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(54) **GALLSTONE REMOVAL THROUGH CHOLECYSTODUODENAL FISTULA BY ANASTOMOSIS DEVICE**

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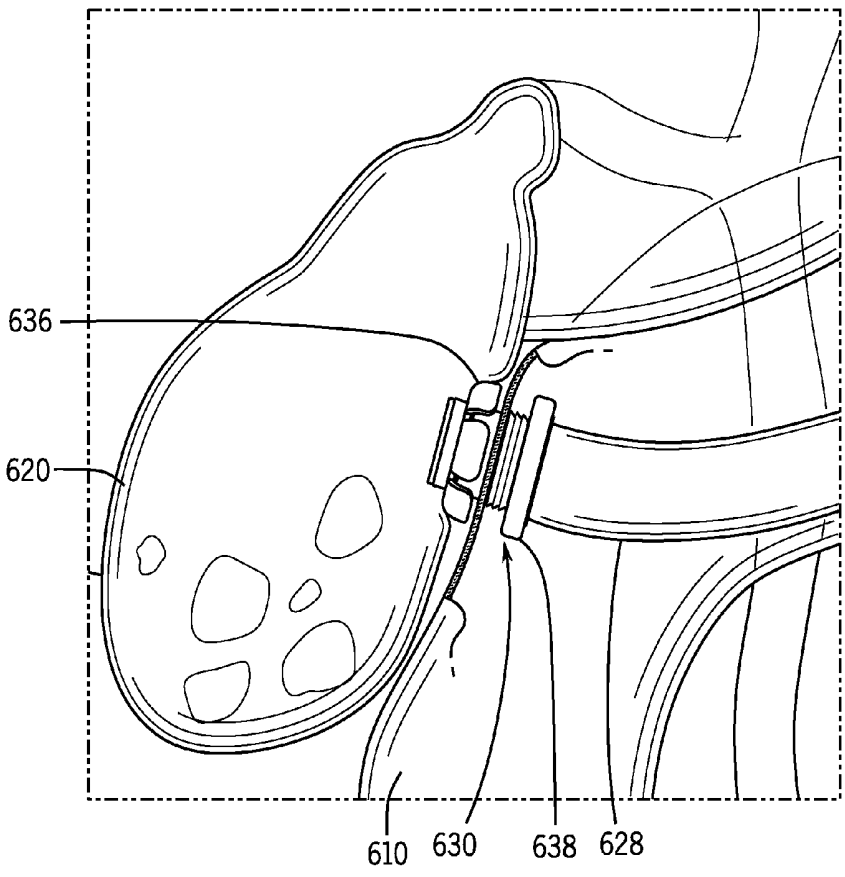
(57) **ABSTRACT**

An anastomosis device may include a base member defining a passageway between a first end and a second end of the base member, a first support member connected to the base member proximal to the first end, and a second support member connected to the base member proximal to the second end. The base member may have a cutting element to cut tissue from the first end. At least one of the first support member and the second support member may be movable along a length of the base member to secure a portion of tissue between the first and second support members.



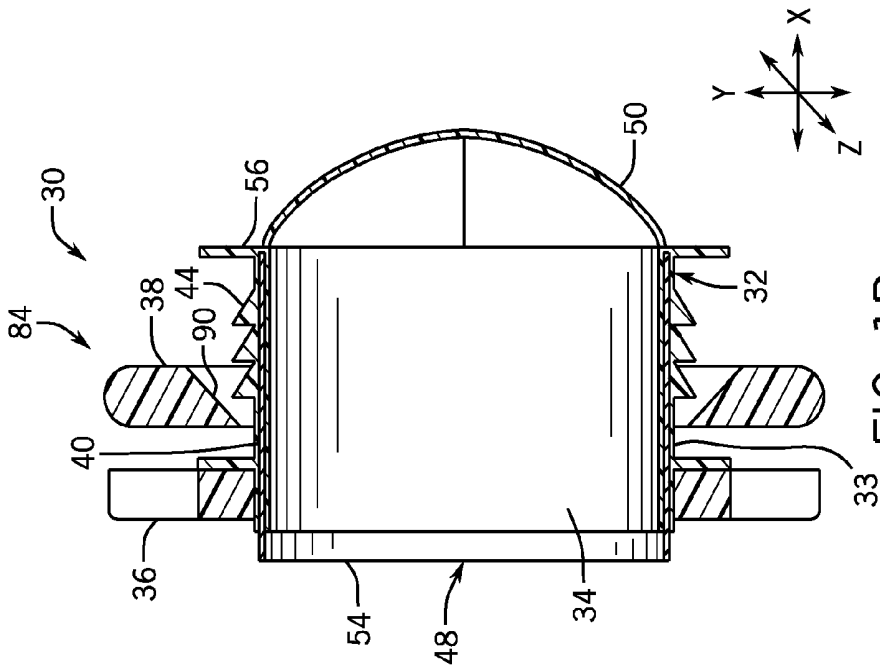

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FIG. 1B

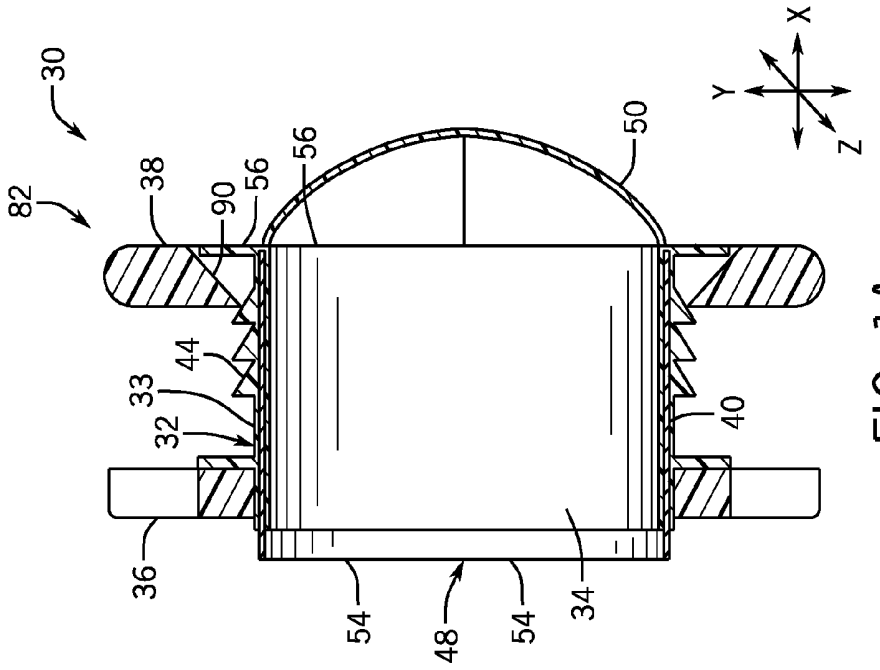
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FIG. 1A

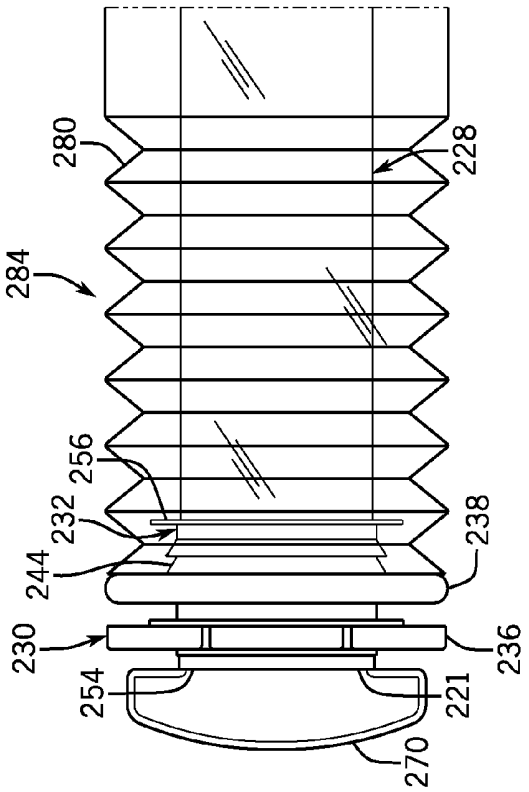
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FIG. 2B

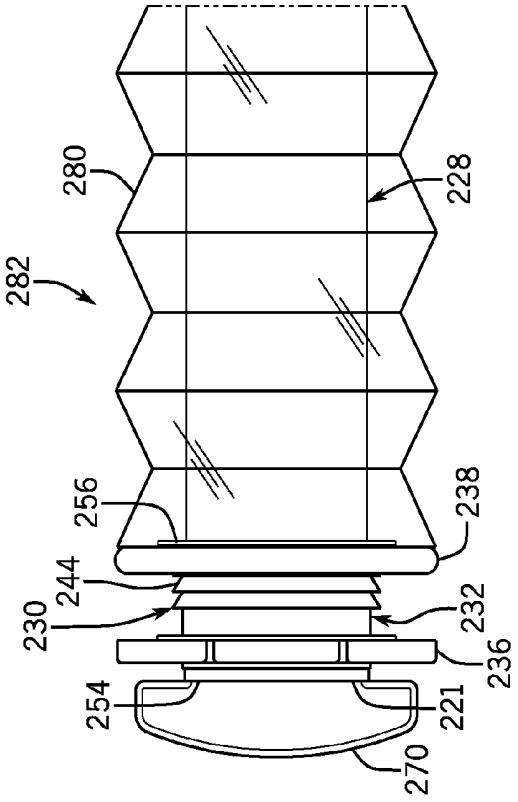
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FIG. 2A

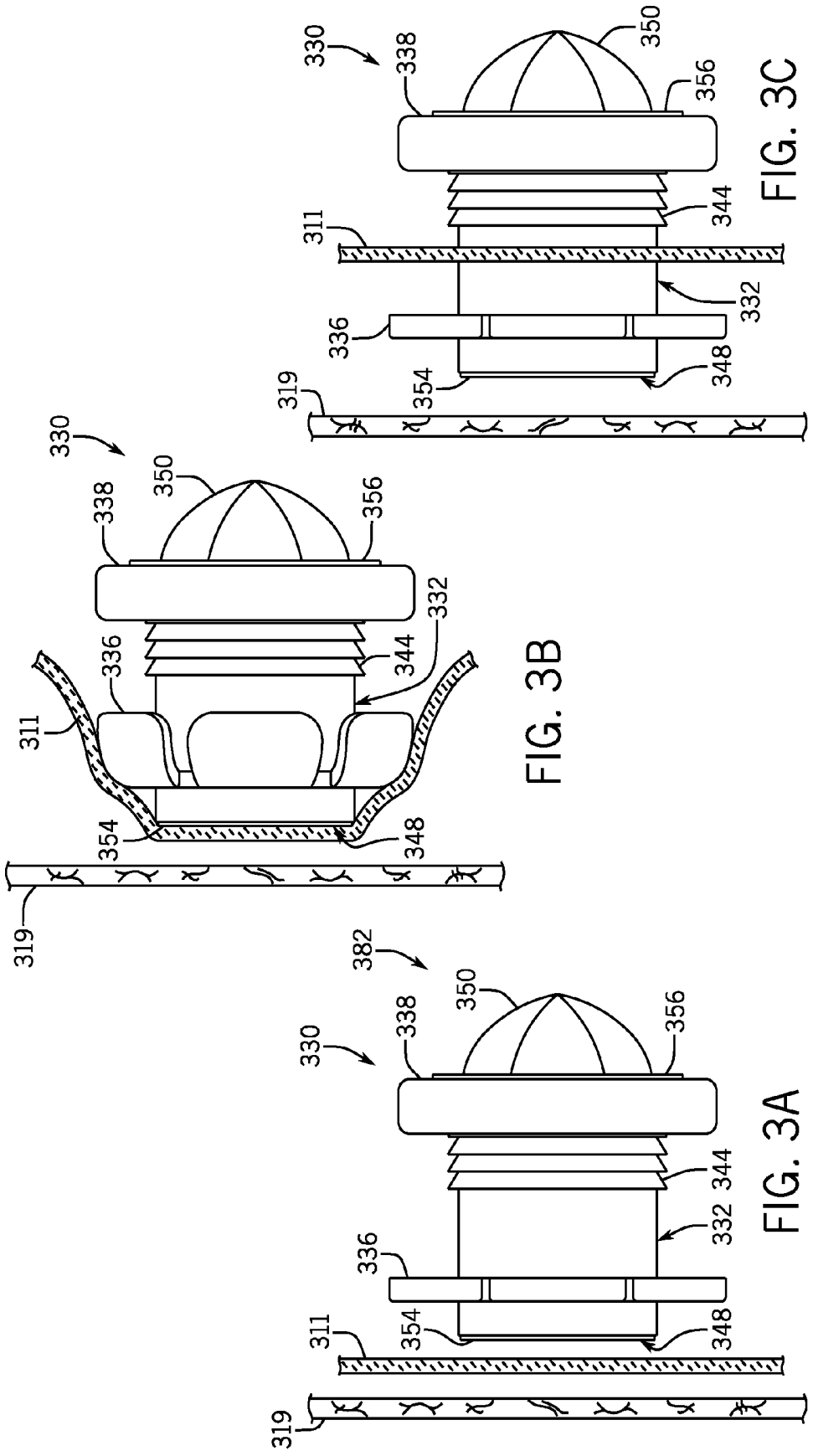

FIG. 3C

FIG. 3B

FIG. 3A

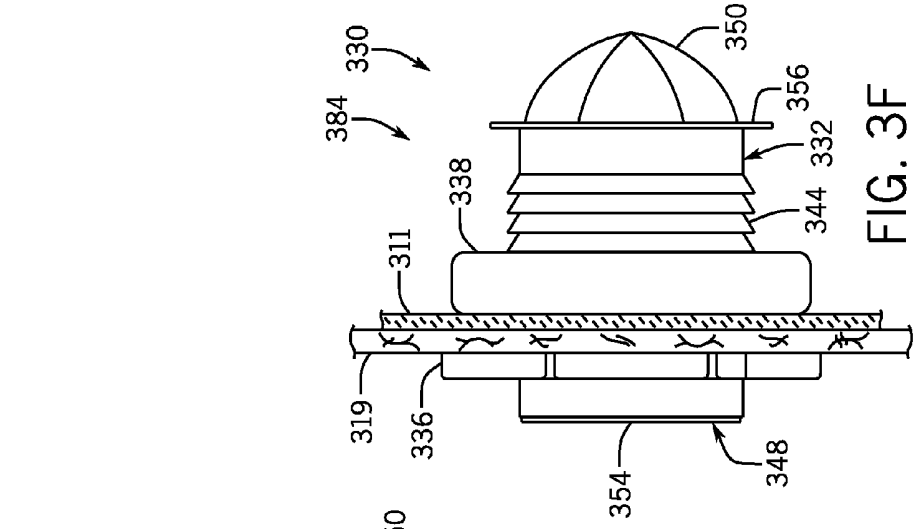

FIG. 3F

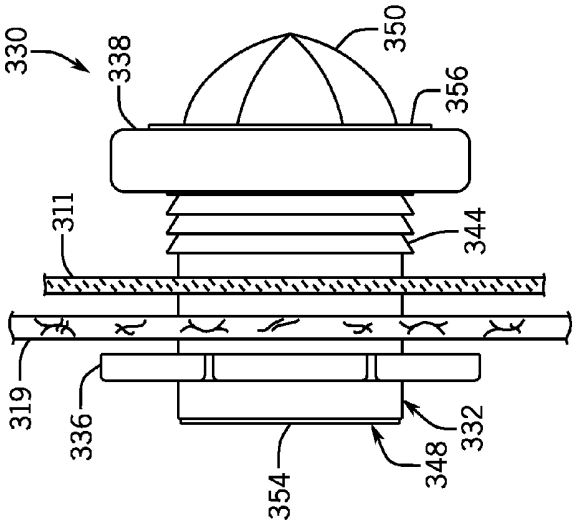

FIG. 3E

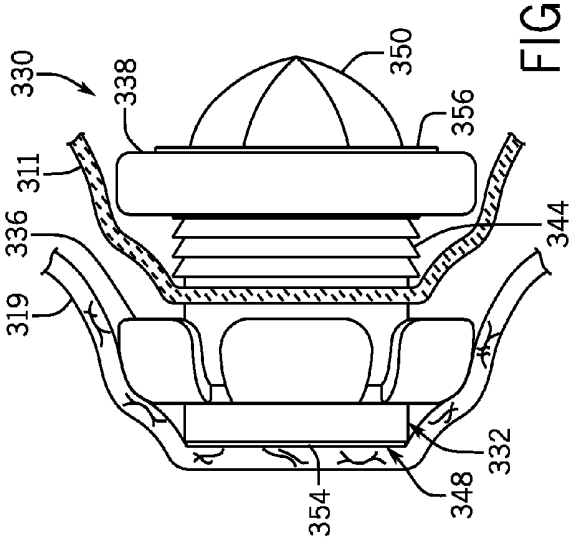

FIG. 3D

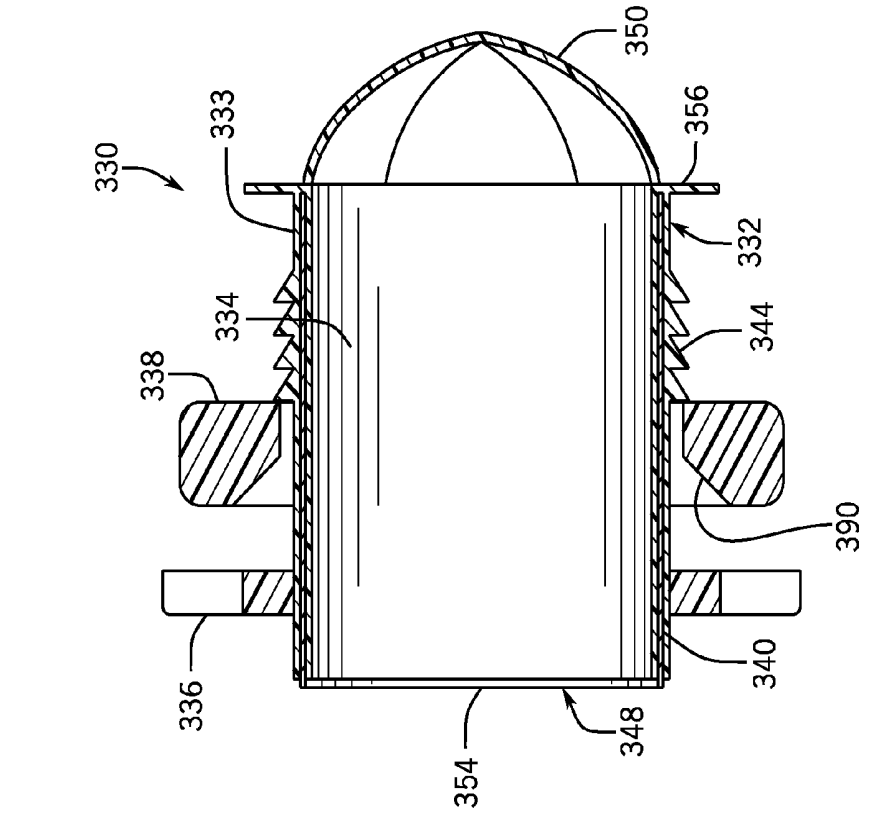
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FIG. 3H

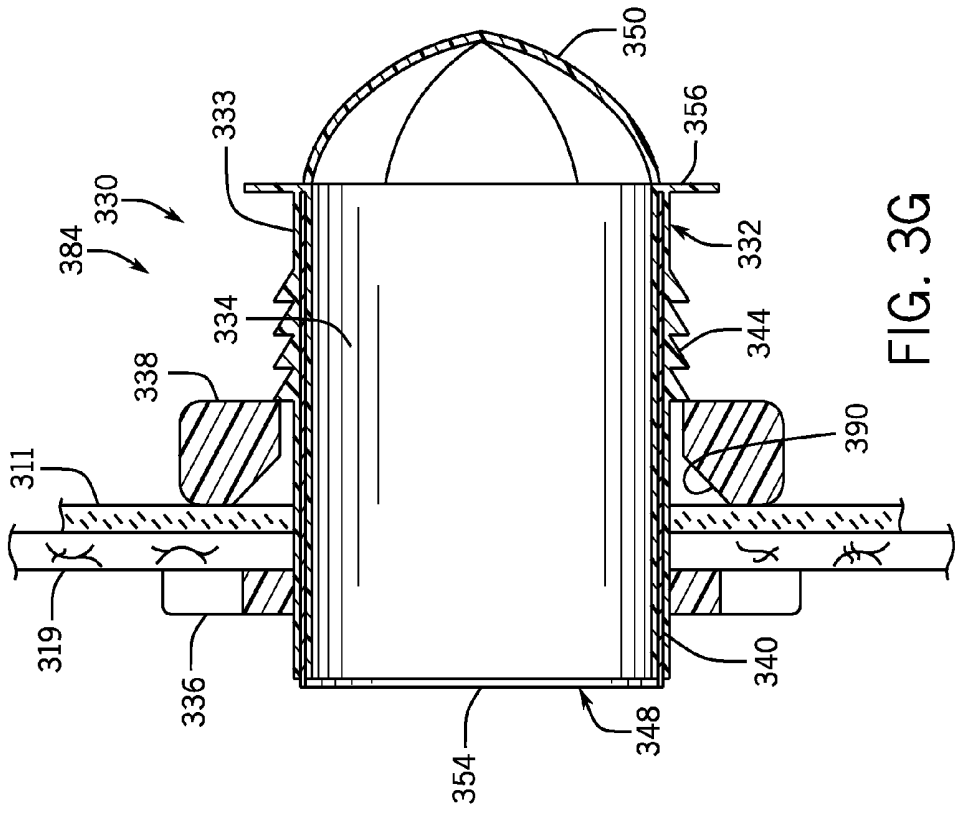
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FIG. 3G

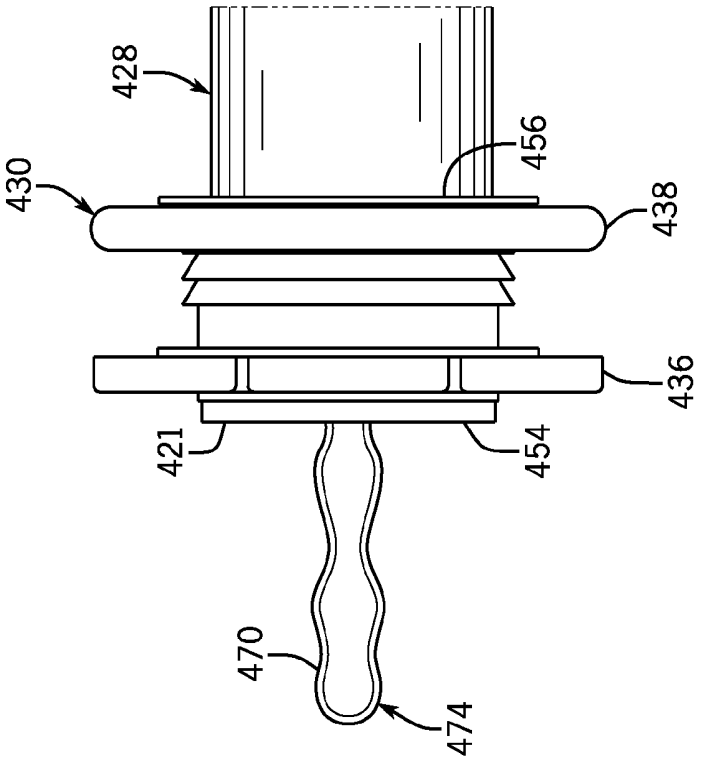
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FIG. 4B

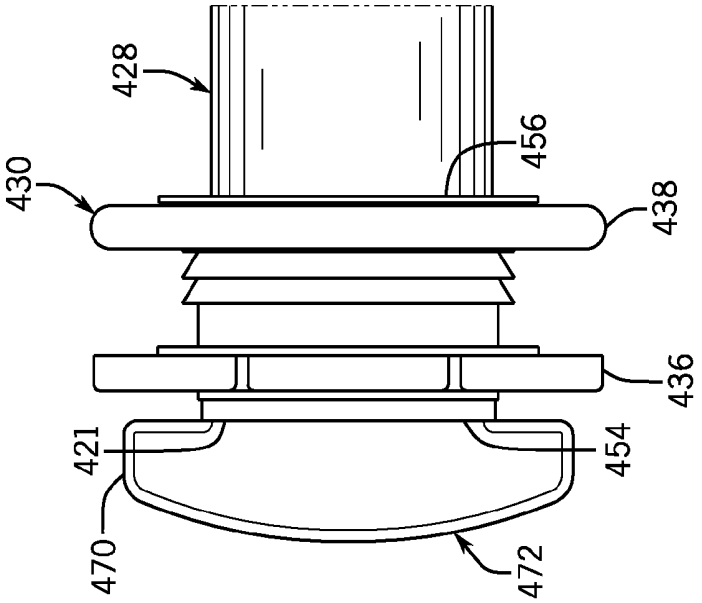
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FIG. 4A

FIG. 5A

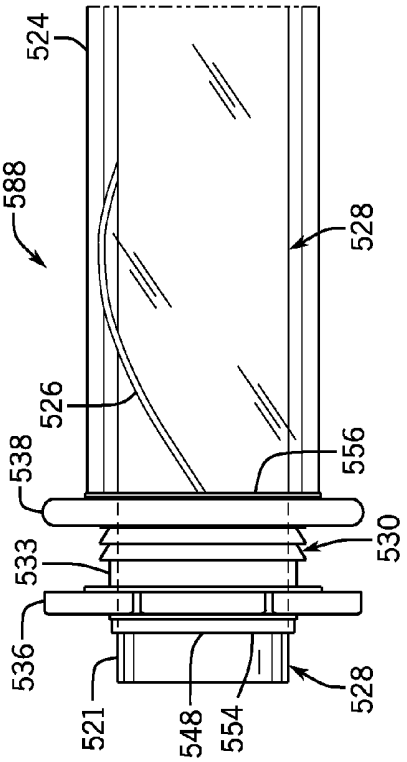


FIG. 5C

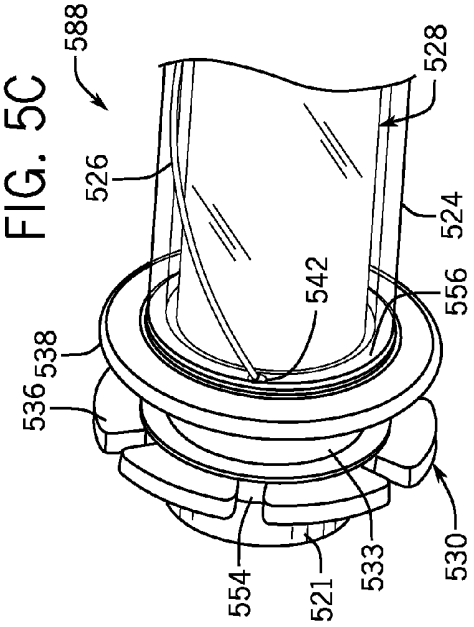
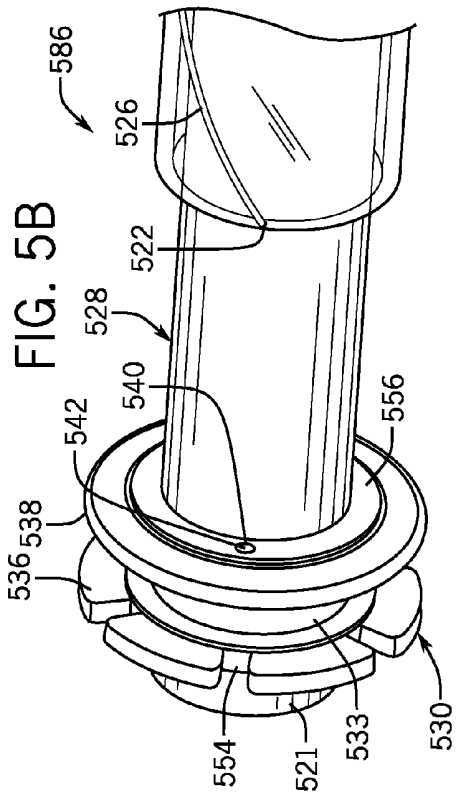


FIG. 5B



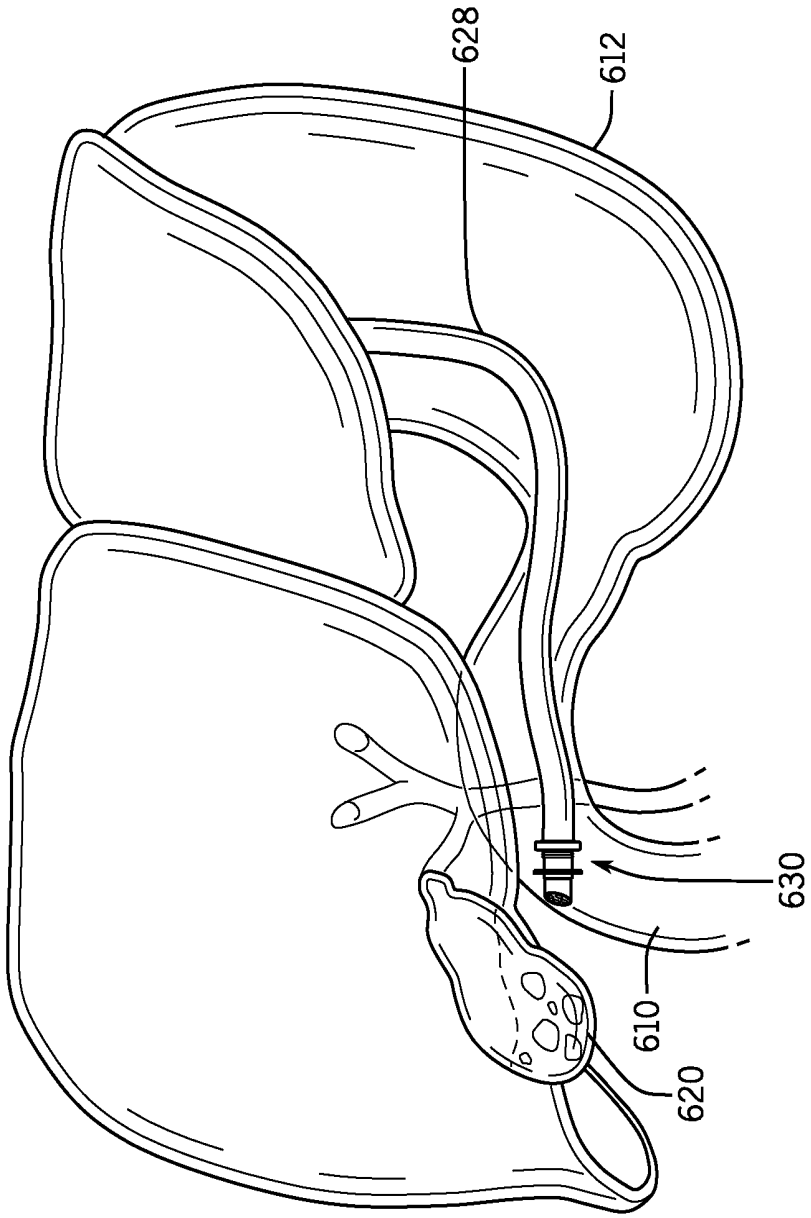


FIG. 6A

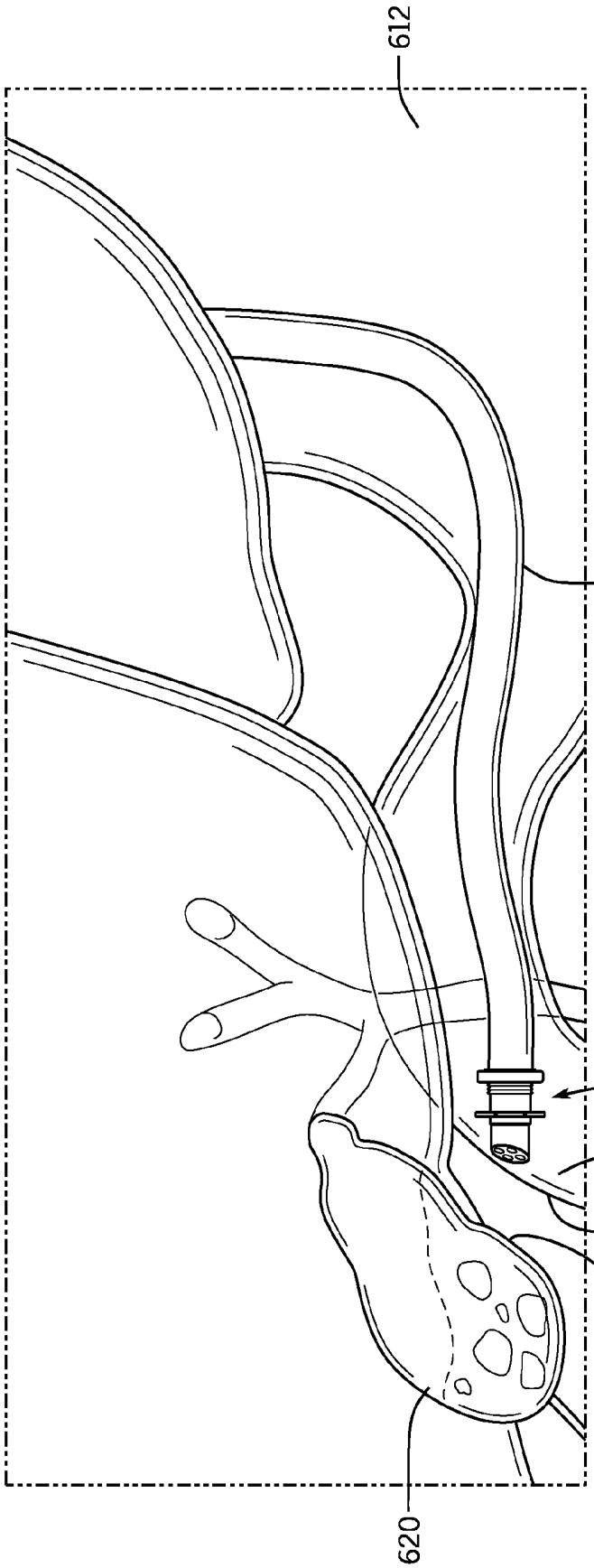


FIG. 6B

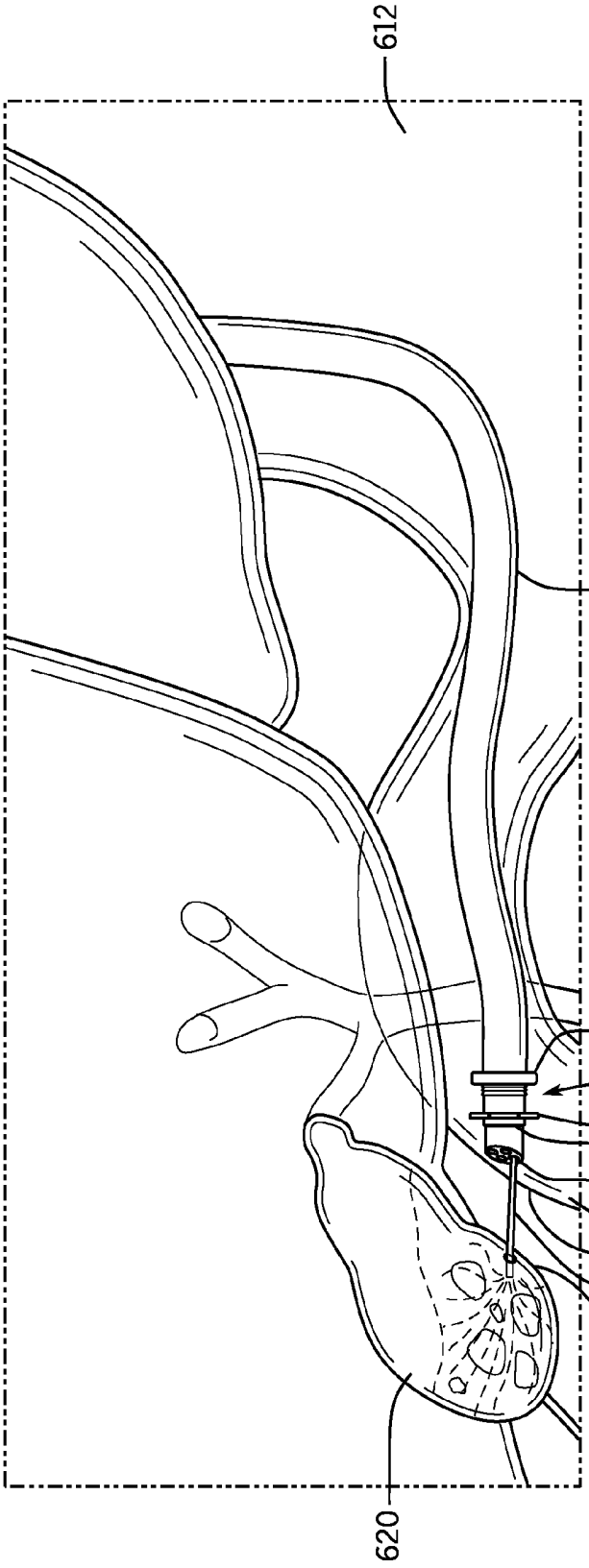


FIG. 6C

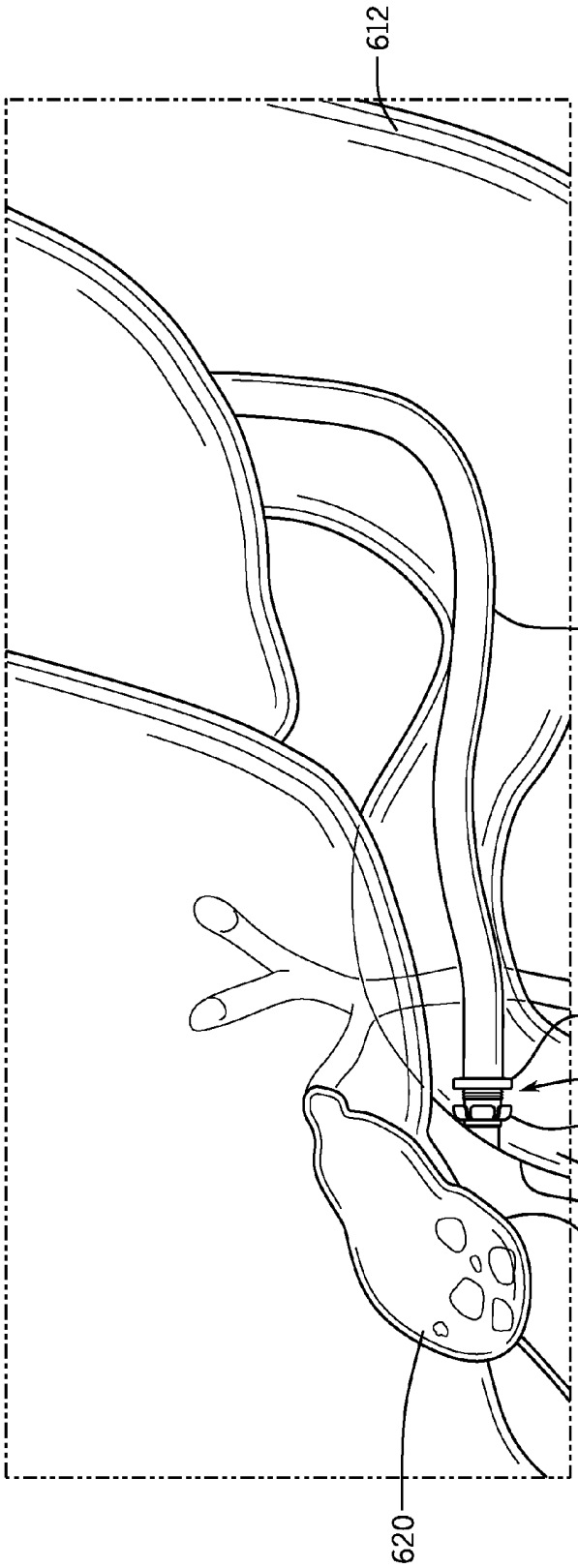


FIG. 6D

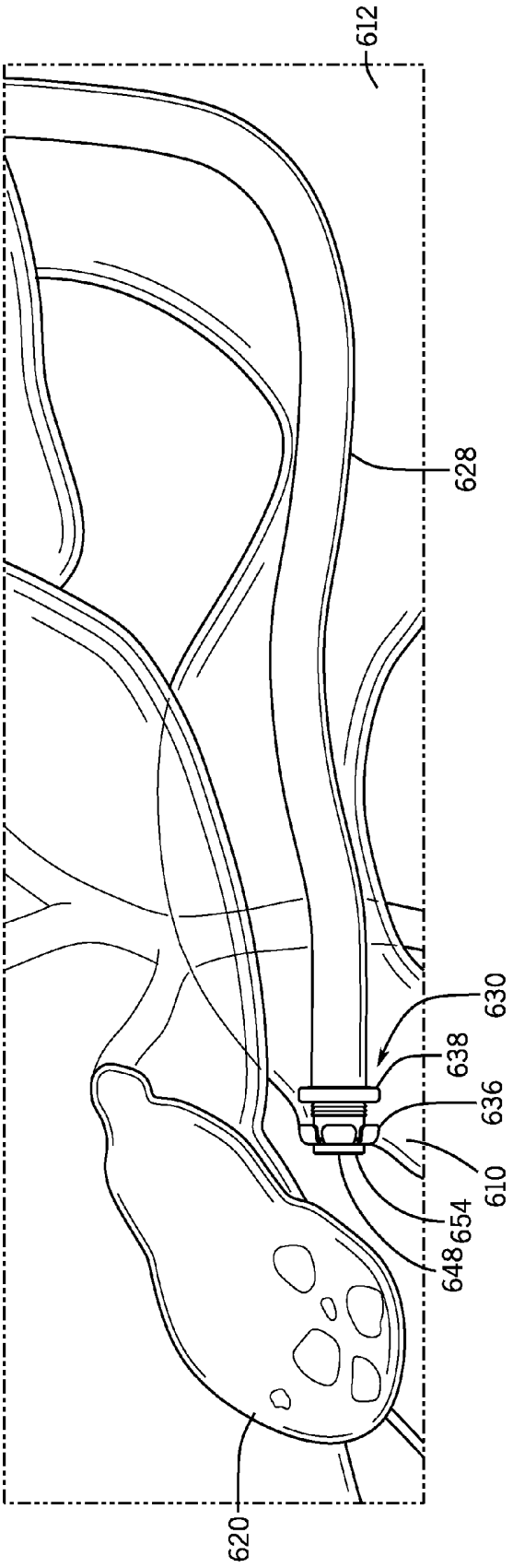


FIG. 6E

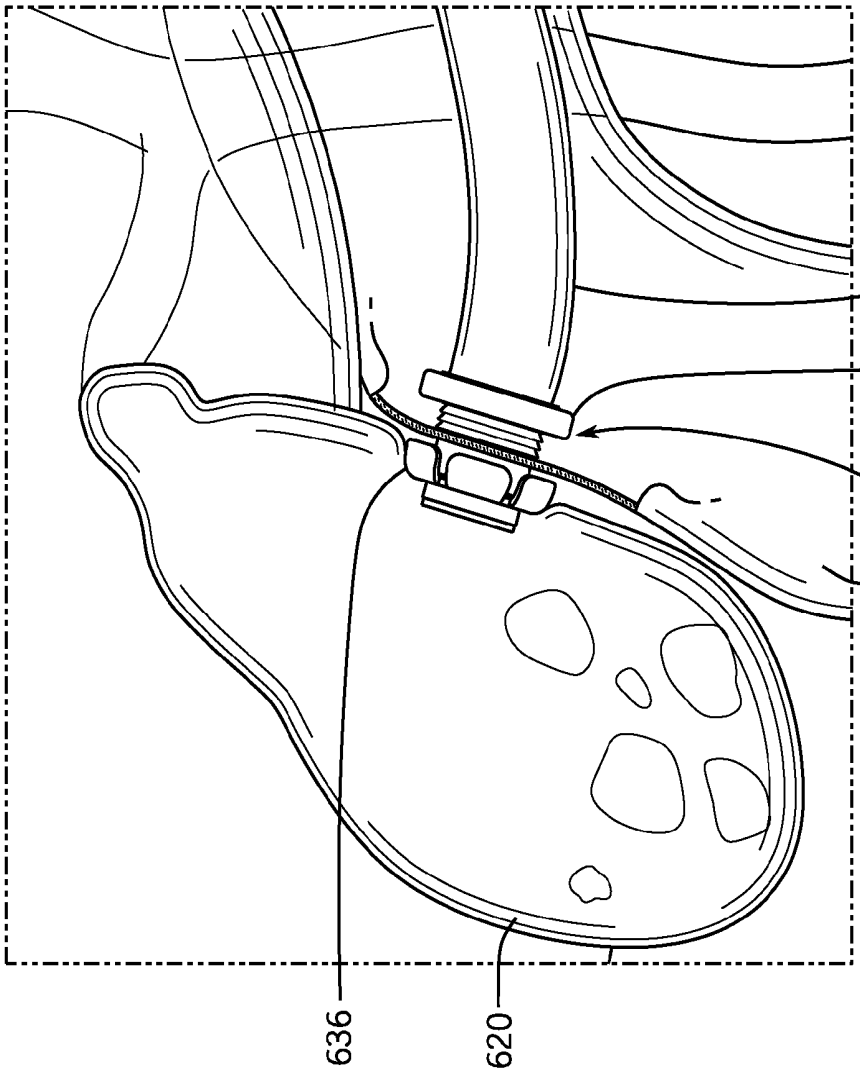


FIG. 6F

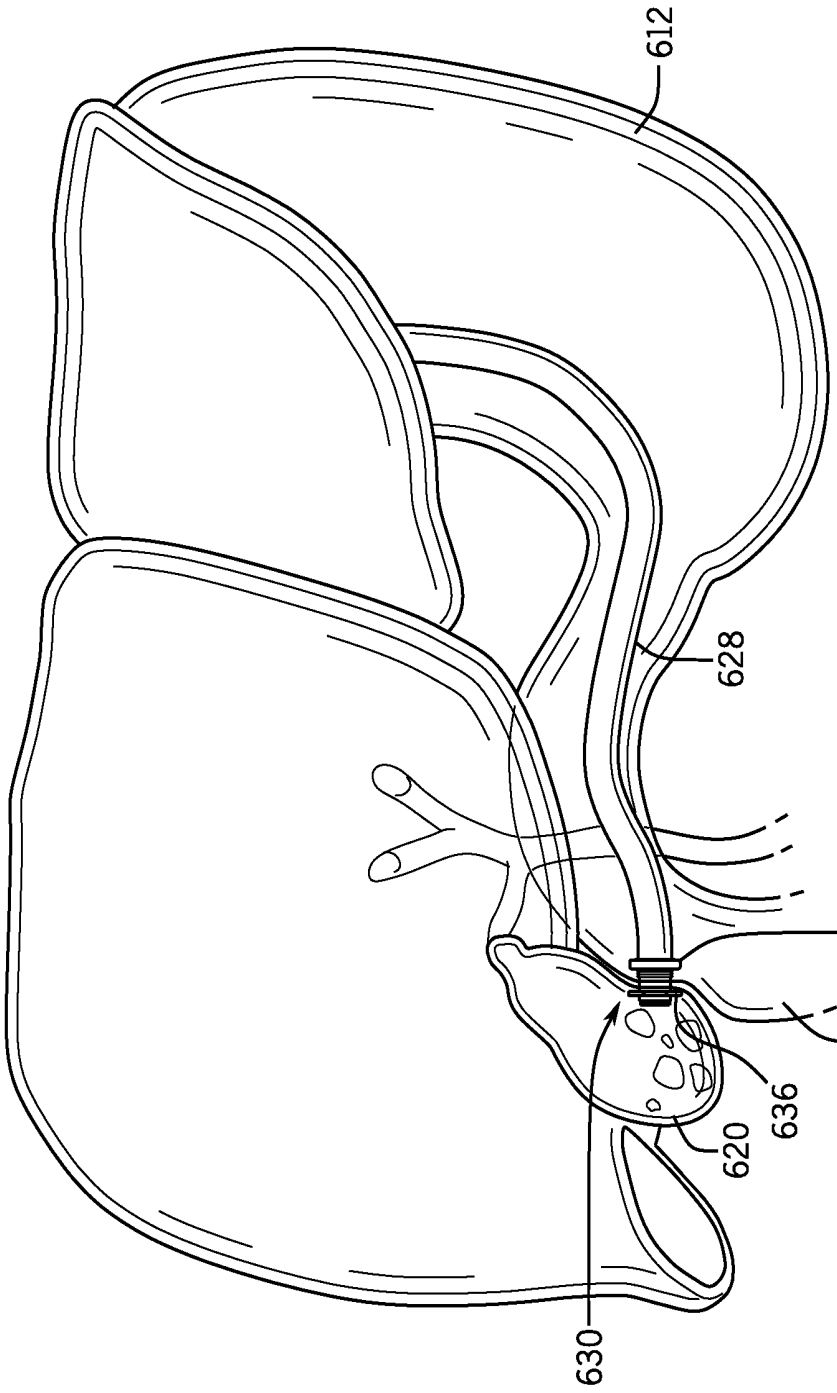


FIG. 6G

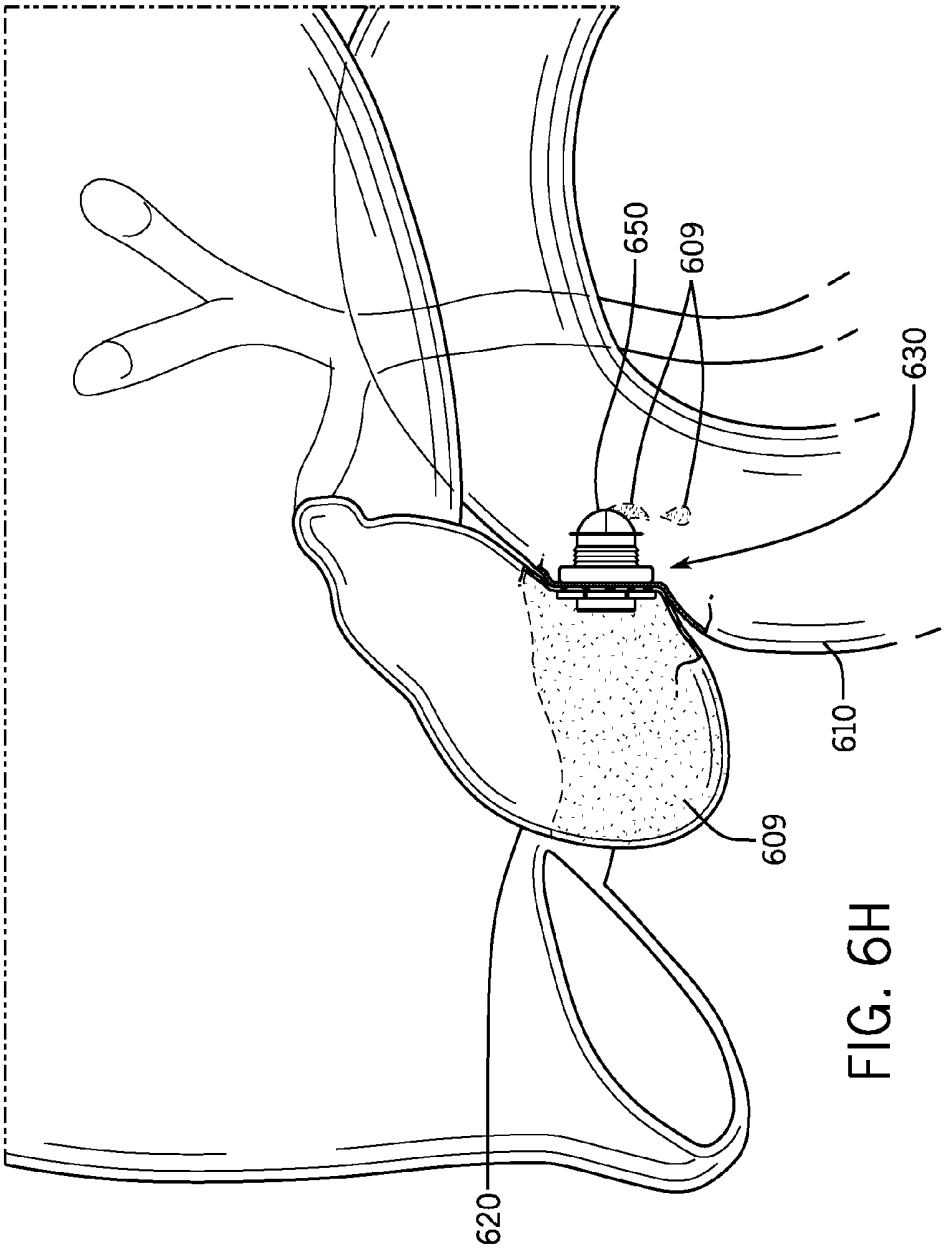


FIG. 6H

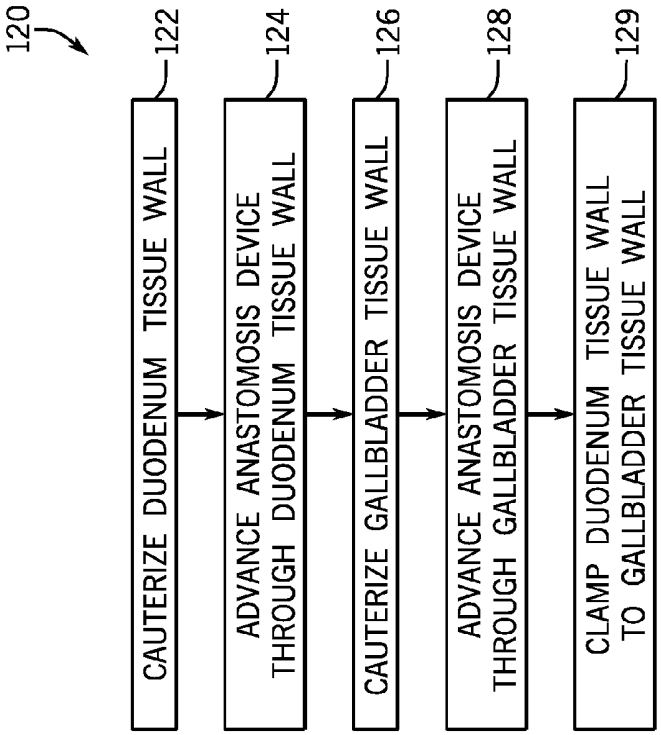

120
122
CAUTERIZE DUODENUM TISSUE WALL
124
ADVANCE ANASTOMOSIS DEVICE THROUGH DUODENUM TISSUE WALL
126
CAUTERIZE GALLBLADDER TISSUE WALL
128
ADVANCE ANASTOMOSIS DEVICE THROUGH GALLBLADDER TISSUE WALL
129
CLAMP DUODENUM TISSUE WALL TO GALLBLADDER TISSUE WALL

FIG. 8

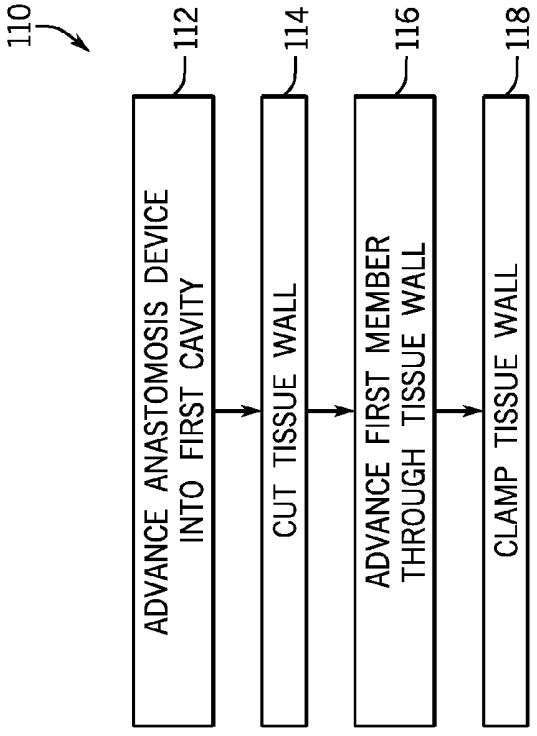

110
112
ADVANCE ANASTOMOSIS DEVICE INTO FIRST CAVITY
114
CUT TISSUE WALL
116
ADVANCE FIRST MEMBER THROUGH TISSUE WALL
118
CLAMP TISSUE WALL

FIG. 7

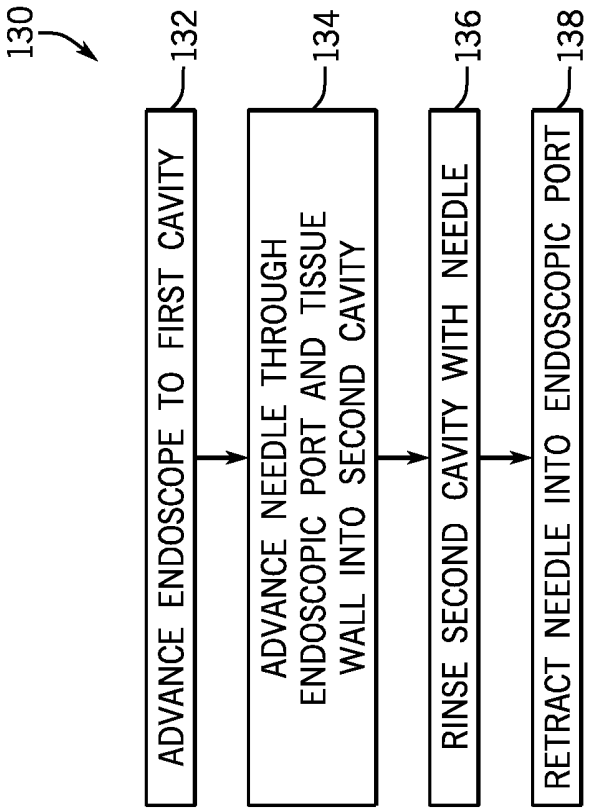

130
132
ADVANCE ENDOSCOPE TO FIRST CAVITY
134
ADVANCE NEEDLE THROUGH ENDOSCOPIC PORT AND TISSUE WALL INTO SECOND CAVITY
136
RINSE SECOND CAVITY WITH NEEDLE
138
RETRACT NEEDLE INTO ENDOSCOPIC PORT

FIG. 9

GALLSTONE REMOVAL THROUGH CHOLECYSTODUODENAL FISTULA BY ANASTOMOSIS DEVICE

BACKGROUND

[0001] The gallbladder is a small, pear-shaped pouch below the liver in the upper right portion of the abdomen of a human body. The gallbladder connects to the liver and the bowel through the bile duct, which is also attached the pancreas. The gallbladder may store bile produced by the liver until needed. Bile may be used to help digest fats or other substances. As food is ingested, the gallbladder contracts to push and release bile through ducts and into the small intestine to help with digestion. The ducts include hepatic ducts (which carry bile out of the liver), cystic ducts (which take bile to and from the gallbladder), and the common bile duct (which takes bile from the cystic and hepatic ducts to the small intestine).

[0002] However, due to a variety of reasons, gallstones may develop within the gallbladder or bile ducts. Gallstones may form when the bile hardens into pieces of stone-like material. The gallstones may cause severe pain in the upper abdomen. Gallstones can block the normal flow of bile if the gallstones move from the gallbladder and lodge in any of the ducts carrying bile from the liver to the small intestine.

[0003] There are several different types of gallstones. For example, cholesterol gallstones, a common type of gallstone, may form as a result of excess cholesterol in the bile and are common in overweight patients and patients with ileal disease or with small bowel resection. Pigment gallstones, a relatively less common type of gallstone, may form when there is excess bilirubin in the bile. Pigment gallstones may also develop as a result of liver disease, hemolytic anemias, cirrhosis, an infection in the bile duct, or an inherited blood disorder, such as sickle cell anemia, where blood cells are broken down by the body too quickly.

[0004] About 10% of the general population has gallstones. Gallstones are approximately two times more common in females than in males. Overweight women in the middle years may, in particular, be susceptible to gallstones. Approximately 5-20% of women between 20-55 years and 25-30% of women over 55 years have gallstones. The prevalence for males is approximately half than that of women in any given age group.

[0005] Gallstones may cause sudden or long-term inflammation to the gallbladder (e.g., acute or chronic cholecystitis), inflammation of the pancreas and bile ducts, gallstone ileus, jaundice, and/or gallbladder cancer. Untreated gallstones may be life-threatening.

[0006] Surgery may be used to remove the gallbladder (i.e. cholecystectomy) in order to treat or remove the gallstones. About 500,000 Americans undergo cholecystectomy every year and this number has been increasing. Surgery may result in many different complications, such as injury to one of the bile ducts. If a bile duct is torn, bile can leak into the abdominal cavity, which may result in a painful and potentially life-threatening infection, as well as an additional surgery.

[0007] Additionally, 10-15% of patients suffer from post-cholecystectomy syndrome as a result of the cholecystectomy. This syndrome is characterized by a continuation of symptoms attributed to gallbladder disease or the development of new gastrointestinal symptoms.

[0008] Aside from the complications, surgery is also not ideal since there are benefits to keeping the gallbladder and not all patients may be able to have the surgery. Other techniques to remove the gallstones may not prevent gallstone reoccurrence and require complex procedures.

SUMMARY

[0009] According to one embodiment, an anastomosis device may include a base member defining a passageway between a first end and a second end of the base member, a first support member connected to the base member proximal to the first end, and a second support member connected to the base member proximal to the second end. The base member may have a cutting element to cut tissue from the first end. At least one of the first support member and the second support member may be movable along a length of the base member to secure a portion of tissue between the first and second support members.

[0010] According to another embodiment, an anastomosis method may include advancing an anastomosis device into a first cavity with a first tissue wall, cutting the first tissue wall with the first end of the anastomosis device, advancing the first support member through the first tissue wall to a second tissue wall of a second cavity, cutting the second tissue wall with the first end of the anastomosis device, advancing the first support member through the second tissue wall, and clamping the first and second tissue walls between the first support member and the second support member. The anastomosis device may include a base member defining an inner passage between a first end and a second end, and a first support member and a second support member extending outwardly from the base member.

[0011] According to yet another embodiment, a method for accessing a gallbladder may include cauterizing a duodenum tissue wall of a duodenum with a first end of an anastomosis device, advancing the anastomosis device at least partially through the duodenum tissue wall, and cauterizing a gallbladder tissue wall of the gallbladder with the first end of the anastomosis device. A base member of the anastomosis device may define a passageway through the anastomosis device from the first end to the second end of the anastomosis device. The method may further include advancing the anastomosis device at least partially through the gallbladder tissue wall and clamping the duodenum tissue wall to the gallbladder tissue wall around an outer circumference of the base member between the first end and a second end. The anastomosis device may at least partially remain in the duodenum.

[0012] According to still another embodiment, a method for cleaning a cavity within a body may include advancing an endoscope to a tissue wall of a first cavity within the body, advancing a needle through the endoscopic port and the tissue wall into a second cavity, rinsing the second cavity with the needle, and retracting the needle into the endoscopic port. Adistal end of the endoscope may include an endoscopic port,

[0013] The foregoing summary is illustrative only and is not intended to be in any way limiting. In addition to the illustrative aspects, embodiments, and features described above, further aspects, embodiments, and features will become apparent by reference to the drawings and the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] FIGS. **1**A-**1**B are cross-sectional, side views of an anastomosis device in a undeployed position and a deployed position, respectively, according to one embodiment.

[0015] FIGS. **2**A-**2**B are side views of an anastomosis device in a undeployed position and a deployed position, respectively, and attached to a delivery device according to another embodiment.

[0016] FIGS. **3**A-**3**F are side views of an anastomosis device moving through two tissue walls and from a undeployed position to a deployed position according to one embodiment.

[0017] FIG. **3**G is a cross-sectional, side view of the anastomosis device of FIG. **3**F.

[0018] FIG. **3**H is a cross-sectional, side view of the anastomosis device of FIG. **3**F without tissue walls.

[0019] FIGS. **4**A-**4**B are side views of an anastomosis device with a balloon in an inflated state and a deflated state, respectively, according to one embodiment.

[0020] FIG. **5**A is a side view of an anastomosis device attached to a delivery device according to another embodiment.

[0021] FIGS. **5**B-**5**C are perspective views of the anastomosis device of FIG. **5**A with a sheath in an unattached position and an attached position, respectively.

[0022] FIG. **6**A is a partially transparent, side view of an anastomosis device according to one embodiment in the duodenum.

[0023] FIG. **6**B is a partially transparent, side, enlarged view of the anastomosis device of FIG. **6**A.

[0024] FIG. **6**C is a partially transparent, side view of a needle extending into the gallbladder from the anastomosis device of FIG. **6**A.

[0025] FIG. **6**D is a partially transparent, side view of the anastomosis device of FIG. **6**A within the duodenum.

[0026] FIG. **6**E is a partially transparent, side view of the anastomosis device of FIG. **6**A extending partially out of the duodenum.

[0027] FIG. **6**F is a partially transparent, partially cross-sectional, side view of the anastomosis device of FIG. **6**A extending into the gallbladder from the duodenum.

[0028] FIG. **6**G is a partially transparent, side view of the anastomosis device of FIG. **6**A anastomosing the duodenum and the gallbladder.

[0029] FIG. **6**H is a partially transparent, partially cross-sectional, side view of the anastomosis device of FIG. **6**A draining the gallbladder into the duodenum.

[0030] FIG. **7** is a flow diagram of an anastomosis method according to one embodiment.

[0031] FIG. **8** is a flow diagram of a method for accessing a gallbladder according to another embodiment.

[0032] FIG. **9** is a flow diagram of a method for cleaning a cavity within a body according to yet another embodiment.

DETAILED DESCRIPTION

[0033] In the following detailed description, reference is made to the accompanying drawings, which form a part thereof. In the drawings, similar symbols typically identify similar components, unless context dictates otherwise. The illustrative embodiments described in the detailed description, drawings, and claims are not meant to be limiting. Other embodiments may be utilized, and other changes may be made, without departing from the spirit or scope of the subject matter presented here.

[0034] Referring generally to the disclosure, described herein is an anastomosis device and methods to provide access to the gallbladder through the intestinal tract and allow gallstones to be easy and conveniently removed. More specifically, the anastomosis device may create a passage between the duodenum and the gallbladder to provide access to the gallbladder. The gallstones may be removed from the gallbladder through the anastomosis device. The gallstones may be moved into the duodenum to be excreted from the body or removed from the body through a delivery device.

[0035] Generally speaking, the anastomosis device is delivered into the body of the patient through, for example, the mouth and may follow the digestive track to advance into the duodenum. The anastomosis device may first clean the gallbladder by extending a needle into the gallbladder from the duodenum. Once the gallbladder has been cleaned with a needle, the anastomosis device may begin to join the duodenum and the gallbladder. For example, a first end of the anastomosis device may cauterize the duodenum tissue wall to create an aperture in the duodenum tissue wall. Part of the anastomosis device may be advanced through the cauterized aperture and may be extended toward the gallbladder tissue wall. Subsequently, the anastomosis device may cauterize the gallbladder tissue wall to create an aperture in the gallbladder tissue wall and the anastomosis device may be advanced within the gallbladder. One of the support members of the anastomosis device may remain in the duodenum while the other support member may advance into the gallbladder. Accordingly, once the anastomosis device is in position, at least one of the support members may move toward the other to pinch the tissue walls between the support members and secure the anastomosis device to the tissue. The anastomosis device may include an inner passageway to allow material to move between the gallbladder and the duodenum. The gallbladder may be further cleaned with the delivery device and/or the delivery device may be detached from the anastomosis device, allowing the anastomosis device to continue draining the gallbladder into the duodenum.

[0036] Accordingly, with the anastomosis device and methods described further herein, bodily material, such as gallstones, may be removed from the body non-invasively and the inside of certain organs, such as the gallbladder, may be easily accessed. Although medicine may be used with the anastomosis device to capture and break the gallstones, the anastomosis device may allow the gallstones to be easily treated and completely extracted mechanically. Further, the anastomosis device may prevent a gap between the duodenum and the gallbladder after attachment, which prevents any leakage of bile to prevent inflammation. Once the anastomosis device is attached within the body, the anastomosis device may allow continual or temporary access into the gallbladder, according to the desired configuration.

Anastomosis Device

[0037] Referring now to FIGS. **1**A-**1**B, there is shown an anastomosis device **30** according to one embodiment. As described further herein, the anastomosis device **30** may be used to cut into tissue and create an opening or connection between at least two areas (e.g., a duodenum and a gallbladder) of the body to allow material, such as gallstones, to

flow between the two areas. "Cutting" may include mechanical penetration and expansion, cauterization, coring, lacerating, or incising.

[0038] The anastomosis device **30** may be sized to be delivered through at least one of a surgical port or a natural orifice of a body and through at least a portion of a gastrointestinal tract of the body of the patient to be delivered to the implantation region. As described further herein, the anastomosis device **30** may be configured to create a cauterized hole or aperture within at least one tissue wall. Accordingly, at least a portion of the anastomosis device **30** may be sized to also fit through the cauterized aperture in the tissue. For example, according to one embodiment, the length and diameter of the anastomosis device **30** may be between approximately 3 to 20 mm and 5 to 25 mm, respectively. According to another embodiment, the length and diameter of the anastomosis device **30** may be between approximately 6 to 10 mm and 7 to 13 mm, respectively.

[0039] As shown in FIGS. **1**A-**1**B, the length, height, and width of the anastomosis device **30** may be defined by the x-axis (the longitudinal axis), y-axis (the vertical axis), and the z-axis (the lateral axis), respectively. The x-, y-, and z-axes are perpendicular to each other. Accordingly, the length of the base member **32** of the anastomosis device **30**, for example, may also be defined along the x-axis of the anastomosis device **30**.

[0040] The anastomosis device **30** may include a body or base member **32**, which, when implanted, may extend at least partially between the duodenum and the gallbladder. The base member **32** may be a variety of different shapes. According to an embodiment, the base member **32** may be a cylindrical tube with openings on either end along the longitudinal length (the x-axis). At least a portion (e.g., the first or distal end) of the base member **32** may be sized to fit or be transported through the cauterized tissue aperture.

[0041] The base member **32** may include a base member shell **33**, which may at least partially encompass a metallic ring **40** (as described further herein). The shell **33** may be constructed out of a variety of different non-conductive materials according to the desired configuration. It may be particularly beneficial for the base member shell **33** to be a non-conductive material in order to prevent the metallic ring **40** from accidentally cauterizing other areas of the body.

[0042] The base member **32** may define an inner passage or passageway **34** through the center of the anastomosis device **30**. The passageway **34** may be a hollow portion of the base member **32** and may extend longitudinally along the base member **32** and between a distal or first end **54** and a proximal or second end **56** of the base member **32**. The first end **54** may be used to cut the tissue and the second end **56** may be used to attach to or interface with the distal end of a delivery device, as described further herein. The passageway **34** may allow material to move between either side of the anastomosis device **30** (and thereby between two cavities within the patient, such as the duodenum and the gallbladder).

[0043] The base member **32** may include a cutting element **48** that is configured to cut tissue from the first end **54** of the base member **32** through a variety of different mechanisms. According to one embodiment, the cutting element **48** may be a cautery mechanism configured to cut the tissue through cauterization. For example, when the anastomosis device **30** is connected to the delivery device (and the delivery device is providing power to the cutting element **48**, as described further herein), the cutting element **48** may act as a monopolar cautery device through the first end **54** of the base member **32**. However, when the power is off or the anastomosis device **30** is disconnected from the delivery device, the cutting element **48** of the anastomosis device **30** may not cauterize or harm any tissue.

[0044] In order to transfer power or electricity from the delivery device to the first end **54** of the base member **32**, the cutting element **48** may include a metallic cylinder, extension, or ring **40**, located within the shell **33** of the base member **32**. Power from the delivery device may be transferred from the second end **56** to the first end **54** of the anastomosis device **30** through the metallic ring **40** in order to provide power for cauterization. The power requirement to cauterize the tissue may be within a standard range supplied by a monopolar electrocautery mechanism.

[0045] The metallic ring **40** may be at least partially embedded and shielded within the base member shell **33** to prevent unintentional injury (e.g., cauterization) within the body. Accordingly, the base member shell **33** may provide insulation around the metallic ring **40**. For example, the base member shell **33** may cover the inner and outer circumferential surfaces of the metallic ring **40**, as well as a portion of one longitudinal end of the metallic ring **40** (corresponding to the second end **56** of the anastomosis device **30**). Additional insulation may optionally be provided around the base member **32**.

[0046] While the anastomosis device **30** is attached to (and powered by) the delivery device, the metallic ring **40** may only exposed through the first end **54** of the base member **32**. On the first end **54** of the anastomosis device **30**, the entire circumference or perimeter of the metallic ring **40** may be exposed or extend out of the base member shell **33** to allow the anastomosis device **30** controllably cauterize, and therefore cut, a complete hole or aperture through at least one tissue through the first end **54**.

[0047] While the anastomosis device **30** is not attached to or disconnected from the delivery device or the power supply, both longitudinal ends of the metallic ring **40** may be at least partially exposed through the first end **54** of the base member shell **33** and a portion of the second end **56**. For example, according to one embodiment as shown in FIG. **5**B, a portion of the metallic ring **540** may be exposed through the second end **556** of the base member shell **533** when the anastomosis device **530** is disconnected from the power supply of the delivery device **528**. This exposed portion of the metallic ring **540** along the second end **556** may be at least one metallic, electrical, or conductive terminal or contact **542**. As shown in FIG. **5**C, the contact **542** is connectable to an electrical contact from a conductive wire **526** on the delivery device **528** in order to access a power supply through the delivery device **528**. The contact **542** may be a part of the metallic ring or a metallic line, area, or strip attached to the metallic ring **540**.

[0048] As shown in FIGS. **1**A-**1**B, the anastomosis device **30** may further include a first flange or support member **36** and a second ring or support member **38**, which may act as tissue-locking members. The support members **36** and **38** may be used to attach or secure at least one tissue wall along a portion of the base member **32** in order to anastomose the duodenum and the gallbladder. For example, according to one embodiment as shown in FIGS. **3**F-**3**G, the support members **336** and **338** of the anastomosis device **330** may

clamp or press the tissue walls **311** and **319** in between the support members **336** and **338**.

[0049] As shown in FIGS. **1**A-**1**B, the support members **36** and **38** may be coupled, connected, or attached to the base member **32** (integrally or as separate components) and may extend outwardly and radially from the base member **32**. The support members **36** and **38** may be approximately perpendicular to the base member **32**. In alternate embodiments, the support members may be situated at an angle to the base member **32**. For example, the support members **36** and/or **38** may have an angle between approximately 30 and 60 degrees relative to the base member **32**. According to another embodiment, the support members **36** and/or **38** may have an angle that is approximately 45 degrees relative to the base member **32**.

[0050] The support members **36** and **38** may be proximate to each other along the length of the base member **32** (e.g., along the x-axis of the anastomosis device **30**). The longitudinal distance between the support members **36** and **38** may vary according to the type and number of tissues to secure in between the support members **36** and **38**. The distance between the support members **36** and **38** may be adjustable, as described further herein. The support members **36** and **38** may be shaped and sized according to the desired configuration and may have identical or mirror configurations or different configurations, as described further herein.

[0051] The first support member **36**, which may be more distally located along the anastomosis device **30** than the second support member **38** and proximal to the first end **54**, may be flexible or deformable in order to flex to be moved or transported through the aperture or hole the anastomosis device **30** may make in the tissue walls of both the duodenum and the gallbladder. According to one embodiment as shown in FIGS. **3**B and **3**D, the first support member **336** may be compressed into an undeployed state for easier delivery through an aperture within the body and may expand into a deployed state in order to maintain the position of the anastomosis device **330** within the body. The support member **336** may be preferentially compressible toward the second support member **338** and away from the cutting element **348** (as shown in FIGS. **3**B and **3**D) in order to prevent any tissue from slipping or falling off of the first end **354** of the anastomosis device **330**.

[0052] The shape of the first support member **36** may help the first support member **36** to be moved through apertures in tissue walls, while still providing sufficient support to hold the tissue walls. For example, as shown in various embodiments (such as FIGS. **3**B, **3**D, **5**B, and **5**C), the first support member **336** or **536** may be a ring surrounded by outwardly extending flanges, petals, extensions, or separately-movable sections. As shown in FIGS. **3**B and **3**D, this configuration of the first support member **336** may allow the first support member **336** to be bent or compressed along the length of the base member **332** to move through the cauterized holes. The first support member **336** may be constructed out of a flexible or compressible material to allow the first support member **336** to bend or flex.

[0053] The first support member **36** may be sized to fit within the tissue aperture in the compressed state. According to one embodiment as shown in FIGS. **3**A-**3**H, the diameter of the first support member **336** in a compressed or undeployed state (as shown, for example, in FIGS. **3**B and **3**D) and in an expanded or deployed state (as shown, for example, in FIGS. **3**A, **3**C, and **3**E-**3**H) may be between approximately 5 to 20 mm and 10 to 30 mm, respectively. According to another embodiment, the diameter of the first support member **336** in a compressed state and an expanded state may be between approximately 10 to 15 mm and 15 to 25 mm, respectively.

[0054] As shown in FIGS. **1**A-**1**B, the second support member **38** may be relatively more rigid or stiff, which may prevent the second support member **38** from moving through the aperture created in the tissue wall and may allow the second support member **38** to act as an anchor within the duodenum. Accordingly, the support member **38** may be a continuous ring around the base member **32** and may not be constructed out of a flexible material. The second support member **38** may be proximal to the second end **56**.

[0055] At least one of the support member **36** or **38** may be movable or adjustable along the length of the base member **32** to change the distance between the support members **36** and **38** and to move the anastomosis device **30** from an undeployed position **82** (as shown in FIG. **1**A) to a deployed position **84** (as shown in FIG. **1**B). According to one embodiment as shown in FIGS. **1**A-**1**B, the support member **38** may move along a portion of the length of the base member **32** (e.g., the steps **44**) toward the support member **36** to move from the undeployed position **82** to the deployed position **84** and the support member **36** may remain in position along the length of the base member **32**. Alternatively or additionally, the first support member **36** may be movable toward the second support member **38** and/or the second support member **38** may be stationary. This movement may allow the tissue walls to be securely clamped and/or held between the support members **36** and **38**. Additionally, depending on how far the support member **36** or **38** is moved along the base member **32**, the distance between the support members **36** and **38** may be easily tailored according to the desired configuration and use (e.g., to hold more tissue walls or thicker tissue walls). The support member **36** or **38** may provide traction or resistance to the other support member **36** or **38** in order to fully secure and compress the tissue between the support members **36** and **38**.

[0056] As shown in FIGS. **1**A-**1**B, the base member **32** may include an engagement structure or traction mechanism in order to secure or lock the second support member **38** (or the first support member **36**) into the deployed position **84** along the base member **32**. The engagement structure may be, for example, at least one discrete ridge, bump, protrusion, tooth, or snap step **44** (similar to stairs or a ladder), along a portion of the length and outside perimeter of the base member shell **33** that at least one of the support members **36** or **38** may move along. The other of the support members **36** or **38** may also move along a second set of steps (which may be angled in a different direction to direct the movement of the support member **36** or **38**) or may be stationary. According to one embodiment, the base member **32** may include multiple steps **44** or a series of sequential steps **44** that the support members **36** or **38** may move along. The steps **44** may keep the support members **36** and/or **38** locked, in place, aligned, and/or in close proximity, thereby also keeping the secured tissue walls aligned and/or in close contact when the anastomosis device **30** is deployed.

[0057] The steps **44** may be angled or wedged toward one end or the center of the base member **32** to allow the support member **36** or **38** to move or slide in only one direction (e.g.,

unilaterally or unidirectionally) over the steps **44** along the base member **32** and to prevent the support member **36** or **38** from moving out of the deployed position **84** and away from the other support member. Once the tissue walls have been positioned between the support members **36** and **38**, the support member **38** may move over the steps **44** from the second end **56** (as shown in FIG. **1**A, tissue not shown) to the first end **54** and the first support member **36** (as shown in FIG. **1**B, tissue not shown). Once the support member **38** has moved toward the support member **36**, the support member **38** may not move backward away from the support member **36** due to the steps **44**. Alternatively or additionally, the angles of the steps **44** may be positioned in different directions to direct the movement of the support members **36** or **38**, according to the desired configuration.

[0058] As shown in FIGS. **1**A-**1**B, the inner surface (or inside diameter or perimeter) of the support member **38** may have a complementary or corresponding structure or wedge **90** to the steps **44**. The wedge **90** may allow the support member **38** to engage with the steps **44** by allowing movement of the support member **38** toward the support member **36** (from the undeployed position **82** to the deployed position **84**) and preventing movement away from the support member **36** by locking the wedge **90** to the steps **44**.

[0059] According to one embodiment as shown in FIGS. **1**A-**1**B, the steps **44** and the wedge **90** may be angled away from each other (while in the undeployed position **82**) at angles between approximately 30 to 60 degrees (and, while in the deployed position **84**, the steps **44** and the wedge **90** are angled toward each other at angles between approximately 120 to 150 degrees). According to another embodiment, the steps **44** and the wedge **90** may be angled toward each other in the undeployed position **82** at approximately 45 degrees (and, in the deployed position **84**, the steps and the wedge **90** are angled away from each other at approximately 135 degrees). According to another embodiment as shown in FIGS. **3**G-**3**H, the steps **344** and the wedge **390** may be angled in the same direction.

[0060] The anastomosis device **30** may optionally use pneumatic, mechanical, and/or electrical forces during and after deployment (e.g., to move the second support member **38**, to clamp the tissue between the support members **36** and **38**, and/or to provide a rigid attachment to the tissue walls). According to an embodiment as shown in FIGS. **2**A-**2**B, in order to move the support members **236** and **238** toward each other and/or to secure tissue in between the support members **236** and **238** to maintain pressure on the tissue, at least one of the support members **236** and **238** may be mechanically and/or pneumatically driven or assisted. A pneumatic sleeve or bellow deployer **280** may be used to move or push the support member **238** along the base member **232**. For example, the pneumatic deployer **280** may slide over the delivery device **228** and/or over a sheath with a conductive wire (as shown in FIGS. **5**A-**5**C) and may attach to the proximal end of the support member **238**. The pneumatic deployer **280** may include a channel to receive fluid (e.g., a gas or liquid). As shown in FIG. **2**A, when the pneumatic deployer **280** is uninflated, the pneumatic deployer **280** may be pulled back toward the proximal end of the delivery device **228** in an undeployed position **282**. In the undeployed position **282**, the support member **238** may remain relatively close to the second end **256** of the anastomosis device **230**. As shown in FIG. **2**B, when the pneumatic deployer **280** is inflated with fluid, the pneumatic deployer **280** may move toward the distal end **221** of the delivery device **228** into a deployed position **284**, which may mechanically move or push the second support member **238** along a portion of the length of the base member **232** (e.g., along the steps **244**) and toward the tissue, the first end **254**, and the first support member **236**.

[0061] As shown in various embodiments (such as FIGS. **1**A-**1**B and **3**A-**3**H), an optional valve **50** or **350** may be used to control the flow of material through the anastomosis device **30** or **330** and may be attached to the base member **32** or **332**. For example, the valve **50** or **350** may be attached to the first end **54** or **354** or the second end **56** or **356** of the base member **32** or **332**. The valve **50** or **350** may also be used to allow the gallstones to be broken down and removed from the gallbladder through a variety of different methods and techniques, as described further herein.

[0062] According to one embodiment, the valve **50** or **350** may be a one-way valve. Accordingly, the valve **50** or **350** may be positioned to allow the bile and the gallstones to move from the gallbladder and into the duodenum and to prevent bile, gallstones, or other matter from moving back into the gallbladder.

[0063] The anastomosis device **30** may be constructed out of a variety of materials, depending on the desired configuration. For example, besides the metallic ring **40**, the components of the anastomosis device **30** may be constructed out of nonconductive materials (such as non-metal material like plastic) in order to shield the patient and device from any bleed off heat and electricity and to prevent unintentional cauterization of tissue. According to one embodiment, the first support member **36** may be constructed out of a flexible material, such as an elastomer or silicon, in order to allow it to compress and flex and fit through the cauterized holes.

[0064] According to one embodiment as shown in FIGS. **3**A-**3**H, a portion of the anastomosis device **330** may be delivered through first tissue wall **311** (e.g., the duodenum tissue wall) and the second tissue wall **319** (e.g., the gallbladder tissue wall). As shown in FIG. **3**A, the anastomosis device **330** may be delivered in the undeployed position **382** to the first tissue wall **311** by a delivery device (described and shown further herein) such that the first end **354** of the anastomosis device **330** (e.g., the end with the cutting element **348**) faces the first tissue wall **311**. In the undeployed position **382**, the first and second support members **336** and **338** may be separated along a length of the base member **332**. For example, the second support member **338** may be positioned on an opposite side of the steps **344** along the base member **332** than the first support member **336**.

[0065] As shown in FIG. **3**B, the anastomosis device **330** may be moved toward the first tissue wall **311**, such that the cutting element **348** abuts the first tissue wall **311** (e.g., the inside surface of the duodenum tissue wall). The cutting element **348** may cut the first tissue wall **311** through cauterization, which may create a hole or aperture in the first tissue wall **311**. As shown in FIGS. **3**G-**3**H, power may be transmitted to the cutting element **348** through the metallic ring **340** (from the delivery device) that extends through the base member shell **333**. In order to move a portion of the anastomosis device **330** through the cauterized aperture in the first tissue wall **311**, the first support member **336** bends, flexes, or compresses (due to the force of the first tissue wall

311) away from the cutting element **348** and toward the base member **332**, thus decreasing the outer diameter of the anastomosis device **330**.

[0066] The first support member **336**, with a portion of the base member **332**, is advanced through the cauterized aperture in the first tissue wall **311** and toward the second tissue wall **319** when the first support member **336** is compressed. As shown in FIG. **3**C, the first support member **336** may radially expand outward from the base member **332** after the first support member **336** has been advanced through the cauterized aperture in the first tissue wall **311**. The base member **332** may extend through the first tissue wall **311**.

[0067] As shown in FIG. **3**D, the anastomosis device **330** may be advanced toward the second tissue wall **319**, such that the cutting element **348** now abuts the second tissue wall **319** (e.g., the outside surface of the gallbladder tissue wall). The cutting element **348** may cut the second tissue wall **319** through cauterization, which may create a hole or aperture in the second tissue wall **319**. In order to move a portion of the anastomosis device **330** through the cauterized aperture in the second tissue wall **319**, the first support member **336** bends, flexes, or compresses (due to the force of the second tissue wall **319**) away from the cutting element **348** and toward the base member **332** again, thus decreasing the outer diameter of the anastomosis device **330**.

[0068] The first support member **336**, with a portion of the base member **32**, is advanced through the cauterized aperture in the second tissue wall **319** when the first support member **336** is compressed. As shown in **3**E, the first support member **336** may radially expand outward from the base member **332** after the first support member **336** has been advanced through the cauterized aperture in the second tissue wall **319**. The base member **332** may extend through the first and second tissue walls **311** and **319** and the first and second support members **336** and **338** may surround the first and second tissue walls **311** and **319** along the base member **332**.

[0069] As shown in FIG. **3**F, the second support member **338** may be moved along the base member **332** down the steps **344** and toward the first support member **336**, thus compressing the first and second tissue walls **311** and **319** toward each other between the support members **336** and **338** into the deployed position **384**. The steps **344** may prevent the second support member **338** from moving away from the first support member **336**. The wedge **390** (as shown in FIGS. **3**G-**3**H) may further prevent the second support member **338** from moving away from the first support member **336**. As shown in FIG. **3**G, the tissue walls **311** and **319** may surround a portion of the base member **332** and be clamped or compressed together by the first and second support members **336** and **338**.

[0070] As shown in FIGS. **3**F-**3**G, the first support member **336** may directly contact the inside or mucosa of the second tissue wall **319** (e.g., the gallbladder tissue wall) and the second support member **338** may directly contact the inside or mucosa of the first tissue wall **311** (e.g., the duodenum tissue wall) in the deployed position **384**. The anastomosis device **330** may directly oppose the outer or serosa surfaces of the first and second tissue walls **311** and **319**, such that the respective serosa surfaces of the tissue walls **311** and **319** directly contact each other. Due to the passageway **334** of the base member **332** and the cauterized holes in the tissue walls **311** and **319**, a passageway is created through the anastomosis device **330** between two organs or areas of the patient.

Delivery Device

[0071] As shown in FIGS. **5**A-**5**C, the anastomosis device **530** may attach to, be fitted to, or connect with a variety of different conventional delivery mechanisms or devices (such as a catheter or endoscope). The delivery device **528** may be designed to access the inside of the patient (as described further herein and shown in FIG. **6**A) and thus may be used to advance and deliver the anastomosis device **530** to the correct location within the body of the patient, as well as provide power to the anastomosis device **530**. The proximal end of the delivery device **528** refers to the end of the delivery device **528** that is configured to remain outside of the patient. The distal end **521** of the delivery device **528** refers to the end of the delivery device **528** that is configured to be inserted into the patient and to attach to the anastomosis device **530**.

[0072] The delivery device **528** may be sized to fit with the anastomosis device **530** and to fit through at least one of a surgical port or natural orifice of the patient for delivery. According to one embodiment, the diameter of the delivery device **528** may be between approximately 2 to 25 mm. According to another embodiment, the diameter of the delivery device **528** may be between approximately 5 to 15 mm.

[0073] According to one embodiment, the anastomosis device **530** may be removably coupled, connected, or attached to (or near) a distal end **521** of the delivery device **528**. The distal end of the delivery device **528** and the anastomosis device **530** may be sized and profiled to fit and attach with each other. As shown in FIG. **5**A, the anastomosis device **530** may slide over a portion of the distal end **521** of the delivery device **528** and may be frictionally fit to the delivery device **528**. Alternatively or additionally, an attachment mechanism, such as clips, snaps, or magnets (not shown), may be used to secure the anastomosis device **530** and the delivery device **528** together. The anastomosis device **530** and the delivery device **528** may remain attached during delivery and deployment (e.g., while the anastomosis device **530** is moved through the tissue walls and the second support member **538** is moved toward the first support member **536**).

[0074] According to one embodiment as shown in FIGS. **4**A-**4**B, in order to further secure and hold the anastomosis device **430** to the delivery device **428**, a compliant supporting balloon **470** may optionally be included with or delivered through the delivery device **428**. The balloon **470** may be attached to a tube (not shown) for inflation and may fit through the delivery device **428** while deflated. Once the balloon **470** is in position within the delivery device **428**, the balloon **470** may be inflated to the deployed or inflated state **472** (as shown in FIG. **4**A). While the balloon **470** is in the inflated state **472**, the balloon **470** may prevent the anastomosis device **430** from sliding or falling off of the delivery device **428**, in particular during delivery. For example, the inflated balloon **470** may extend (both laterally and radially) beyond the distal end **421** of the delivery device **428** to create a barrier along the first end **454** of the anastomosis device **430** and the distal end **421** of the delivery device **428**. Alternatively or additionally, the balloon **470** may expand within a working channel of the delivery device **428** to increase the diameter of the delivery device **428** and fric-

tionally hold the anastomosis device **430** in place along the length of the delivery device **428**. FIGS. **2**A-**2**B depict another balloon **270** included with the delivery device **228** to help secure the anastomosis device **230**, according to another embodiment.

[0075] During delivery and installation, the balloon **470** may be inflated and deflated as needed to expose the first end **454** of the anastomosis device **430** in order to cauterize the tissue (in the deflated state **474**) or to hold the anastomosis device **430** and the delivery device **428** together (in the inflated state **472**). The balloon **470** may also provide traction to allow the second support member **438** to be pushed toward the first support member **436** without moving the anastomosis device **430** off of the delivery device **428**. Accordingly, the second end **456** of the anastomosis device **430** may remain attached to the delivery device **428** during delivery and deployment.

[0076] In order to remove the delivery device **428** from the anastomosis device **430** after the anastomosis device **430** has been delivered, positioned, and clamped to the tissue, the balloon **470** may be deflated into the undeployed or deflated state **474** (as shown in FIG. **4**B) and the delivery device **428** may be removed from within the anastomosis device **430**, leaving the anastomosis device **430** in position within the body of the patient.

[0077] As shown in FIGS. **5**A-**5**C, the delivery device **528** may provide power to certain portions of the anastomosis device **530**, such as the cutting element **548**, in order to cauterize the tissue. The delivery device **528** may include an electrical, metallic or conductive line, strip, trace, lead, or wire **526** that extends along the length of the delivery device **528** to transmit power or carry a current from an outside power source (outside of the patient) at the proximal end of the delivery device **528** to an electrical contact **522** toward the distal end **521** of the delivery device **528**. As shown in FIGS. **5**B-**5**C, the electrical contact **522** on the delivery device **528** is connectable with the electrical contact **542** on the anastomosis device **530** to provide power to the cutting element **548** located on the first end **554** of the anastomosis device **530**.

[0078] According to one embodiment as shown in FIGS. **5**A-**5**C, the conductive wire **526** may be housed or embedded in a separate, flexible sleeve or sheath **524** that is positionable outside of and adjacent to the body of the delivery device **528**. The sheath **524** may slide over the delivery device body to contact and thus provide power to the anastomosis device **530**. According to other embodiments, the conductive wire **526** may be a part of the delivery device **528** or may be inserted through and housed in a separate, designated, and/or working channel within the delivery device **528**. For example, the delivery device **528** may utilize an endoscopic channel to carry or transmit current or power to the distal end **521** of the delivery device **528**. According to another embodiment, the conductive wire **526** (with insulation) may run adjacent to the outer surface of the delivery device **528** without a sheath **524**. According to another embodiment, the anastomosis device **530** may be powered through induction or wireless charging and the anastomosis device **530** or the delivery device **528** may include a receptor. The sheath **524** and/or the various channels or layers of the delivery device **528** may be non-conductive to provide shielding to the conductive wire **526** and prevent any harm to surrounding tissue within the body.

[0079] FIGS. **5**B-**5**C depict the sheath **524** moving from an unattached position **586** (where the sheath and the anastomosis device **530** are not directly connected) to an attached position **588** such that the sheath **524** and the anastomosis device **530** are attached to transmit power to the cutting element **548**. As shown in FIG. **5**B, the distal end of the sheath **524** may have at least one exposed metallic, conductive, or electrical terminal or contact **522** configured to align with, contact, directly interface, and transmit power to the electrical contact **542** on the second end **556** of the anastomosis device **530**. Alternatively, the distal end **521** of the delivery device **528** have include the exposed contact **522** to connect with the electrical contact **542** on the anastomosis device **530**. The contact **522** may correspond to or be complementary to the electrical contact **542** on the second end of the anastomosis device **530** such that the contacts **522** and **542** may be in direct contact to transmit electricity. While the anastomosis device **530** and the delivery device **528** are electrically attached, the respective contact areas are attached and aligned to each other (as shown in FIGS. **5**A and **5**C) and may be shielded by each other. When the power is turned on and the anastomosis device **530** is attached to the delivery device **528**, electric current (e.g., electrocautery power) may be transmitted from the contact **522** on the delivery device **528** to the contact **542** on the anastomosis device **530** to power the cutting element **548**.

[0080] The sheath **524** and the second end **556** of the anastomosis device **530** may attach to each other through a variety of different mechanisms, including but not limited to snaps, clips, and magnets. As shown in FIG. **5**B, the sheath **524** may be retracted or disconnected from the anastomosis device **530**, which may prevent any power from being transmitted to the anastomosis device **530**. The sheath **524** may slide over the body of the delivery device **528** to attach to and electrically connect with the anastomosis device **530** (as shown in FIGS. **5**A and **5**C), such that the anastomosis device **530** may be powered.

[0081] As described further herein and shown in FIGS. **2**A-**2**B, the delivery device **228** may include an additional outer sleeve, such as the pneumatic deployer **280**, which may be used to move at least one support member **236** or **238** along the length of the base member **232** of the anastomosis device **230**.

Gallstone Removal

[0082] FIGS. **6**A-H depict the anastomosis device **630** being deployed and implanted within a patient to allow the gallbladder **620** to drain into the duodenum **610** according to one embodiment. In order to deploy the anastomosis device **630** within the body to access the gallbladder **620** and remove gallstones from the body, the anastomosis device **630** may first be attached to or near the distal end of the delivery device **628**. The delivery device **628** (along with the anastomosis device **630**) may be inserted through a surgical port or a natural orifice of the body of the patient, such as the mouth. The delivery device **628** may be progressed or advanced through the gastrointestinal tract (e.g., through the esophagus and into the stomach **612**) to the duodenum **610**, as shown in FIGS. **6**A-**6**B.

[0083] Once the delivery device **628** has positioned the anastomosis device **630** proximal to the duodenum tissue wall **611** within the duodenum **610**, the gallbladder **620** may be cleaned and rinsed using endoscopic suction and irriga-

tion techniques. As shown in FIG. **6**C, a needle **660** may be used to prevent any obstructions from impeding the removal and clearing of the gallstones. The needle **660** may be coupled or connected to the delivery device **628** and may extend or advance from a port on the distal end **621** of the delivery device **628** (such as an endoscopic port) and forwardly through the first end **654** of the anastomosis device **630**. As the needle **660** is extended through the distal end **621** of the delivery device **628**, the needle **660** may pierce through the duodenum tissue wall **611** and the gallbladder tissue wall **619** and insert at least partially into the gallbladder **620**. The needle **660** may optionally be positioned and inserted between approximately 70-110° to the tissue walls. (According to one embodiment, the needle **660** may be inserted at approximately 90° to the tissue wall.) Once the needle **660** is positioned at least partially within the gallbladder, the needle **660** may clean, rinse, and/or irrigate the gallbladder **620** with, for example, saline solution. The needle **660** may also provide suction to remove material, matter, and/or the saline from the gallbladder **620** and to ensure that the sides of the gallbladder **620** (along the inside of the gallbladder tissue wall **619**) are cleared.

[0084] After the gallbladder **620** has been cleaned and/or rinsed, the needle **660** may be retracted back into the port of the delivery device **628**. After the needle **660** is retracted within or covered by the delivery device **628**, the delivery device **628** may be extended toward the duodenum tissue wall **611**, as shown in FIG. **6**D. According to another embodiment, the needle **660** may remain the gallbladder **620** as the anastomosis device **630** is deployed in order to continuously clear the area (e.g., the gallbladder **620**) during the procedure (not shown).

[0085] The anastomosis device **630** may be advanced toward the duodenum **610**, such that the first end **654** of the anastomosis device **630** is flush with the duodenum tissue wall **611**. (According to another embodiment, if the anastomosis device **630** is not already at the distal end **621** of the delivery device **628**, the anastomosis device **630** may be progressed along the delivery device **628** to the distal end **621** of the delivery device **628**.) Additional pressure may be exerted to ensure that the anastomosis device **630** has complete contact with the duodenum tissue wall **611**. The first support member **636** may begin to abut the duodenum tissue wall **611**, causing the first support member **636** to bend.

[0086] Once the anastomosis device **630** is properly positioned and abuts the inside surface of the tissue wall **611** of the duodenum **610**, the duodenum tissue wall **611** (and, subsequently, the gallbladder tissue wall **619**) may be cut. For example, the cutting element **648** on the first end **654** of the anastomosis device **630** may cut or form an aperture in the tissue walls with at least one of cauterization (e.g., electrocautery or ultrasound cauterization), perforation, radio frequency cutting, mechanical cutting, laser cutting, or harmonic cutting. The electrocautery may optionally be monopolar or bipolar.

[0087] To power the anastomosis device **630** (as shown and described in FIGS. **5**A-**5**C), the delivery device **628** may transmit a current along the length of the delivery device **628** to an electrical contact on the anastomosis device **630**. The electrical contact may subsequently transmit the current through the metallic ring (as described further herein) and toward the cutting element **648** to allow the cutting element **648** to cut the tissue wall.

[0088] Since the distal, exposed, the cutting element **648** is in direct contact with the tissue wall, the anastomosis device **630** may cauterize the tissue wall to create a hole or aperture. Once a hole has been made in the duodenum tissue wall **611**, the anastomosis device **630** may be advanced at least partially through the cauterized hole in the duodenum **610** and beyond the duodenum **610** (toward the gallbladder **620**), as shown in FIG. **6**E. The first support member **636** may also be advanced through the duodenum tissue wall **611** with a portion of the base member of the anastomosis device **630**, while the second support member **638** may remain within the duodenum **610** to act as an anchor.

[0089] The anastomosis device **630** may be further advanced toward the tissue wall of the gallbladder **620** and may be positioned such that the cutting element **648** the anastomosis device **630** is in direct contact with or abuts the outside surface of the gallbladder tissue wall **619** in order for the anastomosis device **630** to cut an aperture in the tissue wall through cauterization, as described further herein. Once the aperture has been cut in the gallbladder tissue wall **619**, the anastomosis device **630** may have access to the inside of the gallbladder **620** and may be progressed at least partially into the gallbladder **620**, as shown in FIG. **6**F. The first support member **636** may also be moved through the aperture in the gallbladder **620**, while the second support member **638** may remain in the duodenum **610**, as shown in **6**G.

[0090] Once the anastomosis device **630** is in position within both the duodenum **610** and the gallbladder **620**, the second support member **638** may be moved along the base member of the anastomosis device **630** toward the first support member **636** (as shown in various embodiments (such as FIGS. **1**A-**1**B and **3**A-**3**H) and described further herein), which may clamp the tissue walls **611** and **619** between the support members **636** and **638** around an outer circumference or perimeter of the base member, thereby deploying the anastomosis device **630**, securing the anastomosis device **630** to the tissues, providing a passageway between the duodenum **610** and the gallbladder **620**, and anastomosing the duodenum **610** and the gallbladder **620**.

[0091] Once the anastomosis device **630** is in place, the inside of the gallbladder **620** may be easily accessed. Due to the strong grip of the anastomosis device **630** on the tissue walls **611** and **619**, the anastomosis device **630** prevents any gaps between the tissue walls, which prevents any leakage of bile, thus preventing any chance of inflammation or contamination.

[0092] The gallstones may be broken down through a variety of different methods. According to one embodiment, the gallstones may be mechanically broken by introducing various medical devices through a port or working channel in the delivery device **628** and through the anastomosis device **630**. Alternatively or additionally, the gallstones may be broken up with lasers, shockwaves, and/or chemicals (e.g., medicine). The delivery device **628** may be also be used to further clean, irrigate, and suction the gallbladder **620** through a port of the delivery device **628**. As shown in FIG. **6**G, the delivery device **628** may remain attached to the deployed anastomosis device **630** in order to allow additional or further procedures to be conducted (to, for example, treat or clear the gallstones).

[0093] The gallbladder **620** may be drained and/or the gallstones may be removed from the gallbladder **620** through the base member of the anastomosis device **630** and into either the duodenum **610** (and subsequently be excreted

from the body through the digestive system) or through the delivery device **628** (and thus removed from the body).

[0094] As shown in FIG. **6**H, the second support member **638** may be moved toward the first support member **636** to secure the tissue walls of the duodenum **610** and the gallbladder **620** together. The delivery device **628** may be detached from the anastomosis device **630** and removed from the body, leaving the anastomosis device **630** in place within the patient. The anastomosis device **630** may continue to anastomose the duodenum **610** and the gallbladder **620** and may allow material or matter **609** (e.g., gallstones and/or bile) to move from the duodenum **610** to the gallbladder **620** through a passageway within the anastomosis device **630**. For example, FIG. **6**H depicts matter **609** (e.g., bile) dripping from the gallbladder **620**, through the valve **650**, and into the duodenum **610**, which may prevent recurrent gallstones from forming. The anastomosis device **630** may be left in place within the body either temporarily or permanently.

[0095] The entire procedure may optionally be internally visualized continuously through, for example, an endoscopic visual camera, ultrasound computed tomography, magnetic resonance imaging guidance, or fluoroscopic guidance. Alternatively or additionally, the procedure may be externally visualized through, for example, radiopaque imaging under ultrasound or computed tomography. A dye may or may not be used with the fluoroscopic guidance.

[0096] Although the duodenum and gallbladder are referred to, it is anticipated that the anastomosis device may attach to and provide a passageway through any tissue walls and may connect or anastomose any combination of hollow or filled cavities, members, organs, structures, lumens, tubes, cysts, tissues, or areas of the body, according to the desired use. For example, the anastomosis device may be configured to anastomose any combination of the stomach, jejunum, duodenum, ilium, gallbladder, cystic ducts, bile ducts, common bile duct, biliary system, a pseudocyst of a pancreas, or a liver. Further, multiple cavities may be connected to each other and multiple tissue walls may be secured between the first and second support members. Although the gastrointestinal tract is referred to, the anastomosis device may be used within any area or tract of the body.

[0097] Referring now to FIG. **7**, a anastomosis method **110** is shown. An anastomosis device may be advanced into a first cavity (**112**). The anastomosis device may include a body defining an inner passage between a first end and a second end. A first member and a second member may extend outwardly from the body of the anastomosis device. A tissue wall may be cut with a cutting element on a first end of the anastomosis device (**114**), which may create an aperture in the tissue wall. Multiple tissue walls may be cut according to the desired use. The first member of the anastomosis device may subsequently be advanced through the at least one tissue wall to a second cavity (**116**) and the second member may remain in the first cavity. The at least one tissue wall may be clamped between the first member and the second member (**118**) by, for example, moving at least one of the first or second members toward the other.

[0098] Referring now to FIG. **8**, a method **120** for accessing a gallbladder is shown. A duodenum tissue wall may be cauterized (**122**) with, for example, a cutting element on a first end of an anastomosis device to create an aperture in the duodenum tissue wall. The body of the anastomosis device may define a passageway through the anastomosis device. The anastomosis device may be advanced at least partially through the duodenum tissue wall (**124**). The anastomosis device may be advanced toward the gallbladder and a gallbladder tissue wall may be cauterized with the cutting element of the anastomosis device (**126**) to create an aperture in the gallbladder tissue wall. Subsequently, the anastomosis device may be advanced at least partially through the gallbladder tissue wall (**128**). The duodenum tissue wall and the gallbladder tissue wall may be clamped together (**129**) around an outer circumference between the first end and a second end of the anastomosis device.

[0099] Referring now to FIG. **9**, a method **130** for cleaning a cavity within a body is shown. An endoscope may be advanced to a first cavity within the body (**132**). A distal end of the endoscope may include an endoscopic port and the first cavity may include a tissue wall. A needle may be advanced through the endoscopic port and the tissue wall into a second cavity (**134**). Subsequently, the second cavity may be rinsed, cleaned, and/or drained with the needle (**136**). The needle may then be refracted back into the endoscopic port (**138**).

[0100] The embodiments disclosed herein anastomose two areas of the body and allow material to move between the cavities. Besides those embodiments depicted in the figures and described in the above description, other embodiments are also contemplated.

[0101] It is anticipated that the various components, configurations, systems, methods, and features of the different embodiments of the anastomosis device may be combined or used alone according to the desired use and configuration.

[0102] Although the figures may show a specific order of method steps, the order of the steps may differ from what is depicted. Also two or more steps may be performed concurrently or with partial concurrence. Such variation will depend on the software and hardware systems chosen and on designer choice. All such variations are within the scope of the disclosure. Likewise, software implementations could be accomplished with standard programming techniques with rule based logic and other logic to accomplish the various connection steps, processing steps, comparison steps and decision steps.

[0103] While various aspects and embodiments have been disclosed herein, other aspects and embodiments will be apparent to those skilled in the art. The various aspects and embodiments disclosed herein are for purposes of illustration and are not intended to be limiting, with the true scope and spirit being indicated by the following claims.

Various Embodiments

[0104] According to one embodiment, an anastomosis device may include a base member defining a passageway between a first end and a second end of the base member, a first support member connected to the base member proximal to the first end, and a second support member connected to the base member proximal to the second end. The base member may have a cutting element to cut tissue from the first end. At least one of the first support member and the second support member may be movable along a length of the base member to secure a portion of tissue between the first and second support members.

[0105] In any of the embodiments, the base member may be releasably engagable to a distal end of a delivery device.

[0106] In any of the embodiments, the base member may be configured to slide over the distal end of the delivery device.

[0107] In any of the embodiments, the anastomosis device may include a supporting balloon that is inflatable and deflatable at the distal end of the delivery device. The supporting balloon may prevent the base member from detaching from the delivery device when inflated.

[0108] In any of the embodiments, the delivery device may be an endoscope.

[0109] In any of the embodiments, the cutting element may be powered by the delivery device.

[0110] In any of the embodiments, the delivery device may include a separate channel to house an electrical line that is configured to carry a current.

[0111] In any of the embodiments, current may be transmitted through a conductive delivery device contact on the delivery device to a conductive anastomosis contact on the second end of the base member when the conductive delivery device contact and the conductive anastomosis contact are in direct contact.

[0112] In any of the embodiments, the anastomosis device may include a needle connected to the delivery device and configured to be extended forwardly from the base member.

[0113] In any of the embodiments, the anastomosis device may include a sheath with an electrical line extending along the sheath and configured to transmit power from a proximal end of the delivery device to the distal end of the delivery device. The sheath may be configured to slide over the delivery device to contact the second end of the base member.

[0114] In any of the embodiments, the first support member and the second support member may be configured to clamp together tissue from at least two organs to anastomose the at least two organs.

[0115] In any of the embodiments, the two organs may be a duodenum and a gallbladder.

[0116] In any of the embodiments, the first support member may abut a tissue wall of the gallbladder and the second support member may abut a tissue wall of the duodenum.

[0117] In any of the embodiments, the diameter of the base member may be between 7 to 13 mm.

[0118] In any of the embodiments, a shell of the base member may provide insulation around the cutting element. The cutting element may be exposed through the shell along the first end of the base member.

[0119] In any of the embodiments, the cutting element may utilize at least one of cauterization, perforation, monopolar or bipolar electrocautery, ultrasound cauterization, radio frequency cutting, mechanical cutting, laser cutting, or harmonic cutting.

[0120] In any of the embodiments, the first support member and the second support member may be configured to clamp a tissue wall of a gallbladder and a tissue wall of a duodenum therebetween.

[0121] In any of the embodiments, the first support member may be deformable.

[0122] In any of the embodiments, the first support member may include an elastomer.

[0123] In any of the embodiments, the first support member may include silicon.

[0124] In any of the embodiments, the base member may include an engagement structure along at least a portion of an outside perimeter of a shell of the base member and at least one of the first support member or the second support member may be movable along the engagement structure.

[0125] In any of the embodiments, the engagement structure may be a series of sequential steps angled toward a center of the base member to allow at least one of the first support member or the second support member to move in one direction along the outside perimeter of the shell.

[0126] In any of the embodiments, an inner circumference of one of the first support member or the second support member may include at least one wedge that is complementary to the steps.

[0127] In any of the embodiments, the anastomosis device may include a pneumatic deployer configured to push one of the first support member and the second support member along the base member when inflated.

[0128] In any of the embodiments, the anastomosis device may include a one-way valve attached to the base member.

[0129] In any of the embodiments, the base member may be configured to provide a passage between at least one of two cavities, tissues, lumens, tubes, organs, hollow members, or cysts.

[0130] According to another embodiment, an anastomosis method may include advancing an anastomosis device into a first cavity with a first tissue wall, cutting the first tissue wall with the first end of the anastomosis device, advancing the first support member through the first tissue wall to a second tissue wall of a second cavity, cutting the second tissue wall with the first end of the anastomosis device, advancing the first support member through the second tissue wall, and clamping the first and second tissue walls between the first support member and the second support member. The anastomosis device may include a base member defining an inner passage between a first end and a second end, and a first support member and a second support member extending outwardly from the base member.

[0131] In any of the embodiments, the step of cutting the first and second tissue walls may include cauterizing the first and second tissue walls.

[0132] In any of the embodiments, the anastomosis method may include delivering the anastomosis device through at least one of a surgical port or a natural orifice of a patient.

[0133] In any of the embodiments, the anastomosis method may include delivering the anastomosis device through at least a portion of the gastrointestinal tract of the patient.

[0134] In any of the embodiments, the anastomosis method may include providing a passage through the anastomosis device between the first cavity and the second cavity.

[0135] In any of the embodiments, the anastomosis method may include using pneumatic forces to move the second support member toward the first support member along the base member to clamp the first and second tissue walls between the first support member and second support member.

[0136] In any of the embodiments, the anastomosis method may include moving the second support member along a length of the base member.

[0137] In any of the embodiments, the anastomosis method may include releasably attaching the anastomosis device to an endoscope and advancing the anastomosis device with the endoscope.

[0138] In any of the embodiments, the anastomosis method may include inflating a supporting balloon to maintain the attachment between the anastomosis device and the endoscope and deflating the supporting balloon to release the anastomosis device from the endoscope.

[0139] In any of the embodiments, the anastomosis method may include powering the anastomosis device with the endoscope.

[0140] In any of the embodiments, the step of powering the anastomosis device may include transmitting a current from a conductive endoscopic contact on the endoscope to a conductive anastomosis contact on the second end of anastomosis device when the conductive endoscopic contact and the conductive anastomosis contact are in direct contact.

[0141] In any of the embodiments, the anastomosis method may include providing a one-way valve on the second end of the anastomosis device.

[0142] In any of the embodiments, the anastomosis method may include cleaning the second cavity with a needle prior to cutting the first tissue wall.

[0143] In any of the embodiments, the anastomosis method may include guiding the anastomosis device with fluoroscopic guidance.

[0144] In any of the embodiments, the anastomosis method may include using a dye with the fluoroscopic guidance.

[0145] In any of the embodiments, the anastomosis method may not using a dye with the fluoroscopic guidance.

[0146] In any of the embodiments, the anastomosis method may include using at least one of ultrasound computed tomography or magnetic resonance imaging guidance.

[0147] In any of the embodiments, the anastomosis method may include anastomosing the first cavity and the second cavity.

[0148] In any of the embodiments, the anastomosis method may include anastomosing two organs in the gastrointestinal tract of a patient.

[0149] According to yet another embodiment, a method for accessing a gallbladder may include cauterizing a duodenum tissue wall of a duodenum with a first end of an anastomosis device, advancing the anastomosis device at least partially through the duodenum tissue wall, cauterizing a gallbladder tissue wall of the gallbladder with the first end of the anastomosis device, advancing the anastomosis device at least partially through the gallbladder tissue wall, and clamping the duodenum tissue wall to the gallbladder tissue wall around an outer circumference of the base member between the first end and the second end. A base member of the anastomosis device may define a passageway through the anastomosis device from the first end to the second end of the anastomosis device. The anastomosis device may at least partially remain in the duodenum.

[0150] In any of the embodiments, the method for accessing a gallbladder may include at least one of draining, removing stones from, or performing a procedure on a gallbladder.

[0151] In any of the embodiments, the method for accessing a gallbladder may include delivering the anastomosis device through at least one of a surgical port or a natural orifice of a patient.

[0152] In any of the embodiments, the method for accessing a gallbladder may include delivering the anastomosis device through at least a portion of the gastrointestinal tract of the patient.

[0153] In any of the embodiments, the method for accessing a gallbladder may include providing a passage between the gallbladder and the duodenum.

[0154] In any of the embodiments, the method for accessing a gallbladder may include moving at least one of a first support member and a second support member along a length of the base member. The first support member and the second support member may be configured to clamp the duodenum tissue wall and the gallbladder tissue wall together.

[0155] In any of the embodiments, the method for accessing a gallbladder may include using at least one of pneumatic, mechanical, and electrical forces to move at least one of the first support member and the second support member.

[0156] In any of the embodiments, the method for accessing a gallbladder may include releasably attaching the anastomosis device to an endoscope and advancing the anastomosis device with the endoscope.

[0157] In any of the embodiments, the method for accessing a gallbladder may include inflating a supporting balloon to maintain the attachment between the anastomosis device and the endoscope and deflating the supporting balloon to release the anastomosis device from the endoscope.

[0158] In any of the embodiments, the method for accessing a gallbladder may include powering the anastomosis device with the endoscope.

[0159] In any of the embodiments, the step of powering the anastomosis device may include transmitting a current from a conductive endoscopic contact on the endoscope to a conductive anastomosis contact on the second end of anastomosis device when the conductive endoscopic contact and the conductive anastomosis contact are in direct contact.

[0160] In any of the embodiments, the method for accessing a gallbladder may include providing a one-way valve on the second end of the anastomosis device.

[0161] In any of the embodiments, the method for accessing a gallbladder may include cleaning the gallbladder with a needle prior to cauterizing the duodenum and the gallbladder.

[0162] In any of the embodiments, the method for accessing a gallbladder may include guiding the anastomosis device with fluoroscopic guidance.

[0163] In any of the embodiments, the method for accessing a gallbladder may include using at least one of ultrasound computed tomography or magnetic resonance imaging guidance.

[0164] In any of the embodiments, the method for accessing a gallbladder may include anastomosing the gallbladder and the duodenum.

[0165] According to still another embodiment, a method for cleaning a cavity within a body may include advancing an endoscope to a tissue wall of a first cavity within the body, advancing a needle through the endoscopic port and the tissue wall into a second cavity, rinsing the second cavity with the needle, and retracting the needle into the endoscopic port. A distal end of the endoscope may include an endoscopic port.

[0166] In any of the embodiments, the step of rinsing the second cavity may include irrigating the second cavity.

[0167] In any of the embodiments, the method for cleaning a cavity may include rinsing the second cavity with a saline solution.

[0168] In any of the embodiments, the method for cleaning a cavity may include clearing matter along a tissue wall of the second cavity.

[0169] In any of the embodiments, the method for cleaning a cavity may include using endoscopic suction to clean the second cavity.

[0170] In any of the embodiments, the method for cleaning a cavity may include cleaning the second cavity continuously.

[0171] In any of the embodiments, the method for cleaning a cavity may include anastomosing the first cavity and the second cavity after cleaning the second cavity.

[0172] In any of the embodiments, the method for cleaning a cavity may include advancing the needle through multiple tissues to reach the second cavity.

[0173] In any of the embodiments, the method for cleaning a cavity may include advancing the needle through the endoscopic port at approximately 90 degrees to the tissue wall.

[0174] In any of the embodiments, the method for cleaning a cavity may include guiding the needle with fluoroscopic guidance.

[0175] In any of the embodiments, the method for cleaning a cavity may include using at least one of ultrasound computed tomography or magnetic resonance imaging guidance.

1. An anastomosis device comprising:

a base member defining a passageway between a first end and a second end of the base member,

wherein the base member has a cutting element to cut tissue from the first end;

a first support member connected to the base member proximal to the first end; and

a second support member connected to the base member proximal to the second end, wherein at least one of the first support member and the second support member is movable along a length of the base member to secure a portion of tissue between the first and second support members.

2. The anastomosis device of claim **1**, wherein the base member is releasably engagable to a distal end of a delivery device.

3. The anastomosis device of claim **2**, wherein the base member is configured to slide over the distal end of the delivery device.

4. The anastomosis device of claim **3**, further comprising a supporting balloon that is inflatable and deflatable at the distal end of the delivery device, wherein the supporting balloon prevents the base member from detaching from the delivery device when inflated.

5. (canceled)

6. (canceled)

7. The anastomosis device of claim **2**, wherein the delivery device includes a separate channel to house an electrical line that is configured to carry a current.

8. The anastomosis system of claim **2**, wherein current is transmitted through a conductive delivery device contact on the delivery device to a conductive anastomosis contact on the second end of the base member when the conductive delivery device contact and the conductive anastomosis contact are in direct contact.

9. The anastomosis system of claim **2**, further comprising a needle connected to the delivery device and configured to be extended forwardly from the base member.

10. The anastomosis device of claim **1**, further comprising a sheath with an electrical line extending along the sheath and configured to transmit power from a proximal end of the delivery device to the distal end of the delivery device, wherein the sheath is configured to slide over the delivery device to contact the second end of the base member.

11. The anastomosis device of claim **1**, wherein the first support member and the second support member are configured to clamp together tissue from at least two organs to anastomose the at least two organs.

12. The anastomosis device of claim **11**, wherein the two organs are a duodenum and a gallbladder.

13. (canceled)

14. (canceled)

15. The anastomosis device of claim **1**, wherein a shell of the base member provides insulation around the cutting element, wherein the cutting element is exposed through the shell along the first end of the base member.

16. The anastomosis device of claim **1**, wherein the cutting element utilizes at least one of cauterization, perforation, monopolar or bipolar electrocautery, ultrasound cauterization, radio frequency cutting, mechanical cutting, laser cutting, or harmonic cutting.

17. The anastomosis device of claim **1**, wherein the first support member and the second support member are configured to clamp a tissue wall of a gallbladder and a tissue wall of a duodenum therebetween.

18. The anastomosis device of claim **1**, wherein the first support member is deformable.

19. (canceled)

20. (canceled)

21. The anastomosis device of claim **1**, wherein the base member includes an engagement structure along at least a portion of an outside perimeter of a shell of the base member, wherein at least one of the first support member or the second support member is movable along the engagement structure.

22. The anastomosis device of claim **21**, wherein the engagement structure is a series of sequential steps angled toward a center of the base member to allow at least one of the first support member or the second support member to move in one direction along the outside perimeter of the shell.

23. The anastomosis device of claim **22**, wherein an inner circumference of one of the first support member or the second support member includes at least one wedge that is complementary to the steps.

24. The anastomosis device of claim **1**, further comprising a pneumatic deployer configured to push one of the first support member and the second support member along the base member when inflated.

25. The anastomosis device of claim **1**, further comprising a one-way valve attached to the base member.

26. (canceled)

27. An anastomosis method, comprising:

advancing an anastomosis device into a first cavity with a first tissue wall, the anastomosis device comprising a base member defining an inner passage between a first end and a second end, and a first support member and a second support member extending outwardly from the base member;

cutting the first tissue wall with the first end of the anastomosis device;

advancing the first support member through the first tissue wall to a second tissue wall of a second cavity;

cutting the second tissue wall with the first end of the anastomosis device;

advancing the first support member through the second tissue wall; and

clamping the first and second tissue walls between the first support member and the second support member.

28.-**72**. (canceled)

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专利名称(译)	通过吻合器通过胆囊十二指肠瘘切除胆石		
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摘要(译)

吻合装置可以包括基部构件，该基部构件在基部构件的第一端和第二端之间限定通道，在靠近第一端处连接到基部构件的第一支撑构件，以及连接到基部构件近端到第二端。基底构件可以具有切割元件以从第一端切割组织。第一支撑构件和第二支撑构件中的至少一个可以沿着基部构件的长度移动，以将组织的一部分固定在第一和第二支撑构件之间。