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(54) **ENDOSCOPIC ULTRASOUND-GUIDED ANCHOR DEVICE FOR TRANSLUMINAL APPOSITION**

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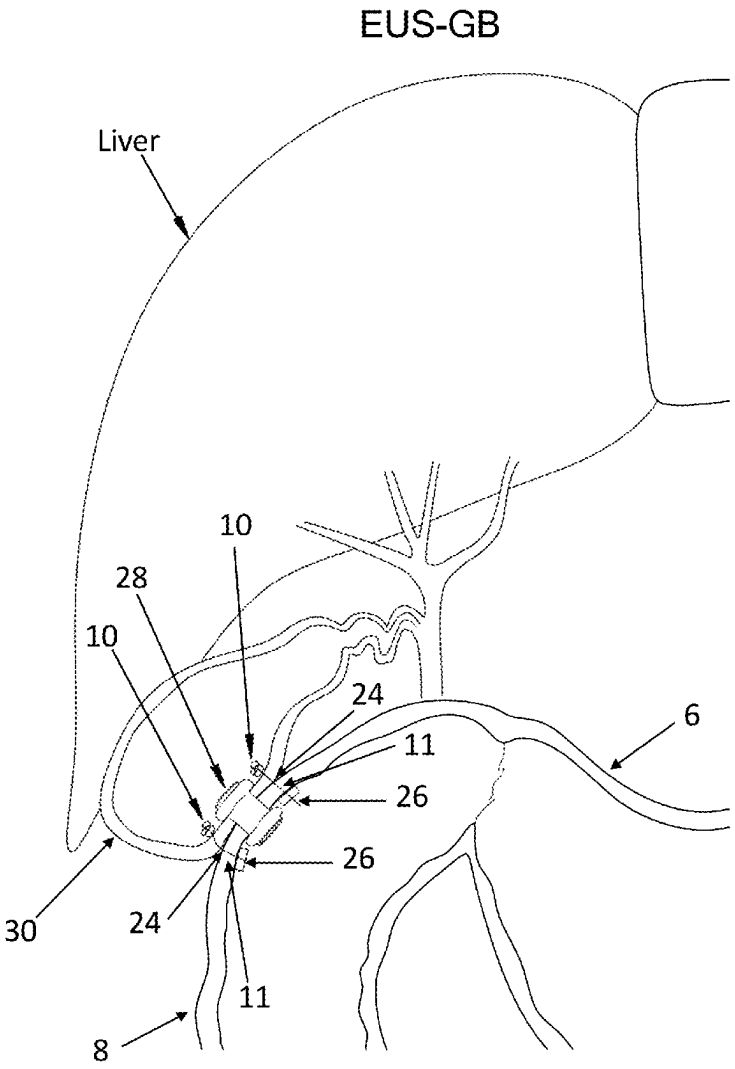
CPC .. ***A61B 17/0401*** (2013.01); *A61B 2017/0409* (2013.01)

(57) **ABSTRACT**

In illustrative embodiments, an anchor device comprising an anchor assembly and a locking device connected via a single flexible strand fixes a stomach wall to an organ wall so that a stent may be positioned between the stomach (or duodenum) and the organ, such as a small intestine, or a gallbladder. An anchor assembly is implanted through the stomach wall into a wall of an internal organ for fixation of the stomach wall to the internal organ wall. Fixing the two organs together with the anchor device at the correct location prior to puncturing an opening between the two organs increases the ease and accuracy of making the incision in each of the organ walls. Fixation of the two organ walls with of the anchor device also simplifies the placement and deployment of the stent by reducing the shifting and movement of the organ walls relative to each other.



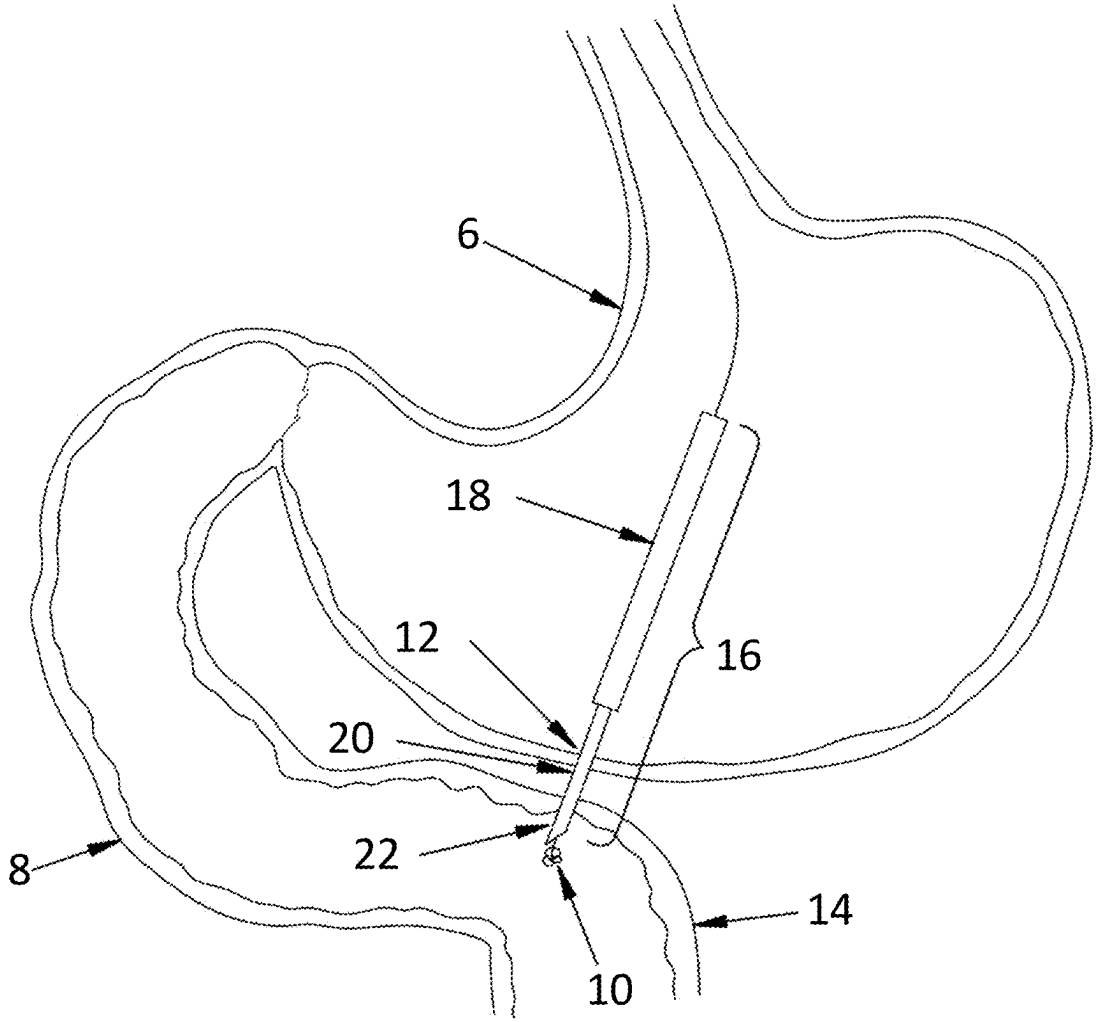


FIG. 1A

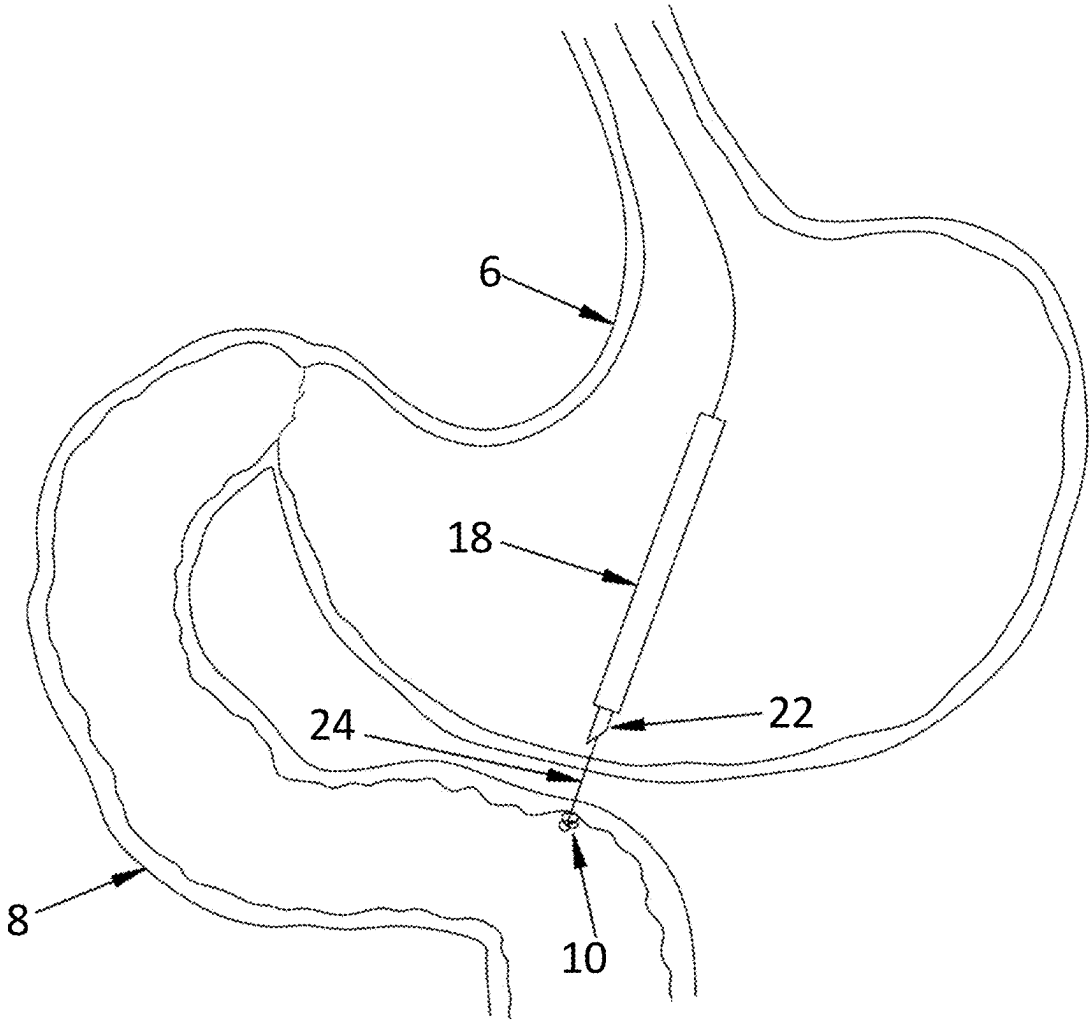


FIG. 1B

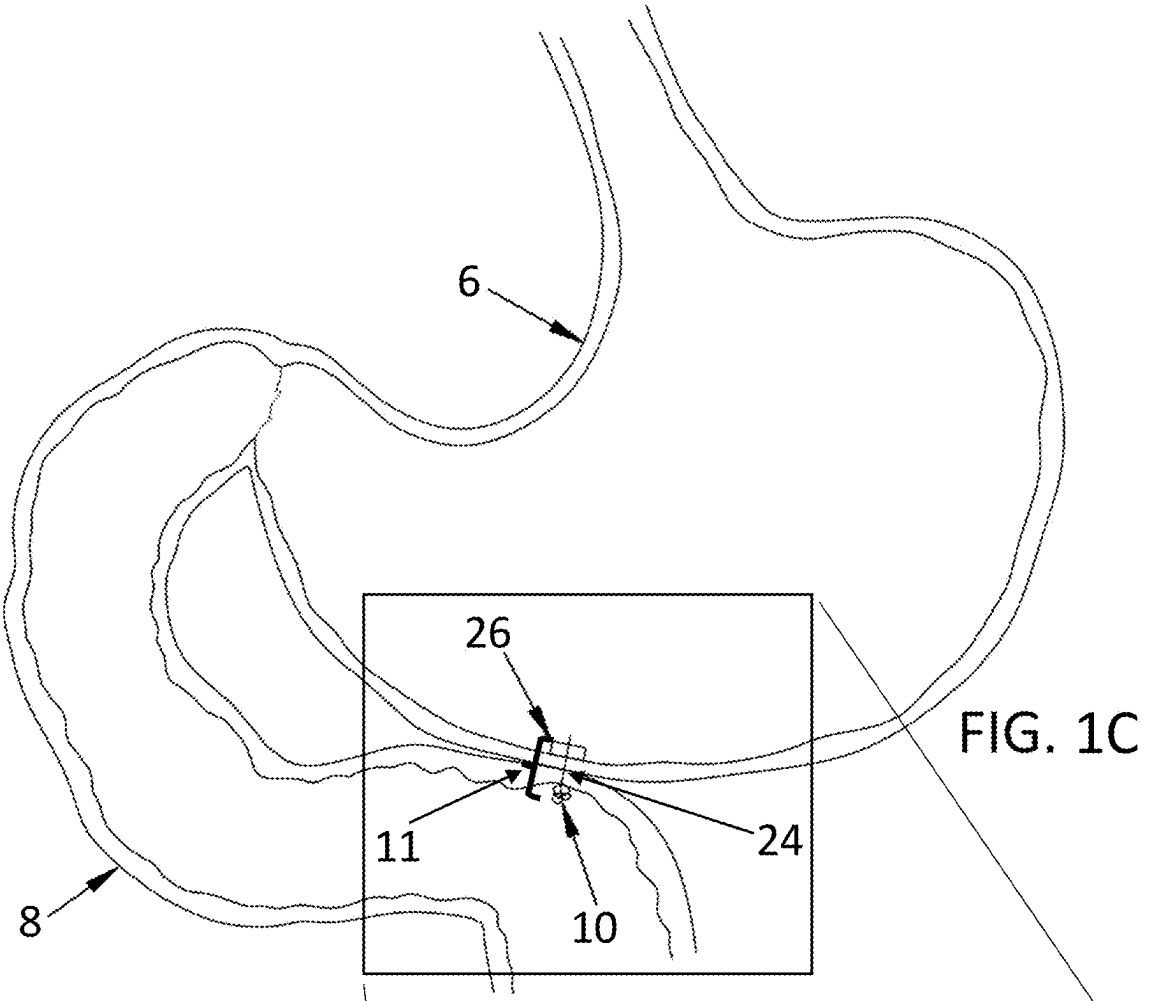


FIG. 1C

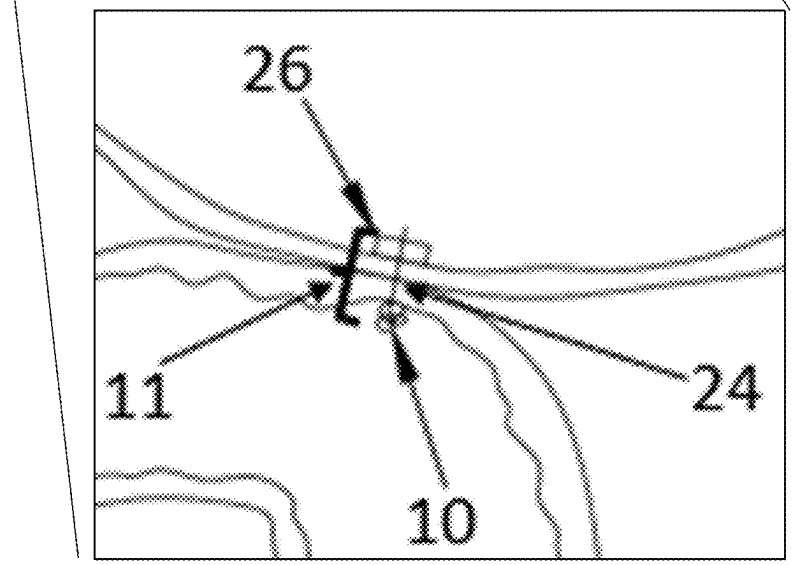


FIG. 1D

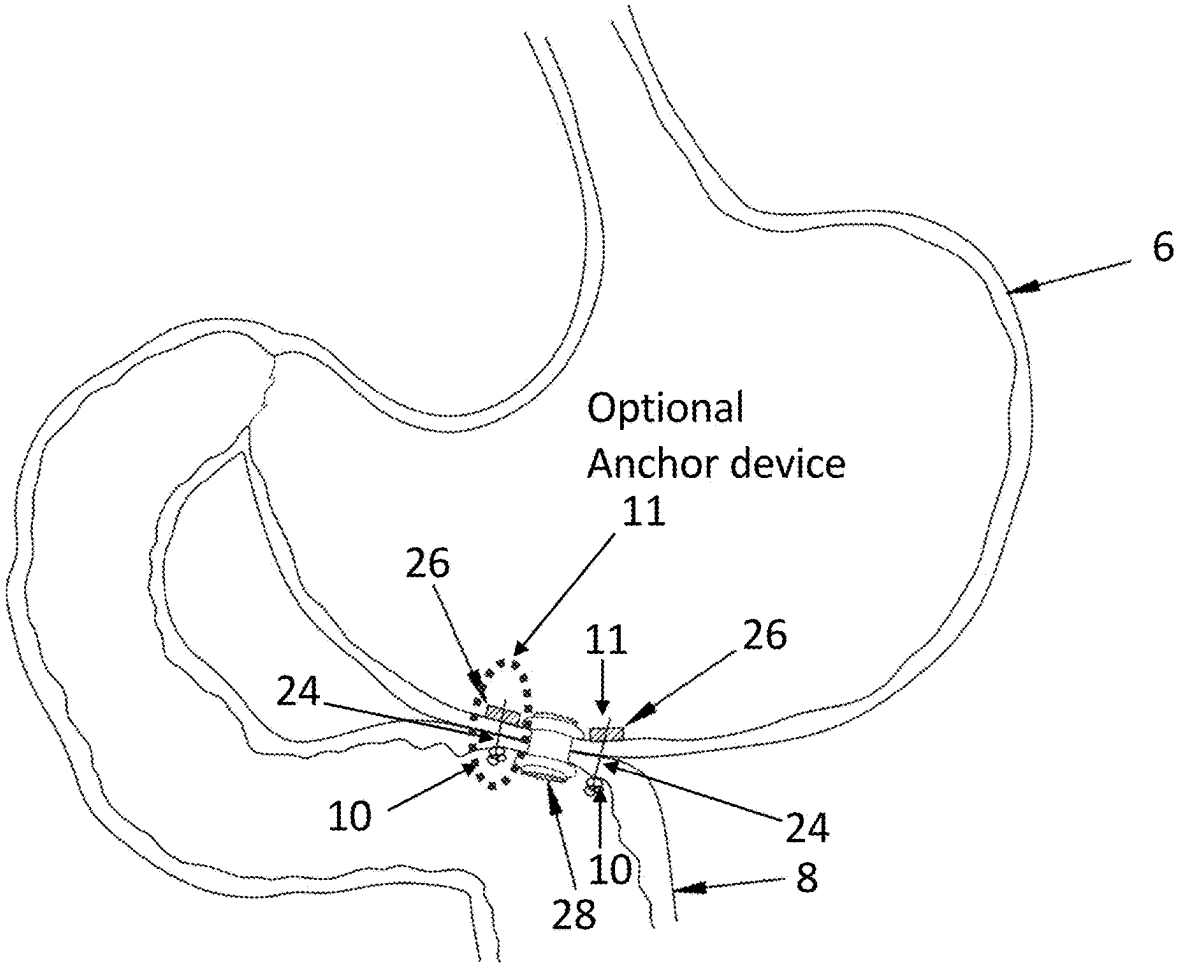


FIG. 2

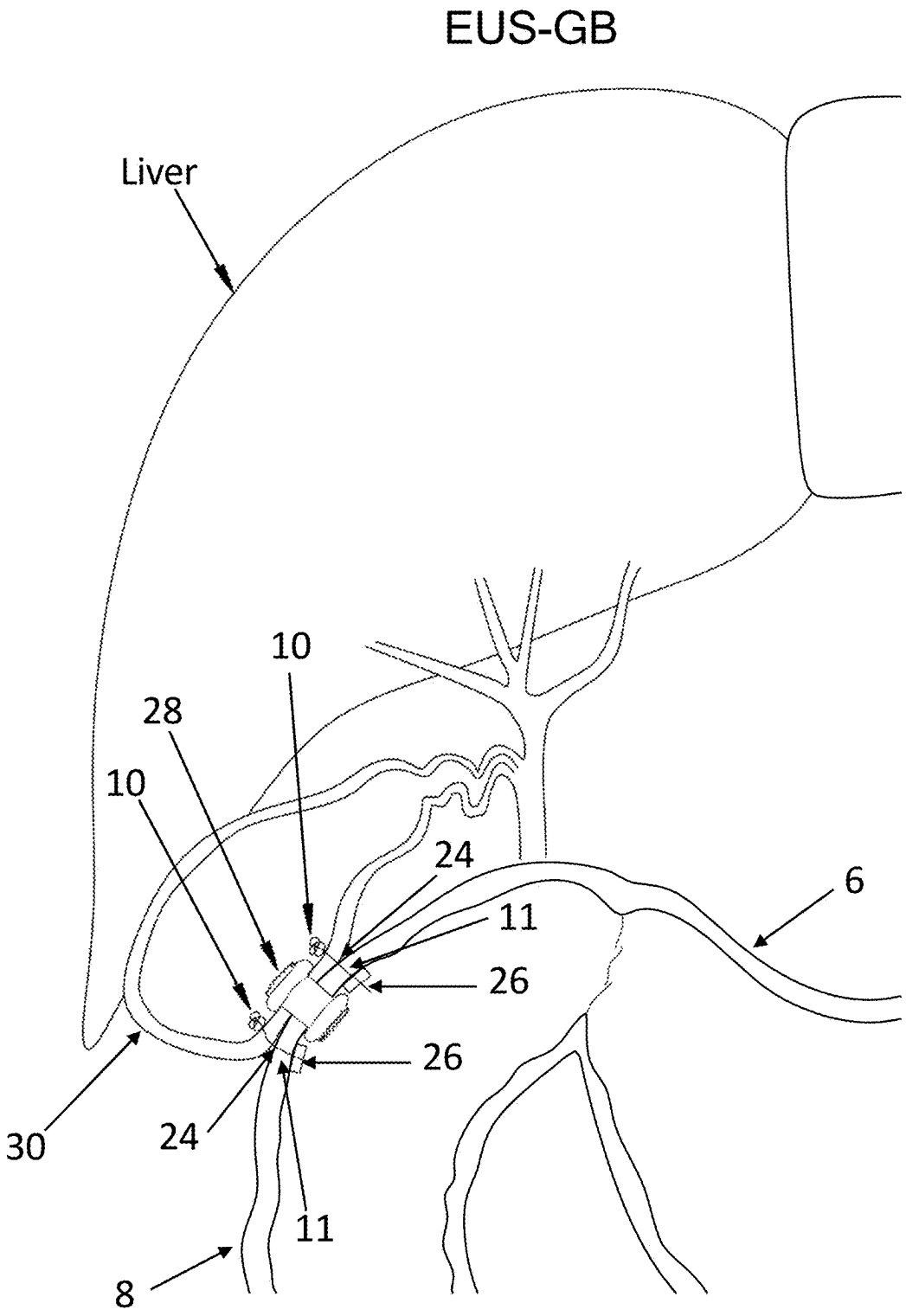


FIG. 3

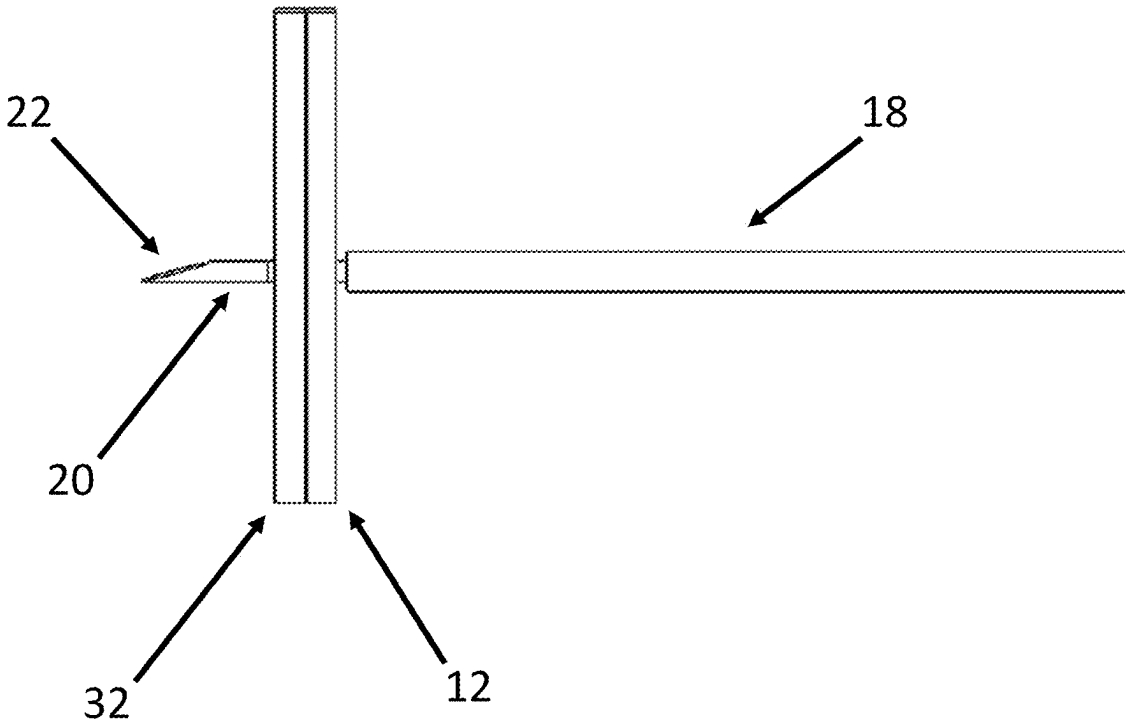


FIG. 4A

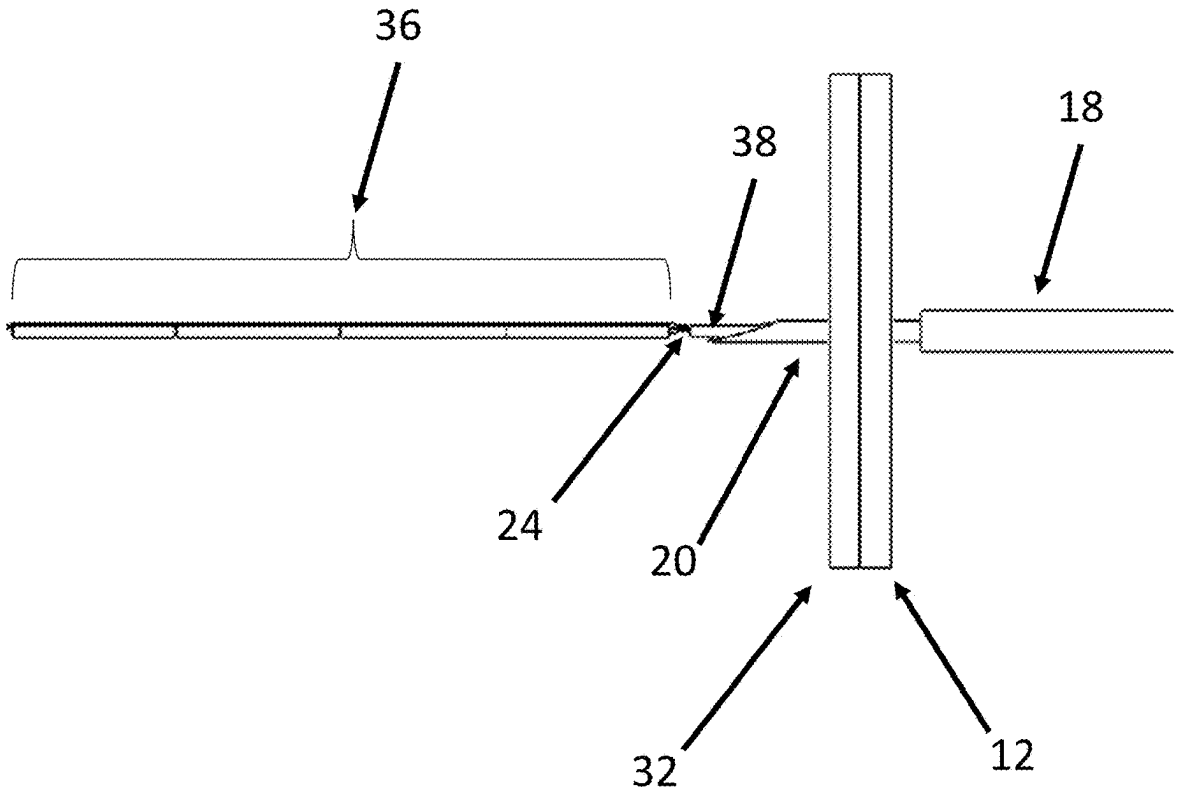


FIG. 4B

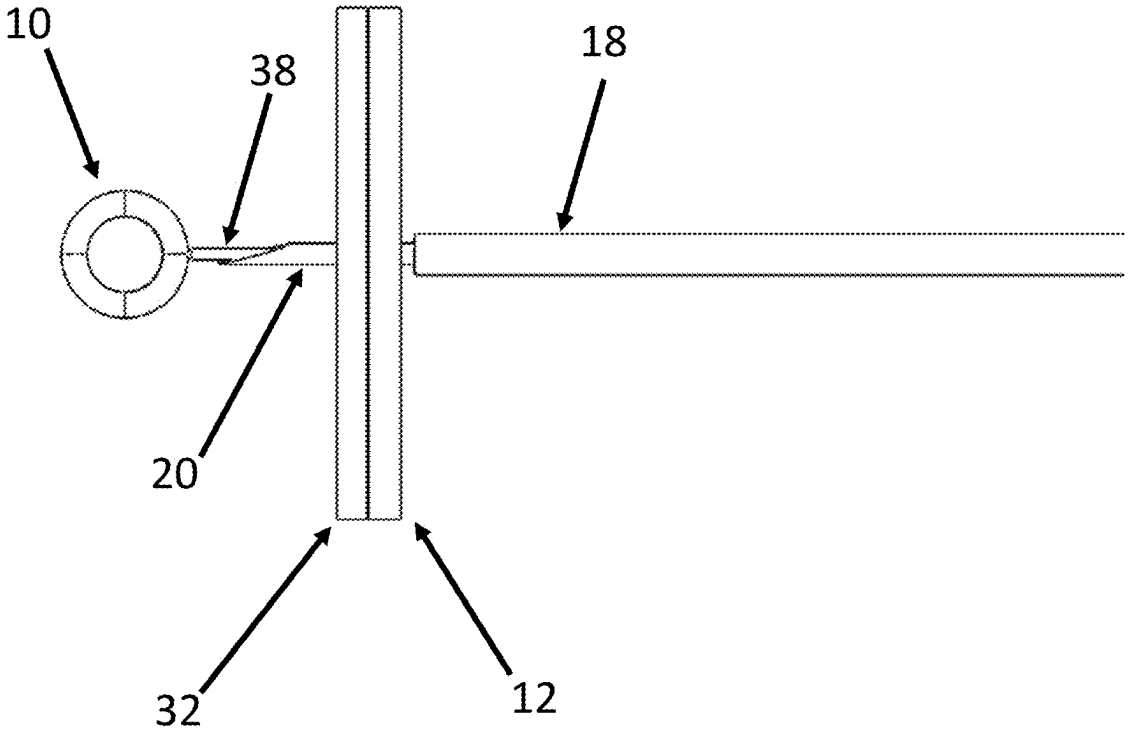


FIG. 4C

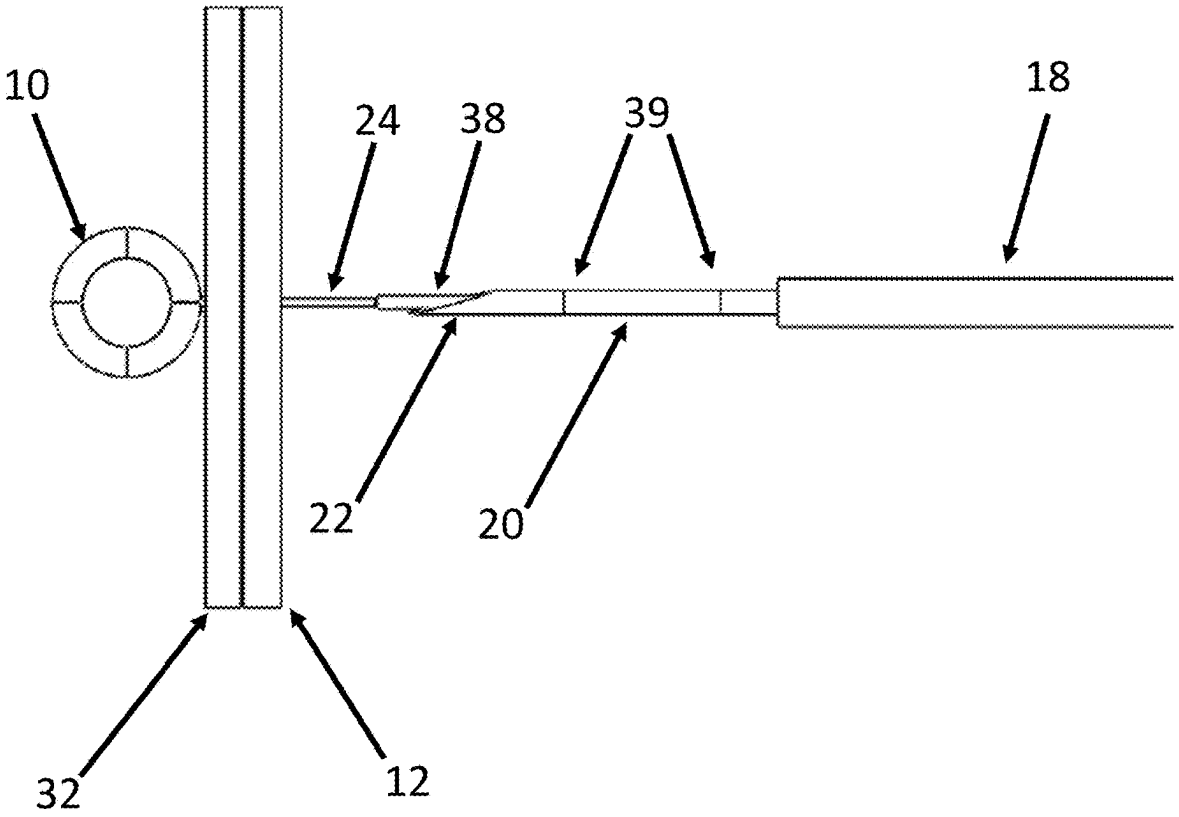


FIG. 4D

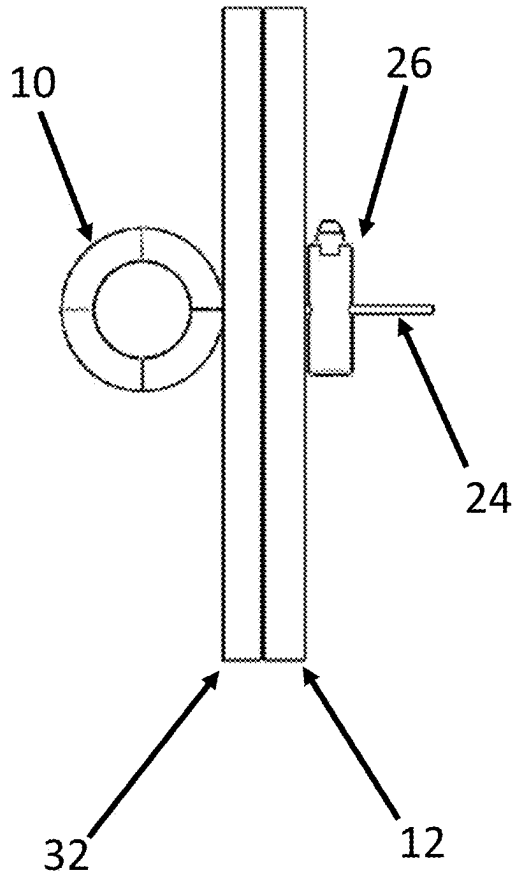


FIG. 4E

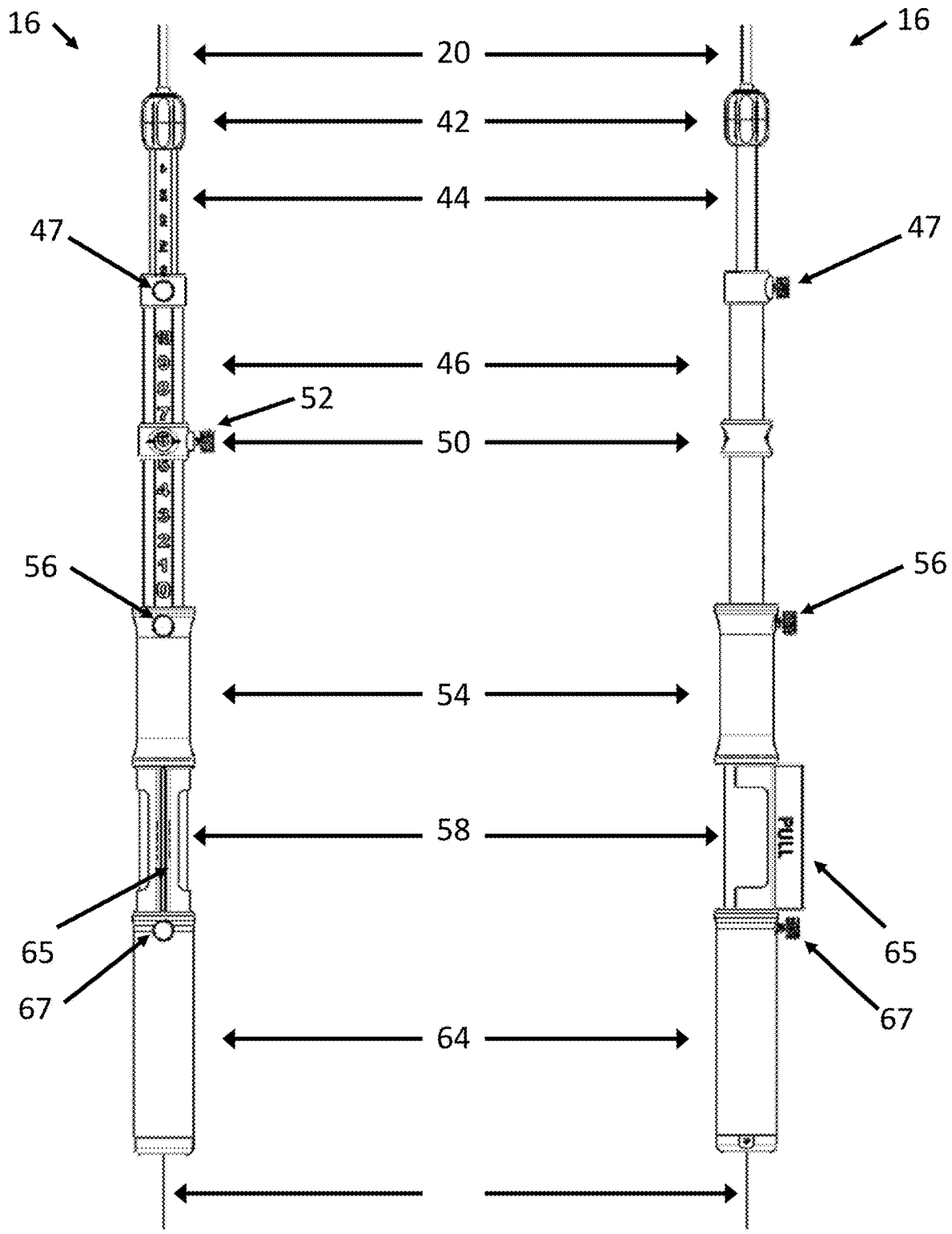


FIG. 5A FIG. 5B

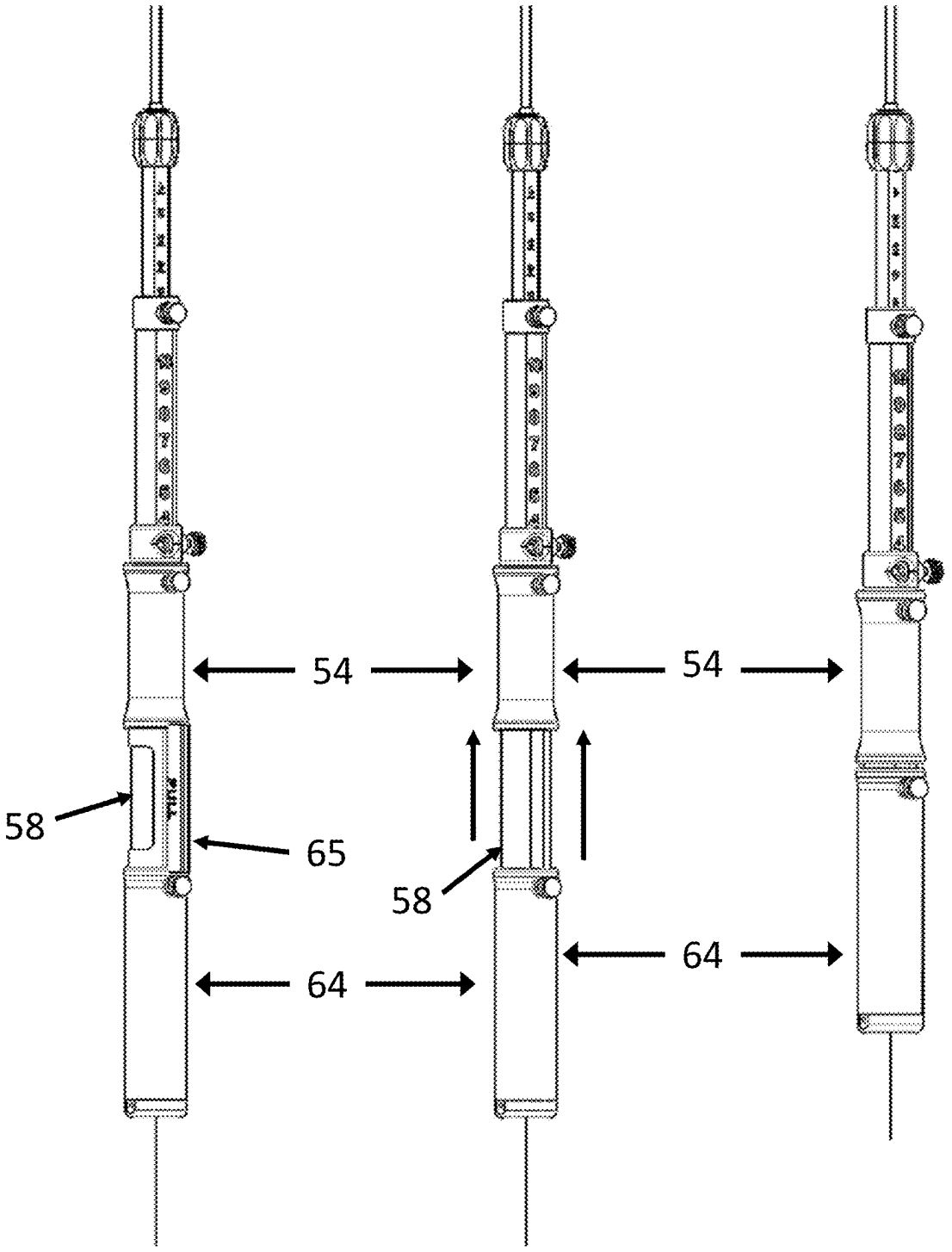


FIG. 6A FIG. 6B FIG. 6C

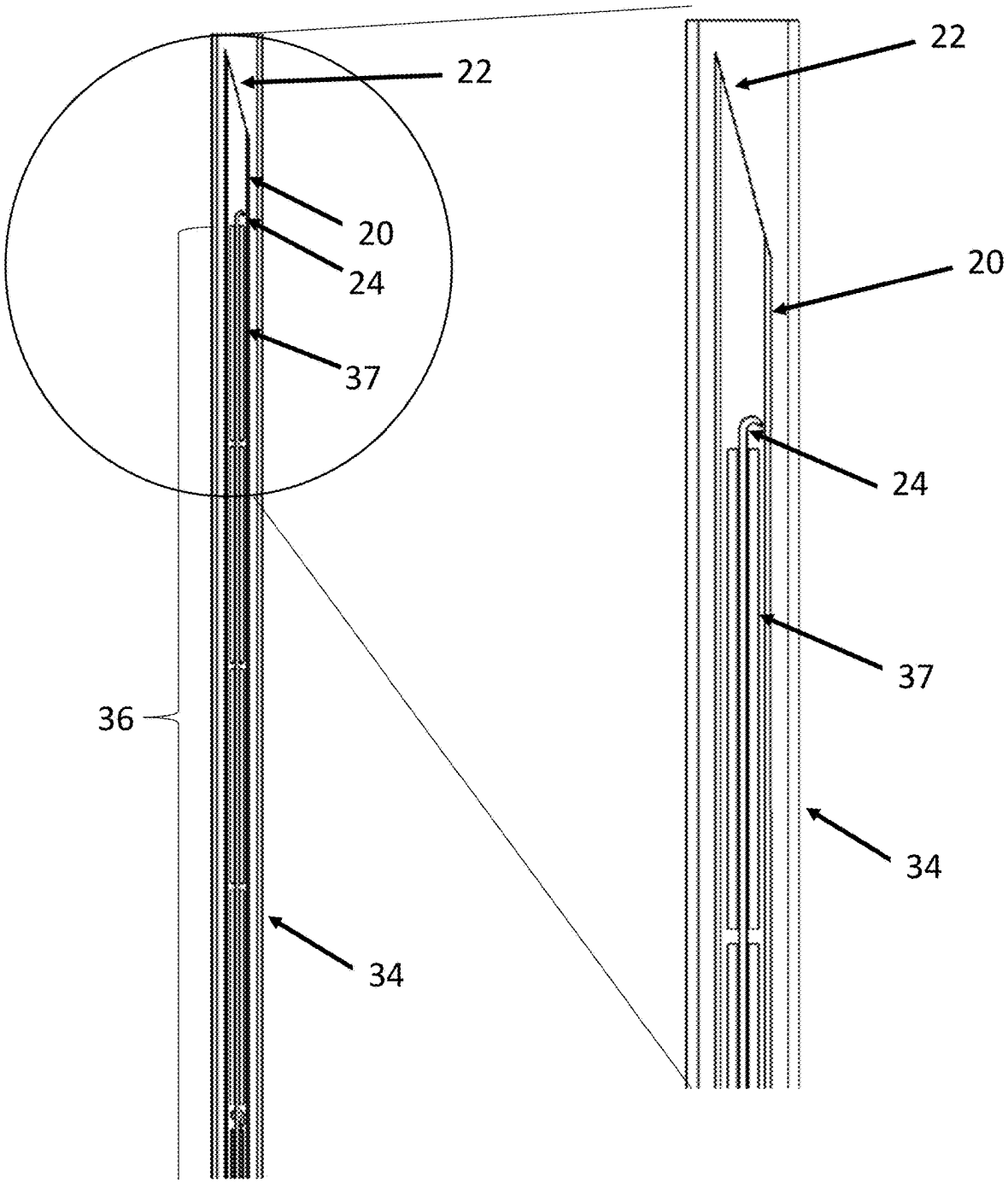


FIG. 7A

FIG. 7B

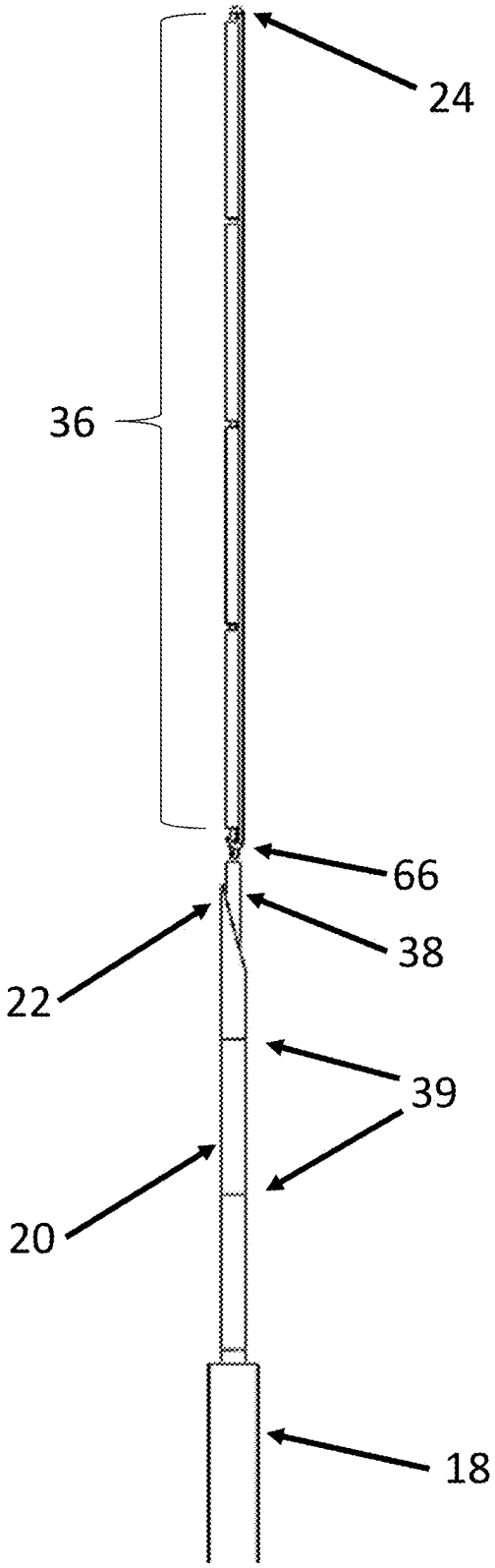


FIG. 8

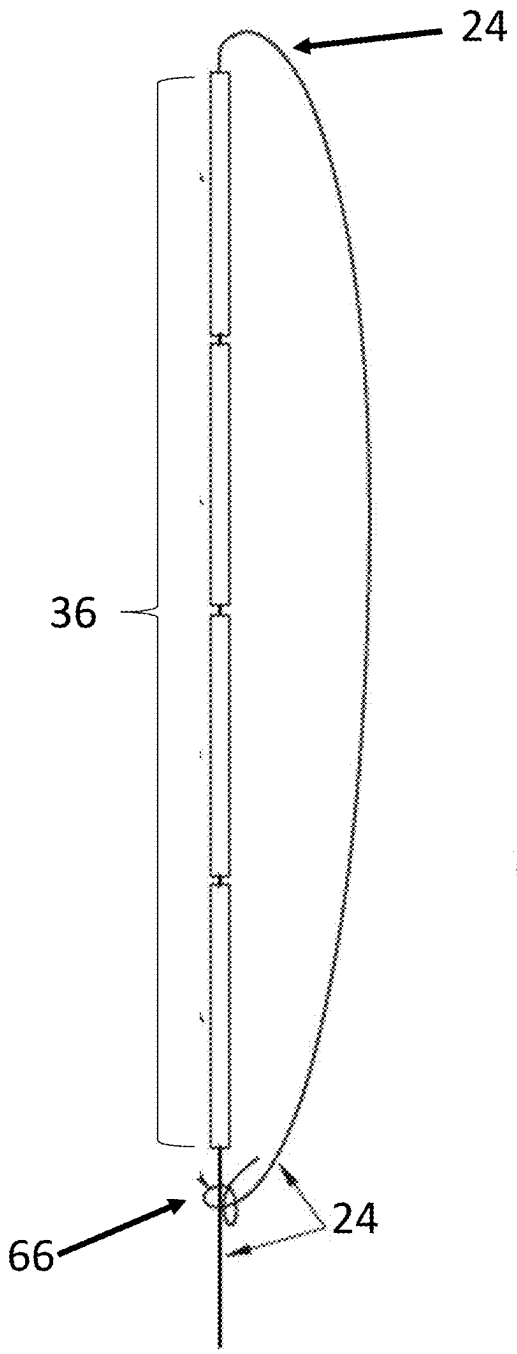


FIG. 9A

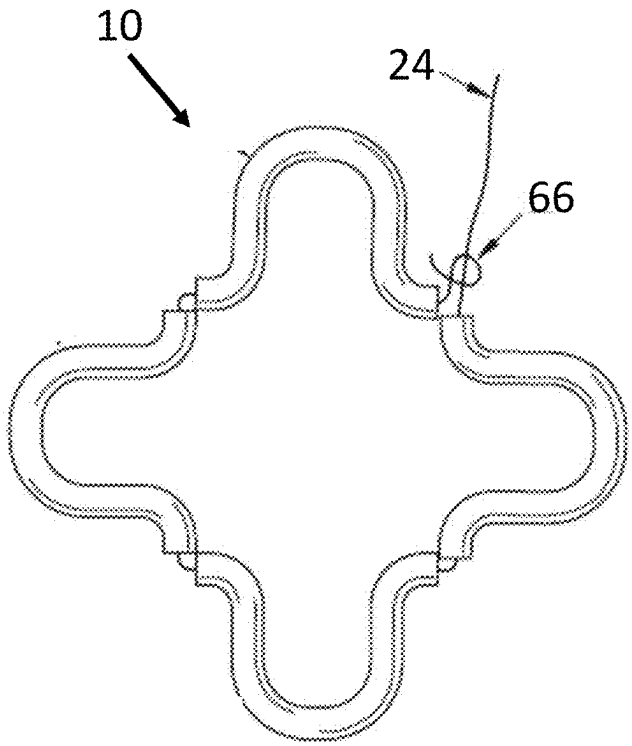


FIG. 9B

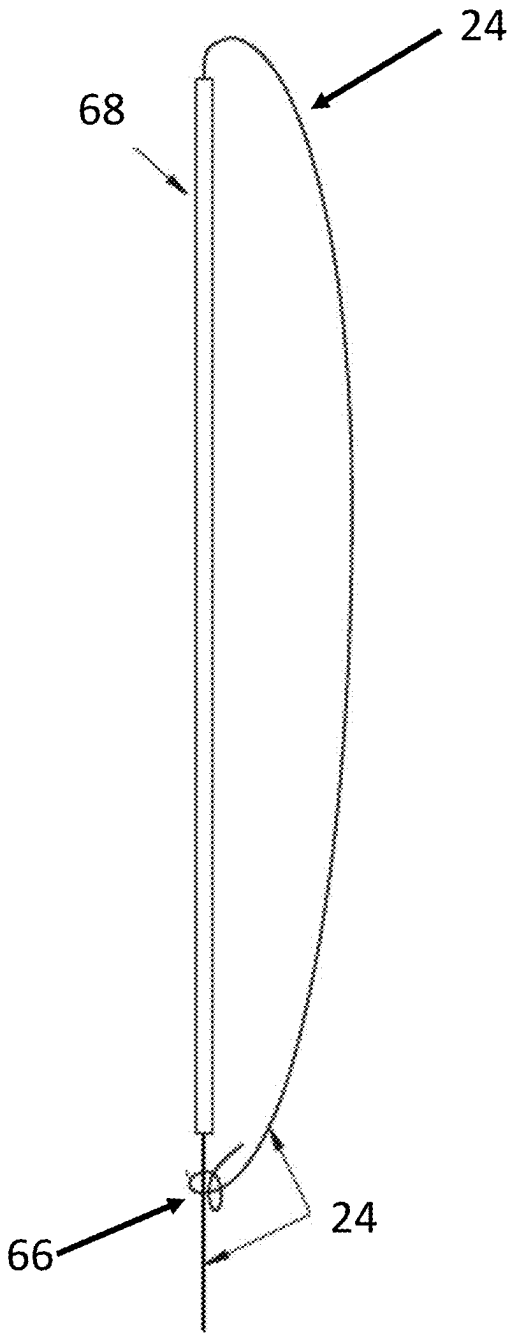


FIG. 10A

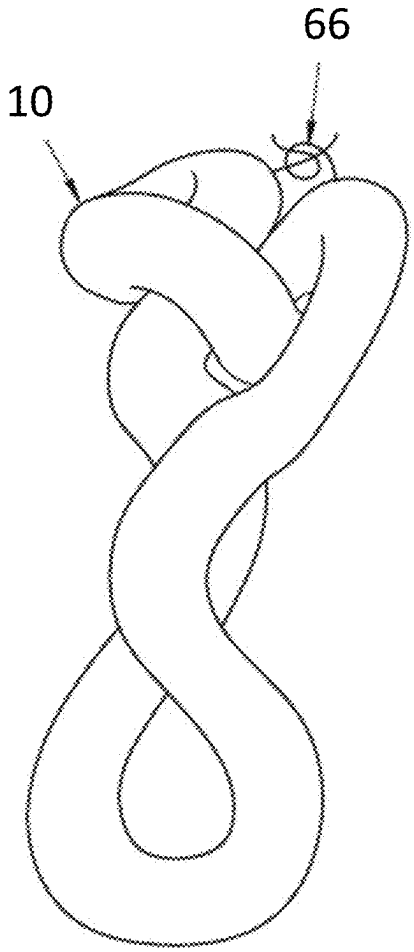


FIG. 10B

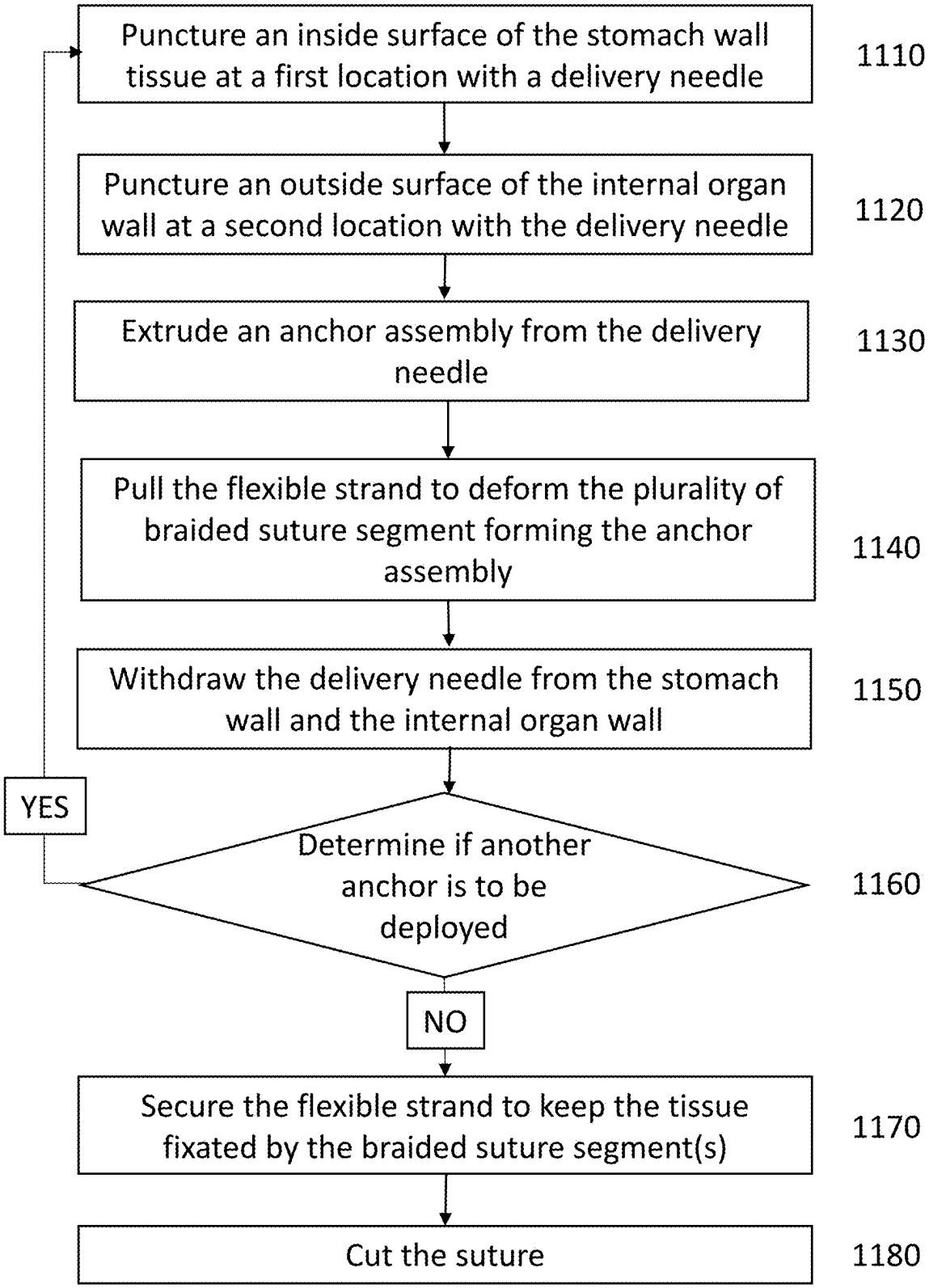

Puncture an inside surface of the stomach wall tissue at a first location with a delivery needle
1110
Puncture an outside surface of the internal organ wall at a second location with the delivery needle
1120
Extrude an anchor assembly from the delivery needle
1130
Pull the flexible strand to deform the plurality of braided suture segment forming the anchor assembly
1140
Withdraw the delivery needle from the stomach wall and the internal organ wall
1150
YES
Determine if another anchor is to be deployed
1160
NO
Secure the flexible strand to keep the tissue fixated by the braided suture segment(s)
1170
Cut the suture
1180

FIG. 11

ENDOSCOPIC ULTRASOUND-GUIDED ANCHOR DEVICE FOR TRANSLUMINAL APPOSITION

PRIORITY

[0001] This patent application claims priority from provisional U.S. patent application No. 63/553,271, filed Feb. 14, 2024, entitled, "ENDOSCOPIC ULTRASOUND-GUIDED ANCHOR DEVICE FOR TRANSLUMINAL APPOSITION," and naming Rickey Hart as inventor, the disclosure of which is incorporated herein, in its entirety, by reference.

FIELD

[0002] Illustrative embodiments of the invention generally relate to devices and methods for endoscopic surgery and, more particularly, various embodiments of the invention relate to anchor devices.

BACKGROUND

[0003] Endoscopic ultrasound-guided gastrojejunostomy (EUS-GJ) and endoscopic ultrasound-guided gallbladder drainage (EUS-GBD) are minimally invasive procedures that create a bypass between the stomach and small intestine (EUS-GJ), and inserting a stent into the gallbladder through the wall of the small intestine or stomach (EUS-GBD), respectively. These procedures are used to treat gastric outlet obstruction caused by tumors, chronic diseases, etc. (EUS-GJ), as well as treating gallbladder infections and obstructions (EUS-GBD).

[0004] These procedures involve inserting a stent between the stomach (or duodenum) and into the wall of the small intestine, or into the gallbladder. A significant challenge to the process of installing the stent between the stomach and the other end of the stent is locating the target of the puncture in the small intestine or gall bladder. Another challenge is holding (e.g., fixing) the second organ (the small intestine or the gall bladder) in place while the puncture is made and the stent is placed. There is a particular need in the medical procedures of endoscopic ultrasound-guided gastrojejunostomy and endoscopic ultrasound-guided gallbladder drainage for fixing the two organs together at the correct location prior to puncturing the opening between the organs and placing the stent.

SUMMARY OF VARIOUS EMBODIMENTS

[0005] In accordance with one embodiment of the invention, an anchor assembly for fixation of a stomach wall to an internal organ wall includes a flexible strand; and a plurality of braided anchor segments slidably coupled to the flexible strand. The flexible strand passes through a bore hole that traverses from a proximal end to a distal end of each of the plurality of braided anchor segments such that the proximal end of a first braided anchor segment is adjacent to a distal end of a second braided anchor segment. The plurality of braided anchor segments are cinched together forming an anchor assembly to provide tissue fixation.

[0006] Each of the plurality of braided anchor segments may include straight braided suture segments that have been deformed by application of tension on the flexible strand. The flexible strand may be a monofilament. The flexible strand may be a suture. The suture may be a braided polyester suture.

[0007] Each of the plurality of braided anchor segments may be standard braided polyester suture that is cut into predetermined lengths.

[0008] The cinched plurality of braided anchor segments may have a purse string effect on the plurality of braided anchor segments such that the plurality of flexible braided anchor segments is drawn together to provide tissue fixation.

[0009] In accordance with another embodiment of the invention, a method for implanting anchor assembly connected via a single flexible strand for fixation of a stomach wall to an internal organ wall includes puncturing an inside surface of the stomach wall tissue at a first location with a delivery needle, puncturing an outside surface of the internal organ wall at a second location with the delivery needle, and extruding an anchor assembly from the delivery needle.

[0010] The anchor assembly includes the single flexible strand, and a plurality of braided anchor segments slidably coupled to the single flexible strand. The single flexible strand passes through a bore hole that traverses from a proximal end to a distal end of each of the plurality of braided anchor segments such that the proximal end of a first braided anchor segment is adjacent to a distal end of a second braided anchor segment. Pulling the flexible strand a first time to deform the plurality of braided anchor segments forms the anchor assembly. The anchor assembly is configured to anchor an outside surface of the stomach wall to the outside surface of the internal organ wall, and prevent the anchor assembly from being pulled thru internal organ wall to the stomach wall.

[0011] The method further includes withdrawing the delivery needle from the stomach wall and the internal organ wall, securing the flexible strand to keep the stomach wall anchored to the internal organ wall fixated by the anchor assembly, and cutting the flexible strand. The flexible strand is cut a distance away from the proximal end of a final braided anchor segment of the plurality of the braided anchor segments.

[0012] The extruding the anchor assembly may be accomplished by advancing a drive tube to push the plurality of braided anchor segments out of the delivery needle.

[0013] The securing the flexible strand may include locking the flexible strand in place using a locking mechanism including at least one of a tag, a barb, a cinch, a toggled needle, or a distel knot. The securing the flexible strand may include a locking device or an overhand knot that can be run down to a fixation site.

[0014] Puncturing the outside surface of the internal organ wall at the second location with the delivery needle may follow continuously from puncturing the inside surface of the stomach wall tissue at the first location with the same delivery needle. The stomach may include a duodenum.

[0015] In accordance with another embodiment of the invention, a surgical device for implanting a flexible braided anchor assembly for affixing a stomach wall to an internal organ wall includes a handle assembly. The handle assembly has a cylindrical bore passing through the handle assembly on a center axis along a length of the handle assembly.

[0016] The surgical device further includes an outer tube positioned in the cylindrical bore of the handle assembly. The outer tube is hollow and has a common center line with the cylindrical bore of the handle assembly. The outer tube includes a delivery needle having a needle tip at a distal end of the outer tube.

[0017] The surgical device further includes a plurality of braided suture segments slidably coupled to a flexible strand. The flexible strand is translationally threaded through plurality of braided suture segments, and the plurality of braided suture segments are positioned in the outer tube.

[0018] The surgical device further includes a first drive tube positioned in the outer tube and having a common center line with the outer tube. The first drive tube is configured to extrude the braided suture segments.

[0019] Each of the plurality of braided suture segments may be a hollow braided suture segment. The suture may be a monofilament strand, and the plurality of braided suture segments may be a plurality of hollow braided suture segments aligned end to end having the monofilament strand threaded through the aligned plurality of hollow braided suture segments.

[0020] A column strength of the plurality of hollow braided suture segments may be increased by application of at least one of heat or a cyanoacrylate coating to each of the segments of the plurality of hollow braided suture segments.

[0021] A braided suture segment of the plurality of braided suture segments may have a length of between about 5 mm and about 50 mm. Each of the braided suture segments of the plurality of braided suture segments may a length of between about 5 mm and about 12 mm.

[0022] A distal end of the flexible strand threaded thru the first braided suture segment may be looped around the first braided suture segment and knotted around the flexible strand between the first braided suture segment and the first drive tube.

[0023] Each of the plurality of braided suture segments may be treated to increase a rigidity of the plurality of braided suture segments slidably coupled to the flexible strand. The treatment may include heating each of the plurality of braided suture segments, or applying a cyanoacrylate coating to each of the plurality of braided suture segments.

[0024] In accordance with another embodiment of the invention, a method for implanting an anchor assembly connected via a single flexible strand through a drain tube placed from the outside of a body for fixation of a gall bladder wall to a stomach wall includes puncturing an inside surface of the gall bladder wall tissue at a first location with a delivery needle. The delivery needle is brought into the interior of the gall bladder through a drain tube placed between outside of the body and the gall bladder.

[0025] The method further includes puncturing an outside surface of the stomach wall at a second location with the delivery needle, and extruding an anchor assembly from the delivery needle. The anchor assembly includes the single flexible strand, and a plurality of braided anchor segments slidably coupled to the single flexible strand. The single flexible strand passes through a bore hole that traverses from a proximal end to a distal end of each of the plurality of braided anchor segments such that the proximal end of a first braided anchor segment is adjacent to a distal end of a second braided anchor segment.

[0026] The method further includes pulling the flexible strand a first time to deform the plurality of braided anchor segments forming the anchor assembly. The anchor assembly is configured to anchor an inside surface of the stomach wall to the outside surface of the gall bladder wall, and prevent the anchor assembly from being pulled thru the stomach wall to the gall bladder wall.

[0027] The method further includes withdrawing the delivery needle from the stomach wall and the gall bladder wall, securing the flexible strand to keep the stomach wall anchored to the gall bladder wall fixated by the anchor assembly, and cutting the flexible strand. The flexible strand is cut a distance away from the proximal end of a final braided anchor segment of the plurality of the braided anchor segments.

BRIEF DESCRIPTION OF THE DRAWINGS

[0028] Those skilled in the art should more fully appreciate advantages of various embodiments of the invention from the following "Description of Illustrative Embodiments," discussed with reference to the drawings summarized immediately below.

[0029] FIG. **1**A schematically shows a portion of a procedure for fixing one organ to another according to one embodiment of the present disclosure.

[0030] FIG. **1**B schematically shows another portion of a procedure for fixing one organ to another according to one embodiment of the present disclosure.

[0031] FIG. **1**C schematically shows another portion of a procedure for fixing one organ to another according to one embodiment of the present disclosure.

[0032] FIG. **1**D shows an expansion of the indicated region of the schematic drawing of FIG. **1**C.

[0033] FIG. **2** shows a schematic drawing illustrating an embodiment of an endoscopic ultrasound-guided gastrojejunostomy according to one embodiment of the present disclosure.

[0034] FIG. **3** shows a schematic drawing illustrating an embodiment of an endoscopic ultrasound-guided gallbladder drainage according to one embodiment of the present disclosure.

[0035] FIG. **4**A shows a schematic cross section illustration of a delivery device with a delivery needle having a needle tip according to one embodiment of the present disclosure.

[0036] FIG. **4**B shows a schematic cross section illustration of a plurality of braided suture segments after being extruded from the needle tip according to one embodiment of the present disclosure.

[0037] FIG. **4**C shows a schematic cross section illustration of the flexible braided suture segments after the suture has been pulled taut according to one embodiment of the present disclosure.

[0038] FIG. **4**D shows a schematic cross section illustration of the flexible braided suture segments and the suture after the delivery device has been pulled back according to one embodiment of the present disclosure.

[0039] FIG. **4**E shows a schematic cross section illustration of the anchor assembly fixed to the organ wall and the stomach wall according to one embodiment of the present disclosure.

[0040] FIG. **5**A shows a top view of the delivery device according to one embodiment of the present disclosure.

[0041] FIG. **5**B shows a side view of the delivery device according to one embodiment of the present disclosure.

[0042] FIG. **6**A shows an angled top view of the delivery device with the safety pull in position on the delivery device according to one embodiment of the present disclosure.

[0043] FIG. **6**B shows an angled top view of the delivery device with the safety pull removed from its position on the delivery device according to one embodiment of the present disclosure.

[0044] FIG. **6**C shows an angled top view of the delivery device with the safety pull removed and pusher **64** having been advanced toward the front handle according to one embodiment of the present disclosure.

[0045] FIG. **7**A shows a schematic cross section illustration of the flexible braided anchor segments located in the delivery needle which is concentrically positioned in the outer tube according to one embodiment of the present disclosure.

[0046] FIG. **7**B shows a schematic cross section illustration of an expansion of FIG. **7**A according to one embodiment of the present disclosure.

[0047] FIG. **8** shows a top view of the delivery device with the delivery needle extended according to one embodiment of the present disclosure.

[0048] FIG. **9**A shows a schematic drawing of the plurality of braided suture segments with the suture looping back to be formed in a slip knot according to one embodiment of the present disclosure.

[0049] FIG. **9**B shows a schematic drawing of the plurality of braided suture segments after the suture has been pulled and the plurality of braided suture segments has been deformed into the anchor assembly according to one embodiment of the present disclosure.

[0050] FIG. **10**A shows a schematic illustration of an embodiment of a long braided suture segment on a suture according to one embodiment of the present disclosure.

[0051] FIG. **10**B shows a schematic illustration of a long braided anchor assembly) segment as it is deployed on the distal side of a tissue according to one embodiment of the present disclosure.

[0052] FIG. **11** shows steps of an embodiment of a method for implanting braided anchor segments connected via a single flexible strand for tissue fixation according to one embodiment of the present disclosure.

DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

[0053] In illustrative embodiments, an anchor device comprising an anchor assembly and a locking device connected via a single flexible strand fixes a stomach wall to an organ wall so that a stent may be positioned between the stomach (or duodenum) and the organ, such as a small intestine, or a gallbladder. An anchor assembly is implanted through the stomach wall into a wall of an internal organ for fixation of the stomach wall to the internal organ wall. Fixing the two organs together with the anchor device at the correct location prior to puncturing an opening between the two organs increases the ease and accuracy of making the incision in each of the organ walls. Fixation of the two organ walls with of the anchor device also simplifies the placement and deployment of the stent by reducing the shifting and movement of the organ walls relative to each other. The anchor assembly comprises at least one braided suture segment, or a plurality of braided anchor segments that is implanted using a delivery device with a handle assembly and is positioned and controlled through an endoscope. The anchor assembly, formed of at least one braided suture segment, is extruded through a needle tip at the distal end of a delivery needle. Details of illustrative embodiments are discussed below.

[0054] FIG. **1**A, FIG. **1**B, and FIG. **1**C schematically illustrate fixing a stomach **6** to a small intestine **8** prior to placing a stent between the stomach **6** and the small intestine **8** as an initial step for minimally invasive endoscopic ultrasound-guided gastrojejunostomy (EUS-GJ) procedure that creates a bypass between the stomach and small intestine.

[0055] As shown in FIG. **1**A, the EUS-GJ procedure begins with implanting an anchor assembly **10**, comprising a flexible braided anchor assembly, for affixing the stomach wall **12** to the small intestine wall **14**. An incision is made on the inside of the stomach wall **12** with a delivery device **16** having a handle assembly **18** including a delivery needle **20** with a needle tip **22** at the distal end of the delivery needle **20**.

[0056] The needle tip **22** is then pushed into the outside surface of the small intestine **14** to puncture the small intestine **8**. In some embodiments, the needle tip **22** is pushed continuously through the inside surface of the stomach **12** and into the outside surface of the small intestine **14**. In some embodiments, once the needle tip **22** is pushed through the inside surface of the stomach **12**, the delivery device **16** is repositioned under ultrasound guidance, and the needle tip **22** is pushed and into the outside surface of the small intestine **14**. Once the needle tip **22** is inside of the small intestine **8**, the anchor assembly **10** may be extruded from the needle tip **22**. After extrusion, the anchor assembly **10**, comprised of a flexible braided anchor assembly and a flexible strand **24** (e.g., a suture), is positioned inside the small intestine **8**.

[0057] Once positioned in the small intestine **8**, the flexible strand **24** is pulled a first time to deform the plurality of braided anchor segments forming the anchor assembly **10**. The anchor assembly is configured to anchor an outside surface of the stomach wall to the outside surface of the small intestine wall, and to prevent the anchor assembly **10** from being pulled thru small intestine wall **14** to the stomach wall **12**.

[0058] As shown in FIG. **1**B, once the braided anchor segments are extruded into the small intestine and the have been deformed into the anchor assembly **10**, the delivery device **16** is retracted from the small intestine **8** and the stomach wall **12**. The suture **24** is pulled and the small intestine **8** is drawn toward the stomach wall **12**. Once the small intestine wall **14** is drawn toward the stomach wall **12**, the suture may be secured and cut.

[0059] FIG. **1**C shows a schematic drawing of the anchor device **11** fixing the stomach **6** to the small intestine **8**. Now the delivery device can be removed and a locking device **26** (e.g., locking mechanism) such as a cinch or special knot can be pushed down to complete and lock the fixation. Additional locking mechanisms that may be used include a tag, a barb, a cinch, a toggled needle, or distal knot. The anchor assembly **10** may be secured against the inside surface of the small intestine by pulling the suture **24** tight and attaching a locking device **26** to the suture **24** to keep the tension in the suture **24**. Once the locking device **26** is secured in position, the suture **24** is cut to a predetermined length and the anchor device **11** is in position.

[0060] FIG. **1**D shows an expansion of the indicated region of the schematic drawing of FIG. **1**C. The anchor

device **11** fixing the stomach wall **6** to the intestine wall **8** is shown as comprising the anchor assembly **10**, the suture **24**, and the locking device **26**.

[0061] FIG. **2** shows a schematic drawing illustrating an embodiment of an endoscopic ultrasound-guided gastrojejunostomy (EUS-GJ), a minimally invasive procedure that creates a bypass between the stomach **6** and the small intestine **8**. In embodiments, the EUS-GJ procedure may include implanting one or more anchor devices **11** prior to placing the stent **28**. In some embodiments, more than one anchor device **11** may be placed to secure the tissues. FIG. **2** illustrates how the placement of a second anchor device **11** is optional. The stent **28** has a flange on each end of the stent **28** to lock the stent **28** in place between the flexible stomach wall **14** and small intestine wall **14**.

[0062] FIG. **3** shows a schematic drawing illustrating an embodiment of an endoscopic ultrasound-guided gallbladder drainage (EUS-GBD), a minimally invasive procedure that creates a bypass between the stomach and the gall bladder. In embodiments, the EUS-GB procedure may include implanting one or more anchors prior to placing the stent **28**. The stent **28** has a flange on each end of the stent **28** to lock the stent **28** in place between the flexible stomach wall **14** and gall bladder wall **30**.

[0063] FIGS. **4**A-**4**E show simplified schematic cross section illustrations of some embodiments of delivery devices deploying an assembly of braided anchor segments. For clarity of illustration, the figures FIGS. **4**A-**4**E have been simplified and may not necessarily show every detail of the delivery devices.

[0064] FIG. **4**A shows a simplified schematic cross section illustration of a handle assembly **18** with a delivery needle **20** having a needle tip **22** after puncturing a stomach wall **12** and an organ wall **32** according to an embodiment of the present disclosure. In some embodiments, the organ wall **32** may be a small intestine wall **14**, a gall bladder wall **30**, or a wall of another organ **32**. The needle **22** punctures a first hole in the stomach wall **12** and then the organ wall **32**. The needle **22** is at a distal end of an outer tube, and the outer tube is coupled to the handle assembly **18**.

[0065] In some embodiments, the needle **22** and the outer tube may be fabricated as a single piece, whereas in other embodiments, the needle **22** and the outer tube may be assembled from separate pieces. The needle **22** and the outer tube may be fabricated from one or more rigid materials, such as a steel, aluminum, titanium, and so on. The rigid material may also include metallic alloys such as nitinol. In embodiments, when the needle **22** and the outer tube are assembled from separate pieces, the needle **22** and the outer tube may be fabricated from different rigid materials.

[0066] FIG. **4**B shows a simplified schematic cross section illustration of a plurality of braided suture segments **36** (e.g., a flexible braided anchor assembly) after being extruded from the needle **20** on the distal side of the an organ wall **32**. The plurality of braided suture segments **36** is pushed out distally out of the needle **20** by a drive tube **38**. The flexible strand (e.g., suture) **24** is shown threaded thru the flexible braided suture segments **36**, looped around, and knotted with a slidable slip knot around the suture between proximal braided suture segment and the drive tube **38**. In some embodiments, at least one braided suture segment may be used in place of a plurality of braided suture segments.

[0067] In embodiments, the flexible strand (e.g., suture) **24** may be a monofilament. In other embodiments, the flexible strand **24** may be a suture. The suture **24** may be a braided polyester suture. In embodiments, the suture **24** may be a FiberWire®, TigerWire®, or FiberChain® suture, although any type of suture **24** may be utilized, including cored or coreless sutures. In another embodiment, the flexible strand **24** may be suture tape, such as FiberTape®. The flexible strand **24** may include any soft, flexible strand of material.

[0068] In some embodiments, the braided suture segments **36** may be strengthened by heating the braided suture segments **36**. The braided suture segments **36** may also be strengthened by coating them with a cyanoacrylate coating.

[0069] FIG. **4**C shows a simplified schematic cross section illustration of the flexible braided suture segments **36** after the suture **24** has been pulled taut a first time. As a result of the suture **24** being pulled tight, the flexible braided suture segments **36** has been deformed into an anchor assembly **10**. In some embodiments, the anchor assembly **10** may have circular shapes, while in other embodiments the anchor assembly may have a irregular shapes.

[0070] FIG. **4**D shows a simplified schematic cross section illustration of the anchor assembly **10** and the suture **24** after the handle assembly **18** with the delivery needle **20** and the needle tip **22** have been pulled back and retracted from the organ wall **32** and the stomach wall **12**. By pulling the suture **24**, the slip knot is tightened to secure the anchor assembly **10** on the distal surface of the organ wall **32**. Depth line marks **39** on the needle **20** are used to gauge the length of needle extending out of the handle assembly **18**.

[0071] FIG. **4**E shows a simplified schematic cross section illustration of the anchor assembly **10** (e.g., deformed plurality of flexible braided suture segments) fixed to the organ wall **32** and the stomach wall **12**. The anchor assembly **10** is secured by locking the suture **24** in place with a locking device **26**. In embodiments, the anchor assembly **10** may be secured in place with any one of locking mechanisms including a locking device **26**, a tag, a barb, a cinch, a toggled needle, or a distel knot.

[0072] FIG. **5**A shows a top view of the delivery device **16**, and FIG. **5**B shows a side view of the delivery device **16**. The delivery device **16** includes a delivery needle **20** positioned concentrically in a scope attachment **42** and a scope adjustment shaft **44**. The scope attachment shaft **44** is concentrically positioned in a shaft **46** with a shaft adjustment thumb screw **47**. A slide indicator **50** with a slide indicator thumb screw **52** is slidably mounted on the shaft **46**. The slide indicator **50** allows for the length of the needle **20** that extends beyond the handle assembly to be controlled. The depth line marks **39** can be used with the slide indicator **50** to index the extension length of the needle **20**. The shaft **46** is concentrically mounted in a front handle **54**. The front handle **54** has a front handle thumb screw **56**. A rear handle **58** with a end cap is concentrically mounted between the front handle **54** and a pusher **64**. A safety pull **65** is removably mounted on the rear handle **58** between the front handle **54** and a pusher **64**. The pusher **64** includes a pusher thumb screw **67**. The flexible strand (e.g., suture) is threaded concentrically through the entire delivery device **16**.

[0073] FIGS. **6**A through **6**C illustrate how the delivery device **16** is mechanically operated to extrude the a flexible braided anchor assembly **36**. FIG. **6**A shows an angled top view of the delivery device **16** with the safety pull **65** in position on the rear handle **58** between the front handle **54** and a pusher **64**.

[0074] FIG. **6**B shows an angled top view of the delivery device **16** with the safety pull **65** removed from the position on the rear handle **58** between the front handle **54** and a pusher **64**. The arrows indicate a direction that the pusher **64** is moved to push the flexible anchor assembly **36** out of the needle point **22**.

[0075] FIG. **6**C shows an angled top view of the delivery device **16** with the safety pull **65** removed and pusher **64** having been advanced toward the front handle **54**. After removing the safety pull **65**, the pusher **64** may be moved forward, as indicated by the direction arrows next to rear handle **58**. Moving the pusher forward engages an inner drive tube that pushes the flexible braided anchor assembly **36** out of the delivery needle **20**.

[0076] FIG. **7**A shows a schematic cross section illustration of the flexible braided anchor segments **36** located in the delivery needle **20** which is concentrically positioned in the clear outer sheath **34**. The suture **24** is shown extending out of the distal end of the distal anchor segment **37**. In use, the needle **20** is pushed out of the clear outer sheath **34** to create the incisions, and retracted back into the clear outer sheath **34** to allow for the handle assembly **18** to be manipulated inside of the body without created unwanted cuts or incisions.

[0077] FIG. **7**B shows a schematic cross section illustration of an expansion of FIG. **7**A showing the flexible braided anchor segments **36** located in the delivery needle **20** which is concentrically positioned in the clear outer sheath **34**.

[0078] FIG. **8** shows a top view of a delivery device **16** with the delivery needle **20** extended out of the clear outer sheath **34**. The drive tube **38** has pushed the plurality of braided suture segments **36** out of the needle tip **22**. The suture **24** is shown being threaded through the braided suture segments **36** and looping around the distal end of the distal suture segment back to the proximal end of the proximal suture segment where the suture forms a slip knot **66**.

[0079] FIG. **9**A shows a schematic drawing of the plurality of braided suture segments **36** with the suture **24** looping back to be formed in a slip knot **66**. In this embodiment, the series of braided suture segments are strung on a suture with a slip knot **66** being positioned after the final braided suture segment on the suture **24**. In this embodiment, a slip knot **66** is positioned proximal to the fourth braided suture segment **36**. In this embodiment, the slip knot is positioned following the final braided suture segment threaded onto the suture. In some embodiments, the plurality of suture segments may include two, three, four, five, six, seven, eight, nine, or **10**, or more suture segments.

[0080] FIG. **9**B shows a schematic drawing of the plurality of braided suture segments **36** after the suture **24** has been pulled and the plurality of braided suture segments **36** has been deformed into the anchor assembly **10**. As shown in FIG. **4**C, above, when the suture **24** is pulled tight once it has been implanted into the organ, the suture **24** is pulled toward the slip knot **66** and becomes deformed. The deformed braided suture segments **36** become the anchor assembly **10**.

[0081] In other embodiments, a slip knot or other locking mechanism may be positioned proximally to any segments of an assembly of braided suture segments. That is, a slip knot **66** or other locking mechanism may be positioned proximal to any of suture segments.

[0082] FIG. **9**B shows a shows a schematic illustration of an assembly of braided anchor segments as they are deployed on the distal side of a tissue. In this non-exclusive embodiment, the assembly of braided suture segments is only anchored to the tissue at where the slip knot is pulled taut. In this embodiment, the assembly of braided anchor segments has a large surface area that enables a large securing surface formed against the tissue.

[0083] FIG. **10**A shows a schematic illustration of an embodiment of a long braided suture segment **68** on a suture **24**. In this embodiment the long braided suture segment **68** may be between 10 mm and 70 mm. In some embodiments, the at least one braided suture segment may be the long braided suture segment **68**. In this embodiment, a slip knot **66** is positioned proximal to the long braided suture segment **68**. In this embodiment, the long braided anchor **68** segment has a large surface area that enables a large securing surface with only one hole formed in the tissue. This may be useful in fixing tissue of one organ to another organ and holding it in place while other procedures are being undertaken, such as placing a stent between the two organs.

[0084] FIG. **10**B shows a schematic illustration of a long braided anchor assembly **10** (e.g., deformed long braided suture segment **68**) segment as it is deployed on the distal side of a tissue, such as an organ wall. In this embodiment, the deformed long braided anchor segment **68** is only anchored to the tissue at where the slip knot is pulled taut. In this embodiment, the long braided anchor segment **10** has a large surface area that enables a large securing surface with only one hole formed in the tissue. This may be useful in fixing tissue of one organ to another organ and holding it in place while other procedures are being undertaken, such as placing a stent between the two organs.

[0085] FIG. **11** shows steps of an embodiment of a method for implanting braided anchor segments connected via a single flexible strand (e.g., suture) for tissue fixation.

[0086] At **1110**, puncture an inside surface of the stomach wall tissue at a first location with a delivery needle. The needle having a needle tip punctures the tissue from a proximal side of the tissue (e.g., stomach wall) to a distal side of the tissue. The needle is at a distal end of an outer tube, and the outer tube is coupled to a handle assembly.

[0087] At **1120**, puncture an outside surface of the internal organ wall at a second location with the delivery needle. The needle having a needle tip punctures the tissue from a proximal side of the tissue (e.g., outside surface of the organ wall) to a distal side of the tissue. In some embodiments, the process of puncturing the outside surface of the internal organ wall can be performed continuously following the puncturing of the inside surface of the stomach wall. In some embodiments, the process of puncturing the outside surface of the internal organ wall may not be performed continuously following the puncturing of the inside surface of the stomach wall. That is, there may be some process that is engaged in between puncturing the stomach wall and the internal organ wall.

[0088] At **1130**, extrude an anchor assembly from the delivery needle. The braided suture segment is slidably coupled to a flexible strand, from the delivery needle. The braided suture segment is extruded from the needle on the distal side of the tissue. The braided suture segment is pushout distally out of the needle by the first drive tube.

[0089] At **1140**, pull the flexible strand to deform the plurality of braided suture segment forming the anchor

assembly. As a result of the flexible strand being pulled tight, the first braided suture segment is deformed into a first braided anchor segment. The anchor assembly is configured to anchor an outside surface of the stomach wall to the outside surface of the internal organ wall, and prevent the anchor assembly from being pulled thru internal organ wall to the stomach wall.

[0090] At **1150**, withdraw the delivery needle from the tissue. The delivery needle is withdrawn from the tissue leaving behind the braided anchor segment on the distal side of the tissue. When the delivery needle is retracted, the anchor assembly is left on the distal side of the tissue, (e.g., organ wall) to fix the two tissues together.

[0091] At **1160**, determine if another anchor is to be deployed. A determination is made as to whether an additional braided anchor segment is required to fixate the tissue. If it is determined that an additional braided anchor segment is necessary to fixate the tissue, then the method returns to step **1110** to initiate placing an additional braided anchor segment on the distal side of the tissue. If it is determined that an additional braided anchor segment is not necessary to fixate the tissue, then the method advances to step **1170** to secure the flexible strand.

[0092] At **1170**, secure the flexible strand to keep the tissue fixated by the braided suture segment(s). The flexible strand (e.g., suture) is secured by engaging a locking mechanism (e.g., cinch) with the suture to lock the suture and prevent the fixated tissue from pulling apart.

[0093] At **1180**, cut the suture. The suture (e.g., flexible strand) is cut on the distal side of the locking mechanism after the flexible strand has been pulled taut and secured by the locking mechanism.

[0094] The embodiments of the invention described above are intended to be merely exemplary; numerous variations and modifications will be apparent to those skilled in the art. Such variations and modifications are intended to be within the scope of the present invention as defined by any of the appended claims.

What is claimed is:

1. An anchor assembly for fixation of a stomach wall to an internal organ wall, comprising:

a flexible strand; and

at least one braided anchor segment slidably coupled to the flexible strand, the flexible strand passing through a bore hole that traverses from a proximal end to a distal end of the at least one braided anchor segment;

wherein the at least one braided anchor segment is cinched forming an anchor assembly to provide tissue fixation.

2. The assembly of claim **1**, wherein the at least one braided anchor segment comprises a straight braided suture segment that has been deformed by application of tension on the flexible strand.

3. The assembly of claim **1**, wherein:

the at least one braided anchor segment comprises a plurality of braided anchor segments; and

the plurality of braided anchor segments is slidably coupled to the flexible strand, the flexible strand passing through a bore hole that traverses from a proximal end to a distal end of each of the plurality of the braided anchor segments such that the proximal end of the first braided anchor segment is adjacent to a distal end of a second braided anchor segment.

4. The assembly of claim **1**, wherein the flexible strand comprises a suture.

5. The assembly of claim **4**, wherein the suture comprises a braided polyester suture.

6. The assembly of claim **3**, wherein each of the plurality of braided anchor segments comprise standard braided polyester suture that is cut into predetermined lengths.

7. The assembly of claim **3**, wherein the cinched plurality of braided anchor segments has a purse string effect on the plurality of braided anchor segments such that the plurality of flexible braided anchor segments is drawn together to provide tissue fixation.

8. A method for implanting an anchor assembly connected via a single flexible strand for fixation of a stomach wall to an internal organ wall, comprising:

puncturing an inside surface of the stomach wall tissue at a first location with a delivery needle;

puncturing an outside surface of the internal organ wall at a second location with the delivery needle;

extruding an anchor assembly from the delivery needle, the anchor assembly comprising:

the single flexible strand; and

a plurality of braided anchor segments slidably coupled to the single flexible strand, the single flexible strand passing through a bore hole that traverses from a proximal end to a distal end of each of the plurality of braided anchor segments such that the proximal end of a first braided anchor segment is adjacent to a distal end of a second braided anchor segment;

pulling the flexible strand a first time to deform the plurality of braided anchor segments forming the anchor assembly, the anchor assembly configured to: anchor an outside surface of the stomach wall to the outside surface of the internal organ wall; and prevent the anchor assembly from being pulled thru internal organ wall to the stomach wall;

withdrawing the delivery needle from the stomach wall and the internal organ wall;

securing the flexible strand to keep the stomach wall anchored to the internal organ wall fixated by the anchor assembly; and

cutting the flexible strand, the flexible strand is cut a distance away from the proximal end of a final braided anchor segment of the plurality of the braided anchor segments.

9. The method of claim **8**, wherein the extruding the anchor assembly is accomplished by advancing a drive tube to push the plurality of braided anchor segments out of the delivery needle.

10. The method of claim **8**, wherein:

the plurality of braided anchor segments comprises a slip knot placed around the flexible strand at the proximal end of the proximal braided anchor segment; and

the securing the flexible strand comprises locking the flexible strand in place using a locking mechanism comprising at least one of a tag, a barb, a cinch, a toggled needle, or a distel knot.

11. The method of claim **8**, wherein the securing the flexible strand comprises a locking device or an overhand knot that can be run down to a fixation site.

12. The method of claim **8**, wherein puncturing the outside surface of the internal organ wall at the second

location with the delivery needle follows continuously from puncturing the inside surface of the stomach wall tissue at the first location with the same delivery needle.

13. A surgical device for implanting a flexible braided anchor assembly for affixing a stomach wall to an internal organ wall, comprising:

a handle assembly, the handle assembly having a cylindrical bore passing through the handle assembly on a center axis along a length of the handle assembly;

a delivery needle positioned in the cylindrical bore of the handle assembly, the delivery needle being hollow and having a common center line with the cylindrical bore of the handle assembly, the delivery needle comprising an outer tube having a needle tip at a distal end of the delivery needle;

at least one braided suture segment slidably coupled to a flexible strand, the flexible strand being translationally threaded through of the at least one braided suture segment, the at least one braided suture segment positioned in the delivery needle;

a first drive tube positioned in the delivery needle and having a common center line with the delivery needle, the first drive tube configured to extrude the at least one braided suture segment.

14. The surgical device of claim **13**, wherein the at least one braided suture segment comprises a hollow braided suture segment.

15. The surgical device of claim **13**, wherein:

the flexible strand comprises a monofilament strand;

the at least one braided anchor segment comprises a plurality of braided anchor segments;

the plurality of braided anchor segments is slidably coupled to the flexible strand, the flexible strand passing through a bore hole that traverses from a proximal end to a distal end of each of the plurality of the braided anchor segments such that the proximal end of the first braided anchor segment is adjacent to a distal end of a second braided anchor segment; and

the plurality of braided suture segments comprises a plurality of hollow braided suture segments aligned end to end having the monofilament strand threaded through the aligned plurality of hollow braided suture segments.

16. The surgical device of claim **15**, wherein a column strength of the plurality of hollow braided suture segments is increased by application of at least one of heat or a cyanoacrylate coating to each of the segments of the plurality of hollow braided suture segments.

17. The surgical device of claim **15**, wherein a braided suture segment of the plurality of braided suture segments has a length of between about 5 mm and about 50 mm.

18. The surgical device of claim **15**, wherein each of the braided suture segments of the plurality of braided suture segments has a length of between about 5 mm and about 12 mm.

19. The surgical device of claim **16**, wherein a distal end of the flexible strand threaded thru the first braided suture segment is looped around the first braided suture segment and knotted around the flexible strand between the first braided suture segment and the first drive tube.

20. The surgical device of claim **15**, wherein each of the plurality of braided suture segments is treated to increase a rigidity of the plurality of braided suture segments slidably coupled to the flexible strand.

21. The surgical device of claim **20**, wherein the treatment comprises:

heating each of the plurality of braided suture segments; or

applying a cyanoacrylate coating to each of the plurality of braided suture segments.

22. The surgical device of claim **13**, wherein the stomach comprises a duodenum.

23. A method for implanting an anchor assembly connected via a single flexible strand through a drain tube placed from the outside of a body for fixation of a gall bladder wall to a stomach wall, comprising:

puncturing an inside surface of the gall bladder wall tissue at a first location with a delivery needle, the delivery needle being brought into the interior of the gall bladder through a drain tube placed between outside of the body and the gall bladder;

puncturing an outside surface of the stomach wall at a second location with the delivery needle;

extruding an anchor assembly from the delivery needle, the anchor assembly comprising:

the single flexible strand; and

at least one braided anchor segment slidably coupled to the single flexible strand, the single flexible strand passing through a bore hole that traverses from a proximal end to a distal end of the at least one braided anchor segment;

pulling the flexible strand a first time to deform the at least one braided anchor segment forming the anchor assembly, the anchor assembly configured to: anchor an inside surface of the stomach wall to the outside surface of the gall bladder wall; and prevent the anchor assembly from being pulled thru the stomach wall to the gall bladder wall;

withdrawing the delivery needle from the stomach wall and the gall bladder wall;

securing the flexible strand to keep the stomach wall anchored to the gall bladder wall fixated by the anchor assembly; and

cutting the flexible strand, the flexible strand is cut a distance away from the proximal end of the at least one braided anchor segments.

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