



(43) International Publication Date
25 September 2014 (25.09.2014)

- (51) International Patent Classification:
A61F 5/00 (2006.01) *A61B 17/12* (2006.01)
- (21) International Application Number:
PCT/US2014/022515
- (22) International Filing Date:
10 March 2014 (10.03.2014)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
61/791,880 15 March 2013 (15.03.2013) US
- (71) Applicant: THE CLEVELAND CLINIC FOUNDATION [US/US]; 9500 Euclid Avenue, Cleveland, Ohio 44195 (US).
- (72) Inventor: SCHAUER, Philip; 9500 Euclid Avenue, Cleveland, Ohio 44195 (US).
- (74) Agent: WESORICK, Richard S.; Tarolli, Sundheim, Covell & Tummino LLP, 1300 East Ninth Street, Suite 1700, Cleveland, Ohio 44114 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

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(54) Title: GASTRIC PLICATION GUIDE

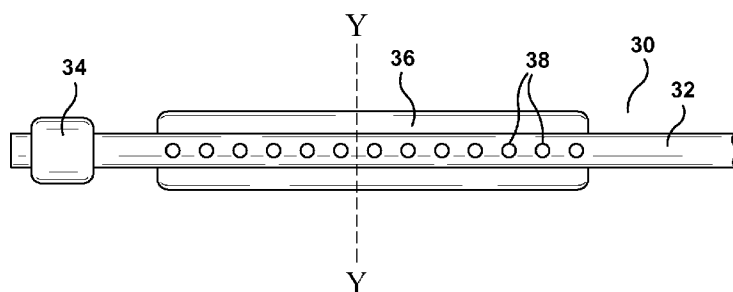


Fig. 2a

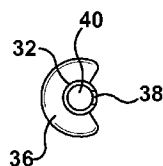


Fig. 2b

(57) Abstract: A device for helping a surgeon to fold the correct amount of tissue when conducting a gastric plication procedure is described. The guide device includes an elongated flexible guide, a securing device positioned on the distal end of the guide, and means for guiding stomach tissue during a gastric plication procedure that are positioned longitudinally along the distal end of the guide and proximal to the securing device. The means for guiding stomach tissue include the use of a shaping balloon to serve as a guide for final stomach volume and/or a groove on the guide device to regulate formation of the tissue fold. Methods for using the guide device to carry out gastric plication procedures are also described.



Published:

— *with international search report (Art. 21(3))*

GASTRIC PLICATION GUIDE

Related Applications

[0001] This application claims the benefit of U.S. Provisional Patent Application Serial No. 61/791,880, filed March 15, 2013, the entirety of which is hereby incorporated by reference in its entirety for all purposes.

BACKGROUND

[0002] There are currently about 225,000 bariatric surgeries carried out in the U.S. each year, with a roughly equal number being carried out outside of the U.S. Bariatric surgery is prescribed to treat morbid obesity (defined as a body mass index greater than 40), type 2 diabetes, hypertension, sleep apnea, and other co-morbid conditions. The majority of these surgeries are gastric bypass, with the remaining being a fairly even mix of sleeve gastrectomy and gastric banding procedures.

[0003] Gastric bypass (GB) surgery divides the stomach into a small upper pouch and a much larger lower "remnant" pouch and then re-arranges the small intestine to connect to both. GB surgery leads to a marked reduction in the functional volume of the stomach, accompanied by an altered physiological and physical response to food. However, a recent study revealed that 15% of patients experience complications as a result of gastric bypass, and 0.5% of patients died within six months of GB surgery due to complications.

[0004] Gastric banding and sleeve gastrectomy are two additional bariatric surgical procedures that have been developed. In gastric banding, an inflatable band is placed around the upper part of the stomach to create a smaller stomach pouch. Gastric banding is the least invasive type of bariatric surgery, but its efficacy has recently been called into question. Sleeve gastrectomy is a surgical weight-loss procedure particularly useful for extremely obese patients in which the stomach is reduced to about 25% of its original size, by surgical removal of a large portion of the stomach, following the major curve. The open edges of the stomach are then attached together to form a sleeve or tube. However, because sleeve gastrectomy permanently removes a portion of the stomach, it is not reversible.

[0005] Gastric plication is a variation of the sleeve gastrectomy procedure in which a portion of the stomach is folded in upon itself. Because a portion of the stomach is folded rather than removed, the procedure is reversible. However, if too much tissue is folded in, food cannot pass through the stomach. On the other hand, if insufficient tissue is folded in, the patient will not lose enough weight. Accordingly, it is very important to be precisely control stomach size when conducting a gastric plication procedure.

SUMMARY

[0006] A gastric plication guide is described herein that helps a surgeon fold in the correct amount of tissue when carrying out a gastric placation procedure to help the patient lose weight without blocking the stomach.

[0007] In one aspect, a gastric plication guide device is provided that includes an elongated flexible guide, a securing device positioned on the distal end of the guide, and means for guiding stomach tissue during a gastric plication procedure, positioned longitudinally along the distal end of the guide and proximal to the securing device. Various means for guiding stomach tissue are provided. In one embodiment, the means for guiding stomach tissue comprise a shaping balloon. In some embodiments, the shaping balloon is used alone, while in other embodiments the shaping balloon includes additional smaller balloons to further assist in formation of the tissue fold. In further embodiments, the flexible guide includes a lumen including one or more ports in communication with the lumen to apply suction during the procedure. In yet further embodiments, the means for guiding stomach tissue include a groove sized to accommodate folded stomach tissue.

[0008] Another aspect of the invention provides methods for using the gastric plication guide devices described herein to carry out a gastric plication procedure.

BRIEF DESCRIPTION OF THE FIGURES

[0009] Figure 1 provides a cross-sectional view of the prior art method of gastric plication, with 1(a) showing a side view of the stomach, figure 1(b) showing an x-plane cross-sectional view of the stomach before the procedure has begun with the suture points marked, figure 1(c) showing an x-plane cross-sectional view of the stomach after the initial tissue fold has been formed by the first line of sutures, and figure 1(d) showing an x-plane cross-sectional view of the stomach after the full tissue fold has been formed and the second line of sutures have been placed.

[0010] Figure 2 provides (a) a view of the gastric plication guide including a shaping balloon and suction ports while (b) provides a y-plane cross-sectional view of the gastric plication guide including a shaping balloon.

[0011] Figure 3 provides a side view of a stomach in which the gastric plication guide has been positioned at the outset of a gastric plication procedure.

[0012] Figure 4 provides x-plane cross sectional views of a stomach showing three steps of a gastric plication procedure using a gastric plication guide including a shaping balloon and suction ports, with the first step (a) showing the gastric plication guide that has been adhered to the side of the stomach by suction through the ports at the beginning of the procedure, a second step (b) showing the partial inflation of the balloon, formation of the initial tissue fold, and application of the first line of sutures, and a third step (c) showing full inflation of the balloon, formation of the full tissue fold, and application of the second line of sutures.

[0013] Figure 5 provides a schematic view of the steps involved in using a gastric plication guide including suction ports and a shaping balloon to carry out a gastric plication procedure.

[0014] Figure 6 provides cross-sectional views of a gastric plication procedure in which three additional balloons are together with the shaping balloon to assist in formation of the tissue fold, with the first step (a) showing inflation of the central and peripheral guide balloons to induce formation of a tissue fold, second step (b)

showing further expansion of the peripheral guide balloons to capture the tissue fold and application of the first line of sutures, and (c) deflation of the central guide balloon and partial deflation of the peripheral guide balloons to allow further development of the tissue fold and application of the second line of sutures upon re-inflation of the peripheral guide balloons to re-capture the tissue fold.

[0015] Figure 7 provides a schematic view of the steps involved in a gastric plication procedure using additional guide balloons.

[0016] Figure 8 provides views of gastric plication guides including a tissue groove, with (a) providing a view of the gastric plication guide with a tissue groove, (b) providing the associated y-plane cross-sectional view of the gastric plication guide with a tissue groove, (c) providing a view of a gastric plication guide with a tissue groove including embedded suction ports and (d) providing an associated y-plane cross-sectional view of a gastric plication guide with a tissue groove including embedded suction ports.

[0017] Figure 9 provides a schematic view of the steps involved in a gastric plication procedure including a groove to accommodate formation of the tissue fold.

[0018] The following detailed description is to be read with reference to the figures, in which like elements in different figures have like reference numerals. The figures, which are not necessarily to scale, depict selected embodiments and are not intended to limit the scope of the invention. Skilled artisans will recognize the embodiments provided herein have many useful alternatives that fall within the scope of the invention.

DETAILED DESCRIPTION

[0019] Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this application pertains. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of the exemplary embodiments, suitable methods and materials are described below. In case of

conflict, the present specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and not intended to be limiting.

Definitions

[0020] The terminology as set forth herein is for description of the embodiments only and should not be construed as limiting the application as a whole. Unless otherwise specified, "a," "an," "the," and "at least one" are used interchangeably. Furthermore, as used in the description of the application and the appended claims, the singular forms "a", "an", and "the" are inclusive of their plural forms, unless contraindicated by the context surrounding such.

[0021] The recitations of numerical ranges by endpoints include all numbers subsumed within that range (*e.g.*, 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, 5, *etc.*).

[0022] It is understood that all spatial references, such as "horizontal," "vertical," "top," "upper," "lower," "bottom," "left," and "right," are for illustrative purposes only and can be varied within the scope of the disclosure.

[0023] A prior art method for carrying out a gastric plication procedure is shown in Figure 1(a-d). Figure 1(a) shows a side view of the stomach **10**, which is a generally tubular organ. The esophagus **12** leads to the stomach **10**, while the small intestine **14** leads away from the stomach **10**. The pyloric valve **16** is positioned between the stomach **10** and the small intestine **14**. Figures 1(b-d) provide an X-plane cross-section view of the stomach shown in Figure 1a. Figure 1(b) shows the stomach **10** and the initial suture points **18** and the final suture points **20**. A gastric plication procedure is done by first adjoining stomach tissue by suturing it together at the initial suture points **18**, as shown in 1(c), thereby forming a first line of sutures **22** and an initial tissue fold **24**. The initial tissue fold (*i.e.*, an intraluminal fold) is formed by taking a portion of the stomach (*e.g.*, of the anterior gastric wall) and folding it inwards (*e.g.*, from the fundus to the antrum), and runs along a substantial portion of the length of the stomach. An example of a suitable suture is a 2-0 polypropylene running suture. This process is then repeated as shown in Figure 1(d) by increasing

the size of the tissue fold **24** to form a final tissue fold by adjoining and suturing the stomach tissue together at the final suture points **20** using a second line of sutures **26**. As can be seen on the figure, the first line of sutures **22** end up around the middle of the final tissue fold, and well within the stomach. The sutures can be placed via a laparoscopic procedure. A detailed description of the laparoscopic version of the procedure is described by Brethauer *et al.*, and is incorporated in its entirety by reference in herein. Brethauer *et al.*, Surg Obes Relat Dis., 7(1): 15-22 (2011).

[0024] Disclosed herein are a variety of gastric plication guides that help a surgeon fold in the correct amount of tissue and/or govern the size of a stomach altered by the gastric plication procedure to help the patient lose weight without blocking the stomach. Accordingly, in one aspect, the present invention provides a gastric plication guide device that includes an elongated flexible guide **32**, a securing device **34** positioned on the distal end of the guide, and means for guiding stomach tissue during a gastric plication procedure, positioned longitudinally along the distal end of the guide **32** and proximal to the securing device **34**. The guide need be flexible only to the extent to allow it to be maneuvered into the stomach and to allow proper positioning therein. The securing device can be a balloon or a thick sleeve that helps to position the gastric plication guide **30** within the stomach **10**, generally by resting against the pyloric valve **16**. Guiding, as used herein, refers to any positioning assistance for formation of the tissue fold within the stomach or for setting the final size of the stomach after completion of the procedure.

[0025] In some embodiments, the gastric plication guide includes a shaping balloon **36**. The shaping balloon **36** should be made from a suitable material such as rubber or latex, and will have a shape suitable to conform to the interior of the stomach (*i.e.*, generally ovoid or cylindrical). The shaping balloon **36** should also be connected to an air source through an air line so that the balloon can be inflated and deflated during the gastric plication procedure. The shaping balloon **36** can be used to regulate the final size of the stomach, and/or to assist in creating a tissue fold **24** having a suitable size. As used herein, full inflation refers to inflating the balloon to its largest intended size in the context of the surgical procedure, partial inflation

refers to less than full inflation, but enough inflation to substantially increase the size of the balloon (e.g., to 25%, 50%, or 75% of its final fully inflated size), and deflation refers to returning the balloon to its original size, except for partial deflation, which provides a balloon having the same sizes described for a partially inflated balloon.

[0026] An embodiment including a shaping balloon **36** is shown in Figure 2. In the particular embodiment shown, the shaping balloon **36** is positioned along one side of the gastric plication guide **30**. In this embodiment, the flexible guide **32** of the gastric plication guide **30** includes a lumen **40** and one or more ports **38** in communication with the lumen **40** positioned along the guide **32** opposite from the shaping balloon **36**. The ports **38** can be used to position the flexible guide **32** against the interior of the stomach **10** using suction. As few as one port can be included, but generally the ports **38** comprise a plurality of longitudinally-spaced ports to provide suction along the length of the desired tissue fold **24**. Figure 3 shows this embodiment of the gastric plication guide positioned within the stomach before suction has been used to temporarily adhere the flexible guide **32** against the stomach wall. As shown in Figure 3, the securing device **34** is placed across the pyloric valve **16** to position the gastric plication guide, though it should be noted that in some embodiments a portion of the guide may extend past the pyloric valve **16**.

[0027] The steps involved in using this embodiment of the gastric plication guide are shown in Figures 4 and 5. The gastric plication guide **30** is first inserted through the esophagus **12** and into the stomach **10** of a subject, and positioned by placing the securing device **34** of the guide adjacent to the pyloric valve **16** of the subject. A portion of the stomach **10** is then contacted with one or more ports **38** of the flexible guide **32**, and suction is applied, as shown in Figure 4(a), to adhere the guide to the stomach lining. The shaping balloon **36** is then partially inflated as shown in Figure 4(b) to draw the initial suture points **18** together and infold a portion of the stomach **10** to form the initial tissue fold **24**. A first line of sutures **22** is then sewn along the base of the initial tissue fold **24**. After the surgeon has run the first line of sutures, the shaping balloon **36** is then fully inflated to provide a size corresponding to the desired final stomach size. As shown in Figure 4(c), when the shaping balloon **36** is fully expanded, the tissue fold **24** is drawn further into the stomach by infolding an

additional portion of the stomach **10** to form the final tissue fold **24**. The final tissue fold **24** is then secured by sewing a second suture line **26** along the base of the final tissue fold. Once all of the sutures have been placed, the shaping balloon **36** is deflated, the securing device **34** is disengaged, and the gastric plication guide **30** is removed from the stomach of the subject. In some embodiments, the first and second lines of sutures are sewn laparoscopically.

[0028] Another embodiment of the gastric plication guide including a shaping balloon **36** is shown in Figure 6. In this embodiment, the shaping balloon **36** further comprises a cylindrical central guide balloon **40** positioned on the outside of the shaping balloon **36**, and two cylindrical peripheral guide balloons **42** and **44** positioned within the shaping balloon **36** on each side of and in parallel with the central guide balloon **40**. The additional balloons are used to grab the tissue that is folded into the stomach to form the tissue fold **24**. Rather than showing the entire gastric plication guide device, Figure 6 focuses on the shaping balloon itself, and the roles played by the additional balloons in forming the tissue fold **24**. However, it should be understood that the shaping balloon **36** is appropriately positioned on a gastric plication guide **30** so that it will inflate within the stomach when the gastric plication guide has been positioned using the securing device **34**. Figure 7 provides a flowchart calling out the specific steps involved in carrying out a gastric plication procedure using this embodiment of the invention.

[0029] The first step in using the multi-balloon embodiment of the gastric plication guide involves inserting the gastric plication guide **30** through the esophagus **12** and into the stomach **10** of the subject, and positioning the device by placing the securing device **34** adjacent to the pyloric valve **16** of the subject. The shaping balloon **36** is then inflated to a size corresponding to the desired final stomach size. As shown in Figure 6(a), the central guide balloon **40** is then fully inflated, and the peripheral guide balloons **42** and **44** are partially inflated. Additional lines can be provided within the lumen **40** of the gastric plication guide **30** that are connected to an air source in order to inflate and deflate the central and peripheral guide balloons. Force is then applied between the two peripheral guide balloons **42** and **44** to cause a portion of the stomach to infold and form an initial tissue fold **24**. For example, force

can be manually applied by the surgeon. The tissue fold **24** is secured in place by fully inflating the peripheral guide balloons **42** and **44**, as shown in Figure 6(b). A first suture line **22** is then sewn along the base of the initial tissue fold **24**. The central guide balloon **40** is then deflated, and the peripheral guide balloons **42** and **44** are partially deflated to encourage infolding of an additional portion of the stomach to form the final tissue fold **24**, as shown in Figure 6(c). The second suture line **26** is then sewn along the base of the final tissue fold **24**. The shaping balloon **36** is then deflated and the gastric plication guide is withdrawn from the stomach of the subject. In some embodiments, the first and second suture lines are sewn laparoscopically.

[0030] In another aspect, the means for guiding stomach tissue of the gastric plication guide is a groove **50** sized to accommodate the tissue fold **24**. In one embodiment, the gastric plication guide is a bougie **48** with a groove **50** running longitudinally approximately along the length of the bougie **48** that will sit within the stomach **10** during the gastric plication surgery. A bougie is a shaping device that generally does not include an internal lumen, although an internal lumen can be included connect to an air supply to inflate an anchoring balloon, if a balloon is used as the securing device **34**. Prior art bougies used in bariatric surgeries generally are defined based on their diameter alone. When this embodiment of the gastric plication guide has been positioned within the stomach, the physician will push a portion of the stomach wall into the groove **50** from the outside of the stomach to form a tissue fold, with the groove governing the size of the fold to prevent it from being too small or too large.

[0031] In further embodiments of the gastric plication guide that includes a groove, the flexible guide further includes a lumen **54** and one or more ports **52** positioned within the groove **50** and in communication with the lumen **54**. A single port can be used, but preferably the ports include a plurality of longitudinally-spaced ports that are positioned along the base of the groove **50** so that suction is provided along the length of the tissue fold **24**. When used in surgery, the surgeon defines the suture line by suctioning stomach tissue into the groove of the gastric plication guide **30**, thereby folding the stomach tissue into the stomach to form a tissue fold **24**.

[0032] Methods of using the gastric plication guides shown in Figure 8 are illustrated in schematic form in Figure 9. The first step is to insert the gastric plication guide (**30** or **48**) through the esophagus **12** and into the stomach **10** of a subject. The securing device **34** is then placed adjacent to the pyloric valve **16** in order to correctly position the gastric plication guide. A portion of the stomach is then contacted with the groove **50** of the guide. In embodiments that include suction ports **52**, suction may then be applied to the stomach **10** through the ports in order to encourage formation of a tissue fold within the groove **50**. A portion of the stomach is then folded into the groove **50** to form an initial tissue fold **24**. A first suture line **22** is then sewn along the base of the initial tissue fold **24**. An additional portion of the stomach is then folded into the groove **50** of the gastric plication guide to form a final tissue fold **24**, with the groove serving to limit the amount of stomach tissue included. Vacuum can also be applied through suction ports **52**, if present, during this step to assist with lengthening of the tissue fold **24**. A second suture line **26** is then sewn along the base of the final tissue fold **24**. Finally, the gastric plication guide is withdrawn from the stomach of the subject.

[0033] The complete disclosure of all patents, patent applications, and publications, and electronically available material cited herein are incorporated by reference. The foregoing detailed description and examples have been given for clarity of understanding only. No unnecessary limitations are to be understood therefrom. The invention is not limited to the exact details shown and described, for variations obvious to one skilled in the art will be included within the invention defined by the claims.

CLAIMS

What is claimed is:

1. A gastric plication guide device, comprising:
an elongated flexible guide,
a securing device positioned on the distal end of the guide, and
means for guiding stomach tissue during a gastric plication procedure,
positioned longitudinally along the distal end of the guide and proximal to the
securing device.
2. The gastric plication guide of claim 1, wherein the means for guiding stomach
tissue comprise a shaping balloon.
3. The gastric plication guide of claim 2, wherein the flexible guide includes a
lumen, wherein the shaping balloon is positioned along one side of the guide,
and the lumen includes one or more ports in communication with the lumen
positioned along the guide opposite from the shaping balloon.
4. The gastric plication guide of claim 3, wherein the ports comprise a plurality of
longitudinally-spaced ports.
5. The gastric plication guide of claim 2, wherein the shaping balloon further
comprises a cylindrical central guide balloon positioned on the outside of the
shaping balloon, and two cylindrical peripheral guide balloons positioned
within the shaping balloon on each side of and in parallel with the central
guide balloon.
6. The gastric plication guide of claim 1, wherein the means for guiding stomach
tissue comprise a groove sized to accommodate folded stomach tissue.
7. The gastric plication guide of claim 6, wherein the flexible guide includes a
lumen and one or more ports positioned within the groove and in
communication with the lumen.

8. The gastric plication guide of claim 7, wherein the ports comprise a plurality of longitudinally-spaced ports positioned along the base of the groove.
9. A method of guided gastric plication, comprising the steps of:
inserting a gastric plication guide device according to claim 2 through the esophagus and into the stomach of the subject,
placing the securing device of the guide adjacent to the pyloric valve of the subject,
infolding a portion of the stomach to form an initial tissue fold,
sewing a first suture line along the base of the initial tissue fold,
infolding an additional portion of the stomach to form a final tissue fold,
sewing a second suture line along the base of the final tissue fold, and
withdrawing the gastric plication guide device from the stomach of the subject,
wherein the method further comprises the step of inflating the shaping balloon within the stomach to a size corresponding to the desired final stomach size subsequent to the guided gastric plication, and deflating the shaping balloon before withdrawing the gastric plication guide device.
10. The method of claim 9, wherein the shaping balloon further comprises a cylindrical central guide balloon positioned on the outside of the shaping balloon, and two cylindrical peripheral guide balloons positioned within the shaping balloon on each side of and in parallel with the central guide balloon, wherein the shaping balloon is inflated to a size corresponding to the desired final stomach size after placing the securing device of the guide adjacent to the pyloric valve of the subject, and further comprising the steps of:
fully inflating the central guide balloon and partially inflating the peripheral guide balloons before infolding a portion of the stomach to form an initial tissue fold,
fully inflating the peripheral guide balloons to secure the initial tissue fold before sewing a first suture line along the base of the initial tissue fold,
fully deflating the central guide balloon and partially deflating the peripheral guide balloons before infolding an additional portion of the stomach to form a

final tissue fold, and fully inflating the peripheral guide balloons to secure the final tissue fold before sewing a second suture line along the base of the final tissue fold.

11. The method of claim 10, wherein the first and second suture lines are sewn laparoscopically.
12. The method of claim 9, wherein the flexible guide includes a lumen, wherein the shaping balloon is positioned along one side of the guide, and the lumen includes one or more ports in communication with the lumen positioned along the guide opposite from the shaping balloon, and the method further comprises the steps of:
contacting a portion of the stomach with the one or more ports of the flexible guide and applying suction through the ports before infolding a portion of the stomach to form the initial tissue fold,
partially inflating the shaping balloon to assist formation of the initial tissue fold,
applying suction through the ports before infolding an additional portion of the stomach to form the final tissue fold, and fully inflating the shaping balloon to correspond to the desired final stomach size to assist formation of the final tissue fold.
13. The method of claim 12, wherein the first and second suture lines are sewn laparoscopically.
14. A method of guided gastric plication, comprising the steps of:
inserting a gastric plication guide device according to claim 6 through the esophagus and into the stomach of a subject,
placing the securing device of the guide adjacent to the pyloric valve of the subject and contacting a portion of the stomach with the groove of the flexible guide,
infolding a portion of the stomach into the groove to form an initial tissue fold, sewing a first suture line along the base of the initial tissue fold,

infolding an additional portion of the stomach into the groove of the guide device to form a final tissue fold,
sewing a second suture line along the base of the final tissue fold, and
withdrawing the gastric plication guide device from the stomach of the subject.

15. The method of claim 14, wherein the flexible guide includes a lumen and one or more ports positioned within the groove and in communication with the lumen, and the method further comprises applying suction to the stomach through the ports before infolding a portion of the stomach into the groove to form the initial tissue fold and/or the final tissue fold.
16. The method of claim 14, wherein the first and second suture lines are sewn laparoscopically.

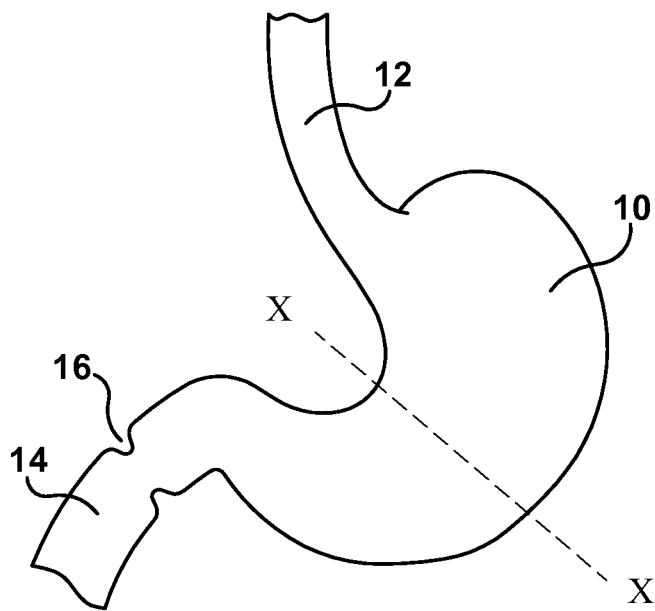


Fig. 1a
(Prior Art)

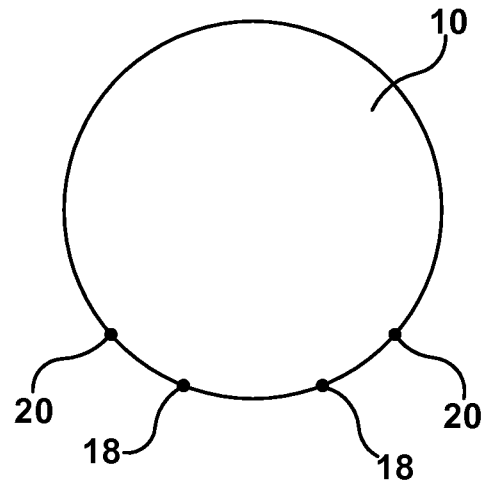


Fig. 1b
(Prior Art)

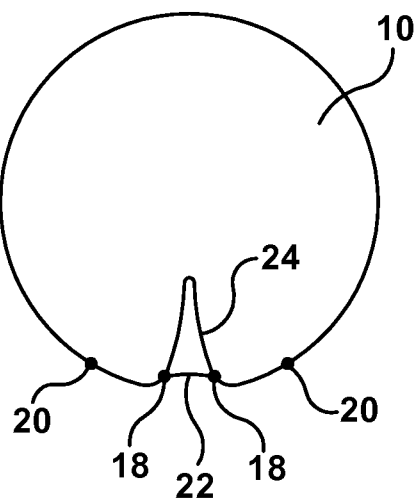


Fig. 1c
(Prior Art)

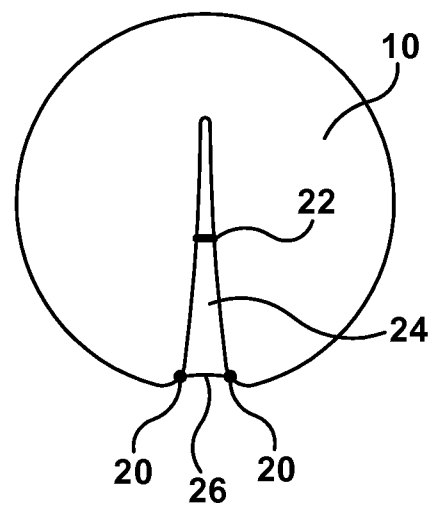


Fig. 1d
(Prior Art)

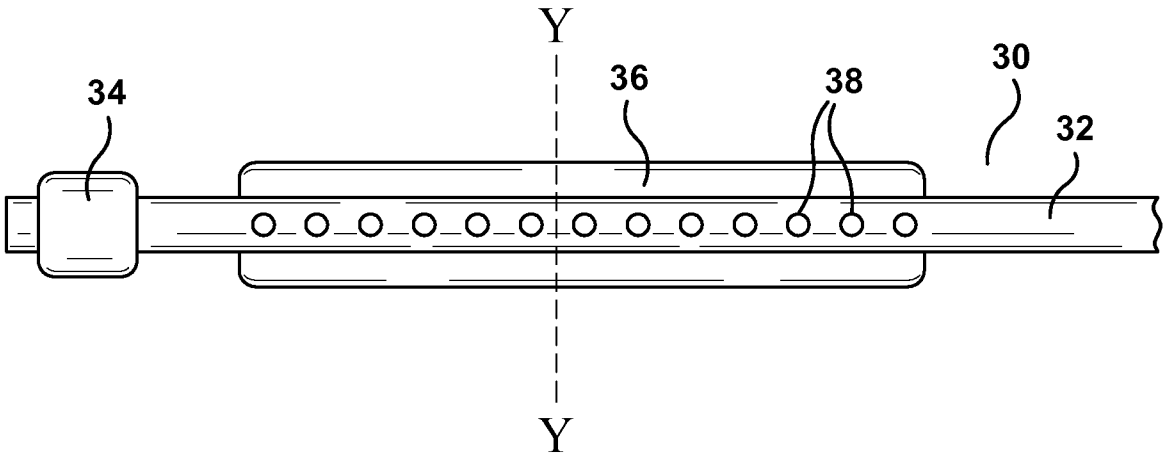


Fig. 2a

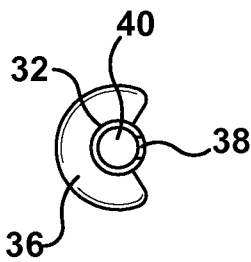


Fig. 2b

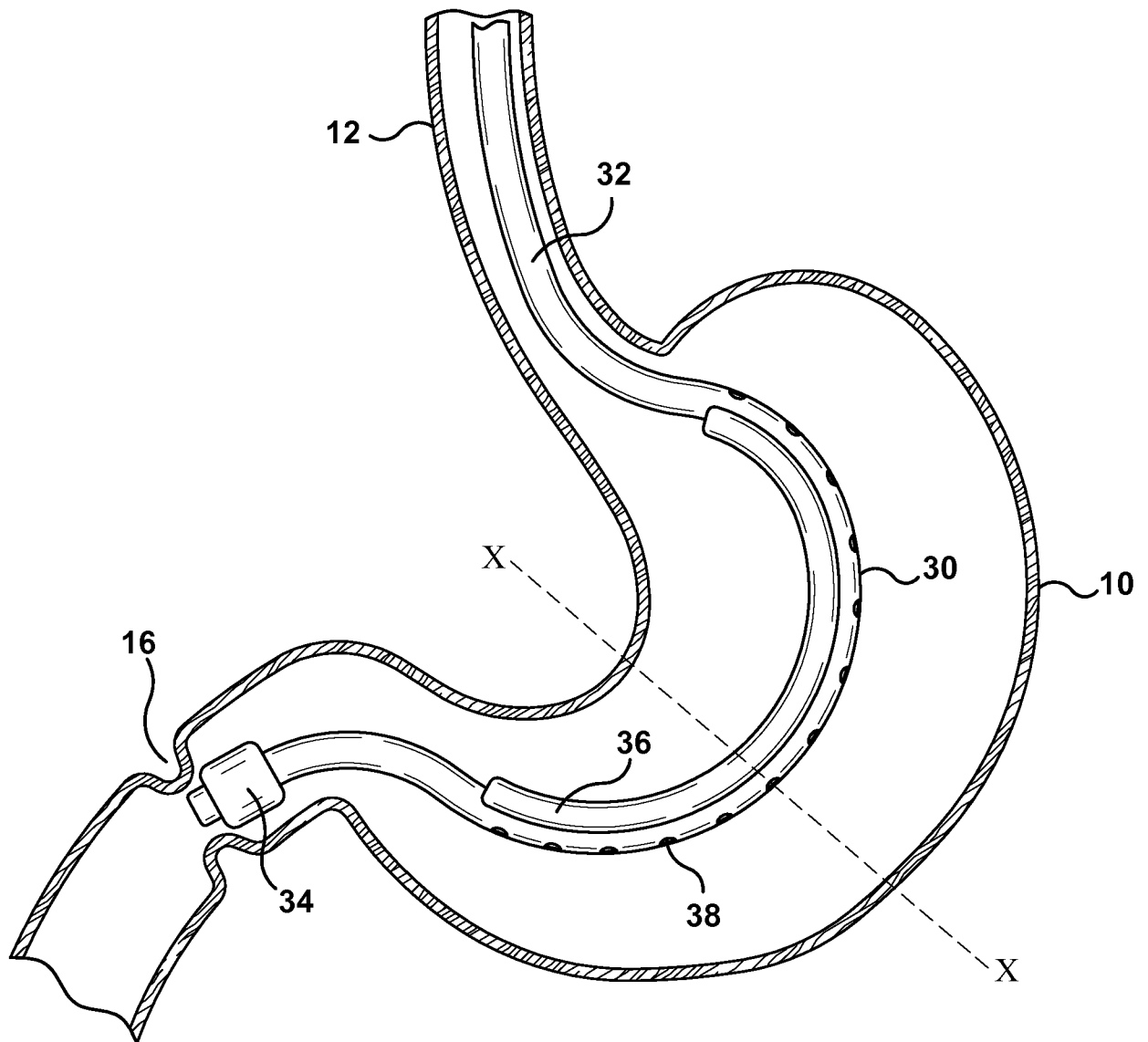


Fig. 3

Fig. 4a

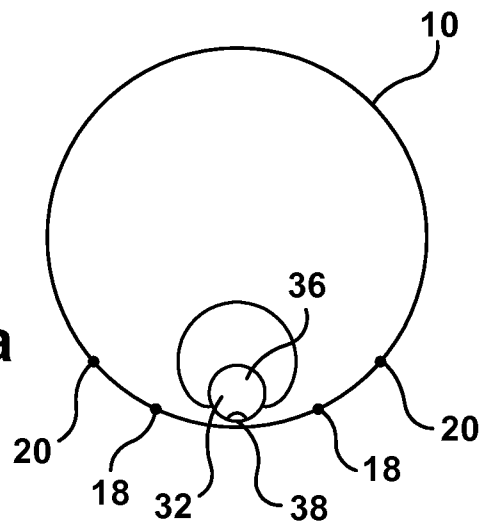


Fig. 4b

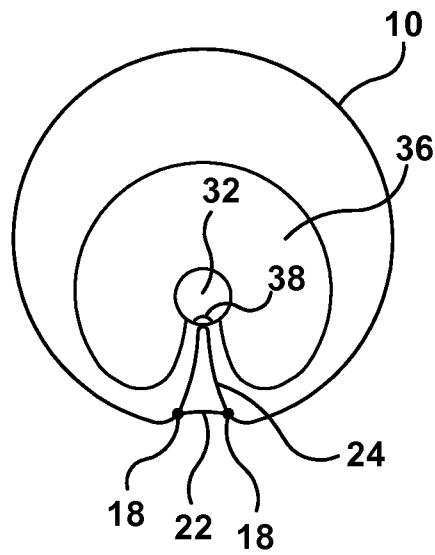
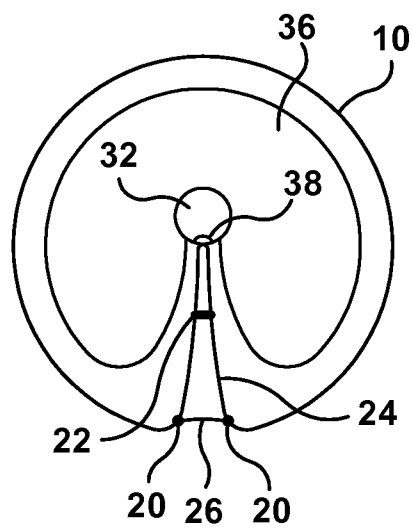
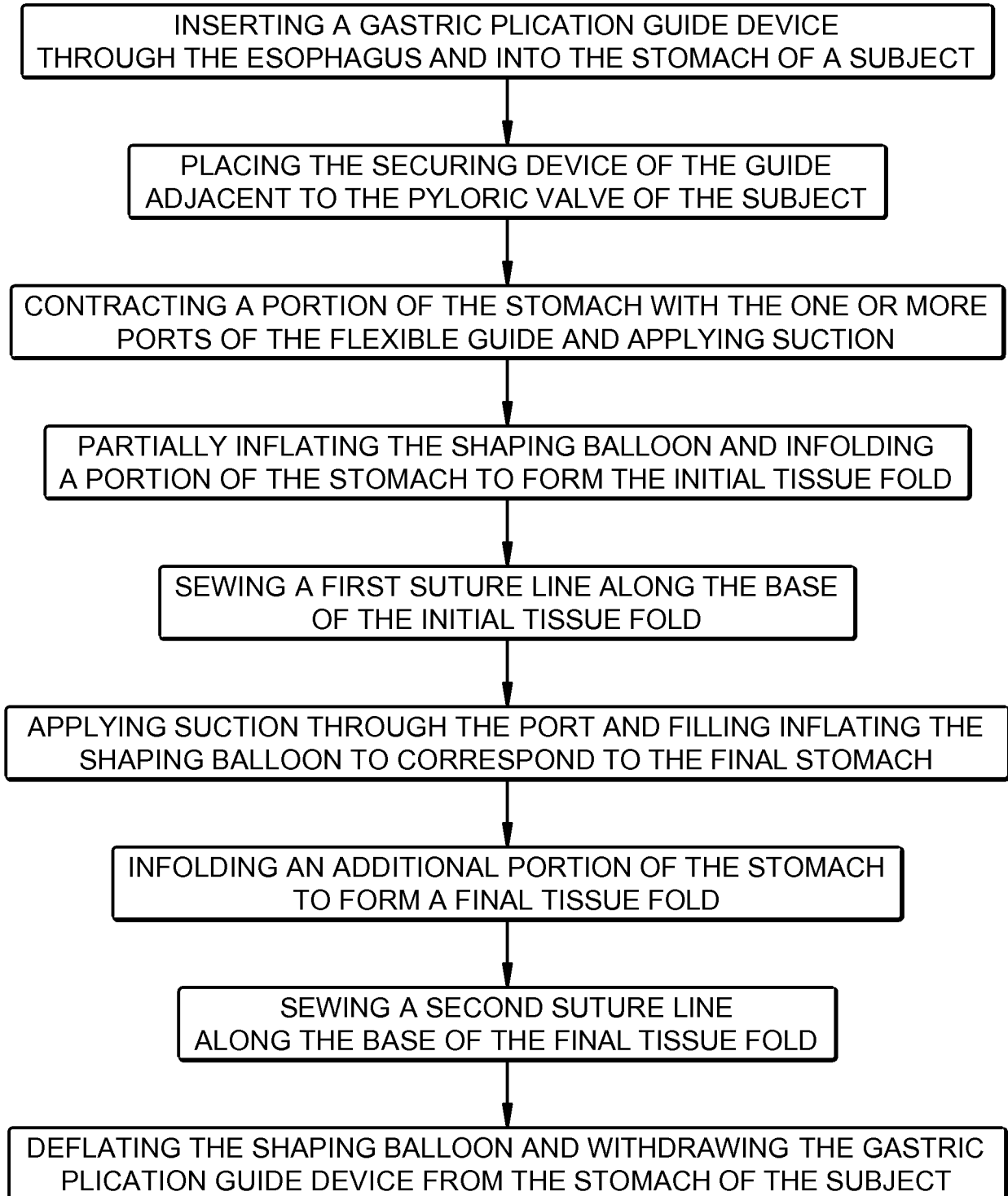


Fig. 4c



**Fig. 5**

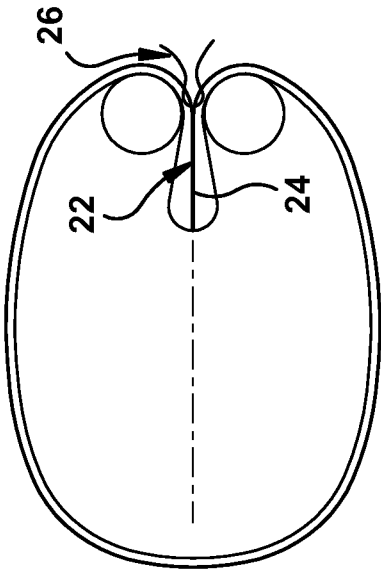


Fig. 6a

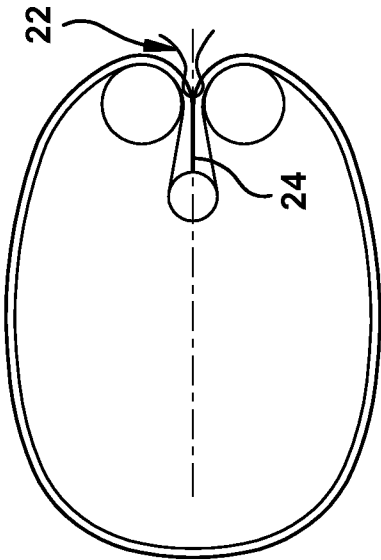


Fig. 6b

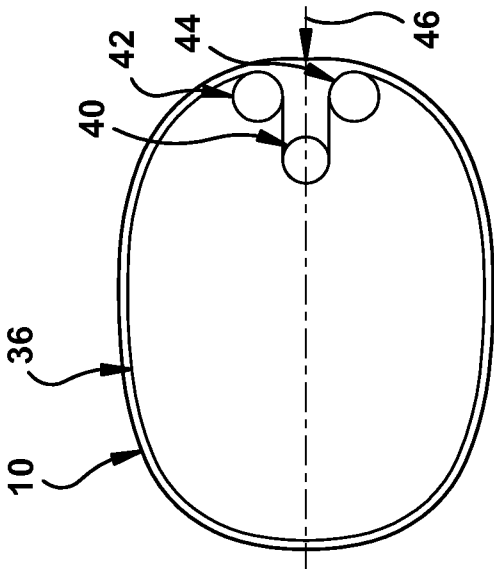
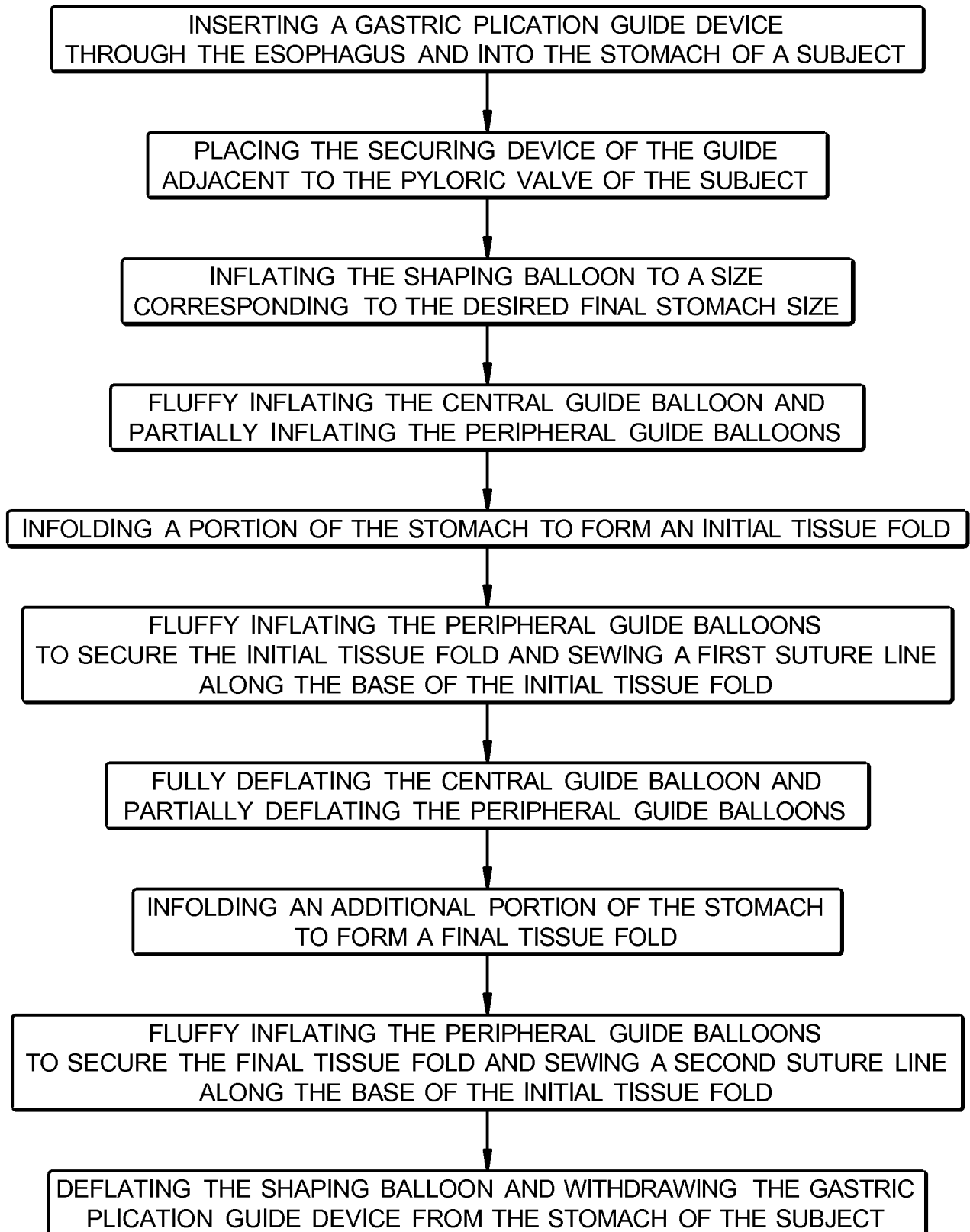


Fig. 6c

**Fig. 7**

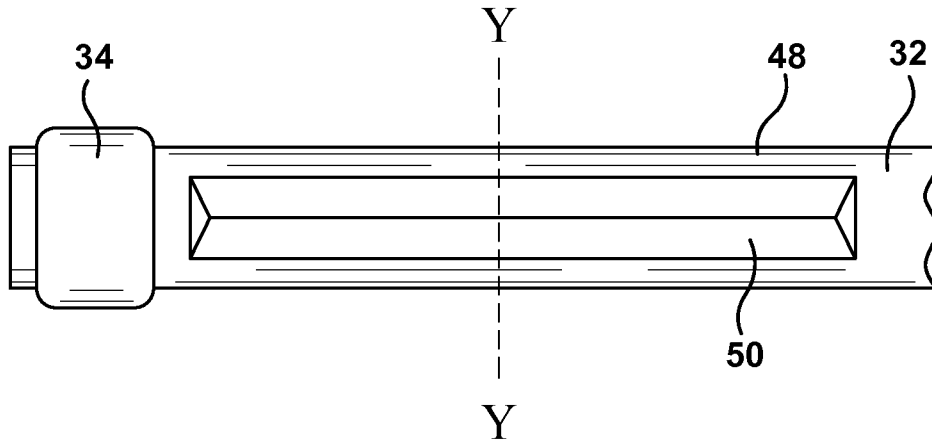


Fig. 8a

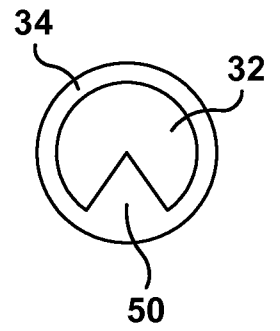


Fig. 8b

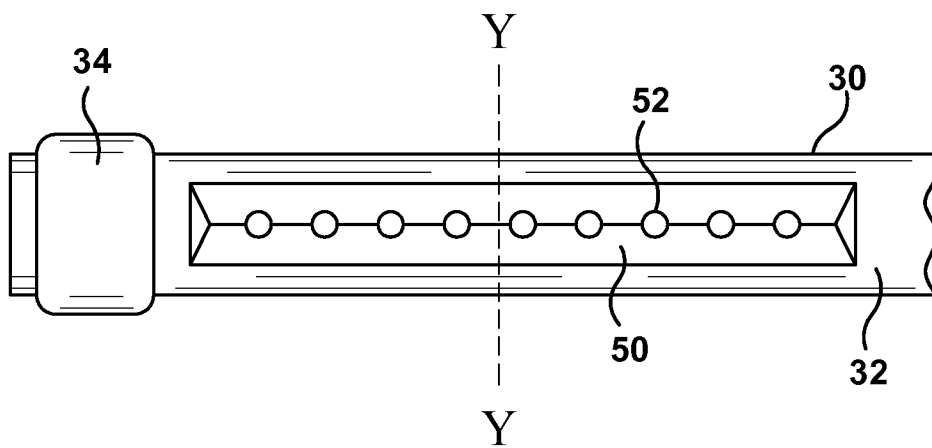


Fig. 8c

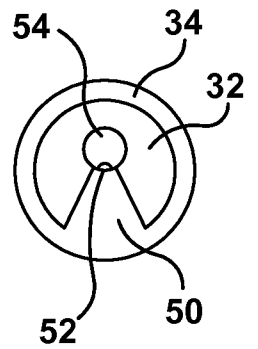
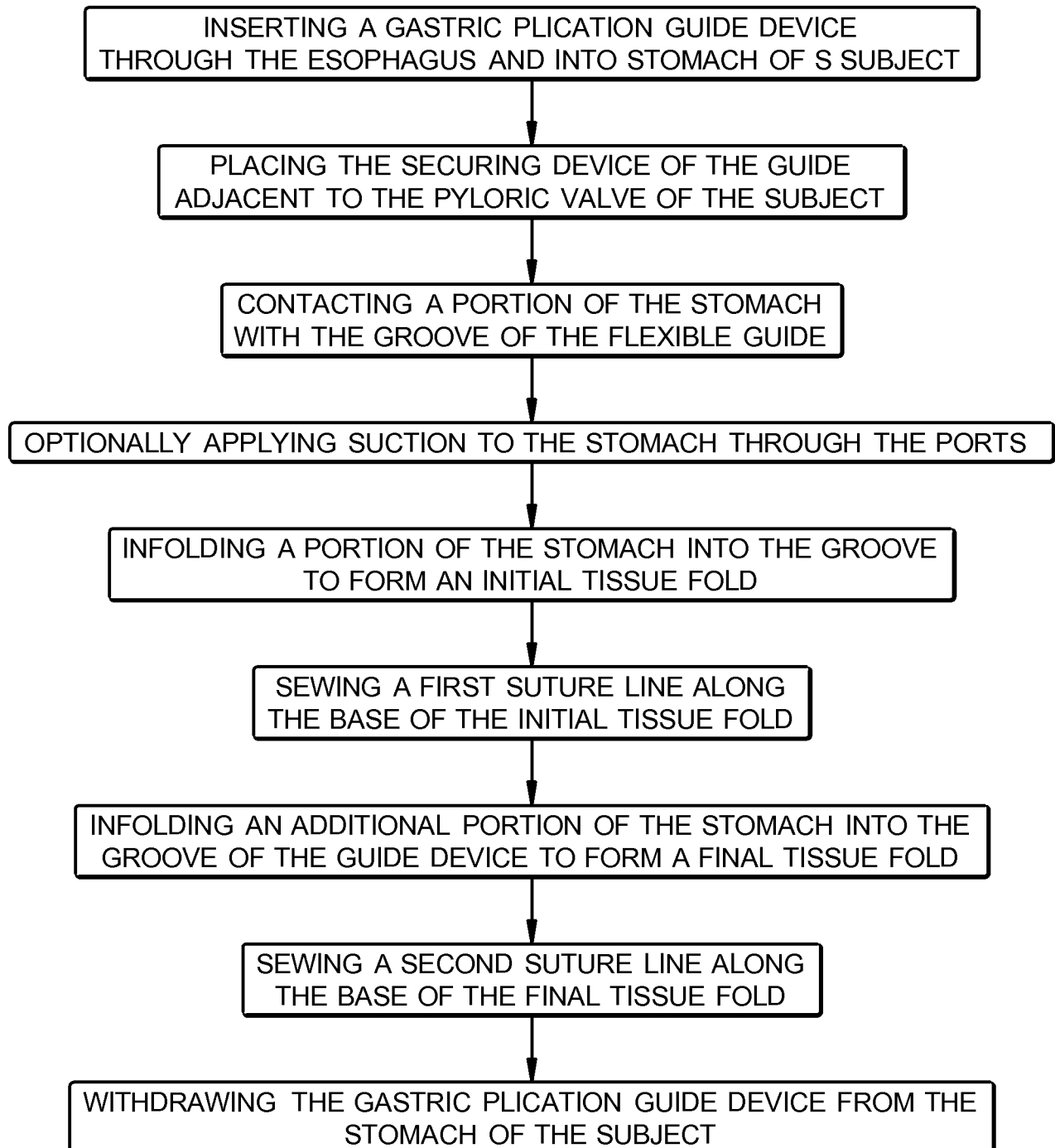


Fig. 8d

**Fig. 9**

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2014/022515

A. CLASSIFICATION OF SUBJECT MATTER
 INV. A61F5/00 A61B17/12
 ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B A61F

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EP0-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2012/138737 A1 (DE LA TORRE ROGER [US]; SCOTT J STEPHEN [US]) 11 October 2012 (2012-10-11)	1-4
A	figure 1	5
X	US 2002/183768 A1 (DEEM MARK E [US] ET AL) 5 December 2002 (2002-12-05)	1,6-8
A	figures 3A,3B	5
X	WO 2009/134999 A1 (ETHICON ENDO SURGERY INC [US]; STOKES MICHAEL J [US]; ALBRECHT THOMAS) 5 November 2009 (2009-11-05)	1-4,6-8
A	page 11, line 3 - page 14, line 7; figures 1-3,7,8	5
X	WO 2009/134983 A1 (ETHICON ENDO SURGERY INC [US]; ORTIZ MARK S [US]; ALBRECHT THOMAS E [U]) 5 November 2009 (2009-11-05)	1-4
A	figures 3-7	5

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

☒ See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

11 June 2014

Date of mailing of the international search report

20/06/2014

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel. (+31-70) 340-2040,
 Fax: (+31-70) 340-3016

Authorized officer

Grieb, Christian

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/022515

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

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

1. ☒ Claims Nos.: **9-16**
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery (method of gastric plication)
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2014/022515

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2012138737 A1	11-10-2012	US 2014018722 A1 WO 2012138737 A1	16-01-2014 11-10-2012
US 2002183768 A1	05-12-2002	US 2002183768 A1 US 2003109892 A1 US 2003120265 A1 US 2004024386 A1 US 2004122452 A1 US 2004122453 A1 US 2007118158 A1 US 2007118159 A1 US 2007167963 A1 US 2007213740 A1 US 2007213748 A1 US 2007219570 A1 US 2007250083 A1 US 2007282349 A1 US 2011152899 A1 US 2013296899 A1	05-12-2002 12-06-2003 26-06-2003 05-02-2004 24-06-2004 24-06-2004 24-05-2007 24-05-2007 19-07-2007 13-09-2007 13-09-2007 20-09-2007 25-10-2007 06-12-2007 23-06-2011 07-11-2013
WO 2009134999 A1	05-11-2009	CA 2722683 A1 CN 102014808 A EP 2313033 A1 JP 2011519618 A RU 2010149073 A US 2009275937 A1 WO 2009134999 A1	05-11-2009 13-04-2011 27-04-2011 14-07-2011 10-06-2012 05-11-2009 05-11-2009
WO 2009134983 A1	05-11-2009	CA 2723137 A1 CN 102046113 A EP 2309952 A1 JP 2011519614 A RU 2010149078 A US 2009275942 A1 WO 2009134983 A1	05-11-2009 04-05-2011 20-04-2011 14-07-2011 10-06-2012 05-11-2009 05-11-2009

专利名称(译)	胃折叠指南		
公开(公告)号	EP2967955A1	公开(公告)日	2016-01-20
申请号	EP2014718217	申请日	2014-03-10
[标]申请(专利权)人(译)	克里夫兰诊所基金会		
申请(专利权)人(译)	克利夫兰诊所基金会		
当前申请(专利权)人(译)	克利夫兰诊所基金会		
[标]发明人	SCHAUER PHILIP		
发明人	SCHAUER, PHILIP		
IPC分类号	A61F5/00 A61B17/12		
CPC分类号	A61B2017/00818 A61B2017/22052 A61B2017/22055 A61B2017/22068 A61B2017/306 A61F5/0086		
代理机构(译)	范尼、PETER JOHN		
优先权	61/791880 2013-03-15 US		
外部链接	Espacenet		

摘要(译)

描述了一种用于在进行胃褶皱手术时帮助外科医生折叠正确量的组织的装置。引导装置包括细长的柔性引导件，定位在引导件的远端上的固定装置，以及用于在胃褶皱手术期间引导胃组织的装置，其沿着引导件的远端纵向定位并且靠近固定装置。用于引导胃组织的装置包括使用成形气囊作为最终胃容积的引导和/或引导装置上的凹槽以调节组织褶皱的形成。还描述了使用引导装置进行胃褶皱手术的方法。