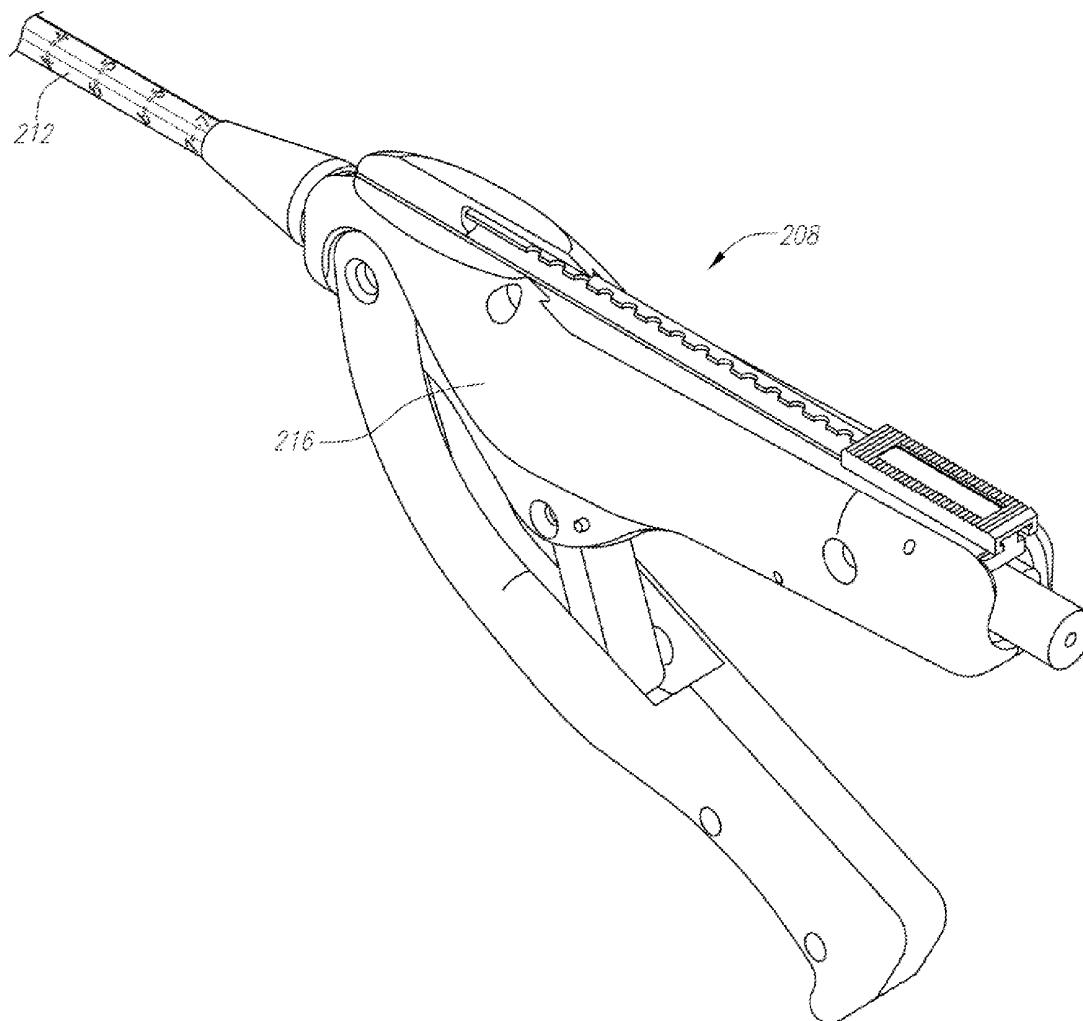




US 20110208209A1

(19) **United States**(12) **Patent Application Publication**
EWERS et al.(10) **Pub. No.: US 2011/0208209 A1**(43) **Pub. Date: Aug. 25, 2011**(54) **DEVICES AND METHODS FOR
LAPAROSCOPIC GASTRIC TISSUE
RECONFIGURATION****Publication Classification**(51) **Int. Cl.**
A61B 17/10 (2006.01)(52) **U.S. Cl.** **606/139**(75) Inventors: **Richard C. EWERS**, Fullerton, CA
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CA (US); **Tracy D. MAAHS**, Yorba
Linda, CA (US); **Stuart MORAN**,
San Clemente, CA (US); **Cang C.**
LAM, Tustin, CA (US)(73) Assignee: **USGI Medical, Inc.**, San Clemente,
CA (US)(21) Appl. No.: **13/033,485**(22) Filed: **Feb. 23, 2011****Related U.S. Application Data**(60) Provisional application No. 61/307,376, filed on Feb.
23, 2010.(57) **ABSTRACT**

Devices and methods for forming and securing tissue folds and elongated invaginations in gastric tissue are used as a treatment for obesity. In several embodiments, a plurality of tissue folds is formed along the greater curvature of the stomach using laparoscopic tissue anchor deployment devices. Additional embodiments include various combinations of tissue folds, elongated invaginations, and other reconfigurations of stomach tissue using laparoscopic devices or laparoscopic devices in combination with endoscopic devices.



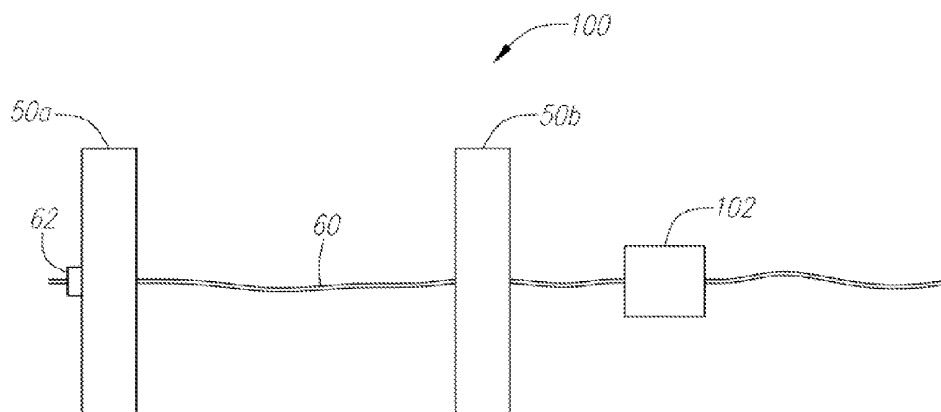


FIG. 1

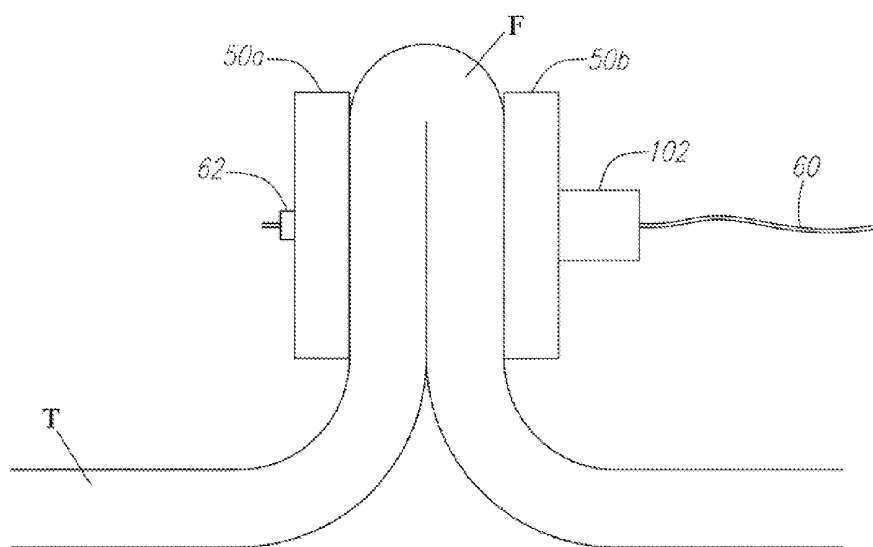


FIG. 2

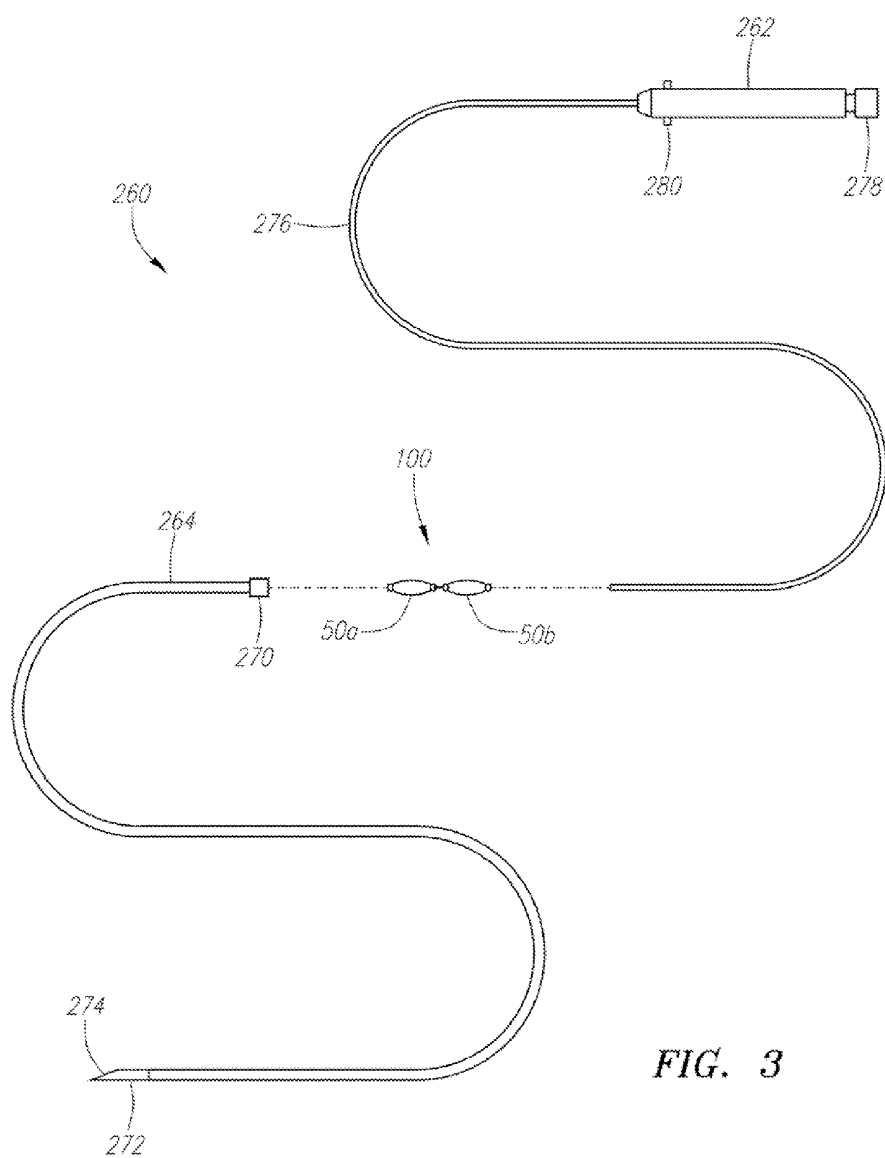


FIG. 3

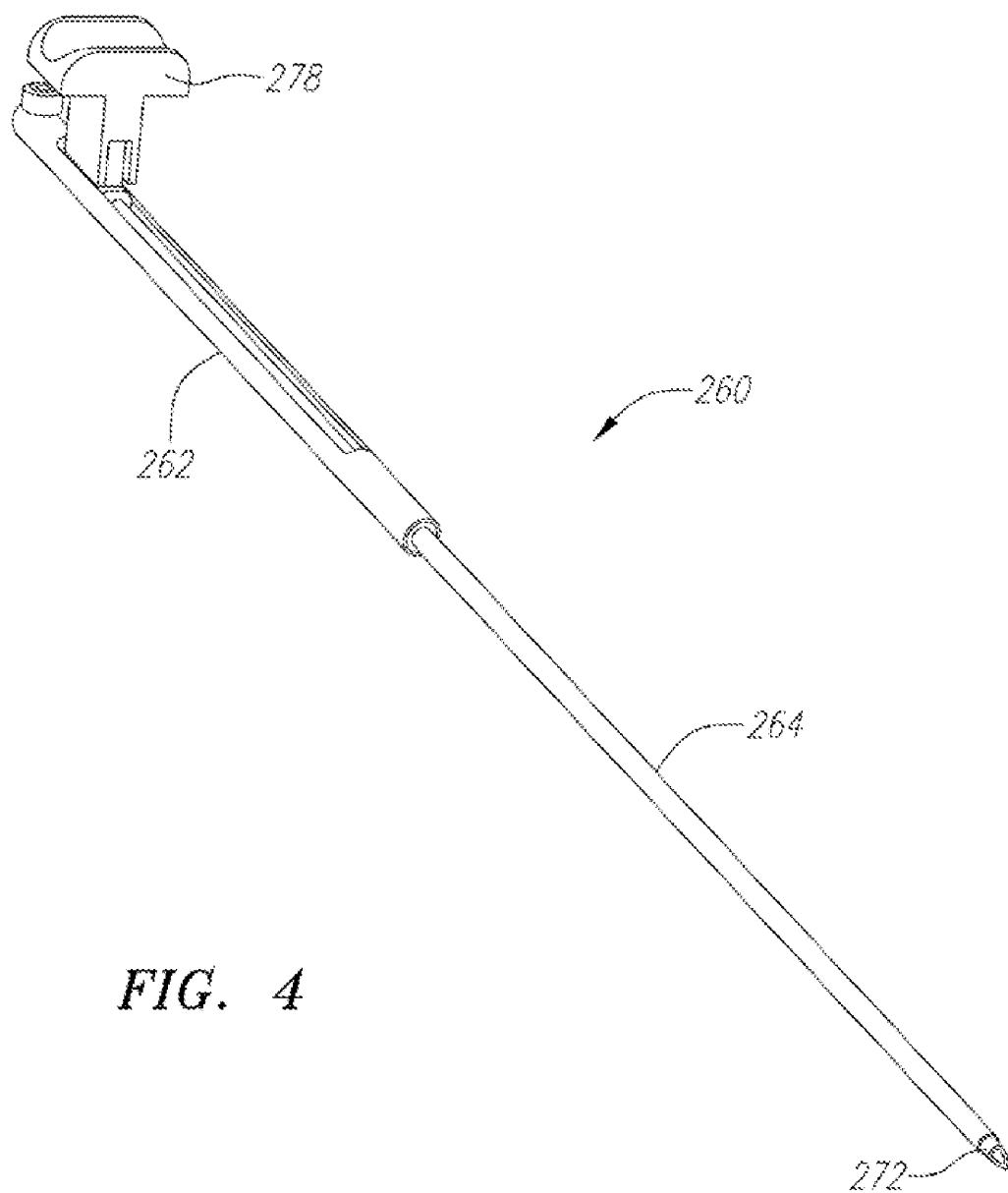
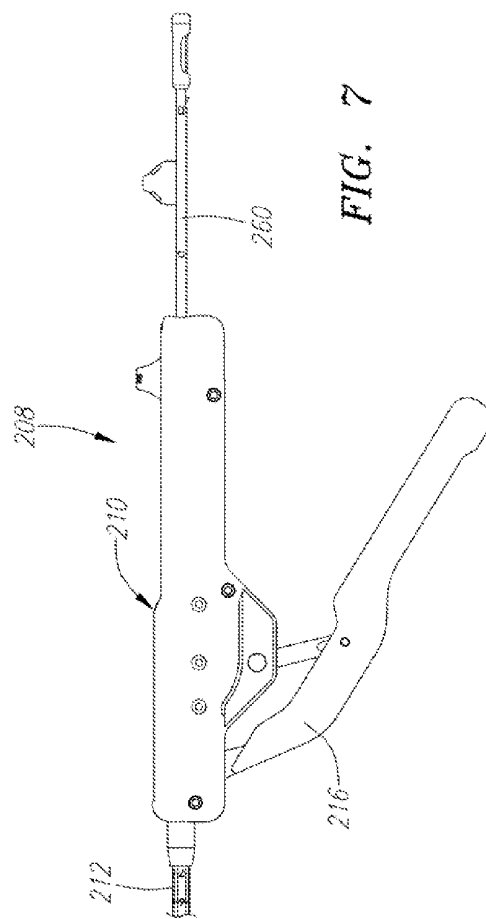
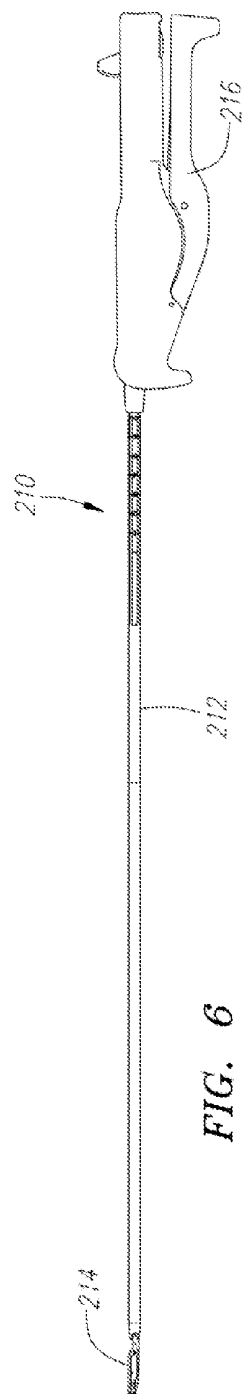
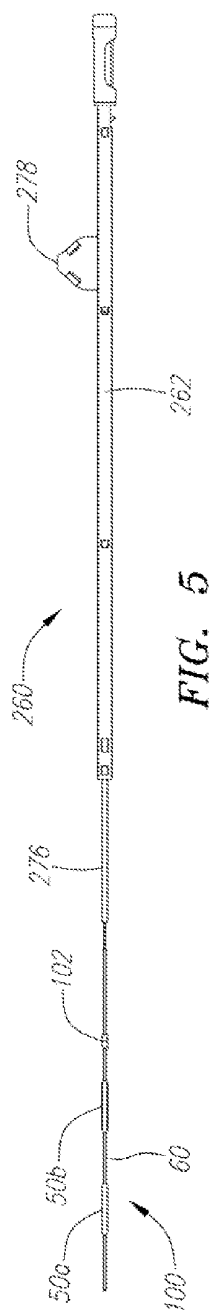
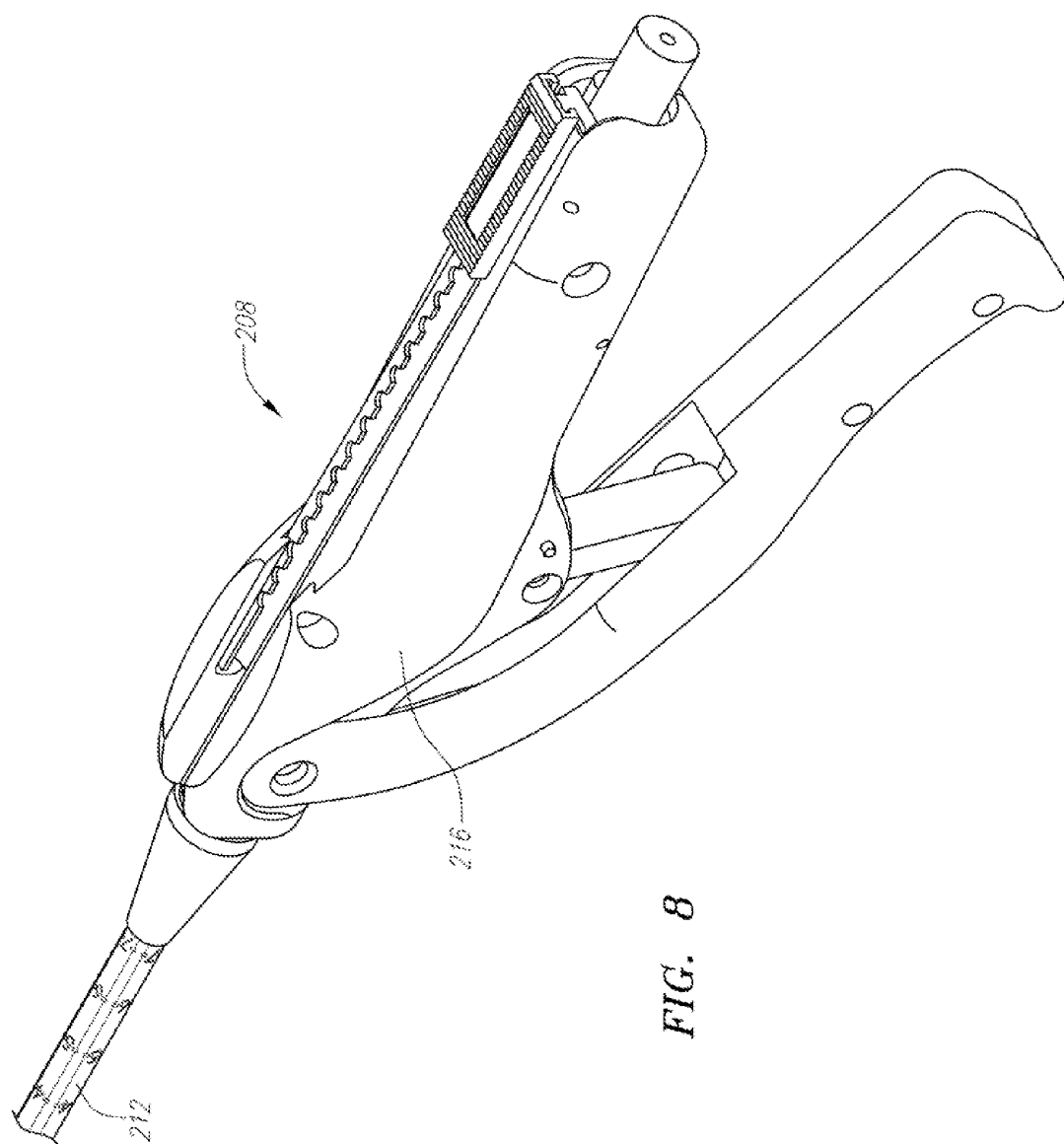


FIG. 4





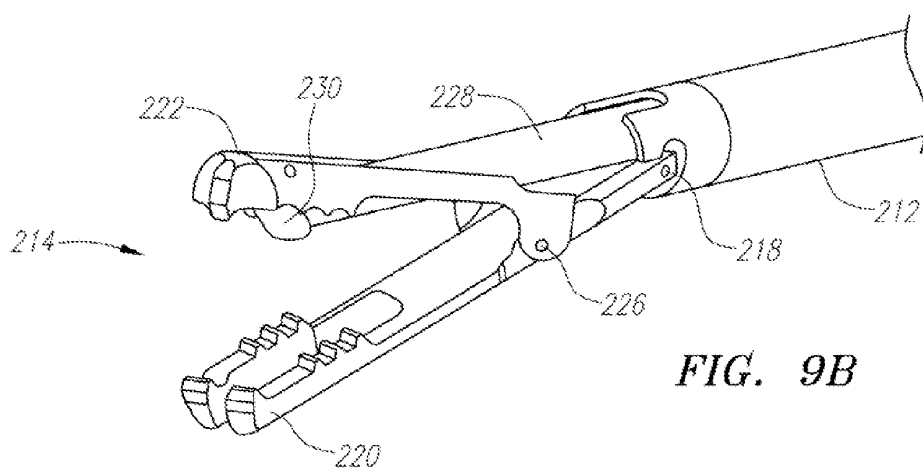
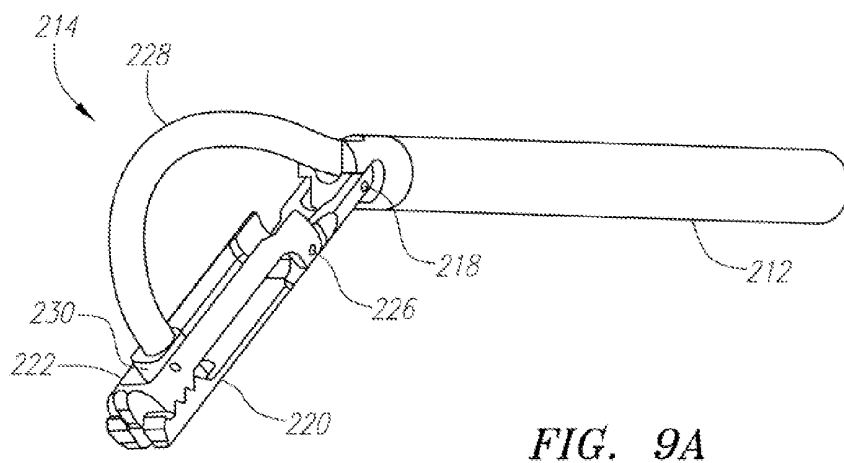


FIG. 9C

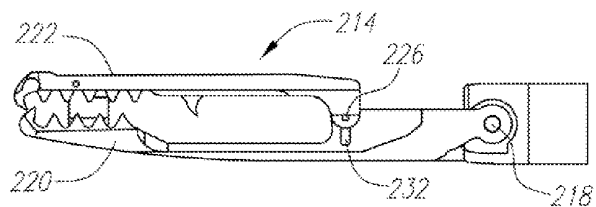


FIG. 9D

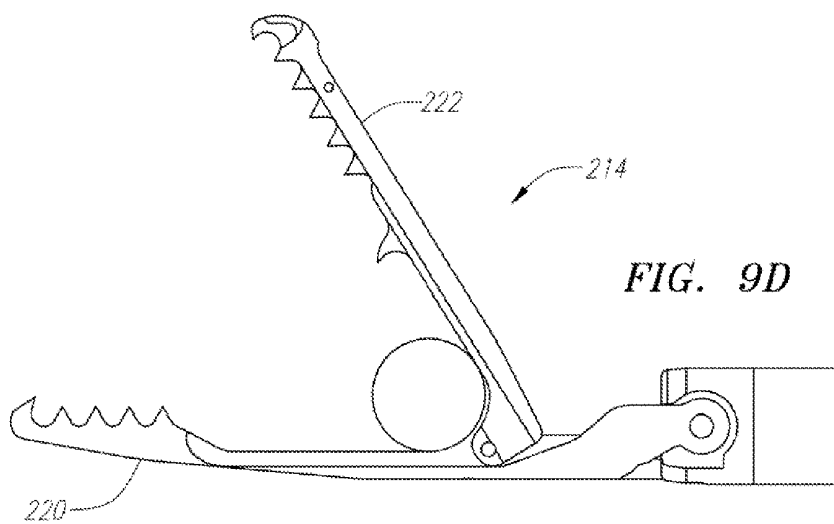
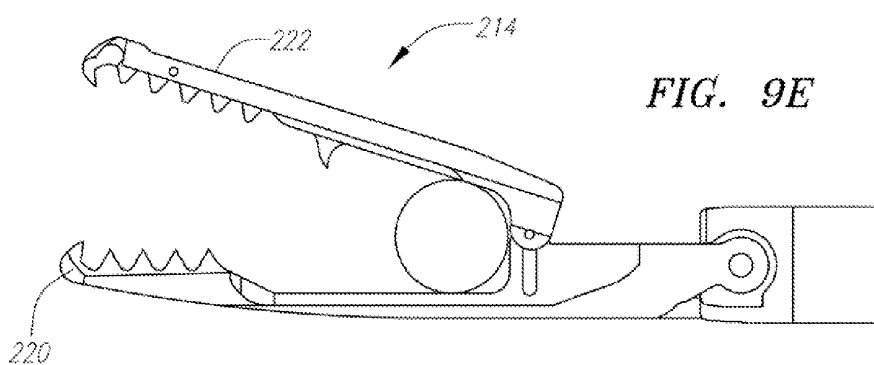
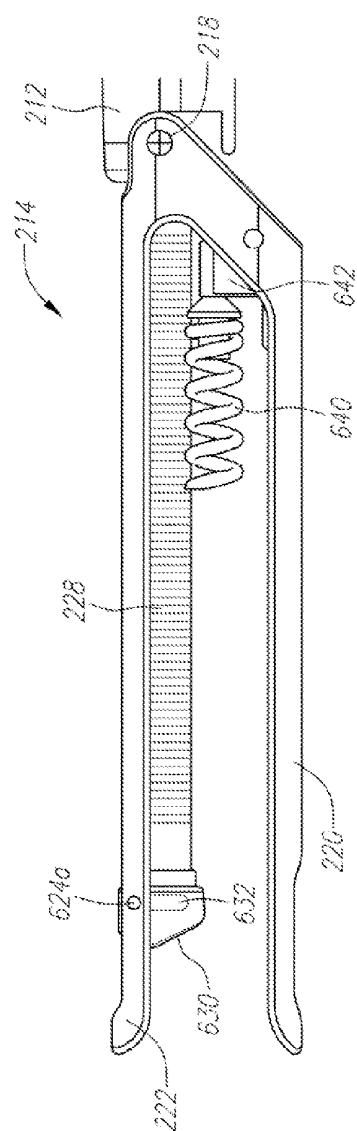
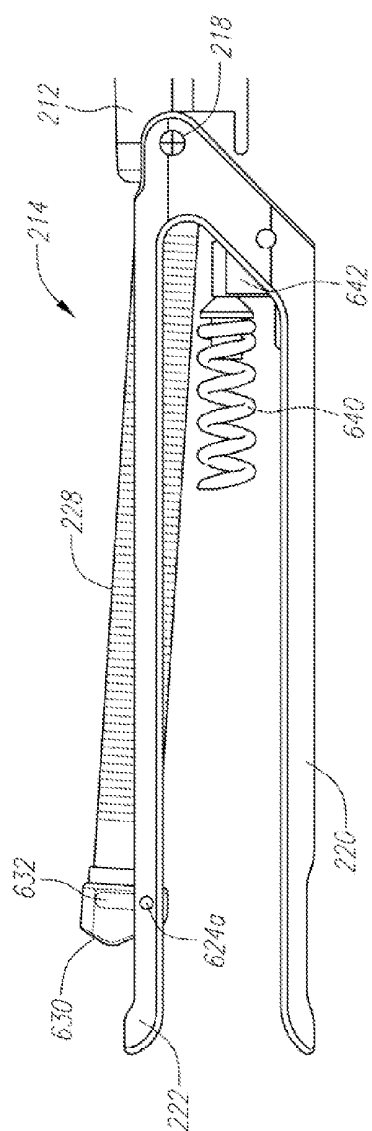


FIG. 9E





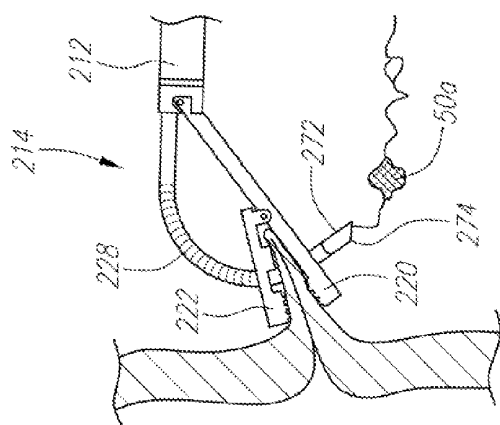


FIG. 10

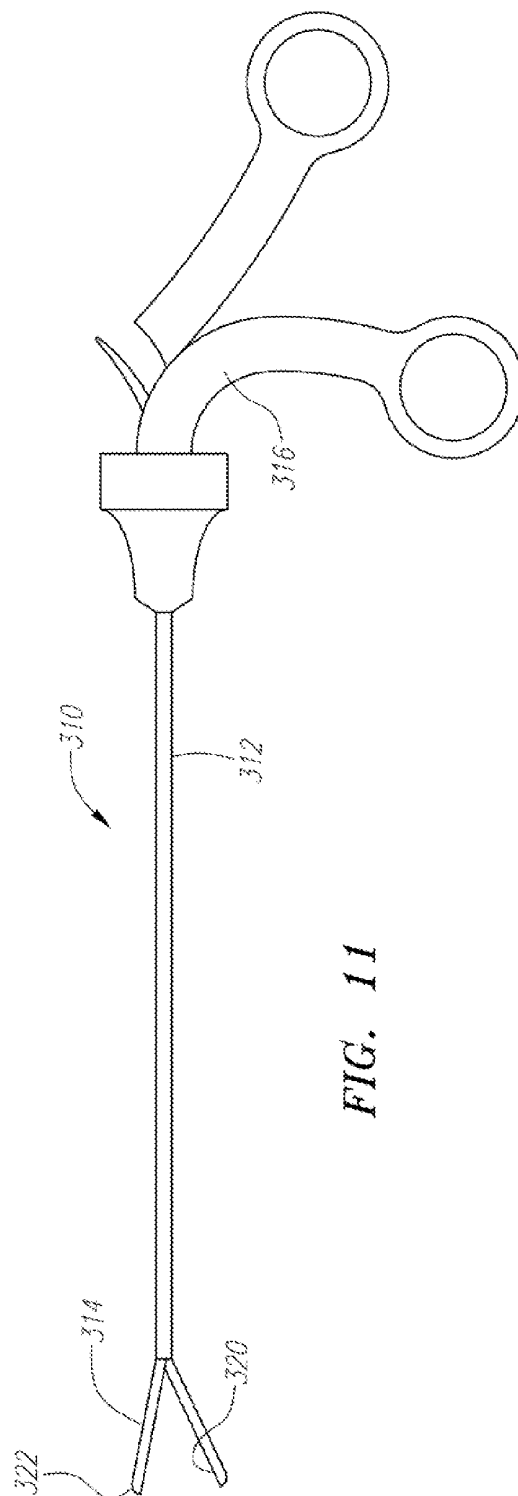
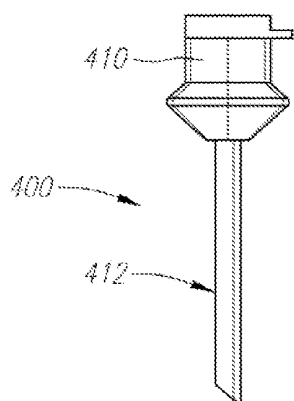
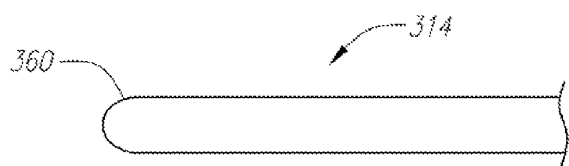
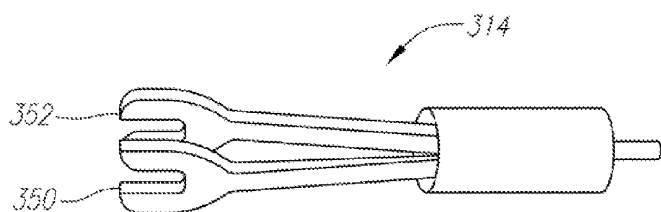
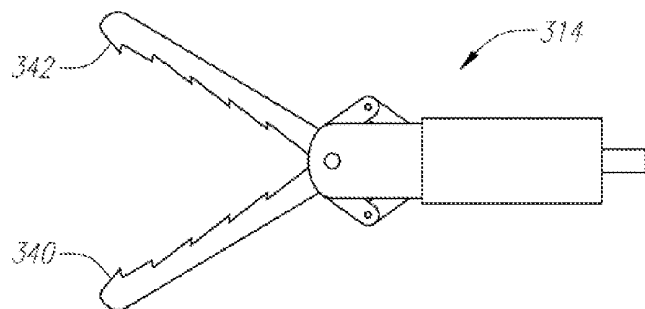
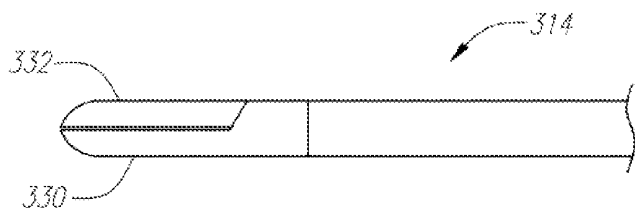


FIG. 11



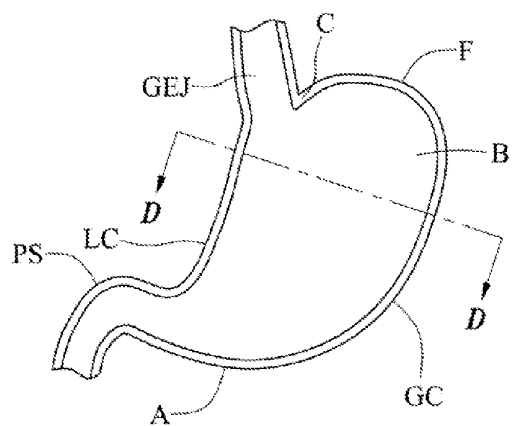


FIG. 14

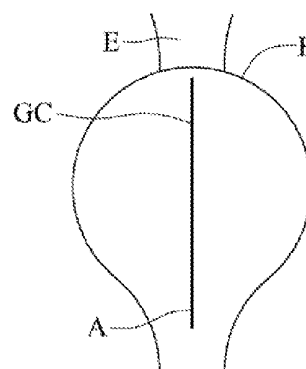


FIG. 15

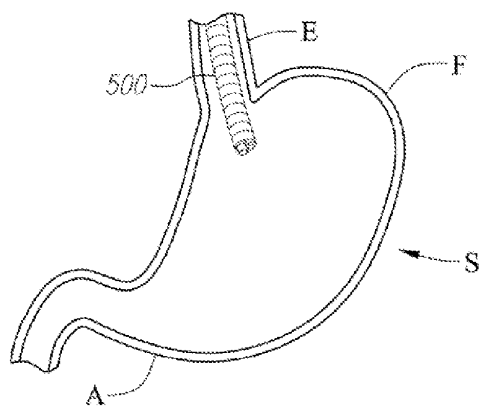


FIG. 16

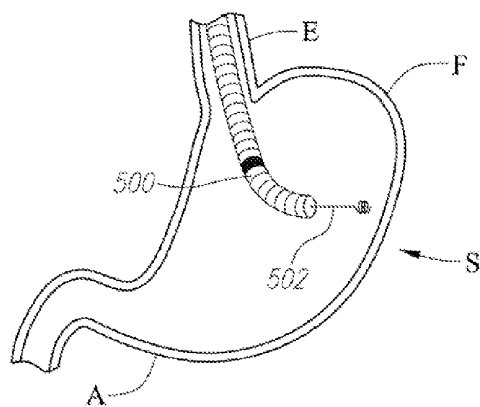


FIG. 17

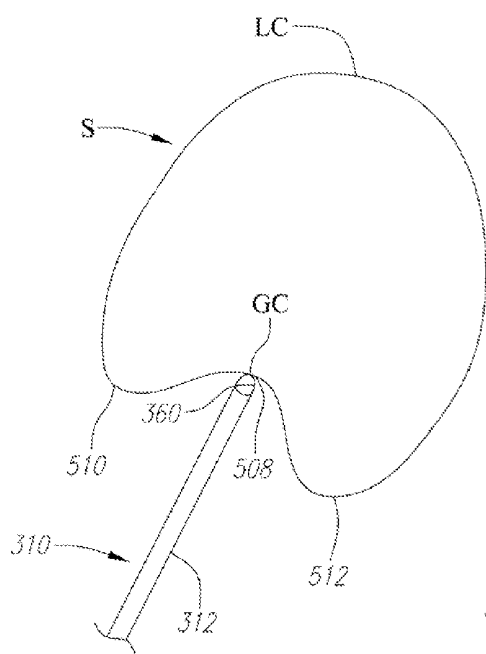


FIG. 18

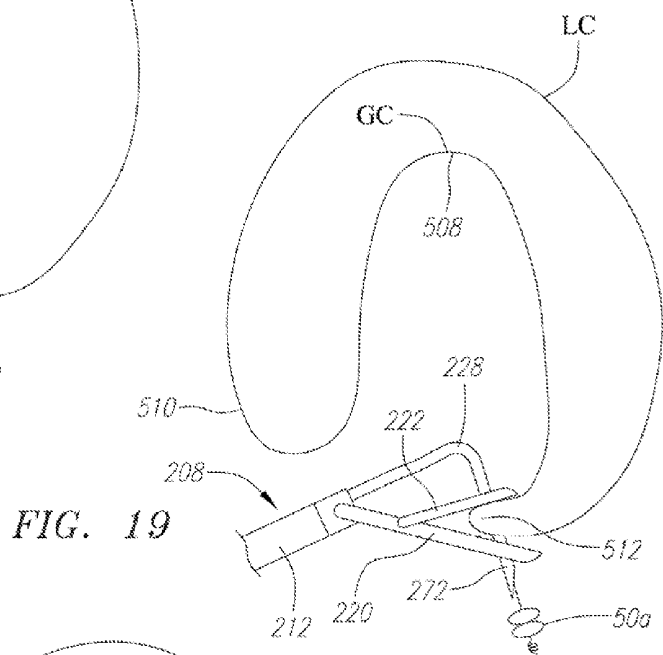


FIG. 19

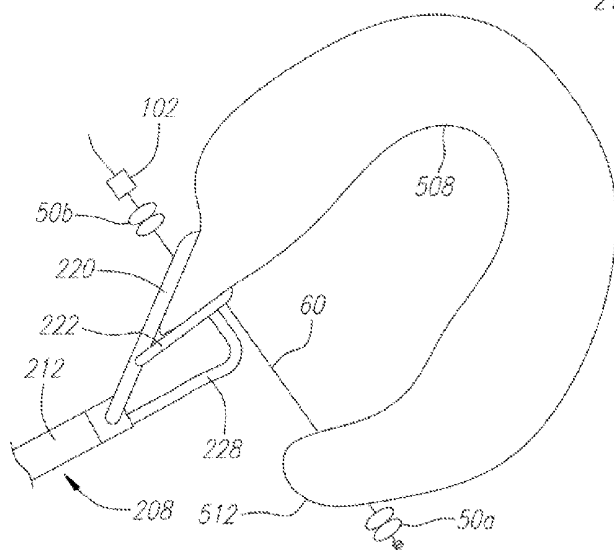


FIG. 20

FIG. 21

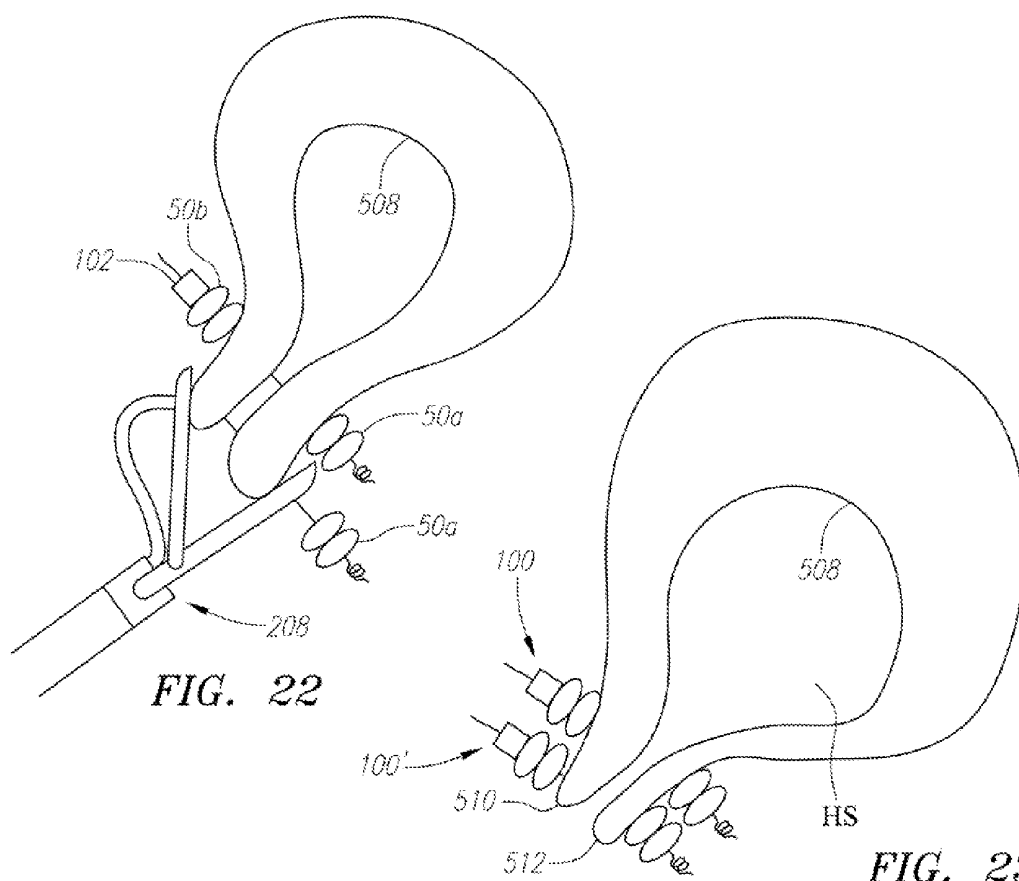
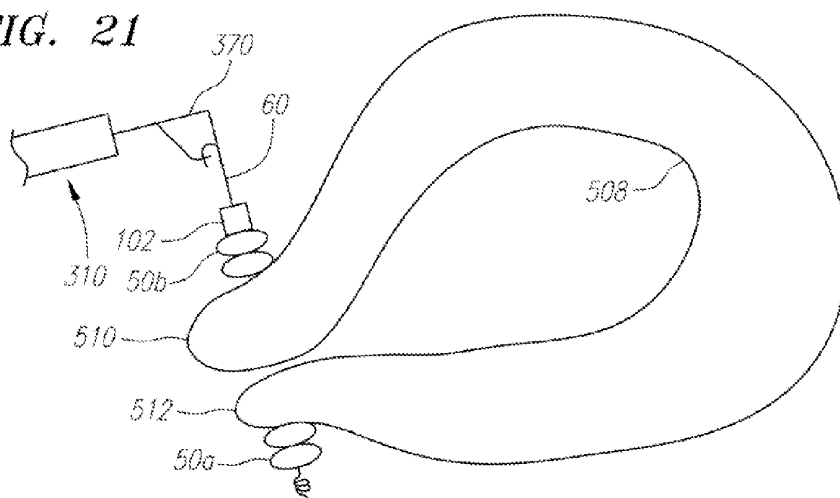


FIG. 23

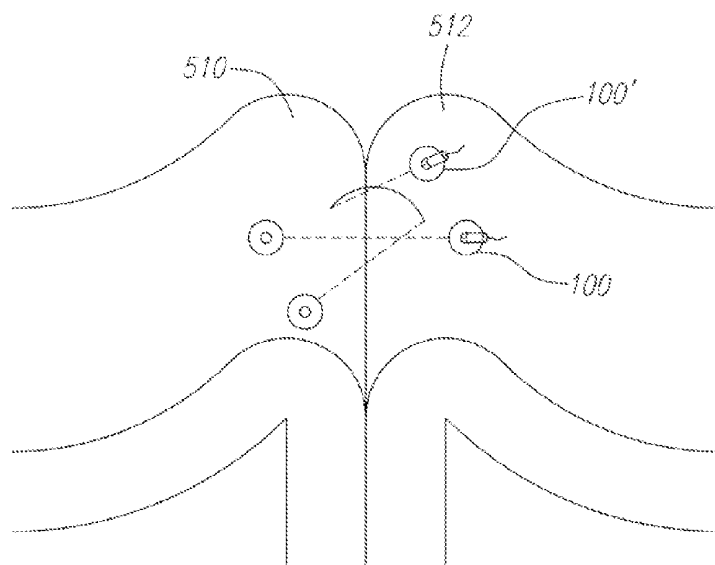


FIG. 24

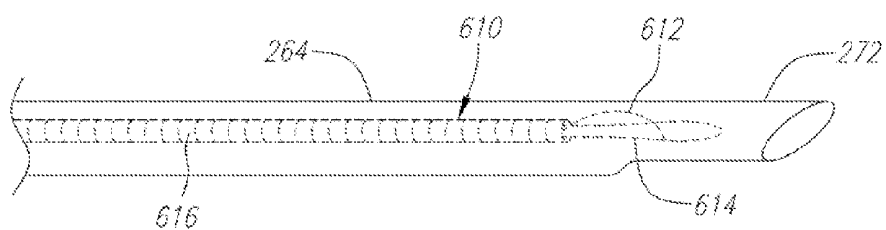


FIG. 25A

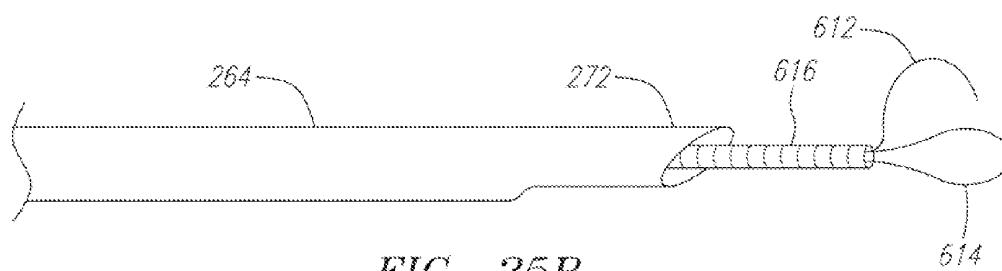
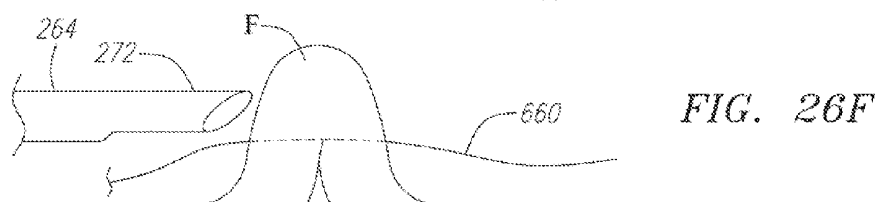
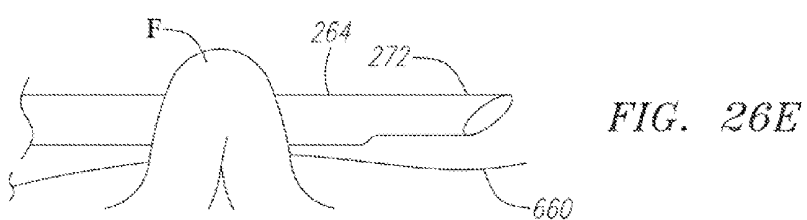
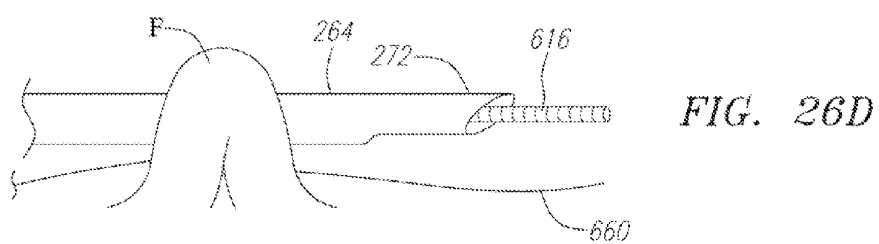
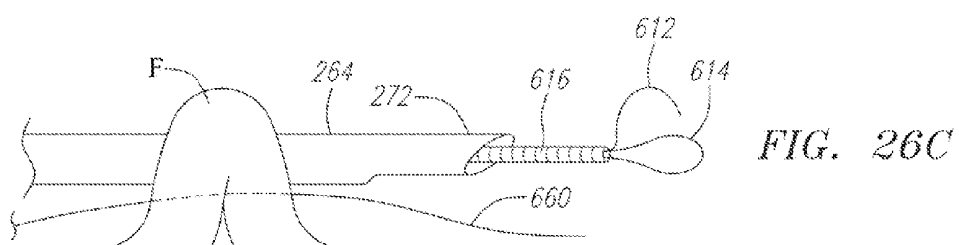
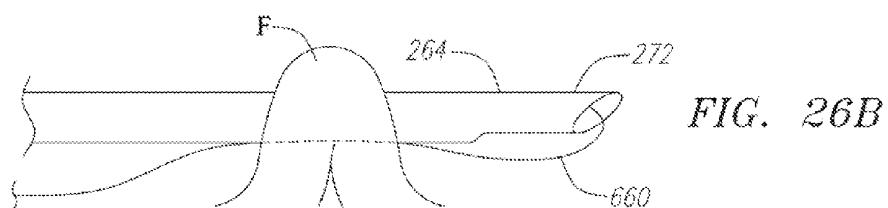
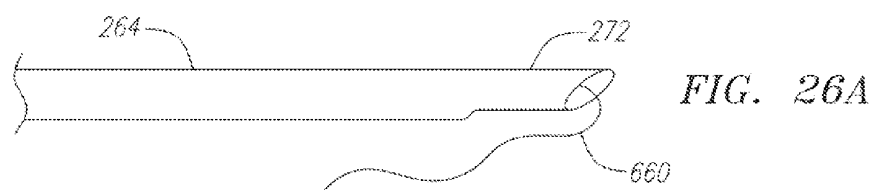


FIG. 25B



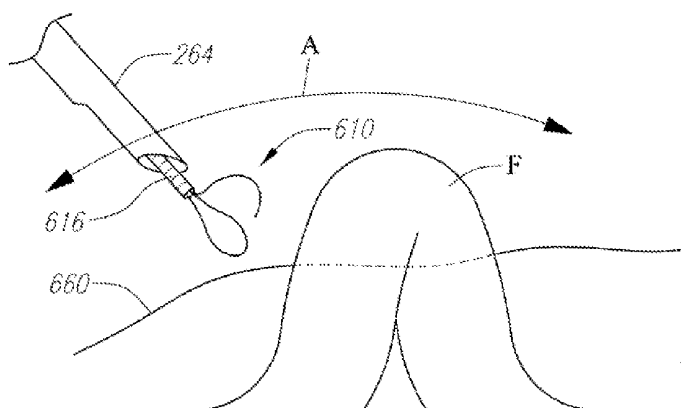


FIG. 26G

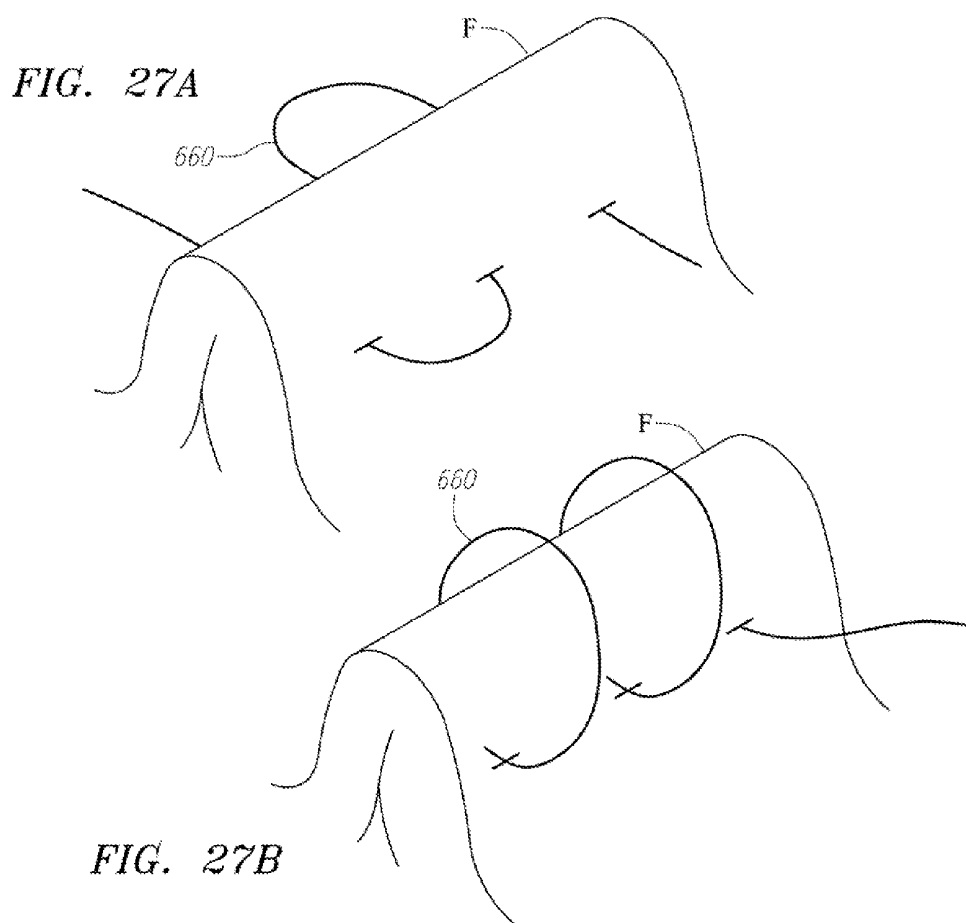
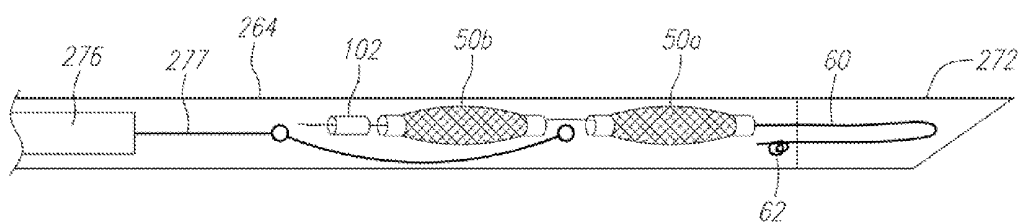
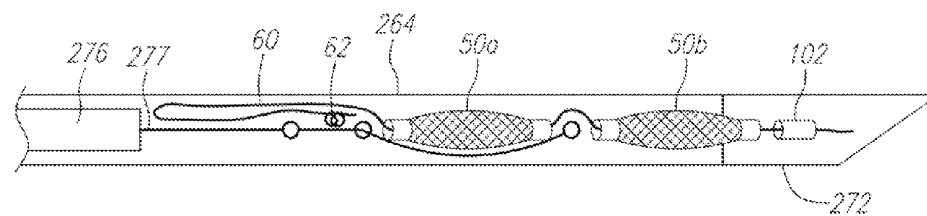
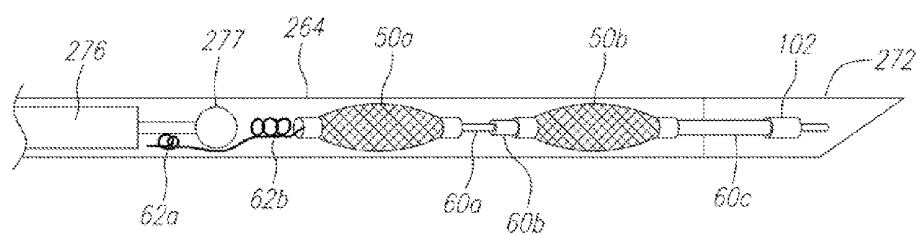
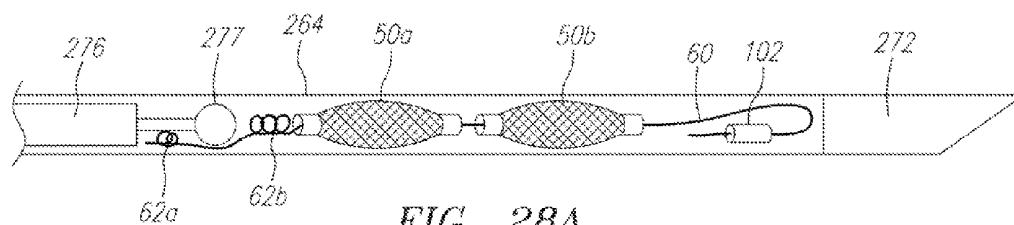
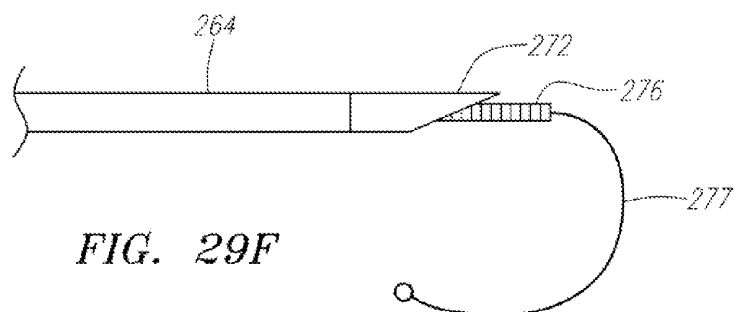
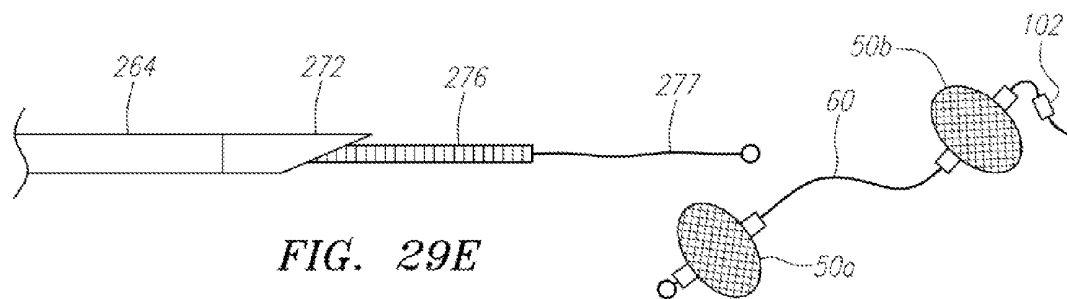
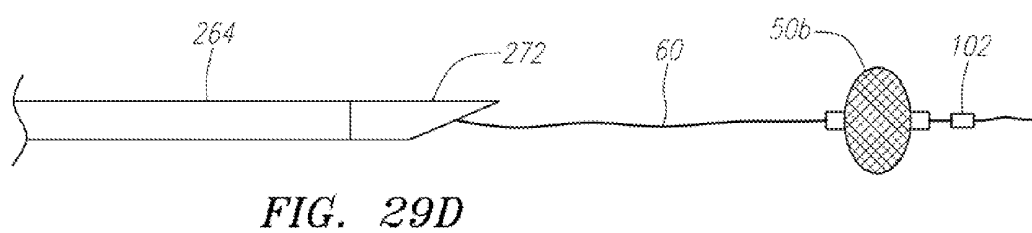
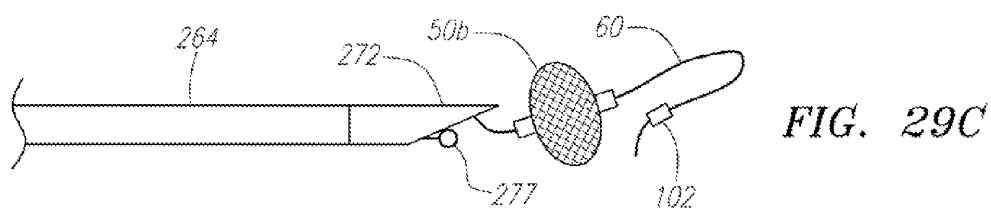
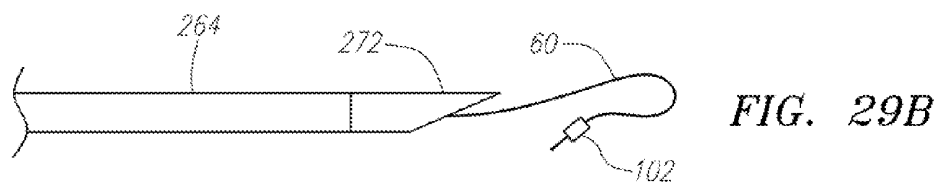
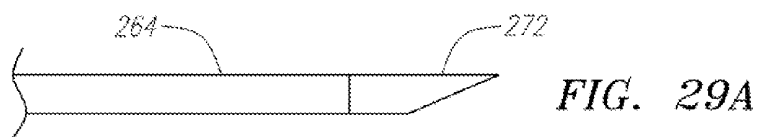


FIG. 27B





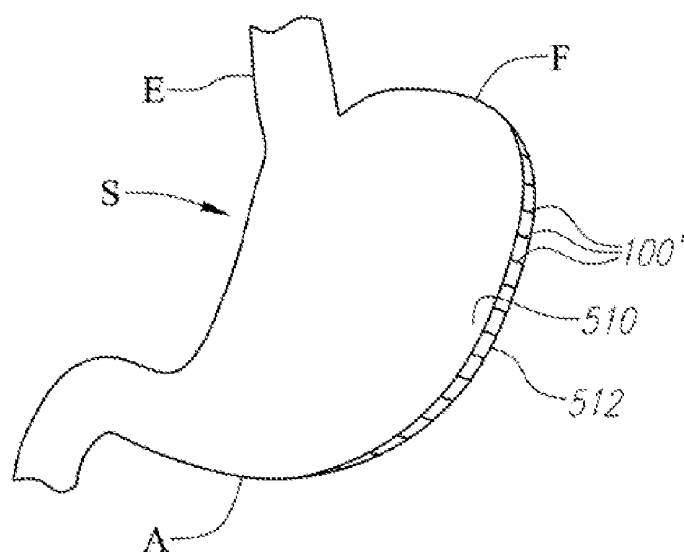


FIG. 30A

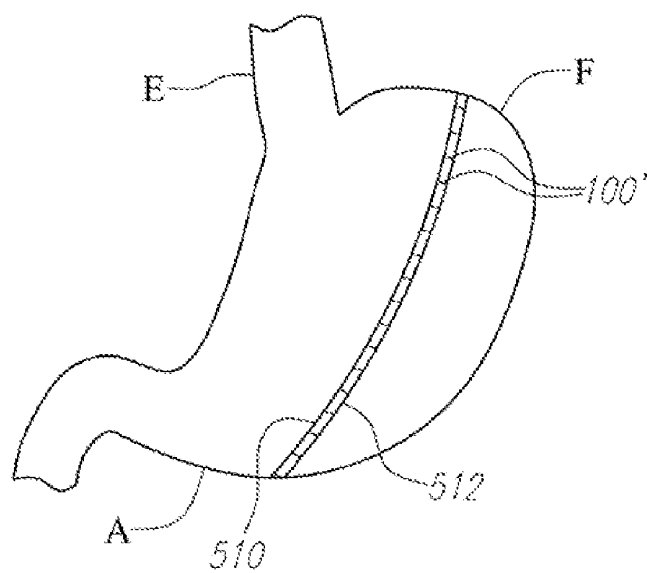
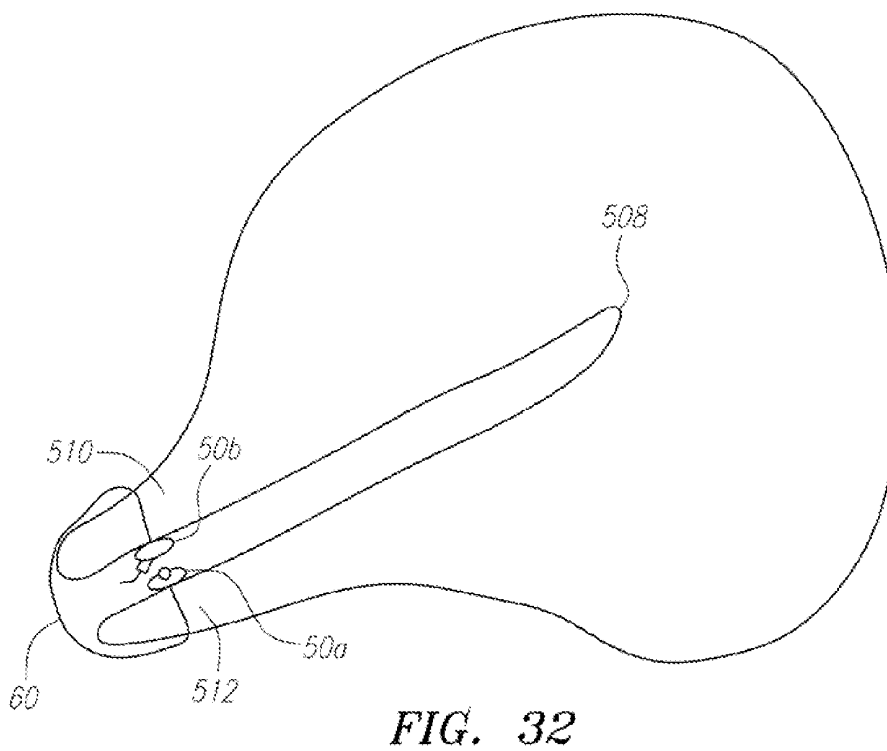
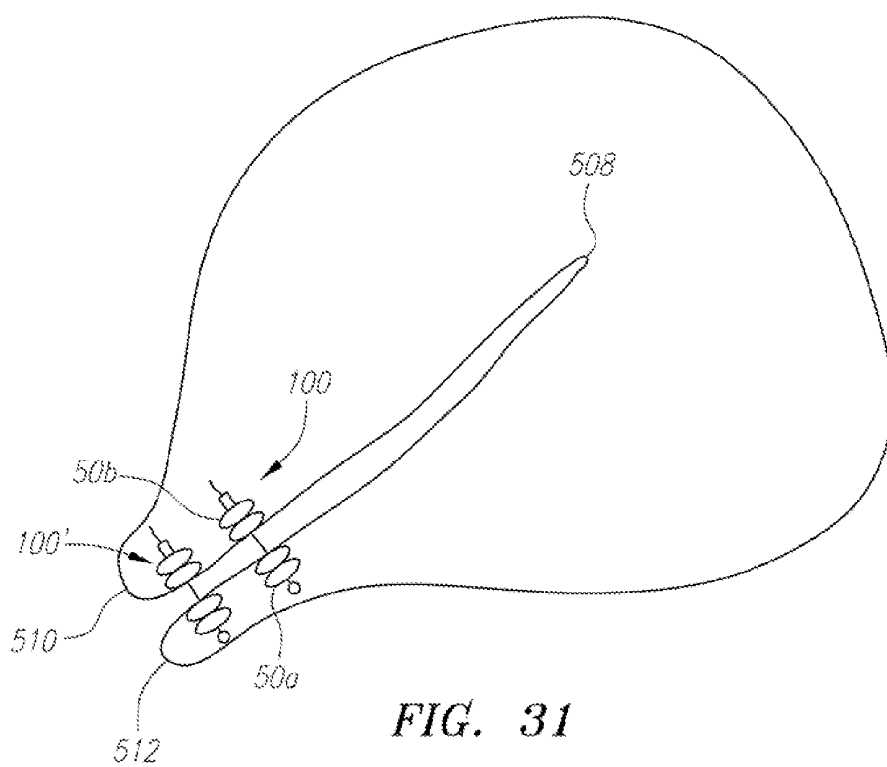


FIG. 30B



DEVICES AND METHODS FOR LAPAROSCOPIC GASTRIC TISSUE RECONFIGURATION

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority to U.S. Provisional Patent Application No. 61/307,376, filed on Feb. 23, 2010, the contents of which are incorporated herein by reference in their entirety. This application also relates to U.S. Provisional Patent Application Ser. No. 61/239,709, filed on Sep. 3, 2009, U.S. Provisional Patent Application Ser. No. 61/432,537, filed Jan. 13, 2011, U.S. patent application Ser. No. 12/409,335, filed on Mar. 23, 2009, U.S. patent application Ser. No. 12/486,578, filed on Jun. 17, 2009, and U.S. patent application Ser. No. 12/876,029, filed Sep. 3, 2010, the contents of each of which are incorporated herein by reference in their entirety.

BACKGROUND

[0002] The present disclosure pertains to devices and methods for laparoscopic gastric tissue reconfiguration. More particularly, the present disclosure relates to devices and methods for laparoscopically manipulating stomach tissue, forming and securing tissue folds, forming and securing tissue invaginations, altering stomach tissue configuration, restricting the ability of stomach tissue to distend, altering the function of nerves located in or near stomach tissue, and/or altering hormone production from cells associated with stomach tissue. The devices and methods described herein have particular application to methods and treatments for obesity.

[0003] The National Institutes of Health (NIH) estimate that about two-thirds of adults—133.6 million people—in the U.S. are overweight or obese, while almost 5% of adults—15 million Americans—are considered extremely obese. Obese adults are at increased risk of type II diabetes, hypertension, stroke, certain cancers, and other dangerous conditions.

[0004] The NIH estimates that being overweight or obese leads to \$117 billion in medical spending a year, with \$61 billion in direct costs and \$56 billion in indirect costs.

[0005] As obesity rates continue to rise, patients are increasingly seeking surgical weight loss options. Bariatric surgery aids weight loss by restricting food intake and, in some operations, altering the digestive process. The Roux-en-Y Gastric Bypass Procedure (RYGBP) is the most commonly performed bariatric procedure, estimated to account for approximately 65% of weight loss surgeries performed in the U.S.

[0006] A study from the Agency for Healthcare Research and Quality (AHRQ) found that the number of bariatric surgeries grew by 400 percent between 1998 and 2002. In 2007, an estimated 205,000 people with morbid obesity in the U.S. underwent bariatric surgery and these numbers are expected to grow. Only 1% of the clinically eligible population is currently being treated for morbid obesity through bariatric surgery.

[0007] A major retrospective study published in the New England Journal of Medicine showed that gastric bypass reduced the risk of death in extremely obese patients by over 40% by lowering the incidence of diabetes, coronary artery disease and cancer.

[0008] The Roux-en-Y gastric bypass procedure involves creating a small stomach pouch out of a portion of the stom-

ach and attaching it directly to the jejunum, bypassing a large part of the stomach and duodenum. The stomach is made very small to restrict the amount of food that can be consumed. The opening between the stomach pouch and the small intestine (called the stoma) is also made very small to slow the passage of food from the stomach. These restrictions help the patient feel full and limit the amount of food that can be eaten. In addition, by altering the path of the intestines, consumed food bypasses the duodenum so fat absorption is substantially reduced.

[0009] The RYGB procedure is performed either laparoscopically or in an open surgery. Alternative procedures for obtaining some or all of the benefits of the RYGB procedure with fewer of the associated complications, risks, limitations, and costs would be preferred.

SUMMARY

[0010] In a first aspect, laparoscopic treatment of obesity includes a number of methods and devices. The devices are introduced laparoscopically (e.g., via one or more trocars, etc.) into the patient's body and into the peritoneal cavity to approach the exterior of the stomach at or near the greater curvature. The stomach is then mobilized by dissecting the connecting tissue (e.g., greater omentum) attached to the stomach. Once the instruments are positioned near the exterior of the greater curvature of the stomach, the external tissue of the stomach is temporarily engaged and/or grasped and the engaged tissue is manipulated by a surgeon or practitioner from outside the patient's body.

[0011] In engaging, manipulating, and/or securing the tissue, various methods and devices may be implemented. For instance, tissue securement devices may be delivered and positioned through the abdominal wall via one or more trocars. The tissue securement devices include end effectors suitable for contacting the exterior stomach wall, manipulating stomach tissue, creating one or more tissue folds, and/or deploying one or more tissue anchors through the tissue fold(s). The tissue anchor(s) extending on a connecting member (e.g., a suturing element) may be disposed through at least the serosa layers of the stomach wall. A tissue manipulation assembly positioned at the distal end of a tissue securement device may be used for engaging the tissue and deploying the tissue anchor to secure the tissue with the tissue anchor. A second tissue anchor may then be deployed in a second tissue fold, after which the tissue folds are brought into apposition by decreasing the length of the connecting member extending between the two tissue anchors. In some embodiments, this is done by advancing an uni-directional cinching element along the connecting member.

[0012] In some embodiments, the foregoing method is repeated at a plurality of locations along the greater curvature of the stomach extending between the fundus and the antrum to thereby form an extended invagination of the stomach. This extended invagination has as one effect the reduction of stomach volume.

[0013] In some embodiments, an endoscope or other device is advanced through a patient's mouth and esophagus and into the patient's stomach. The endoscope is used to provide visualization, insufflation, and/or other functional features desired by the user. One or more endoscopic instruments may be advanced through a working channel of the endoscope or other access device and extended from a distal end thereof to assist with the laparoscopic methods described above.

[0014] In some embodiments, the extended invagination is located substantially along the greater curvature of the stomach. In other embodiments, the extended invagination is located substantially on the anterior wall of the stomach. In still other embodiments, two or more extended invaginations are formed in the body region of the stomach along the greater curvature, the anterior wall, and/or the posterior wall.

[0015] In alternative embodiments, various combinations of tissue folds, extended invaginations, and other tissue reconfigurations are formed and secured at selected regions of the stomach. The tissue folds, invaginations, and other reconfigurations have the effects of reducing stomach volume, inhibiting distention of stomach tissue, more effectively and more quickly forcing food distally to the antrum, and/or favorably altering the nerve function and/or hormone production of stomach tissue to thereby create signals of satiety.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] FIG. 1 is a schematic representation of a tissue anchor assembly.

[0017] FIG. 2 is a schematic representation of a tissue anchor assembly securing a tissue fold.

[0018] FIG. 3 is an exploded view of a first embodiment of an anchor deployment catheter.

[0019] FIG. 4 is a perspective view of a second embodiment of an anchor deployment catheter.

[0020] FIG. 5 is a side view of a third embodiment of an anchor deployment catheter.

[0021] FIG. 6 is a side view of a laparoscopic tissue manipulation and anchor deployment device.

[0022] FIG. 7 is a side view of a first embodiment of a handle portion of the laparoscopic tissue manipulation and anchor deployment device of FIG. 6.

[0023] FIG. 8 is a perspective view of second embodiment of a handle portion of the laparoscopic tissue manipulation and anchor deployment device of FIG. 6.

[0024] FIGS. 9A through 9G are perspective and side views of embodiments of end effectors of the laparoscopic tissue manipulation and anchor deployment device of FIG. 6.

[0025] FIG. 10 is a side view of the distal end effector of an embodiment of the laparoscopic tissue manipulation and anchor deployment device of FIG. 6 deploying a tissue anchor assembly through a tissue fold.

[0026] FIG. 11 is a side view of a laparoscopic instrument.

[0027] FIGS. 12A through 12D are side views of alternative end effectors for the laparoscopic instrument of FIG. 11.

[0028] FIG. 13 is a side view of a trocar.

[0029] FIG. 14 is a cross-sectional anterior side view of a human stomach.

[0030] FIG. 15 is a side view of the stomach shown in FIG. 14 viewed from the side of the Greater Curvature.

[0031] FIGS. 16 and 17 are cross-sectional anterior side views of a human stomach.

[0032] FIGS. 18 through 23 are cross-sectional top views taken along line D-D of the human stomach shown in FIG. 14 illustrating a progression of a laparoscopic stomach tissue reconfiguration procedure.

[0033] FIG. 24 is a perspective view of a portion of stomach tissue showing a first tissue anchor assembly apposing a pair of tissue folds and a second tissue anchor assembly in a figure-of-eight orientation reinforcing the first tissue anchor assembly.

[0034] FIGS. 25A-B are side cross-sectional and side views, respectively, of a snare-type suture grasping device.

[0035] FIGS. 26A-G are illustrations of the progression of a method for laparoscopic suturing.

[0036] FIGS. 27A-B are illustrations of running stitches applied using the method shown in FIGS. 26A-G.

[0037] FIGS. 28A-D are side cross-sectional view of four embodiments of an anchor retention mechanism.

[0038] FIGS. 29A-F are illustrations of the progression of an anchor deployment method using an anchor retention mechanism.

[0039] FIGS. 30A-B are anterior side views of a human stomach after undergoing a laparoscopic tissue reconfiguration.

[0040] FIGS. 31 and 32 are cross-sectional top views taken along line D-D of the human stomach shown in FIG. 14 illustrating alternative embodiments of a laparoscopic stomach tissue reconfiguration procedure.

DETAILED DESCRIPTION

[0041] Laparoscopic surgical devices and methods for engaging, manipulating, reconfiguring, and securing stomach tissue are described herein. In several embodiments, the methods entail performing surgery through one or a limited number of trocars, eliminating the need for an open surgical procedure. Laparoscopic procedures provide faster healing times, less scarring, and less pain which could lead to reduced hospitalization and quicker recovery in comparison to most open surgical procedures.

[0042] In several embodiments, the laparoscopic surgical procedures are performed using devices that have been developed by USGI Medical, Inc. of San Clemente, Calif. Several tissue manipulation and tissue anchor delivery devices are described in the following United States patent applications:

TABLE 2

U.S. patent application Ser. No.	Filing Date
10/612,109	Jul. 1, 2003
10/639,162	Aug. 11, 2003
10/672,375	Sep. 26, 2003
10/734,547	Dec. 12, 2003
10/734,562	Dec. 12, 2003
10/735,030	Dec. 12, 2003
10/840,950	May 7, 2004
10/955,245	Sep. 29, 2004
11/070,863	Mar. 1, 2005
12/486,578	Jun. 17, 2009
61/432,537	Jan. 13, 2011

The foregoing applications describe several tissue manipulation and tissue anchor delivery devices and embodiments, including flexible devices used for endolumenal procedures. Several tissue anchor delivery devices suitable for laparoscopic use are described more fully below.

[0043] Endolumenal tissue grasping devices are described in several of the United States patent applications listed above, and in the following United States patent applications:

TABLE 3

U.S. patent application Ser. No.	Filing Date
11/736,539	Apr. 17, 2007
11/736,541	Apr. 17, 2007

[0044] Tissue anchors are described in several of the United States patent applications listed above, and in the following United States patent applications:

TABLE 4

U.S. patent application Ser. No.	Filing Date
10/841,411	May 7, 2004
11/404,423	Apr. 14, 2006
11/773,933	Jul. 5, 2007

[0045] Each of the foregoing patent applications is hereby incorporated by reference in its entirety.

Tissue Anchors and Delivery Devices and Methods

[0046] Several embodiments of the laparoscopic surgical procedures described herein include the steps of grasping stomach tissue to form a tissue fold and deploying or implanting a fold retaining device (e.g., a tissue anchor assembly) that is used to maintain the fold. For simplicity, the discussion herein will describe tissue anchor assemblies holding tissue folds, with it being understood that other portions or sections of tissue that do not constitute tissue folds are suitably retained by the tissue anchor assemblies. The following sections include descriptions of several embodiments of devices that are suitable for performing these and other laparoscopic surgical procedures.

[0047] In several embodiments, a tissue anchor assembly is used to maintain a tissue fold in the stomach tissue. The preferred tissue anchor assemblies include tissue anchors such as those described in several of the United States patent applications incorporated by reference above, including Ser. Nos. 10/841,411, 11/404,423, and 11/773,933. A schematic representation of a suitable tissue anchor assembly is shown in FIG. 1. Those skilled in the art will recognize that tissue anchors other than those described herein may be suitable for use in some embodiments. For example, “T”-type anchors or “T”-tags having a pair across members attached to each other by a connecting member are known in the art and may be suitable for use in the methods described herein.

[0048] Preferably, the tissue anchor assemblies include a pair of tissue anchors **50a**, **50b** slidably retained by a connecting member, such as a suture **60**. A locking mechanism, such as a cinch **102**, is also slidably retained on the suture **60**. The cinch **102** is configured to be slidable on the suture **60** in only a single direction (one-way or uni-directional), in particular, toward the distal end of the suture. In this way, the cinch **102** is configured to provide a cinching force against the anchors **50a**, **50b** in order to impart a tension force on the suture. Accordingly, the tissue anchor assembly **100** is adapted to hold a fold of tissue, as shown in FIG. 2. In addition, as described below, the position of the cinch **102** on the suture **60** is able to be adjusted by the user during deployment of the tissue anchor assembly, thereby allowing the user to adjust the amount of tension force applied to the suture **60**, and the amount of force that the anchors **50a**, **50b** impart to the tissue fold F.

[0049] In several embodiments, a delivery device is used to deploy the tissue anchors and tissue anchor assemblies **100** laparoscopically. An example of a suitable delivery device is shown in FIGS. 6-8. Embodiments of the device shown in FIGS. 6-8 but having a flexible shaft for use in endolumenal procedures are described in substantial detail in U.S. patent application Ser. Nos. 10/955,245, 11/070,863, 12/486,578,

and 61/432,537, each of which is hereby incorporated by reference in its entirety (including all references cited therein) as if fully set forth herein. The laparoscopic embodiment of the delivery device **208** is described briefly below.

[0050] In manipulating tissue or creating tissue folds, a device having a handle **216**, a substantially rigid shaft **212**, and a distal end effector **214** is advanced laparoscopically, e.g., via a trocar, etc., into the patient's body, e.g., through the abdominal wall and into the peritoneal cavity. The end effector **214** is moved to the site of the target tissue, e.g., the external surface of the stomach. The stomach tissue may be engaged or grasped and the engaged tissue may be manipulated by a surgeon or practitioner from outside the patient's body. Examples of creating and forming tissue plications are described in further detail in the '245, '863, '578, and '537 applications incorporated by reference above.

[0051] The delivery device **208** shown in FIGS. 6-8 generally comprises a tissue manipulation assembly **210** and a needle deployment assembly **260**. (Embodiments of the needle deployment assembly **260** are shown in FIGS. 3-5 and are described more fully below). The tissue manipulation assembly **210** includes a catheter or tubular body **212** that is configured to be substantially rigid for laparoscopic advancement via a trocar into the peritoneal cavity. The tubular body **212** is configured to be torqueable through various methods, e.g., utilizing a stainless steel or other substantially rigid tubular construction, such that when a handle **216** is manipulated and/or rotated by a practitioner from outside the patient's body, the longitudinal and/or torquing force is transmitted along the body **212** such that the distal end of the body **212** is advanced, withdrawn, or rotated in a corresponding manner.

[0052] A tissue manipulation end effector **214** is located at the distal end of the tubular body **212** and is generally used to contact and form tissue folds and/or to otherwise bring portions of tissue into apposition. Several embodiments of the distal end effector are shown in FIGS. 9A-G. In some embodiments, the tissue manipulation end effector **214** is connected to the distal end of the tubular body **212** via a pivotable coupling **218**. A lower jaw member **220** extends distally from the pivotable coupling **218** and an upper jaw member **222**, in this example, is pivotably coupled to the lower jaw member **220** via a jaw pivot **226**. The location of the jaw pivot **226** may be positioned at various locations along the lower jaw **220** depending upon a number of factors, e.g., the desired size of the “bite” or opening for accepting tissue between the jaw members, the amount of closing force between the jaw members, etc. In other embodiments, the end effector **214** is connected to the distal end of the tubular body in a non-pivoting manner in which the lower jaw **220** is fixedly attached to the tubular body **212**. One or both jaw members **220**, **222** may optionally include a number of protrusions, projections, grasping teeth, textured surfaces, etc. on the surface or surfaces of the jaw members **220**, **222** facing one another to facilitate the adherence of tissue between the jaw members **220**, **222**. In alternative embodiments, the surfaces of the jaw member **220**, **222** are provided with a smooth, textured, or other atraumatic surface in order to decrease or eliminate the incidence of tissue injury.

[0053] Turning to FIGS. 9C-E, three additional embodiments of the tissue manipulation end effector **214** are shown. For clarity, the tubular body **212** and launch tube **228** are not shown in the drawings. In the embodiment shown in FIG. 9D, the upper jaw **222** is pivotably coupled to the lower jaw **220**

via a jaw pivot **226** that is fixedly attached to the lower jaw **220**, as described above in relation to FIGS. 9A-B. In the embodiment shown in FIGS. 9C and 9E, a slotted jaw construction includes a jaw pivot **226** that is able to slide within an upright slot **232** formed in the frame of the lower jaw **220**. In an alternative embodiment not shown, the jaw pivot **226** is fixed to the lower jaw **220** and slides within a slot **232** formed on the frame of the upper jaw **222**. The capability of the jaw pivot **226** to slide within the upright slot **232** provides the end effector **214** with adjustable jaw geometries to better accommodate tissue folds (or other targets) having a wider range of sizes. For example, as shown by the illustrations in FIGS. 9D-E, the end effector **214** embodiment having the upright slot **232** (shown in FIG. 9E) is able to accommodate a comparably-sized target located at the vertex between the upper jaw **222** and lower jaw **220** without having to be opened as widely as is necessary with the end effector **214** embodiment that does not have the upright slot (shown in FIG. 9D).

[0054] Those skilled in the art will recognize that the slotted jaw construction described above and shown in FIGS. 9C and 9E is adaptable for use in other laparoscopic instruments (or other instruments) having a pair of jaws oriented to grasp, trap, or engage tissue or other materials between the jaws. For example, the slotted jaw construction may be adapted for use with a laparoscopic stapling device in order to provide improved orientation between an upper staple cartridge and a lower anvil portion of the device. Other uses of the slotted jaw construction are also possible.

[0055] In the embodiments described above, a distal end of the launch tube **228** is pivotally connected to the upper jaw member **222** at a launch tube pivot **230**. The launch tube pivot **230** is pivotable around an axis defined by a pin that is attached to the upper jaw member **222** and that extends through a hole in the pivot **230**. In several other embodiments, shown in FIGS. 9F-G, an alternative pivot **630** is provided that is capable of ranges of motion in addition to pivoting relative to the upper jaw member **222**. For example, FIGS. 9F-G show alternative embodiments of an end effector **214** that includes a lower bail **220** having a distal slot **621** and an upper bail **222** having a distal slot **623**. The lower bail **220** and upper bail **222** are maintained in a fixed spatial relationship relative to one another and are connected to the tubular body **212** by a pivotable coupling **218**. A helical grasper **640** having a tissue piercing tip is movably retained within a slider **642** that slides in a slot formed in the lower fixed bail **220**. The helical grasper **640** includes a shaft that extends proximally to the handle **216** of the anchor delivery device **208**, where it is actuatable by the user. The helical grasper **640** is able to be moved proximally and distally under the control of the user, as guided by the slider **642**. In this way, the helical grasper **640** may be used to grasp tissue and retract the tissue into the space defined between the lower fixed bail **220** and the upper fixed bail **222**.

[0056] A pivot **630** is pivotably and slidably connected to the upper fixed bail **222** via a pair of pivot pins **624a**, **624b** that are formed on the upper fixed bail **222**. The pivot pins **624a**, **624b** are formed on opposing sides of a slot defined by the upper fixed bail **222**, and define a pivot axis about which the pivot **630** is able to rotate. In a first embodiment, shown in FIGS. 9F-G, the pivot **630** includes two pivot slots **632** formed on opposite sides of the external surface of the pivot. Each pivot slot **632** has an elongated shape defined by a pivot slot upper end and a pivot slot lower end. The pivot **630** has a width that is slightly less than the width of the slot defined in the upper fixed bail **222**. Accordingly, the pivot pins **624a**,

624b are able to reside within the spaces defined by the pivot slots **632** formed on each side of the pivot **630**. In this way, the pivot **630** is able to rotate (pivot) around the axis defined by the pivot pins **624a**, **624b**, and the body of the pivot **630** is also able to slide relative to the axis defined by the pivot pins **624a**, **624b** a distance defined by the length of the pivot slots **632**. In this way, the pivot **630** may be rotated around the axis defined by the pivot pins **624a**, **624b**, and/or the pivot **630** may be moved into and out of the space between the lower fixed bail **220** and upper fixed bail **222** and/or proximally and distally relative to axis defined by the pivot pins **624a**, **624b** (depending upon the orientation of the pivot **630** relative to the upper fixed bail **222**).

[0057] A launch tube **228** extends from the handle **216**, through the tubular body **212**, and distally from the end of the tubular body **212** where a distal end of the launch tube **228** is pivotally connected to the upper jaw member **222** at a launch tube pivot **230**. A distal portion of the launch tube **228** may be pivoted into position within a channel or groove defined in the upper jaw member **222**, to facilitate a low-profile configuration of the tissue manipulation end effector **214**. When articulated, either via the launch tube **228** or other mechanism, the jaw members **220**, **222** are urged into an open configuration to receive tissue in the opening between the jaw members **220**, **222**.

[0058] The launch tube **228** may be advanced from its proximal end at the handle **216** such that the portion of the launch tube **228** that extends distally from the tubular body **212** is forced to rotate at a hinge or pivot **230** and reconfigure itself such that the exposed portion forms a curved or arcuate shape that positions the launch tube opening perpendicularly relative to the upper jaw member **222**. The launch tube **228**, or at least the exposed portion of the launch tube **228**, may be fabricated from a highly flexible material or it may be fabricated, e.g., from Nitinol tubing material which is adapted to flex, e.g., via circumferential slots, to permit bending.

[0059] Once the tissue has been engaged between the jaw members **220**, **222**, a needle deployment assembly **260** is urged through the handle **216**, through the tubular body **212**, and out through the launch tube **228**. Embodiments of the needle deployment assembly are shown in FIGS. 3-5, and are described in substantial detail in U.S. patent application Ser. Nos. 10/955,245, 11/070,863, and 12/486,578, which are hereby incorporated by reference in their entireties (including all references cited therein) as if fully set forth herein. The needle deployment assembly **260** may pass through the lower jaw member **220** via a needle assembly opening (not shown in the drawings) defined in the lower jaw member **220** to pierce through the grasped tissue. Once the needle deployment assembly has been passed through the engaged tissue, one or more tissue anchors **50a** of a tissue anchor assembly **100** (see FIG. 10) are deployed for securing the tissue, as described in further detail herein and in U.S. patent application Ser. No. 10/955,245, which has been incorporated by reference above.

[0060] Referring to FIGS. 3-5, each shows additional details relating to embodiments of a needle deployment assembly **260**. As mentioned above, a needle deployment assembly **260** may be deployed through the tissue manipulation assembly **210** by introducing the needle deployment assembly **260** into the handle **216** and through the tubular body **212** such that the needle deployment assembly **260** is advanced from the launch tube **228** and into or through approximated tissue. Once the needle deployment assembly **260** has been advanced through the tissue, the anchor assem-

bly **100** may be deployed or ejected. The anchor assembly **100** is normally positioned within the distal portion of a tubular sheath **264** that extends from a needle assembly control or housing **262**. Once the anchor assembly **100** has been fully deployed from the sheath **264**, the spent needle deployment assembly **260** may be removed from the tissue manipulation assembly **210** and another needle deployment assembly may be introduced without having to remove the tissue manipulation assembly **210** from the patient. The length of the sheath **264** is such that it may be passed entirely through the length of the tubular body **212** to enable the deployment of the needle deployment assembly **260** into and/or through the tissue.

[0061] The elongate sheath or catheter **264** extends removably from the needle assembly control or housing **262**. The sheath or catheter **264** and the housing **262** may be interconnected via an interlock **270** which may be adapted to allow for the securement as well as the rapid release of the sheath **264** from the housing **262** through any number of fastening methods, e.g., threaded connection, press-fit, releasable pin, etc. The needle body **272**, which may be configured into any one of the variations described above, extends from the distal end of the sheath **264** while maintaining communication between the lumen of the sheath **264** and the needle opening **274**.

[0062] An elongate pusher **276** comprises a flexible wire, coil, or hypotube that is translationally disposed within the sheath **264** and movably connected within the housing **262**. A proximally-located actuation member **278** is rotatably or otherwise connected to the housing **262** to selectively actuate the translational movement of the elongate pusher **276** relative to the sheath **264** for deploying the anchors from the needle opening **274**. The tissue anchor assembly **100** is positioned distally of the elongate pusher **276** within the sheath **264** for deployment from the sheath **264**. Needle assembly guides **280** protrude from the housing **262** for guidance through the locking mechanism described above.

[0063] The laparoscopic tissue anchor delivery device **208** is typically used in conjunction with one or more additional laparoscopic instruments to perform the tissue reconfiguration procedures described herein. Several conventional laparoscopic instruments are known to those having ordinary skill in the art, and the details of those instruments are beyond the scope of the present description. FIG. **11** is an exemplary illustration of a laparoscopic instrument **310** having a shaft **312**, an end effector **314**, and a handle **316**. In the embodiment shown, the instrument includes a substantially rigid shaft **312** and an end effector **314** in the form of a grasper having a pair of grasping jaws **320**, **322**. In FIGS. **12A-D**, several alternative end effector embodiments are shown, including an alternative pair of grasping jaws **330**, **332** shown in FIG. **12A**, a pair of alligator grasper jaws **340**, **342** shown in FIG. **12B**, a pair of tong-style grasping members **350**, **352** shown in FIG. **12C**, and a blunt obturator **360** shown in FIG. **12D**. Other optional laparoscopic instruments are suitable for use, including Babcock-style graspers, Maryland-style graspers, and other devices known to those skilled in the art.

[0064] FIG. **13** illustrates a conventional trocar **400**, including a cannula head portion **410** and a cannula tube portion **412**.

Laparoscopic Treatment of Obesity

[0065] Referring to FIGS. **14-15**, the anatomy of the stomach can be divided into different segments on the basis of the mucosal cell types and in relation to external anatomical boundaries. The cardiac segment C is immediately subjacent

to the gastroesophageal junction GEJ and is a transition zone of the esophageal squamous epithelium into the gastric mucosa. The fundus F is the portion of the stomach that extends above the gastroesophageal junction. The body B or corpus of the stomach extends from the fundus F to the incisura angularis on the lesser curvature LC of the stomach. The majority of parietal acid forming cells are present in this segment. The fundus F and the body B function as the main reservoir of ingested food. The antrum A extends from the lower border of the body B to the pyloric sphincter PS. The majority of gastrin producing or G-cells are present in the antral mucosa. The main blood supply is variable but typically courses from the celiac axis into the gastric and gastro-epiploic arcades. Nutrient vessels to the stomach course from the vascular arcades of the greater and lesser curvatures. These vessels penetrate the gastric wall in a perpendicular fashion and arborize horizontally in a dense vascular plexus throughout the wall of the stomach. For the most part, gastric innervation is provided by the vagus nerves which form a plexus around the esophagus and then reform into vagal trunks above the esophageal hiatus. An extensive myenteric plexus is formed within the muscular wall of the stomach. Impulses from stretch or tension receptors within the gastric wall are transmitted to the nucleus tractus solitarius of the brain stem by afferent vagal fibers. These stretch/tension receptors within the fundus F and body B detect gastric distension or gastric pressure from ingested food.

[0066] The gastrointestinal lumen, including the stomach, includes four tissue layers, wherein the mucosa layer is the inner tissue layer followed by submucosa connective tissue, the muscularis layer and the serosa layer. When stapling or suturing from the peritoneal side of the GI tract, it is easier to gain access to the serosal layer. In endoluminal approaches to surgery, the mucosa layers are visualized, and the muscularis and serosal layers are difficult to access because they are only loosely adhered to the mucosal layer. In order to create a durable tissue fold or other approximation with suture or staples or some form of anchor, it is important to create a muscularis and/or serosa to serosa approximation. This is because the mucosa and submucosa connective tissue layers typically do not heal together in a way that can sustain the tensile loads imposed by normal movement of the stomach wall during ingestion and processing of food. In particular, folding the serosal layers in a way that they will heal together will form a durable tissue fold, plication, or elongated invagination.

[0067] Utilizing the instruments and systems described above in relation to FIGS. **1-13**, various laparoscopic tissue reconfiguration and obesity-related procedures may be performed. For example, FIGS. **14-24** illustrate portions of the progression of a tissue reconfiguration and obesity treatment procedure being performed on a stomach. The remaining anatomy, including portions of the stomach S, has been omitted only for clarity.

[0068] Initially, one or more trocars **400** are inserted into the abdominal wall to provide access for the instruments into the peritoneal cavity and to the external surface of the stomach S. In some embodiments, a laparoscope is inserted through one of the trocars **400** in order to provide visualization and other possible functional features. Also, in some embodiments, the peritoneal cavity is insufflated to provide a desired amount of visualization and physical access to the external surface of the stomach S. Other suitable methods for

providing and obtaining access to the external surface of the stomach S are also suitably employed.

[0069] As shown in FIG. 16, in some embodiments, an endoscope 500 or other device is inserted into the stomach of the patient transorally to provide visualization, insufflation, and/or other functions or features from within the interior space of the stomach S.

[0070] Once access to the external surface of the stomach is obtained, in some embodiments, the stomach S is mobilized by dissecting or partially dissecting the greater omentum along the greater curvature GC generally from the fundus F to the antrum A. (See FIG. 15). After mobilization, a large fold or invagination is formed in the stomach by pushing or pulling the tissue along the greater curvature GC into the interior of the stomach. For example, as shown in FIG. 18, a laparoscopic instrument 310 having a blunt obturator 360 may be used to push or poke the stomach S along the greater curvature GC into the interior space of the stomach to thereby form a large internal invagination 508 of the greater curvature GC, which is also defined by a pair of large external tissue folds 510 and 512. Alternatively, a laparoscopic instrument 310 having a pair of grasping jaws 320, 322 or other end effector 314 may be used to form the invagination 508 at the greater curvature GC. In still other embodiments, a grasping laparoscopic instrument 310 may be used to grasp and pull or fold over the tissue near the locations of the external tissue folds 510 and 512 to form or assist in forming the large invagination 508 along the greater curvature GC. In still other embodiments, a combination of the foregoing instruments and methods are used to generally and substantially form the invagination 508 and the external tissue folds 510 and 512.

[0071] As shown in FIG. 17, in still other embodiments, an endoscopic grasper 502 or other retractor is optionally extended through a working channel of the endoscope 500 to grasp the internal surface of the stomach along the greater curvature GC and retract the tissue from inside the stomach. In embodiments in which the endoscope 500 is provided with a locking mechanism for the working channel, the grasper/retractor 502 may be locked in place to thereby hold the large invagination 508 in a fixed position while the procedure described below is undertaken. Moreover, the visualization functionality provided by the endoscope 500 provides the user with the capability of confirming the size, location, and relationship of the invagination 508 in relation to the interior of the gastrointestinal tract in order to assess the likely risk of obstruction or other complications.

[0072] Upon formation of the large invagination 508, or as the large invagination 508 is being formed, the tissue anchor delivery device 208 is deployed through a trocar 400 and the end effector 214 is brought near one of the external tissue folds 510 or 512, as shown in FIG. 19. In some embodiments, the launch tube 228 is retracted to open the space between the jaws 220, 222, which are then placed on either side of the tissue fold 512. In other embodiments, the tissue fold 510, 512 is retracted into the space between the jaws/bails 220, 222. The jaws 220, 222 are oriented on the tissue fold 512 such that the launch tube 228 is located between the tissue folds 510 and 512—thereby causing the tissue anchors 50a and 50b to be deployed on the exterior surfaces of the tissue folds 510, 512, as described in more detail below. The launch tube 228 is then advanced to close the jaws 220, 222 on the tissue fold 512, after which the needle deployment assembly 260 is actuated to cause the needle 272 to extend through the tissue fold 512. In the embodiment shown, the distal anchor

50a is then deployed from the needle 272. The needle 272 is then retracted back into the needle deployment assembly 260, leaving the distal anchor 50a deployed against the surface of the tissue fold 512 and the suture 60 extending through the tissue fold 512. The launch tube 228 is then retracted, the jaws 220, 222 opened, and the tissue fold 512 is released from the delivery device 208.

[0073] Next, turning to FIG. 20, the delivery device 208 is “flipped” along its axis and is moved to the other tissue fold 510, as shown in FIG. 20. The suture 60 is paid out from the needle deployment assembly 260 through the needle 272 as the delivery device 208 is moved. Once in position, the delivery device 208 is closed upon the other tissue fold 510 and the proximal anchor 50b and cinch 102 of the anchor assembly 100 are deployed through the other tissue fold 510. After deployment, the launch tube 228 is retracted, the jaws 220, 222 opened, and the tissue fold 510 is released from the delivery device 208. At this point, the suture 60 of the anchor assembly 100 extends through the tissue folds 510, 512 and is loosely held in place by the distal anchor 50a, distal anchor 50b, and cinch 102.

[0074] Turning to FIG. 21, a laparoscopic instrument 310 is provided having an end effector 314 suitable for cinching the anchor assembly deployed through the tissue folds 510 and 512 in the procedures described above. Examples of end effectors for cinching instruments are described in U.S. patent application Ser. Nos. 12/054,297 and 10/954,665, which are hereby incorporated by reference in their entireties. Suitable end effectors include a simple pair of grasping jaws, a finger snare, or other mechanism. In the embodiment shown, the laparoscopic instrument 310 includes a finger snare 370 adapted to acquire and grasp the suture 60, and to apply a tension force upon the suture 60 to thereby slide the unidirectional cinch 102 up against the proximal anchor 50b. This action shortens the length of suture 60 between the proximal anchor 50b and distal anchor 50a, thereby bringing the tissue folds 510 and 512 into apposition.

[0075] The foregoing method steps are repeated at several locations along the greater curvature GC between the fundus F and antrum A of the stomach S until the large invagination 508 extends through all or most of the length of the stomach S, as shown, for example, in FIG. 30A. For example, in some embodiments, additional tissue anchor assemblies 100 are deployed along the greater curvature 100 at intervals of approximately 0.5 cm to about 2 cm, or sufficiently near each other to avoid gaps large enough that the tissue folds 510 and 512 will not heal together. In addition, although the illustrations shown in FIGS. 19-23 show an open or hollow space HS formed within the interior of the invagination 508, it is believed that the tissue surfaces opposing one another within the space HS will be in contact with each other and will reform or remodel due to the reconfiguration created by the foregoing method steps.

[0076] In some alternative embodiments, one or both of the tissue anchors 50a, 50b are deployed through only a single layer of the tissue folds 508, 510, such that the tissue anchors 50a, 50b are located on the interior of the stomach. (See FIG. 31). In some other alternative embodiments, one or both of the tissue anchors 50a, 50b are deployed such that the anchors 50a, 50b are located between the tissue folds 510, 512 after the tissue folds are approximated toward one another by the tissue anchor assemblies 100. In these embodiments, the delivery device 208 is located upon the tissue folds 510, 512 and the tissue anchors 50a, 50b are deployed through the

tissue folds **510**, **512** in the opposite direction to the embodiment discussed above in relation to FIGS. **19-20**. Once the anchor assemblies **100**, **100'** are fully deployed and the anchors **50a**, **50b** are cinched together, the tissue folds **510**, **512** are brought into apposition in the manner shown in FIG. **32**.

[0077] After the full stomach has been reconfigured according to the above procedures, in some embodiments additional tissue anchor assemblies **100'** are deployed to provide further strength to the reconfigured tissue folds **508**, **510**, and/or **512**. For example, in FIGS. **22-23** there is shown an additional reinforcing tissue anchor assembly **100'** that is deployed in a single plication deployment using the tissue anchor deployment device **208** deployed through the pair of tissue folds **510** and **512**. In other embodiments, the additional tissue anchor assembly **100'** is deployed in a Figure-of-Eight deployment (see FIG. **24**) or using the tissue fold-apposition deployment method described above in relation to FIGS. **19-21** and/or FIGS. **31-32**. Other deployment methods are also contemplated and are possible. In still other embodiments, the reconfigured tissue folds **508**, **510**, and/or **512** are reinforced by oversewing using a running stitch, an interrupted stitch, or other method(s) using the laparoscopic instruments described herein, or other instruments known to those skilled in the art. In still other embodiments, the reconfigured tissue folds **508**, **510**, and/or **512** are approximated and/or reinforced using staples, clips, or other fasteners known to those skilled in the art.

[0078] Turning to FIGS. **25A-B**, **26A-G**, and **27A-B**, there are shown devices and methods for laparoscopic suturing that are particularly adapted to the present tissue reconfiguration methods. For example, FIGS. **25A-B** show a suture grasping device snare-style grasper **610** having a hook **612** and an eyelet **614** attached to the distal end of an elongated shaft **616**. The snare-style grasping device **610** is adapted to be slidably and rotatably retained within, for example, a flexible sheath **264** and needle body **272** of, for example, the tissue anchor deployment device **208** described above in relation to FIGS. **3-10**. The Figures illustrate the distal portion of a sheath **264** and needle body **272** along with the snare device **610**. The remaining portions of the delivery device **208** have been omitted only for clarity.

[0079] As the snare is extended out of the distal end of the needle body **272**, the hook **612** expands upward away from the eyelet **614**, and the eyelet expands outward **614** away from the hook **612**, thereby defining an open space between the hook **612** and eyelet **614**. (See FIG. **25B**). When the snare is retracted back into the needle body **272** and sheath **264**, (see FIG. **25A**), the hook **612** collapses into the eyelet **614**, trapping anything (e.g., a suture **660**) placed within the open space when it was open. In this way, the deployment device **208** may be used to perform laparoscopic suturing, as described in more detail below.

[0080] In FIG. **26A**, a snare device (not shown) is slidably retained within a sheath **264** and needle body **272** of a deployment device (also not shown). The snare device has captured a portion of suture **660** and retracted it into the sheath **264**. The needle body **272** is then pierced through a tissue fold **F**, carrying with it the suture **660**, as shown in FIG. **26B**. After advancement of the needle **272** and sheath **264** through the tissue fold, the snare device **610** is advanced distally by advancing the elongated shaft **616**, thereby expanding the hook **612** and eyelet **614** and releasing the suture **660**. (See FIG. **26C**). The snare device **610** is then retracted back into

the sheath **264**, (FIGS. **26D-E**), and the sheath **264** is withdrawn from the tissue fold **F**, (FIG. **26F**). This leaves the suture **660** extending through the tissue fold **F**, and leaves the user with the snare device **610** in position to perform another operation. As shown by the arrow "A" in FIG. **26G**, the elongated shaft **616** may be extended to expose the snare device **610** to grasp the suture **660** on either side of the tissue fold **F**. Once grasped, the process may be repeated any number of times in order to route the suture **660** through the tissue fold **F** and thereby perform a suturing procedure.

[0081] FIGS. **27A** and **27B** illustrate two examples of running stitches that are applied laparoscopically to tissue using the deployment device **208** carrying the snare device **610** described herein. The laparoscopic suturing procedures may be completed by securing the suture ends with tissue anchors described herein, or by other methods known to those skilled in the art. For example, the suture ends may be secured by tying knots in the suture **660** or by passing one or more suture knots via a knot pusher, by applying a clip or other securing device to the suture **660** using a clip applicator or similar device, or by other means. In other embodiments, a barbed suture **660** is used to thereby eliminate the need for separately securing the suture.

[0082] Turning to FIGS. **28A-D** and **29A-F**, in some embodiments, the needle deployment assembly **260** provided in the tissue anchor delivery device **208** with an anchor retention mechanism that facilitates deployment of a single anchor of a tissue anchor assembly **100** (such as the distal anchor **50a** shown in FIG. **19**) without inadvertently deploying both anchors of the assembly. FIGS. **28A-D** and **29A-F** illustrate the distal portion of a sheath **264** and needle body **272** of a needle deployment assembly **260**. The remaining portions of the delivery device **208** have been omitted only for clarity.

[0083] In the embodiment shown in FIG. **28A**, the elongate pusher **276** is provided with an extension arm **277** having an enlarged portion at its distal end. The enlarged portion of the extension arm **277** traps a first knot **62a** formed at a proximal end of the suture of the tissue anchor assembly **100** within the interior space of the sheath **264**. A second knot **62b** formed distally of the first knot **62a** is attached (e.g., with glue or other adhesive) to the distal anchor **50a**, thereby providing the pusher **276**—to which the extension arm **277** is attached—with the capability of positively controlling the position of the distal anchor **50a** within the sheath **264**. Accordingly, as the pusher **276** is advanced distally within the sheath **264**, the distal anchor **50a** (and the components that are within the sheath **264** distal of the distal anchor) will be advanced distally. As the pusher **276** is retracted proximally within the sheath **264**, the distal anchor **50a** will be retracted proximally. This capability reduces the possibility that the distal anchor **50a** will be deployed inadvertently.

[0084] The embodiment shown in FIG. **288** is similar to the one shown in FIG. **28A**, except rather than having the distal anchor **50a** being adhered to the second knot **62b**, the distal anchor **50a** is prevented from moving distally relative to the suture **60** by the inclusion of a step up in thickness of the suture relative to the diameter of the passageway through the distal anchor **50a**. For example, the suture has a first thickness at region **60a** that is small enough that the distal anchor **50a** is able to slide freely back and forth along the suture **60a**. However, at region **60b**, the suture has a thickness that is larger, such that the distal anchor **50b** is not able to traverse the transition from region **60a** to region **60b**. In this way, the distal anchor **50a** is thereby trapped within a pre-determined

region of travel by the elongate pusher **276**, thereby reducing the possibility that the distal anchor **50a** will be deployed inadvertently.

[0085] In the embodiments shown in FIGS. **28C** and **28D**, the extension arm **277** includes a region that physically traps the entire distal anchor **50a**, thereby directly controlling the location of the distal anchor with the pusher **276**.

[0086] Turning to FIGS. **29A-F**, the manner of operation of the retention mechanisms described above is shown. A needle **272** and sheath **264** of a needle deployment assembly **260** are deployed from a tissue anchor deployment device **208**. As the pusher **276** is advanced, the cinch **102** and suture **60** are expelled from the distal end of the needle body **272**, as shown in FIG. **29B**. Further advancement of the pusher **276** causes the proximal anchor **50b** to be expelled. (See FIG. **29C**). In FIG. **29C**, the enlarged distal end of the extension arm **277** is seen extending from the distal opening of the needle body **272**, but the distal anchor **50a** remains held within the sheath **264**. As the deployment device **208** is retracted, such as when the device is moved to the location of a second tissue fold, the suture **60** is paid out, as shown in FIG. **29D**. Finally, the pusher **276** is fully extended outside of the sheath **264** and needle body **272**, thereby releasing the distal anchor **50a**. (See FIG. **29E**). In an alternative embodiment, the extension arm **277** is provided with a shape memory curve, (see FIG. **29F**), to prevent inadvertent engagement or interference with the target tissue.

[0087] The described methods include several embodiments, including all of the embodiments described herein as well as all combinations of each of those embodiments. Additional combinations of the therapeutic methods described herein will obtain similar results. In addition, other versions of the foregoing methods have been contemplated and are within the scope of the present methods. For example, the large invagination **508** may be formed at locations on the stomach other than on or near the greater curvature **508** shown in FIG. **30A**, such as along the anterior wall of the patient's stomach, as shown in FIG. **30B**. In other embodiments,

invaginations are formed at multiple locations on the stomach. In addition, the invaginations may be provided having smaller or larger sizes than those shown in the embodiments described herein.

[0088] Although various illustrative embodiments are described above, it will be evident to one skilled in the art that various changes and modifications are within the scope of the invention. It is intended in the appended claims to cover all such changes and modifications that fall within the true spirit and scope of the invention.

What is claimed is:

1. A method for reconfiguring tissue of a hollow organ within the body of a patient, comprising:
 - positioning an anchor delivery device in proximity to an external surface of the hollow organ;
 - forming a first tissue fold and a second tissue fold on the external surface of the hollow organ such that an invaginated portion of the hollow organ located between the first and second tissue folds is invaginated within the hollow organ;
 - deploying a first anchor of a first anchor assembly from the anchor delivery device into the first tissue fold and a second anchor of the first anchor assembly from the anchor delivery device into the second tissue fold, with the first and second anchors being connected to one another by a connecting member; and
 - moving at least one of the first anchor or second anchor along the connecting member to thereby decrease the distance between the first and second anchors and to approximate the first and second tissue folds.
2. The method of claim 1, further comprising the step of accessing an external surface of a hollow organ.
3. The method of claim 1, further comprising deploying a second anchor assembly into the first and second tissue folds.
4. The method of claim 1, further comprising deploying a plurality of additional anchor assemblies into the first and second tissue folds.

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摘要(译)

用于在胃组织中形成和固定组织褶皱和细长内陷的装置和方法用作肥胖症的治疗。在若干实施例中，使用腹腔镜组织锚固部署装置沿着胃的较大曲率形成多个组织褶皱。另外的实施例包括使用腹腔镜装置或腹腔镜装置结合内窥镜装置的组织褶皱，细长内陷和胃组织的其他重新配置的各种组合。

