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(74) Agents: **GRAY, Richard, O.** et al.; GRAYBEAL JACKSON HALEY LLP, 155 - 108th Ave NE, Suite 350, Bellevue, WA 98004-5973 (US).

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(71) Applicant (*for all designated States except US*): **ENDOGASTRIC SOLUTIONS, INC.** [US/US]; 15385 NE 90th Street, Redmond, WA 98052-3562 (US).

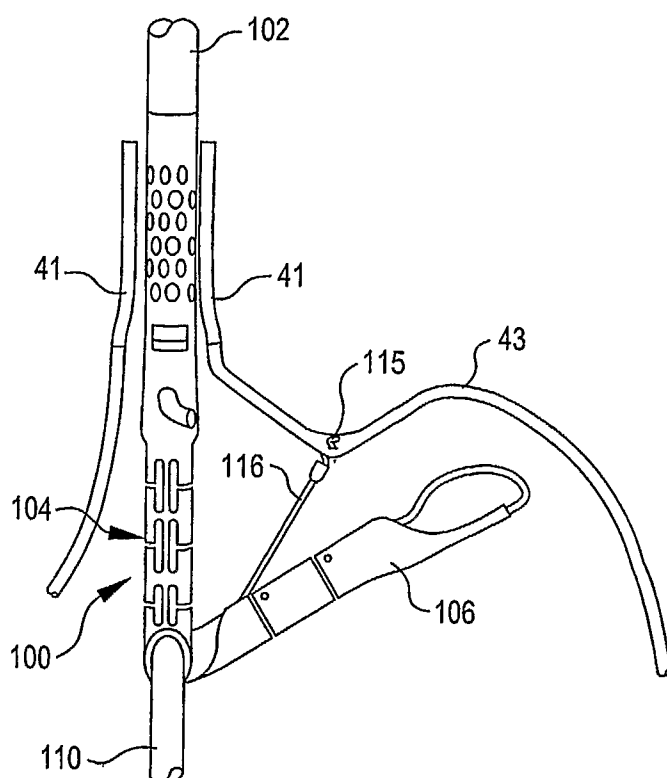
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(72) Inventors; and

(75) Inventors/Applicants (*for US only*): **KRAEMER, Stefan, J. M.** [DE/US]; 4212 E Edgewater Pl, Apt 242, Seattle, WA 98112-2539 (US). **CARTER, Brett, J.** [US/US]; 15061 176th Ave SE, Monroe, WA 98272-2724 (US).

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(54) Title: APPARATUS AND METHOD FOR MANIPULATING STOMACH TISSUE AND TREATING GASTROESOPHAGEAL REFLUX DISEASE



(57) Abstract: Stomach tissue is manipulated to form, for example, a restored flap of a gastroesophageal flap valve. The manipulation includes gripping stomach tissue from within the stomach while the stomach is inflated to promote visualization and stabilization of the gripped stomach tissue. Once the stomach tissue is gripped, the stomach is deflated and pulled into a mold. The molded tissue is then fastened with at least one fastener. The stomach is inflated to a first pressure during visualization and then to a second higher pressure during the stomach tissue gripping.

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**APPARATUS AND METHOD FOR MANIPULATING STOMACH TISSUE AND
TREATING GASTROESOPHAGEAL REFLUX DISEASE**

Field of the Invention

[1] The present invention generally relates to
5 manipulation of stomach tissue as by folding, molding,
and/or fastening and to treating gastroesophageal reflux
disease using such techniques. The present invention more
particularly relates to locating tissue fixation devices for
fixing stomach tissue to stomach tissue in surgical
10 environments to promote reliable fixating of stomach tissue.

Background

[2] Gastroesophageal reflux disease (GERD) is a
chronic condition caused by the failure of the anti-reflux
barrier located at the gastroesophageal junction to keep the
15 contents of the stomach from splashing into the esophagus.
The splashing is known as gastroesophageal reflux. The
stomach acid is designed to digest meat, and will digest
esophageal tissue when persistently splashed into the
esophagus.

20 [3] A principal reason for regurgitation associated
with GERD is the mechanical failure of a deteriorated
gastroesophageal flap to close and seal against high
pressure in the stomach. Due to reasons including
lifestyle, a Grade I normal gastroesophageal flap may
25 deteriorate into a malfunctioning Grade III or absent valve
Grade IV gastroesophageal flap. With a deteriorated
gastroesophageal flap, the stomach contents are more likely
to be regurgitated into the esophagus, the mouth, and even
the lungs. The regurgitation is referred to as "heartburn"
30 because the most common symptom is a burning discomfort in
the chest under the breastbone. Burning discomfort in the
chest and regurgitation (burping up) of sour-tasting gastric

juice into the mouth are classic symptoms of gastroesophageal reflux disease (GERD). When stomach acid is regurgitated into the esophagus, it is usually cleared quickly by esophageal contractions. Heartburn (backwashing
5 of stomach acid and bile onto the esophagus) results when stomach acid is frequently regurgitated into the esophagus and the esophageal wall is inflamed.

[4] Complications develop for some people who have GERD. Esophagitis (inflammation of the esophagus) with
10 erosions and ulcerations (breaks in the lining of the esophagus) can occur from repeated and prolonged acid exposure. If these breaks are deep, bleeding or scarring of the esophagus with formation of a stricture (narrowing of the esophagus) can occur. If the esophagus narrows
15 significantly, then food sticks in the esophagus and the symptom is known as dysphagia. GERD has been shown to be one of the most important risk factors for the development of esophageal adenocarcinoma. In a subset of people who have severe GERD, if acid exposure continues, the injured
20 squamous lining is replaced by a precancerous lining (called Barrett's Esophagus) in which a cancerous esophageal adenocarcinoma can develop.

[5] Other complications of GERD may not appear to be related to esophageal disease at all. Some people with GERD
25 may develop recurrent pneumonia (lung infection), asthma (wheezing), or a chronic cough from acid backing up into the esophagus and all the way up through the upper esophageal sphincter into the lungs. In many instances, this occurs at night, while the person is in a supine position and
30 sleeping. Occasionally, a person with severe GERD will be awakened from sleep with a choking sensation. Hoarseness can also occur due to acid reaching the vocal cords, causing a chronic inflammation or injury.

[6] GERD never improves without intervention. Life style changes combined with both medical and surgical treatments exist for GERD. Medical therapies include antacids and proton pump inhibitors. However, the medical therapies only mask the reflux. Patients still get reflux and perhaps emphysema because of particles refluxed into the lungs. Barrett's esophagus results in about 10% of the GERD cases. The esophageal epithelium changes into tissue that tends to become cancerous from repeated acid washing despite the medication.

[7] Several open laparotomy and laparoscopic surgical procedures are available for treating GERD. One surgical approach is the Nissen fundoplication. The Nissen approach typically involves a 360-degree wrap of the fundus around the gastroesophageal junction. The procedure has a high incidence of postoperative complications. The Nissen approach creates a 360-degree moveable flap without a fixed portion. Hence, Nissen does not restore the normal movable flap. The patient cannot burp because the fundus was used to make the repair, and may frequently experience dysphagia. Another surgical approach to treating GERD is the Belsey Mark IV (Belsey) fundoplication. The Belsey procedure involves creating a valve by suturing a portion of the stomach to an anterior surface of the esophagus. It reduces some of the postoperative complications encountered with the Nissen fundoplication, but still does not restore the normal movable flap. None of these procedures fully restores the normal anatomical anatomy or produces a normally functioning gastroesophageal junction. Another surgical approach is the Hill repair. In the Hill repair, the gastroesophageal junction is anchored to the posterior abdominal areas, and a 180-degree valve is created by a system of sutures. The Hill procedure restores the moveable flap, the cardiac notch

and the Angle of His. However, all of these surgical procedures are very invasive, regardless of whether done as a laparoscopic or an open procedure.

[8] New, less surgically invasive approaches to
5 treating GERD involve transoral endoscopic procedures. One procedure contemplates a machine device with robotic arms that is inserted transorally into the stomach. While observing through an endoscope, an endoscopist guides the machine within the stomach to engage a portion of the fundus
10 with a corkscrew-like device on one arm. The arm then pulls on the engaged portion to create a fold of tissue or radial plication at the gastroesophageal junction. Another arm of the machine pinches the excess tissue together and fastens the excess tissue with one pre-tied implant. This procedure
15 does not restore normal anatomy. The fold created does not have anything in common with a valve. In fact, the direction of the radial fold prevents the fold or plication from acting as a flap of a valve.

[9] Another transoral procedure contemplates making a
20 fold of fundus tissue near the deteriorated gastroesophageal flap to recreate the lower esophageal sphincter (LES). The procedure requires placing multiple U-shaped tissue clips around the folded fundus to hold it in shape and in place.

[10] This and the previously discussed procedure are
25 both highly dependent on the skill, experience, aggressiveness, and courage of the endoscopist. In addition, these and other procedures may involve esophageal tissue in the repair. Esophageal tissue is fragile and weak, in part due to the fact, that the esophagus is not
30 covered by serosa, a layer of very sturdy, yet very thin tissue, covering and stabilizing all intraabdominal organs, similar like a fascia covering and stabilizing muscle. Involvement of esophageal tissue in the repair of a

gastroesophageal flap valve poses unnecessary risks to the patient, such as an increased risk of fistulas between the esophagus and the stomach.

[11] A new and improved apparatus and method for
5 restoration of a gastroesophageal flap valve is fully
disclosed in U.S. Patent No. 6,790,214, issued September 14,
2004, is assigned to the assignee of this invention, and is
incorporated herein by reference. That apparatus and method
provides a transoral endoscopic gastroesophageal flap valve
10 restoration. A longitudinal member arranged for transoral
placement into a stomach carries a tissue shaper that non-
invasively grips and shapes stomach tissue. A tissue
fixation device is then deployed to maintain the shaped
stomach tissue in a shape approximating a gastroesophageal
15 flap.

[12] Whenever tissue is to be maintained in a shape as,
for example, in the improved assembly last mentioned above,
it is necessary to first grip stomach tissue and then fasten
at least two layers of gripped tissue together. In
20 applications such as gastroesophageal flap valve
restoration, it is desirable to grip stomach tissue
displaced from the esophageal opening into the stomach so
that when the stomach tissue is pulled aborally to form a
flap, the flap will have sufficient length to cover the
25 opening and function as a flap valve. With the
gastroesophageal anatomy thus restored, the GERD will be
effectively treated.

[13] Locating the proper gripping point in the stomach
is not a simple matter. When the stomach is empty, it is
30 normally in a collapsed state. Visualization within the
stomach is extremely difficult. Once a desired gripping
point is found, it is then necessary to form the GEFV flap
and maintain its shape without involving the esophageal

tissue. Still further, these manipulations of the stomach tissue must be repeated many times about the esophageal/stomach opening. Such further manipulation must repeat the dimensions of the manipulated stomach tissue to result in a valve structure of uniform geometry. This is, of course, extremely difficult under the circumstances provided by the anatomy of the stomach.

[14] In maintaining the shape of the manipulated stomach tissue, fasteners may be employed. However, care must be taken against inadvertently fixing esophageal tissue to stomach tissue. As previously mentioned, this is fraught with potential complications.

[15] Still further, the mere act of gripping stomach tissue may be problematic. For example, one way stomach tissue may be gripped is snare it with a helical coil. In doing so, the helical coil is screwed into the tissue. Unfortunately, the mere act of turning the coil can cause the stomach tissue to also rotate and "ball-up" about the helix. Such an event greatly complicates the therapeutic procedure.

[16] Hence, there is a need in the art for techniques and devices which enable more ready manipulation of stomach tissue from within the stomach. The present invention addresses these and other issues.

25

Summary

[17] The invention provides a method of restoring a flap of a gastroesophageal flap valve associated with a stomach. The method comprises inflating the stomach, gripping stomach tissue from within the stomach at a point displaced from the esophageal opening of the stomach, and deflating the stomach. The method further comprises pulling the gripped stomach tissue into a mold to form molded

tissue, and deploying at least one fastener through the molded tissue.

[18] The method may further comprise gripping a wall of the esophagus prior to gripping the stomach. The step of
5 gripping a wall of the esophagus may include gripping the wall of the esophagus with a vacuum.

[19] The method may further comprise reinflating the stomach before deploying the at least one fastener. The inflating step may include inflating the stomach to a first
10 pressure. The method may further comprise visualizing the stomach from within the stomach after inflating the stomach to the first pressure, and increasing inflation pressure within the stomach to a second pressure after visualizing the stomach before gripping stomach tissue.

15 [20] The invention further provides a method of restoring a flap of a gastroesophageal flap valve associated with a stomach, comprising gripping stomach tissue from within the stomach at a point displaced from the esophageal opening of the stomach and collapsing the stomach. The
20 method further comprises pulling the gripped stomach tissue into a mold to form folded flap of tissue and deploying at least one fastener through the folded flap of tissue.

[21] The gripping, collapsing, pulling, and deploying steps may be repeated for forming another folded flap of
25 tissue. Another fastener displaced from the at least one fastener may be deployed. The method may further comprise inflating the stomach before deploying the at least one fastener.

[22] The method may further comprise inflating the
30 stomach before gripping the stomach tissue. The method may then comprise the further step of re-inflating the stomach prior to deploying the at least one fastener.

[23] Before the gripping step, the stomach may be inflated to a first pressure. This may be followed by visualizing the stomach from within the stomach, and inflating the stomach to a second pressure. The second pressure may be greater than the first pressure. The method may further comprise repeating the inflating, gripping, collapsing, pulling, and deploying steps for forming another folded flap of tissue and deploying at least one other fastener displaced from the at least one fastener. The method may further comprise measuring from the folded flap of tissue prior to repeating the gripping step.

[24] The invention still further provides a method of gripping stomach tissue from within a stomach. The method comprises visualizing the stomach from within the stomach to determine a gripping location, inflating the stomach, and gripping the stomach at the gripping location while the stomach is inflated.

[25] The invention still further provides an assembly for restoring a gastroesophageal flap valve associated with a stomach. The assembly comprises an elongated member having a distal end for placement in the stomach, and a gastroesophageal flap valve restoration device. The device includes a chassis and a bail carried at the elongated member distal end. The chassis has a proximal end connected to the elongated member distal end and a distal end hingedly coupled to the bail. The chassis and bail are arranged to mold stomach tissue there between. The chassis further includes a window that permits gastroesophageal anatomy visualization.

[26] The window is at the proximal end of the chassis. The device may further comprise a passage that slidably receives an endoscope adjacent the window.

[27] The device may further include a fastener deployment guide having a predetermined orientation relative to the window. The fastener deployment guide may comprise at least one guide lumen.

5 [28] The window may include a location marker. The device may further include a fastener deployment guide that guides a fastener into molded tissue. The deployment guide may have a predetermined orientation relative to the location marker. A fastener deployer may then deploy a
10 fastener in molded tissue at a predetermined location relative to the location marker.

[29] The invention still further provides a method of deploying a fastener through stomach tissue a predetermined distance from a gastroesophageal junction. The method
15 comprises providing a fastener deployment apparatus including a window permitting visualization of gastroesophageal anatomy when placed in an esophagus, a location marker viewable in the window, and a fastener deployer that ejects a fastener for deployment at a
20 predetermined location relative to the location marker. The method further comprises feeding the apparatus down the esophagus, aligning the location marker with respect to the gastroesophageal junction to cause the fastener deployer to be aboral of the gastroesophageal junction, and ejecting a
25 fastener from the fastener deployer with the location marker aligned with respect to the gastroesophageal junction.

[30] The invention further provides a fastener deployment apparatus that deploys a fastener in body tissue. The apparatus comprises a window permitting visualization of
30 internal body anatomy when placed in a body, a location marker viewable in the window, and a fastener deployer having a predetermined orientation relative to the location

marker that ejects a fastener for deployment at a predetermined location relative to the location marker.

Brief Description of the Drawings

[31] The features of the present invention which are
5 believed to be novel are set forth with particularity in the
appended claims. The invention, together with further
objects and advantages thereof, may best be understood by
making reference to the following description taken in
conjunction with the accompanying drawings, in the several
10 figures of which like reference numerals identify like
elements, and wherein:

[32] FIG. 1 is a front cross-sectional view of the
esophageal-gastro-intestinal tract from a lower portion of
the esophagus to the duodenum;

15 [33] FIG. 2 is a front cross-sectional view of the
esophageal-gastro-intestinal tract illustrating a Grade I
normal appearance movable flap of the gastroesophageal flap
valve (in dashed lines) and a Grade III reflux appearance
gastroesophageal flap of the gastroesophageal flap valve (in
20 solid lines);

[34] FIG. 3 is a side view of an apparatus for
restoring the flap of a GEFV according to an embodiment of
the invention;

[35] FIG. 4 is a simplified side view of an apparatus
25 according to an embodiment of the invention being fed down
an esophageal passage of a patient;

[36] FIG. 5 is a side view, partly in cross-section, of
a device according to an embodiment of the invention after
having been initially fed into a stomach to initiate a GERD
30 treatment procedure according to an embodiment of the
invention;

- [37] FIG. 6 is a view similar to FIG. 5 showing the device and stomach after the stomach has been inflated to a first pressure;
- [38] FIG. 7 is a view similar to FIG. 5 showing the device and stomach at a further stage of the procedure;
- [39] FIG. 8 is a view similar to FIG. 5 showing the device centered and gripping the esophagus;
- [40] FIG. 9 is a view similar to FIG. 5 showing the device initially gripping the stomach tissue after the stomach has been reinflated to a second, higher pressure;
- [41] FIG. 10 is a view similar to FIG. 5 showing the stomach partially deflated and gripped stomach tissue being pulled aborally towards the device;
- [42] FIG. 11 is a view similar to FIG. 5 showing the gripped stomach tissue being pulled to almost within the device;
- [43] FIG. 12 is a view similar to FIG. 5 showing the gripped stomach tissue with the device, being molded, and ready to receive a fastener;
- [44] FIG. 13 is a view similar to FIG. 5 showing the molded stomach tissue after receiving a fastener;
- [45] FIG. 14 is a perspective view illustrating a manner in which the device of FIGS. 3-13 may deploy a fastener through gripped stomach tissue layers; and
- [46] FIG. 15 is a perspective view showing a fastener fully deployed.

Detailed Description

- [47] FIG. 1 is a front cross-sectional view of the esophageal-gastro-intestinal tract 40 from a lower portion of the esophagus 41 to the duodenum 42. The stomach 43 is

characterized by the greater curvature 44 on the anatomical left side and the lesser curvature 45 on the anatomical right side. The tissue of the outer surfaces of those curvatures is referred to in the art as serosa tissue. As
5 will be seen subsequently, the nature of the serosa tissue is used to advantage for its ability to bond to like serosa tissue.

[48] The fundus 46 of the greater curvature 44 forms the superior portion of the stomach 43, and traps gas and
10 air bubbles for burping. The esophageal tract 41 enters the stomach 43 at an esophageal orifice below the superior portion of the fundus 46, forming a cardiac notch 47 and an acute angle with respect to the fundus 46 known as the Angle of His 57. The lower esophageal sphincter (LES) 48 is a
15 discriminating sphincter able to distinguish between burping gas, liquids, and solids, and works in conjunction with the fundus 46 to burp. The gastroesophageal flap valve (GEFV) 49 includes a moveable portion and an opposing more stationary portion.

20 [49] The moveable portion of the GEFV 49 is an approximately 180 degree, semicircular, gastroesophageal flap 50 (alternatively referred to as a "normal moveable flap" or "moveable flap") formed of tissue at the intersection between the esophagus 41 and the stomach 43.
25 The opposing more stationary portion of the GEFV 49 comprises a portion of the lesser curvature 45 of the stomach 43 adjacent to its junction with the esophagus 41. The gastroesophageal flap 50 of the GEFV 49 principally comprises tissue adjacent to the fundus 46 portion of the
30 stomach 43. It is about 4 to 5 cm long (51) at its longest portion, and its length may taper at its anterior and posterior ends.

[50] The gastroesophageal flap 50 is partially held against the lesser curvature 45 portion of the stomach 43 by the pressure differential between the stomach 43 and the thorax, and partially by the resiliency and the anatomical structure of the GEFV 49, thus providing the valving function. The GEFV 49 is similar to a flutter valve, with the gastroesophageal flap 50 being flexible and closeable against the other more stationary side.

[51] The esophageal tract is controlled by an upper esophageal sphincter (UES) in the neck near the mouth for swallowing, and by the LES 48 and the GEFV 49 at the stomach. The normal anti-reflux barrier is primarily formed by the LES 48 and the GEFV 49 acting in concert to allow food and liquid to enter the stomach, and to considerably resist reflux of stomach contents into the esophagus 41 past the gastroesophageal tissue junction 52. Tissue aboral of the gastroesophageal tissue junction 52 is generally considered part of the stomach because the tissue protected from stomach acid by its own protective mechanisms. Tissue oral of the gastroesophageal junction 52 is generally considered part of the esophagus and it is not protected from injury by prolonged exposure to stomach acid. At the gastroesophageal junction 52, the juncture of the stomach and esophageal tissues form a zigzag line, which is sometimes referred to as the "Z-line." For the purposes of these specifications, including the claims, "stomach" means the tissue aboral of the gastroesophageal junction 52.

[52] FIG. 2 is a front cross-sectional view of an esophageal-gastro-intestinal tract illustrating a Grade I normal appearance movable flap 50 of the GEFV 49 (shown in dashed lines) and a deteriorated Grade III gastroesophageal flap 55 of the GEFV 49 (shown in solid lines). As previously mentioned, a principal reason for regurgitation

associated with GERD is the mechanical failure of the deteriorated (or reflux appearance) gastroesophageal flap 55 of the GEFV 49 to close and seal against the higher pressure in the stomach. Due to reasons including lifestyle, a Grade I normal gastroesophageal flap 50 of the GEFV 49 may deteriorate into a Grade III deteriorated gastroesophageal flap 55. The anatomical results of the deterioration include moving a portion of the esophagus 41 that includes the gastroesophageal junction 52 and LES 48 toward the mouth, straightening of the cardiac notch 47, and increasing the Angle of His 57. This effectively reshapes the anatomy aboral of the gastroesophageal junction 52 and forms a flattened fundus 56.

[53] The deteriorated gastroesophageal flap 55 shown in FIG. 2 has a gastroesophageal flap valve 49 and cardiac notch 47 that are both significantly degraded. Dr. Hill and colleagues developed a grading system to describe the appearance of the GEFV and the likelihood that a patient will experience chronic acid reflux. L.D. Hill, et al., *The gastroesophageal flap valve: in vitro and in vivo observations*, *Gastrointestinal Endoscopy* 1996:44:541-547. Under Dr. Hill's grading system, the normal movable flap 50 of the GEFV 49 illustrates a Grade I flap valve that is the least likely to experience reflux. The deteriorated gastroesophageal flap 55 of the GEFV 49 illustrates a Grade III (almost Grade IV) flap valve. A Grade IV flap valve is the most likely to experience reflux. Grades II and III reflect intermediate grades of deterioration and, as in the case of III, a high likelihood of experiencing reflux. With the deteriorated GEFV represented by deteriorated gastroesophageal flap 55 and the fundus 46 moved inferior, the stomach contents are presented a funnel-like opening directing the contents into the esophagus 41 and the

greatest likelihood of experiencing reflux. Disclosed subsequently is a device, assembly, and method which may be employed to advantage according to an embodiment of the invention in restoring the normal gastroesophageal flap valve anatomy.

[54] Referring now to FIG. 3, it shows a device 100 according to an embodiment of the present invention. The device 100 includes a longitudinal member 102 for transoral placement of the device 100 into the stomach. The device further includes a first member 104, hereinafter referred to as the chassis, and a second member 106, hereinafter referred to as the bail. The chassis 104 and bail are hingedly coupled at 107. The chassis 104 and bail 106 form a tissue shaper which, as described subsequently in accordance with this embodiment of the present invention, shapes tissue of the stomach into the flap of a restored gastroesophageal flap valve. The chassis 104 and bail 106 are carried at the distal end of the longitudinal member 102 for placement in the stomach.

[55] The device 100 has a longitudinal passage 101 to permit an endoscope 110 to be guided through the device and into the stomach. This permits the endoscope to service as a guide for guiding the device 100 through the patient's throat, down the esophagus, and into the stomach. It also permits the gastroesophageal flap valve restoration procedure to be viewed at each stage of the procedure.

[56] As will be seen subsequently, to facilitate shaping of the stomach tissue, the stomach tissue is drawn in between the chassis 104 and the bail 106. Further, to enable a flap of sufficient length to be formed to function as the flap of a gastroesophageal flap valve, the stomach tissue is pulled down so that the fold line is substantially juxtaposed to the opening of the esophagus into the stomach.

Hence, as will be seen, the stomach is first gripped at a point out and away from the esophagus and the grip point is pulled to almost the hinged connection 107 of the chassis 104 and bail 106. As described in copending application
5 Serial No. 11/001,666, filed November 30, 2004, entitled FLEXIBLE TRANSORAL ENDOSCOPIC GASTROESOPHAGEAL FLAP VALVE RESTORATION DEVICE AND METHOD, which application is incorporated herein by reference, the device 100 is fed down the esophagus with the bail 106 substantially in line with
10 the chassis 104. To negotiate the bend of the throat, and as described in the aforementioned referenced application, the chassis 104 and bail 106 are rendered flexible. The chassis 104 is rendered flexible by the slots 108 and the bail 106 is rendered flexible by the hingedly coupled links
15 112. Further details concerning the flexibility of the chassis 104 and the bail 106 may be found in the aforementioned referenced application.

[57] As further shown in FIG. 3, the device further includes a tissue gripper 114. The gripper 114, in this
20 embodiment, comprises a helical coil 115. The coil 115 is carried at the end of a cable 116 and may be attached to the end of the cable or be formed from the cable. In this embodiment, the helical coil 115 is attached to the cable 116 and is preceded by a guide 118 whose function will be
25 described subsequently.

[58] The helical coil 115 is shown in an approximate position to engage the stomach tissue out and away from the opening of the esophagus to the stomach. The helical coil 115 is guided into position by a guide structure 120 carried
30 on the bail 106. The guide structure 120 comprises a guide tube 122. When the device 100 is first introduced down the esophagus into the stomach, the helical coil 115 is caused to reside well within the guide tube 122 to preclude the

helical coil from accidentally or inadvertently snagging esophageal or stomach tissue.

[59] The guide tube includes a longitudinal slit 126 having a circuitous configuration. The slit 126 permits the end of the cable to release or disassociate from the bail after the stomach tissue is gripped. The circuitous configuration of the slit 126 assures confinement of the cable 116 within the guide tube 122 until release of the cable is desired. The proximal end of the slit 126 has an enlarged portion or opening (not shown). This opening permits the cable and helical coil to reenter the lumen when the device 100 is readied for a repeated stomach tissue shaping procedure. To that end, the guide 118 has a conical surface that serves to guide the cable end back into the opening of the slit 126.

[60] With continued reference to **FIG. 3**, the device 100 further comprises a fastener deployer 140. The fastener deployer includes at least one fastener deployment guide 142. The fastener deployment guide 142 takes the form of a guide lumen. Although only one guide lumen 142 is shown, it will be appreciated that the device 100 may include a plurality of such lumens without departing from the invention. The guide lumen terminates at a delivery point 144 where a fastener is driven into the molded stomach tissue. The fastener deployer may take the form of any one of the assemblies fully described and claimed, for example, in

[61] The device 100 further includes a window 130 within the chassis 104. The window is formed of a transparent or semi-transparent material. This permits gastroesophageal anatomy, and more importantly the gastroesophageal junction (Z-line) to be viewed with the endoscope 110. The window includes a location marker 132

which has a know position relative to the fastener delivery point 144. Hence, by aligning the marker with a known anatomical structure, the fastener will be delivered a known distance from or at a location having a predetermined relation to the marker. For example, by aligning the marker with the Z-line, it will be know that the fastener will be placed aboral of the Z-line and that serosa tissue will be fastened to serosa tissue. As previously mentioned, this has many attendant benefits.

10 [62] It may also be mentioned at this point that the device 100 further includes an invaginator 145 including a plurality of orifices 146. These orifices 146, which alternatively may be employed on the longitudinal member 102, are used to pull a vacuum to cause the device 100 to grip the inner surface of the esophagus. This will serve to stabilize the esophagus and maintain device positioning during the procedure. This vacuum gripping of the esophagus may also be used to particular advantage if the patient suffers from a hiatal hernia. Upon being thus gripped, the esophagus may be moved downwardly with the device toward the stomach to eliminate the hiatal hernia.

[63] Now that a device 100 according to the present invention and which may be used in a method of restoring the flap of a gastroesophageal flap valve according to this embodiment of the present invention has been described, reference may now be made to **FIG. 4**. The procedure, according to this embodiment, for restoring the flap of the gastroesophageal flap valve begins with loading a fastener or a plurality of fasteners into the device 100. As will be seen hereinafter, the fastener deployer includes a stylet which guides each fastener into the tissue to be fastened. The process of loading a fastener, according to this embodiment, includes snapping a fastener onto the stylet. A

representative fastener and stylet will be described subsequently with respect to **FIGS. 14 and 15.**

[64] Next, the bail 106 is moved to be substantially in line with the chassis 104. Next, the endoscope 110 is
5 inserted into the device with an appropriate lubricant on the endoscope. Next, a bite block, of the type well known in the art, is inserted into the patient's mouth. A lubricant may be applied to the device and the device may now be inserted through the bite block in the subject's
10 mouth. With the endoscope leading the device as illustrated in **FIG. 4**, the endoscope and device combination are fed down the esophagus 141 into the stomach. Of course, when the endoscope 110 reaches its fully inserted position, the device 100 may be further advanced on the endoscope
15 utilizing the endoscope as a guide to within the stomach of the patient.

[65] As previously mentioned, the device 100 is able to clear the bend in the patient's throat by virtue of being flexible as previously described. With the endoscope
20 serving as a guide tube, very little force should be needed to get the device around the neck into the pharynx and down into the esophagus.

[66] **FIG. 5** shows the device 100 upon reaching the interior of the stomach 43. Here it may be seen that the
25 bail 106 is substantially in line with the chassis 104. The endoscope 110 remains within the device 100. Also in **FIG. 5** it may be noted that the stomach is deflated. This is the normal condition of the stomach when the stomach is empty.

[67] Once the device is positioned in the stomach as shown in **FIG. 5**, the stomach is inflated as shown in **FIG. 6**
30 by passing air through the endoscope into the stomach. The inflation of the stomach may be noted by the outward arcuate

deflection of the stomach 43. The stomach should be inflated to a first pressure just sufficient to open the stomach and provide good visibility of gastric folds on the interior wall 59 of the stomach. Visualization of such gastric folds permits discernment of a proper point to grip the stomach for forming the gastroesophageal flap valve flap in a manner to be described hereinafter. Once the stomach has been inflated to the first pressure, the device is placed in a desired position relative to the Z-line by placing the marker of the window 130 in a desired position relative to the Z-line 52 marking the transition from the esophagus 41 to the stomach 43. In accordance with this embodiment, the marker 132 is aligned with the Z-line 52. In order to visualize the marker and the Z-line, the endoscope 110 is pulled back into the device 100 and more particular adjacent the marker 132 to visualize when the marker is aligned with the Z-line 52. With the marker 132 aligned with the Z-line 52, the distance from the marker 132 to a proximal point of the elongated member 102 relative to a rather fixed anatomy site of the patient, such as an incisor may be measured. This measurement may be marked on the elongated member 102 and later utilized for positioning the marker 132 adjacent the Z-line 52.

[68] Referring now to **FIG. 7**, with the stomach still inflated to the first pressure, the endoscope is positioned inside the device just past the hinged connection 107 of the bail 106 and chassis 104. With the endoscope being located just past the hinged connection 107, the bail is then actuated to an approximately one-half closed position as illustrated. As the bail moves, the bail should be watched to make sure that it moves towards the greater curve 56 so it can move freely in the open space of the gastric cavity.

With the endoscope in the position as shown in **FIG. 7**, the bail should be visible at all times.

[69] Referring now to **FIG. 8**, the endoscope 110 is advanced back into the stomach 43 and brought to a reflexed view as illustrated so that it may look back on the device 100. With the operating end of the device in clear view, the device 100 is positioned in the center of the gastroesophageal flap valve to be formed where the posterior and anterior groove should be. This position is typically opposite the lesser curve 45.

[70] Next, the device positioning relative to the Z-line 52 is checked to make sure that the marker 132 is in its desired position relative to the Z-line 52. In accordance with this embodiment, the marker 132 is placed adjacent or is aligned with the Z-line 52.

[71] With the device in the correct starting position as shown in **FIG. 8**, a vacuum pump communicating with orifices 146 is energized to pull a vacuum through the orifices 146. This causes the orifices to engage the wall of the esophagus 41 for gripping the esophagus. As previously mentioned, this invagination permits the esophagus to be pushed into the stomach by distal movement of the elongated member 102 to treat a hiatal hernia and to stabilize the position of the device within the stomach. The vacuum is continued to be pulled through the orifices 146 until the vacuum is above the 50 kps mark on the vacuum pump. The device is then pushed gently aborally to reposition the esophagus to correct a hiatal hernia. It may be noted that this maneuver can also be used to visually check the position of the faster delivery point 144 relative to the Z-line. During this maneuver, the esophagus may roll back on itself and expose the esophageal Mucosa and the Z-line adjacent to the fastener delivery ports.

[72] Referring now to **FIG. 9**, with the device locked in position by the vacuum orifices 146, the area in which the helical coil is to be engaged may be identified. The gripping location may be largely determined by the size or length of the flap to be restored of the restored gastroesophageal flap valve. This of course may differ from one patient to another depending on the severity of the hiatal hernia and the degree of valve degradation. Once the gripping location is selected, the stomach 43 is inflated to a second and higher pressure. The inflation pressure of the stomach is increased to the second and higher pressure so that the Mucosa appears tight and the folds essentially flatten. With the correct gripping spot identified, the bail 106 is moved to position the tip of a helical coil 115 at the correct gripping spot. Next, the device 100 is gently pulled upwardly or orally until the bail contacts the tissue at the desired gripping spot. Next, the helix 115 is advanced by the pushing of the cable 116 until the helix pushes into the Mucosa. Next, the cable 116 is turned to likewise turn the helix 115 in a clockwise direction to screw the helix into the tissue. As the cable is turned, some wind-up may be filled in the helix drive cable.

[73] With the helical coil 115 firmly seated in the tissue, the wind-up in the cable 116 is released. Referring now to **FIG. 10**, with the retractor firmly seated in the tissue, the device 100 may be advanced slightly orally while at the same time the bail 116 may be opened slightly. This releases the cable 116 from the guide tube which has now been pulled back into the bail 106. The cable 116 exits the guide tube 122 (**FIG. 3**) by slipping through the circuitous slit 126. This operation is more particularly described in the aforementioned U.S. patent application Serial No. 11/061,318, filed February 18, 2005, incorporated herein by

reference. Also at this time, the correct positioning of the device relative to the Z-line may be verified.

[74] With the bail 106 slightly opened and the helix 115 engaged with the tissue 43, the interior of the stomach is now deflated through the endoscope 110. The stomach should be deflated such that the tissue appears loose and collapsed with the Mucosa folds being prominent. However, enough room should be left to view the device.

[75] Referring now to **FIG. 11**, the gastric tissue is now gently pulled with the helix 115 and cable 116 towards the hinged connection 107 and the valve mold to be formed by the chassis 104 and closing bail 106. Once the helix is fully retracted into the bail 116, it is locked in place. The bail 106 may now be closed and the device and anatomy will appear as shown in **FIG. 12**. Here it will be noted that the stomach tissue aboral of the Z-line 52 is confined between the bail 106 and chassis 104 to create a fold 150. The fold is also adjacent the fastener delivery point 144 at the end of the fastener guide lumen. Since the fastener deployment point 144 is a known predetermined distance from the marker 132 of the window 130, and since the marker 132 is aligned with the Z-line 52, when a fastener is delivered from the fastener deployer of the device, the fastener will exit the fastener delivery point 144 at a point known to be aboral of the Z-line 52. This assures that only serosa tissue is being adhered to serosa tissue in the fixation of the stomach tissue in creating the flap 150. The flap 150 comprises layers 180 and 182 of stomach tissue.

[76] With the tissue layers 180 and 182 now disposed within the mold of the chassis 104 and bail 106, the bail 106 may now be locked with respect to the chassis 104. It is now time to fasten the tissue layers 180 and 182 together

by ejecting a fastener from the fastener deployer lumen 142 at the fastener delivery point 144.

[77] Before a fastener is ejected from the fastener deployer lumen 142, the stomach is once again inflated through the endoscope 110. The stomach is inflated to a point where one has a good view of the tissue fold and bail 106.

[78] FIGS. 14 and 15 illustrate a manner in which the device 100 of FIGS. 3-13 may deploy a fastener 200 through the layers 180 and 182 of gripped stomach tissue. The fastener 200 generally includes a first member 202, a second member 204, and a connecting member 206. As may be noted in FIG. 15, the first member 202 and second member 204 are substantially parallel to each other and substantially perpendicular to the connecting member 206 which connects the first member 202 to the second member 204.

[79] The first member 202 is generally cylindrical or can any shape. It has a channel 212 that extends therethrough. The though channel 112 is dimensioned to be slidably received on a tissue piercing deployment wire 264.

[80] The first member 202 includes a pointed tip 224. The tip 224 may be conical and more particularly takes the shape of a truncated cone. The tip can also be shaped to have a cutting edge in order to reduce tissue resistance.

[81] The first member 202 also has a continuous lengthwise slit 225. The slit 225 includes an optional slot 226 that communicates with the through channel 212. The slot 226 has a transverse dimension for more readily enabling receipt of the tissue piercing deployment wire 264 during deployment of the fastener 200. Also, because the fastener member 202 is formed of flexible material, the slit 225 may be made larger through separation to allow the

deployment wire to be snapped into and released from the through channel 212.

[82] In addition to the fastener 200 and the deployment wire 264, the assembly shown in **FIGS. 14** and **15** further includes a pusher 266 and a guide tube 268. The subassembly of the tissue piercing wire 264, fastener 200, and pusher 266 may be guided to its intended location relative to the tissue layers 180 and 182 by the guide tube 268. The tissue piercing wire 264, fastener 200, and the pusher 266 are all initially within the guide tube 268. The guide tube 268 is representative of the fastener deployment guide and to that end, includes the fastener deployment guide lumen 142. The subassembly of the tissue piercing wire 264, fastener 200, and pusher 266 may be guided to its intended location relative to the tissue layers 180 and 182 by the guide lumen 142.

[83] As shown in **FIGS. 14** and **15**, the tissue piercing wire 264 has a tip 270 helping it pierce the tissue layers 180 and 182 that will form the restored gastroesophageal flap valve flap 150. The pusher 266 has pushed the first member 202 of the fastener 200 through the tissue layers 180 and 182 on the tissue piercing wire 264. This may be accomplished by moving the wire 264 and the pusher 266 together.

[84] As may be further noted in **FIG. 14**, the first member 202 is clearing the wire 264 and tissue layer 182. The tissue piercing wire 264 may now be retracted into the pusher 266 and the tissue piercing wire 264 and pusher 266 may be withdrawn.

[85] **FIG. 15** illustrates the fastener 200 in its fully deployed position. It will be noted that the fastener has returned to its original shape. The tissue layers 180 and

182 are fastened together between the first member 202 of the fastener 200 and the second member 204 of the fastener 200. The connecting member 206 extends through the tissue layers 180 and 182.

5 [86] In accordance with a further method of utilizing the fastener deployment assembly of **FIGS. 14** and **15**, the tissue piercing wire 264 may be first advanced through the tissue layers 180 and 182 by a full stroke and then locked. The tip 270 of the deployment wire 264 should extend through
10 the bail 206 with minimal tenting of the tissue. Next, the pusher 266 is advanced. Visual confirmation that the first fastener member 202 is through the tissue is then made. In doing so, the very distal end of the pusher 266 may be visible when the first member 202 of the fastener 200 is
15 fully deployed. Next, while holding the pusher 266 at the last noted position, the tissue piercing wire 264 is retracted. The first member 202 of the fastener 200 will fall to the side when the tissue piercing wire 264 reaches the pusher 266. When the tissue piercing wire 264 reaches
20 the pusher 266 and after the fastener 200 is deployed, the pusher 266 is pulled back with the tissue piercing wire. If additional fastener deployment guides are provided, the foregoing steps for deploying a fastener such as fastener 200 may be repeated.

25 [87] With the fasteners successfully deployed, the vacuum pull through orifices 146 may now be turned off to release the device from the esophagus wall as illustrated in **FIG. 13**. At this time, the bail 106 of the device 100 may be slightly opened and the helical coil 115 may be released
30 from the stomach tissue. As may be seen in **FIG. 13**, the procedure just described results in a flap 150 to be formed. At this time, an additional fastener or fasteners may be

loaded onto the tissue piercing deployment wire 264 at the proximal end of the longitudinal member 102.

[88] To render the flap uniform about the opening of the orifice into the stomach, it is necessary at this time
5 to rotate the device 102 and repeat the previously described procedure for forming a further flap portion. Before this is done, however, it is desirable to position the bail 106 to an almost closed position. Then, the device 100 is moved aborally further into the stomach until the tip end 107 of
10 the bail 106 comes to rest on the tip 151 of the newly formed flap portion. This is the location where the helical coil 115 will next engage the stomach tissue for molding and fixating as previously described.

[89] The foregoing is repeated until a complete valve
15 flap is formed. When the appearance of the valve flap is satisfactory as viewed through the endoscope for visual confirmation, the helical coil 115 is reloaded back into its original position with the device 100. The vacuum suction through orifices 146 is turned off to release the wall of
20 the esophagus from the device. The bail 106 is then moved to a fully opened position as seen, for example, in **FIG. 5**. The endoscope may now be retracted along with the stylet and pusher controls. With the retraction of the foregoing verified, the stomach may now be deflated and the device 100
25 may be removed from the stomach and esophagus. This then completes the procedure according to this embodiment of the invention.

[90] While particular embodiments of the present invention have been shown and described, modifications may be
30 made, and it is thereto intended in the appended claims to cover all such changes and modifications which fall within the true spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. A method of restoring a flap of a gastroesophageal flap valve associated with a stomach, comprising:
 - 5 inflating the stomach;
 - gripping stomach tissue from within the stomach at a point displaced from the esophageal opening of the stomach;
 - deflating the stomach;
 - pulling the gripped stomach tissue into a mold to form
 - 10 molded tissue; and
 - deploying at least one fastener through the molded tissue.
2. The method of claim 1, wherein the stomach is associated with an esophagus and wherein the method further
- 15 comprises gripping a wall of the esophagus prior to gripping the stomach.
3. The method of claim 2, wherein the step of gripping a wall of the esophagus includes gripping the wall of the esophagus with a vacuum.
- 20 4. The method of claim 1, further comprising reinflating the stomach before deploying the at least one fastener.
5. The method of claim 1, further comprising releasing the grip on the stomach tissue after the at least one
- 25 fastener is deployed.
6. The method of claim 1, further comprising repeating the inflating, gripping, deflating, pulling, and deploying steps for deploying at least one other fastener displaced from the at least one fastener.
- 30 7. The method of claim 6, further comprising measuring from the molded tissue prior to repeating the gripping step.
8. The method of claim 1, wherein the inflating step includes inflating the stomach to a first pressure, wherein the method further comprises visualizing the stomach from

within the stomach after inflating the stomach to the first pressure, and increasing inflation pressure within the stomach to a second pressure after visualizing the stomach before gripping stomach tissue.

5 9. The method of claim 8, wherein the stomach is associated with an esophagus and wherein the method further comprises gripping a wall of the esophagus after inflating the stomach to the first pressure and prior to gripping the stomach.

10 10. A method of restoring a flap of a gastroesophageal flap valve associated with a stomach, comprising:

 gripping stomach tissue from within the stomach at a point displaced from the esophageal opening of the stomach;
 collapsing the stomach;

15 pulling the gripped stomach tissue into a mold to form folded flap of tissue; and

 deploying at least one fastener through the folded flap of tissue.

 11. The method of claim 10, wherein the stomach is
20 associated with an esophagus and wherein the method further comprises gripping a wall of the esophagus prior to gripping the stomach.

 12. The method of claim 11, wherein the step of
25 gripping a wall of the esophagus includes gripping the wall of the esophagus with a vacuum.

 13. The method of claim 10, further comprising repeating the gripping, collapsing, pulling, and deploying steps for forming another folded flap of tissue and
30 deploying at least one other fastener displaced from the at least one fastener.

 14. The method of claim 10, further comprising inflating the stomach before deploying the at least one fastener.

15. The method of claim 10, further comprising releasing the grip on the stomach tissue after the at least one fastener is deployed.

16. The method of claim 10, further comprising
5 inflating the stomach before gripping the stomach tissue.

17. The method of claim 16, comprising the further step of re-inflating the stomach prior to deploying the at least one fastener.

18. The method of claim 10, further comprising, before
10 the gripping step, inflating the stomach to a first pressure, visualizing the stomach from within the stomach, and inflating the stomach to a second pressure, the second pressure being greater than the first pressure.

19. The method of claim 18, wherein the stomach is
15 associated with an esophagus and wherein the method further comprises gripping a wall of the esophagus after inflating the stomach to the first pressure and prior to gripping the stomach.

20. The method of claim 18, comprising the further
20 step of re-inflating the stomach prior to deploying the at least one fastener.

21. The method of claim 18, further comprising repeating the inflating, gripping, collapsing, pulling, and deploying steps for forming another folded flap of tissue
25 and deploying at least one other fastener displaced from the at least one fastener.

22. The method of claim 21, further comprising measuring from the folded flap of tissue prior to repeating the gripping step.

23. The method of claim 10, further comprising, before
30 the gripping step, inflating the stomach to a first pressure, visualizing the stomach from within the stomach, and increasing inflation pressure within the stomach to a second pressure after visualizing the stomach.

24. The method of claim 23, wherein the stomach is associated with an esophagus and wherein the method further comprises gripping a wall of the esophagus after inflating the stomach to the first pressure and prior to gripping the stomach.

25. The method of claim 23, comprising the further step of re-inflating the stomach prior to deploying the at least one fastener.

26. The method of claim 23, further comprising repeating the inflating, increasing, gripping, collapsing, pulling, and deploying steps for forming another folded flap of tissue and deploying at least one other fastener displaced from the at least one fastener.

27. The method of claim 26, further comprising measuring from the folded flap of tissue prior to repeating the gripping step.

28. A method of gripping stomach tissue from within a stomach, comprising:

visualizing the stomach from within the stomach to determine a gripping location;
inflating the stomach; and
gripping the stomach at the gripping location while the stomach is inflated.

29. The method of claim 28, wherein the inflating step includes inflating the stomach to a first pressure before the visualizing step and increasing inflation pressure to a second pressure before the gripping step.

30. The method of claim 29, wherein the stomach is associated with an esophagus and wherein the method further comprises gripping a wall of the esophagus after inflating the stomach to the first pressure and prior to gripping the stomach.

31. An assembly for restoring a gastroesophageal flap valve associated with a stomach, comprising:

an elongated member having a distal end for placement in the stomach; and

5 a gastroesophageal flap valve restoration device including a chassis and a bail carried at the elongated member distal end, the chassis having a proximal end connected to the elongated member distal end and a distal end hingedly coupled to the bail, the chassis and bail arranged to mold stomach tissue there between, the chassis further including a window that permits gastroesophageal
10 anatomy visualization.

32. The apparatus of claim 31, wherein the window is at the proximal end of the chassis.

33. The apparatus of claim 32, wherein the device further comprises a passage that slidably receives an
15 endoscope adjacent the window.

34. The apparatus of claim 31, wherein the device further includes a fastener deployment guide having a predetermined orientation relative to the window.

35. The apparatus of claim 34, wherein the fastener
20 deployment guide comprises at least one guide lumen.

36. The apparatus of claim 31, wherein the window includes a location marker.

37. The apparatus of claim 36, wherein the device further includes a fastener deployment guide that guides a
25 fastener into molded tissue.

38. The apparatus of claim 37, wherein the deployment guide has a predetermined orientation relative to the location marker.

39. The apparatus of claim 36 further comprising a
30 fastener deployer that deploys a fastener in molded tissue at a predetermined location relative to the location marker.

40. A method of deploying a fastener through stomach tissue a predetermined distance from a gastroesophageal junction, comprising:

providing a fastener deployment apparatus, the apparatus including a window permitting visualization of gastroesophageal anatomy when placed in an esophagus, a location marker viewable in the window, and a fastener
5 deployer that ejects a fastener for deployment at a predetermined location relative to the location marker;

feeding the apparatus down the esophagus;

aligning the location marker with respect to the gastroesophageal junction to cause the fastener deployer to
10 be aboral of the gastroesophageal junction; and

ejecting a fastener from the fastener deployer with the location marker aligned with respect to the gastroesophageal junction.

41. A fastener deployment apparatus that deploys a
15 fastener in body tissue, comprising:

a window permitting visualization of internal body anatomy when placed in a body;

a location marker viewable in the window; and

a fastener deployer having a predetermined orientation
20 relative to the location marker that ejects a fastener for deployment at a predetermined location relative to the location marker.

42. A device for folding tissue, comprising a chassis and a bail, the chassis having a distal end hingedly coupled
25 to the bail, the chassis and bail arranged to fold tissue there between, the chassis further including a window that permits anatomy visualization.

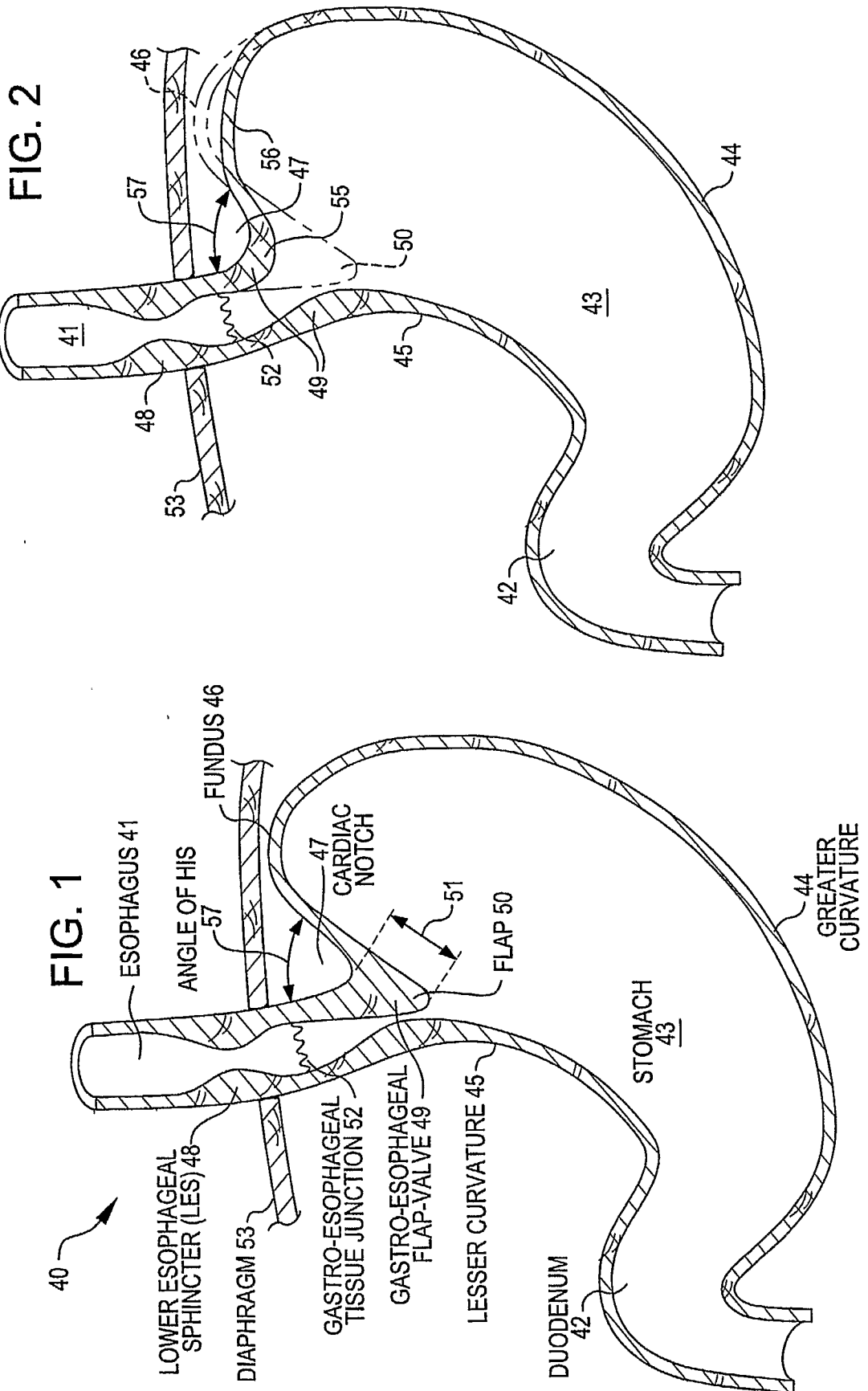


FIG. 4'

FIG. 3

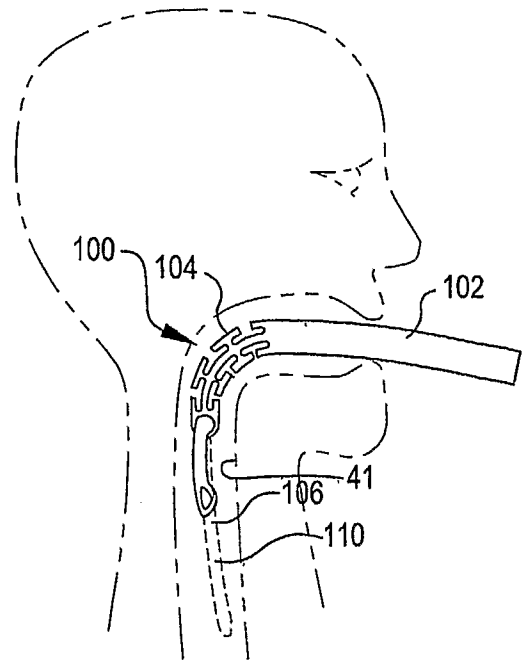
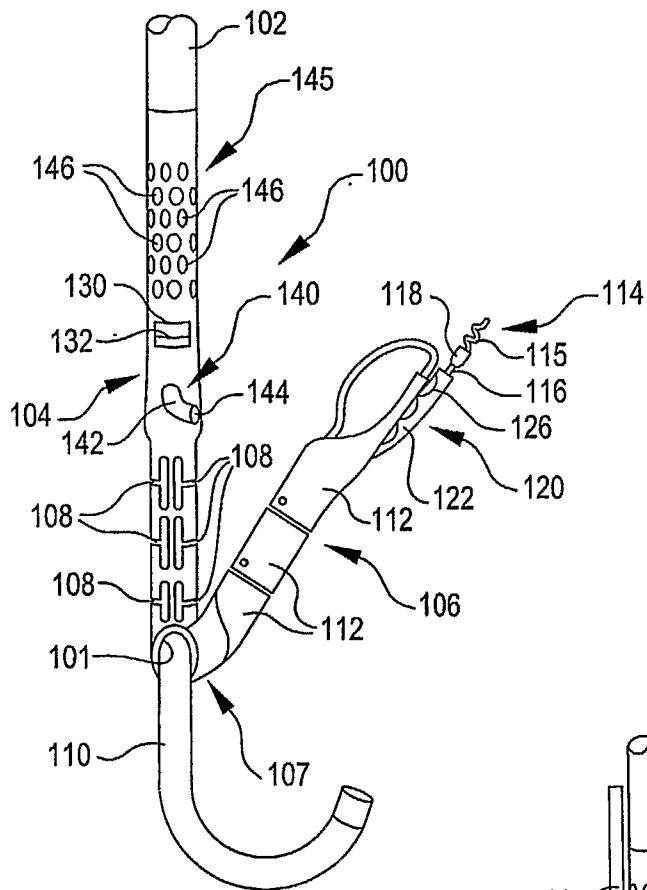
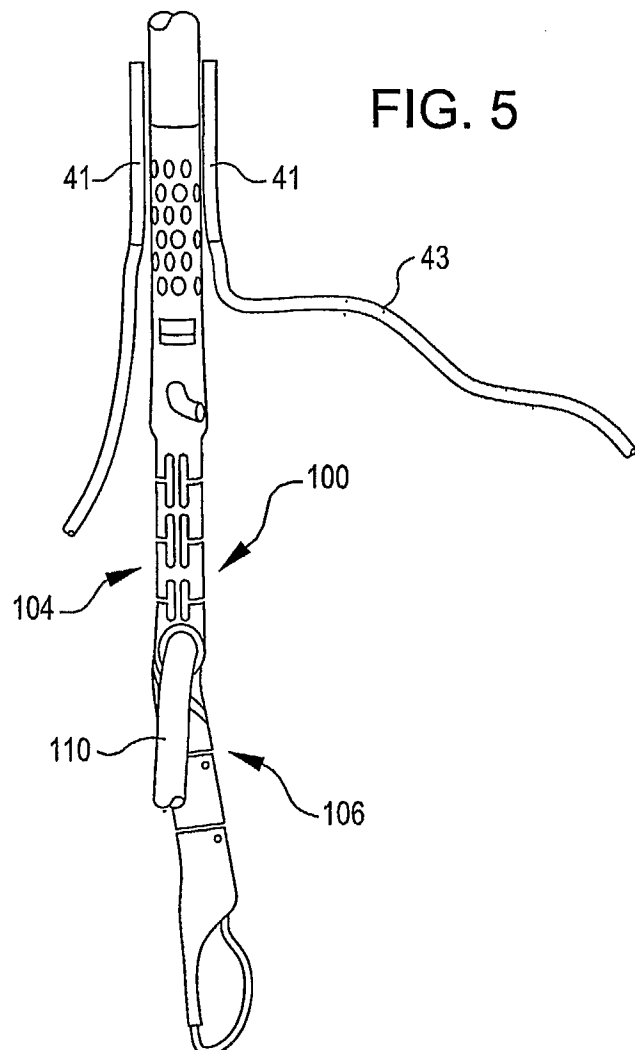


FIG. 5



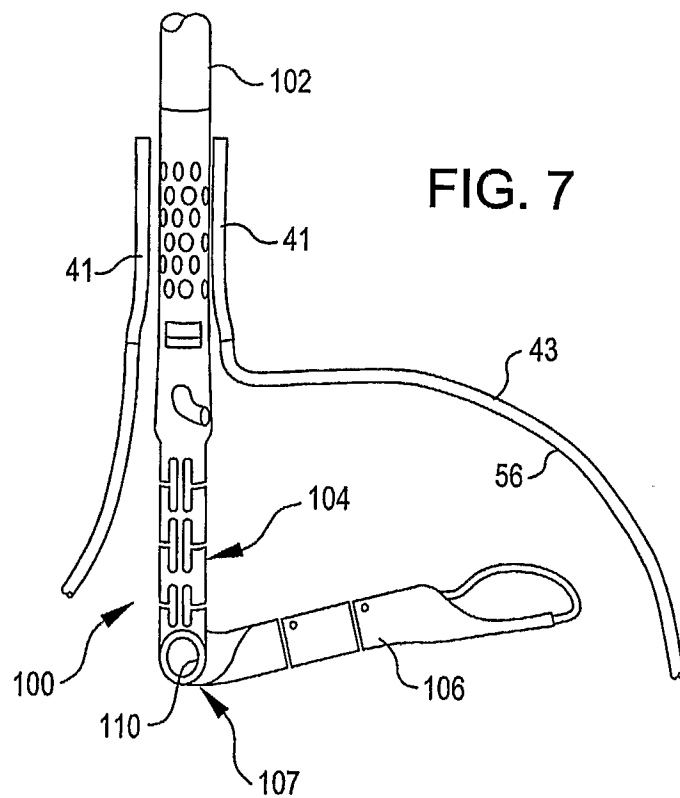
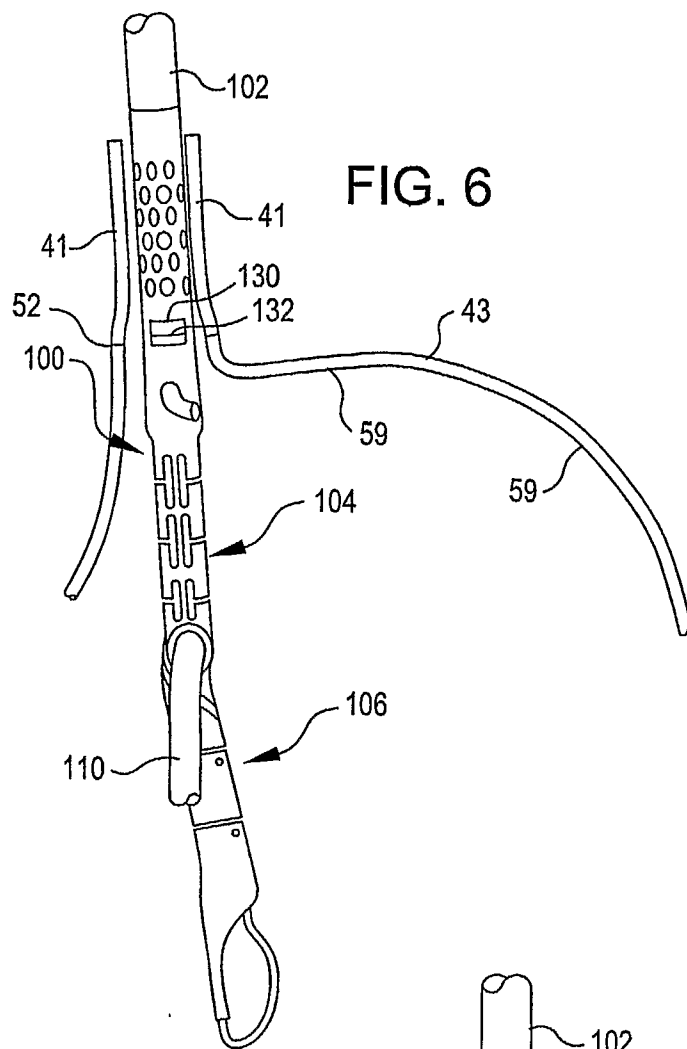


FIG. 8

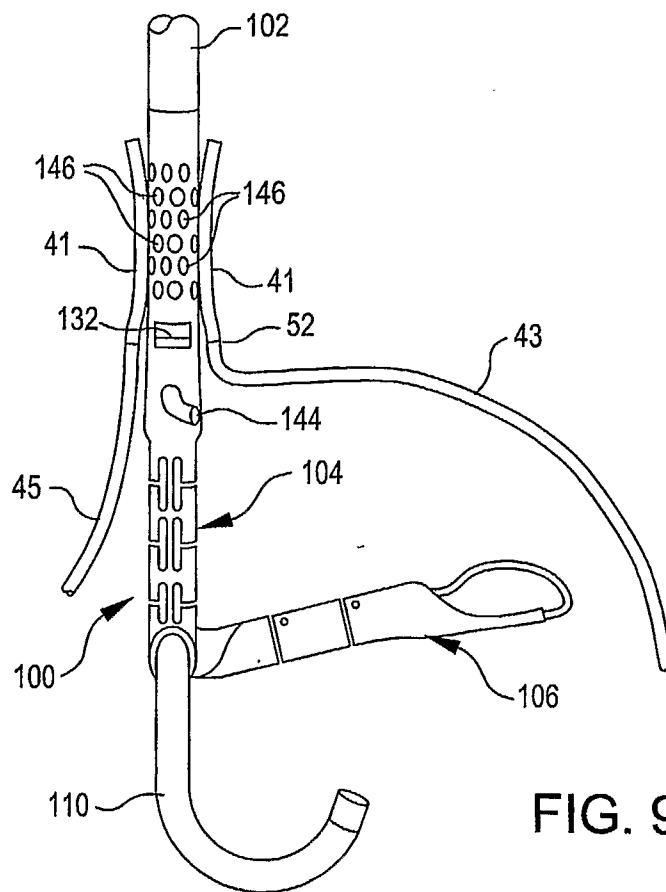


FIG. 9

