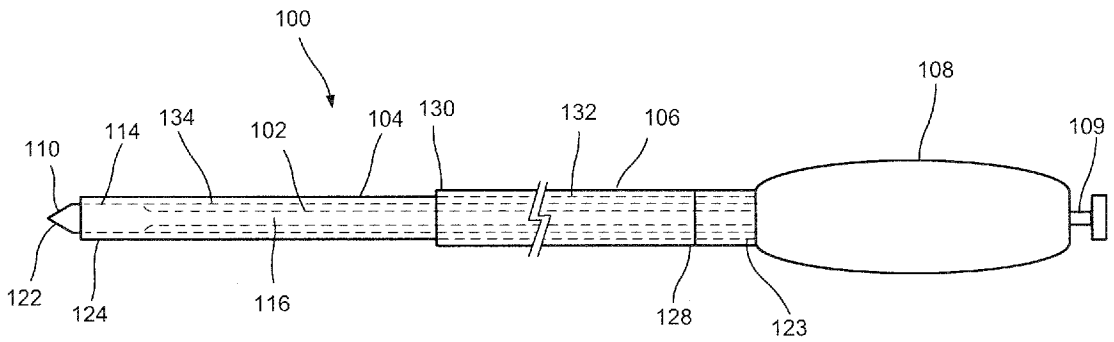

FIG. 1

(57) Abstract: A system (100) for endoscopic ultrasound guided drainage includes an access sheath (104) including an elongated tube extending longitudinally from a proximal end (123) to a distal end (124) and including an access lumen (134) extending therethrough from the proximal end (123) to the distal end (124) and a flexible tip (122) coupled to the distal end (124) of the elongated tube, the flexible tip (122) biased to a curved configuration. The system (100) also includes a sharp (102) slidably received within the access lumen (134), the sharp (102) extending longitudinally from a proximal end (109) to distal end (110) and including a channel extending therethrough, the channel configured to receive a fluid therethrough. In addition, the system (100) includes a dilating sheath (106) extending longitudinally from a proximal end (128) to a distal end (130) and including a dilating lumen (132) extending therethrough, the dilating lumen (132) sized and shaped to slidably receive the access sheath (104). The dilating lumen (132) is sized and shaped to slidably receive the access sheath (104).

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ENDOSCOPIC ULTRASOUND GUIDED ACCESS DEVICE

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Priority Claim

[0000] The present disclosure claims priority to U.S. Provisional Patent Application Serial No. 62/468,210 filed March 3, 2017; the disclosure of which is incorporated herewith by reference

Background

[0001] The pancreas and biliary system together form an important part of the digestive system. The pancreas and liver produce digestive fluids (pancreatic juice and bile) which help in the process of digestion (i.e., the breakdown of foods into parts which can be absorbed easily and used by the body). These digestive fluids are passed through the pancreatic duct and ducts of the biliary system prior to exiting into the intestine. Blockage of any of these ducts by, for example, a cancer, gallstone or scarring, may result in the duct becoming backed up and filled with fluid, requiring drainage.

Summary

[0002] The present disclosure relates to a system for endoscopic ultrasound guided drainage comprising an access sheath including an elongated tube extending longitudinally from a proximal end to a distal end and including an access lumen extending therethrough from the proximal end to the distal end and a flexible tip coupled to the distal end of the elongated tube, the flexible tip biased to a curved configuration, a sharp slidably received within the access lumen, the sharp extending longitudinally from a proximal end to distal end and including a channel extending therethrough, the channel configured to receive a fluid therethrough, and a dilating sheath extending longitudinally from a proximal end to a distal end and including a dilating lumen extending therethrough, the dilating lumen sized and shaped to slidably receive the access sheath.

[0003] In an embodiment, the curved configuration of the flexible tip is a J-shape.

[0004] In an embodiment, the flexible tip is formed of a flexible polymeric material which permits the curved distal portion to be moved to a straightened configuration when the sharp is received therein.

[0005] In an embodiment, the access sheath is formed of a polymer coated metal coil to allow torque transmission in both the clockwise and counter clockwise direction.

[0006] In an embodiment, the access sheath includes laser cut sections for increased flexibility.

[0007] In an embodiment, the system includes a handle assembly coupled to a proximal end of each of the sharp, access sheath and dilating sheath.

[0008] In an embodiment, the handle assembly includes an actuator for moving the dilating sheath longitudinally relative to the access sheath.

[0009] In an embodiment, the handle assembly includes a generator connection coupled to the actuator.

[0010] In an embodiment, the dilating sheath including an insulated coil conductor at a distal end thereof configured to cauterize tissue.

[0011] In an embodiment, a distal portion of the sharp has a multi-facet puncture tip including holes to allow fluid to flow therethrough.

[0012] In an embodiment, the access sheath is fluoroscopically visible.

[0013] The present disclosure also relates to a system for endoscopic drainage comprising an access sheath extending longitudinally from a proximal end to a distal end and including an access lumen extending therethrough from the proximal end to the distal end, a sharp slidably received within the access lumen, the sharp extending longitudinally from a proximal end to distal tip and including a channel extending therethrough, the channel configured to receive a fluid therethrough, a dilating sheath extending longitudinally from a proximal end to a distal end and including a dilating lumen extending therethrough, the dilating lumen sized and shaped to slidably receive the access sheath, and a handle assembly including a sharp attachment mechanism coupled to a proximal end thereof, the sharp exiting the handle assembly via a proximal opening therein such that a proximal end of the sharp is coupled to the sharp attachment mechanism.

[0014] In an embodiment, the sharp attachment mechanism includes an injection port for injecting fluid into the channel of the sharp.

[0015] In an embodiment, the handle assembly includes an access sheath rotation knob at a proximal end thereof.

[0016] In an embodiment, the attachment mechanism is coupled to the handle assembly by one of a press fit, mechanical lock or friction fit.

[0017] The present disclosure also relates to a method for endoscopic ultrasound guided drainage comprising inserting an access sheath and a sharp through a working channel of an endoscope into a target duct within a body, the sharp extending through a lumen of the access sheath such that a distal tip of the sharp extends distally past a distal end of the access sheath so that the distal tip punctures the target duct, rotating the access sheath via a rotation knob at a proximal end thereof to adjust the direction of the sharp, injecting a contrast media through a channel of the sharp into the target duct to visually verify that the target duct is filled with fluids, and advancing a dilating sheath distally over the access sheath and into the target duct to dilate

the target duct.

[0018] In an embodiment, the method further includes removing the sharp from the access sheath so that a distal portion of the access sheath reverts to a curved configuration.

[0019] In an embodiment, the method further includes dilating a puncture point in a surface of the target duct via an electrode of the dilating sheath.

[0020] In an embodiment, the electrode is an coil conductor.

[0021] In an embodiment, the method further includes cauterizing a surface of the target duct via a ceramic dilating sheath tip.

Brief Description of the Drawings

[0022] Fig. 1 shows a longitudinal cross-sectional view of a system according to an exemplary embodiment of the present disclosure;

[0023] Fig. 2 shows a longitudinal partial cross-sectional view of a distal portion of a sharp assembly according to the system of claim 1;

[0024] Fig. 3 shows a longitudinal partial cross-sectional view of a distal portion of a sharp assembly according to a second exemplary embodiment of the present disclosure;

[0025] Fig. 4 shows a longitudinal cross-sectional view of an access sheath according to the system of Fig. 1;

[0026] Fig. 5 shows a side view of a portion of the access sheath according to another exemplary embodiment of the present disclosure;

[0027] Fig. 6 shows a cross-sectional view of a dilating sheath according to an exemplary embodiment of the present disclosure;

[0028] Fig. 7 shows a perspective view of a handle assembly of the system of Fig. 1;

[0029] Figs. 8A and 8B show side views of a sharp attachment mechanism of the system of Fig. 1 according to a first exemplary embodiment;

[0030] Fig. 9 shows a side view of a sharp attachment mechanism according to a second exemplary embodiment;

[0031] Fig. 10 shows a side view of a sharp attachment mechanism according to a third exemplary embodiment; and

[0032] Figs. 11A, 11B and 11C show a side, top and side views, respectively, of a sharp attachment mechanism according to a fourth exemplary embodiment.

Detailed Description

[0033] The present disclosure may be further understood with reference to the following description and the appended drawings, wherein like elements are referred to with the same reference numerals. The present disclosure is directed to endoscopic medical devices and, in particular, relate to endoscopic ultrasound (EUS) guided drainage. Exemplary embodiments describe a EUS guided drainage systems comprising a sharp for injecting a fluid into a fluid-filled duct, an access sheath through which the sharp is inserted and a dilating sheath for dilating the fluid-filled duct to facilitate drainage. It will be understood by those of skill in the art that the system and method of the present disclosure may be used to drain, for example, a bile duct, a pancreatic duct, cysts, gallbladder, etc. It should be noted that the terms "proximal" and "distal" as used herein are intended to refer to a direction toward (proximal) and away from (distal) a user of the device.

[0034] As shown in Figs. 1 – 11C, a system 100 according to an exemplary embodiment of the present disclosure comprises a sharp 102 for puncturing a fluid-filled tract and injecting a fluid (e.g., contrast media) thereinto and an access sheath 104 for providing access into the fluid-filled tract. The system 100 further comprises a dilating sheath 106 for dilating the tract to facilitate drainage. The system 100 is sized and shaped to be passed through a working channel of an endoscope to be visualized under ultrasound guidance. The system 100 may further comprise a handle assembly 108, which remains outside of a living body while the sharp 102 and the access sheath 104 are inserted therein (e.g., along a tortuous path through a natural body lumen accessed via a naturally occurring body orifice). The handle assembly 108 permits the sharp 102 to be removed therefrom while the access sheath 104 remains in the target duct. The handle assembly 108 also includes an actuator for advancing the access sheath 104 beyond the dilating sheath 106 and another actuator for advancing the dilating sheath 106 over the access sheath 104 and into the target duct.

[0035] As shown in Figs. 2-3, a sharp 102 extends along a longitudinal axis from a proximal end 109 to a distal end 110 and includes a channel 112 extending therethrough. The sharp 102 may be formed from Nitinol, Stainless Steel or any variety of bio-compatible metals with a similar stiffness. In an alternate embodiment, the sharp 102 may be formed of plastic or another suitable polymer. In an embodiment, the sharp 102 may be formed with a flexbile design such as, for example, a coil or a spiral cut design. The sharp 102 may be configured as a hypotube with a multi-facet distal tip 105 at a distal end thereof for puncturing the target duct. The tip 105 according to this embodiment include holes 107 open to the channel 112 to allow fluid injection (e.g. contrast media) from the proximal end through the channel 112 to exit the distal end of the device. In an exemplary embodiment, the tip 105 may be attached to the hypotube via welding, bonding, or mechanical fastening such as threads. In an alternate embodiment, the hypotube 103 and tip 105 may be formed of a plastic or any other suitable polymer. In this embodiment, the plastic tip 105 may be constructed from one or two components. In the single body design, the tip 105 may be constructed, for example, through molding. In the double component design, a

distal tapered portion 111 may be attached to a base tube 113, as seen in Fig. 3, via adhesive, melting or heat shrink application. The channel 112 extends from the proximal end 109 of the sharp 102 along the longitudinal axis thereof to a distal end 110 extending through the tip 105. In another exemplary embodiment, the puncture sharp 102 may be formed as a hypotube with either a sharpened wall or beveled edge along the circumference of the distal leading edge to promote puncture and allow a large opening for fluid injection. In this embodiment, the channel 112 extends from a proximal portion 116 of the sharp 102 and is open at the distal end 110 of the sharp 102. A fluid such as, for example, contrast media, may be injected into the target duct via the channel 112 to verify that the target duct is filled with fluid (e.g., digestive fluid).

[0036] As shown in Fig. 4, the access sheath 104 includes a hollow tube 121 and a flexible tip 122. The hollow tube 121 extends longitudinally from a proximal end 123 to a distal end 124 and includes a lumen 134 extending therethrough. The lumen 134 is sized and shaped so that the sharp 102 can slight through. In particular, an inner diameter of the lumen 134 in this embodiment substantially corresponds to an outer diameter of the sharp 102 so that when the sharp 102 is received therein it completely fills the lumen 134 of the hollow tube 121. Flexible tip 122 extends from a proximal end 125 to a distal end 127 and includes a lumen 135 extending therethrough. Similar to the hollow tube lumen 134, the flexible tip lumen 135 is sized and shaped to slidably receive the sharp 102 therein and may have an inner diameter substantially equal to the inner diameter of the hollow tube 121. In particular, an inner diameter of the flexible tip lumen 135 in this embodiment substantially corresponds to an outer diameter of the sharp 102 so that when the sharp 102 is received therein it completely fills the lumen 134 of the flexible tip 122 to facilitate puncturing the target duct when the access sheath 104, with the sharp 102 received therein, is inserted into the target duct. Furthermore, the flexible tip 122 of this embodiment may be biased to assume, when not constrained, a desired a curvature along a distal portion 127 thereof to direct the inserted sharp 102 and a guidewire toward a target site. In one exemplary embodiment, the distal portion 127 of the flexible tip 122 is biased toward a J configuration (i.e., a curve in which the distal portion 127 arcs away from an axis of more proximal portions of the sheath 104 along an arc of 90° or less) for directing a guidewire in

another desired direction. The distal end 127 of the flexible tip 122 may have a taper or a rounded edge to minimize initial puncture forces and ensure the flexible tip 122 follows the sharp tip 105 into the target area. The proximal end 125 of the flexible tip 122 is coupled to the distal end 124 of the hollow tube 121 such that the hollow tube lumen 134 is aligned with and open to the lumen 135 of the flexible tip 122.

[0037] The flexible tip 122 may be formed of a polymer that is sufficiently flexible so that when the sharp 102 is received therein, the distal portion of the flexible tip122 is straightened. Once the sharp 102 is extended distally therefrom, however, the flexible tip 122 is permitted to revert to its curved configuration. The curved configuration is maintained when a distal floppy end of the guidewire is within the flexible tip 122. The hollow tube 121 and the flexible tip 122 may be formed of the same or different materials. In an exemplary embodiment, the access sheath 104 is formed of braid reinforced polyamide. In another embodiment, the access sheath 104 is formed of multiple polymeric layers such as multilayer braid constructions. In a further embodiment, the access sheath 104 is insulated or coated along its length or at portions thereof. For example, the hollow tube 121 may be formed of PTFE, ETFE, or other polymer coated single-wire or dual-wire-counter-wound metal coils that allow transmission of torque in both clockwise and counter clockwise direction in 1-to-1 ratio. The torque transmission permits the user to rotate and direct the guidewire with the formed tip toward a target site and the coating allows for compatibility with electrosurgical activation as will be discussed in more detail below. The coating also reduces friction and promotes electrosurgical compatibility with the metal used to form the hollow tube 121. It will be understood that insulation or coating is only required on portions of the access sheath 104 that could come into contact with the operator or patient. In another exemplary embodiment, the hollow tube 121 is formed as a parylene or a similar polymer coated solid or laser cut hypotube 121 that allows transmission of torque in both the clockwise and counter-clockwise directions in a 1-to-1 ratio. In an embodiment, the solid hypotube 121 is made of Nitinol and has an inner diameter of 0.0365 +/- 0.0005 inches and an outer diameter of 0.0435 +/- 0.0005 inches. In another embodiment, the hypotube 121 has laser cut sections that increase flexibility in the hypotube. An exemplary laser cut design can be seen

in Fig. 5 with cuts 131 tapered over the length of the device. The cuts 131 are concentrated in certain areas where increased flexibility is needed due to aspects of the procedure and the tortuosity of the path along which the scope extends. The parylene coating reduces friction and promotes electrosurgical compatibility with the metal used to form the hollow tube 121. The access sheath 104 assembly including the hollow tube 121 and the flexible tip 122 is fluoroscopy and EUS compatible. For example, the flexible tip 122 polymer may be loaded with Bismuth or Tungsten. In another example, marker bands may be added to the flexible tip 122 to facilitate visual determination of the position and orientation of the device. In a further example, echogenic features may be added to the hollow tube 121 to enhance ultrasonic imaging of the device as would be understood by those skilled in the art.

[0038] The dilating sheath 106 similarly extends longitudinally from a proximal end 128 to a distal end 130 and includes a lumen 132 extending therethrough and a distal portion 131. The lumen 132 is sized and shaped to slidably receive the access sheath 104 therein so that the dilating sheath 106 may be advanced over the access sheath 104 to the target duct to dilate the obstructed duct, thereby facilitating drainage thereof. The dilating sheath 106 may be a cold dilator such as, for example, a sohendra type dilator and/or a balloon dilator. Alternatively, the dilating sheath 106 may be a hot dilator such as, for example, a cystome or needleknife, which includes electrosurgical capabilities. For example, the dilating sheath 106 may include an electrode 137 extending along the distal portion 131 (immediately adjacent the distal end 130) thereof for cauterizing tissue. In particular, the dilating sheath 106 may be configured to utilize electrosurgical dissection to facilitate dilation or to burn a lesion as the dilating sheath 106 is inserted into the target duct. For example, the electrode may be an insulated coil conductor that is exposed at a distal end to supply cut/cautery energy. In another example, the distal portion 131 of the dilating sheath may be formed as a a tip (not shown) made from ceramic or another material with either a wire wrapped around the base or a gold-based painted on pattern extending to the distal end 130 of the sheath. It will be understood that the pattern may, in other examples, be any suitable material such as platinum, silver, titanium, stainless steel, niobium, titanium nitride, tungsten, copper or graphite-based inks. The tip may be configured as a cone, dome or

any of a variety of configurations facilitating insertion into the target duct. In another embodiment, using "cold" dilation, the dilating sheath 106 may have a balloon (not shown) attached to the distal end 130. The balloon may be used in conjunction with previous tip designs or by itself. The balloon may be connected to a pump that inflates/deflates the balloon once it is in position. Once the dilating sheath 106 has been advanced over the access sheath 104 and inserted into the target duct, the dilating sheath 106 may be actuated to dilate or expand the target duct. For example, the dilating sheath 106 may have one or more stepped diameters at discrete distances from the distal end or one or more additional sheaths that may be independently actuated to expand the path to the target duct. The dilating sheath 106 may be fluoroscopically and EUS compatible. That is, the properties of the tip and the electrode provide visibility which aids with dilation of the access region.

[0039] As shown in Fig. 7, the handle assembly 108 includes a grip portion 136 extending from a proximal end 138 to a distal end 140 and an extension portion 142 coupled to the distal end 140 of the grip portion 136 and couplable to the proximal end 128 of the dilating sheath 106. The access sheath 104 may be received within and coupled to the grip portion 136 such that the access sheath 104 extends through the lumen 132 of the dilating sheath 106. The sharp 102 extends through the grip portion 136 and the extension portion 142 with the proximal end of the sharp 102 extending proximally of the proximal end 138 of the grip portion and the length of the sharp 102 extending through the lumen 134 of the access sheath 104. Since the proximal end 109 of the sharp 102 extends proximally from the grip portion 136, the sharp 102 may be removed from the access sheath 104 by simply pulling the sharp 102 proximally relative to the handle assembly 108. The distal end 110 of the sharp 102 extends distally past the distal end 124 of the access sheath 104 so that the tapered tip 122 may puncture the target duct once the system 100 has been inserted into the body. The handle assembly 108 also includes an actuator 144 which moves the dilating sheath 106 longitudinally relative to the access sheath 104. In particular, the actuator 144 may include a tab that is moved distally and proximally with respect to the grip portion 136 of the handle assembly 108 to advance and retract, respectively, the dilating sheath 106 over the access sheath 104. The handle assembly 108 may include an access

sheath lock 144' which locks how far the access sheath 104 extends beyond the dilating sheath 106. The handle may also include a dilating sheath lock (not shown) which locks the dilating sheath 106 in a specific location. In use, the access sheath lock may be unlocked while the access sheath/style assembly is through into the target tissue beyond the dilating sheath tip, then the dilating sheath 106 is unlocked and the dilating sheath 106 is advanced over the access sheath 106. As noted above, in embodiments in which the dilating sheath 106 includes an electrode, an active wire (not shown) is used to provide a current to the electrode. In a preferred embodiment, the active wire is long enough to run the length of the device in the extended position (before any cautery or puncture activation) and the contracted position (puncture and cautery activated). In the current embodiment, the wire may be coiled around the access sheath 104 in the handle assembly 108. Coiling the wire prevents it from kinking during handle actuation and while permitting the wire to have a length sufficient for both the extended and contracted handle configurations. In an alternate embodiment, the handle assembly 108 may include a generator connection 141 located at a proximal portion thereof. The generator connection 141 may be attached to the actuator 144 and may move with the actuator during actuation. Thus, in this embodiment, slack management of the active wire 139 would not be required. The handle assembly 108 further includes an access sheath rotation knob 143 located at a proximal end thereof. The rotation knob 143 is coupled to the proximal end of the access sheath 104 via an access sheath hub (not shown) at the handle and is rotatable, allowing transmission of torque in both the clockwise and counter clockwise direction in a 1-to-1 ratio.

[0040] The handle assembly 108 includes a sharp attachment mechanism 150 which allows the sharp 102 to be easily attached to, and removed from, the handle assembly 108. The sharp 102 extends proximally from a proximal end of the handle assembly 108, with a proximal end 109 thereof coupled to the sharp attachment mechanism 150. The sharp attachment mechanism 150 also allows for fluid to be injected into the sharp channel 112 through an injection port 152. It is noted that in an exemplary embodiment, the injection port 152 may be added to the access sheath 104 to allow injection through the access sheath lumen. A first exemplary sharp attachment mechanism 150 uses a "top hat" design as seen in Figs. 8A and 8B. This "top hat" mechanism

154 utilizes a mechanical side lock 156 to attach the sharp 102 to the handle assembly 108. When side lock 156 is depressed, an inner lumen (not shown) of the lock 156 aligns with a handle top feature 158, unlocking the sharp 102 from the handle assembly 108. The "top hat" attachment mechanism 154 also engages an inner portion of the rotation knob 143 via the side lock 156 to facilitate rotation of the access sheath 104. Another exemplary embodiment of the sharp attachment mechanism 150 uses a "press fit" design as seen in Fig. 9. The "press fit" attachment 164 uses friction fit to attach the sharp 102 to the handle assembly 108. The 90-degree component 166 uses a friction fit to hold the sharp within a lumen 145 of the access sheath rotation knob 143. Similar to the "top hap" design 154, the 90-degree component 166 of the "press fit" design 164 includes a side port 168 for injection of fluid into the sharp channel 112. Another exemplary attachment mechanism 150 uses a "harp" design as seen in Fig. 10. This design utilizes a mechanical lock to attach the sharp 102 to the handle 108. The "harp" attachment 174 includes two side wings 176 which may be pressed simultaneously inward so that a clamp 177 that holds the sharp 102 to the handle 108 is released, allowing the sharp 102 to be retracted into the handle assembly 108. The "harp" attachment 174 includes an injection port 178 at its proximal end. A further exemplary embodiment of the sharp attachment mechanism 150 uses a "snap cap" design as seen in Figs. 11A-11C. The "snap cap" attachment 184 includes a press fit lock to attach the sharp 102 to the handle 108. The attachment includes a proximal half portion 186 and a distal half portion188, with the distal half portion 188 secured in the handle assembly 108. The proximal half portion 186 is removably attached to the distal half portion 188 via a locking slot 185 extending about the diameter of the bottom half portion 188. The proximal half portion 186 includes a coil portion 187 that moves over the distal half portion 188 of the design and sits in the locking slot 185 when the two components are attached. Similar to the "top hat" and "harp" attachments 154, 174, the "snap cap" attachment 184 includes an injection port at its proximal end 189.

[0041] According to a method using the system 100 according to an exemplary embodiment of the present disclosure, the system 100 is inserted through a working channel of an endoscope via, for example, ultrasound guidance to a target duct within the body. In an insertion configuration,

the access sheath 104 according to an exemplary embodiment is fully housed within the dilating sheath 106 to protect an interior surface of a working channel of an endoscope or other insertion device through which the system 100 is inserted from the sharp distal tip 122 of the sharp 102. Upon insertion through the endoscope, the dilating sheath 106 may be in a proximal position so that the dilating sheath 106 does not extend distally over the portion of the access sheath 104 being inserted into the target duct. At this point, the distal end 110 of the sharp 102 extends distally past the distal end 124 of the access sheath 104. The access sheath 104 and sharp 102 is then advanced distally to penetrate the target duct. Once the sharp 102 and the access sheath 104 have been inserted into the target duct, contrast media (e.g., radiopaque dye) may be inserted, via the injection port 152, through the channel 112 of the sharp 102, out of the holes 107 of the sharp tip 105 into the target duct so that a user of the system 100 may visually verify that the duct has been filled with fluid and requires drainage. The sharp 102 may then be removed from the access sheath 104 by drawing the sharp 102 proximally relative to the access sheath 104 so that only the access sheath 104 remains in the target duct. Upon removal of the sharp 102, the flexible tip 122 of the access sheath 104 is freed to revert to the curved configuration to either anchor the access sheath 104 in the target duct or to direct a guidewire therethrough in a desired direction. If the access sheath 104 is in the target duct, a guidewire may be inserted through the lumen 134 of the access sheath 104 and into the target duct. As would be understood by those skilled in the art, a tip of the guidewire passed through the access sheath 104 will be directed in a direction corresponding to a curvature of the distal portion 126 of the access sheath 104 to contact an interior surface of the target duct. Rotation of the handle may then be used to manipulate the position of the j-shape, thus allowing the operator to advance the guidewire in a chosen direction. It will be understood that direction may or may not be set before guidewire advancement. As would be understood by those skilled in the art, prior to inserting the guide wire into the access sheath 104, the access sheath 104 may be rotated by manipulating the access sheath rotation knob 143 to direct the curved flexible tip 122 toward a desired direction.

[0042] Once the access sheath 104 has been anchored in the target duct, the dilating sheath 106 may be advanced over the access sheath 104 into the target duct. At this point, the generator

connection 141 may be connected to a surgical generator such as, for example, a high-frequency (HF), alternating current (AC) surgical generator to provide an active current to the wire 139. As described above, the dilating sheath 106 is advanced by moving the actuator 144 distally with respect to the grip portion 136 of the handle assembly 108. The distal end 130 of the dilating sheath 106 is configured to facilitate insertion of the dilating sheath 106 into the target duct and to be advanced to a site at which the duct is blocked. In one embodiment, an electrode at the distal end 130 is activated to electrosurgically dissect and/or cauterize a surface tissue of the target duct to facilitate insertion therein. Insertion of the dilating sheath 106 over the site of the blockage enlarges the portion of the duct surround the obstruction to permit drainage of the target duct. It will be understood by those of skill in the art that the dilating sheath 106 may dilate the target duct in any of a number of ways. In one previously described example, the dilating sheath 106 includes an expansible balloon activated to expand the target duct. It will be understood by those of skill in the art that a user may also implement further treatment of the blocked duct. In particular, a stent may be implanted in the duct at the location of the blockage to maintain the duct in an enlarged configuration to ensure continued drainage thereof.

[0043] It will be apparent to those skilled in the art that various modifications may be made in the present disclosure, without departing from the scope of the disclosure. Thus, it is intended that the present disclosure cover the modifications and variations of his disclosure provided that they come within the scope of the appended claims and their equivalents.

What is claimed is:

1. A system for endoscopic ultrasound guided drainage, comprising:

an access sheath including an elongated tube extending longitudinally from a proximal end to a distal end and including an access lumen extending therethrough from the proximal end to the distal end and a flexible tip coupled to the distal end of the elongated tube, the flexible tip biased to a curved configuration;

a sharp slidably received within the access lumen, the sharp extending longitudinally from a proximal end to distal end and including a channel extending therethrough, the channel configured to receive a fluid therethrough; and

a dilating sheath extending longitudinally from a proximal end to a distal end and including a dilating lumen extending therethrough, the dilating lumen sized and shaped to slidably receive the access sheath.

2. The system of claim 1, wherein the curved configuration of the flexible tip is a J-shape.

3. The system of either claim 1 or 2, wherein the flexible tip is formed of a flexible polymeric material which permits the curved distal portion to be moved to a straightened configuration when the sharp is received therein.

4. The system of any one of claims 1 to 3, wherein the access sheath is formed of a polymer coated metal coil to allow torque transmission in both the clockwise and counter clockwise direction.

5. The system of any one of claims 1 to 3, wherein the access sheath includes laser cut sections in a thin walled hypotube for increased flexibility.

6. The system of any one of claims 1 to 5, further comprising a handle assembly coupled to a proximal end of each of the sharp, access sheath and dilating sheath.

7. The system of claim 6, wherein the handle assembly includes a first actuator for moving the access sheath assembly relative to the dilating sheath and a second actuator for moving the dilating sheath longitudinally relative to the access sheath.

8. The system of either claim 6 or 7, wherein the handle assembly includes a generator connection coupled to the actuator.

9. The system of any one of claims 1 to 8, wherein the dilating sheath includes a coild conductor at a distal end thereof.

10. The system of any one of claims 1 to 9, wherein a distal portion of the sharp has a multi-facet puncture tip including holes to allow fluid to flow therethrough.

11. The system of any one of claims 1 to 10, wherein the access sheath is fluoroscopically visible.

12. A system for endoscopic drainage, comprising:

an access sheath extending longitudinally from a proximal end to a distal end and including an access lumen extending therethrough from the proximal end to the distal end;

a sharp slidably received within the access lumen, the sharp extending longitudinally from a proximal end to distal tip and including a channel extending therethrough, the channel configured to receive a fluid therethrough;

a dilating sheath extending longitudinally from a proximal end to a distal end and including a dilating lumen extending therethrough, the dilating lumen sized and shaped to slidably receive the access sheath; and

a handle assembly including a sharp attachment mechanism coupled to a proximal end thereof, the sharp exiting the handle assembly via a proximal opening therein such that a proximal end of the sharp is coupled to the sharp attachment mechanism.

13. The system of claim 12, wherein the sharp attachment mechanism includes an injection port for injecting fluid into the channel of the sharp.

14. The system of either claim 12 or 13, wherein the handle assembly includes an access sheath rotation knob at a proximal end thereof.

15. The system of any one of claims 12 to 14, wherein the attachment mechanism is coupled to the handle assembly by one of a press fit, mechanical lock or friction fit.

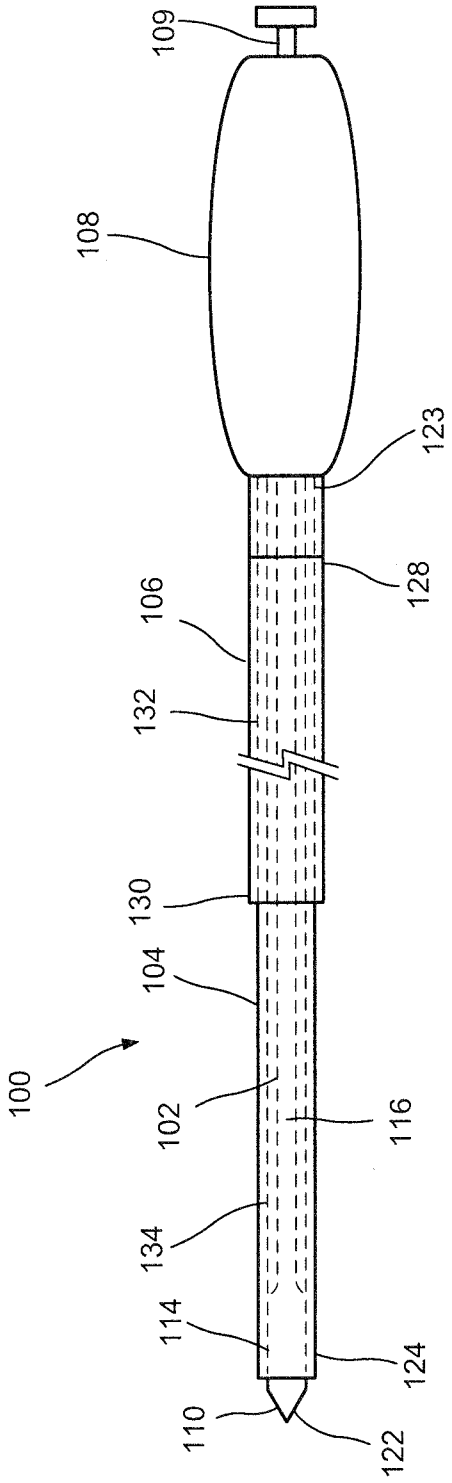


FIG. 1

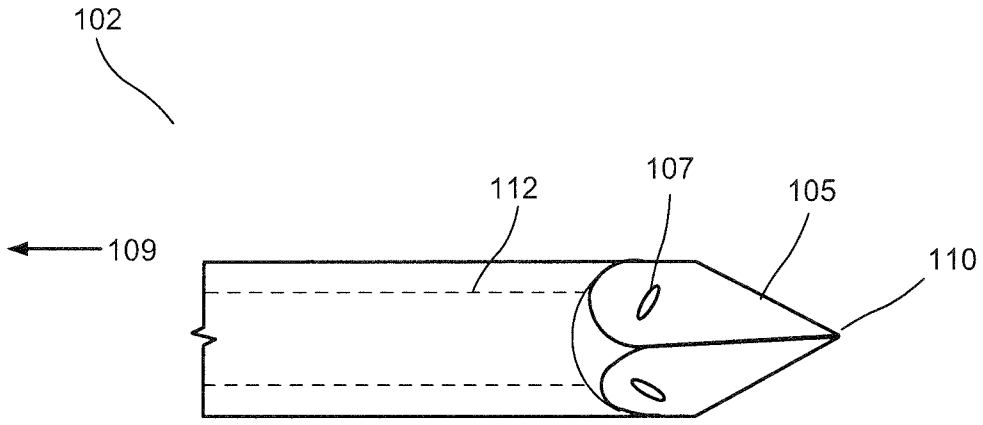


FIG. 2

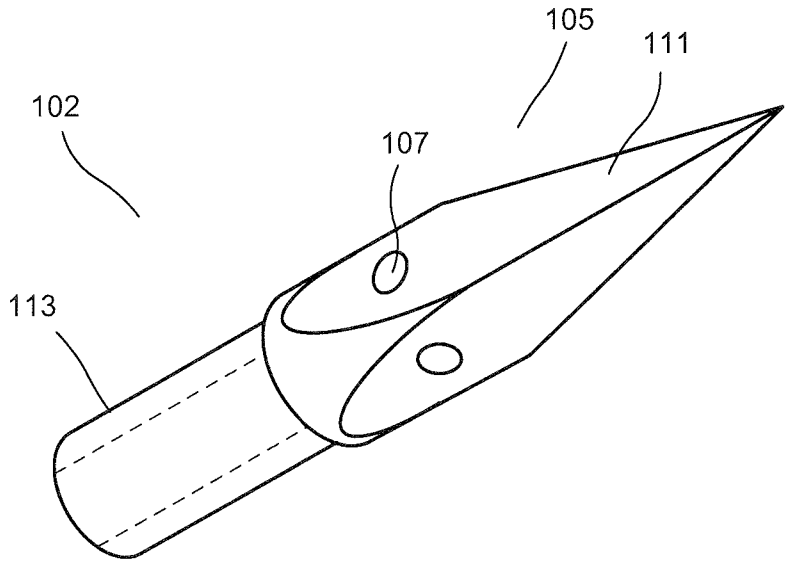


FIG. 3

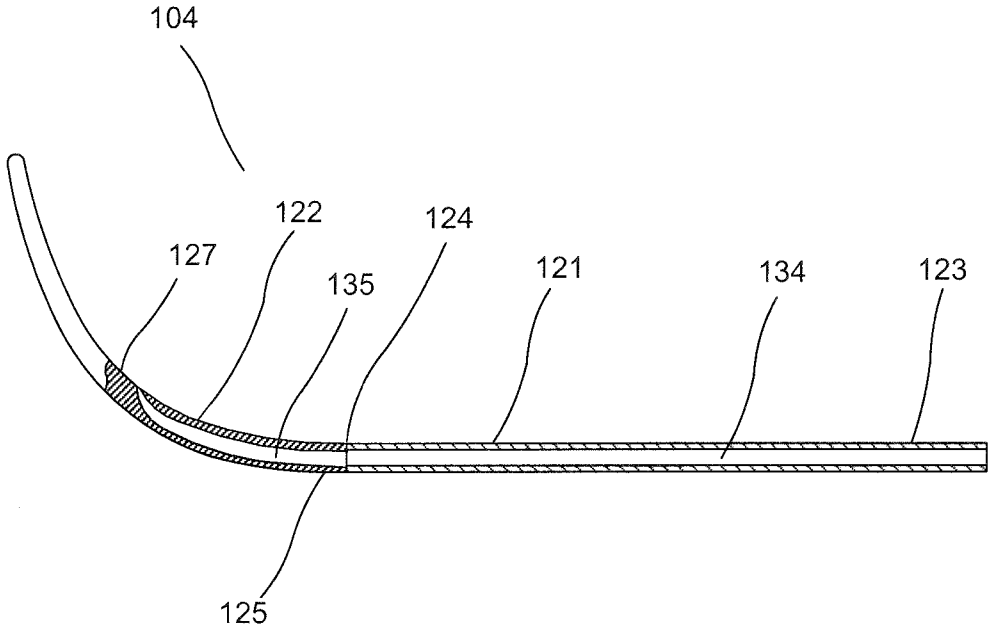


FIG. 4

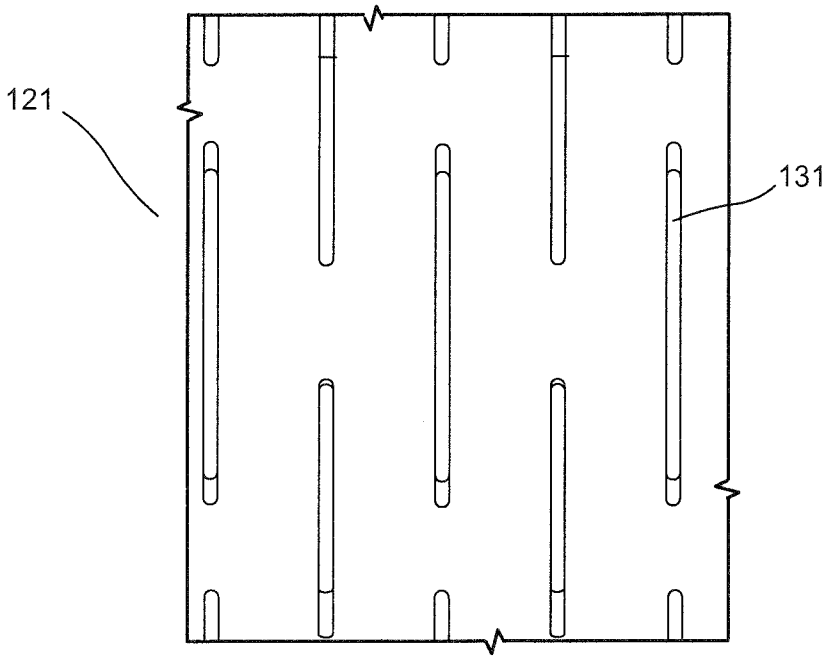
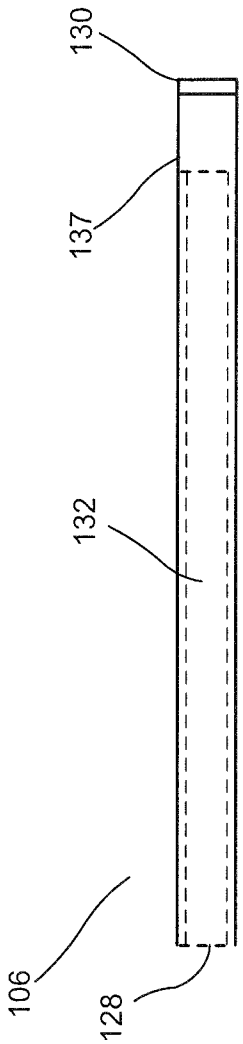


FIG. 5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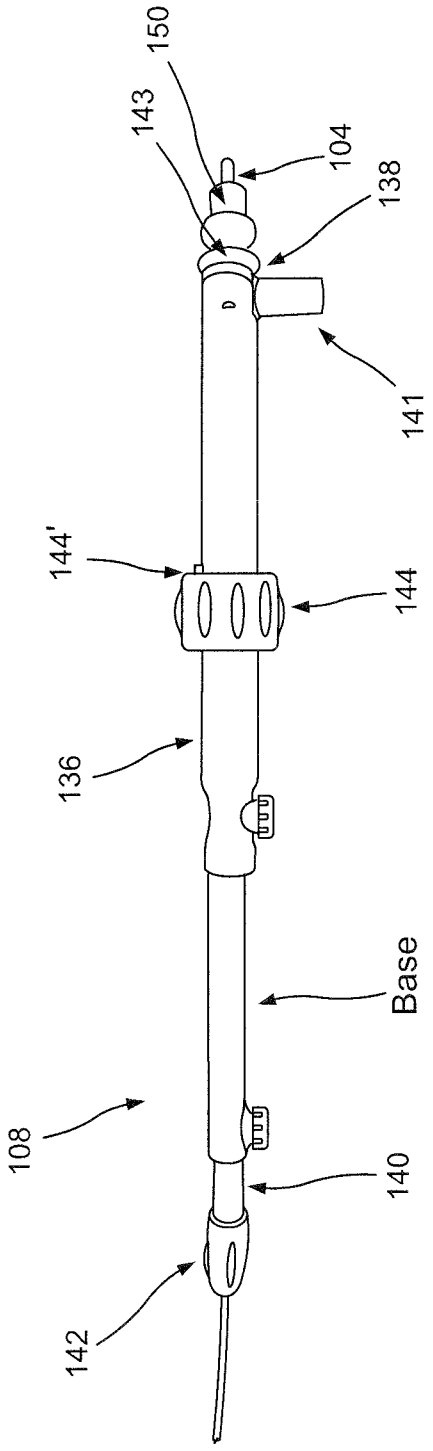
137
132
106
128

FIG. 6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138
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144'
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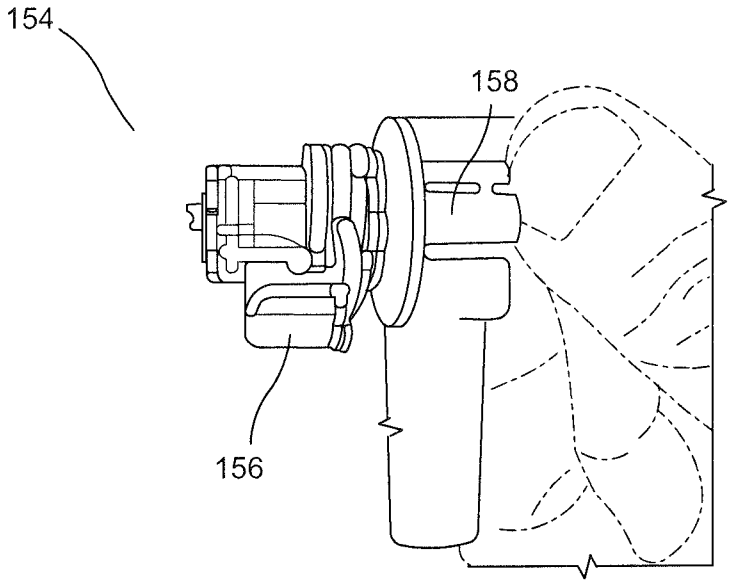
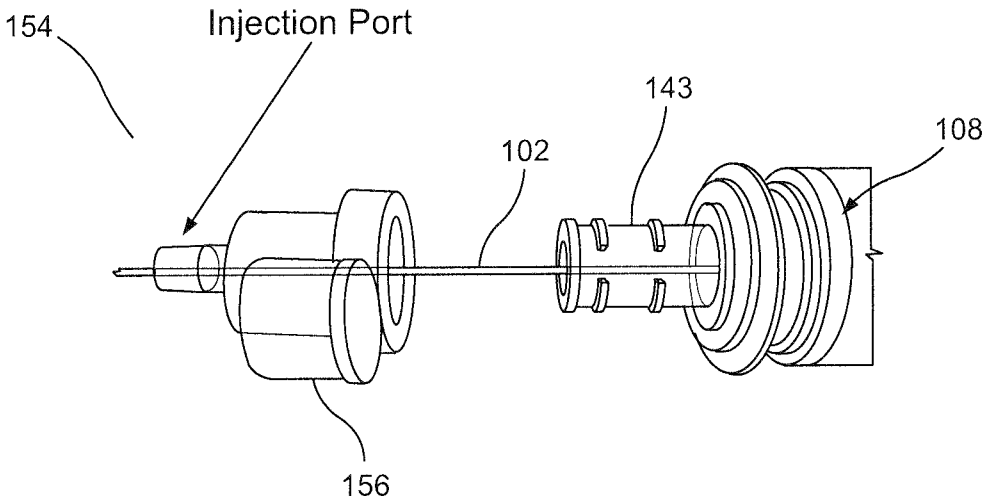
136
Base
108
140
142

FIG. 7



F I G. 8A



F I G. 8B

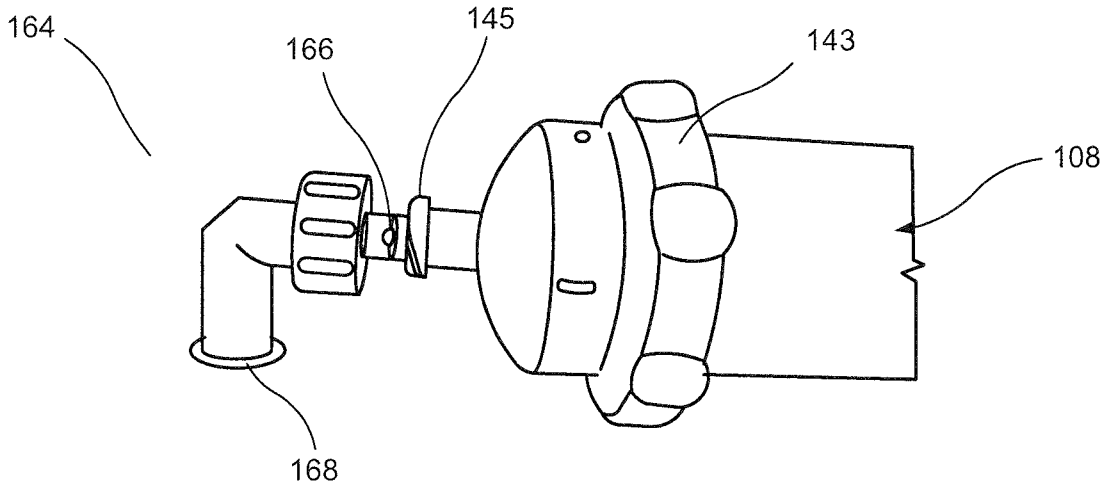


FIG. 9

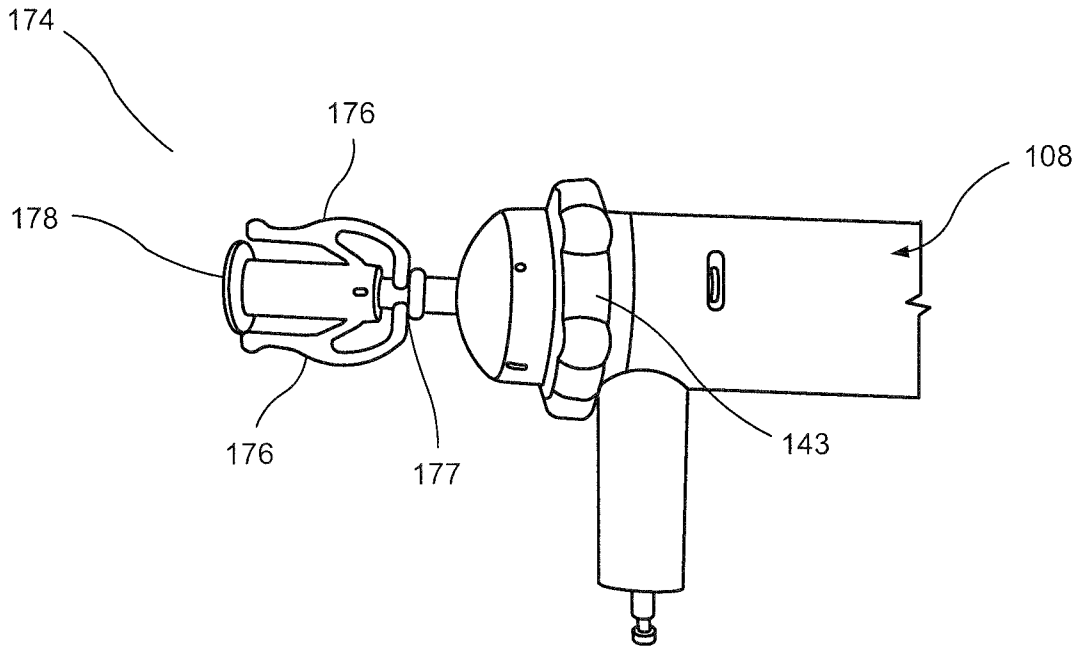


FIG. 10

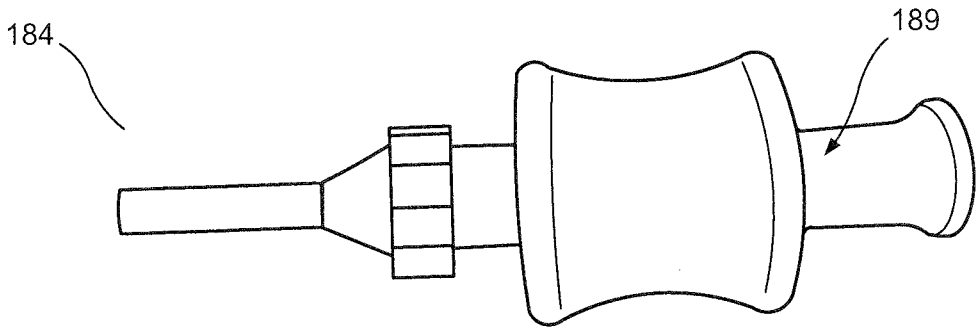


FIG. 11A

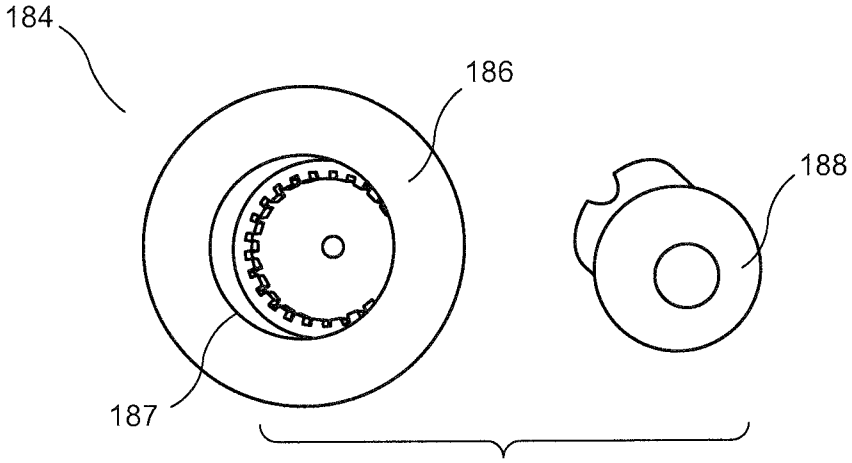


FIG. 11B

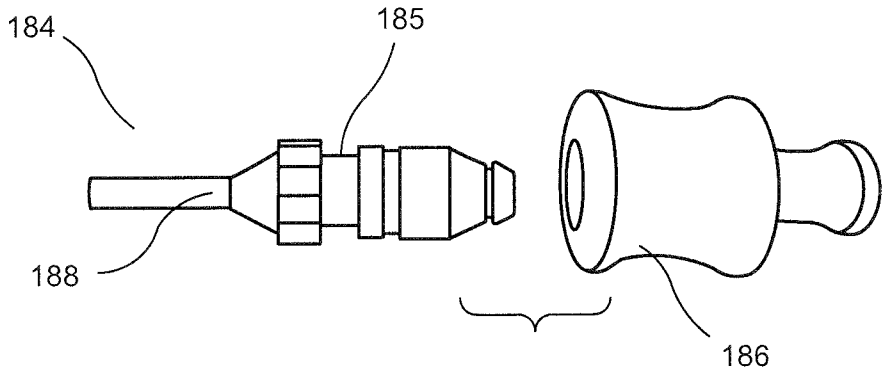


FIG. 11C

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/021178

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

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

B. FIELDS SEARCHED

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

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2016/015421 A1 (BENNING CHRISTOPHER A [US] ET AL) 21 January 2016 (2016-01-21)	1-5,11
Y	figure 1 figure 2 paragraph [0023] - paragraph [0027]	9,10

Y	US 5 403 311 A (ABELE JOHN E [US] ET AL) 4 April 1995 (1995-04-04) figure 2 column 5, line 37 - column 6, line 13	9

Y	WO 93/10837 A1 (YOON INBAE [US]) 10 June 1993 (1993-06-10) figure 14 page 16, line 14 - page 17, line 1	10

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

☒ See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
7 May 2018	19/07/2018

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

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/021178

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

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

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

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

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

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

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

see additional sheet

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

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

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

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

1-5, 9-11

Remark on Protest

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

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

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-5, 9-11

an endoscopic ultrasound guided drainage device

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2. claims: 6-8, 12-15

a handle for an endoscopic drainage device

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2018/021178

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2016015421 A1	21-01-2016	AU 2015290019 A1	12-01-2017
		CA 2954633 A1	21-01-2016
		CN 106535779 A	22-03-2017
		EP 3169256 A1	24-05-2017
		ES 2672381 T3	14-06-2018
		JP 2017524441 A	31-08-2017
		US 2016015421 A1	21-01-2016
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		EP 0858778 A2	19-08-1998
		US 5330432 A	19-07-1994
		US 5336176 A	09-08-1994
		US 5423760 A	13-06-1995
		US 5423770 A	13-06-1995
		WO 9310837 A1	10-06-1993

专利名称(译)	内窥镜超声引导下进入装置		
公开(公告)号	EP3544531A1	公开(公告)日	2019-10-02
申请号	EP2018713480	申请日	2018-03-06
[标]申请(专利权)人(译)	波士顿科学西美德公司		
申请(专利权)人(译)	BOSTON SCIENTIFIC SCIMED，INC.		
当前申请(专利权)人(译)	BOSTON SCIENTIFIC SCIMED，INC.		
[标]发明人	BENNING CHRISTOPHER GESSLER III RAYMOND PHELAN JESSICA PALKHIWALA KUSHAL BANNON BRYAN DAYTON PETER WHITNEY ANDREW		
发明人	BENNING, CHRISTOPHER GESSLER, III, RAYMOND PHELAN, JESSICA PALKHIWALA, KUSHAL BANNON, BRYAN DAYTON, PETER WHITNEY, ANDREW		
IPC分类号	A61B17/34		
CPC分类号	A61B17/3415 A61B17/3417 A61B1/00131 A61B17/3403 A61B18/1482 A61B18/1492 A61B2017/00296 A61B2017/00818 A61B2017/3413 A61B2018/00535 A61B2018/00595 A61B2018/00982		
优先权	62/468210 2017-03-07 US		
外部链接	Espacenet		

摘要(译)

用于内窥镜超声引导引流的系统（100）包括进入护套（104），该进入护套（104）包括从近端（123）纵向延伸到远端（124）的细长管，并且包括从近端延伸穿过其中的进入管腔（134）。在远端（124）的端部（123）和连接到细长管的远端（124）的柔性尖端（122），柔性尖端（122）偏置到弯曲构型。系统（100）还包括可滑动地容纳在进入腔（134）内的尖锐物（102），尖锐物（102）从近端（109）纵向延伸到远端（110）并包括延伸穿过其中的通道，通道配置为通过其接收流体。另外，系统（100）包括扩张护套（106），该扩张护套（106）从近端（128）纵向延伸到远端（130）并且包括延伸穿过其中的扩张腔（132），扩张腔（132）的尺寸和成形为可滑动地容纳进入护套（104）。扩张内腔（132）的尺寸和形状设计成可滑动地容纳进入护套（104）。