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Zeiner et al.

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(54) **HYBRID ENDOSCOPIC/LAPAROSCOPIC METHOD FOR FORMING SEROSA TO SEROSA PLICATIONS IN A GASTRIC CAVITY**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1493 days.

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(65) **Prior Publication Data**

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(51) **Int. Cl.**
A61B 17/10 (2006.01)

(52) **U.S. Cl.**
USPC **606/139**

(58) **Field of Classification Search**
USPC 606/60, 72, 139, 142, 143, 151, 232; 623/13.13, 13.14, 19.11, 23.72; 128/898
See application file for complete search history.

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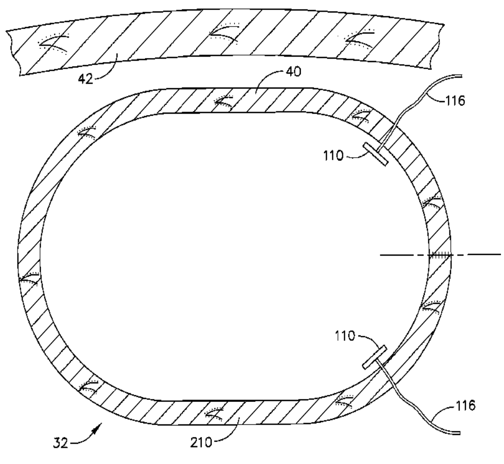
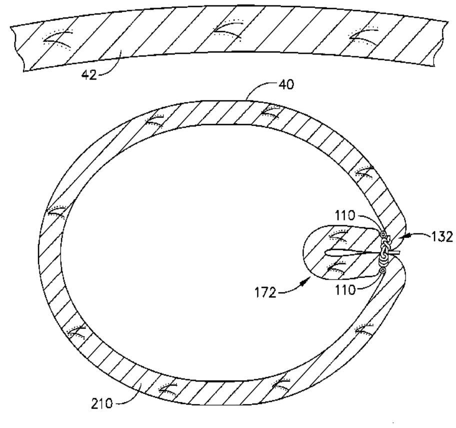
Primary Examiner — Melanie Tyson

(57) **ABSTRACT**

A method for treating obesity by reducing the volume and/or alter the functioning of the gastric cavity to limit food consumption and induce early satiety. The method includes accessing the cavity endoscopically to visualize the interior of the cavity. The peritoneal cavity is accessed through a small incision in the abdominal wall. Using endoscopic visualization, suture anchoring devices are introduced into the peritoneal cavity through the incision and deployed from the exterior surface through the gastric cavity wall. Suture from pairs of the anchoring devices is drawn through the gastric cavity wall and tightened outside of the cavity to form a serosa to serosa plication. Any number of plications may be formed in the cavity wall and the contacting tissue within a plication may be treated to promote healing and a more durable bond.

25 Claims, 41 Drawing Sheets





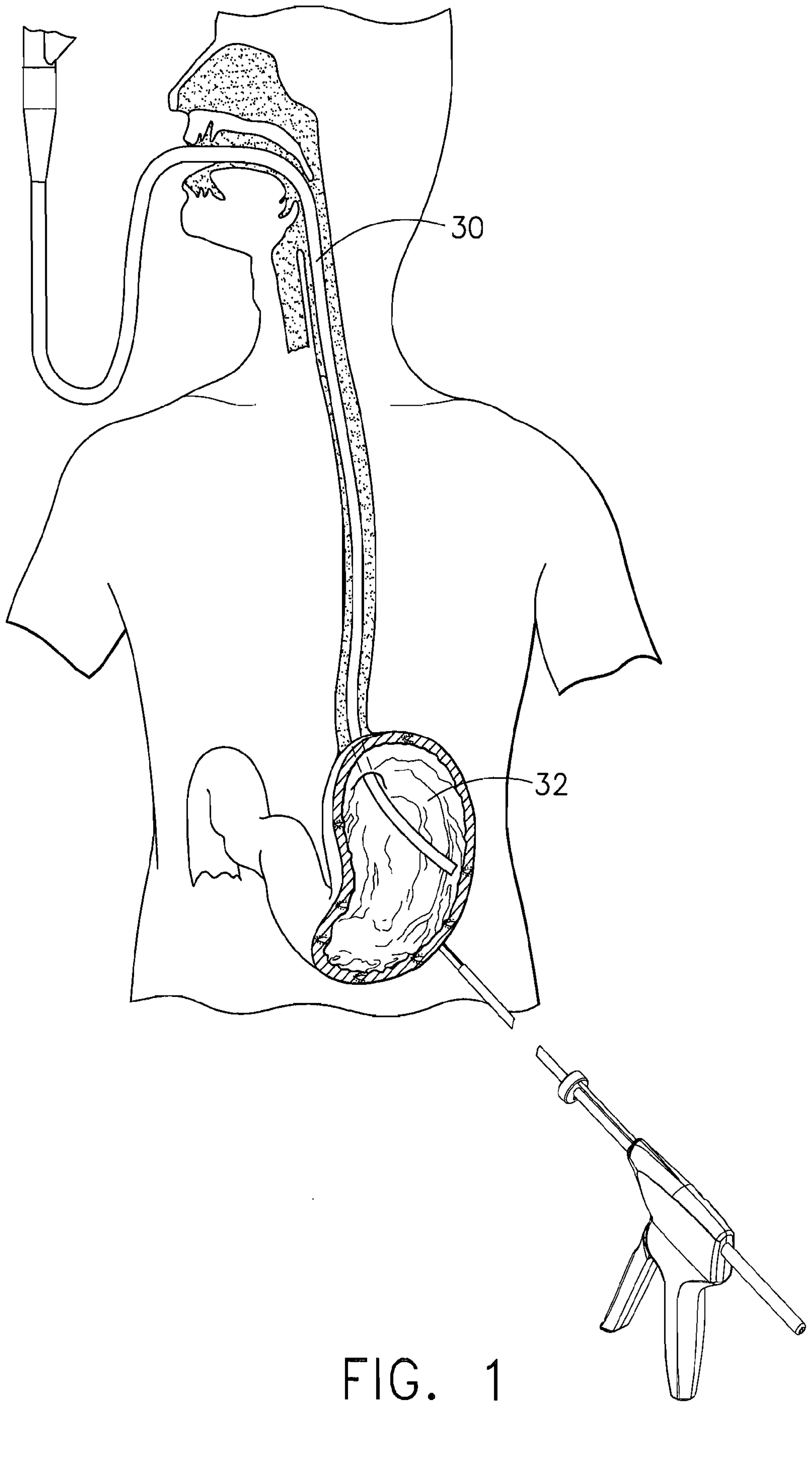


FIG. 1

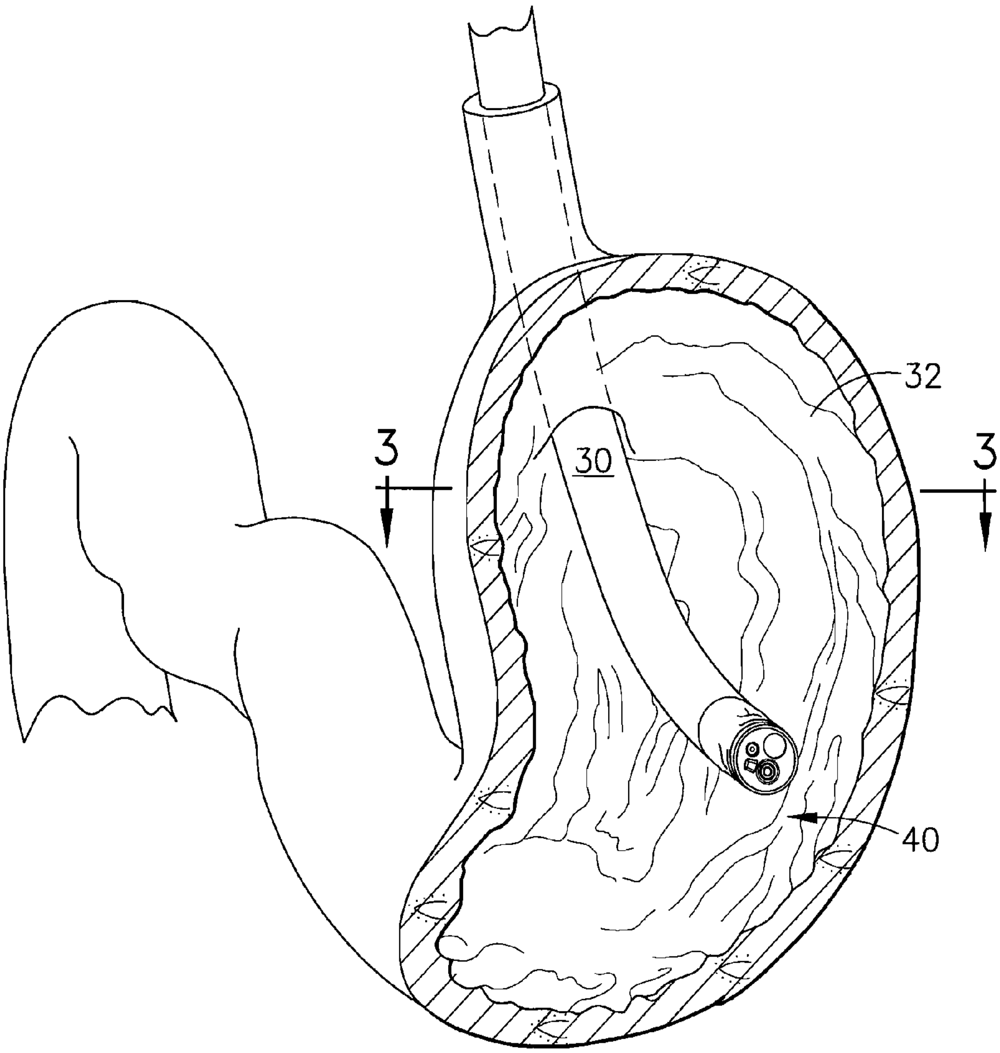
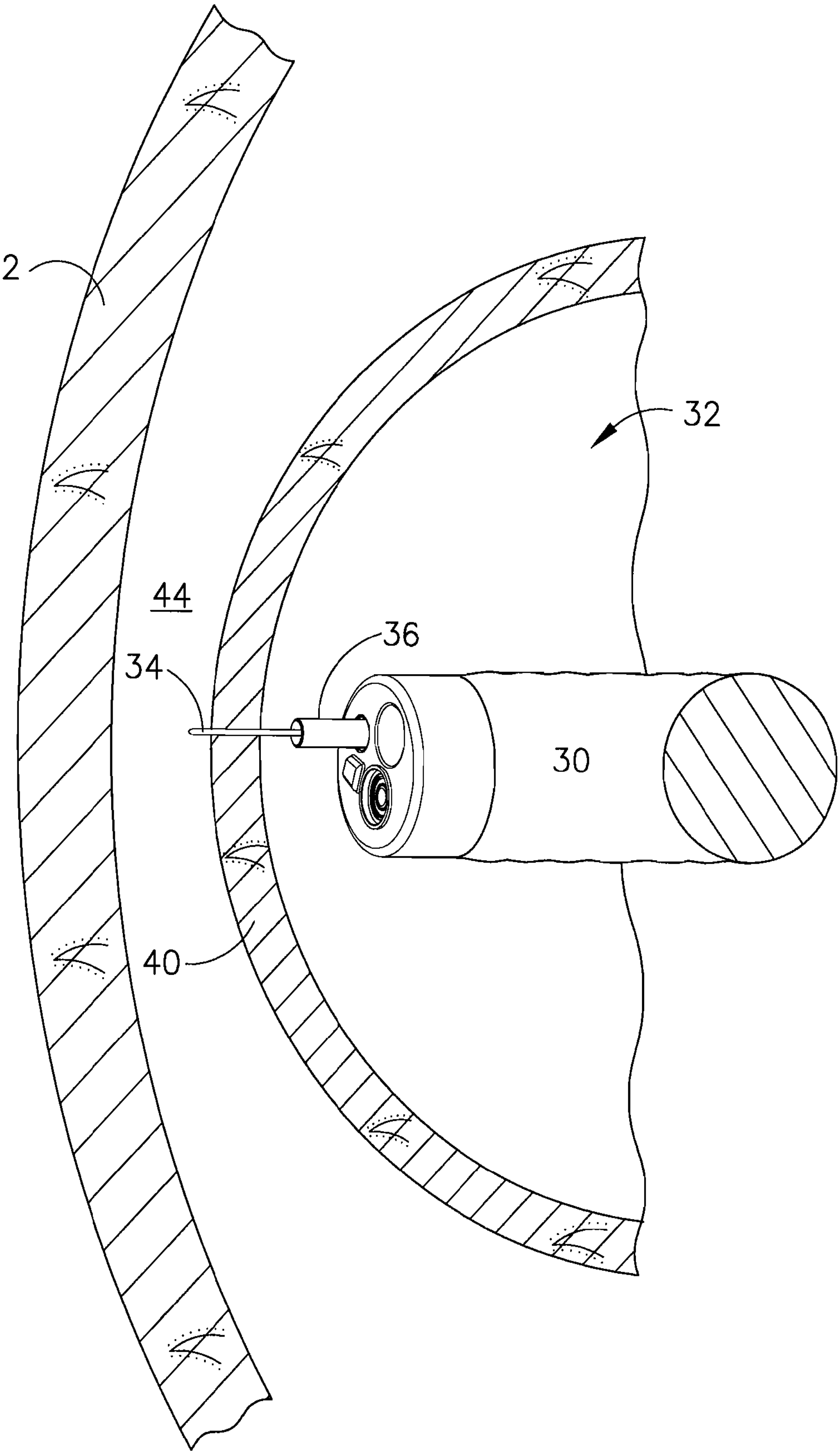


FIG. 2



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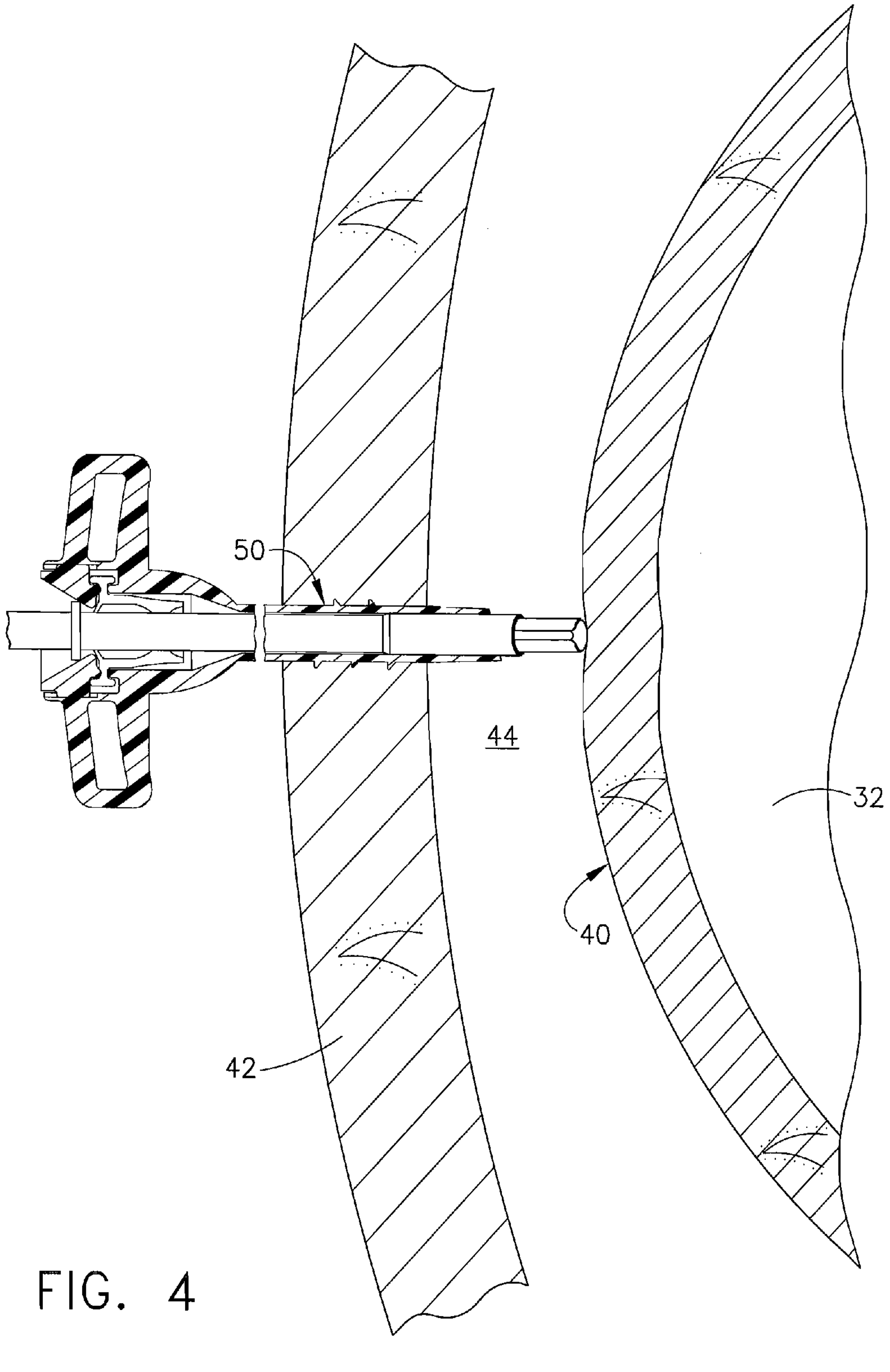

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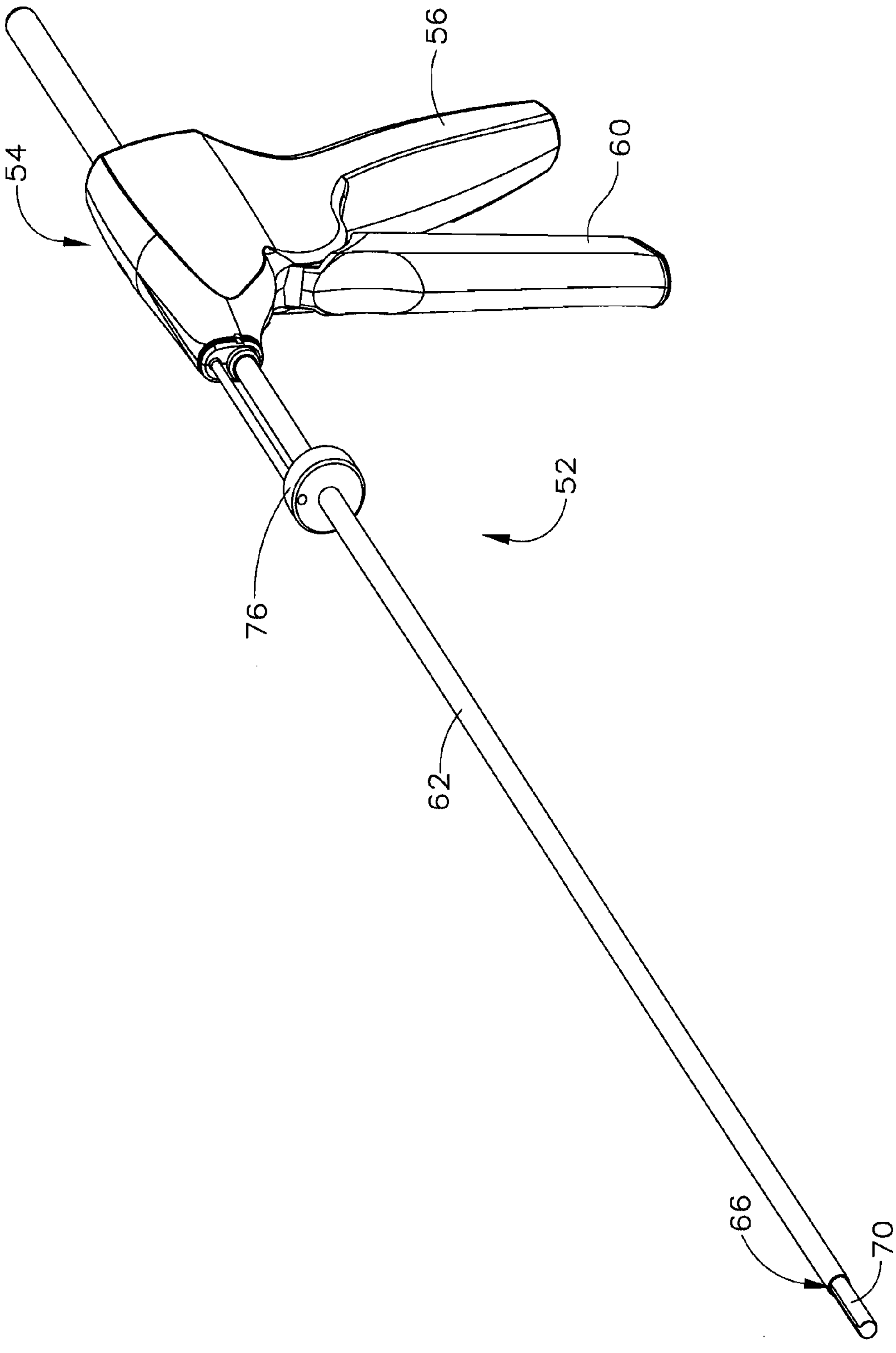

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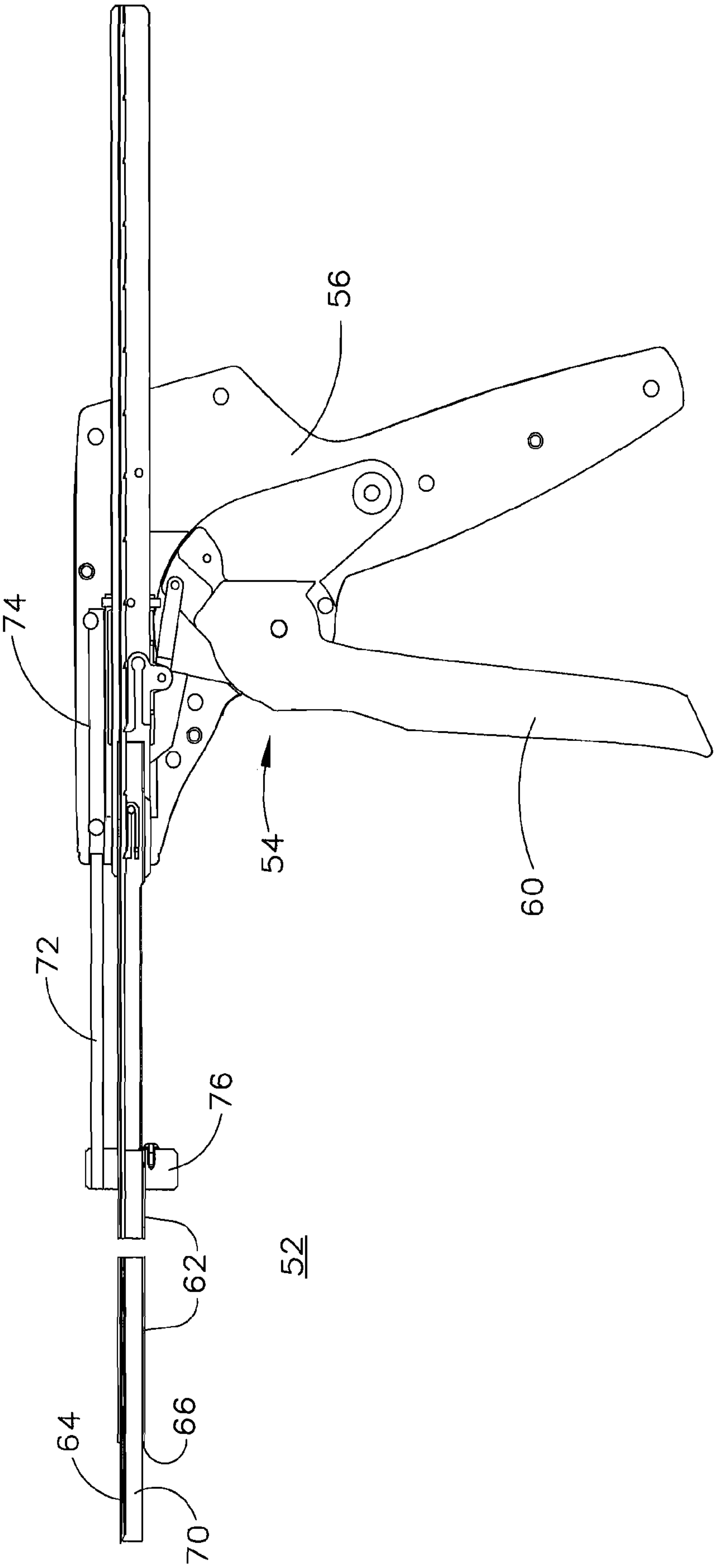


FIG. 6a

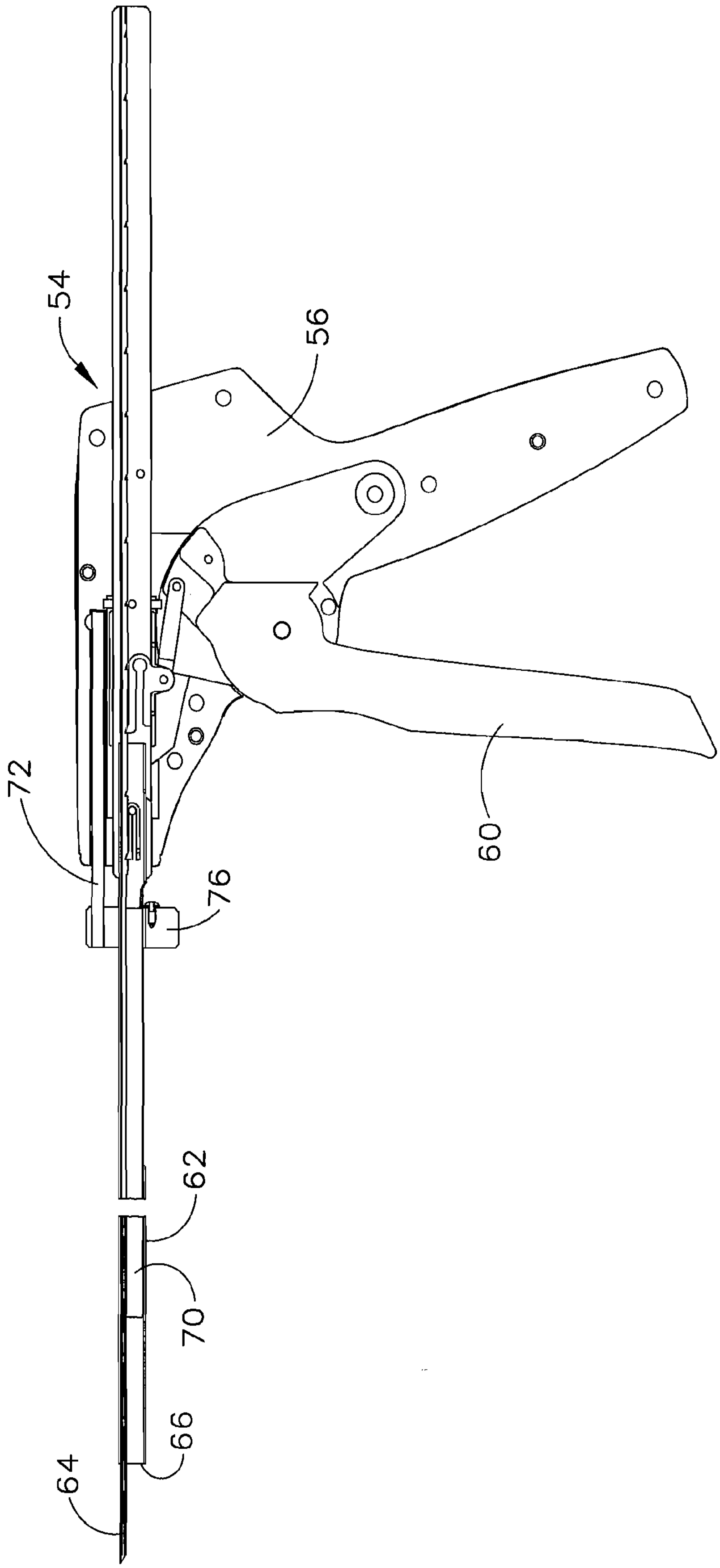
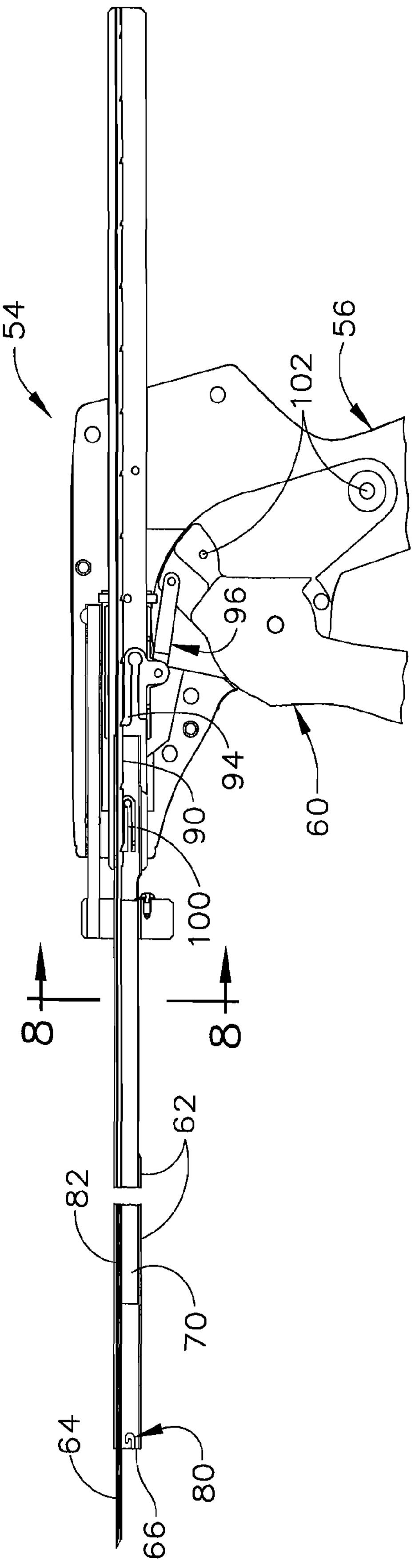


FIG. 6b



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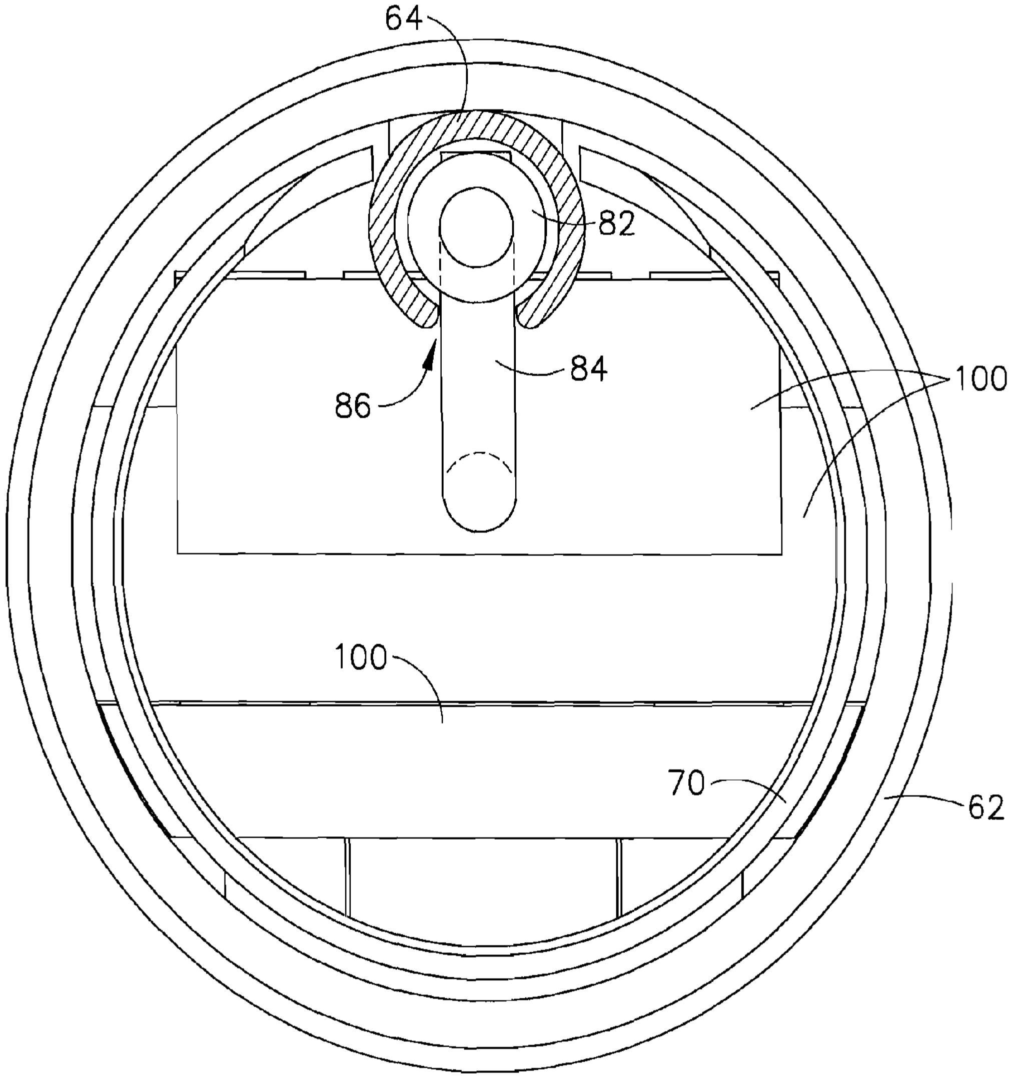
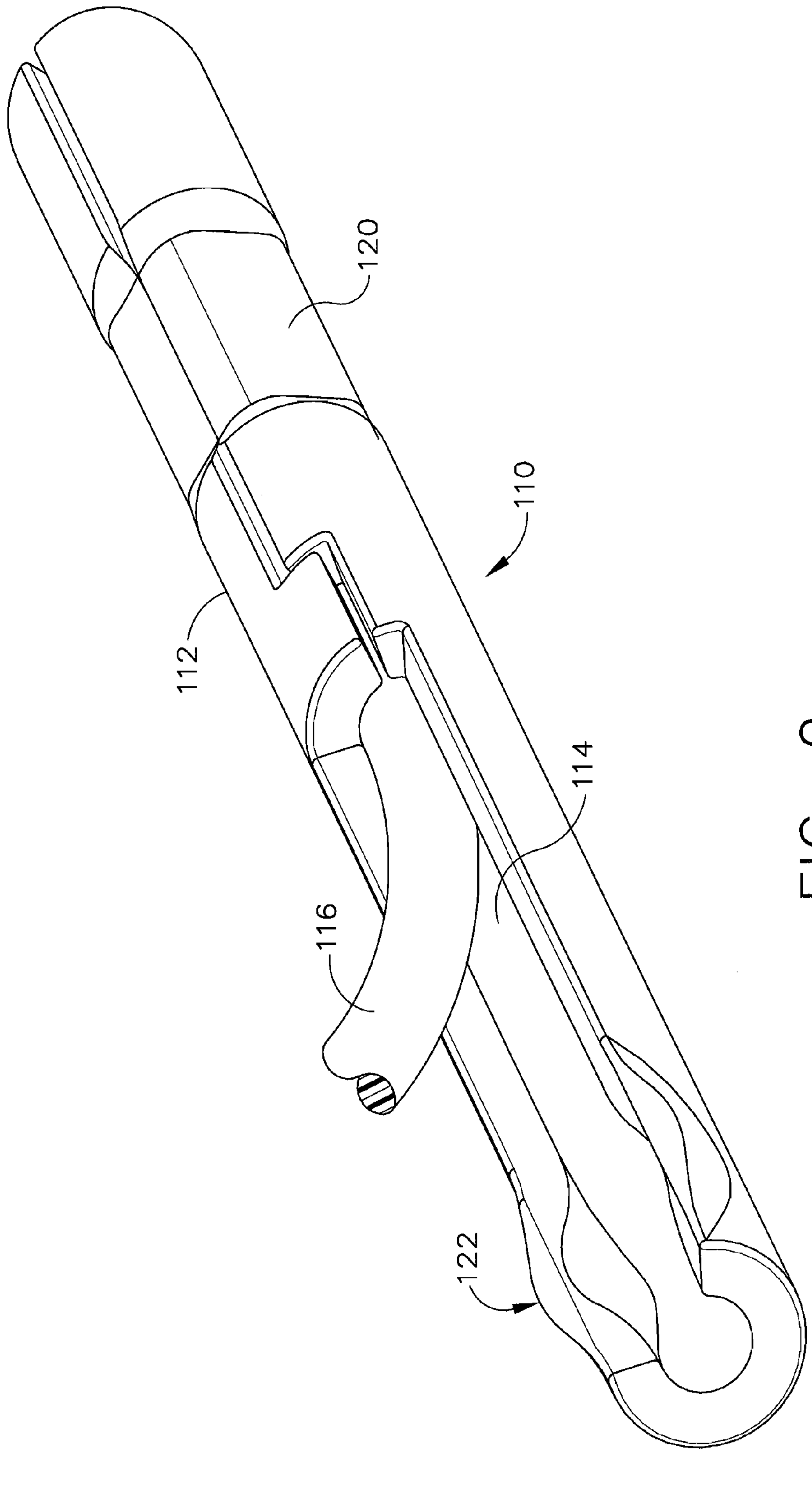


FIG. 8



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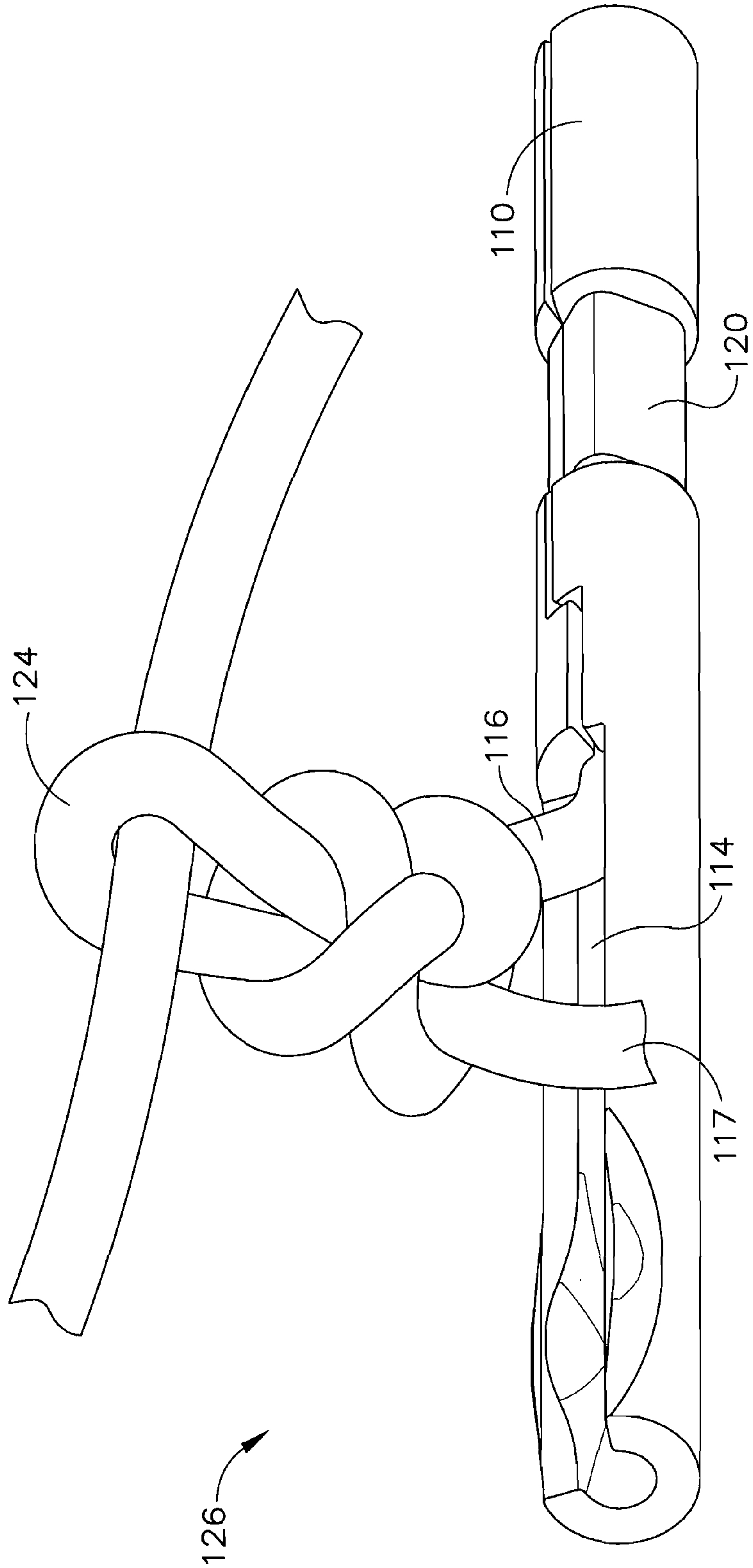
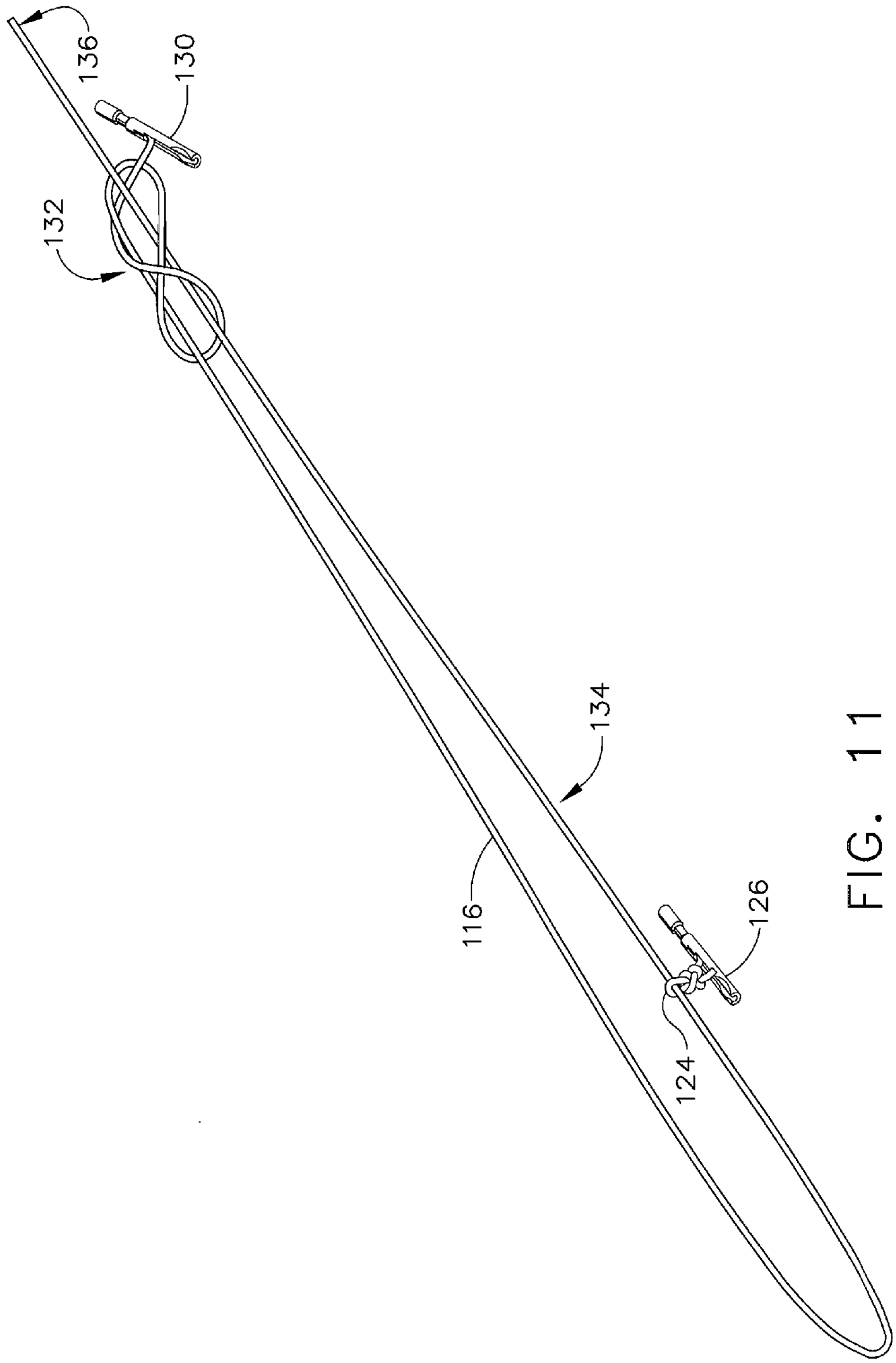


FIG. 10



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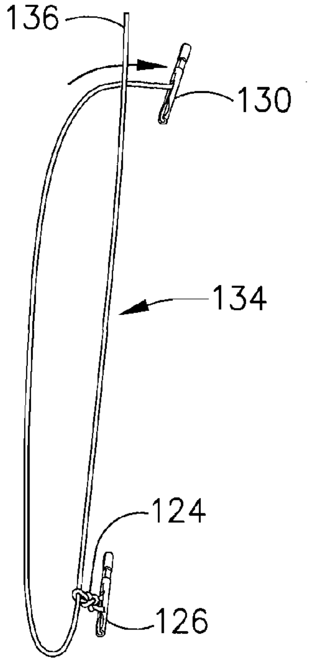


FIG. 12a

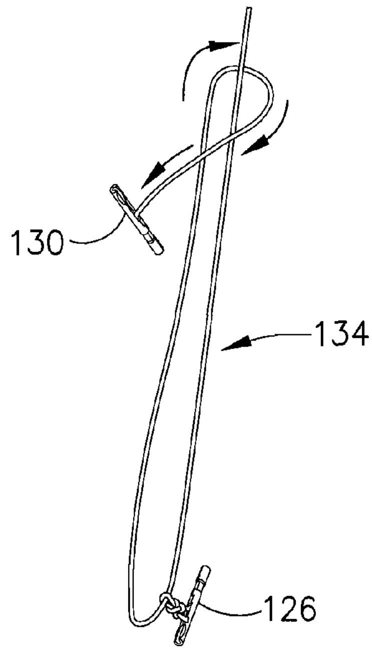


FIG. 12b

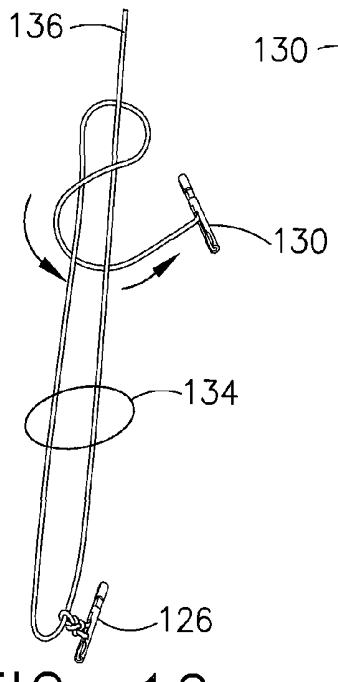


FIG. 12c

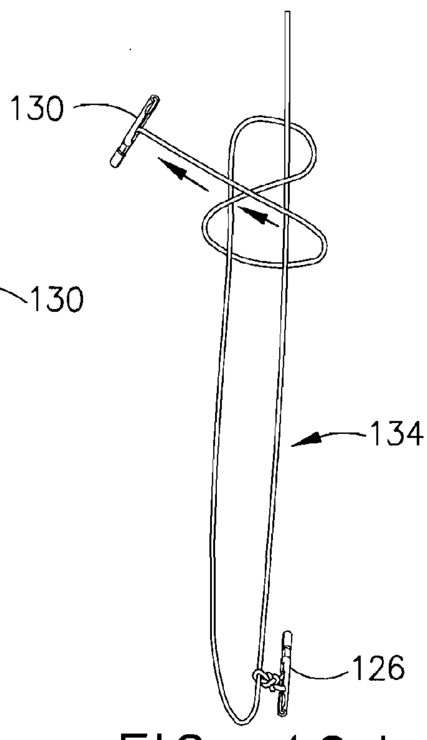


FIG. 12d

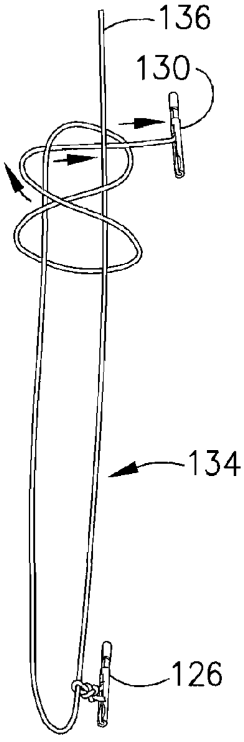
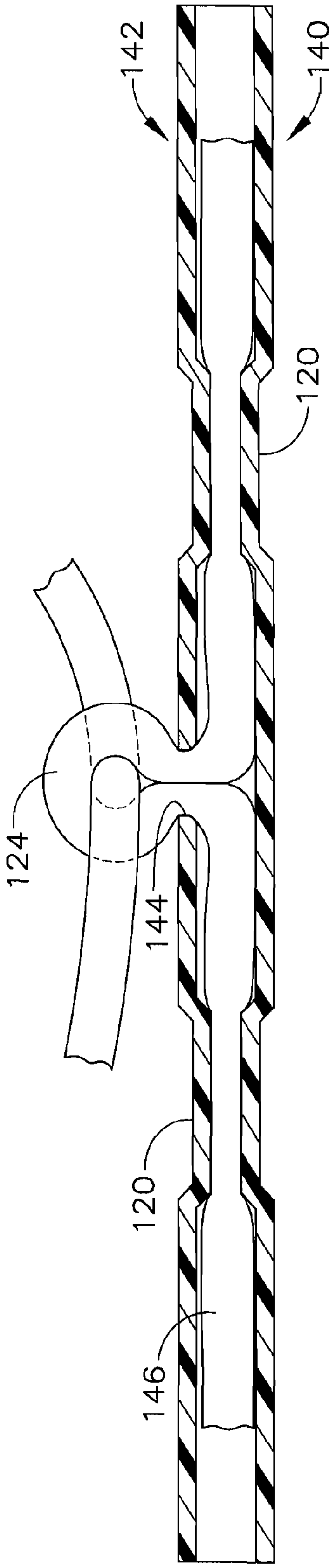


FIG. 12e



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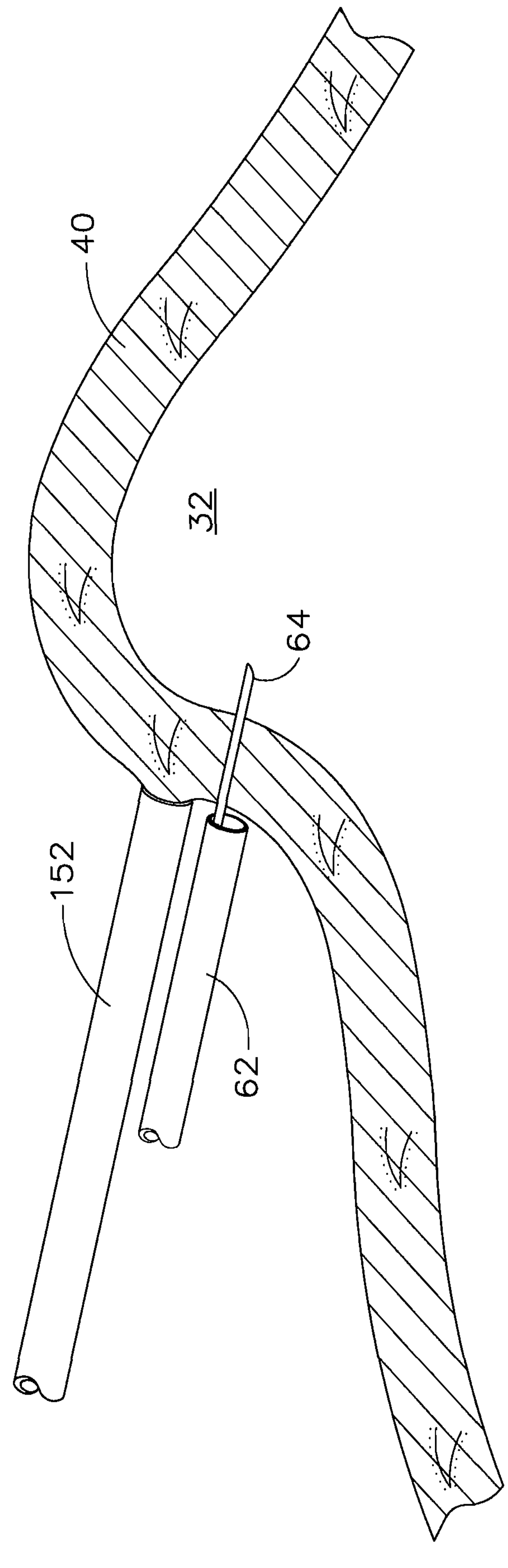

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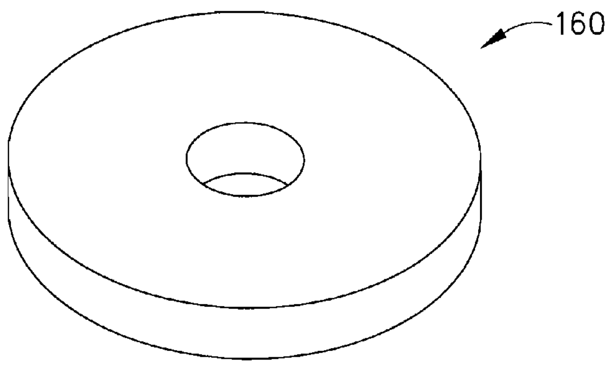

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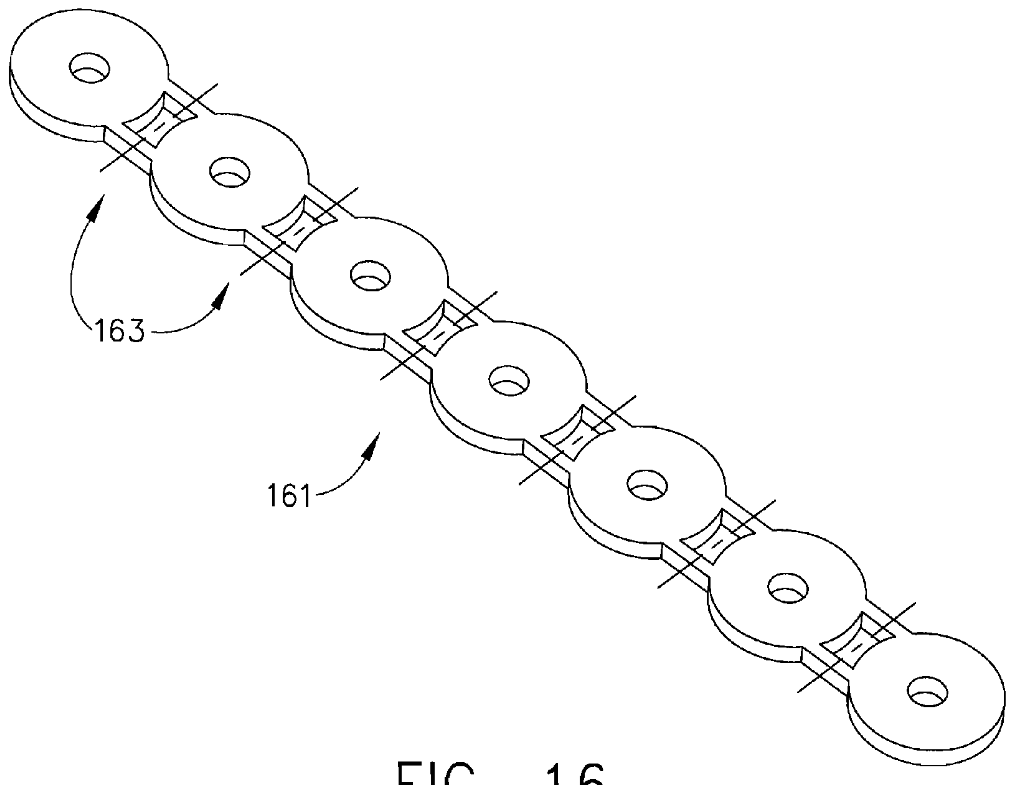

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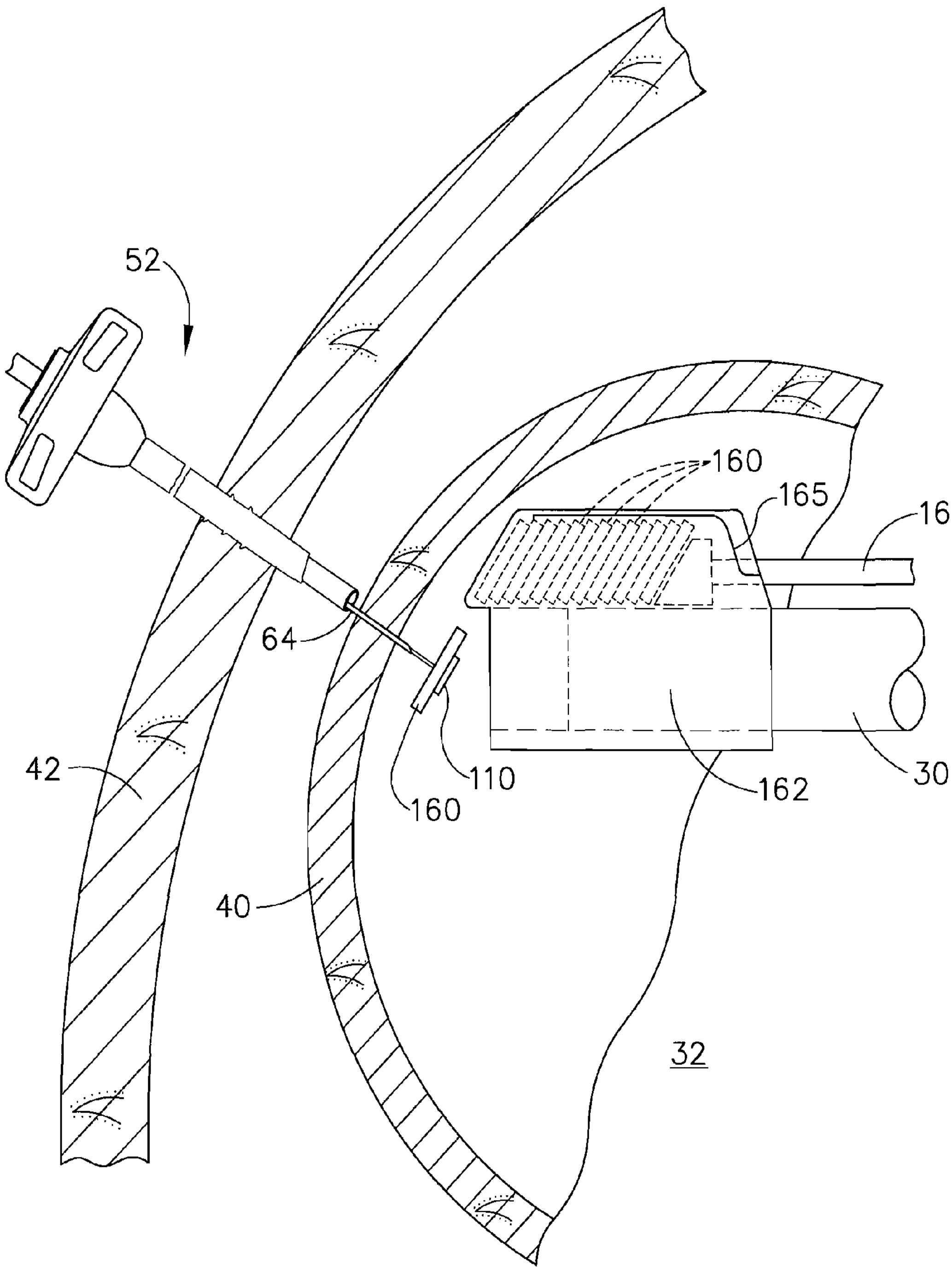
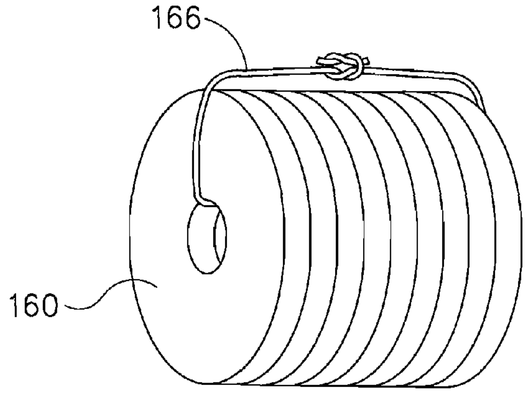


FIG. 17



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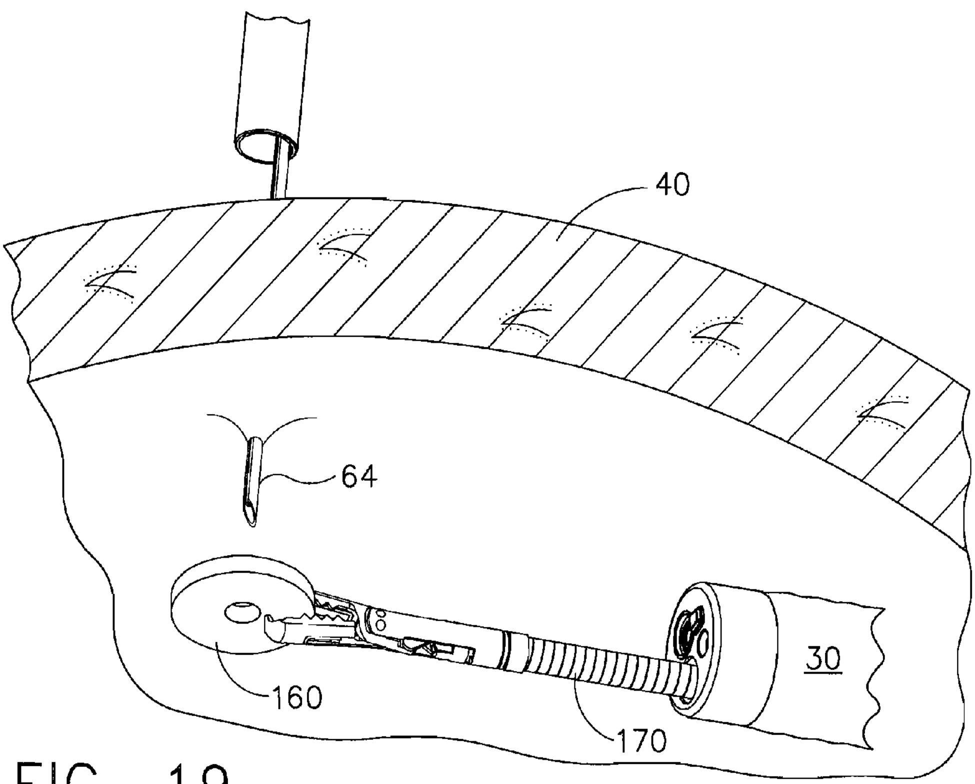

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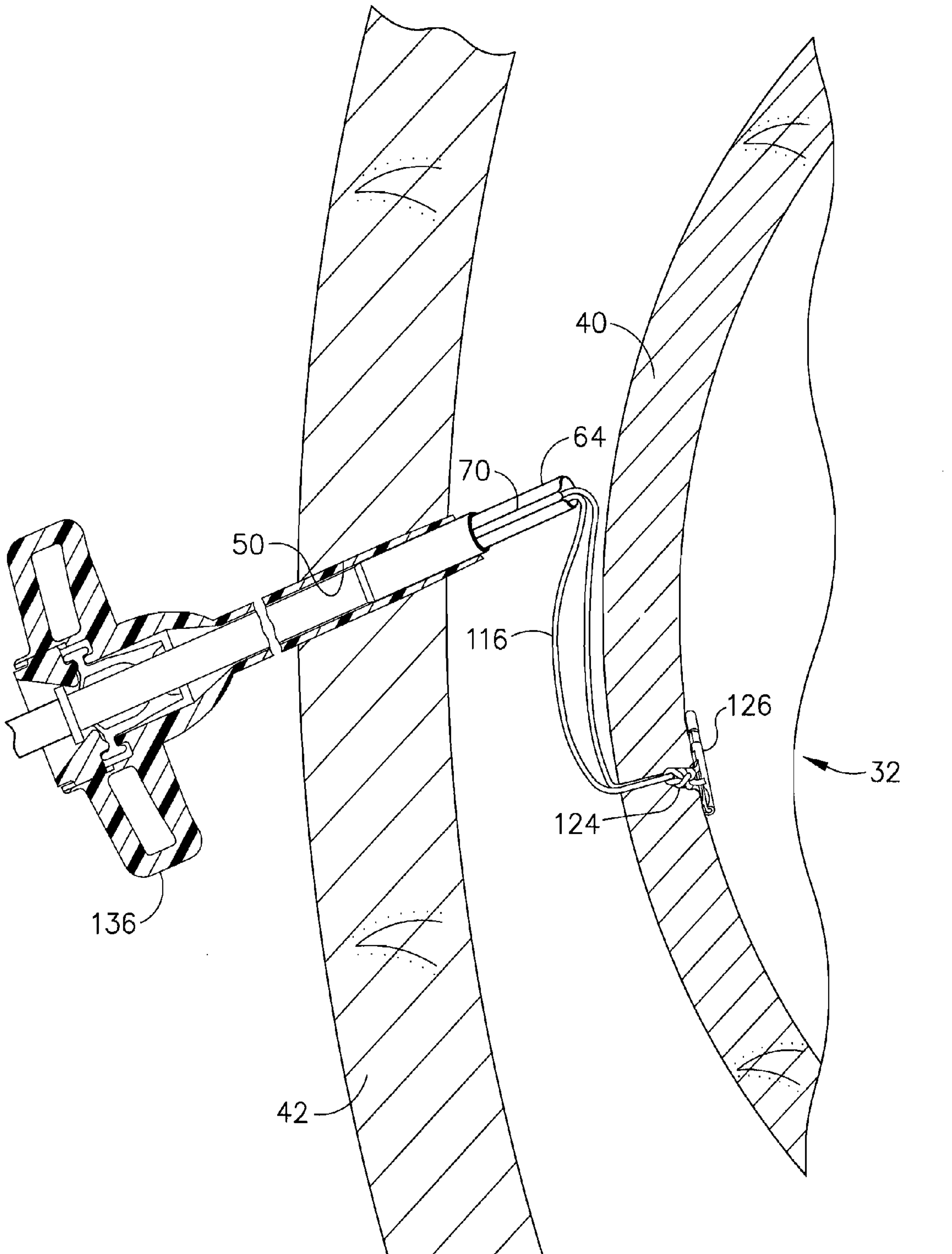

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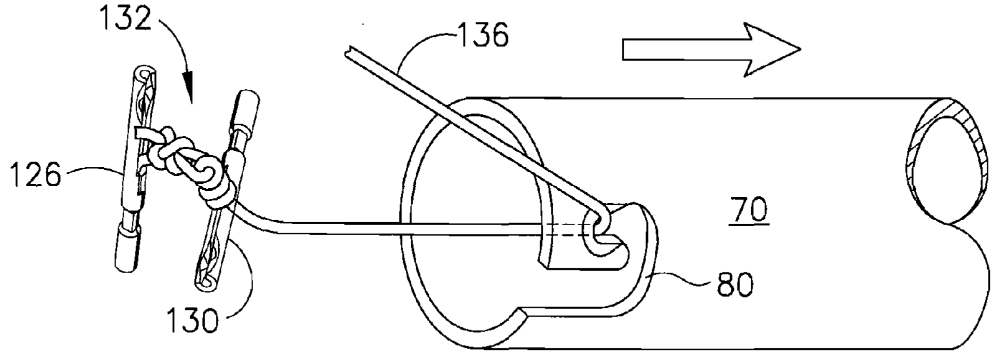

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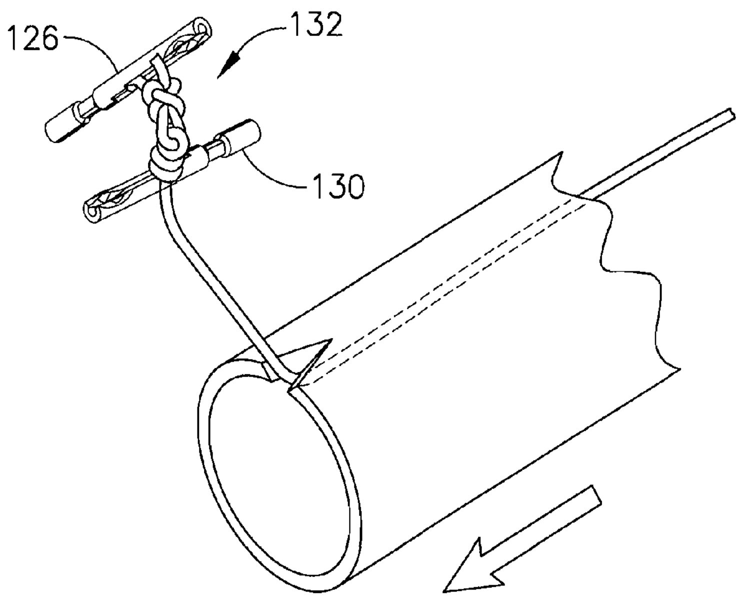

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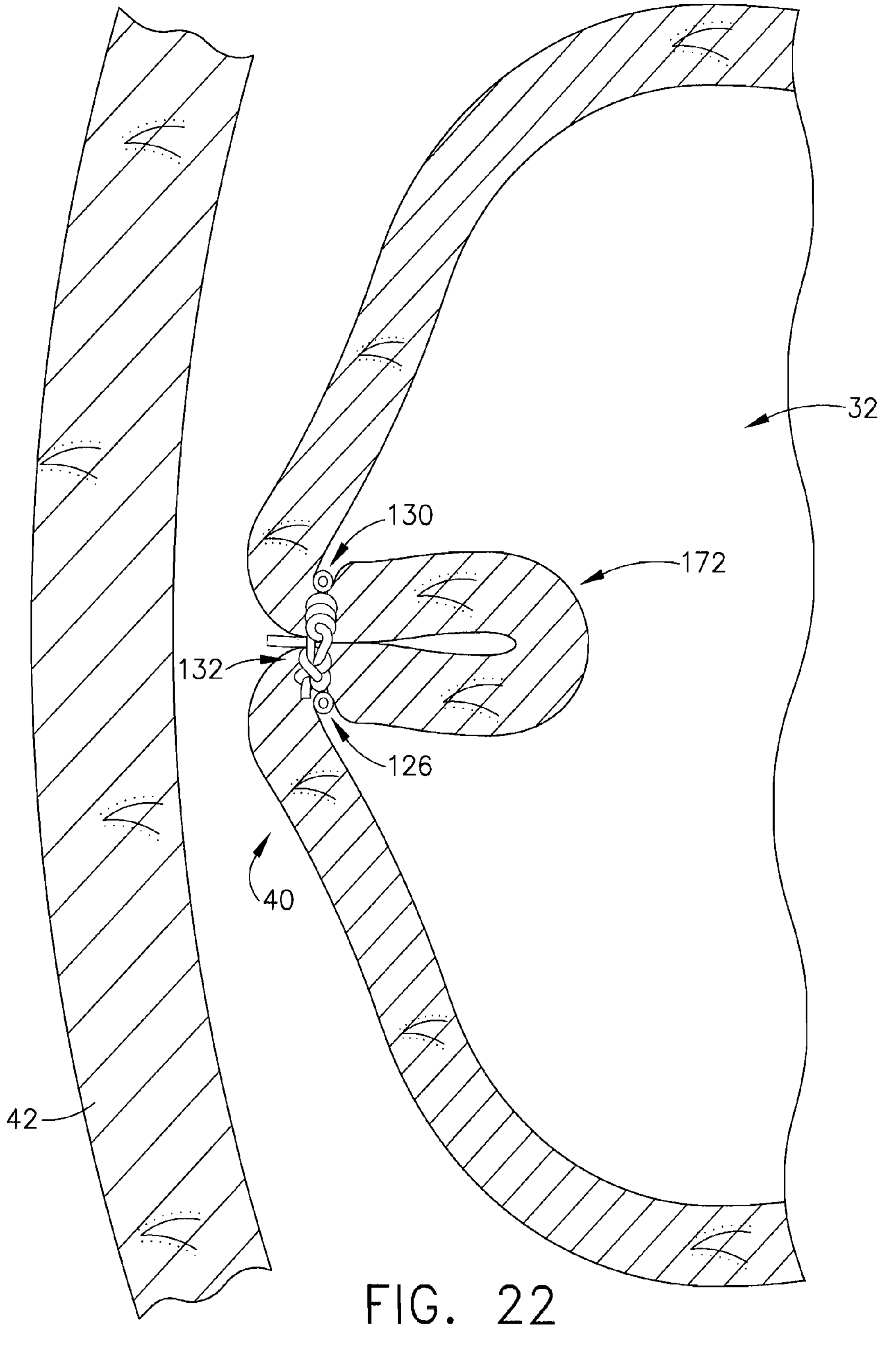
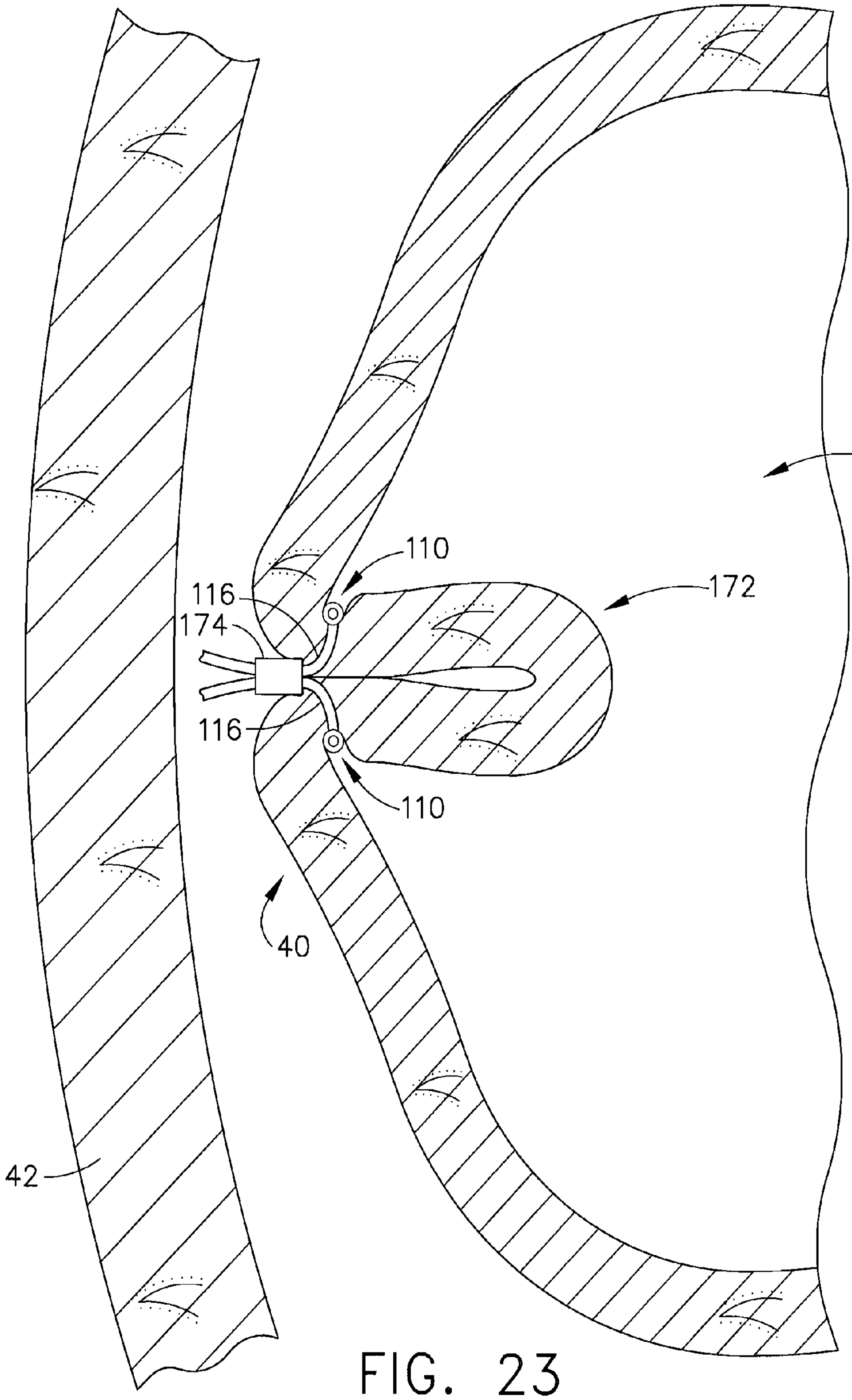


FIG. 22



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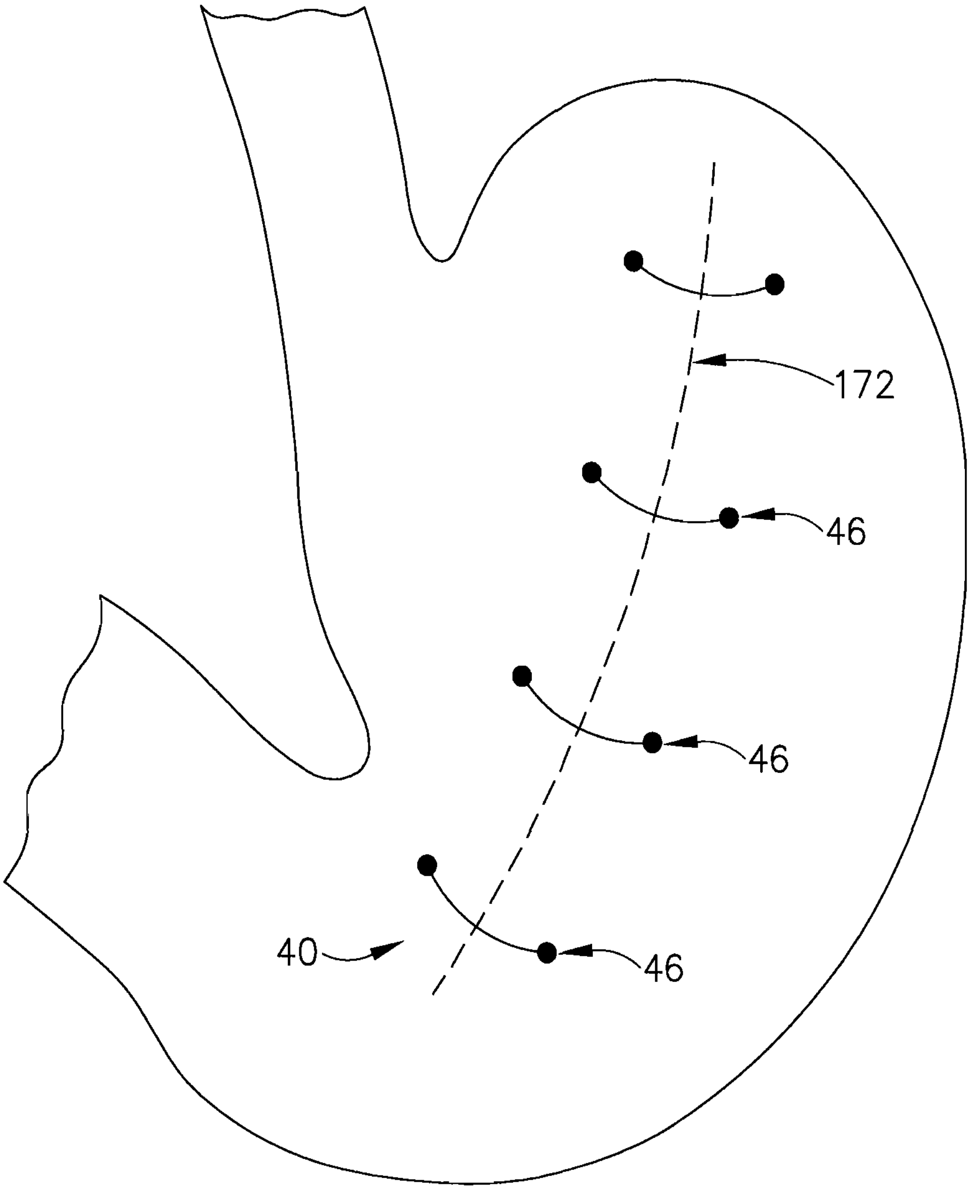

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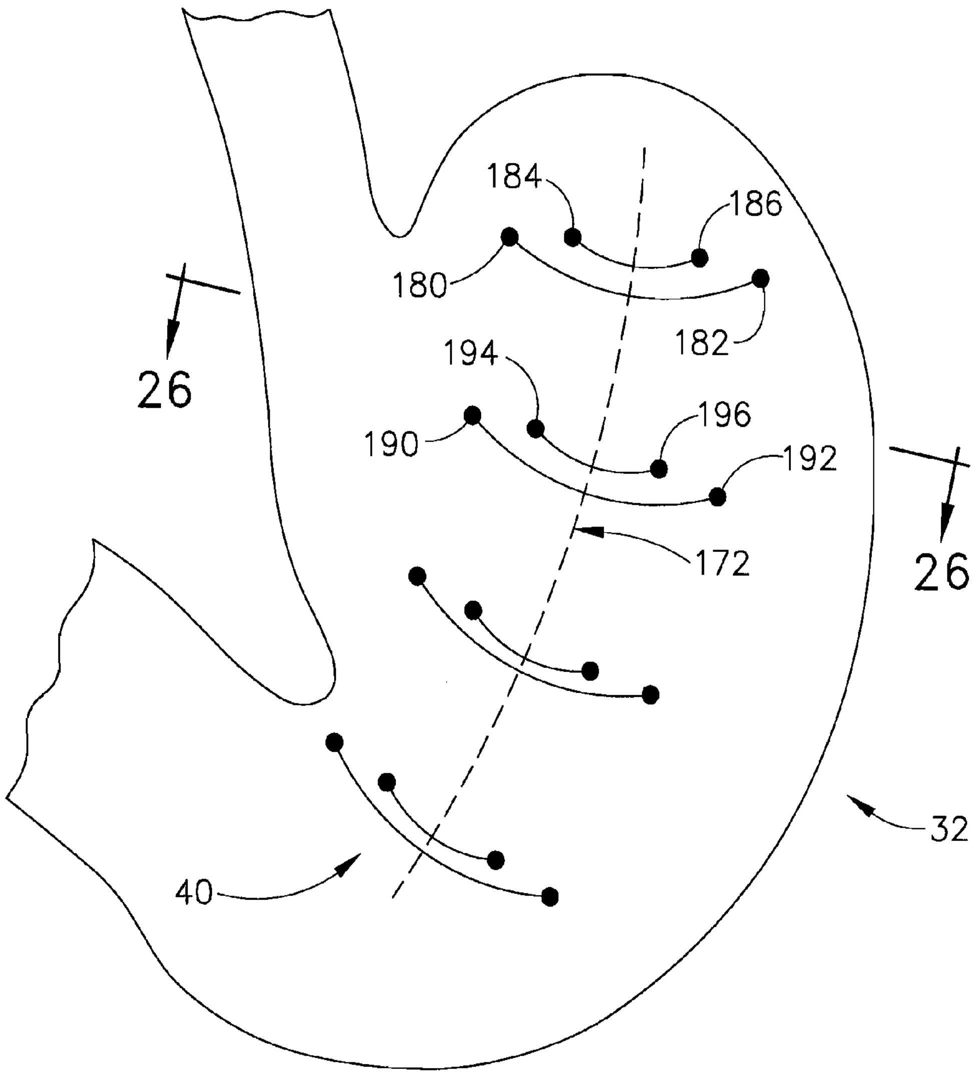

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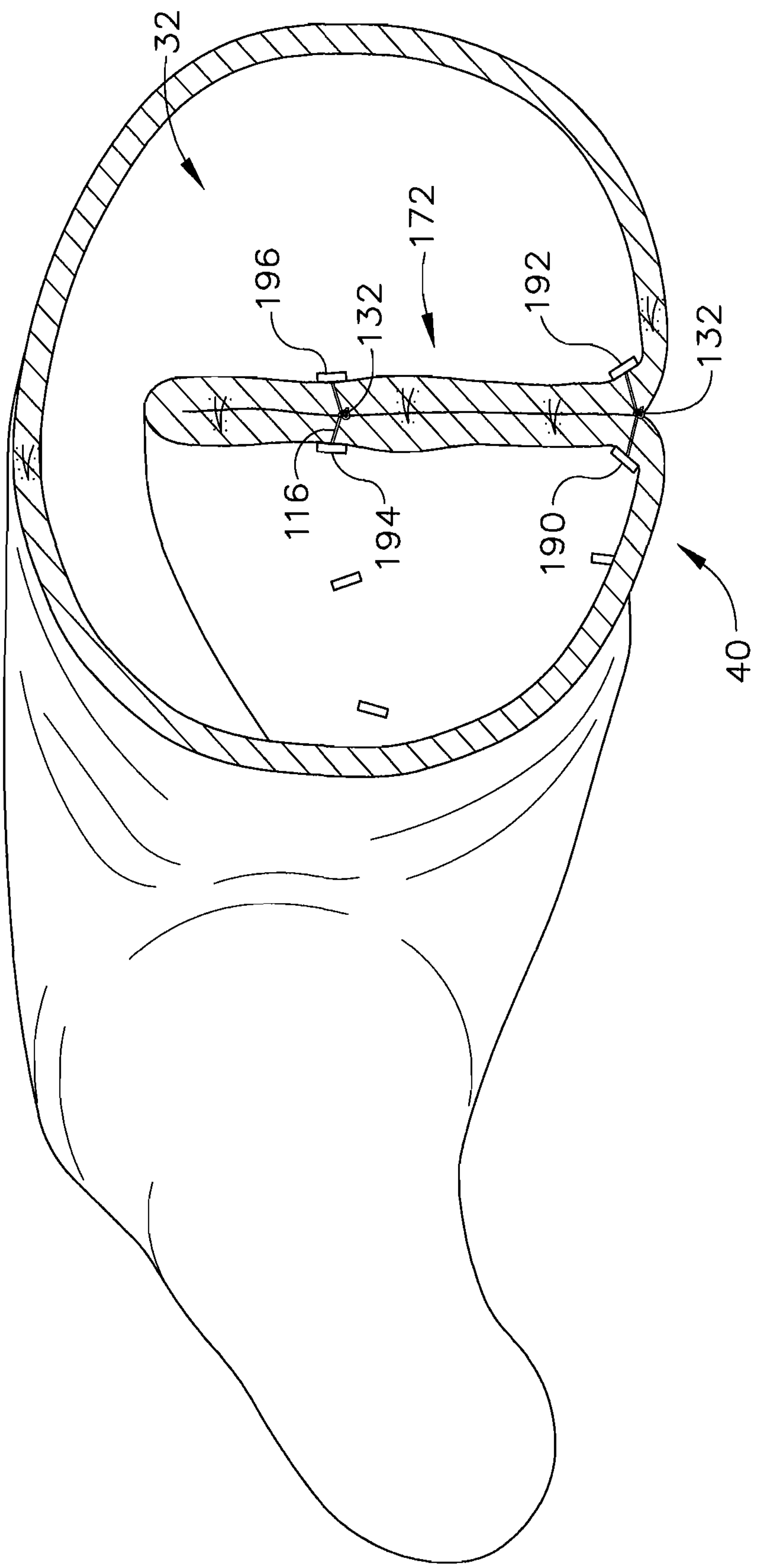

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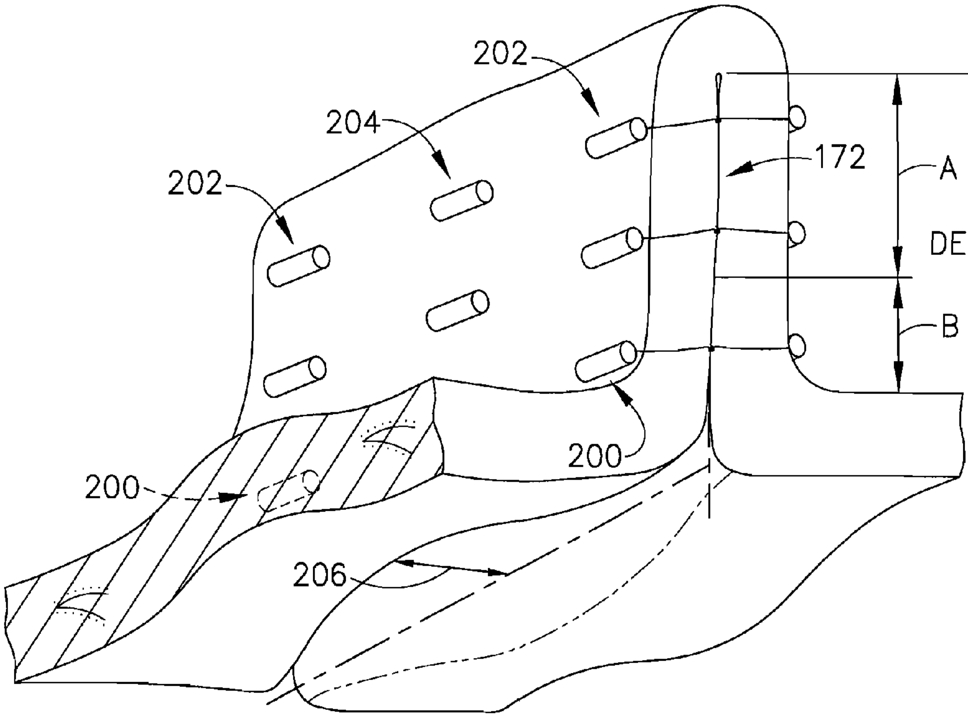

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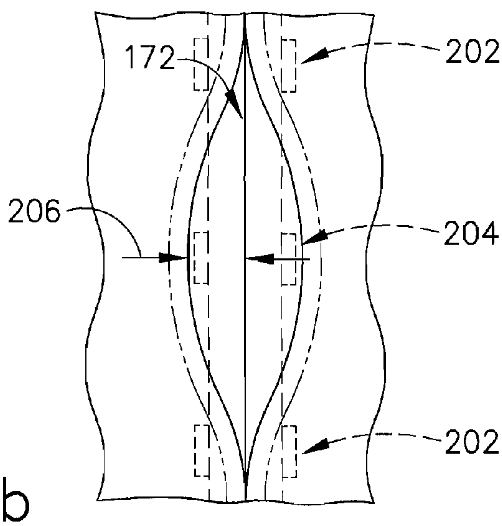

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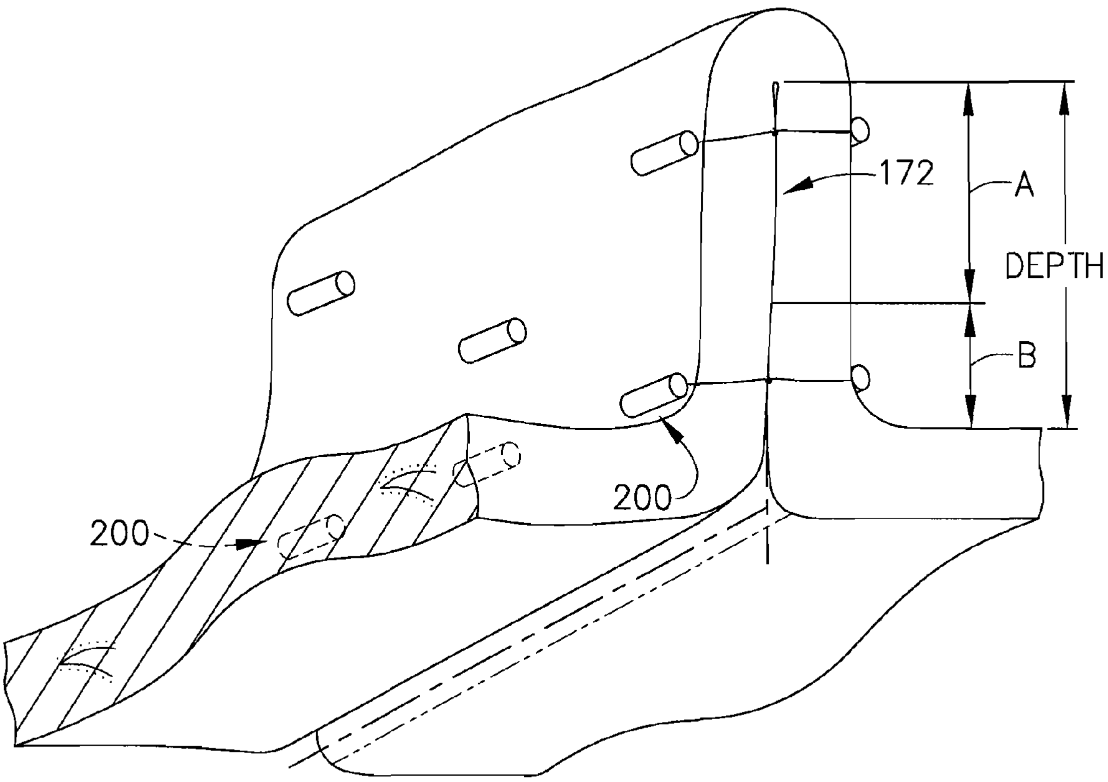


FIG. 28

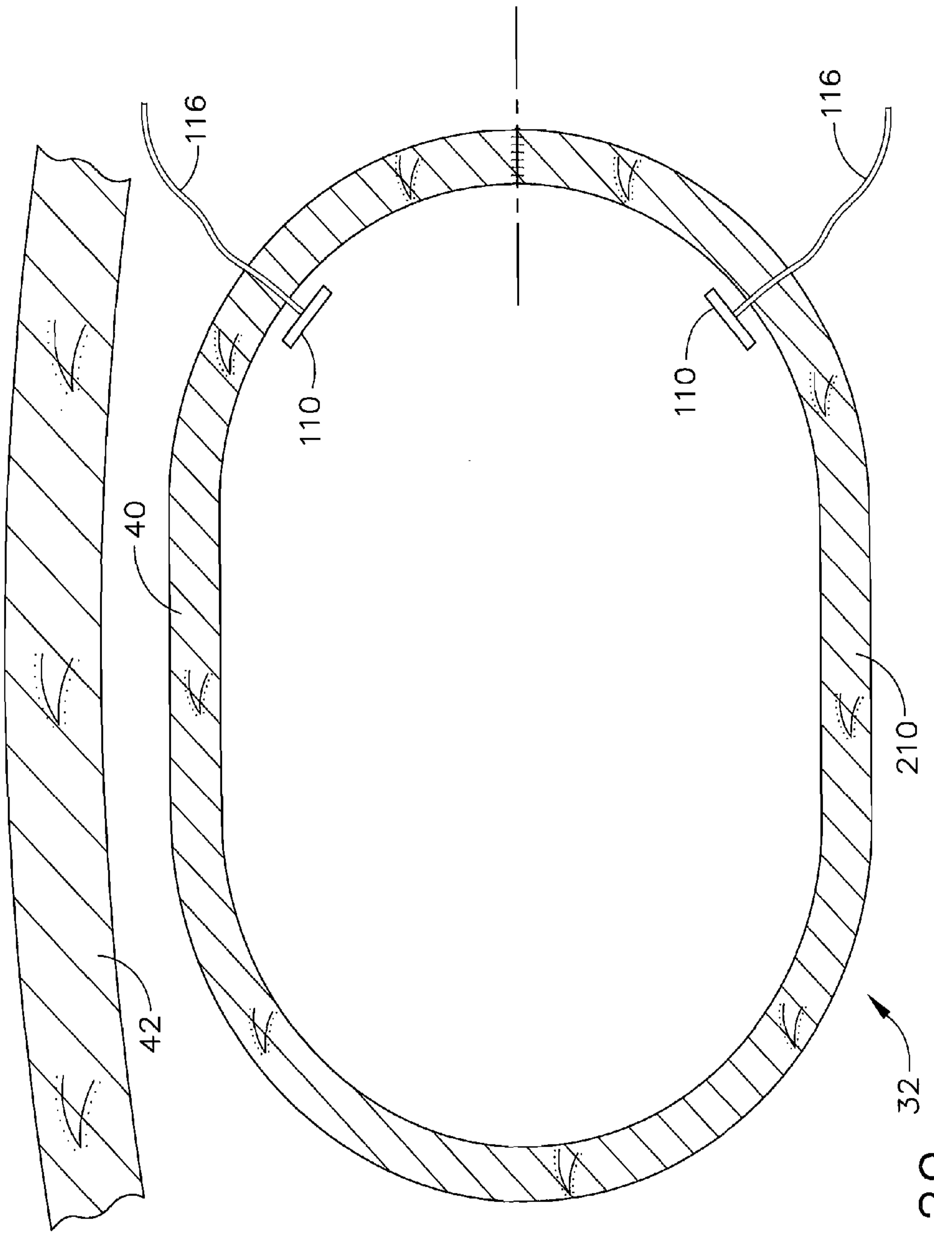


FIG. 29

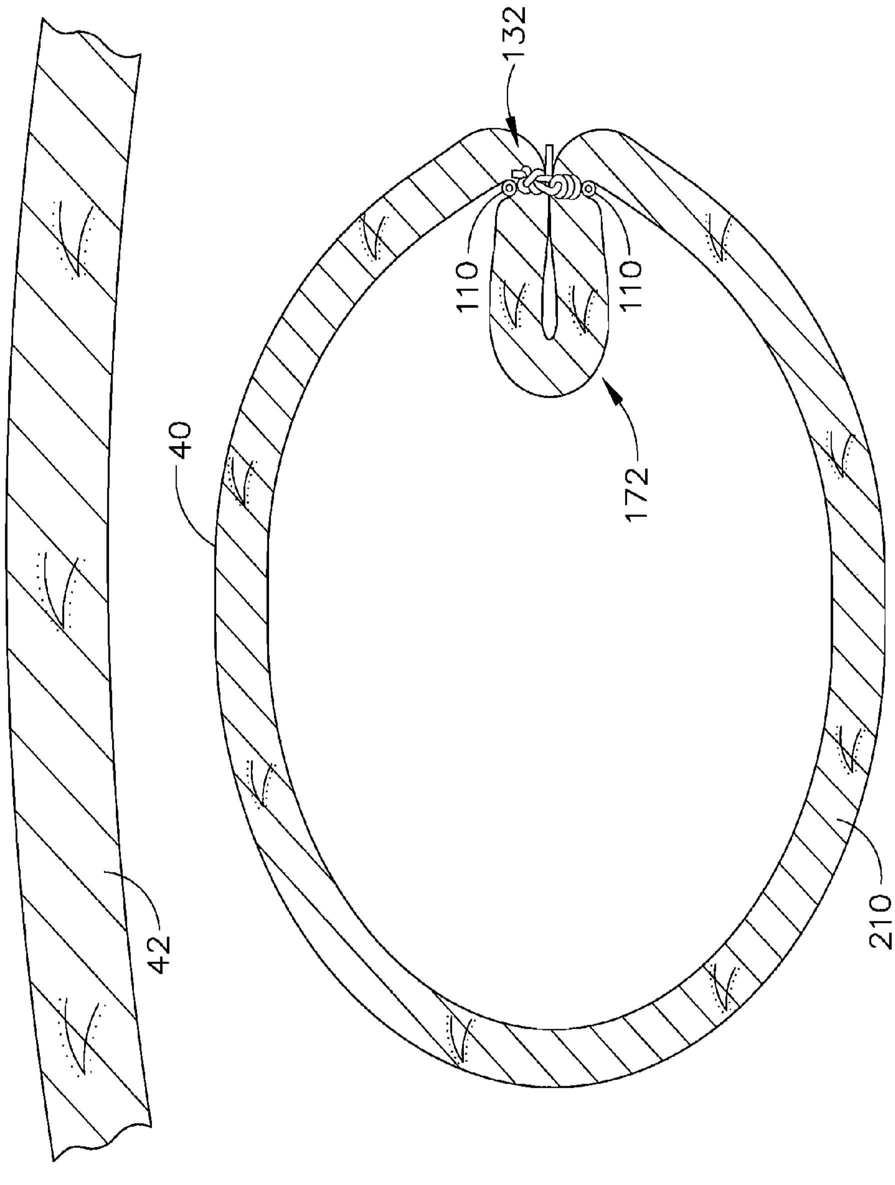


FIG. 30

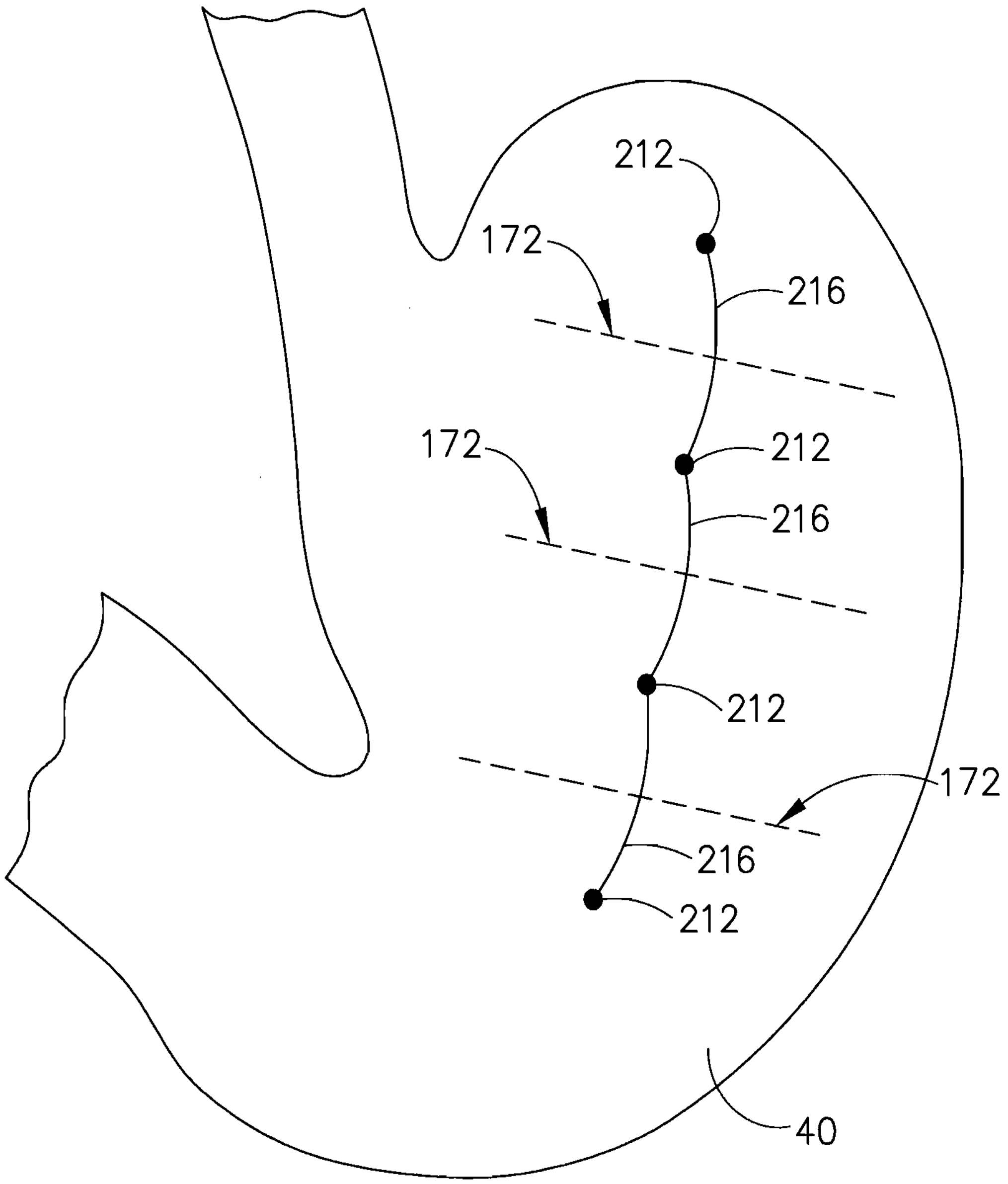


FIG. 31

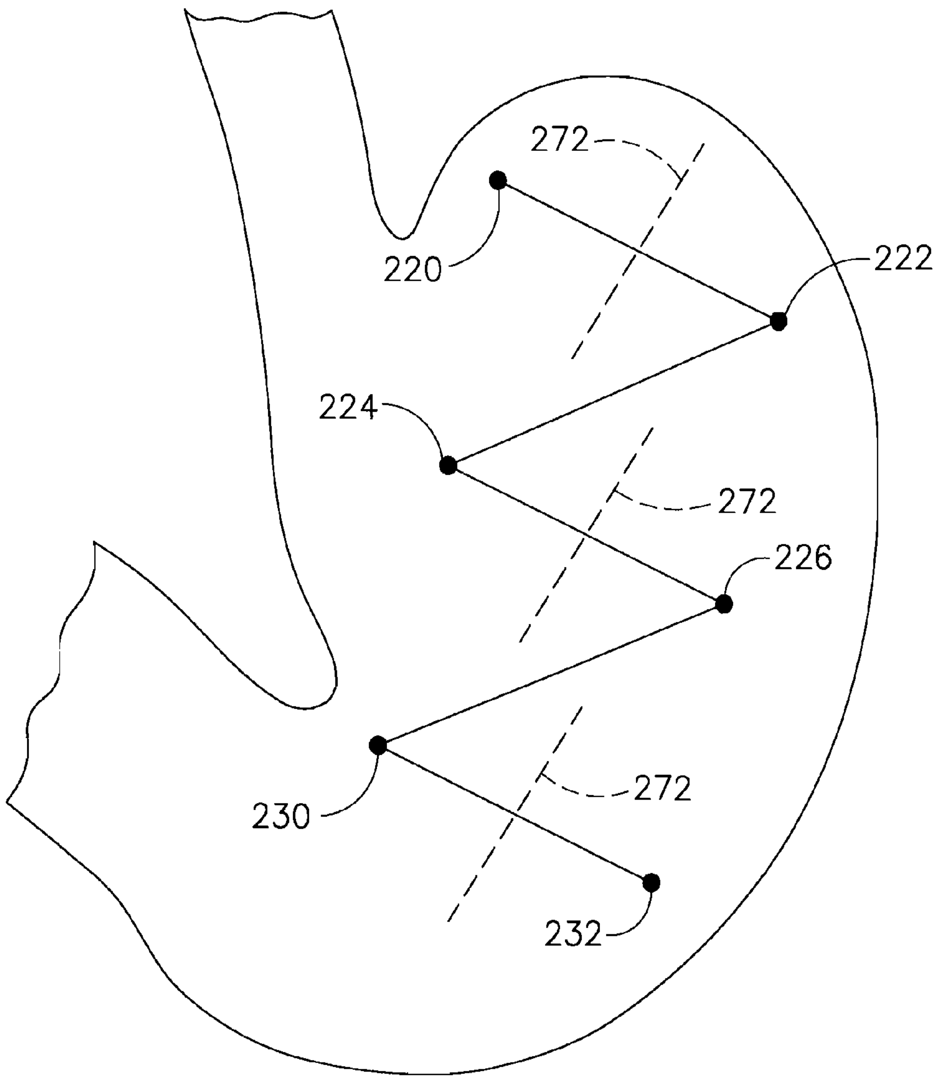


FIG. 32

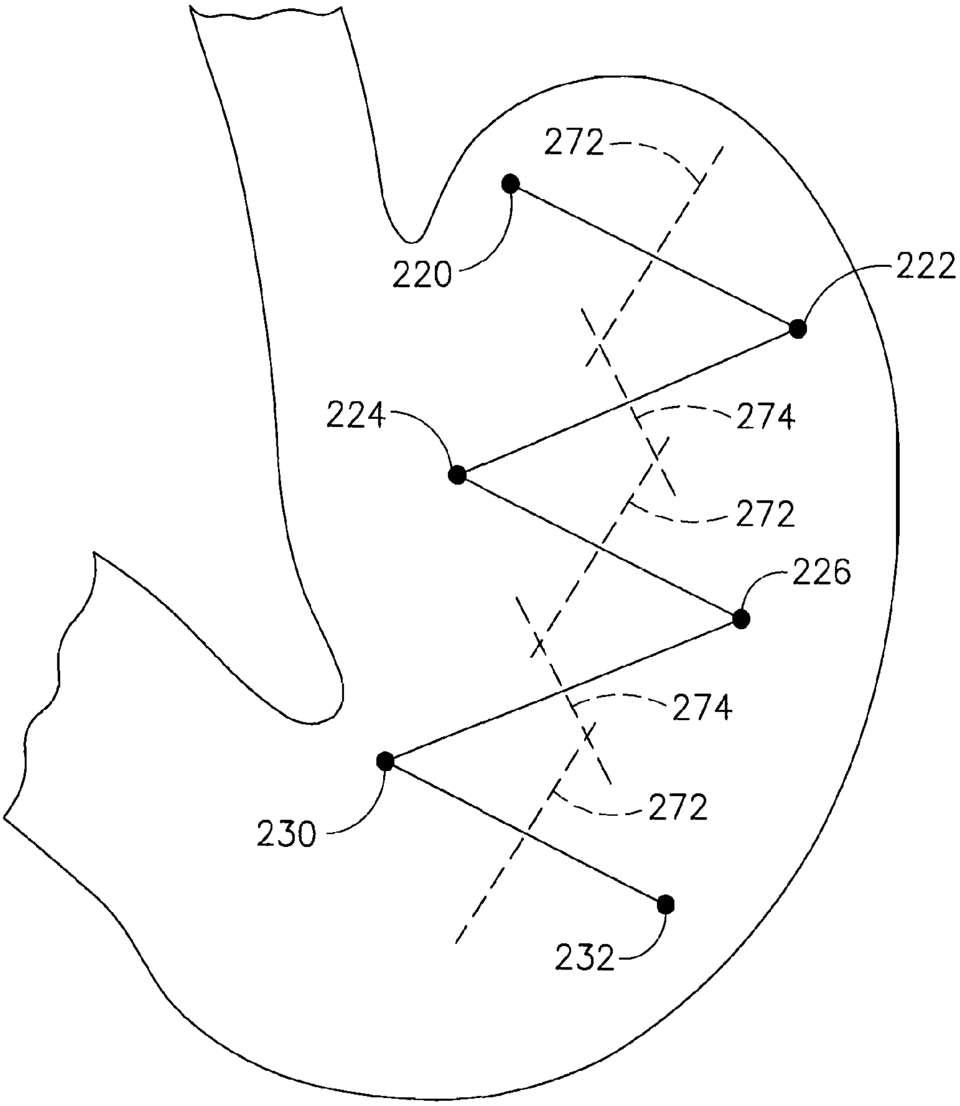


FIG. 33

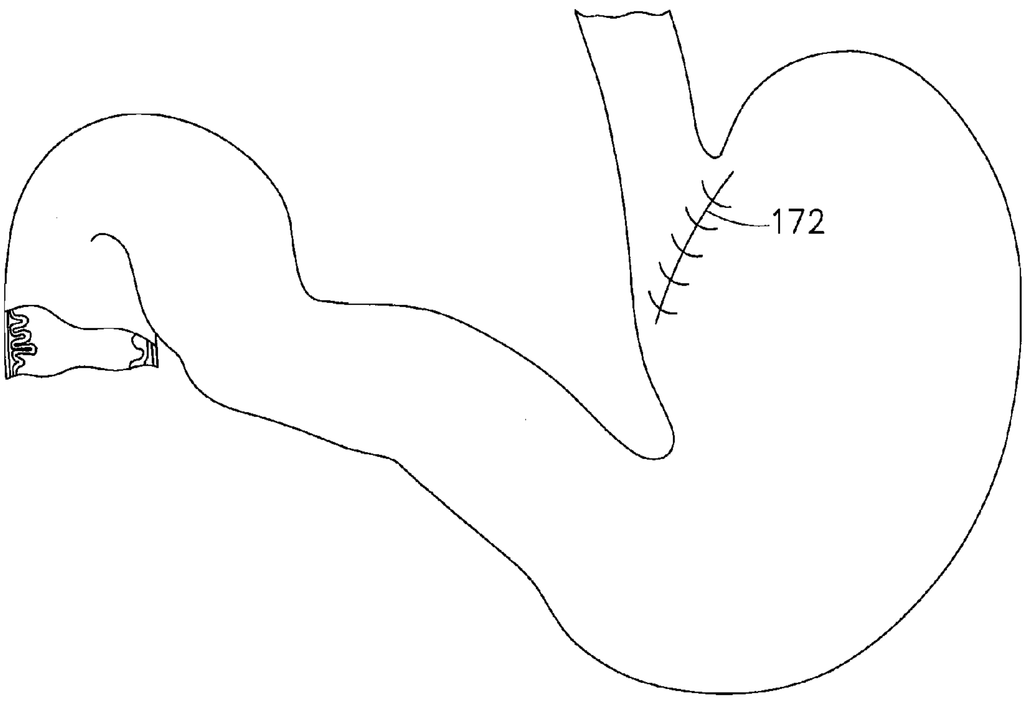
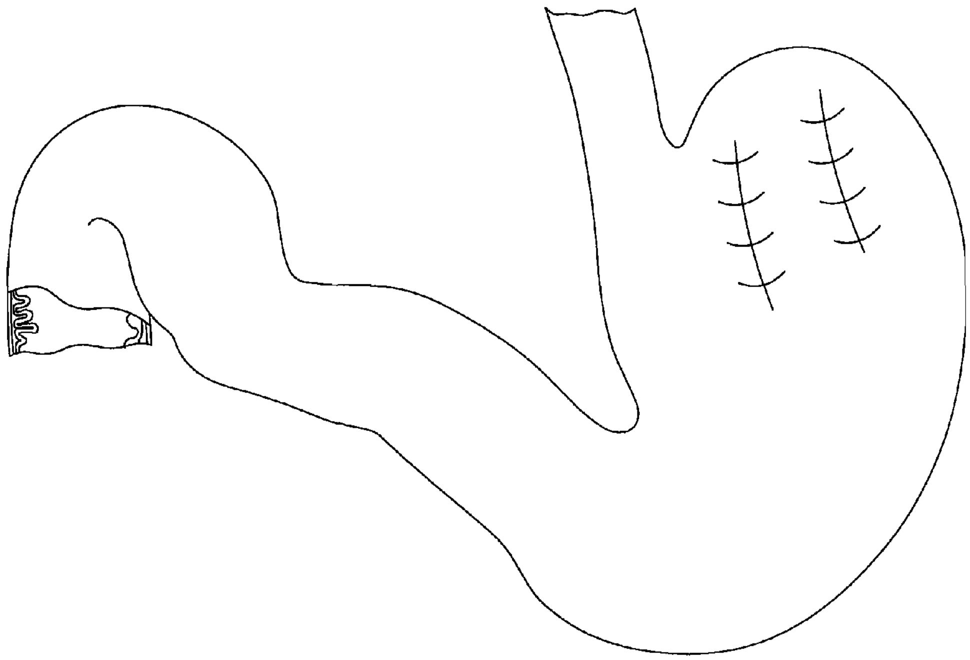


FIG. 34



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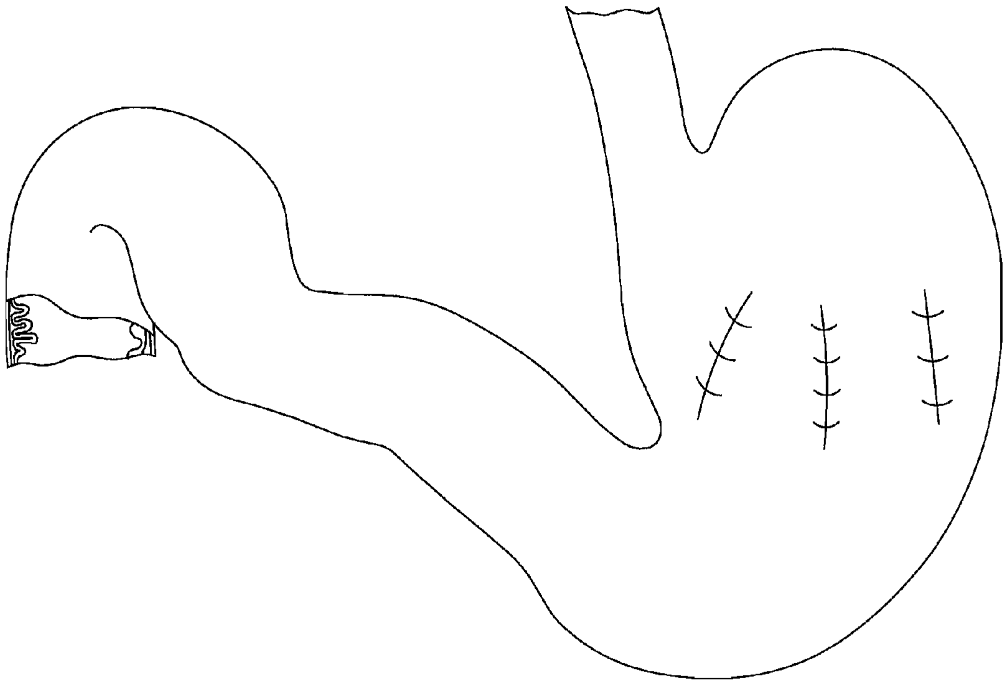

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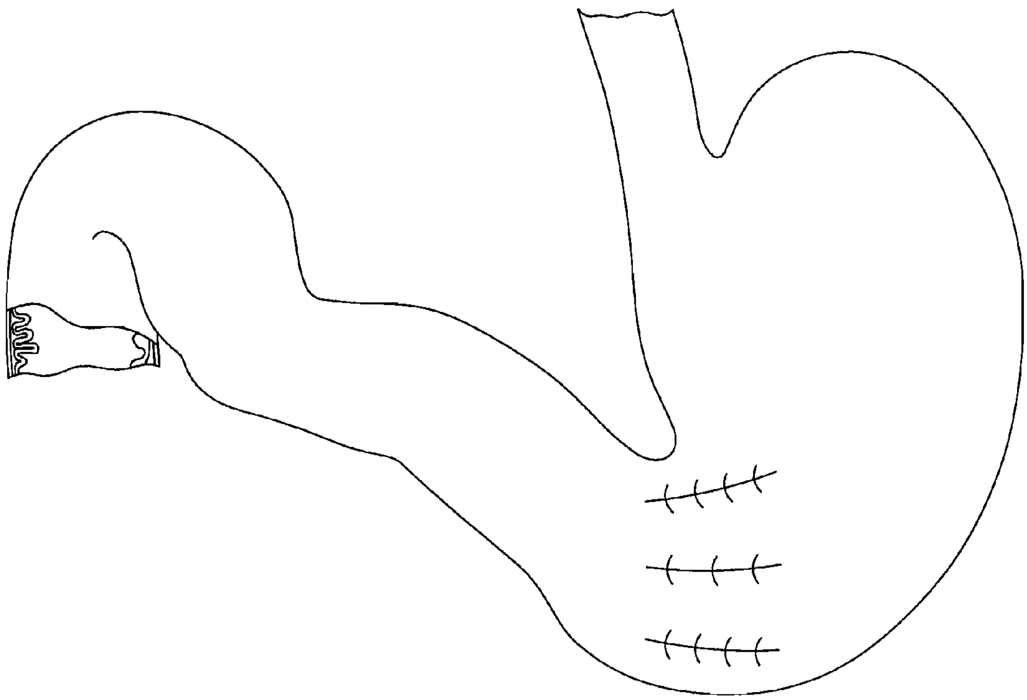

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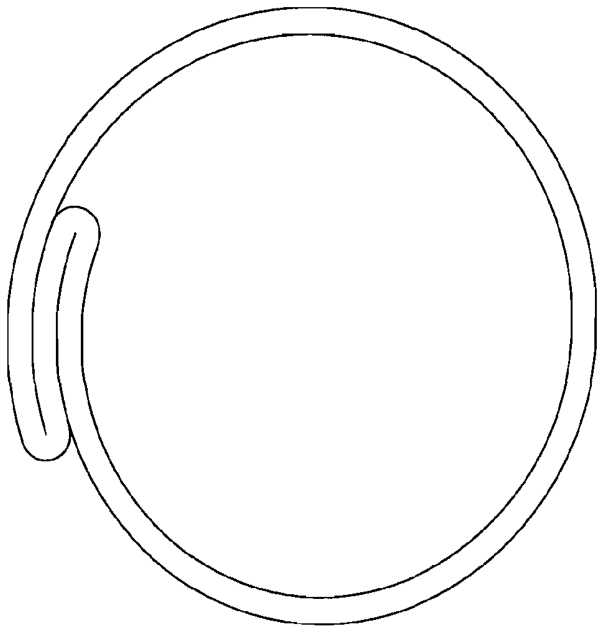

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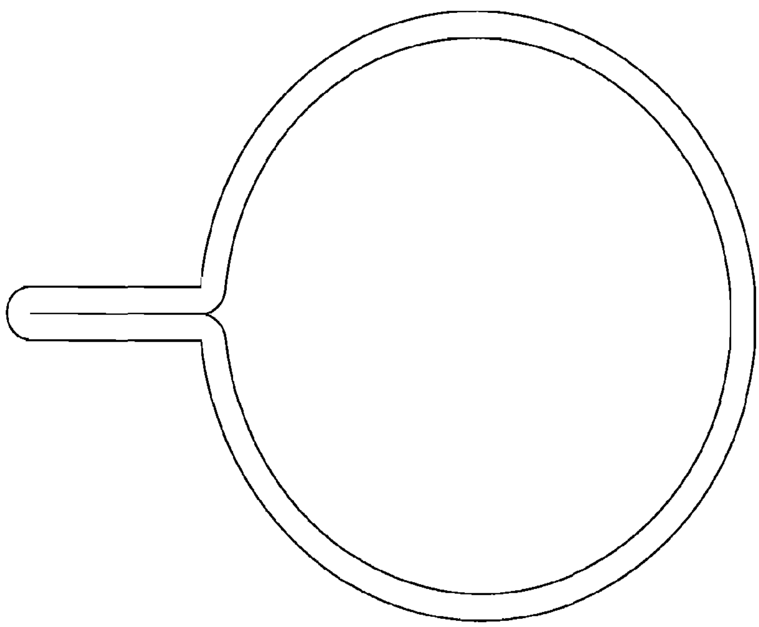

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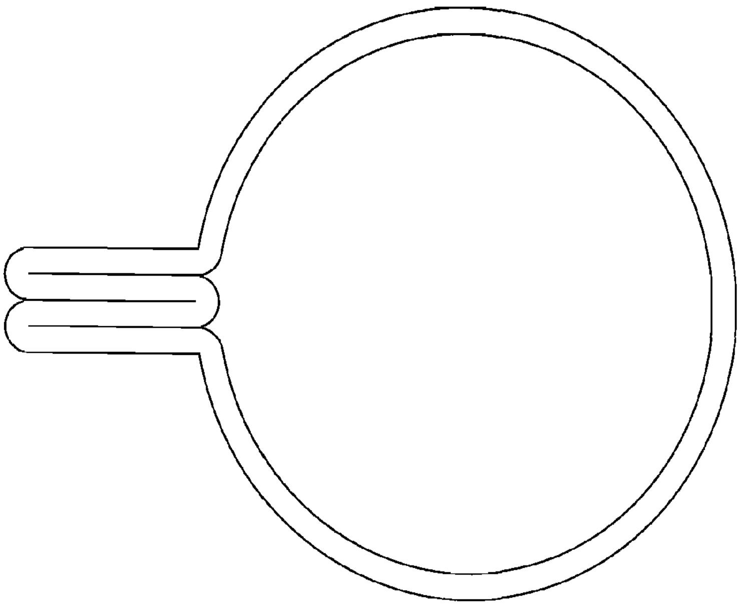

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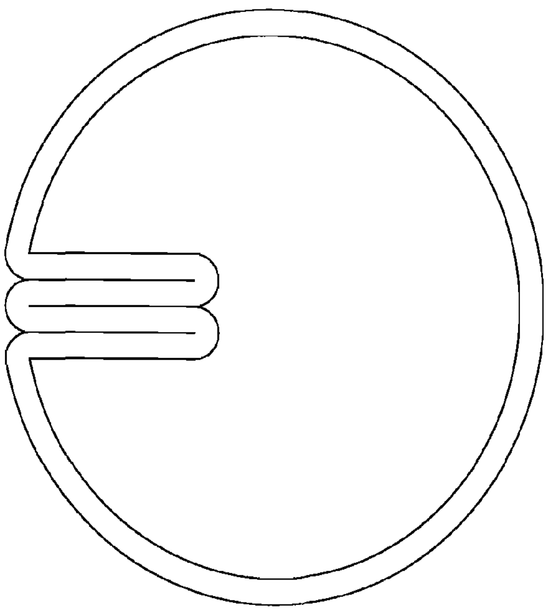

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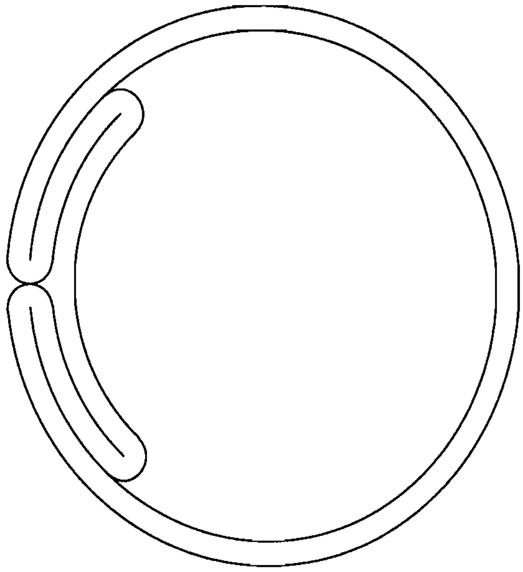
FIG. 43

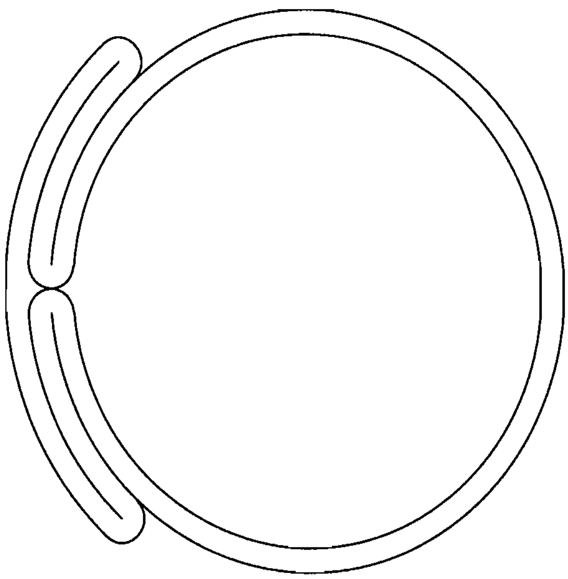
FIG. 42

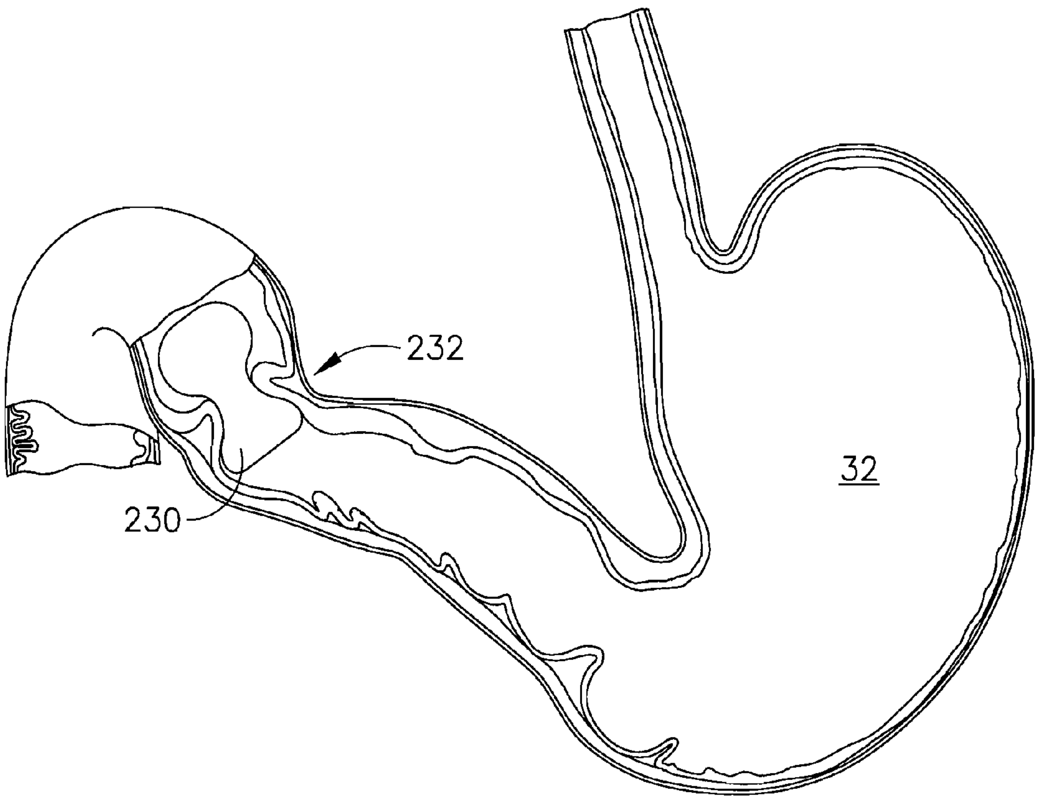

FIG. 44

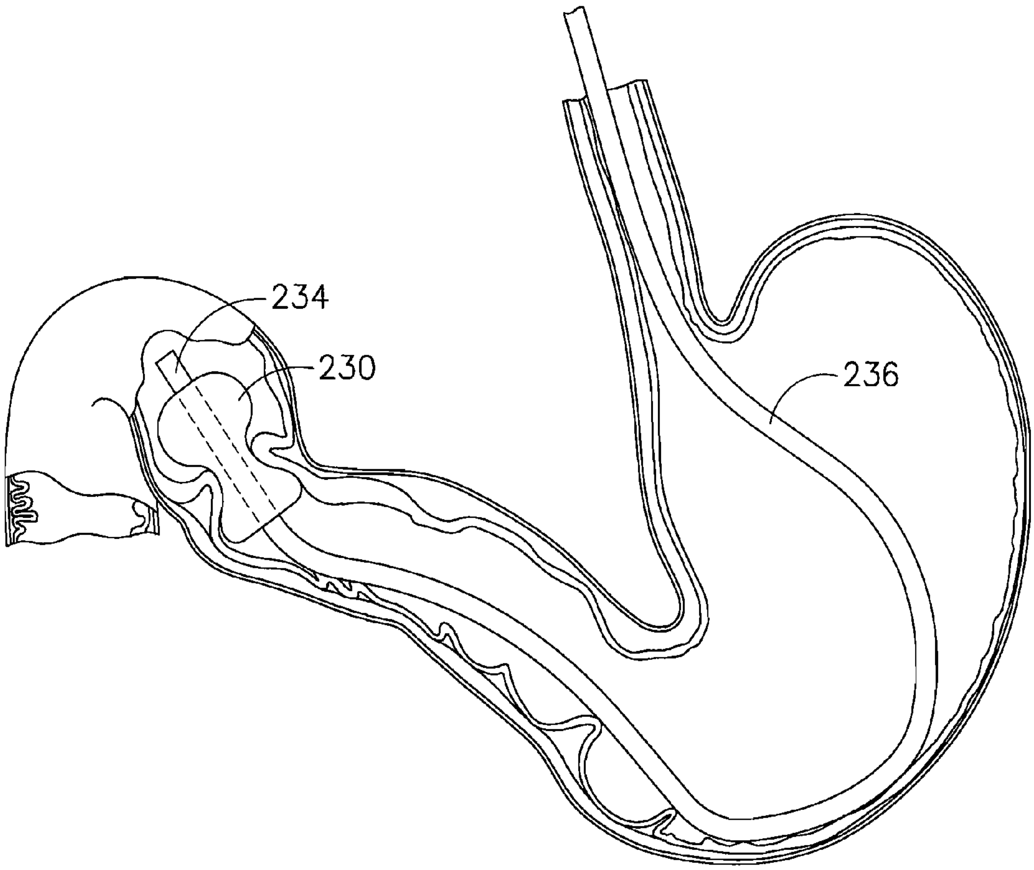

FIG. 45

HYBRID ENDOSCOPIC/LAPAROSCOPIC METHOD FOR FORMING SEROSA TO SEROSA PLICATIONS IN A GASTRIC CAVITY

FIELD OF THE INVENTION

The present invention relates generally to gastric reduction surgery and, more particularly, to a method for reducing gastric cavity volume by involuting the cavity wall in a hybrid endoscopic-laproscopic procedure to form one or more serosa to serosa contact folds.

BACKGROUND OF THE INVENTION

Obesity is a medical condition affecting more than 30% of the population in the United States. Obesity affects an individual's personal quality of life and contributes significantly to morbidity and mortality. Obese patients, i.e. individuals having a body mass index ("BMI") greater than 30, often have a high risk of associated health problems (e.g., diabetes, hypertension, and respiratory insufficiency), including early death. With this in mind, and as those skilled in the art will certainly appreciate, the monetary and physical costs associated with obesity are substantial. In fact, it is estimated the costs relating to obesity are in excess of 100 billion dollars in the United States alone. Studies have shown that conservative treatment with diet and exercise alone may be ineffective for reducing excess body weight in many patients.

Bariatrics is the branch of medicine that deals with the control and treatment of obesity. A variety of surgical procedures have been developed within the bariatrics field to treat obesity. The most common currently performed procedure is the Roux-en-Y gastric bypass (RYGB). This procedure is highly complex and is commonly utilized to treat people exhibiting morbid obesity. In a RYGB procedure a small stomach pouch is separated from the remainder of the gastric cavity and attached to a resectioned portion of the small intestine. This resectioned portion of the small intestine is connected between the "smaller" gastric cavity and a distal section of small intestine allowing the passage of food therebetween. The conventional RYGB procedure requires a great deal of operative time. Because of the degree of invasiveness, post-operative recovery can be quite lengthy and painful. Still more than 100,000 RYGB procedures are performed annually in the United States alone, costing significant health care dollars.

In view of the highly invasive nature of the RYGB procedure, other less invasive procedures have been developed. These procedures include gastric banding, which constricts the stomach to form an hourglass shape. This procedure restricts the amount of food that passes from one section of the stomach to the next, thereby inducing a feeling of satiety. A band is placed around the stomach near the junction of the stomach and esophagus. The small upper stomach pouch is filled quickly, and slowly empties through the narrow outlet to produce the feeling of satiety. In addition to surgical complications, patients undergoing a gastric banding procedure may suffer from esophageal injury, spleen injury, band slippage, reservoir deflation/leak, and persistent vomiting. Other forms of bariatric surgery that have been developed to treat obesity include Fobi pouch, bilio-pancreatic diversion and gastroplasty or "stomach stapling".

Morbid obesity is defined as being greater than 100 pounds over one's ideal body weight. For individuals in this category, RYGB, gastric banding or another of the more complex procedures may be the recommended course of treatment due to

the significant health problems and mortality risks facing the individual. However, there is a growing segment of the population in the United States and elsewhere who are overweight without being considered morbidly obese. These persons may be 20-30 pounds overweight and want to lose the weight, but have not been able to succeed through diet and exercise alone. For these individuals, the risks associated with the RYGB or other complex procedures often outweigh the potential health benefits and costs. Accordingly, treatment options should involve a less invasive, lower cost solution for weight loss.

It is known to create cavity wall plications though endoscopic only procedures. However, operating solely within the interior of the gastric cavity limits the plication depth that can be achieved without cutting. Furthermore, access and visibility within the gastric and peritoneal cavities is limited in a purely endoscopic procedure as the extent of the reduction increases.

With the foregoing in mind, it is desirable to have a surgical weight loss procedure that is inexpensive, with few potential complications, and that provides patients with a weight loss benefit while buying time for the lifestyle changes necessary to maintain the weight loss. Further, it is desirable that the procedure be minimally invasive to the patient, allowing for a quick recovery and less scaring. The present invention provides such a procedure.

SUMMARY OF THE INVENTION

The present invention provides a method for treating obesity by forming one or more plications in a wall of the gastric cavity through a hybrid laparoscopic/endoscopic procedure. The plication(s) reduce the volume of the gastric cavity, thereby limiting the available food capacity and creating an earlier feeling of satiety. The plication(s) may also serve to alter gastric motility reducing the efficiency by which the stomach contributes to the digestion of food. Further, the plication(s) may also restrict the flow of food both into and out of the gastric cavity. In the hybrid cavity folding procedure, an endoscope is passed into the gastric cavity to insufflate the interior of the cavity. At least one incision is created through the abdominal wall to gain laparoscopic access to the peritoneal cavity. One or more folds are formed on the exterior surface of the gastric wall through the incision. Within a fold, two areas of serosa tissue are brought together into contact substantially along the length of the fold. Although it is possible to create folds of substantial depth with a single approximation site, a fold is preferably fastened at two or more locations along the depth of the fold to maintain the serosa to serosa contact throughout the depth of the fold. The fold may be fastened by knotting or otherwise locking together suture attached to two or more anchoring devices deployed into the cavity through the exterior cavity surface.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic view of a patient during a hybrid endoscopic-laparoscopic procedure;

FIG. **2** is a diagrammatic, exterior view of a gastric cavity, partially broken way to show an endoscope positioned against the interior surface of the anterior cavity wall;

FIG. **3** is a cross-sectional view of an abdominal wall and gastric cavity showing a needle inserted through the gastric cavity wall into the peritoneal cavity;

FIG. **4** is a cross-sectional view of an abdominal wall and gastric cavity showing a laparoscopic device probing tissue within the peritoneal cavity

FIG. **5** is an isometric view of an exemplary suture anchor deployment device;

FIGS. **6***a* and **6***b* are side cross-sectional views of the suture anchor deployment device shown in FIG. **5**;

FIG. **7** is a more detailed, cross-sectional view of the suture anchor deployment device of FIG. **5**;

FIG. **8** is a cross-sectional view taken along line **8**-**8** of FIG. **7**, showing the needle shaft and handle portions of the suture anchor deployment device;

FIG. **9** is an isometric view of an exemplary T-Tag anchoring device;

FIG. **10** is a side view of the T-Tag anchoring device of FIG. **9**, showing a first method for forming a suture loop;

FIG. **11** is an isometric view of a slip knot formed between a pair of T-Tag anchors, showing the knot in a loosened form;

FIGS. **12***a*-**12***e* show a method of tying the slip knot between the T-Tag anchors;

FIG. **13** is a side view of a second exemplary T-Tag anchoring device, showing a second method for forming a suture loop;

FIG. **14** is a cross-sectional view of an isolated area of the gastric cavity wall during a needle insertion;

FIG. **15** is a perspective view of an exemplary buttressing device;

FIG. **16** is an isometric view of a plurality of the buttressing devices of FIG. **15** interconnected together;

FIG. **17** is a cross-sectional view of a portion of the abdominal and anterior cavity walls during a T-Tag anchor and exemplary buttressing device deployment;

FIG. **18** is a perspective view of a second exemplary embodiment for delivering buttressing devices;

FIG. **19** is a perspective view of the gastric cavity interior during a T-Tag anchor and second exemplary buttressing device deployment;

FIG. **20** is a cross-sectional view of an abdominal wall and gastric cavity showing a needle probing the gastric cavity for a second suture anchor location;

FIGS. **21***a* and *b* show detailed, perspective views of two separate distal cutting edges of the protective sheath, shown severing a suture;

FIG. **22** is a cross-sectional view of an abdominal wall and gastric cavity showing a first embodiment for forming and locking a fold in a gastric cavity wall;

FIG. **23** is a cross-sectional view of an abdominal wall and gastric cavity showing a second embodiment for forming and locking a fold in a gastric cavity wall;

FIG. **24** is a diagrammatic, exterior view of a gastric cavity showing the placement of a first series of suture anchors;

FIG. **25** is a diagrammatic, exterior view of a gastric cavity showing the placement of two series of suture anchors;

FIG. **26** is a cross-sectional view taken along line **26**-**26** of FIG. **25**, showing the interior of a gastric cavity with a uniform wall fold;

FIGS. **27***a* and *b* show a perspective and an external view of a portion of a gastric cavity wall fold showing three rows of anchors, the third of which are spaced farther apart than the previous two rows;

FIG. **28** shows a perspective view of a portion of a gastric cavity wall fold showing three rows of anchors, the third of which is spaced closer together than the previous two rows

FIG. **29** is a cross-sectional view of a gastric cavity showing T-Tag anchors deployed into the anterior and posterior cavity walls;

FIG. **30** is a cross-sectional view of a gastric cavity similar to FIG. **29**, showing the anterior and posterior walls cinched together into a fold;

FIG. **31** is an exterior view of a gastric cavity showing a first alternative wall folding embodiment;

FIG. **32** is an exterior view of a gastric cavity showing a second alternative wall folding embodiment;

FIG. **33** is an exterior view of a gastric cavity similar to FIG. **32**, showing suture tensioned to form an additional set of wall folds;

FIG. **34** is an exterior view of a gastric cavity showing a fold placed near the gastroesophageal junction to create a reduced size food pouch or inlet restriction;

FIG. **35** is an exterior view of a gastric cavity showing folds placed in the fundic region of the cavity reducing gastric capacity and interfering with fundic pressures forcing food into the antral pump;

FIG. **36** is an exterior view of a gastric cavity showing folds placed between fundic and distal portions of the cavity reducing volume capacity and altering organ motility;

FIG. **37** is an exterior view of a gastric cavity showing a plurality of folds placed in the antrum region of the cavity reducing volume capacity while altering gastric motility and/or introducing an outlet restriction;

FIGS. **38**-**43** show several cross-sectional views of different folding patterns;

FIG. **44** is a cross-sectional view of a gastric cavity showing a small bowel obstructing member; and

FIG. **45** is a cross-sectional view of a gastric cavity showing a small bowel obstructing member with a venting or evacuation tube.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to the drawing figures, in which like numerals indicate like elements throughout the views, FIG. **1** is a diagrammatic view of a patient during a hybrid endoscopic-laparoscopic procedure. In the method of the present invention, folds are formed in the gastric cavity wall through a hybrid laparoscopic-endoscopic approach. In the hybrid approach, visualization of the one or more fold locations can be achieved by passing an endoscope into the interior of the gastric cavity. As shown in FIG. **1**, a flexible endoscope **30** can be passed transesophageally into the gastric cavity **32**. Endoscope **30** provides insufflation, illumination, and visualization of gastric cavity **32**, as well as a passageway into the cavity. Gastric cavity **32** is insufflated through endoscope **30** to create a sufficiently rigid working surface that may be pierced without damaging the opposing wall of the cavity. Insufflation of the gastric cavity also allows the boundaries of the cavity and the desired location for a fold to be mapped out by external palpation of the abdomen. The pressure on the abdominal wall is observed within gastric cavity **32** through endoscope **30** and may aid in determining the appropriate placement of one or more trocars, or other type of port allowing abdominal, laparoscopic access. Using endoscope **30** to visualize the plication locations may reduce or eliminate the need for visualization on the outside of the cavity.

Eliminating the need to visualize the outside of the gastric cavity also reduces or eliminates the need to insufflate the abdominal cavity. However, where deemed necessary, the abdominal cavity may be insufflated prior to placement of a trocar to expand the working area inside the cavity. Typically, the abdominal cavity is insufflated using a Veress needle that is inserted at the umbilicus or left upper quadrant of the cavity in order to introduce carbon dioxide (CO_2) into the cavity. Although common practices involve using a Veress needle to create additional working space in the abdominal cavity for safer trocar insertion, it introduces a small risk of organ perforation or infection due to the lack of guidance in inserting the needle. An alternative method to potentially reduce this risk involves transorally insufflating the abdomen by inserting a shielded needle into the working channel of endoscope **30** prior to passage of the scope into the gastric cavity. Inside gastric cavity **32**, the endoscope **30** is pointed towards the distal anterior surface of the cavity, as shown in FIG. **2**. The needle **34** is extended out the distal end of endoscope **30**, and a protective shield **36** withdrawn from the needle tip, so that the needle can be inserted through the anterior cavity wall **40**, as shown in FIG. **3**. Needle **34** is inserted to a position between anterior cavity wall **40** and the abdominal wall **42**. The distal anterior surface of the gastric cavity is a desirable area to puncture with the needle due to the absence of critical organs in this area. With needle **34** outside of the cavity wall, a suitable abdominal insufflation gas such as CO_2 is pumped through the needle and into the peritoneal cavity **44** to provide an area within the cavity to insert the trocar.

After the gastric cavity has been mapped through the endoscope, and the abdominal cavity insufflated if necessary, a trocar is inserted into the abdominal wall to provide access to the peritoneal cavity. FIG. **4** shows a trocar **50** inserted through an incision in abdominal wall **42**. Trocar **50** is inserted directly above gastric cavity **32**. The placement of trocar **50** will depend upon the intended location of the fold. Trocar **50** preferably has a small diameter to allow an adequate passageway for instruments while minimizing the size of the incision. Trocars with diameters in the range of 3-5 mm provide suitable access to the cavity. Percutaneous approaches with device diameters less than 3-5 mm remain a possibility however, with the size of the hole defined by the diameter of the anchor (if penetrating anchors are used) or the diameter of the piercing needle. With trocar **50** inserted into abdominal wall **42**, a suture anchor deployment device is passed through the trocar and into the peritoneal cavity **44** to facilitate and secure a fold.

Alternative trocar placements may of course be used at the preference of the practitioner. As one skilled in the art will recognize, three 5 mm trocars readily allow the simultaneous use of a laparoscopic camera, tissue manipulation instrument (grasper, etc.) and tissue approximation and fixation device (suture anchor deployment device, etc.). When needed a fourth ~5 mm incision may be used for liver retraction. Standard laparoscopic techniques often require higher abdominal insufflation pressures to provide adequate laparoscopic visualization and ease to freely manipulate laparoscopic instrumentation. Higher abdominal insufflation pressures may require the procedure to be performed under general anesthesia. Conscious sedation procedures require lower sustained abdominal insufflation pressures. One method to avoid general anesthesia, or maintain conscious sedation as a viable option is to sustain low abdominal insufflation pressures and temporarily increase pressures for short periods only when needed.

As natural orifice procedures and the tools that enable them become more commonplace, procedures requiring fewer skin incisions will become more prevalent. One natural orifice method to accomplish external cavity wall folding includes passing a flexible endoscope or colonoscope into the colon, creating a colotomy, and guiding the endoscope to a hollow body organ such as the stomach. Once in position, a T-Tag or other tissue anchor delivery system delivers multiple anchor sets in the desired pattern into or through the cavity wall. Cinching, tying, or otherwise securely apposing anchor sets can create tissue folds having the desired effect.

There are multiple minimally invasive methods available to permit the desired folding procedure including the hybrid endoscopic and laparoscopic procedures discussed. Percutaneous access approaches may also be used to further reduce incision sizes. Ultimately, natural orifice procedures (involving transgastric, transcolonic, transvaginal, etc) will be performed eliminating skin incisions. However, one skilled in the art will readily acknowledge that there are a multitude of surgical approaches to gain access to the peritoneal cavity involving one or more abdominal incisions. A completely feasible option remains performing this procedure in an open surgical setting.

FIG. **5** illustrates an exemplary suture anchor deployment device **52** for use during a cavity wall folding procedure. The exemplary device shown and described below deploys multiple T-Tag type suture anchors for facilitating a tissue fold. However, T-Tag type suture anchors are only one of numerous types of tissue fasteners that can be utilized for forming a cavity wall fold. Various other tissue fasteners which are suitable for apposing and securing tissue such as, for example, simple suture knots and laparoscopically deployable suture anchors, may also be utilized without departing from the scope of the invention. As one skilled in the art will recognize, examples of fasteners suitable for this task include but are not limited to the T-type anchors (mentioned above and described in more detail below), reconfigurable "basket"-type anchors (which generally comprise a number of configurable struts or legs extending between two collars or support members), and linear anchors (elongate anchors which are configured to fold or become compressed into a bowed or expanded configuration). In general, anchor characteristics are such that prior to deployment they can easily be placed into or through tissue(s), but after deployment, have an altered configuration providing at least one dimension sufficiently large to maintain the anchor in place. As shown in FIG. **5**, the exemplary deployment device includes a handle **54** having a pistol grip **56** and a movable trigger **60**. An elongated, tubular housing **62** extends distally from handle **54**. Housing **62** has sufficient length (on the order of 18") to enable use within an obese patient at numerous trocar access sites. Likewise, housing **62** is sized to allow for passage through a small (3-5 mm) diameter trocar.

As shown in FIG. **6***a*, a needle **64** extends distally within the lumen of housing **62** from handle **54** through the open distal housing tip **66**. A retractable, protective sheath **70** extends distally through housing **62** and over the exposed tip of needle **64**. A rod **72** is attached to protective sheath **70** by a ring **76** that extends about the circumference of housing **62**. To retract the sheath, ring **76** is pulled proximally, causing rod **72** to slide within a track **74** in handle **54**. As rod **72** slides within track **74**, the attached sheath **70** is drawn in a proximal direction away from the needle tip. Rod **72** bottoms out within track **74** when sheath **70** is in a fully retracted position, as shown in FIG. **6***b*. Rod **72** is bent slightly so that the rod must be manually manipulated to slide through track **74**. This slight bend in rod **72** prevents the rod from unintentionally retracting into track **74** and leaving the tip of needle **64** exposed. Numerous methods to protect the needle and to shield the needle from accidental sticks may be employed as those skilled in the art will recognize. The deployment device preferably includes a cutting edge for severing suture following T-Tag deployment. In the device shown in FIGS. **5-7**, the cutting edge is a hook shaped cutout **80** formed into the distal end of protective sheath **70**. Suture extending through housing **62** can be drawn into the stem of the cutout and trapped and severed at the hook tip. The cutting may be accomplished by shaping the stem of the hook so that it necks down in a sharp 'V' shape, so that when the device pulls the suture into the 'V', it is cut (FIG. **21***a*). Alternatively, with the suture seated in the stem, a separate sheath may be translated (linear or rotational translation) shearing in a scissors fashion the suture within the stem. Yet another variant is to have a 'V' shaped slit at the distal end of sheath **70** with the open end of the 'V' located distal on the device (FIG. **21***b*). By simply advancing the device so that the suture is forced into the 'V', the suture may be cut. Numerous other methods involving slicing, shearing, and heating the suture causing it to separate may be employed.

Needle **64** includes a slotted lumen that extends proximally from the sharpened tip through housing **62** for retaining T-Tag anchors. Needle **64** can retain and deploy from one to twenty (or more depending on anchor length) T-Tag anchors, with the particular number of anchors loaded into the needle dependent upon the selected deployment scheme. Multiple T-Tags, indicated by reference numeral **82**, can be stacked one against another within the needle lumen. The T-Tag anchors are stacked such that the suture from each tag, identified by reference numeral **84** in FIG. **8**, exits the tag in the midsection, perpendicular to the axis of the anchor. The T-Tag anchors and needle slot **86** are aligned so that suture **84** from the T-Tags passes through needle slot **86**.

As shown in FIG. **7**, device **52** includes an actuating mechanism for expelling T-Tag anchors. The actuating mechanism includes a pushrod **90** at the proximal end of the T-Tag anchor stack **82** for advancing and expelling the anchors from the needle. Pushrod **90** includes a plurality of notches which engage a drive pawl **94** for advancing the pushrod distally. Drive pawl **94** is in turn connected through a link **96** to trigger **60**. As trigger **60** is pivoted towards pistol grip **56**, pushrod **90** is advanced distally (through the link and drive pawl) against the proximal most T-Tag anchor in stack **82**. The contact force of pushrod **90** propels anchor stack **82** towards the open distal end of the needle. For each squeeze of trigger **60**, a single T-Tag anchor is expelled through the distal tip of the needle and into the adjacent tissue as the stack is advanced distally the length of one T-Tag. As a T-Tag anchor is released, the attached suture exits the deployment device through needle slot **86**. An anti backup pawl **100** in handle **54** prevents push rod **90** from moving proximally when trigger **60** is released. An extension spring (not shown) extends between connection points **102** on handle **54** and trigger **60** to provide the necessary force to return the trigger, drive pawl **94** and link **96** to their initial positions when the manual pressure on the trigger is released. The exemplary deployment device shown includes the capability to store and deliver multiple T-Tag anchors during a procedure. Preferably, the deployment device can be reloaded with additional T-Tag anchors when the initial stack is depleted, so that the device may be reused as necessary during the procedure.

FIG. **9** shows a first exemplary T-Tag anchor **110** for deployment from device **52**. As shown in the Figure, T-Tag anchor **110** comprises an elongated tube **112** having an opening or slot **114** extending approximately one-half the length of the tube. The remaining length of the tube is closed into a cylindrical shape. One end of a length of flexible material, such as suture **116**, is inserted into the closed length of tube **112**. The end is retained within the tube by crimping the midsection of the cylindrical length, as indicated by **120**. The remaining portion of suture **116** protrudes freely out the slotted opening **114**. T-Tag anchor **110** may be formed in this manner from flat sheet stock that is rolled into a small diameter tube. A gap may be left in the sheet stock to form slot **114** when the sheet is rolled. T-Tag anchor **110** can also be formed from alternative materials such as, for example, injection molded plastics, or can be manufactured as a solid cylindrical tube with a hole drilled or otherwise formed through the midsection for the suture to protrude through. As shown in FIG. **9**, an outwardly extending projection or bulge **122** is preferably formed along the length of T-Tag anchor **110**. Bulge **122** creates friction between the inner diameter of needle **64** and the T-Tag anchor **110** when the anchor is held within the deployment device. This friction between the needle and T-Tag anchor prevents the anchor from being unintentionally released from the device. Alternatively, friction between the needle and a single T-Tag anchor may be applied by reducing the needle inner diameter at a distal location so that only the most distal T-Tag anchor is in contact with the high friction area. When loaded into needle **64**, T-Tag anchor **110** is positioned so that opening **114** extends adjacent to needle slot **86**, so that the free end of suture **116** passes from the anchor through the needle slot. Additional alternative embodiments of T-Tag anchor **110** are described in further detail in pending U.S. patent application Ser. No. 11/274,352, filed on Nov. 15, 2005, U.S. patent application Ser. No. 11/274,358, filed on Nov. 15, 2005, and U.S. patent application Ser. No. 11/437,441, filed on May 19, 2006; each of which is hereby incorporated herein by reference in its entirety. Further embodiments of T-Tag anchor **110** are described in U.S. Application Publication Number 2006/0025819, the contents of which is hereby incorporated herein by reference in its entirety.

In a first preferred embodiment for forming a tissue plication, a pair of T-Tag anchors are pre-tied together prior to loading the tags into the deployment device. To tie the T-Tag anchors together, a loop or other slidable connecting member **124**, such as shown in FIG. **10**, is formed in the suture of a first T-Tag anchor. One skilled in the art will clearly recognize that loop **124** may be formed by a variety of different types of knots, such as, for example, a square knot, one or more ½ hitch knots, or a hangman's knot. Alternatively, loop **124** can be formed by drawing suture through an opening **144** in a T-Tag anchor, such as shown in FIG. **13**. In this second loop embodiment, a short length of suture **146** extends within an anchor tube **142**, and is crimped within the tube at opposite ends, as indicated by **120**. Between the crimped ends, the suture is pulled through opening **144** to form loop **124**. In an alternative embodiment, an opening can be formed through a first T-Tag anchor so that the anchor itself serves as the slidable member, thereby eliminating the need for a suture loop. In this embodiment, the suture from the second T-Tag anchor is passed through the opening in the first T-Tag anchor to allow the first anchor to slide relative to the second anchor along the length of the suture.

The second T-Tag anchor of the pair is attached at the end of a length of suture. To connect the anchor pair, the suture from the second T-Tag anchor is passed through suture loop **124** of the first T-Tag anchor to allow the first T-Tag anchor to slide relative to the second T-Tag anchor along the length of the suture. After the first T-Tag anchor has been slidingly attached to the suture from the second T-Tag anchor, a one-way slip knot is formed within the suture. The suture knot serves to pull together and lock the T-Tag anchors when the anchors are under load following deployment.

FIG. **11** illustrates an exemplary suture slip knot **132** for drawing together and securing a pair of T-Tag anchors **126**, **130**. To form slip knot **132**, which is one variation of a hangman's noose, the suture length attached to second T-Tag **130** is doubled over, as indicated by reference numeral **134**, and the second T-Tag anchor **130** is passed under the suture, as shown in FIG. **12***a*. Second T-Tag anchor **130** is then encircled back over the doubled suture length **134**, as shown in FIG. **12***b*, and passed back under the doubled suture, as shown in FIG. **12***c*. To complete the encircling of the doubled suture length **134**, second T-Tag **130** is brought over the top of the encircling suture, as shown in FIG. **12***d*. To complete the slip knot, second T-Tag anchor **130** is brought under the doubled suture length **134** and back over the first encircling pass, as shown in FIG. **12***e*. When slip knot **132** is fully formed, as shown in FIGS. **11** and **12***e*, knot **132** is tightened setting the distance between knot **132** and T-Tag **130**, while allowing the doubled suture length **134** to be reduced. Once T-Tag anchors **126**, **130** are deployed into tissue, pulling on loose suture end **136** relative to the fixed T-Tag anchors reduces the size of the doubled suture length **134** until it cannot be further reduced because of loop **124**. As slip knot **132** is tightened, first and second T-Tag anchors **126**, **130** are drawn together. The final distance between first and second T-Tag anchors **126**, **130** is defined by the distance from loop **124** to T-Tag **126** and the distance from knot **132** to T-Tag **130**. The size of loop **124** may also be used to adjust this overall distance. Additionally, where loop **124** is formed by tying a knot in the suture of a first T-Tag anchor **126**, suture knot **132** may be pre-tied in the length of suture before the T-tag anchors are attached. Following formation of the slip knot **132**, first T-Tag anchor **126** is attached to suture length **134** by tying a knot to form loop **124**. Second T-Tag anchor **130** is attached to an end of the suture length by crimping the end within the anchor, and may be done after knot **132** is created and tightened. Slip knot **132** is only one example of a suitable knot for fastening together a pair of deployed T-Tag anchors. One skilled in the art will recognize that other slip knots tied such that one anchor is slidably attached to a doubled over portion of the slip knot (such as **134**) while the other anchor is secured to a tail or free end of the slip knot remain cinched when forces seeking to loosen the knot are applied only to the anchors in the system. Additionally evident, although not shown, is that a single piece of suture may be used to create slip knot **132** and loop **124**. This is accomplished by connecting **136** and **117**.

After the suture knot and T-Tag anchor pair are assembled, the anchor pair is preferably loaded into deployment device **52**, such that the first "looped" T-Tag anchor **126** deploys initially, followed by the second "attached" T-Tag anchor **130** although the order may be switched. Multiple pairs of the pre-tied T-Tags may be loaded into the deployment device for use during a procedure. For each T-Tag pair, the loose suture end **136** extends from needle slot **86** proximally through the interior of housing **62**. Outside the proximal end of the housing **62**, the loose suture lengths from the multiple pairs of T-Tag anchors are color-coded, labeled, or otherwise distinguished to identify the order of the pairs within the needle stack.

With the pre-tied T-Tag anchor pairs loaded into laparoscopic deployment needle **64**, the sheathed tip of the needle is pressed against anterior wall **40** of gastric cavity **32** to probe the outside surface of the cavity, as shown in FIG. **4**. The cavity wall indentation can be visualized through endoscope **30** to determine the proper location to insert the needle. Laparoscopic visualization may be used in addition to or in place of the endoscopic view to determine the proper location. After the proper insertion location is determined, protective sheath **70** is drawn proximally along the shaft of needle **64**, and the tip of the needle is inserted into anterior wall **40** to reach the interior of gastric cavity **32**. Needle **64** is inserted into cavity **32** with sufficient force to prevent the needle from glancing off of the exterior surface of anterior wall **40**. Appropriate gastric insufflation pressures ideally provide a sufficiently rigid surface through which the needle may be passed. To prevent the gastric wall from tenting into the cavity interior as needle **64** is inserted (which may allow the posterior gastric wall to be pierced), a grasper may be passed through endoscope **30** and placed against the inside surface of the cavity wall. The grasper provides support on the inside of the cavity wall as the laparoscopic needle is inserted through the wall. Laparoscopic instruments may alternatively be used alone, or in conjunction with endoscopic assistance to allow the needle to safely penetrate a single gastric wall.

When inserting needle **64** through the cavity wall, it is desirable to have as close to normal an angle as possible between the needle tip and the targeted surface of the cavity wall. To facilitate a more direct needle insertion angle, a vacuum assist may be used in conjunction with deployment device **52** to draw the targeted cavity surface against the face of the device just prior to T-Tag anchor deployment. The vacuum assist may be connected to the deployment device, with a vacuum tube extended through the lumen of housing **62** alongside needle **64**. Alternatively, a vacuum tube **152** may be run along the outside of deployment device housing **62** through trocar **50**. The tip of vacuum tube **152** and the tip of deployment device **52** simultaneously act upon the same area of tissue, as shown in FIG. **14**, to draw the tissue against the face of the deployment device. Following delivery of the T-Tag anchor, the vacuum moves along with the deployment device to additional targeted tissue surfaces.

Sutures or suture anchoring devices deployed into and/or through the gastric cavity wall occasionally pull out of the tissue and fail due to the contact pressure between the suture or device and the impacted tissue. This tendency is particularly acute when tension is consistently applied to the devices by large food volumes caused by patient non-compliance with dietary requirements. To reduce the potential for anchoring device failure in the hybrid cavity wall folding procedure, a buttressing device may be used in conjunction with the T-Tag suture anchors. The buttressing device distributes the load from the T-Tag anchors across a wider area of the cavity tissue, thereby reducing the possibility that tension will pull an anchor through the cavity wall. The cavity wall folding procedure can, however, also be performed without the application of a buttressing device or material.

A number of different types of material and configurations can be utilized to form a buttressing device. FIG. **15** shows an embodiment in which a buttressing device **160** has a washer-type shape with a center hole for insertion of the laparoscopic deployment needle. The washer-type device can be made from silicone, closed-cell foam, PEEK, or any other biocompatible, elastically-deformable material. Additionally, buttressing device **160** may be made from an absorbable material, and/or contain medicinal agents that promote healing or scarring to increase the strength of the surrounding tissue. As shown in FIG. **16**, in addition to an individual unit, buttressing devices **160** can be formed as a continuous strip **161** which can include segmented perforations, indicated by dashed lines **163**, to break or tear upon application.

In a hybrid cavity wall folding procedure, buttressing devices are delivered to the interior of the gastric cavity transorally using the endoscope. The buttressing devices may be delivered by use of a conveyor, pull string, or endoscopic cartridge, among other mechanisms. FIG. **17** depicts a first exemplary buttress delivery mechanism in which washer-like buttressing devices **160** are passed transorally into cavity **32** through a cartridge **162**. Cartridge **162** is attached to the distal end of endoscope **30**. Multiple buttressing devices **160** are stacked along a track within cartridge **162**. An advancement rod **164** applies distal pressure to the proximal most device in the stack, to advance the devices towards the distal end of the cartridge. At the distal most end of the cartridge, pushrod **165** is positioned to individually advance individual devices **160** one at a time. Pushrod **165** is preferably made out of a super-elastic material such as nitinol, but one skilled in the art will recognize that multiple mechanisms may be used to dispense individual devices **160** one at a time. Endoscope **30** may be positioned adjacent anterior cavity wall **40** to align the discharging buttressing device with the insertion location of needle **64**. Once aligned, needle **64** is passed through the discharging buttressing device **160** to deploy a T-Tag anchor **110** on the interior side of the device. Needle **64** may of course be first passed through the gastric wall in which case the buttressing device is guided over the needle, however, the buttressing device may also be positioned against the gastric wall in the desired location. In the latter circumstance, needle **64** is guided to the correct location and then pierces the gastric wall and buttressing device. Cartridge **162** may have features that aid in guiding the needle to the correct location. One skilled in the art will recognize that the shape of the cartridge, as well as light from the endoscope or cartridge may also aid in locating the correct location.

FIG. **18** depicts a second exemplary buttress delivery method. In this method, multiple buttressing devices **160** are delivered as a unit transorally into the gastric cavity. The devices can be delivered using the endoscope **30** or through an ancillary channel (not shown) into the cavity. Inside gastric cavity **32**, buttressing devices **160** are separated by releasing or freeing (cutting, untying, unhooking, etc) the connecting suture or cable **166**. An endoscopic grasper **170** is passed through the working channel of endoscope **30** and utilized in conjunction with the endoscope **30** to individually place and hold buttressing devices **160** against the interior stomach surface, as shown in FIG. **19**. Each buttressing device **160** is positioned at an intended needle insertion location. With the buttress in place, needle **64** is inserted through anterior cavity wall **40**. Inside gastric cavity **32**, needle **64** is pushed through the buttressing device. A T-Tag or other suture anchoring device is deployed on the interior side of device **160**, so that the attached suture extends through the buttress before passing through the cavity wall. The needle may pass through a hole in the buttress if present, or it may pierce through the buttress.

In yet another exemplary buttress delivery method, multiple buttressing devices **160** can be placed on the distal end of an endoscopic grasper prior to passage of the grasper into gastric cavity **32**. The grasper jaws are opened to prevent the buttressing devices from falling off the distal end of the grasper. With the buttressing devices loaded on, the grasper is passed transorally into the gastric cavity. Inside the cavity, the grasper jaws are closed to release the buttressing devices inside the cavity. The devices are retrieved as needed from inside the cavity for reinforcement during the plication procedure. If support is desired on the exterior (serosal) surface of the cavity wall, a buttressing device can be passed into the peritoneal cavity through a trocar. The device can be positioned against the exterior wall surface by a grasper passed through a secondary trocar. In this scenario, the deployment needle is passed through the buttressing device prior to puncturing the cavity wall.

In all cases, the buttress as well as the anchors themselves may be comprised of materials that permit the delivery of therapeutic agents that promote healing, prevent infection, reduce nausea, prevent erosions, induce weight loss, or otherwise provide the patient with a beneficial outcome. The therapeutic agent may be disposed in the implant so as to diffuse or degrade over time in order to advance the treatment or promote healing. U.S. Pat. No. 7,217,425, which is hereby incorporated herein by reference in its entirety, describes implantable devices that incorporate a medicinal agent as a coating. Exemplary medicinal agents for use in the present cavity wall folding procedure include Topomax® brand topiramate, available from Ortho-MacNeil Neurologics, Inc., in Titusville, N.J. Topiramate can reduce the need for food and can be used as an adjunct to the surgical procedure. One skilled in the art will recognize that oral medications may also be used to supplement these effects and that these combination therapies may promote synergies that ultimately greatly increase the efficacy of the surgical procedure.

As an alternative to the washer-like device shown in FIG. **15**, a buttressing device can be formed of a solid material that is easily penetrated by a suture anchor deployment needle. A buttressing device can also be formed from a sheet of mesh material having a plurality of spaced openings. When using a mesh or solid material, the material may be configured into a first insertion shape that is sufficiently small to be inserted transorally. After insertion, the material may be reconfigured into an expanded shape or form for use. This shape transformation may be made using different methods including shape memory materials, mechanical compression, folding, tying or a combination of the above.

In addition to buttressing devices, the serosal tissue on the outside surface of the cavity may be treated to reinforce the plication anchors. These treatments may also serve to promote healing between serosal surfaces. Treatment may include abrasion, thermal damage, electrical damage or chemical damage which has the effect of creating scar tissue along the serosal surface. When the treated tissue areas are joined together into a fold, the trauma, treatment, or damage induces an earlier and more rapid healing response that may also serve to promote a stronger, more durable bond. Another method for reinforcing the serosa to serosa fold is to inject a chemical solution into the cavity wall. The injected solution toughens the surrounding tissue area to decrease the likelihood of the T-Tag anchors eroding through the cavity wall. Chemical solutions (or bulking agents) suitable for this application include schlersoants, tgf-bea, keratin, PMMA (polymethymethaccrolade) among others. Medications that promote healing, such as Vitamin C which raises ascorbic acid levels in the body may also be used to aid in the rapid and durable serosa to serosa healing. Such medications may also be delivered through the buttress, anchors, or taken orally.

After first T-Tag anchor **126** is deployed into cavity **32**, either with or without a buttressing device, needle **64** is removed from the cavity. In the preferred case where suture loop **124** tightly surrounds the suture of the doubled over section **134**, when needle **64** is removed, a portion of the doubled over section **134** remains in the gastric wall. Alternatively, if suture loop **124** is sufficiently large, as needle **64** is removed, suture loop **124** is drawn from T-Tag anchor **126** back through the cavity wall. After needle **64** is removed from cavity **32**, protective sheath **70** is preferably drawn back over the tip of the needle. The anterior wall is again probed with the sheathed needle tip, as shown in FIG. **20**, to determine the location for the second T-Tag anchor. To facilitate the anterior wall probing, trocar **50** may be flexed at different angles within abdominal wall **42**, as shown in FIG. **20**, without removing the trocar from the abdominal wall. Trocar **50** is angled within abdominal wall **42** to enable needle **64** to enter gastric cavity **32** at different locations and in as direct an angle as possible to the exterior cavity surface. Once the proper placement location is determined, needle **64** is once again inserted through anterior wall **40** into gastric cavity **32**. With needle **64** inside gastric cavity **32**, the second of the pre-tied T-Tag anchors **130** is deployed into the interior of the cavity. Second T-Tag anchor **130** can be deployed with or without a buttressing device.

After second T-Tag anchor **130** is deployed, needle **64** is removed from anterior wall **40**, drawing the attached suture

116 back through the wall. With the two T-Tag anchors deployed through the cavity wall, tension is applied to loose suture end **136** through deployment device housing **62**, to reduce the size of the doubled over suture **134**. As this occurs, T-Tag anchors **126**, **130** are drawn together, apposing the serosal tissues surrounding each T-Tag anchor. After the T-Tag anchors and connecting suture have been utilized to appose the cavity wall, the loose suture end **136** is maneuvered into the stem of cutout **80** and around the angled cutting edge as shown in FIG. **21***a*. With tension applied to the proximal, loose end of the suture from outside the deployment device, protective sheath **70** is retracted in the direction indicated by the arrows, to draw the suture taut within cutout **80** and sever the suture. Following severing, loose suture end **136** is withdrawn proximally through trocar **50**. FIG. **22** shows gastric cavity **32** with T-Tag anchors **126**, **130** cinched and locked together by slip knot **132** to appose the exterior, serosal layer of the gastric cavity wall and form a fold **172**. Of course, laparoscopic cutting instruments (such as scissors) may also be used to cut the suture.

As an alternative to using pre-tied T-Tag anchor pairs, T-Tag anchors having separate, attached lengths of suture may be deployed in a spaced relationship through the cavity wall. In this approach, the separate strands of suture from each of the T-Tag anchors extends through the anterior wall and proximally through deployment device housing **62**. Tension is applied to the proximal ends of the suture strands outside of the deployment device to appose the cavity wall tissue surrounding the T-Tag anchors. To lock the suture strands and surrounding tissue in a tensioned, apposed state, a knotting element can be applied to the proximal suture ends and advanced through the trocar to the exterior edge of the cavity wall fold. A knotting element is applied by passing the loose, proximal ends of the suture strands through a knotting element applier, such as the knotting element device which is described in pending U.S. patent application Ser. No. 11/437,440, filed May 19, 2006, which is hereby incorporated herein by reference in its entirety.

As an alternative for applying a knotting element, the knotting element applier can be loaded or otherwise incorporated into deployment device housing **62** along with a pair of T-Tag anchors, so that the T-Tags and knotting element are all delivered through the deployment device. In this case, the deployment device **52** is loaded with the two T-Tag anchors, and the suture strands from the anchors are extended out needle slot **86**. The suture strands are loaded through the knotting element applier, and the applier passed through a slot in device housing **62** and inside protective sheath **70**. After the pair of T-Tag anchors is deployed, the knotting element applier is extended distally from the open end of device housing **62**. The proximal ends of the suture strands are pulled to appose the tissue surrounding the T-Tag anchors. When satisfactory apposition is achieved, the knotting element device is deployed to fasten the sutures together and cut the sutures. FIG. **23** shows gastric cavity **32** with a pair of T-Tag anchors **110** deployed through the cavity wall. Suture strands **116** from each of the T-Tag anchors are tensioned to pull the surrounding wall tissue into a fold **172**. A knotting element **174** is shown applied to the tensioned suture material **116** to maintain the cavity wall in the apposed, folded position. Knotting element **174** may also serve as a delivery means for therapeutic agents that provide the patient with an improved outcome.

In addition to separately loading T-Tag anchors and a knotting element applier into a deployment device, the T-Tag anchors and knotting element applier can be assembled together as a cartridge. The cartridge releasably mates with a deployment device so that a single deployment device can fire multiple sets of T-Tag anchors from multiple cartridges. Likewise, a pair of T-Tag anchors and a knotting element applier may be combined together into a single use, disposable deployment device that fires a pair of anchors, cinches suture from the anchors, and then deploys a knotting element to fasten and cut the suture. In another embodiment, a deployment device cartridge may incorporate a Suture Assistant type knot to cinch and fasten suture from T-Tag anchors. As discussed previously, one skilled in the art will recognize variations of knots that can be easily tailored for this application. In this embodiment, the elements of the design for delivering the knot in the Suture Assistant comprise the top half of the device, and the bottom half of the device contains a pair of T-Tag anchors, a retractable needle, a length of suture connecting the T-Tag anchors, and a hook/gaff for grabbing and tensioning the suture after T-Tag anchor deployment to appose tissue. More description in further detail on the Suture Assistant can be found in U.S. Pat. No. 5,846,254, which is hereby incorporated herein by reference in its entirety.

In addition to applying a knotting element, suture strands **116** can be locked in a tensioned state by tying a knot in the proximal ends of the suture strands. The knot may be tied laparoscopically through trocar **50**. Alternatively, the knot may be tied external of the body, and the finished knot passed back through trocar **50** to a point between abdominal wall **42** and anterior wall **40**.

As shown diagrammatically in FIG. **24**, one or more additional pairs of suture anchoring devices, indicated by reference numeral **46**, may be deployed along the longitudinal length of the cavity wall. The trocar may be flexed within the abdominal wall, or removed and repositioned within the abdominal wall as necessary, in order to reach all of the desired suture anchor locations. Suture material is cinched together between each pair of the devices to extend the length of the cavity wall fold **172**. The number of suture anchor pairs used to form a fold will depend upon the desired length for the fold and the desired spacing selected between anchor pairs. Preferably, each of the pairs of suture anchors is evenly spaced apart along the length of the desired fold line. Likewise, within each individual pair the suture anchors are evenly spaced apart across the fold line, so that a uniform tissue fold is formed without distortion or bunching. The proper relative spacing of the suture anchoring devices can be ascertained through the endoscope. Alternatively, an additional trocar may be inserted into the abdominal wall and used in conjunction with an optical instrument to visually determine the proper locations for the suture anchoring devices laparoscopically.

After an initial series of T-Tag anchor pairs are deployed into anterior wall **40** and cinched together to form fold **172**, a second series of T-Tag anchor pairs is preferably deployed. The second series of T-Tag anchor pairs is deployed to form a second fold about the first fold, increasing the depth of the fold. The depth of fold **172** is determined by the distance between pairs of T-Tag anchors located at the same point along the length of the fold. FIG. **25** shows the exterior surface of anterior wall **40** with a second series of T-Tag anchors deployed to increase the depth of fold **172**. In the second series of T-Tag anchors, the anchors are deployed in a spaced relationship from the initial series of T-Tag anchors in a direction away from fold line **172**. Accordingly, in the second series of anchoring devices, T-Tags **180**, **182** are deployed outside of the initial pair of anchoring devices identified by reference numbers **184**, **186**. Likewise, second series anchors **190**, **192** are deployed outside of the first series anchors identified as **194**, **196**. Each of the second series of

T-Tag anchors are positioned and deployed in the same manner as the initial series of T-Tag anchors. After deployment of each second series T-Tag anchor pair, the anchors are cinched together by tensioning the loose suture end to appose the surrounding cavity wall tissue. The cinched T-Tag anchors are held in place either by a suture knot, such as slip knot **132**, by a knotting element, or by other secure means such as the Lapra-Ty® Absorbable Suture Clip, available from Ethicon Endo-Surgery in Cincinnati, Ohio.

As shown in FIG. **25**, the second series of suture anchoring devices preferably includes the same number of anchoring pairs as the first series, so that a uniform depth fold is created. Each of the pairs of anchoring devices in the second series is aligned longitudinally along the length of the fold with the other pairs of anchoring devices to maintain a uniform line for the fold. FIG. **26** shows two rows of longitudinally spaced T-Tag anchor pairs forming fold **172** in the interior of gastric cavity **32**. As shown in this Figure, fold **172** involutes into the interior of the gastric cavity so that the serosal layer of the cavity wall is brought into contact with itself along the center of the fold. As shown in FIG. **26**, each pair of T-Tag anchors is pulled together by the attached suture, and the tension in the suture locked in by tightening a slip knot **132**. Alternatively, tension may be locked into the suture to hold the cinched tissue together by a knotting element or other type of suture knot. The T-Tag anchoring devices are placed through the cavity wall to maintain the serosal to serosal contact within the fold during healing.

To promote healing along fold **172**, the serosa may be affected where the cavity wall portions abut within the fold. The serosa may be affected physically by abrading, or thermally or electrically damaging the targeted areas of the serosa, via the trocar, prior to drawing the tissue areas together. The serosa may also be affected chemically by applying shcelorsants, TGF Beta, Keratin or other known surface affecting agents. Traumatizing the serosa in this fashion, either to induce an injury (abrasion), or to enhance healing (Keratin), produces a healing response within the tissue producing a more rapid and potentially more durable formation of an adhesive bond between the contacting serosal surfaces.

Following deployment of the second series of anchoring devices, additional series of anchoring devices may be deployed to further increase the depth of the fold. The additional series of anchoring devices are deployed in a spaced relationship from the previous series of suture anchoring devices in a direction away from the fold line. Additional series of anchoring devices may be deployed to permanently increase the depth of the fold in which case the spacing between anchor sets is small resulting in a dense line of anchor sets. Alternatively, an additional series of anchoring devices may be deployed to provide reinforcement during the healing process. Following formation of the serosa to serosa fold, healing may not occur over the full depth of the fold due to less than full contact between the abutting serosa layers. Accordingly, where deeper healing is desired, a reinforcement series of suture anchors may be deployed to temporarily increase the depth of the fold.

FIG. **27***a* shows a gastric wall fold section in which a third series of T-Tag anchoring devices is deployed to temporarily increase the fold depth. The third series of anchoring devices, indicated by reference number **200**, may be placed at a lower density than the initial series of anchors, yet still promote deeper healing within the fold than would occur without the reinforcement anchors. In FIGS. **27***a* and **27***b*, the reinforcement series of anchoring devices **200** is shown with anchors placed only at every other location of the permanent anchors. Thus, three series of suture anchors are deployed at locations **202**, while only two series of suture anchors are deployed at location **204**. In this example, good serosa to serosa healing would occur in zone A, while only marginal healing would occur in zone B, due to the lack of an additional row of suture anchors. Portions of the tissue fold opening may bulge, as indicated by reference numeral **206**, due to the reduced number of anchoring devices in the reinforcement series. Bulges **206** coincide with the areas of the fold line that lack a reinforcement anchor. The reinforcement anchors may be designed to fail, be absorbed into the body, or otherwise degrade over time after healing has occurred along the primary depth of the fold. In addition to deploying extra rows of suture anchors through the exterior surface of the cavity, the fold may be reinforced by applying fastening devices including anchors, staples, etc. to the internal side of the cavity wall.

T-Tag pairs in Zone B are exposed to gastric wall tensions whereas T-Tag pairs in Zone A are likely exposed to much lower stresses. The pattern deployed in FIG. **27***a* may serve to ensure serosa-to-serosa healing in Zone A, while sacrificing it in Zone B. To increase the likelihood of serosa-to-serosa healing in Zone B, buttress may be selectively used in the region. Yet another alternative to the pattern in FIG. **27***a* is to have a very dense suture anchor pattern in Zone B, and a less dense pattern in Zone A (see FIG. **28**). Numerous patterns can be employed with patterns including numerous combinations of high and low density regions. Buttress may be deployed randomly (if at all), or targeted to high stress areas such as the ends of rows or partially or completely through a load bearing row.

As an alternative to a single, centralized fold in the anterior wall, a large fold may be formed apposing the anterior and posterior walls along the greater curve of the cavity. To form this larger fold, T-Tag anchors **110** are deployed into both anterior wall **40** and posterior wall **210** as shown in FIG. **29**. Posterior wall **210** can be accessed through the laparoscope by cutting through the cavity attachment points along the greater curvature. The attachment points can be safely severed provided one of the many redundant blood supplies to the gastric cavity remains intact. After T-Tag anchors **110** are placed in both the anterior and posterior walls, suture attached to the anchors is cinched together and secured by a knot or knotting element to form a deep fold **172** along the greater curve, as shown in FIG. **30**.

As an alternative to using T-Tags or other suture anchoring devices as described above, cavity wall folds may be formed using suture material alone, without an additional anchoring device. In this alternative method, serosa-to-serosa folds are formed by manipulating needles and suture to create suture bites through the cavity wall. Pairs of the suture bites may be cinched together to approximate the tissue into a fold. This suture only method can be accomplished through manual open/laparoscopic techniques, or through the use of open/laparoscopic/endoscopic suturing devices. A number of different commercially available suture applying devices may be utilized to form suture bites in this method. These devices include, but are not limited to, the Ethicon Endo-Surgery Suture Assistant, Auto-Suture (Tyco/US Surgical) Endo-Stitch, Paré Surgical Quick Stitch, Ethicon Endo-Surgery Endoscopic Suturing System, Paré Surgical Flexible Endoscopic Suturing System, and the LSI Solutions Sew-Right suturing system. Following cinching of the suture bites, the cavity wall fold may be secured by laparoscopically tying knots or applying knotting elements as described above.

FIG. **31** shows an alternative embodiment for forming folds in anterior wall **40**. In this embodiment, a plurality of suture anchoring devices **212** are longitudinally spaced along the length of anterior wall **40**. Suture anchoring devices **212** may be T-Tag anchors, as described above, or any of a variety of other types of tissue fastening devices. Suture material, identified as **216**, is cinched and secured between each of the anchoring devices **212** to produce one or more, parallel folds **172** extending across the width of anterior wall **40**. In this embodiment, volume reduction is achieved by creating a number of smaller tissue folds, rather than creating a single, long fold. In this example, fold lines do not run proximal to distal, but roughly perpendicular to the midline of the stomach. Of course, any range of angles relative to the midline can be used. One skilled in the art will recognize that orientation as well as length and depth of these one or more folds can be easily varied to achieve the desired effect. As an example and in addition to volume reduction, one or more of these folds may be positioned to create inlet or outlet restrictions.

FIGS. **32** and **33** show a third alternative embodiment for achieving volume reduction through gastric wall folding. In this embodiment, a series of suture anchoring devices is deployed in anterior wall **40**. Individual pairs of suturing anchoring devices are diagonally spaced across the width and length of gastric cavity **32** to form a plurality of folds. In FIG. **32**, suture extending between each of the anchoring device pairs **220**-**222**, **224**-**226**, and **230**-**232** is tensioned to form parallel-extending, diagonal folds **272**. In the embodiment shown in FIG. **33**, suture is also cinched between anchoring device pairs **222**-**224**, and **226**-**230** to form an additional set of parallel extending folds **274**. Suture extending between the anchoring device pairs may be cinched together and held in place by tightening the pre-tied slip knots between the suture anchor pairs. Where alternative types of suture anchors are utilized, the suture may be cinched and secured by knotting elements, standard suture knots, or the like. In the embodiment shown in FIG. **33**, the two different sets of parallel extending fold lines **272**, **274** are in different planes, thereby creating a bunching effect within the gastric cavity which reduces the available food volume.

In addition to the embodiments described above, numerous other patterns and locations may be utilized for folding the gastric cavity wall. For example, a fold **172** may be formed in a location between the gastroesophageal junction and the lesser curve of the cavity, as shown in FIG. **34**. The fold may be angled towards the lesser curve relative to the gastroesophageal junction to create a reduced-size pouch for food intake and digestion. As discussed above, this type of fold may also create a restriction to food entering the gastric cavity forcing the patient to more thoroughly chew their food. FIG. **35** shows another alternative placement for cavity wall folds. In this example, a pair of folds is placed in the fundic region of the gastric cavity. Locating the folds in the fundic region may lessen distension of the region in response to food intake. The folds may also inhibit the fundic reservoirs ability to produce contractions by either attenuating or baffling the frequency and/or intensity of the contractions, to slow digestion and reduce gastric emptying time. FIGS. **36** and **37** show other alternative placements for cavity wall folds. In these examples, a plurality of folds are placed in the lower region of the gastric cavity. In this location, the folds slow gastric emptying by interfering with the pumping action within the region. In FIG. **36**, the folds are placed within the lower region of the cavity extending angularly between the fundic region and a distal portion of the cavity. In FIG. **37**, the folds are placed in the antrum region of the cavity. In addition to the above-described embodiments, numerous other fold placements may be utilized without departing from the scope of the invention. The locations, angles and numbers of cavity wall folds may vary depending upon the particular outcome or treatment sought from the procedure. The effects of these folds may include one or more of the following, all of which serve as aids for the patient to lose weight: reduce gastric capacity; restrict passage of food into the gastric cavity; impair breakdown and movement of food within the gastric cavity; restrict passage of food from the gastric cavity; increase production of satiety producing hormones; etc.

One skilled in the art will quickly realize that a wide range of folds shapes and sizes can be used to induce one or more of the effects described above. FIGS. **38**-**43** show several examples of alternative fold patterns that may also be created with the present invention.

In the cavity wall folding procedures described above, the suture may be coated with a medicinal or antimicrobial agent to promote healing and treatment or to prevent infection. Methods to prepare a packaged antimicrobial medical device are described in further detail in pending U.S. patent application Ser. No. 11/301,364, filed on Dec. 13, 2005 and U.S. patent application Ser. No. 11/301,365, filed on Dec. 13, 2005; each of which is hereby incorporated herein by reference in its entirety. The suture may also be coated to facilitate passage of the suture through the gastric cavity wall. Exemplary suture coatings and coating methods are described in U.S. Pat. No. 6,712,838, the entire contents of which is hereby incorporated herein by reference. In addition to coating the suture, a medicinal agent may be disposed within the suture anchoring device or applied as a coating on the outside of the anchoring device.

In the above-described embodiments, the gastric cavity may require insufflation through the endoscope to provide satisfactory visualization and maintain adequate internal pressure against the cavity walls. During insufflation of the gastric cavity (either transesophageal insufflation in the case of some open and laparoscopic access approaches or transgastric insufflation in the case of some natural orifice approaches), a portion of the pressurized gas can pass into the jejunum through the pyloric sphincter and insufflate the small bowel. This insufflation of the bowel lumen can hinder the wall folding procedure by occluding a laparoscopic view of the peritoneal cavity. Accordingly, for wall folding procedures in which the abdominal cavity is visualized through a laparoscope, it is desirable to either block the passage of the gas into the small bowel, or to vent the bowel. FIG. **44** depicts an exemplary technique for blocking the passage of pressurized gas into the small bowel. In this technique, an obstructing member **230** is inserted into the pyloric sphincter **232** transorally. Endoscope **30** may be used to deliver the obstructing member **230** through a working channel within endoscope **30**. It may also be delivered to the site by endoscope **30** in such a way that obstructing member **230** is all or partially external to the endoscope **30**. Endoscope **30** may also be used to deliver a guidewire over which obstructing member **230** is simultaneously or subsequently passed. Obstructing member **230** may be inflatable, or made of a conformable material that can be compressed during passage through the endoscope and later expanded to fill the area within the pyloric sphincter. Obstructing member **230** may have a "dog-bone" type shape that enables the member to be more easily retained within the muscular band of the sphincter, preventing migration of obstructing member **230** through the gastrointestinal tract. FIG. **45** depicts another exemplary technique for reducing bowel insufflation, in which an obstructing member **230** is again placed into pyloric sphincter **232**. In this technique, an elongated lumen such as a vent **234** is passed through obstructing member **230** to suction or release any fluid that may have bypassed the obstructing member into the jejunum. Vent **234** may contain a one way valve permitting fluid flow in a preferred direction. Fluids from vent **234** are released outside of the body through a transorally extending tube **236**. Vacuum assist may be used to evacuate gas through tube **236**.

The devices disclosed herein can be designed to be disposed of after a single use, or they can be designed to be used multiple times. In either case, however, the device can be reconditioned for reuse after at least one use. Reconditioning can include any combination of the steps of disassembly of the device, followed by cleaning or replacement of particular pieces, and subsequent reassembly. In particular, the device can be disassembled, and any number of the particular pieces or parts of the device can be selectively replaced or removed in any combination. Upon cleaning and/or replacement of particular parts, the device can be reassembled for subsequent use either at a reconditioning facility, or by a surgical team immediately prior to a surgical procedure. Those skilled in the art will appreciate that reconditioning of a device can utilize a variety of techniques for disassembly, cleaning/replacement, and reassembly. Use of such techniques, and the resulting reconditioned device, are all within the scope of the present application.

Preferably, the invention described herein will be processed before surgery. First, a new or used instrument is obtained and if necessary cleaned. The instrument can then be sterilized. In one sterilization technique, the instrument is placed in a closed and sealed container, such as a plastic or TYVEK bag. The container and instrument are then placed in a field of radiation that can penetrate the container, such as gamma radiation, x-rays, or high-energy electrons. The radiation kills bacteria on the instrument and in the container. The sterilized instrument can then be stored in the sterile container. The sealed container keeps the instrument sterile until it is opened in the medical facility.

The foregoing description of preferred embodiments of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise form disclosed. Obvious modifications or variations are possible in light of the above teachings. The embodiments were chosen and described in order to best illustrate the principles of the invention and its practical application to thereby enable one of ordinary skill in the art to best utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the claims appended hereto.

What is claimed is:

1. A method for manipulating gastric tissue, said method comprising the steps of:

a. creating at least one incision to gain access to the peritoneal cavity;

b. forming at least one fold on the exterior of the gastric tissue by apposing the anterior and posterior walls centralizing said fold along a greater curvature of the tissue, cutting through an attachment point along the greater curvature, said fold being formed through said incision, said fold having serosa to serosa contact substantially along its entire length; and

c. securing said fold with a fastener.

2. The method of claim **1** further comprising the step of introducing a visualization element through a natural orifice into the gastric tissue to observe the forming of the fold.

3. The method of claim **1**, wherein the fold forming step further comprises deploying a pair of suture anchors with attached suture into the gastric tissue for forming the fold.

4. The method of claim **3**, wherein the fold forming step further comprises cinching the attached suture from the suture anchor pair to fold gastric tissue adjacent to the suture anchors.

5. The method of claim **4**, wherein the securing fold step further comprises securing the cinched suture.

6. The method of claim **5**, wherein a slip knot is formed within the attached suture, and the step of securing the cinched suture comprises tightening the slip knot to pull the suture anchors together.

7. The method of claim **3**, wherein the fold forming step further comprises deploying the pair of suture anchors into the anterior wall of the gastric cavity.

8. The method of claim **1** further including the step of insufflating the interior of the gastric tissue.

9. The method of claim **1** further including the step of introducing a therapeutic agent into the patient.

10. A method for manipulating gastric tissue, said method comprising the steps of:

a. creating at least one incision to gain access to the peritoneal cavity;

b. forming a first fold on the exterior of the gastric tissue by apposing the anterior and posterior walls centralizing said fold along a greater curvature of the tissue, said fold being formed through said incision, said first fold having serosa to serosa contact substantially along its entire length, securing said first fold with a fastener, cutting through an attachment point along the greater curvature; and

c. forming a second fold on the exterior of the gastric tissue through said incision, said second fold being formed about said first fold, said second fold having serosa to serosa contact substantially along its entire length securing said second fold with a fastener.

11. The method of claim **10** further comprising the step of introducing a visualization element through a natural orifice into the gastric tissue to observe the forming of the fold.

12. The method of claim **10**, wherein the fold forming step further comprises deploying a pair of suture anchors with attached suture into the gastric tissue for forming the fold.

13. The method of claim **12**, wherein the fold forming step further comprises cinching the attached suture from the suture anchor pair to fold gastric tissue adjacent to the suture anchors.

14. The method of claim **13**, wherein the securing fold step further comprises securing the cinched suture.

15. The method of claim **14**, wherein a slip knot is formed within the attached suture, and the step of securing the cinched suture comprises tightening the slip knot to pull the suture anchors together.

16. The method of claim **12**, wherein the fold forming step further comprises deploying the pair of suture anchors into the anterior wall of the gastric cavity.

17. The method of claim **10** further including the step of introducing a therapeutic agent into the patient.

18. A method for manipulating gastric tissue, said method comprising the steps of:

a. creating at least one incision to gain access to the peritonial cavity;

b. traumatizing the exterior of an area of the gastric tissue along a greater curvature of the tissue, said traumatizing being done through said incision;

c. forming at least one fold by apposing the anterior and posterior walls centralizing said fold along the greater curvature, said fold forming about said area of the gastric tissue through said incision, said fold having serosa to serosa contact substantially along its entire length, cutting through an attachment point along the greater curvature; and

d. securing said fold with a fastener.

19. The method of claim **18** further comprising the step of introducing a visualization element through a natural orifice into the gastric tissue to observe the forming of the fold.

20. The method of claim **18**, wherein the fold forming step further comprises deploying a pair of suture anchors with attached suture into the gastric tissue for forming the fold.

21. The method of claim **20**, wherein the fold forming step further comprises cinching the attached suture from the suture anchor pair to fold gastric tissue adjacent to the suture anchors.

22. The method of claim **21**, wherein the securing fold step further comprises securing the cinched suture.

23. The method of claim **22**, wherein a slip knot is formed within the attached suture, and the step of securing the cinched suture comprises tightening the slip knot to pull the suture anchors together.

24. The method of claim **20**, wherein the fold forming step further comprises deploying the pair of suture anchors into the anterior wall of the gastric cavity.

25. The method of claim **18** further including the step of introducing a therapeutic agent into the patient.

* * * * *

专利名称(译)	混合内窥镜/腹腔镜方法，用于在胃腔中形成浆膜浆膜性瘢痕		
公开(公告)号	US8551118	公开(公告)日	2013-10-08
申请号	US11/779322	申请日	2007-07-18
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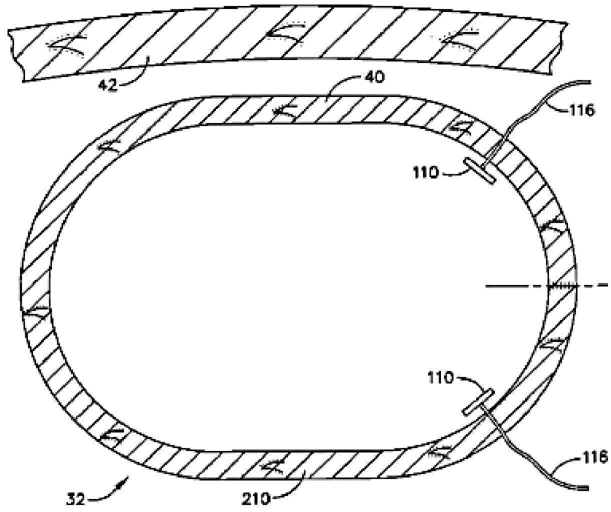
其他公开文献	US20090024163A1		
外部链接	Espacenet USPTO		

摘要(译)

一种通过减少胃腔的体积和/或改变胃功能以限制食物消耗和诱导早期饱腹感来治疗肥胖症的方法。该方法包括通过内窥镜进入腔体以使腔体内部可视化。通过腹壁上的小切口进入腹膜腔。使用内窥镜可视化，缝线锚固装置通过切口被引入腹膜腔并从外表面穿过胃cavity壁展开。来自成对的锚固装置的缝合线穿过胃cavity壁并在腔体外部收紧以形成浆膜到浆膜褶皱。可以在腔壁中形成任何数量的褶皱，并且可以治疗褶皱内的接触组织以促进愈合和更持久的粘合。



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