(12) STANDARD PATENT (11) Application No. **AU 2010308498 B2**
(19) AUSTRALIAN PATENT OFFICE

(54) Title
Bariatric device and method for weight loss

(51) International Patent Classification(s)
A61M 29/00 (2006.01)

(21) Application No: **2010308498** (22) Date of Filing: **2010.07.13**

(87) WIPO No: **WO11/049651**

(30) Priority Data

(31) Number	(32) Date	(33) Country
61/262,040	**2009.11.17**	**US**
61/264,651	**2009.11.25**	**US**
61/253,816	**2009.10.21**	**US**
61/262,045	**2009.11.17**	**US**

(43) Publication Date: **2011.04.28**
(44) Accepted Journal Date: **2016.02.11**

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(56) Related Art
WO 2006/044640
US 2009/0196210
US 2009/0012553
US 2009/0082644
US 2004/0092892
US 2005/0228504
US 2007/0185374

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
28 April 2011 (28.04.2011)

PCT

(10) International Publication Number
WO 2011/049651 A1

(51) International Patent Classification:
A61M 29/00 (2006.01)

(21) International Application Number:
PCT/US2010/041774

(22) International Filing Date:
13 July 2010 (13.07.2010)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

61/253,816	21 October 2009 (21.10.2009)	US
61/262,045	17 November 2009 (17.11.2009)	US
61/262,040	17 November 2009 (17.11.2009)	US
61/264,651	25 November 2009 (25.11.2009)	US

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(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, 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, IS, JP, KE, KG, KM, 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, PE, PG, PH, PL, PT, RO, RS, RU, 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, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, 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, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *of inventorship (Rule 4.17(iv))*

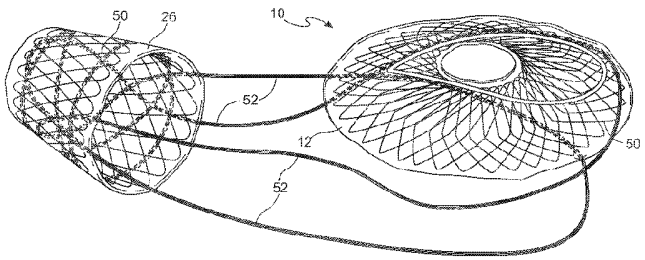
Published:

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

WO 2011/049651 A1

(54) **Title**: BARIATRIC DEVICE AND METHOD FOR WEIGHT LOSS

Fig. 39A



(57) **Abstract**: A bariatric device for use in inducing weight loss, comprising a cardiac element, a pyloric element, and a connecting element between the two other elements, wherein the connecting element provides structure between the cardiac and pyloric elements, keeping them largely in place and at least intermittently touching and applying pressure to the stomach's cardiac, adjacent fundic and pyloric regions, respectively, which produces a satiety signal to the user, giving the recipient a feeling of fullness and reducing his or her hunger feelings. In an alternative embodiment, the pyloric and connecting elements may be replaced with a positioning element, which keeps the cardiac element in its relative position by pushing against various structures in the stomach. In any of the embodiments, the bariatric device may be made from multiple sizes or adjustable, either manually, automatically or remotely, to optimally size and/or position the device to produce the desired satiety signals and weight loss.

BARIATRIC DEVICE AND METHOD FOR WEIGHT LOSS

[0001] This application claims the benefit of U.S. Provisional Application No. 61/253,816, filed October 21, 2009, U.S. Provisional Application No. 61/262,040, filed November 17, 2009, U.S. Provisional Application No. 61/262,045, filed November 17, 2009, and U.S. Provisional Application No. 61/264,651, filed November 25, 2009.

Bariatric Device and Method for Weight Loss

TECHNICAL FIELD

[0002] This invention relates to a bariatric device for weight loss, and ancillary items such as sizing, deployment, and removal apparatus.

BACKGROUND

[0003] Obesity has been steadily increasing worldwide and poses serious health risks, which if untreated, can become life threatening. There are various methods for reducing weight such as diet, exercise, and medications but often the weight loss is not sustained. Significant advances have been made in the surgical treatment of obesity. Surgical procedures such as the gastric bypass and gastric banding have produced substantial and lasting weight loss for obese patients. These procedures and products have been shown to significantly reduce health risks over time, and are currently the gold standard for bariatric treatment.

[0004] Although surgical intervention has been shown to be successful at managing weight loss, both procedures are invasive and carry the risks of surgery. Gastric bypass is

2010308498 03 Dec 2015

a highly invasive procedure which creates a small pouch by segmenting and/or removing a large portion of the stomach and rerouting the intestines permanently. Gastric bypass and its variations have known complications. Gastric banding is an invasive procedure which creates a small pouch in the upper stomach by wrapping a band around the stomach to segment it from the lower stomach. Although the procedure is reversible, it also carries known complications.

[0005] Less invasive or non-invasive devices that are removable and capable of significant weight loss are desirable.

SUMMARY

[0005A] According to a first aspect the present invention provides a bariatric device for placement into a stomach to achieve weight loss, comprising:

a. a cardiac element, the cardiac element comprising:
    i. a contact member having a substantially flattened frustoconical shape, the contact member defining a substantially circular opening adapted to correspond to the cardiac opening of a stomach, the contact member being constructed of materials flexible enough to be collapsed for placement and expanded for operation; and
    ii. a stiffening member inside the contact member that can be collapsed for placement and will cause the contact member to substantially return to and maintain its desired shape in the stomach after the cardiac element is expanded for operation;
b. a pyloric element, the pyloric element comprising:
    i. a second contact member adapted to engage the pyloric region of the stomach, having a steep frustoconical shape, sized to prevent the pyloric element from passing through the stomach's pyloric valve, the second contact member being constructed of materials flexible enough to be collapsed for placement and expanded for operation; and
    ii. a second stiffening member inside the second contact member that can be collapsed for placement and will cause the second contact member to substantially return to and maintain its desired shape in the stomach after the pyloric element is expanded for operation; and
    iii. an opening sized and adapted to allow chyme in the stomach to pass from the stomach through the pyloric valve; and

2010308498 03 Dec 2015

c. a connecting element coupled with the pyloric element and the cardiac element, constructed of resilient shape-holding material and shaped so that it causes the cardiac element to at least intermittently contact the upper stomach.

[0005B] According to a second aspect the present invention provides a bariatric device for placement into a stomach to achieve weight loss, comprising:

a. a cardiac element adapted to engage the upper stomach,

b. a pyloric element adapted to engage the pyloric region of the stomach, having an opening sized and adapted to allow chyme in the stomach to pass from the stomach through the pyloric valve; and

c. a connecting element coupling the cardiac element and the pyloric element, shaped such that the cardiac element maintains at least intermittent contact with the upper stomach and the pyloric element maintains at least intermittent contact with the pyloric region of the stomach.

[0005C] According to a third aspect the present invention provides a bariatric device for placement into a stomach to achieve weight loss, comprising a cardiac element adapted to engage the upper stomach, and at least one of the following chosen from the group consisting of:

a. a pyloric element adapted to engage the pyloric region of the stomach and having an opening sized and adapted to allow chyme in the stomach to pass from the stomach through the pyloric valve, and a connecting element coupling the cardiac element and the pyloric element, shaped such that the cardiac element maintains at least intermittent contact with the upper stomach and the pyloric element maintains at least intermittent contact with the pyloric region of the stomach,

b. a positioning element adapted to contact a region of the stomach outside the cardia and shaped such that the cardiac element maintains at least intermittent contact with the upper stomach,

c. a positioning element adapted to contact a region of the stomach outside the cardia and shaped such that the cardiac element maintains at least intermittent contact with the upper stomach, and a pyloric feature to preclude the positioning element from moving substantially past the pyloric valve.

[0005D] According to a fourth aspect the present invention provides a bariatric device for placement into a stomach to achieve weight loss, comprising:

a. a cardiac element adapted to fit the cardiac region of the stomach,

2010308498 03 Dec 2015

b. a pyloric element adapted to fit the pyloric region of the stomach, having an opening sized and adapted to allow chyme in the stomach to pass from the stomach through the pyloric valve,

c. a connecting element coupled with the cardiac element and the pyloric element, and

d. a constriction member coupled with the pyloric element.

[0006] The bariatric device described herein induces weight loss by engaging the upper and lower regions of the stomach. One embodiment of the bariatric device disclosed herein is based on applying force or pressure on or around the cardiac opening or gastroesophogeal (GE) junction and upper stomach. It may also include pressure in the lower esophagus. The device can be straightened or compressed to allow for introduction down the esophagus and then change into the desired shape inside the stomach. This device may not require any sutures or fixation and would orient inside the stomach based on the device's geometry. The device may be constructed of 2 main elements:

[0007] 1) A cardiac element that contacts or intermittently contacts the upper stomach around the GE junction and may also contact the lower esophagus.

[0008] 2) A positioning element that maintains the position of the first element in the stomach.

[0009] One of the purposes of the cardiac element which contacts the upper stomach or cardia is to at least intermittently apply direct force or pressure to this region of the stomach. Applying force or pressure to this region of the stomach replicates the forces and pressures that are generated during eating and swallowing. It also engages or stimulates the stretch receptors that are present in this region of the stomach. During eating, as the stomach fills, peristalsis starts and generates higher pressures in the stomach for digestion, which activates the stretch receptors to induce a satiety response, and may also trigger a neurohormonal response to cause satiety or weight loss. The cardiac element replicates this type of pressure on the stretch receptors. The cardiac element could take the form of many different shapes such as a ring, a cone, a frusto-cone, a sphere, an oval, an ovoid, a pyramid, an open or closed polyhedron, a square, a spiral, a kidney shape, multiple protuberances, multiple spheres or multiples of any shape or other structure. It could also be an inflatable balloon or contain an inflatable balloon. This balloon could be spherical, or it could be a torus or a sphere with channels on the side to allow food to pass, or it could be a cone or other. For the purpose of the claims of this patent, the "upper stomach" includes the cardiac region (a band of tissue in the stomach that surrounds the gastroesophogeal (GE) junction), and the fundus adjacent to the cardiac region, and may be either of these two areas, or both.

[0010] Some of the purposes of the positioning element are to provide structure for the device to maintain its relative placement location, provide support for the cardiac element to apply constant, intermittent, or indirect pressure against the upper stomach, and to prevent the device from migrating into the duodenum or small intestine. The positioning

element may also be constructed in such a manner as to impart an outwardly biasing force between the stomach and the cardiac element, so that the cardiac element can maintain at least intermittent pressure against the upper stomach, including the cardiac region and the adjacent portion of the fundus. This positioning element would be preferentially in the stomach above the pyloric valve. The positioning element could also take the form of a wire, a taper, a tube, a ribbon, a spiral of a single diameter, a spiral of varying diameter, an I-beam, or other suitable shapes. Similarly, the positioning element could comprise multiple members to improve its structural integrity. The positioning element could be generally curved to match the greater curve or lesser curve of the stomach, or both, or could be straight, or a combination of any of the above. Similar to the cardiac element, the positioning element could also take several different shapes, such as a ring, a cone, a sphere, an oval, a kidney shape, a pyramid, a square, a spiral, multiple protuberances, multiple spheres or multiples of any shape or other. It could also be an inflatable balloon or contain an inflatable balloon. This balloon could be spherical, or it could be a torus or a sphere with channels on the side to allow food to pass, or it could be a cone, a portion of a cone or other shape. The positioning element could be a combination of a curved wire and a balloon or any combination of the above mentioned forms. The form and structure of the cardiac and positioning elements may vary to adapt appropriately for their purpose. The positioning element may activate stretch receptors or a neurohormonal response to induce satiety or another mechanism of weight loss by contacting or stretching certain portions of the stomach, to induce satiety, delayed gastric emptying or another mechanism of weight loss.

[0011] After eating or drinking, the stomach goes through peristalsis to grind up the consumed food, and to propel the contents through the pyloric valve into the duodenum. Peristalsis causes the stomach to constantly change shape, length and diameter. Due to this constant motion, it is anticipated that this embodiment will move within the stomach. The positioning element may slide back and forth along the greater curve, the lesser curve or along the side walls of the stomach. . The positioning element may intermittently engage the lower stomach or pyloric valve, but be of a large enough size to prevent passage through the valve into the duodenum. The positioning element may include elements that are compressible to allow them to pass from a larger portion of the stomach into a smaller portion of the stomach such as from the body into the pyloric region, while exerting pressure or intermittent pressure on the cardiac element. Alternatively, the positioning element could have limited compressibility to maintain its position within the stomach.

[0012] In another embodiment of the bariatric device disclosed herein, the device may be constructed of three main elements:

[0013] 1) A cardiac element that engages the upper stomach around the GE junction including the cardiac region and adjacent fundus and may include the lower esophagus.

[0014] 2) A pyloric element that engages the pyloric region which includes the pyloric antrum or lower stomach.

[0015] 3) A connecting element that connects the cardiac and pyloric elements.

[0016] One of the purposes of the cardiac element which contacts the upper stomach or cardiac region would be to apply at least intermittent pressure or force to engage a satiety response and / or cause a neurohormonal response to cause a reduction in weight. This

element could take the form of many different shapes such as a ring, a cone, frusto-cone, a sphere, an oval, a pyramid, a square, a spiral, multiple protuberances, multiple spheres or multiples of any shape or other suitable shapes. It could also be an inflatable balloon or contain an inflatable balloon. This balloon could be spherical, or it could be a torus or a sphere with channels on the side to allow food to pass, or it could be a cone, a portion of a cone or other shapes. The cardiac element may be in constant or intermittent contact with the upper stomach based on the device moving in the stomach during peristalsis.

[0017] Some of the purposes of the pyloric element are to engage the pyloric region or lower stomach, and to act in conjunction with the connecting element to provide support for the cardiac element to apply constant, intermittent, or indirect pressure against the upper stomach and or GE junction and lower esophagus. It is also to prevent the device from migrating into the duodenum or small intestine. This pyloric element would be preferentially placed at or above the pyloric valve and could be in constant or intermittent contact with the pyloric region based on movement of the stomach. Depending on the size relative to the stomach, this element may apply radial force, or contact force or pressure to the lower stomach which may also cause a satiety or neurohormonal response. Due to peristalsis of the stomach, the bariatric device may toggle back and forth in the stomach which may cause intermittent contact with the upper and lower stomach regions. The device may also have features to accommodate for the motion to allow for constant contact with the upper and lower regions. Similar to the cardiac element, the pyloric element could take several different shapes such as a ring, a cone, a frusto-cone, a sphere, an oval, a pyramid, a square, a spiral, multiple protuberances, multiple spheres or multiples of any

shape or other. It could also be an inflatable balloon. This balloon could be spherical, or it could be a torus or a sphere with channels on the side to allow food to pass, or it could be a cone, a portion of a cone or other shape. This element may activate stretch receptors or a neurohormonal response to induce satiety or another mechanism of weight loss by contacting or stretching certain portions of the stomach, to induce satiety, delayed gastric emptying or another mechanism of weight loss. The form and structure of the cardiac and pyloric elements may vary to adapt appropriately for their purpose. For example, the cardiac element may be a ring while the pyloric element may be a cone or frusto-cone.

[0018] Some of the purposes of the connecting element are to connect the cardiac and pyloric elements, to provide structure for the device to maintain its relative placement location, and to provide tension, pressure, or an outwardly biasing force between the pyloric and cardiac elements. The connecting element could take several different forms such as a long curved wire, a curved cylinder of varying diameters, a spiral of a single diameter, a spiral of varying diameter, a ribbon, an I-beam, a tube, a taper, a loop, a curved loop or other. Similarly, the connecting element could comprise multiple members to improve its structural integrity and positioning within the stomach. The connecting element could be generally curved to match the greater curve or lesser curve of the stomach, both, or could be straight, or a combination of any of the above. The connecting element could also be an inflatable balloon or incorporate an inflatable balloon.

[0019] The connecting and/or positioning elements **25, 13** could also be self-expanding or incorporate a portion that is self expanding. Self expansion would allow the element or a portion of the element to be compressible, but also allow it to expand back into its

original shape to maintain its function and position within the stomach, as well as the function and position of the other element(s). Self expansion would allow the elements to compress for placement down the esophagus, and then expand its original shape in the stomach. This will also allow the element to accommodate peristalsis once the device is in the stomach. This self-expansion construction of the connecting and positioning elements may impart an outwardly biasing force on the cardiac element, the pyloric element, or both.

[0020] In any of the embodiments disclosed herein, the device may be straightened or collapsed for insertion down the esophagus, and then reformed to the desired shape in the stomach to apply pressure at the upper and lower stomach regions or other regions as described above. At least a portion of the device could be made of a shape memory alloys such as Nitinol (nickel titanium), low density polyethylene or polymers to allow for it to compress or flex and then rebound into shape in the stomach. For placement of the device into the stomach, a flexible polymer tube, such as a large diameter overtube, could be placed down the esophagus to protect the esophagus and stomach. The device could then be straightened and placed into the tube for delivery into the stomach, and then would regain its proper shape in the stomach once it exits the tube. Another variation for placement would be a custom delivery catheter to compress the device during placement and then allow the device to deploy out of the catheter once in the stomach.

[0021] The bariatric device could be made of many different materials. Elements of the device could be made with materials with spring properties that have adequate strength to hold their shape after reforming, and/or impart an outwardly biasing force. The

materials would also need to be acid resistant to withstand the acidic environment of the stomach. Elements of the device could be made of Nitinol, shape memory plastics, shape memory gels, stainless steel, titanium, silicone, elastomers, teflons, polyurethanes, polynorborenes, styrene butadiene co-polymers, cross-linked polyethylenes, cross-linked polycyclooctenes, polyethers, polyacrylates, polyamides, polysiloxanes, polyether amides, polyether esters, and urethane-butadiene co-polymers, other polymers, or combinations of the above, or other suitable materials. For good distribution of stress to the stomach wall or to reduce contact friction, the device could be coated with another material or could be placed into a sleeve of acid resistant materials such as teflons, PTFE, ePTFE, FEP, silicone, elastomers or other polymers. This would allow for a small wire to be cased in a thicker sleeve of acid resistant materials to allow for a better distribution of force across a larger surface area.

[0022] The device could take many forms after it reshapes.

BRIEF DESCRIPTION OF DRAWINGS

[0023] Figure 1 depicts a side view of a single wire embodiment the bariatric device of the present invention located within a cross-section of a stomach.

[0024] Figure 2 depicts a side view of an alternative single wire embodiment the bariatric device of the present invention located within a cross-section of a stomach.

[0025] Figure 3 depicts a side view of an embodiment the bariatric device of the present invention located within a cross-section of a stomach.

[0026] Figure 4 depicts a side view of a side view of an embodiment the bariatric device of the present invention located within a cross-section of a stomach.

[0027] Figure 5 depicts a side view of a side view of an embodiment the bariatric device of the present invention located within a cross-section of a stomach.

[0028] Figure 6 depicts a side view of a side view of an embodiment the bariatric device of the present invention located within a cross-section of a stomach.

[0029] Figure 7 depicts a side view of a side view of embodiment the bariatric device of the present invention located within a cross-section of a stomach.

[0030] Figure 8A depicts a side view of a side view of an embodiment the bariatric device of the present invention having a positioning element, located within a cross-section of a stomach.

[0031] Figure 8B depicts a perspective view of a closeup of part of the positioning element shown in Figure 8A.

[0032] Figure 9A depicts a side view of a side view of an embodiment the bariatric device of the present invention having a positioning element, located within a cross-section of a stomach.

[0033] Figure 9B depicts a perspective view of a closeup of part of the positioning element shown in Figure 9A.

[0034] Figure 10 depicts a side view of an embodiment the bariatric device of the present invention located within a cross-section of a stomach.

[0035] Figure 11A depicts a side view of an embodiment the bariatric device of the present invention located within a cross-section of a stomach.

[0036] Figure 11B depicts a side view of an embodiment the bariatric device of the present invention.

[0037] Figure 12 depicts a side view of an embodiment of the bariatric device of the present invention located within a cross-section of a stomach.

[0038] Figure 13 depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[0039] Figure 14 depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[0040] Figure 15 depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[0041] Figure 16 depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[0042] Figure 17 depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[0043] Figure 18 depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[0044] Figure 19 depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[0045] Figure 20 depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[0046] Figure 21 depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[0047] Figure 22 depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[0048] Figure 23A depicts a side view of a cross-section of a stomach, identifying anatomical features.

[0049] Figure 23B depicts a side view of a cross-section of a stomach showing its approximate shape when undergoing contractions due to peristalsis.

[0050] Figure 24 depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[0051] Figure 25 depicts a side view of the embodiment of the present invention shown in Figure 24, located within a cross-section of a stomach that is undergoing contraction due to peristalsis.

[0052] Figure 26 depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[0053] Figure 27 depicts a side view of the embodiment of the present invention shown in Figure 26, located within a cross-section of a stomach that is undergoing contraction due to peristalsis.

[0054] Figure 28 depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[0055] Figure 29 depicts a side view of the embodiment of the present invention shown in Figure 28, located within a cross-section of a stomach that is undergoing contraction due to peristalsis.

[0056] Figure 30 depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[0057] Figure 31 depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[0058] Figure 32A depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[0059] Figure 32B depicts an internal end view of a pyloric element of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach shown in Figure 32A.

[0060] Figure 33A depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[0061] Figure 33B depicts an internal end view of a pyloric element of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach shown in Figure 33A.

[0062] Figure 34A depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[0063] Figure 34B depicts an internal end view of a pyloric element of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach shown in Figure 34A.

[0064] Figure 35 depicts a side view of the embodiment of the present invention shown in Figure 34A, located within a cross-section of a stomach that is undergoing contraction due to peristalsis.

[0065] Figure 36A depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[0066] Figure 36B depicts a side view of the embodiment of the present invention shown in Figure 36A, located within a cross-section of a stomach that is undergoing contraction due to peristalsis.

[0067] Figure 37A depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[0068] Figure 37B depicts a side view of the embodiment of the present invention shown in Figure 37A, located within a cross-section of a stomach that is undergoing contraction due to peristalsis.

[0069] Figure 38A depicts an underside perspective view of an embodiment of the bariatric device of the present invention of the present invention.

[0070] Figure 38B depicts a top view of an embodiment of the bariatric device of the present invention of the present invention.

[0071]

[0072] Figure 39A depicts an underside perspective view of an embodiment of the bariatric device of the present invention.

[0073] Figure 39B depicts a top view of an embodiment the bariatric device of the present invention of the present invention.

[0074] Figure 40A depicts a side view of a pyloric element of an embodiment of the present invention.

[0075] Figure 40B depicts a side view of a pyloric element of an embodiment of the present invention.

[0076] Figure 41 depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[0077] Figure 42A depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[0078] Figure 42B depicts a side view of a connecting element of an embodiment of the present invention.

[0079] Figure 42C depicts a side view of a connecting element of an embodiment of the present invention.

[0080] Figure 42D depicts a side view of a connecting element of an embodiment of the present invention.

[0081] Figure 43 depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[0082] Figure 44A depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[0083] Figure 44B depicts an underside perspective view of an embodiment of the present invention.

[0084] Figure 45A depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[0085] Figure 45B depicts an underside perspective view of an embodiment of the present invention.

[0086] Figure 46A depicts a side view of strap retainer of an embodiment of the present invention.

[0087] Figure 46B depicts a side view of strap retainer of an embodiment of the present invention.

[0088] Figure 46C depicts an end view of strap retainer of an embodiment of the present invention.

[0089] Figure 46D depicts an end view of strap retainer of an embodiment of the present invention.

[0090] Figure 46E depicts a top view of strap retainer retaining a member with two positional beads of an embodiment of the present invention.

[0091] Figure 47A depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[0092] Figure 47B depicts a side view of a retainer strap and clip adjustment mechanism of an embodiment of the present invention.

[0093] Figure 47C depicts a side view of a retainer strap and clip adjustment mechanism of an embodiment of the present invention.

[0094] Figure 47D depicts a side view of a retainer strap and clip adjustment mechanism of an embodiment of the present invention.

[0095] Figure 48 depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[0096] Figure 49A depicts an end view of a retainer clip in a relaxed and closed state, and a bead on a member shown in cross section, of an embodiment of the present invention.

[0097] Figure 49B depicts an end view of a retainer clip shown in Figure 49A in a compressed and open state, and a bead on a member shown in cross section.

[0098] Figure 50A depicts an end view of a retainer clip in a relaxed and closed state, and a bead on a member shown in cross section, of an embodiment of the present invention.

[0099] Figure 50B depicts an end view of a retainer clip shown in Figure 50A in a compressed and open state, and a bead on a member shown in cross section.

[00100] Figure 51A depicts an end view of a keyway, and a bead on a member shown in cross section, of an embodiment of the present invention.

[00101] Figure 51B depicts an end view of a keyway shown in Figure 51A, and a bead on a member shown in cross section that has translated its position relative to Figure 51A.

[00102] Figure 52A depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[00103] Figure 52B depicts an underside perspective view of an embodiment of the present invention.

[00104] Figure 53 depicts a side view of an embodiment of the present invention having an adjustment mechanism in the pyloric element, located within a cross-section of a stomach.

[00105] Figure 54 depicts an end view of the adjustment mechanism in the pyloric element of the embodiment shown in Figure 53.

[00106] Figure 55 depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[00107] Figure 56 depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[00108] Figure 57 depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[00109] Figure 58A depicts a side view of an embodiment of the present invention, having an adjustment mechanism in the pyloric element in an uninflated state, located within a cross-section of a stomach.

[00110] Figure 58B depicts a side view of the embodiment shown in Figure 58A, having an adjustment mechanism in the pyloric element in an inflated state, located within a cross-section of a stomach.

[00111] Figure 59 depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[00112] Figure 60 depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[00113] Figure 61A depicts a side view of an embodiment of the present invention, with a magnetic adjustment mechanism in cross section view, located within a cross-section of a stomach.

[00114] Figure 61B depicts a closeup cross-section view of the magnetic adjustment mechanism shown in Figure 61A, next to a controller magnet.

[00115] Figure 62 depicts a side view of an embodiment of the present invention, equipped with adjustment cones in the pyloric element shown in cross section, located within a cross-section of a stomach.

[00116] Figure 63 depicts a cross-section view of an alternative embodiment of the adjustment cone shown in Figure 62.

[00117] Figure 64 depicts a cross-section view of an alternative embodiment of the adjustment cone shown in Figure 62.

[00118] Figure 65 depicts a side view of an embodiment of the present invention, equipped with adjustment mechanism shown in cross section, located within a cross-section of a stomach.

[00119] Figure 66 depicts a remote controller of an embodiment of the present invention, worn next to the user's body.

[00120] Figure 67 depicts a remote controller of an embodiment of the present invention, used without wearing or placing adjacent to the body.

[00121] Figure 68 depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[00122] Figure 69 depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach.

[00123] Figure 70 depicts a side view of an embodiment of the bariatric device of the present invention, located within a cross-section of a stomach and a duodenum.

[00124] Figure 71A depicts a side view of an adjustment mechanism in an unexpanded state, of an embodiment of the present invention.

[00125] Figure 71B depicts a side view of an adjustment mechanism shown in Figure 71A, in an expanded state.

[00126] Figure 72A depicts a side view of an adjustment mechanism in an unexpanded state, of an embodiment of the present invention.

[00127] Figure 72B depicts a side view of an adjustment mechanism shown in Figure 72A, in an expanded state.

[00128] Figure 73A depicts a side view of an adjustment mechanism in an unexpanded state, of an embodiment of the present invention.

[00129] Figure 73B depicts a side view of an adjustment mechanism shown in Figure 73A, in an expanded state.

[00130] Figure 74 depicts a side view of a delivery sheath containing a medical device.

[00131] Figure 75 depicts a side view of the delivery sheath shown in Figure 74, partially opened to show an expanded medical device.

[00132] Figure 76 depicts a side view of an embodiment of a stomach measurement device.

[00133] Figure 77 depicts a side view of an embodiment of a stomach measurement device showing the frusto-conical member in an inflated state.

[00134] Figure 78 depicts a closeup side view of the stomach measurement device shown in Figure 77, showing the frusto-conical member in a deflated state.

[00135] Figure 79 depicts a perspective view of a pyloric element equipped with a constriction element, in an embodiment of the present invention.

[00136] Figure 80 depicts a perspective view of the pyloric element shown in Figure 79, with the constriction element engaged to constrict the pyloric element.

[00137] Figure 81A depicts a perspective view of a pyloric element equipped with a constriction element with a mechanical stop, in an embodiment of the present invention.

[00138] Figure 81B depicts a perspective view of a pyloric element equipped with a constriction element with a mechanical stop, in another embodiment of the present invention.

[00139] Figure 82 depicts a perspective view of the pyloric element shown in Figure 81B, with the constriction element engaged to constrict the pyloric element.

DETAILED DESCRIPTION OF THE INVENTION

[00140] The detailed description set forth below in connection with the appended drawings is intended as a description of presently-preferred embodiments of the invention and is not intended to represent the only forms in which the present invention may be constructed or utilized. The description sets forth the functions and the sequence of steps for constructing and operating the invention in connection with the illustrated embodiments. It is to be understood, however, that the same or equivalent functions and sequences may be accomplished by different embodiments that are also intended to be encompassed within the spirit and scope of the invention.

[00141] The most basic embodiment of the bariatric device **10** may have a single piece of Nitinol wire **11** which is shape set into a shape, but can be pulled under tension into a generally narrow and straight form, to allow for insertion of the device **10** through the esophagus. In such an embodiment, the elements may all be seamlessly integrated as one wire structure. See Figs. 1 and 2. Depending on the size of the stomach, the shape set

wire may impart an outwardly biasing force to the proximal and distal elements of the bariatric device **10**, which may vary during peristalsis.

[00142] As for the two-element embodiment (cardiac element **12** and positioning element **13**), when tension to stretch the device **10** is released, it may coil into a ring, cone or spiral at one end near the upper stomach or cardia, and curve into a shape to relatively match the lesser and greater curve of the stomach **16, 17** and be of sufficient size to not migrate across the pyloric valve **18** into the duodenum **19**. See Fig. 3 and 4. The positioning element **13** could also have a straighter section that does not follow the lesser curve **16**, but does follow the greater curve **17**. See Fig. 5. In this embodiment, the positioning element **13** could also be in a different plane such that is perpendicular to that shown in Figs. 3, 4, and 5, or the device **10** could contain multiple members that were in the same plane and perpendicular to the plane shown in Figs. 3, 4, and 5. To use a plane perpendicular, the element could follow the midline of the stomach between the greater and lesser curves **17**, **16**, and would contact the posterior and anterior walls of the stomach.

[00143] As noted above, the cardiac element **12** may be in the form of a ring, which can be formed from a single Nitinol wire **11**, or a wide variety of other suitable materials, such as silicone, Nitinol encased in silicone, etc. Preferably, the ring can be compressed or collapsed for insertion through the esophagus, then regain or reform its shape after placement in the stomach. The ring could lock or not lock after forming, or could be continuous prior to placement. A variation may have the ring closed, locked, or continuous prior to placement down the esophagus. See Fig. 4. The ring could be compressed enough to fit within a placement tube or delivery catheter for placement

through the esophagus. The cross-section of the ring could be round, flat, oval, convoluted, wavy or knobby to add pressure points that continuously move to stimulate the upper stomach or cardia during peristalsis and reduce the potential for overstressing a certain area. See Fig. 6. The cardiac element **12** could also be a cone of flexible material or combinations of materials. See Fig. 7. The device **10** need not be fixed into place but may be moveable within the stomach. Once the device **10** is placed, preferably, it is generally self-seating to ensure that it sits in the correct general areas similar to the way a contact lens re-seats itself on the cornea even after it is moderately pushed off center. Since the stomach is nonsymmetrical, the device **10** could be formed to have a bias to ensure that it seats into the upper stomach or cardia and within the lower stomach as needed. Similarly, the action of peristalsis would create additional satiety signals to be sent each time a wave passes by the device **10** it could slip around in the stomach varying the pressure placed on the upper and lower stomach over time pending the force of peristalsis.

[00144] The positioning element **13** could comprise two or more positioning members **20**. For example, a member **20** could follow the curve of the greater curve **17** and the other member **20** could provide the support between the first member and the cardiac element **12**. To further improve the design, the two members **20** of the positioning element **13** could articulate and or rotate relative to one another to accommodate for the movement of the stomach. See Figs. 8A, 8B, 9A and 9B. As shown, the positioning element **13** could also contain a pyloric feature **21** that could translate along the great curve in the pyloric region **42** and prevent the device **10** from passing through the pyloric valve **18**. Another variation for the positioning element **13** with multiple members would be to have a

member that is a loop **22** and is attached to a member with a support that follows the greater curve **17**. See Fig. 10. The loop member **22** could flex in shape to change in length and width to accommodate for the stomachs movement during peristalsis. The positioning member could also be a spiral spring **23** or spring plunger assembly **24**. See Figs. 11A and 11B. This member could also have a manual mechanism for adjusting the maximum length, such as having a set screw block the distance that the plunger could travel. Details on various adjusting mechanisms are discussed below.

[00145] The positioning element **13** could also be a spiral or spring, or multiple spirals or multiple springs to create a flexible structure. See Fig. 11B. The positioning element **13** could also be bisected into two members that stack, telescope or articulate, such as those shown in Figs. 8A-9B. The positioning element **13** could also have a joint such as a ball and socket type joint **29** or may be connected by magnets. As mentioned above, these devices could also contain an additional positioning element **13** that is in a plane perpendicular or other angle to that shown in the figures, so that the positioning element **13** contacts the midline of the stomach between the greater and lesser curves **17**, **16**, and contacts the posterior and anterior walls of the stomach.

[00146] In any of the embodiments discussed herein, the positioning and/or connecting elements **13**, **25** may be constructed of materials, or in such a manner, that may impart an outwardly biasing force, to push on the cardiac and/or positioning or pyloric elements. Such outwardly biasing force may impart constant or intermittent pressure to various parts of the stomach, through the cardiac element **12**, the pyloric element **26**, the positioning or connecting elements **13**, **25**, or any combination thereof.

[00147] In the three-element embodiment (cardiac, pyloric, and connecting elements **12**, **26**, **25**), the three elements may all be seamlessly integrated as one wire structure. When tension to flex, compress or stretch the device **10** is released, it may coil into a ring or loop near the cardia **40**, and coil into a ring or loop near the pyloric region **42**, with a curved member to connect the two elements that is shaped to relatively match the greater curve **17** of the stomach. The curve could also match the lesser curve **16** of the stomach or both. See Fig. 12 and 13. The connecting element **25** could curve into a single ring, or it could curve into a spiral. See Fig. 14.

[00148] As in other embodiments, the rings at each end could lock or not lock after forming, the rings may be closed, locked or continuous prior to placement down the esophagus, and could be compressed enough to fit within a placement tube for placement through the esophagus. See Figs 12 and 13. As with other embodiments, the elements of the bariatric device **10** may have a variety of shapes to add pressure points that continuously move to stimulate the cardiac region **40** during peristalsis. See Figs. 15, 16, and 17. The device **10** need not be fixed into place but may be moveable, and generally self-seating. The device **10** may have a bias to fit the nonsymmetrical stomach shape and ensure that it seats into the cardiac region **40** and pyloric region **42**. Similarly, the action of peristalsis could create additional satiety signals as the device **10** moved in the stomach varying the pressure placed on the cardiac region **40** and/or the pyloric region **42** over time.

[00149] In the three-element design shown in Fig. 12, the connecting element **25** connecting the two rings could follow the natural curve of the stomach to match the greater

or lesser curve of the stomach **17**, **16**, or could have both. This would aid in the seating of the device **10** in the stomach after placement. The connecting element **25** could have one or more connecting members **30** connecting the cardiac and pyloric elements **12**, **26**. See Fig. 13. However, these members **30** should be flexible enough to allow for natural peristalsis to occur, natural sphincter function to occur and to not cause erosion or irritation of the stomach wall or significant migration into the esophagus or duodenum **19**. There could also be struts or supports that help to support the geometric shape of the rings to the connecting element **25**. The connecting element **25** could also be a spiral **28** or multiple spirals to create a flexible structure. See Fig. 14. The connecting element **25** could also be bisected into two members that stack, telescope or articulate. The connecting element **25** could also have a joint such as a ball and socket type joint **29** or may be connected by magnets. See Fig. 18.

[00150] In another variation of the embodiments, there could be several rings **31** at each end of the device **10** to create an area of pressure at the upper stomach or cardia **40**. See Fig. 19. The rings **31** should be sized appropriately to ensure that they do not protrude or slip into the esophagus **32** or into the duodenum **19**, unless a variation of this embodiment is designed to have some portion of the device **10** enter those regions. This will allow the device **10** to apply pressure to the upper stomach or cardia **40** without fixation or sutures. The force against the pyloric region **42** and/or lower stomach will provide the counterforce against the upper stomach or cardia **40**. At the same time, the force or contact against the pyloric region **42** and/or lower stomach may signal the body to stop eating. This force would mimic having a meal in the stomach with subsequent peristalsis, and sending the

signal to stop eating. The multiple rings **31** could take the form of a spiral or could be separate rings **31** connected together. After reforming in the stomach, the rings **31** could lock, not lock, or be continuous. There are several ways that these elements could lock to form a ring.

[00151] Another option for the cardiac element **12** would be to have a surface that contacts the upper stomach or cardia **40** such as a hemispherical or conical shaped shell **33** or balloon. The shape could also be asymmetrical but similar to a cone or hemisphere. This could be a thin walled element and could contain a lumen or no lumen through which food could pass. See Fig. 20. In the case where there is no opening, the food would have to pass over the hemisphere or cone **33** which would have adequate flexibility to allow the food to pass into the stomach. This may require the esophagus **32** to work harder to pass the food over the element and could better stimulate the stretch receptors in the stomach and indirectly in the esophagus. In another alternative, the hemispherical shell **33** could have multiple grooves or channels to aid in allowing food to pass. In the case where there is a lumen in the cardiac element **12**, it could be open or it could have a valve **35** that requires some force to allow food to pass through. An option could also be to have an esophageal member **36** that extends into the esophagus **32** for additional esophageal stimulation. This esophageal member **36** could be tethered by a thin structural member to support the esophageal member **36**, but not prevent the esophageal sphincter from closing. As mentioned above, this may require the esophagus **32** to work harder to pass the food and may better stimulate the stretch receptors in the stomach and indirectly in the esophagus. This esophageal member **36** could be a large tube, a small tube, a ring, a

small sphere, multiple small spheres, or other suitable shapes. This type of embodiment could also be adapted for the 2 element design, where the cardiac element **12** is connected to a positional feature as shown in Fig. 21. All aspects of the above embodiment would apply towards this embodiment as well.

[00152] The pyloric element **26** could contain a lumen or could contain a valve similar to the valve shown in Fig 20 for the cardiac element **12**. This could reduce the speed of food passing through the pyloric element **26** if desired. This valve **35** could be a thin membrane of silicone with a single or multiple slits punch through the center, or other types of valves could be used. Figure 83 shows a pyloric element with a valve **35** passing across the midsection of the pyloric element **26** to slow down the passage of food.

[00153] The connecting element could also be an inflatable balloon **104** or incorporate an inflatable balloon. Figure 83 depicts a connecting element **25** that could be comprised of an inflatable balloon **104**. This inflatable body **104** could be compressed for placement and then inflated with a fluid to provide structure and adjustability after placement in the stomach. An inflation element **74** such as an injection port may be attached to the balloon where an instrument could be used to add or remove fluid to the inflatable balloon **104**. The positioning element **13** could also contain or comprise an inflatable balloon.

[00154] With respect to the three-element design, another alternative embodiment for the pyloric element **26** would be to change the orientation to allow the axis of the loop **37** to be perpendicular to the axis of the pyloric valve **18** similar to some embodiments described for the two-element design. This may simplify manufacturing construction yet perform the

same function. In such an embodiment, the pyloric element **26** could have the loop in a single plane, two crossed planes, or multiple planes. See Fig. 22.

[00155] As mentioned above, the stomach experiences peristaltic waves when something is swallowed. Figure 23A depicts a stomach cross-section showing the Z line and gastroesophageal ("GE") junction **38**, the cardia or cardiac region **40**, the fundus **41**, the pyloric region **42**, the pyloric antrum **43**, the pyloric valve **18**, and the duodenum **19**. Figure 23B depicts the stomach's lesser curve **16** and greater curve **17**. Figures 23A and 23B respectively show a representation of the stomach profile when the stomach is at rest and when the stomach is fully contracted during peristalsis and the change in stomach diameter and length. Due to the change in stomach profile, it may be advantageous to have a design that can flex to change with the stomach profile to allow the design to slide or translate along the greater curve **17** or flex as needed, but maintain the relative position of the cardiac element **12**. As mentioned above, the two-element device **10** could also contain a member or an additional positioning element **13** that is in a plane perpendicular or other angle to that shown in the figures, so that the element contacts the midline of the stomach between the greater and lesser curves **17**, **16**, and contacts the posterior and anterior walls of the stomach. This would maintain the position within the stomach with less flex needed to maintain the position with the greatest motion taking place along the greater curve **17**, and least motion taking place along the lesser curve **16**.

[00156] Figures 24 and 25 show an alternate embodiment of the two-element design to adapt to stomach profile changes. In Fig. 24, it shows the cardiac element **12** engaging the upper stomach region while the positioning element **13** is a spring with two closed loops **44**

at each end which can compress and flex to accommodate peristalsis within the stomach. Fig. 25 shows these loops **44** compressing during peristalsis to allow the device **10** to maintain its relative position in the stomach and preventing it from migrating past the pyloric valve **18**.

[00157] Figures 26 and 27 show an alternate embodiment of the two-element design where the positioning element **13** is a spring with open loop **45** where the loops **45** are allowed to flex as needed to maintain the relative position of the device **10** within the stomach. A mechanical stop for maximum compression is supplied by only allowing the spring to flex until the loop **45** has closed. This ensures that a minimum profile is maintained to prevent the device **10** from potentially migrating past the pyloric valve **18** and into the duodenum **19**.

[00158] Figures 28 and 29 show another alternate embodiment of the two-element design where the cardiac element **12** is in the form of a spiral and the positioning element **13** is a closed loop **46**. The closed loop **46** is allowed to compress as needed during peristalsis to maintain its relative position. This also shows a mechanical stop **47** that could be added inside the loop to prevent the loop from over flexing. The cardiac element **12** could also be a sphere as shown or ring as shown in other figures.

[00159] Figure 30 shows a device **10** similar to one shown in Figure 8A where the positioning element **13** contains two members **20**. One member **20** could contain a loop that could intermittently engage the pyloric region **42** to prevent undue migration.

[00160] Another alternative to this design would be to have a connecting element **25** made up of two members **30** that can slide relative to one another to accommodate for

stomach motion. See Fig. 31. This drawing shows how a flexible wire or ribbon, the connecting element **25**, could fit inside of less flexible pre-curved pyloric element **48**. As the stomach contracts, the connecting element **25** could slide or into the pre-curved pyloric element **48** to reduce the overall length during stomach contraction. Since the connecting element **25** would resist the permanent curvature, it would spring back out of the pre-curved pyloric element **48** to regain its length when the contraction was completed.

[00161] Another embodiment to accommodate for stomach contractions would allow the pyloric element **26** to flex and slide along the lower stomach region or pyloric region **42**. In this embodiment, the pyloric element **26** and connecting element **25** could be combined into a single member. The pyloric element **26** could be a flexible ribbon with an open curve in the end. This curve could flex to create a closed loop which would allow the device **10** to slide within the lower stomach segment to maintain the position of the cardiac element **12** and not migrate beyond the pyloric valve **18**.

[00162] In yet another embodiment, the connecting element **25** may be made up of two or more members **30**. See Figs. 32A and 32B. As shown in the drawing, the cardiac element **12** would contact the upper stomach or cardiac region **40**, while pyloric element **26** contacts the lower stomach or pyloric region **42**. The connecting element **25** has three members **30**, which are shown as curved wires or ribbons. One member **30** curves to match the lesser curve **16** (LC), while two other members **30** curve to match a median line between the lesser and greater curve **17** (GC), and curve to contact the anterior and proximal surfaces of the stomach to maintain its position even during peristalsis. Fig. 32A shows an optional location for the pyloric element **26** in the pyloric region **42**. Figures

33A and 33B shows a similar embodiment with another optional location for the pyloric element **26** closer to the pyloric valve **18**.

[00163] In another embodiment, peristaltic motion may cause the device **10** to move inside the stomach and could cause the pyloric element **26** to slide from the relative locations such as those shown in Figures 34A, 34B and 35. These drawings show a three-element embodiment where the connecting element **25** may have four members **30**. Figs. 34A, 34B and 35 depict a similar embodiment to Figs. 33A and 33B, but with an additional element to match the greater curve **17**. During peristalsis, the greater curve **17** will shorten, and the member **30** that matches could curve inward to a convex form. After the peristaltic action is complete, the member **30** may spring back to its original concave form. Using these concepts, additional members **30** for the connecting element **25** may be used beyond the three and four members **30** described here, and could be located in a variety of locations along the midline, lesser curve **16** or greater curve **17** or any combination.

[00164] Figures 36A and 36B depict an embodiment where the cardiac element **12** may be allowed to intermittently contact the upper stomach during peristalsis. The pyloric element may be a rigid or semi-rigid ring **49** and the connecting element **25** may be a spring to connect to the cardiac element **12**. In this embodiment, the ring **49** could engage the lower stomach at a fixed diameter when the stomach is at rest. Compression of the stomach during peristalsis would push the ring **49** towards the upper stomach to allow the cardiac element **12** to intermittently contact the upper stomach and/or cardiac area **40**. This may be advantageous to prevent overstimulation of the upper stomach or for other purposes.

[00165] In yet another set of embodiments, the bariatric device **10** in either the two-or three-element embodiments may be self expanding. Figures 37A and 37B depict an alternative embodiment where the cardiac and pyloric elements **12, 26** are self expanding. These elements could be self expanding or have a portion that is self expanding to allow the device **10** to flex with peristalsis, but maintain tension to spring open to apply pressure or contact and position within the stomach. The self expanding portion could be made of Nitinol, silicone, polyurethane, Teflons, stainless steel or other suitable materials or combinations of suitable materials. Figure 37A and 37B shows a Nitinol wire mesh pattern **50** applied to a frusto-conical shape to create a shell. The Nitinol wire may act as a stiffening member within the cardiac and pyloric elements **12, 26**. The Nitinol wire could be arranged in many different patterns to allow for the appropriate amount of self expansion while allowing the element to compress during peristalsis. The array pattern could include circular arrays, angular arrays, linear arrays, or other suitable arrays. The pattern could be woven or a continuous spiral.

[00166] The self expanding function may also assist in deployment by allowing the device **10** to compress and then regain its shape. A preferred method of deployment is to compress the bariatric device **10** into a long narrow shape, which is then placed in a deployment tube, sheath or catheter. The collapsed and encased device **10** is then guided down the patient's esophagus **32** and into the stomach, where the bariatric device **10** is released from the deployment tube or catheter. Once released, the device **10** would expand to its original operational shape. The stiffening member, such as Nitinol wire, may

provide adequate stiffness to expand the elements into their operational shape, and maintain that general shape during operation, while allowing flexibility to accommodate peristalsis.

[00167] The embodiment depicted in Figs. 37A and 37B show the cardiac and pyloric elements **12, 26** connected by a connecting element **25** with multiple curved members, which are shown to be a wire mesh array **50**, but could be made of Nitinol wire, silicone, teflon another suitable material, or a combination of these materials. The four members of the connecting element **25** have different lengths to allow for proper alignment and seating within the stomach. Figure 37B depicts how during peristalsis, the stomach will contract and its profile will reduce. The bariatric device **10** may shift and flex within the stomach, but the self expansion feature allows it to spring open and maintain its general position correctly. The connecting element **25** could have a pre-curved bend to form a living hinge to direct where the element to flex during peristalsis as shown in 37B.

[00168] As shown in Figs 37A and 37B, a preferred embodiment of the cardiac element **12** may be a substantially flattened frusto-conical shape, defining a substantially circular opening that is adapted to correspond to the esophageal/cardiac opening of a stomach. Those figures also show that a preferred embodiment of the pyloric element **26** may be a steep frusto-conical shape, or a tapered cylinder, which is adapted to fit the pyloric region **42** of the stomach, and preferably sized so that it does not migrate past the pyloric valve **18**. As discussed above, these elements may have a wide variety of shapes or may be inflatable, and these are only examples

[00169] The four connecting members may be constructed from 2 full loops or 2 loops connected together to create a "figure 8" structure. The loops could be contoured to

generally follow the curves of the stomach, and could be connected to the pyloric and cardiac elements **26, 12** in a variety of locations. The loops could be oriented to intersect at a variety of locations to provide different configurations with varying structural resistance and flexure points. For example, Figs. 38A and 38B depict a bariatric device **10** where there are 2 separate closed loops **51** and the loops **51** are crossed in the pyloric element **26** so that the wires do not obstruct the distal opening of the element. The loops **51** are then aligned in a parallel pattern where they are attached to the cardiac element **12**. This allows the cardiac element **12** to follow the contours of the loops **51** even when the device **10** is laid flat and the loops **51** are compressed together as could be the case inside the stomach. This could allow for more uniform curved contact of the cardiac element **12** with the cardia **40** and adjacent fundus **41**. The parallel orientation of the loops **51** along the cardiac element **12** would provide less resistance of the device **10** just below the GE junction for a more gentle response.

[00170] In another embodiment, the 2 loops **52** are connected in a "Figure 8" pattern where the loops are **52** crossed in the pyloric element **26** and do not obstruct the distal opening of the pyloric element **26**. See Fig. 39. The loops **52** cross again just below the opening of the cardiac element **12**, which allows the cardiac element **12** to flare more when the device **10** is laid flat and the loops **52** are compressed together such as could be the case inside the stomach. This could allow for more focused, linear contact of the cardiac element **12** with the cardia **40** and adjacent fundus **41** in the stomach. The cross of the loops **52** below the opening of the cardiac element **12** would provide more structural strength of the device **10** just below the GE junction **38** for more acute response. To

increase the acute response, a stiffening member such as a wire loop or other could be added cardiac element **12** to direct stiffness in a desired area. Fig. 39 shows one possible orientation for a stiffening member, but other orientations, shapes and additional members could be added to generate a specific response.

[00171] Where the connecting element **25** is formed from loops, the loops could be formed from Nitinol wire and then coated in an acid-resistant coating **53** such as silicone or silicone covering. These loops could also be made of stainless steel, teflons or other suitable materials or combinations of materials. The loops could be closed or connected in a variety of ways. For the example of Nitinol, the loops could be closed by a glue joint where the wire loop ends are glued inside of another tube. They could also be closed by a crimping, swaging, or welding. The loops could also be left open, if a feature is added for adjustability and it is preferred to have the loops open with both ends fixed to the elements as needed.

[00172] The contact members of the elements may be comprised of a variety of materials. For example, the Nitinol wire pattern of the cardiac, pyloric, and or connecting and/or positioning elements **12, 26, 25, 13** may be exposed for direct contact with the stomach or the wire could be covered or sealed in another material, such as silicone, PTFE, polyurethane or other suitable materials. For example, Figure 40A depicts a pyloric element **26** where the wire mesh **50** is covered in another material to create a smooth surface for the contact member **54** to facilitate sliding within the stomach. Alternatively, Figure 40B shows the wire exposed to the stomach mucosa surface. This shows how the wire array **50** could be arranged and formed to add a wavy pattern to

increase to profile of the wire above the element's nominal surface, which in this case is shown as a cone with the wire protruding above the cones surface. This would allow the wire to act as a macro texture surface for the contact member **54** to grip the stomach surface to reduce sliding or it could provide a macro texture for tissue ingrowths. The Nitinol may be treated with a surface finish, passivation or coating to improve its acid resistance within the stomach.

[00173] The contact and stiffening members of the elements may be separate, entirely integrated, or both. For example, if a cardiac element **12** is made entirely of Nitinol wire, the wire acts as both a contact member and a stiffening member. The same would apply if an element were made entirely of silicone; the silicone would act as both a stiffening and contact member. In another embodiment, where Nitinol wire is embedded in another material such as silicone, the Nitinol wire acts as a stiffening member and the silicone acts as a contact member. In another embodiment, the Nitinol wire may be partially exposed and partially covered by the silicone (and/or on the interior of the element), in which case the Nitinol wire acts as both a stiffening and contact member. In certain embodiments, the combination of materials may act as a stiffening member. For example, an embodiment where the contact member is silicone with Nitinol wire embedded, the silicone may act in conjunction with the Nitinol to provide more stiffness than the Nitinol could achieve alone. Various combinations of stiffening and contact members may be apparent to those skilled in the art.

[00174] Yet another embodiment with self expanding features is depicted in Figure 41. In this embodiment, the cardiac, pyloric, and connecting elements **12**, **26**, **25** are all

combined into a single unit, which contours to follow the general shape of the stomach but designed to maintain outwardly biasing pressure at upper and lower stomach regions. The self expansion feature will allow the device **10** to flex and give during peristalsis, but would allow the device **10** to spring open to maintain its position and function. The wire array **55** could be designed to encourage more expansion in one area than in another, or be stiffer in one area or another, to further improve the function of the device **10**.

[00175] Yet another embodiment with self expanding features is depicted in Figure 42A, where the cardiac, pyloric, and connecting elements **12**, **26**, **25** all have self expanding portions. The cardiac and pyloric elements **12, 26** are generally frusto-conical in shape and contain a Nitinol wire pattern **50** for radial and longitudinal expansion. The connecting element **25** is also self expanding and connects the cardiac and pyloric elements **12, 26**. The connecting element **25** can compress and expand to maintain and appropriate amount of pressure on the upper and lower stomach and to maintain the device **10**'s position. The connecting element **25** could be just a bare Nitinol wire array **50** or it could be covered with silicone or other suitable material(s). As described for previous embodiments, the connecting element **25** could match the greater or lesser curve **16**, or go down the center of the stomach or be a combination of both. Covering the device **10** with another material could constrain the compressibility of the length of the device **10**, which may be desirable in order to achieve pressure and/or contact at various portions of the stomach. There may also be another member down the center of the Nitinol tubular array **56** to increase stiffness and to adjust the length. Figure 42B shows the connecting element **25** made up of a wire array **56** at rest. Figures 42C and 42D show how the length of this element **25** may be

adjusted to elongate the length. Adjustability of the length would allow the device **10** to be adjusted to custom fit the device **10** to the patient. Figure 42C shows how an additional ring or feature **57** could be applied to the outside of the tube to reduce the diameter and increase the length. Figure 42D shows how a pin or clip **58** may be placed inside the mesh array **56** to increase the length which subsequently would reduce the diameter. These adjustability features could be applied to any of the self expanding features.

[00176] Figure 43 shows a similar embodiment to above but shows that the connecting element **25** could contain multiple self expanding members **59**. This figure shows one member **59** along the lesser curve **16** and two members **59** along the midline between the lesser and greater curves **16**, **17**, which contact the anterior and posterial surfaces of the stomach walls. These could all contain expansion features as mentioned above. Although Figure 43 depicts three members **59** in the connecting element **25**, it could contain two, four, or any number of members. These members could match the lesser curve **16**, greater curve **17**, stomach midline or all any combination of these.

[00177] As mentioned above, a preferred device **10** has adjustability or adaptability to match any changes in the patient over time. A variation of the above embodiments would be to allow the device **10** to be adjustable via an adjustment element **60**. This adjustability could be in the length, shape, angle or stiffness of the cardiac, pyloric, connecting, and/or positioning elements **12, 26, 25, 13**.

[00178] The bariatric device **10** could be adjustable to allow for adjustment at the time of placement or could be adjusted at a later time. This adjustability could be achieved by having a variable spring tension in one of the elements to allow the device **10** to extend,

contract, or distort as needed. It could also be achieved by adding an expansion joint **75** in a member to elongate or compress as needed. This expansion could be a manual adjustment performed by the physician in the office through a gastroscopic procedure. This expansion could be achieved by various mechanisms, including but not limited to those operated by: rotating a threaded member, ratcheting backwards or forwards, a hydraulic mechanism, a pneumatic mechanism, a cam, a tension mechanism, a telescoping mechanism or other elongation or contraction mechanisms. The outer surface of the connecting element **25** and/or positioning element **13** is preferably smooth with rounded or gently angled edges to prevent irritation of the stomach during peristalsis, although sharp angles may be preferred in some applications. To create a smooth interface, these elements could be encased in a sleeve or sheath that could be removed or remained fixed during the expansion. A sheath may not be required if the expansion joint **75** is designed with smooth contours on its own.

[00179] Manual Actuation

[00180] The device **10** could also be adjusted by manual means inside the stomach by using a gastroscopic instrument to come into direct contact with the device **10**.

[00181] The instrument could also act as a pusher or puller to activate a pulley mechanism or a clipping mechanism. For example, the positioning and/or connecting element 13, **25** could be a ratchet or strut with multiple positional features such as holes, grooves, teeth or wedging action. The device **10** could have a feature to engage the ratchet teeth or positional features such as a pin or clip or

other. The instrument could retract the pin or compress the clip and then reposition this feature in the next available location.

[00182] In another embodiment, the members of the connecting element **25** could have multiple beads or spheres **62** that are captured by a cuff or ring retainer on the cardiac element **12**. An instrument could be used to expand the cuff to pull the bead through for positioning. Similarly, the cuff could have a keyway retainer feature that allows the bead to only fit through a specific location and then lock into position where the beads connect to the wire or ribbon or tube.

[00183] Figs. 44A and 44B, shows a similar feature in the pyloric element **26** where the adjustment element **60** is a single wire. Figs. 45A and 45B shows an adjustment element **60** in the pyloric element **26** where there could be a full loop **64** that has expansion features on both sides of the loop **64**. These features could be beads or clips **62** that can be pulled through a mechanical feature such as a hole or strap retainer **63** and held in place. Figs. 46A, 46B, 46C, 46D, and 46E show side views and top views of optional retaining features **63** that allow for expansion to let a bead or arrowhead **62** pass, but then close to hold the feature in position.

[00184] Fig. 47A, 47B, 47C and 47D shows several examples of compressible clips **65** acting as a "bead" or positional feature that could be used for adjustability. For example a retainer strap **63** of silicone could be bonded on both sides to create a narrow passageway **66** where the clip **65**

could be placed in the compressed position, and then expand open after passing through the strap **63** to maintain its position. Several straps **63** could be bonded in a row to create several positional locations. Fig. 47B and 47D shows the clip **65** in is open, relaxed state, where 47C shows the clip **65** in a compressed state where it can pass through the retainer strap **63**.

[00185] Fig. 48 shows an adjustment element **60** with another option for adjustability where one or more compressible clips **67** are added to one of the connecting element members which has several positional locations. A clip retainer fixed to one side of the connecting element **25** could be compressed to open the clip **67** and then advance it over the positional features such as a bead **62**, and then allow it to spring closed to fix the location of the device **10**. Fig. 49A and 50A show the clips **67** in their relaxed, closed positions where 49B and 50B show the clips **67** in their compressed, open positions sufficient to let the bead **62** pass. Figs. 51A and 51B show options for a keyway for translational adjustability.

[00186] Figs. 52A and 52B depict another option for adjustability where a locking ring **69** is used to fix the location of the connecting loops **70** into the pyloric element **26**. The pyloric element **26** could have several positional features **71** connected to it. The loop **70** could also have several positional features **72** attached to it. When the positional features of the pyloric element **72** and connecting loop **70** are aligned, a locking ring **69** could be placed inside to hold the position of the elements together and to

alter the length of the whole device **10** to be longer or shorter. In another embodiment shown in Figs. 53 and 54, the ring **69** could be fixed to the pyloric element **26** and compressed to capture the positional features **72** located along the connecting element **25**.

[00187] In another embodiment, an instrument could act as a screw driver to rotate a member to thread the two elements **73** closer or farther apart. See Fig. 55.

[00188] The instrument could also have a needle to inject fluid into an inflation element **74**. Such an element may be a self sealing membrane to increase or decrease the length, diameter or stiffness through positive displacement of an expandable body. The self sealing membrane could be an injection port or it could be a self sealing surface on the expandable body, or the entire expandable body could be comprised of a self sealing surface. In all descriptions below, the term inflation element **74** can also refer to an injection port or to an area on the expandable body with a self sealing membrane. The self sealing membrane could also be a self sealing valve which can be accessed by a blunt needle or tube to allow access to add or remove fluid. Fig. 56 shows an inflation element **74** fixed to the pyloric element **26** or the connecting element **25**. This valve or port could be connected by a fluidic path to an expandable body such as a sealed inflatable body inside of an expansion joint **75** such as a piston and cylinder. The valve could be accessed by an endoscopic instrument with a blunt end, while an injection port could be accessed by an endoscopic instrument with a non-coring needle where saline or other suitable fluid could be injected or removed from the port which

would allow the inflatable body to expand or contract to control the length of expansion. Although this figure shows one expansion joint **75**, the device **10** could contain one or more with a manifold set up to deliver fluid from the port to all of the expansion joints. In an alternative embodiment, the system could also have an expandable body such as a syringe type joint which would not require a sealed internal inflatable body.

[00189] In another embodiment, the cardiac and/or pyloric element(s) **12**, **26** could be equipped with one or more inflatable bodies, to increase or decrease the size of those element(s). For example, in Fig. 57, an inflatable body **76** is depicted atop the cardiac element **12**, with an inflation element **74** such as a valve or an injection port on the connecting element **25**. Inflating fluid, which could be saline, water, air, or other suitable substances, may be inserted or removed through the inflation element **74** to increase or decrease the size of the inflatable body **76**. In such manner, the amount of contact and/or pressure imparted by the cardiac element **12** on the cardiac region **40** and/or the upper region of the stomach may be adjusted, either while the device **10** is in the stomach, or prior to placement. This balloon could cover the entire cardiac surface or could only cover portions of the cardiac surface to direct the inflation for a specific response. There may be one or more inflatable portions on the cardiac element **12**. Fig. 57 also depicts a similar inflatable body **77** on the outside surface of the pyloric element **26**. This could be accessed in the same manner as the cardiac inflatable body described above. Similarly, the inflatable body **77** could cover the whole surface of the pyloric

element or could be have a portion or multiple portions for a desired effect. Figs. 58A and 58B, shows a linearly inflatable body **78** on the bottom or distal surface of the pyloric element **26** to primarily allow for elongation of the element. The device **10** could contain linear and radial inflatable bodies.

[00190] A gastroscopic instrument could also deliver heat directly to an expandable body such as a heat expanding mechanism (such as one made of Nitinol) for expansion of a wax or wax-like expansion member.

[00191] For example, a Nitinol clip could clip into a positional location on a strut. The instrument could heat the clip to release and then reposition it into a different location, remove the heat and allow the clip to re-engage the positional feature to lock it into place.

[00192] The instrument could also have an inflatable body or a balloon to allow for physical contact with the device **10** to disengage a feature for repositioning into another location.

[00193] Magnetic actuation. Another adjustment mechanism could use magnets. See Figs. 59, 60, and 61A and 61B.

[00194] For example, the positioning and/or connecting element 13, **25** could contain a thread with a magnetic nut **79** placed over it. Another strong magnet, the controller magnet **80**, could be placed in close proximity to the implanted magnet to cause it to rotate. The rotation of the controller magnet **80** could create a magnetic field which would cause the internal

magnet **79** to turn allowing it to advance and retreat along the threaded member **81**.

[00195] The controller magnet **80** could either be external to the body or it could be placed on the end of a gastroscopic instrument for close proximity.

[00196] The controller magnet could be a magnet or an electromagnet to increase the intensity of the field and to improve magnetic coupling to ensure actuation.

[00197] The controller magnet **80** could also be multiple magnets to improve magnetic coupling.

[00198] Another means of manually adjusting the length of the device **10** would be to have modular pieces that could attach or adhere to the cardiac or pyloric elements **12**, **26**. For example, an additional frusto-cone **82** could be placed over the pyloric element **26** to increase the length of the overall design. Several could be stacked together to create a variety of lengths. See Figs. 62, 63 and 64. Stacking frusto-cones **82** could also be distanced from one another with a balloon on either frusto-cone to increase the distance between the two.

[00199] A variation of this embodiment would be to have an additional member that could be collapsible or compressible and inserted down the center of the pyloric element **26**. Once it passes the pyloric element distal surface **83**, the modular element **82** would expand and attach to the outer surface. Several

modular elements **82** could be stacked together to create a variety of lengths. See Figs. 62 and 63.

[00200] An alternative embodiment could have an additional element that could also pass down the center of the pyloric element **26** and expand past the distal surface **83**, but with a clip **84** that would allow it to remain clipped to the inside surface. See Fig. 64. The attachment mechanism could be positionally based so that the element could be repositioned to several locations for a variety of lengths.

[00201] There could be several other means for manually actuating the design for repositioning.

[00202] As another variation of the above embodiments, the manual expansion mechanism could be adjusted remotely by an apparatus outside the body, and/or automated. The expansion could be achieved by a small motor that could be driven by an implanted power source or driven by a remote power source such as induction. The automated expansion could also be achieved by a pump, a syringe type plunger, a piezoelectric crystal, a bellows, a Nitinol motor, a pH responsive material that changes shape, thermal expansion of a gas, fluid or solid (example wax) expansion, magnet forces or any other type automated expansion or compression mechanism.

[00203] The control for activating this mechanism could be a remote control using a radiofrequency signal which can pass through tissue. The remote control could also be achieved by magnetic fields, time varying magnetic fields, radio waves, temperature

variation, external pressure, pressure during swallowing, pH of any frequency or any other type of remote control mechanism.

[00204] Actuation Mechanisms

[00205] Stepper Motor:

[00206] To adjust the length of the positioning and/or connecting element 13, **25** to increase the direct force onto the upper stomach or cardia **40**, the adjusting element could be the positioning and/or connecting element 13, **25** entirely or partially comprised of a flexible, semi-flexible or rigid screw. A stepper motor **85** could be placed onto the flexible thread and could drive forward or back to allow the positioning and/or connecting element 13, **25** to draw together or push apart the elements. See Figs. 65 and 55. These figures represent a threaded element that can be drawn together or apart.

[00207] The adjusting element may require power to drive the motor **85**. The power could be supplied by an implanted power source such as a battery or it could be powered externally by induction through the coupling of an external antenna and an internal antenna.

[00208] An option would be to embed the internal antenna into any or all of the elements. This would allow for fewer structures in the design by encasing the antenna inside of one or more of the existing elements. The antenna could be a simple ring at the top or bottom or obliquely on either element or it could be placed in the wall of the device **10**. The internal antenna could also be attached by a tether, free floating inside the

esophagus, stomach or intestine. These could be made from materials to make them MRI compatible and/or MRI safe. This feature could be applied towards any actuation method where it is powered by induction.

[00209] For induction, an external hand held controller **86** may be required to transmit power for coupling. See Figs. 66 and 67. The controller **86** could be set up to auto detect the internal antenna's presence and identify when coupling between the two antennas was adequate to allow for transmission and powering to take place, and to inform the user of function. This external controller **86** could then be used to display the distance that the stepper motor **85** had been advanced or retracted to allow the physician to control the adjustment. Similarly, the external controller **86** could be used for communication and control signals as an interface between the physician and the placed device **10**. This feature could be applied towards any actuation method powered by induction.

[00210] An external antenna would be required for induction and could be placed into an external handheld controller **86**. This could be placed directly against or close to the patient's body at the height of the internal bariatric device **10**. The antenna could be housed with the other controller electronics in a single unit. This feature could be applied towards any actuation method powered by induction.

[00211] Another alternative would be to have the external antenna in the form of a belt **87** that would wrap around the patients abdomen at the

height of the device **10** to better align the antennas for improved coupling. This feature could be applied towards any actuation method powered by induction. See Fig. 67.

[00212] The location of the actuation mechanism could also be inside any of the elements, or above or below any of them, or another location as would be best suited for the anatomy and function of the device **10**. This feature could be applied towards any actuation method. Actuation could be accomplished by allowing the screw to be pushed or pulled inside any of the elements to embed the adjustment mechanism internally to one of the other elements. Other actuations mechanisms such as those listed above or others could also be used for this adjustment.

[00213] Induction could also be powered by an intragastric instrument. The instrument could have a flexible shaft that could fit through the mouth and down the esophagus or down the working channel of a gastroscope. Once the instrument was placed within or near the esophagus or stomach, it would allow the instrument to be in close proximity with the actuation mechanism in the device **10**. The end of the instrument could have antenna(e) to allow for inductive powering and/or communication with the actuation mechanism for adjustment. This feature could be applied towards any actuation method.

[00214] Piezoelectric motor

[00215] The adjustment could also be achieved by a piezoelectric element or motor **85**. See Figs. 65 and 55. These figures represent a threaded element that can be drawn together or apart.

[00216] There are several types of piezomotors that could be used for linear actuation. For example, a motor from NewScale Technologies (www.newscaletech.com) called the Squiggle Motor could be used which is very low profile and can be actuated when powered. Other motors or actuation mechanisms could also be used, and the Squiggle motor is just used as an example. In this example, there is a rigid screw that passes through the center of a threaded piezoelectric "tube" or element. When powered the piezoelectric element flexes side to side along the central axis to create an oscillating "hula hoop" action which causes it to translate axially along the rigid screw. The Squiggle motor could be attached to the positioning and/or connecting element 13, **25** to advance or retract the cardiac and/or the pyloric element **12**, **26**. Alternatively, the Squiggle motor could be placed in between any of the elements. Alternatively, more than one Squiggle motor could be placed at these locations. One of the advantages of a piezoelectric motor **85** is that it would allow the device **10** to be MRI compatible and safe. As mentioned with the stepper motor **85** above, the piezoelectric motor **85** could be powered by an internal power source such as a battery or it could be powered by remote induction. The remote induction could be by a handheld external controller or it could be by a gastroscopic instrument placed down the esophagus. This motor could be encased in other materials to keep it dry and protected from the stomach environment.

[00217] Another embodiment of a piezoelectric actuated motor **85** would be to have a rotating piezoelectric member that could thread along one or two threaded members similar to a worm gear.

[00218] Another embodiment of a piezoelectric actuated motor **85** would be to have a piezoelectric crystal that elongates or flexes to actuate another member.

[00219] All of the piezoelectric motors **85** may contain a sealed housing such as an expandable metal or plastic bellows to prevent moisture of fluid from contacting the piezoelectric elements.

[00220] Magnetic actuation

[00221] As mentioned above in the manual adjustment section, another adjustment mechanism could use magnets.

[00222] For example, at least a portion of the second element could be a semi-flexible thread or rigid thread with a magnetic nut placed over it. Another strong magnet, named a controller magnet **80**, could be placed in close proximity to the implanted magnet to cause it to rotate. The rotation of the controller magnet **80** could create a magnetic field which would cause the internal magnet to turn allowing it to advance and retract along the threaded member.

[00223] The controller magnet **80** could either be external to the body or it could be placed on the end of a gastroscopic instrument for close proximity.

[00224] The controller magnet **80** could be a magnet or an electromagnet to increase the intensity of the field and to improve magnetic coupling to ensure actuation.

[00225] The controller magnet **80** could also be multiple magnets to improve magnetic coupling.

[00226] Nitinol Actuation

[00227] The adjustment element could also be actuated by Nitinol or a substance with similar properties. When a current is passed through Nitinol, it heats and causes the Nitinol to change its shape. Nitinol can expand into a variety of different shapes. A linear actuator could be made from Nitinol to advance or retract along an actuation member.

[00228] Heat could be generated from an implanted battery or it could be delivered by induction.

[00229] The second element could have multiple positional features such as holes, grooves, teeth or a wedging feature. A Nitinol clip could have a feature to engage these positional features. The Nitinol clip could be heated to change shape to allow it to advance or retract into different positional features to increase or decrease the length.

[00230] There are other Nitinol actuations that could be provided as well.

[00231] Ultrasound motor

[00232] Another adjustment mechanism could be by use of an ultrasound motor or one powered by external ultrasound. This could use external ultrasound equipment to send sonic waves into the body to actuate the motor. This would also provide an MRI compatible option without requiring an internal power source or induction.

[00233] Hydraulic actuation

[00234] The adjustment element **60** could also be actuated through hydraulic means for radial expansion or linear actuation as previously described. The cardiac or pyloric element **12**, **26** could be inflated with a fluid to increase the diameter or length of the device **10** to increase pressures against the upper stomach or cardia **40**, and pyloric region **42**. It could increase in volume by accessing a self sealing membrane such as a self sealing drug delivery port, self sealing membrane on the expandable body, or a self sealing valve attached to the device **10**. The inflation could be achieved by a piezoelectric pump, a peristaltic pump, a positive displacement pump or a syringe pump.

[00235] Piezoelectric pump: The pump could be comprised of a piezoelectric element which can flex to propel fluid directly or a member that could propel fluid. For example, a piezoelectric disk could be captured in a housing with an incoming channel and an outgoing channel. The disk could be powered to cause it to flex into a dome shape to push fluid into the outgoing channel. A valve would be required to close the incoming channel to ensure directional flow to the outgoing channel. Similarly, the

piezoelectric Squiggle motor as described above could be used to linearly actuate a fluid up or down a tube to hydraulically actuate position.

[00236] Stepper motor pump: Actuation could be achieved by a stepper motor where the motor linearly actuates to compress a reservoir or syringe to move fluid within a tube or constrained volume.

[00237] Wax expansion pump: Fluid could also be propelled by a wax expansion mechanism. When wax is heated to melting it expands by approximately 30%. A solid plug of wax could be heated to expand and drive fluid through a valve to hydraulically actuate lengthening. The lengthening structure could be made to move only in one direction, so that when the wax cools it will not contract. The wax expansion could also be used to actuate other adjustment mechanisms.

[00238] Peristaltic pump: The members could also be driven by a peristaltic pump. In this mechanism, the external diameter of a cylindrical actuator could be used to compress a length of tubing to create an occlusion. The cylindrical actuator could be rotated along the tube to drive fluid forward or backwards inside the tube. The peristaltic pump could also be actuated by a stepper motor or by a piezoelectric element or other.

[00239] Gas expansion / propellant pump: The length could also be actuated by a gas expansion pump where a gas like Freon or others could be used to expand when exposed to a higher temperature. Similar principles to the devices like the Codman pump could be used. This change in volume

could drive the pump forward. Similarly, there could be compressed gas constrained in a pressure vessel with a valve. The valve could be remotely activated to allow gas to propel a syringe, fluid or to compress a constrained volume.

[00240] Positive displacement pump: There are implant grade positive displacement pumps that are available on the market for drug delivery that could be used to displace a specific amount of fluid for hydraulic inflation of the adjustment element **60**.

[00241] Syringe pump: A syringe pump could be made by advancing fluid through a syringe. The syringe could be actuated by a stepper motor, a piezoelectric actuator, a magnet or by a Nitinol actuator as described above.

[00242] Hydrogel: the adjustment element could also be inflated by use of a hydrogel to absorb fluids and could be actuated by changes in temperature, pH or tonicity to change shape or volume

[00243] Hypertonic fluid: the adjustment element **60** could also be inflated by using a hypertonic fluid in the inflation area and allowing it to absorb fluid across a semi permeable membrane.

[00244] Mechanical means for diametrical changes. Similar to the inflation, elongation, and shortening embodiments described above, the device **10** could change diameter by various actuation mechanisms. All of the above-described mechanisms could also be adapted for use for a diametric change instead of a linear change.

[00245] As a variation of the embodiments discussed above, the device **10** could have a sensor **88** that could sense a parameter such as pressure, motion, peristalsis, tension, pH, temperature, or other appropriate parameters, or various parameter combinations. The sensor **88** could output a signal to be used by an actuation element to actuate an adjustment element, to a memory element such as a microchip, or be read by a remote reader or remote controller.

[00246] Sensors **88** could be used to gather important patient data to understand performance, patient status or whether an adjustment needs to be performed. For ease of use and compatibility with the body, wireless sensors would be preferred. The sensors **88** could be direct tissue contact, intermittent patient contact or could monitor the intraluminal pressure inside GI tract. The data could be used for no other reason than to just monitor patient status. Figs. 68 and 69 depict sensors **88**, which could be embedded in any of the elements or it could be tethered to any of the elements to allow it to be suspended inside the GI tract. Based on the sensed parameter, the device **10** could be adjusted. The adjustment could have an open or closed loop system increasing or decreasing the applied force, pressure or sensed parameter. The sensed parameter could detect whether the device **10** was not at an ideal condition, and could then send a signal to a control mechanism for automatically adjusting the system. This mechanism could be under physician control (open system) or without physician control (closed system). It could also control the shape of the cardiac, pyloric, connecting, and/or positioning elements **12, 26, 25, 13** to vary stiffness, size, length, form or shape. In general, the sensor **88** could sense a parameter and then adjust the device **10** as needed to bring the sensed parameter into the ideal range.

There could be an algorithm that controls the ideal parameter or it could be based on a parameter range. The device **10** would be adjustable to meet the needs of the patient.

[00247] In an open loop system, the physician would have control of when the device **10** would adjust. The device **10** could be passive and only inductively powered when in close proximity to an external controller under the supervision of a physician. For example, in the clinic the physician could have a remote controller with the ability of powering the device **10** inductively, and then begin to monitor the sensors feedback signals to see physical parameters of the patient at baseline such as pressure of the device **10** against the cardia. The sensor monitoring could also be performed while the patient is eating or drinking, or not eating or drinking. As the patient consumes, the esophageal and stomach peristaltic waves will increase in intensity as they propel the food or drink from the mouth to the stomach. A sensor **88** could detect when these waves increase in amplitude, frequency, and pressure. The parameter could read on the external controller by the physician, and then the physician could send a signal to the automated expansion mechanism in the device **10** to adjust the device. The physician could then query the sensor **88** again to determine whether the device **10** was in the ideal settings and whether the pressure against the cardia or sensed parameter was optimized. The physician could iteratively control the amount of adjustment and monitor the parameters until the ideal condition was met.

[00248] Alternatively, the physician could read the parameter signals while under his supervision, but have the sensors **88** send a signal directly to the automated expansion mechanism to adjust until the device **10** was within the ideal parameters. The data collected

could be analyzed by the controller for averages, minimums, maximums and standard deviations over time and use an algorithm to determine the ideal settings. The controller could then monitor and adjust on its own until the ideal conditions were met, but while the physician was present to verify all conditions and verify patient acceptance.

[00249] In a closed loop system, the device **10** would be active with its own integrated power source. The device **10** could wake up at routine intervals to monitor or could monitor all the time. The data collected could be analyzed for averages, minimums, maximums and standard deviations over time and use an algorithm to determine the ideal settings. As the patient begins to consume food or drink, the device sensors **88** would detect the sensed parameter and signal the automated expansion/contraction mechanism to adjust the device **10** as needed. In this embodiment, the device **10** could be fully automated and would not require intervention from an outside individual.

[00250] In either the open or closed loop system, there could be multiple sensors **88** on the device **10** to determine the pressure or force areas, or other sensed parameters on the device **10** and where it needs to be varied to meet the ideal conditions for the stomach. In the case where the positioning and/or connecting element 13, **25** has multiple components, this could be used to align the device **10** in the stomach to provide a custom fit for each person. There could also be a mechanism to adjust the alignment of the cardiac and/or pyloric elements **12, 26** relative to the connecting and/or positioning element **25, 13**. The sensor(s) **88** could have a built in power source or it could have a remote power source such as induction so that it would only wake up and activate when an external controller was brought near.

[00251] The device **10** could have integrated memory to allow storage of patient and device **10** data. This could include but is not limited to the serial number, the patient's information such as name, patient number, height, weight; the physician's name, the adjustment history including the date and time, the amount adjustment and the sensed parameters. For the active device, there could be 24 hour data recording of key parameters or there could be data collected at key intervals throughout the day to detect when the patient is eating and whether they are being compliant with their eating. It could record weight tracking, BMI or other data as needed which could be queried by an external controller. This data could also be downloaded into a physician's patient tracking database for ease of patient tracking. Similarly, this data could be downloaded and tracked on an internet tracking website, where the patient could log on and see their history and progress. The patient could add information to the website such as weight or an eating log, adverse events or other conditions that the physician or patient would like to track.

[00252] In the open system, the physician could choose to collect and record data as needed at the time of the adjustment such as weight, date, time, and adjustment amount or other.

[00253] For an open loop system, the device **10** could be adapted to allow for remote adjustments over the phone. This would be especially advantageous for patients living in rural areas where they are far from their physician's office. It could also be for convenience of having an adjustment without having to travel to the physician's office. This would allow a physician to discuss the patient's progress with the patient directly and

then query the device sensor **88** to see how the device performance is. Based on the feedback of the device **10**, the physician could then adjust the patient.

[00254] In yet another embodiment, the device **10** could have an emitter element for dispensing a drug, hormone or bioactive agent to further induce satiety, weight management or other disease management such as diabetes. The drug could be a weight management drug currently on the market or one to be developed. Similarly, it could be a satiety hormone or other bioactive agent. In the published literature, there is a growing mass of information on satiety hormones. The bioactive agent could be applied by the emitter element through a drug eluting coating, a reservoir with a pump, or a permeable membrane placed on the device **10** where the drugs could pass from the device **10** into the gut. The emitter element could release such substances in response to a signal from a sensor **88**, a timed basis, or other release criteria. The device **10** could have a tube that trails into the intestines to allow the drug to be delivered downstream where the pH is higher and would not destroy the bioactive agent.

[00255] The device **10** could have a surface finish or macrotexture for gripping the stomach. If the device **10** could grip the inner mucosa of the stomach, it could elongate or expand to further stretch the stomach in key areas to induce further satiety as needed. For example, the cardiac element **12** could be a conical spiral with a surface texture that lightly grips the mucosa and or stomach musculature. If the spiral were made of Nitinol or other temperature-sensitive substance, the device **10** could expand the spiral by a variation of temperature. By applying a temperature variation, such as by drinking a hot liquid or otherwise, the device **10** could expand and cause a satiety response. The surface could be

multiple protuberances, barbs, a rough bead blast, or other finishes suitable for gripping the stomach wall.

[00256] The device **10** could have a thin flexible tube **89** attached to the pyloric element **26** that could trail into the duodenum **19** to act as a barrier to food absorption. See Fig.70. This tube **89** would be of similar diameter to the duodenum **19** and all food passing through the pyloric element **26** would pass directly into this sleeve. Similar to the rerouting performed in a gastric bypass or Roux en Y bypass, the sleeve **89** would be approximately 100cm long, but could be longer or shorter depending on the amount of malabsorption required. This tube **89** may be made of an acid resistant material such as Teflon, PTFE, ePTFE, FEP, silicone, elastomers or other acid resistant materials.

[00257] As a variation of the device **10**, it could incorporate electrical stimulation to the stomach musculature, stomach nerves or the vagus to further improve satiety stimulation and weight loss. Energy used for this stimulation could be RF, ultrasound, microwave cryogenic, laser, light, electrical, mechanical or thermal. The device **10** could have leads incorporated that could embed into the stomach wall or be surgically placed around a nerve, or the stimulation could be applied directly through surface contact of the device **10** to the stomach mucosa.

[00258] In yet another embodiment, the bariatric device **10** may have an adjustment element **60** that is equipped with a temporary expansion/contraction element **90** that may allow for temporary adjustment based on activation of a material property, sensor **88** or mechanism of the device **10**. This could be applied to any of the above-discussed embodiments. See Figs. 71A, 71B, 72A, 72B, 73A, and 73B. It may be desirable for the

temporary expansion/contraction element **90** to adjust only upon eating, and then retract after eating. It may be desirable for the device **10** to adjust with the pH cycle of the patient where pH will be higher prior to eating and then lower after eating. This would allow for intermittent stimulation of the stretch receptors to avoid receptor fatigue over time. For example, the material could be heat sensitive using materials such as Nitinol, which could expand after consuming a hot liquid. Similarly, the device **10** could have a sensor **88** or material that is pH or glucose sensitive or detect the presence of food, which could activate the temporary expansion/contraction element **90** to expand when a certain threshold for pH has been reached or glucose or fat is present after eating. Similarly, this temporary expansion/contraction element **90** could be activated by a magnetic field such as swallowing a magnetic pill that could temporarily expand the device **10**. In this example, the magnetic pill would be small enough and shaped appropriately for passage through the gastrointestinal tract, and biocompatible. The patient could consume the electromagnetic pill when a satiety signal was desired. It may also be desirable for the device **10** to adjust based on time or sleep cycle such that the device **10** adjusts at specific times of the day or when the patient lays horizontal. Other parameters or mechanisms to trigger the temporary expansion could be used.

[00259] Placement

[00260] As mentioned above, a tube, catheter, or sheath may be required to protect the anatomy during placement of the device **10** down the esophagus and into the stomach. It could be a simple flexible tube such as silicone or urethane tube to aid in straightening and compressing the device **10** while it is being introduced. Insertion of the device **10** into the

tube would require compression of the device **10** into a narrow, insertable shape. A standard gastroscopic tool could be used to push or pull the device **10** down the tube. Similarly, a custom gastroscopic tool or sheath could be used to introduce the device **10** into the stomach through the esophagus or other narrow opening.

[00261] A delivery sheath **91** may be used to insert the device **10** though the esophagus **32** or other narrow opening into the stomach for placement. In one such embodiment, a lightweight fabric, sheeting or material **92** may be used for the sheath **91**, made of a suitable material that is thin, flexible, soft, smooth, compliant, adequately lubricious to slide down the esophagus **32** and adequately strong to hold the device **10** in a compressed state **93** such as fabrics made from polymers such as nylon, teflons, eptfe, polyester, or polymer coated fabrics such as ptfe coated cotton or other fabrics or other sheeting materials. Although a fabric could be used for the material **92**, other substances may be used, such as silicone, polyurethane, thin walled plastic or other suitable substances. First, the bariatric device **10** may be compressed into a narrow shape to fit inside the sheath **91**, and held in a compressed state by a tube, fixtures, or the like. Then the material **92** may be draped around the compressed device **10** lengthwise, and secured in a closed position with a deployment member **94**. The material **92** could also be closed with a deployment member **94** and the collapsed device **93** then inserted inside the closed sheath **91**. The deployment member **94** could be a small gauge wire or lace placed in a single straight stitch along the length of the material **92** around the compressed device **93**, as shown in Figs. 74 and 75. The deployment member **94** may be of any of a variety of suitable materials. In a preferred embodiment, the deployment member **94** is a single thin wire,

preferably capable of holding its original shape even after being bent. Such wire could be made of Nitinol, spring steel, small diameter braided cable or spiral wound guide wire, or other suitable material. Although a deformable wire could be used, it may be more difficult to remove for placement if the bends become too extreme during handling. The deployment member **94** may also be thread material, such silk, rayon, nylon, polyester, eptfe thread, ptfe coated thread and the like. The deployment member **94** may be terminated by stitching the deployment member **94** around the distal end (the end inserted into the body first) of the material **92** to close the distal end of the sheath **91**, and turned back around and inserted inside the material **92** towards the proximal end.

[00262] Alternatively, the distal end of the deployment member **94** may be secured in a pocket attached to the interior or exterior of the material **92** at or near the distal end of the sheath. For the deployment member **94** such pocket may be in the form of a plastic cap, silicone cap or other suitable material that will protect the wire end from poking or snagging tissue during placement. In such an embodiment, the distal end of the material **92** may be folded over towards the proximal end like an envelope so that the deployment member **94** may secure the distal end of the sheath material **92** without having to stitch around the end. The pocket may then be attached to the material **92** at or near the fold.

[00263] The deployment member's proximal end **96** may extend far enough so that it may be accessed outside the patient after the device **10** is placed into the deployment position in the stomach. Preferably, a thin tube **95** made of silicone or plastic is secured to the proximal end of the material **92**, and the deployment member **94** is routed inside the tube **95**. Such a tube **95** may be independently secured to the material **92** so that the distal

end of the tube **95** is just inside the proximal end of the material **92**. Then the compressed device **10** may be placed within the material **92** and secured with the deployment member **94**. The result is a package with a compressed device **93** inside the closed material **92** and a tube **95** also secured inside the proximal end of the material **92**, with the deployment member **94** running through the tube **95**. For adequate stiffness for placement, an additional guide wire may be needed to be placed down the center the sheath assembly.

[00264] For placement, such a sheath package is placed into the esophagus **32** or other narrow opening or surgical incision, and routed into the stomach. Once in deployment position, the deployment member **94** is pulled through the tubing **95**, which releases the closure of the sheath. The device **10** will then expand or regain its operational shape. Then the tube **95**, along with the material **92**, may be removed from the patient leaving only the device **10** in place.

[00265] The delivery sheath **91** may be used for any delivery of any medical device through a narrow opening. If the medical device is naturally narrow, or can be compressed, deflated, or other means of holding it in a narrow shape, it may be placed in a delivery sheath **91** as discussed above. After the deployment member **94** is pulled through the tubing **95**, the medical device may expand or rebound into its operational shape, whether by its construction of shape-retaining materials, or by mechanical, hydraulic, pneumatic, or other means.

[00266] Measurement Tool

[00267] To select the appropriate size device or device adjustment for the patient, a measurement tool may be used. This tool would allow measurement of the lesser and

greater curves, **16**, **17** of the stomach, the distance between the pyloric and cardiac elements, or other features of the stomach.

[00268] In one embodiment, the measurement tool has an inflatable body **97** that is in the same general shape as the pyloric element **26**. This balloon may be affixed to a central tube **98** to allow for a pathway where air can be passed to inflate and deflate the balloon **97**. The central tube **98** may also provide a handle for placing the balloon **97** and maneuvering the balloon into position in the pyloric region **42**. The central tube **98** measurement member may be used alone or in conjunction with additional measurement members. See Figs. 76 and 77. For placement, the inflatable body **97** would be deflated to collapse it to a narrow, low profile, and preferably inserted into the stomach through the esophagus **32**. See Fig. 78.

[00269] A measurement member could be affixed to the inflatable body with adequate length to start a measurement at the base of the pyloric inflatable body **97** and measure along the lesser curve **16** or greater curve **17** to the gastroesophogeal (GE) junction. This measurement member could be long enough to pass up the esophagus for manipulation outside the body or could be long enough to pass the GE junction. This measurement member may be equipped with measurement markings **99**, which could be a thin measurement tape **100**, a tube with length markings **101**, the central tube coupled with the inflatable body, or a clear tube with a plunger to allow for visualization of the plunger with the measurement on the plunger. For the clear tube/plunger embodiment, the measurement markings could be on the tube for visualization by the gastroscope, or the measurement markings may be on the plunger such that when the bottom or other part of the plunger is

aligned with the stomach feature, the measurement is read outside the body by viewing the markings on the plunger relative to a point on the tubing. Once the inflatable body **97** is in position in the pyloric region **42**, the inflatable body **97** could be inflated to match the shape and profile of the pyloric element **26**. Alternatively, the inflatable body **97** may be inflated in the stomach and then pushed into the pyloric region **42**.

[00270] Once the inflatable body **97** is seated in the proper position, various features of the stomach may be measured. For the lesser curve measurement, the inflatable body **97** may be positioned so that the measurement member is located along the lesser curve **16**. Under gastroscope visualization, the measurement member could then be pulled up to position in the GE junction by the member itself or by an instrument, and the measurement reading noted. For the greater curve measurement, the inflatable body may be positioned so that the measurement member is located along the greater curve **17**. Under gastroscope visualization, the measurement member could then be pushed into position along the greater curve **17** and up through the GE junction by the member itself or by an instrument, and the measurement reading noted. The measurement members could be made of silicone, an elastomer or other material that is compliant and smooth. The measurement member should be of adequate strength to maintain a good measurement, but be smooth and complaint for placement down the esophagus and for conforming to the stomach's anatomy.

[00271] In another embodiment, the instrument may contain two measurement members on opposing sides of the inflatable body to measure the greater and lesser curves at the same time as shown in Fig. 77. In another embodiment, the central tube **98** could also be

used as a measurement member and pushed to flex and contour along the greater or lesser curve **16** for a measurement. See Fig 76. Preferably, the inflatable body **97** matches shape of the pyloric element **26** of the device **10**, but it could also take another shape such as a sphere to approximate the size of the pyloric element **26**. The inflatable body may also be shaped for other measurement uses, and adapted to fit whatever area of the stomach may be required. Alternatively, the inflatable body could be replaced with a non-inflatable body if needed. In the embodiment where the central tube **98** is used for measurement, the central tube **98** could be offset from the center of the inflatable body **97** to allow it to better contour to the greater or lesser curves **17**, **16**.

[00272] In another embodiment, the measurement tool may contain a fixed pyloric member and a moveable cardiac member that can translate along a central tube **98** to approximate the distance between the two members in the recipient's stomach. The central tube **98** may contain measurement markings **99** that can be visualized once the cardiac member has been positioned. The cardiac member may include a pressure sensor to guide when adequate pressure has been incurred to represent proper seating of the cardiac device **10** in the stomach.

[00273] In another embodiment, the measurement tool may comprise an inflatable balloon at the pylorus and an inflatable balloon near the cardia. As the cardiac balloon is inflated, it may approximate the location of the cardia. The cardia balloon may contain a pressure sensor internally or externally to guide when an appropriate contact pressure to the cardia has been achieved to approximate the size.

[00274] Removal

[00275] For removal, a flexible tube such as a standard overtube could be used with a standard or custom endoscopic tool. The tube may be placed down the esophagus and the tool then placed down the lumen of the overtube. A standard tool such as a grasper or snare could grasp the device **10** and pull it up the tube. The device **10** would be straightened by the overtube for removal from the stomach and esophagus.

[00276] In another embodiment, the elements may incorporate a collapsing mechanism designed to collapse the element into a compact shape for removal. For example, Figs. 79 and 80 depict a pyloric element **26** with a constriction member **102** comprising a wire or thread sewn spirally around, through, or inside the length of the element. The constriction member **102** could also be sewn through eyelets or features attached to the inside of the pyloric or cardiac element **26**, **12**. The ends of the constriction member **102** may be connected. When the constriction member **102** is pulled, it tightens the circumference of the pyloric element **26** like a drawstring, which collapses the element down to a narrow profile that can be safely removed through the esophagus or other narrow opening, or ease its placement into a tube for removal. Similar collapsing mechanisms can be installed in the cardiac, connecting, and/or positioning elements **12, 25, 13**. The constriction member **102** could be made from Nitinol, stainless steel wire, ptfe thread, eptfe thread or ptfe coated threads or other suitable materials. The constriction member **102** could be integrated into the elements in a variety of patterns such as a continuous spiral, two spirals of reversing orientation, or other.

[00277] The constriction member **102** may also be threaded through a retaining element **103** to aid in maintaining the collapsed position such as a drawstring cord stop or the like.

See Figs. 81A, 81B and 82. This figure shows a stop element that is affixed to the pyloric element **26** and the constriction member is threaded through. For example, this mechanical stop **103** could be a thick sheet of silicone with a slit or small hole punched through the center section, and the retrieval drawstring is pulled through the opening. When the constriction member **102** is pulled, it is drawn through this stop element **103** and the mechanical stop applies resistance to the retrieval drawstring to hold the device **10** in the collapsed state. To further improve the holding capacity of the mechanical stop **103**, a feature could be added to the retrieval drawstring **102** such as a knot tied or an arrowhead or bead attached to the drawstring that allows the feature to be pulled through the slit of the mechanical stop **103**, but creates a mechanical interference to prevent the drawstring from pulling back through the stop. The mechanical stop could also be a cord stop **103** as shown in 81A.

[00278] The foregoing description of the preferred embodiments of the invention has been presented for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise form disclosed. Many modifications and variations are possible in light of the above teaching. It is intended that the scope of the invention not be limited by this detailed description, but by the claims and the equivalents to the claims appended hereto.

INDUSTRIAL APPLICABILITY

[00279] This invention may be industrially applied to the development, manufacture, and use of bariatric devices for weight loss purposes.

2010308498 03 Dec 2015

[00280] Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

[00281] The reference in this specification to any prior publication (or information derived from it), or to any matter which is known, is not, and should not be taken as, an acknowledgement or admission or any form of suggestion that that prior publication (or information derived from it) or known matter forms part of the common general knowledge in the field of endeavour to which this specification relates.

2010308498 03 Dec 2015

The claims defining the invention are as follows:

1. A bariatric device for placement into a stomach to achieve weight loss, comprising:
   a. a cardiac element, the cardiac element comprising:
      i. a contact member having a substantially flattened frustoconical shape, the contact member defining a substantially circular opening adapted to correspond to the cardiac opening of a stomach, the contact member being constructed of materials flexible enough to be collapsed for placement and expanded for operation; and
      ii. a stiffening member inside the contact member that can be collapsed for placement and will cause the contact member to substantially return to and maintain its desired shape in the stomach after the cardiac element is expanded for operation;
   b. a pyloric element, the pyloric element comprising:
      i. a second contact member adapted to engage the pyloric region of the stomach, having a steep frustoconical shape, sized to prevent the pyloric element from passing through the stomach's pyloric valve, the second contact member being constructed of materials flexible enough to be collapsed for placement and expanded for operation; and
      ii. a second stiffening member inside the second contact member that can be collapsed for placement and will cause the second contact member to substantially return to and maintain its desired shape in the stomach after the pyloric element is expanded for operation; and
      iii. an opening sized and adapted to allow chyme in the stomach to pass from the stomach through the pyloric valve; and
   c. a connecting element coupled with the pyloric element and the cardiac element, constructed of resilient shape-holding material and shaped so that it causes the cardiac element to at least intermittently contact the upper stomach.

2. A bariatric device for placement into a stomach to achieve weight loss, comprising:
   a. a cardiac element adapted to engage the upper stomach,
   b. a pyloric element adapted to engage the pyloric region of the stomach, having an opening sized and adapted to allow chyme in the stomach to pass from the stomach through the pyloric valve; and
   c. a connecting element coupling the cardiac element and the pyloric element, shaped such

2010308498 03 Dec 2015

that the cardiac element maintains at least intermittent contact with the upper stomach and the pyloric element maintains at least intermittent contact with the pyloric region of the stomach.

3. The bariatric device of Claim 1 or 2, wherein the connecting element is constructed to impart an outwardly biasing force against both the pyloric element and cardiac element.

4. The bariatric device of Claim 3, further comprising a surface texture on at least one of the cardiac, pyloric, and connecting elements.

5. The bariatric device of Claim 1, wherein the connecting element is comprised of a plurality of members.

6. The bariatric device of Claim 1, further comprising:

a. an inflatable body coupled with the cardiac element, such that when inflated, the inflatable body increases the contact or force between the cardiac element and the upper stomach.

7. The bariatric device of Claim 6, wherein the inflatable body is in the deflated shape of a substantially flattened frusto cone or frusto cone section, coupled with the top of the cardiac element.

8. The bariatric device of Claim 6 or 7, wherein the inflatable body is coupled with an inflation element positioned to allow inflating fluid to be inserted or removed while the bariatric device is in the stomach.

9. The bariatric device of Claim 1, wherein the device is further equipped with an adjustment element, the adjustment element constructed such that the location or orientation of the cardiac element relative to the pyloric element is adjustable while in the stomach.

10. The bariatric device of Claim 3, wherein the device is further equipped with an adjustment element, the adjustment element constructed such that the outwardly biasing force against the cardiac element or pyloric element is adjustable while in the stomach.

11. The bariatric device of Claims 9 or 10, further comprising an actuation element and a remote controller, wherein the actuation element receives signals from a remote controller located outside of the body and actuates the adjustment element.

12. The bariatric device of Claim 11, further comprising a sensor element that generates signals

2010308498 03 Dec 2015

based on sensed conditions within the stomach.

13. The bariatric device of Claims 9 or 10, further comprising a sensor element that generates signals based on sensed conditions within the stomach.

14. The bariatric device of Claim 13, further comprising an actuation element, wherein the actuation element, while in the stomach and in response to signals from the sensor element, activates the adjustment element to adjust the bariatric device.

15. The bariatric device of Claim 13, wherein the sensor element signals can be read outside the body.

16. The bariatric device of Claim 13, wherein the bariatric device is adjusted by automated means in response to signals from the sensor element.

17. The bariatric device of Claim 1, further comprising a delivery sheath, comprising:

a. a sheet of material, having a length with distal and proximal ends, and a width with two sides,

b. a length of flexible tubing, coupled with the proximal end of the material,

c. the bariatric device in a narrow, compressed state, placed lengthwise inside the material,

d. a deployment member with distal and proximal ends, placed as a straight stitch to join the two sides of the material width and to close the distal end of the material, enclosing the bariatric device within the material, the deployment member then running through the length of the flexible tubing.

18. The bariatric device and delivery sheath of Claim 17 wherein the deployment member comprises a thin, flexible, and resilient wire.

19. The bariatric device and delivery sheath of Claim 18, wherein the distal end of the deployment member is located within the enclosure created by the material.

20. The bariatric device and delivery sheath of Claim 18, further comprising a cap coupled with the material, wherein the distal end of the deployment member is contained within the cap.

21. The bariatric device of Claim 2 further comprising a surface texture on at least one of the included elements.

22. The bariatric device of Claims 1 and 2, further comprising a flexible tube coupled with the

2010308498 03 Dec 2015

pyloric element, which extends into the duodenum and acts as a barrier to food absorption.

23. The bariatric device of Claim 2 wherein the bariatric device is constructed of a resilient, shape-retaining material, such that it may be collapsed into a narrow shape for introduction into the stomach through a narrow opening, and rebound into its operational shape once placed in the stomach.

24. The bariatric device of Claim 2, wherein the connecting element is comprised of at least one curved wire.

25. The bariatric device of Claim 24, wherein the connecting element is comprised of two loops.

26. The bariatric device of Claim 25, wherein the connecting element is comprised of two loops connected together and crossed to form a figure 8 structure.

27. The bariatric device of Claim 23 wherein the resilient, shape retaining material causes the bariatric device to be self expanding in response to peristalsis.

28. The bariatric device of Claim 3 further comprising an adjustment element to adjust the outwardly biasing force while the bariatric device is in the stomach.

29. The bariatric device of Claim 28, wherein the adjustment element comprises at least one of:

i. at least one positional feature held in a retainer,
ii. a locking ring which movably engages a positional element,
iii. male and female threaded members,
iv. an expandable body, and
v. an inflatable body, coupled with the top of the cardiac element.

30. The bariatric device of Claim 3, wherein the adjustment element comprises an inflatable body coupled with the pyloric element.

31. The bariatric device of Claim 28, wherein the adjustment element comprises at least one of:

i. a. a rotatable magnetic member equipped with screw threads, and
b. a screw-threaded member threadably coupled with the screw threads of the magnetic member, wherein the magnetic member is rotated by a magnetic field,
ii. a Nitinol actuator, and
iii. a linear hydraulic actuator.

32. The bariatric device of Claims 2, 9 and 10, wherein the adjustment element comprises at least

2010308498 03 Dec 2015

one of:

i. one or more frusto-cones placed over the pyloric element or cardiac element to increase their length, and

ii. a frusto-conical member inside the pyloric element, said frusto-conical member held in place by clips that allow positional adjustment of the frusto-conical member, such that the length of the pyloric element may be effectively adjusted.

33. The bariatric device of Claim 3 further comprising:

a. an adjustment element to adjust the outwardly biasing force while the bariatric device is in the stomach

b. a remote controller that is separate from the bariatric device,

c. an actuation element that receives signals from the remote controller, wherein the actuation element actuates the adjustment element.

34. The bariatric device of Claim 33, wherein the actuation element comprises:

a. a motor coupled with the connecting element,

b. a first threaded member coupled with the motor, and

c. a second threaded member that is threaded into the first threaded member, whereby the motor turns first threaded member to change the length of the connecting element.

35. The bariatric device of Claim 34, wherein the motor is powered by at least one of:

i. a battery,

ii. induction from an external source, and

iii. ultrasonic waves.

36. The bariatric device of Claim 33, further comprising a sensor that senses parameters within the gastrointestinal tract and can send signals to the remote controller, wherein the remote controller is inside the body and responds to signals from the sensor.

37. A bariatric device for placement into a stomach to achieve weight loss, comprising a cardiac element adapted to engage the upper stomach, and at least one of the following chosen from the group consisting of:

a. a pyloric element adapted to engage the pyloric region of the stomach and having an opening sized and adapted to allow chyme in the stomach to pass from the stomach through the pyloric valve, and a connecting element coupling the cardiac element and the pyloric element, shaped such that the cardiac element maintains at least intermittent

2010308498 03 Dec 2015

contact with the upper stomach and the pyloric element maintains at least intermittent contact with the pyloric region of the stomach,

b. a positioning element adapted to contact a region of the stomach outside the cardia and shaped such that the cardiac element maintains at least intermittent contact with the upper stomach,

c. a positioning element adapted to contact a region of the stomach outside the cardia and shaped such that the cardiac element maintains at least intermittent contact with the upper stomach, and a pyloric feature to preclude the positioning element from moving substantially past the pyloric valve.

38. The bariatric device of Claim 37, wherein an outwardly biasing force is applied by at least one of the group consisting of:

a. the connecting element, which applies an outwardly biasing force to the cardiac and pyloric elements, and

b. the positioning element, which applies an outwardly biasing force to the cardiac element.

39. The bariatric device of Claim 38, further comprising a sensor element that generates a signal based on sensed conditions within the stomach.

40. The bariatric device of Claim 39, further comprising:

a. an adjustment element to adjust the outwardly biasing force, while the bariatric device is in the stomach, and

b. an actuation element, which actuates the adjustment element based upon signals received from the sensor element, wherein the sensed condition for adjustment of the outwardly biasing force is at least one chosen from the group of:

a. pressure,

b. force,

c. motion,

d. peristalsis,

e. tension,

f. pH,

g. temperature, and

h. glucose,

the bariatric device further comprising a sensor signal interpretation and control element, which in response to preprogrammed set of signals, adjusts the outwardly biasing force.

2010308498 03 Dec 2015

41. The bariatric device of Claim 37, further comprising an electrical stimulation element, wherein the energy used for the electrical stimulation is at least one chosen from the group consisting of:

a. radio frequency,
b. ultrasound,
c. microwave,
d. cryogenic,
e. laser,
f. light,
g. electrical,
h. mechanical, and
i. thermal.

42. The bariatric device of Claim 39, further comprising an adjustment element that adjusts the outwardly biasing force in response to signals received by a controller located outside of the body, and wherein the signals from the sensor element can be obtained outside of the body, wherein the adjustment of the outwardly biasing force is determined from signals obtained from the sensor element, the bariatric device further comprising a sensed parameter data reader capable of reading the sensed parameter data from outside the body.

43. The bariatric device of Claim 39, further comprising:

a. an emitter element, and
b. a sensor signal interpretation element, which in response to preprogrammed signals, triggers the emitter element to emit a substance into the gastrointestinal tract.

44. A bariatric device for placement into a stomach to achieve weight loss, comprising:

a. a cardiac element adapted to fit the cardiac region of the stomach,
b. a pyloric element adapted to fit the pyloric region of the stomach, having an opening sized and adapted to allow chyme in the stomach to pass from the stomach through the pyloric valve,
c. a connecting element coupled with the cardiac element and the pyloric element, and
d. a constriction member coupled with the pyloric element.

45. The bariatric device of Claim 44, further comprising a mechanical stop for the constriction member.

46. The bariatric device of Claim 44, further comprising a second constriction member coupled with

the cardiac element.

47. The bariatric device of Claim 37, further comprising a coating capable of emitting a substance into the gastrointestinal tract.

48. The bariatric device of Claims 1, 2, or 37, further comprising an esophageal element.

49. The bariatric device of Claims 1, 2, or 37, further comprising a valve in the cardiac element or the pyloric element.

Fig. 1

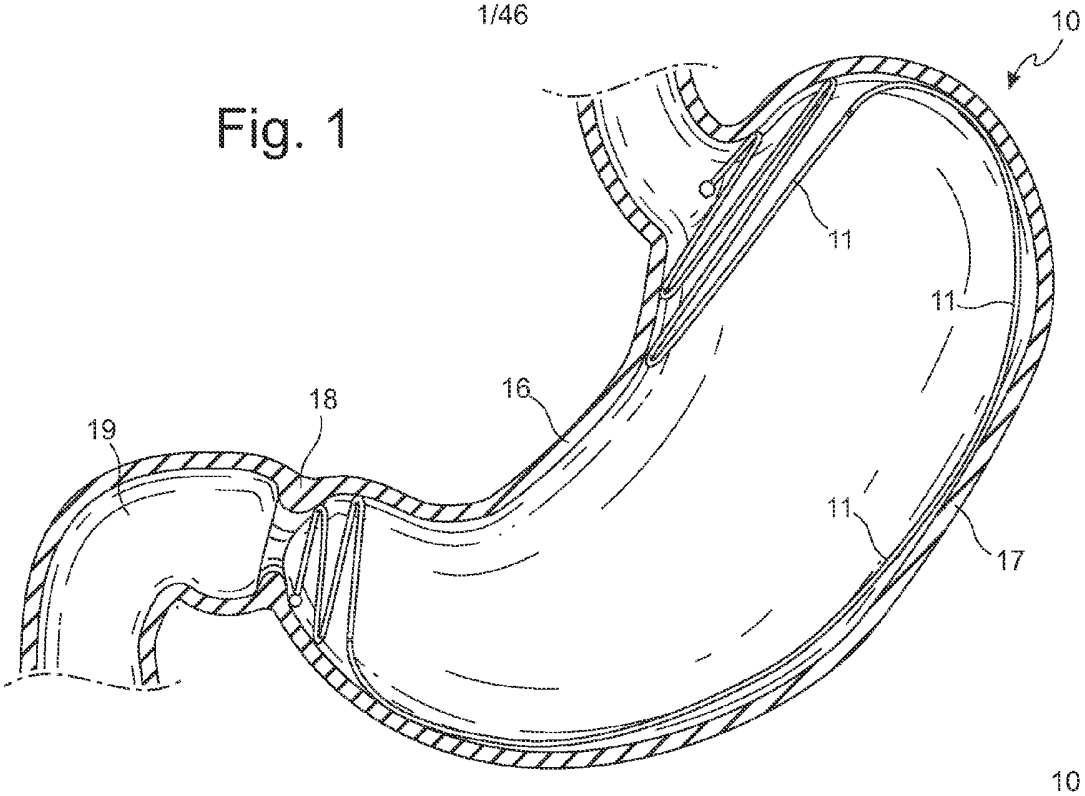


Fig. 2

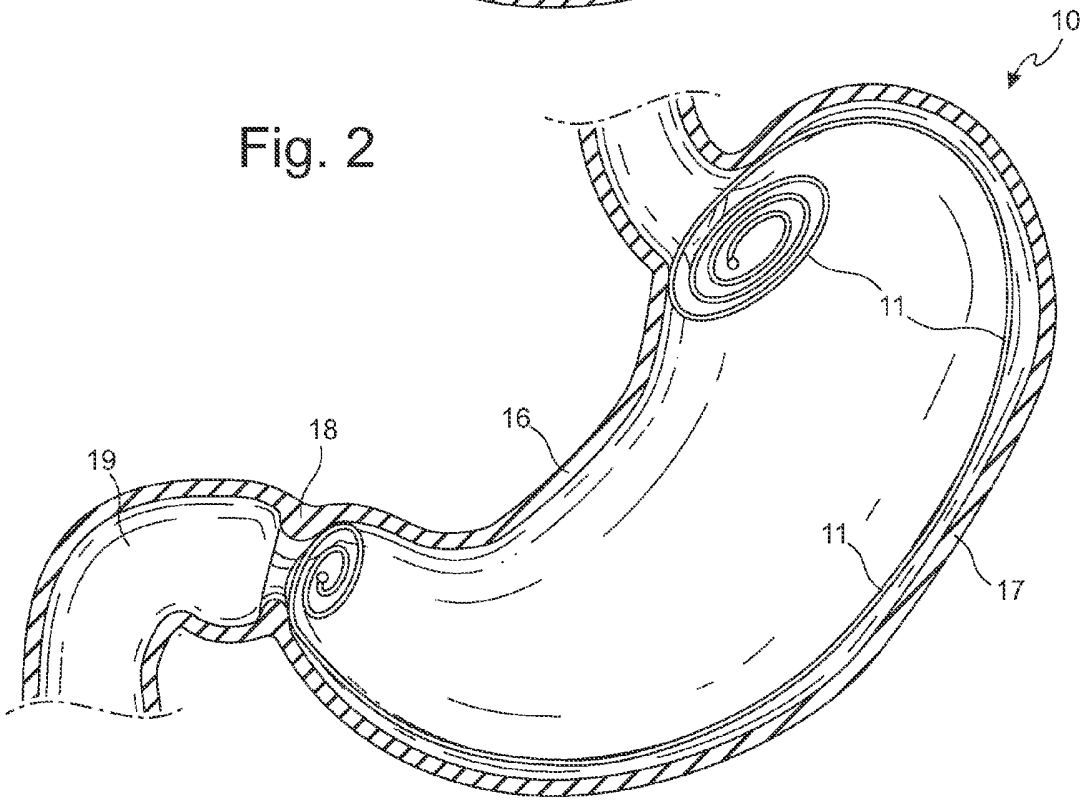


Fig. 3

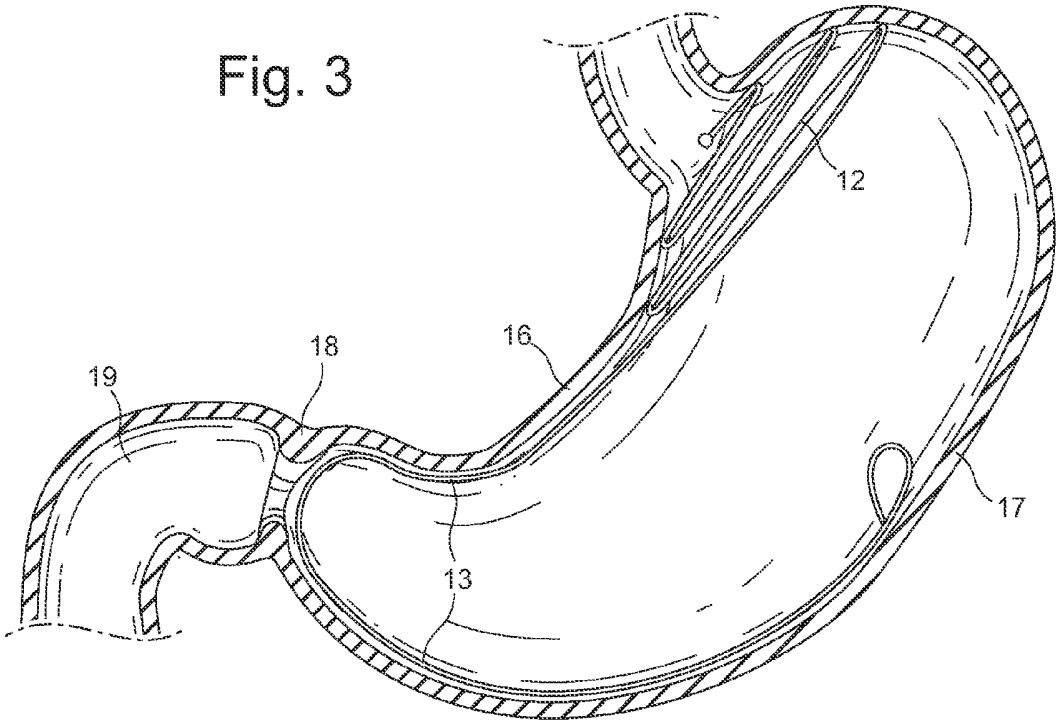


Fig. 4

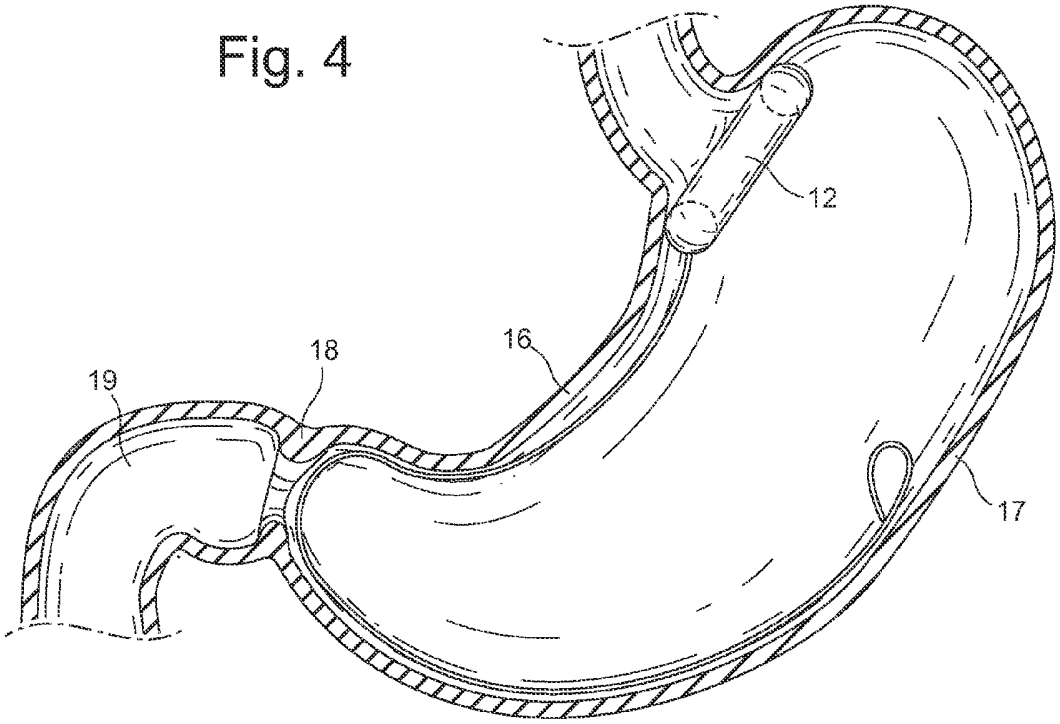


Fig. 5

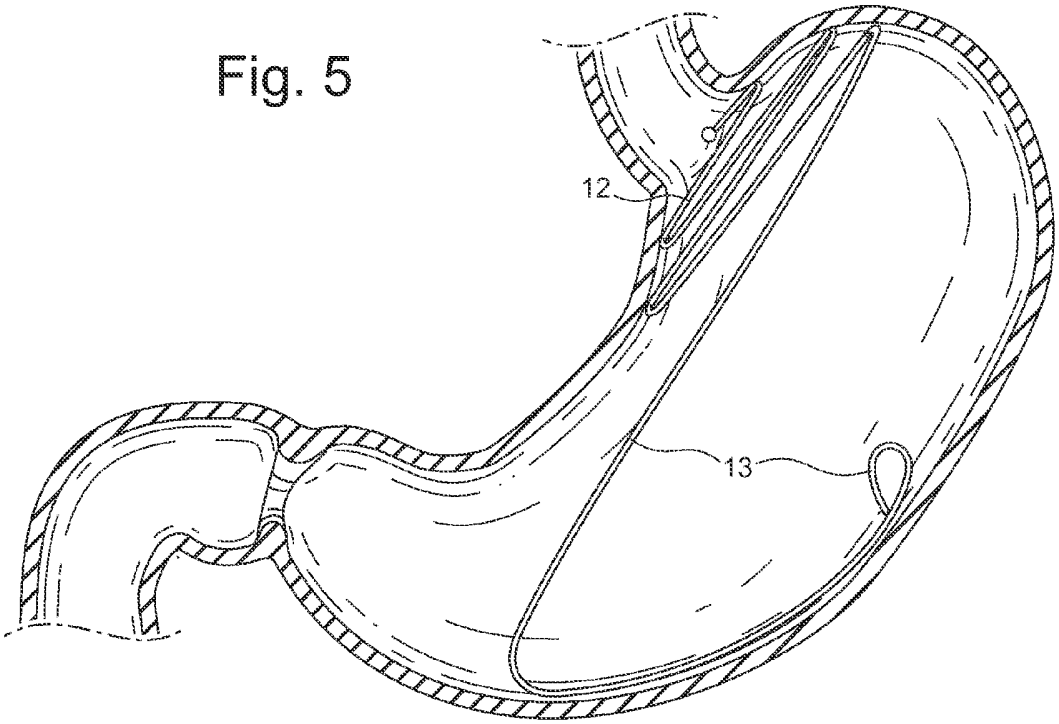


Fig. 6

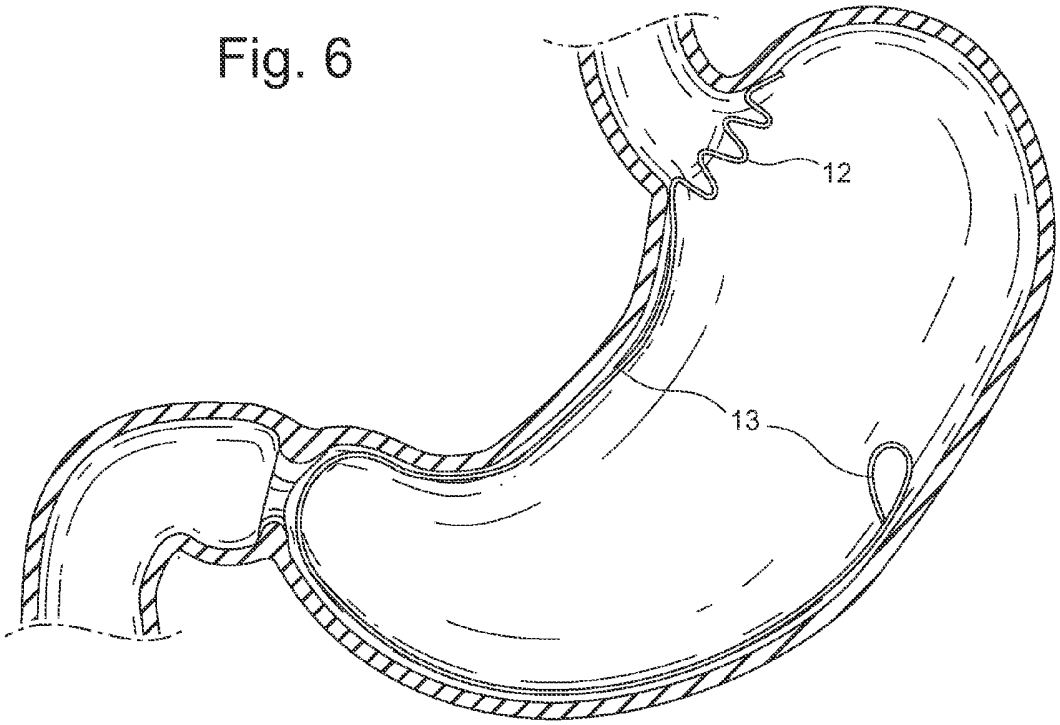


Fig. 7

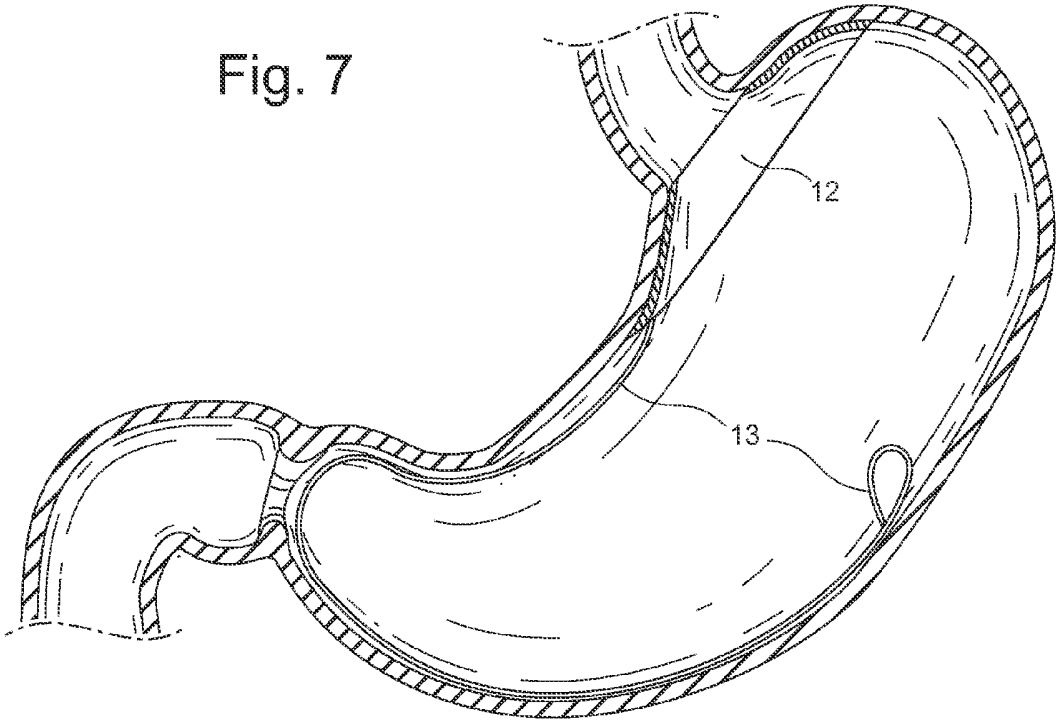


Fig. 8B

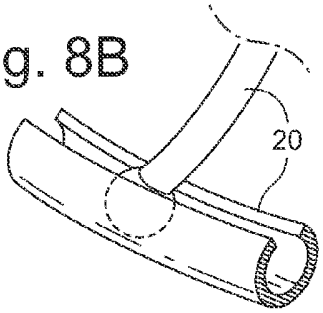


Fig. 8A

Fig. 9B

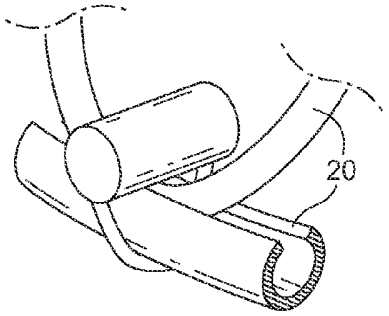


Fig. 9A

Fig. 10

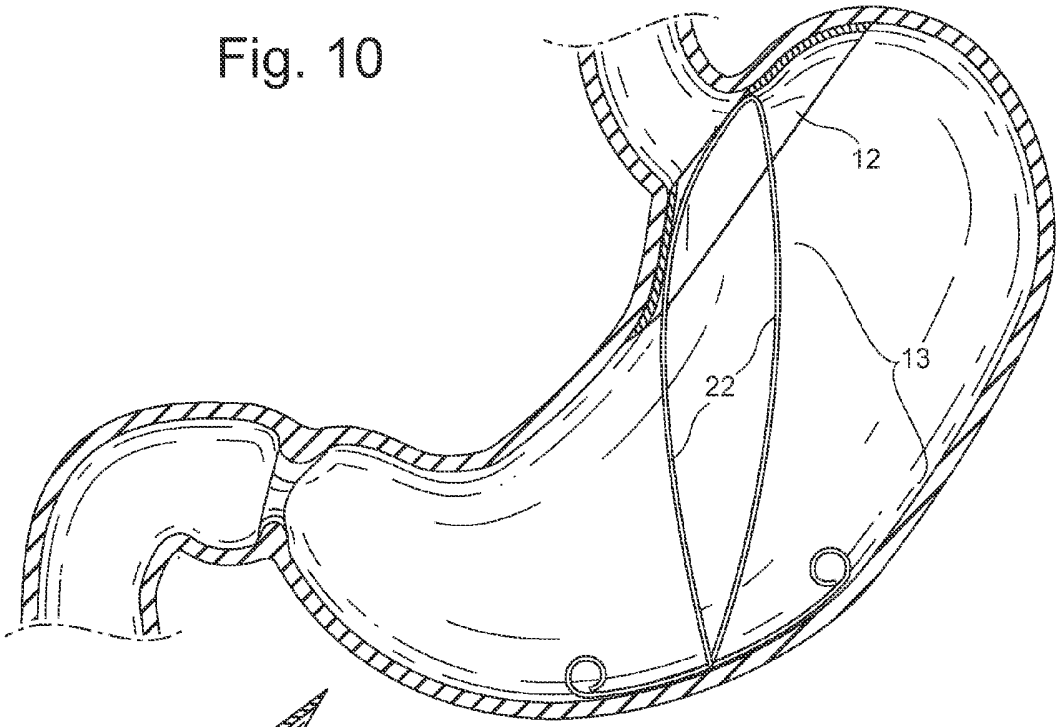


Fig. 11B

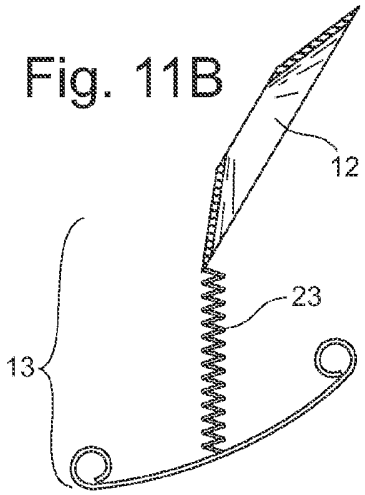


Fig. 11A

Fig. 12

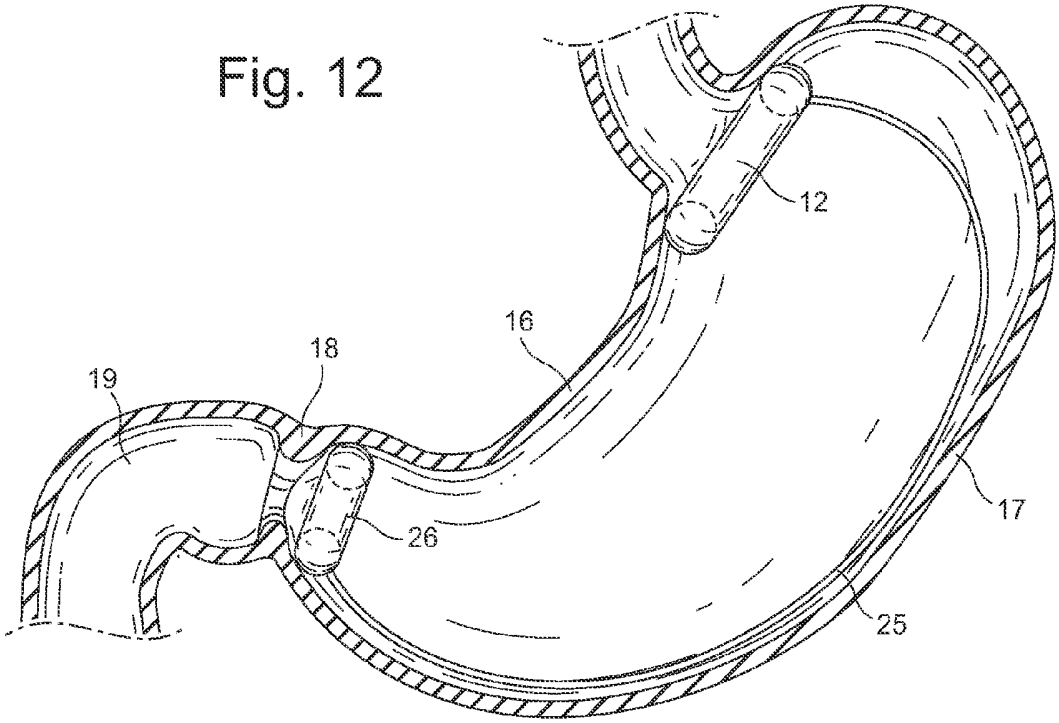


Fig. 13

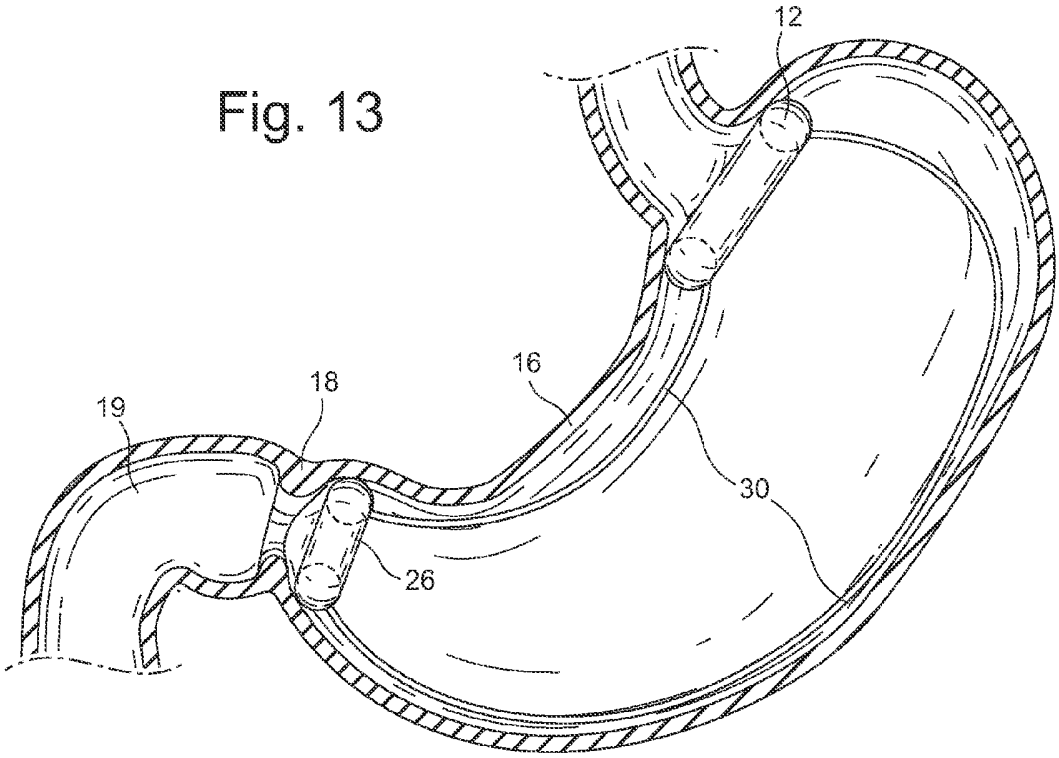


Fig. 14

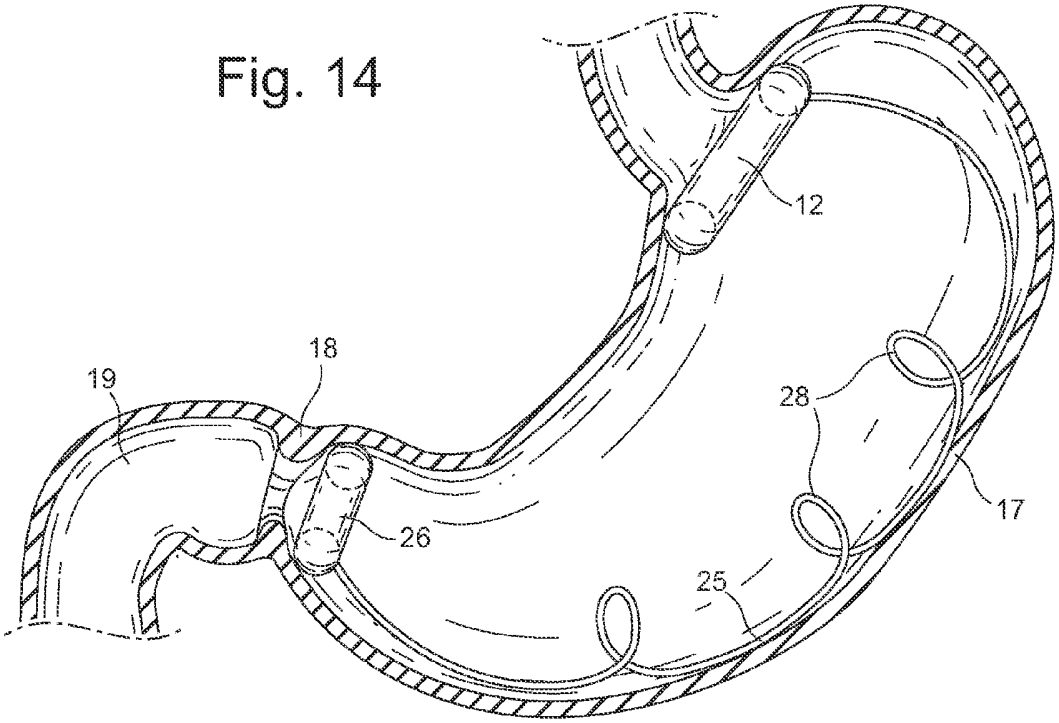


Fig. 15

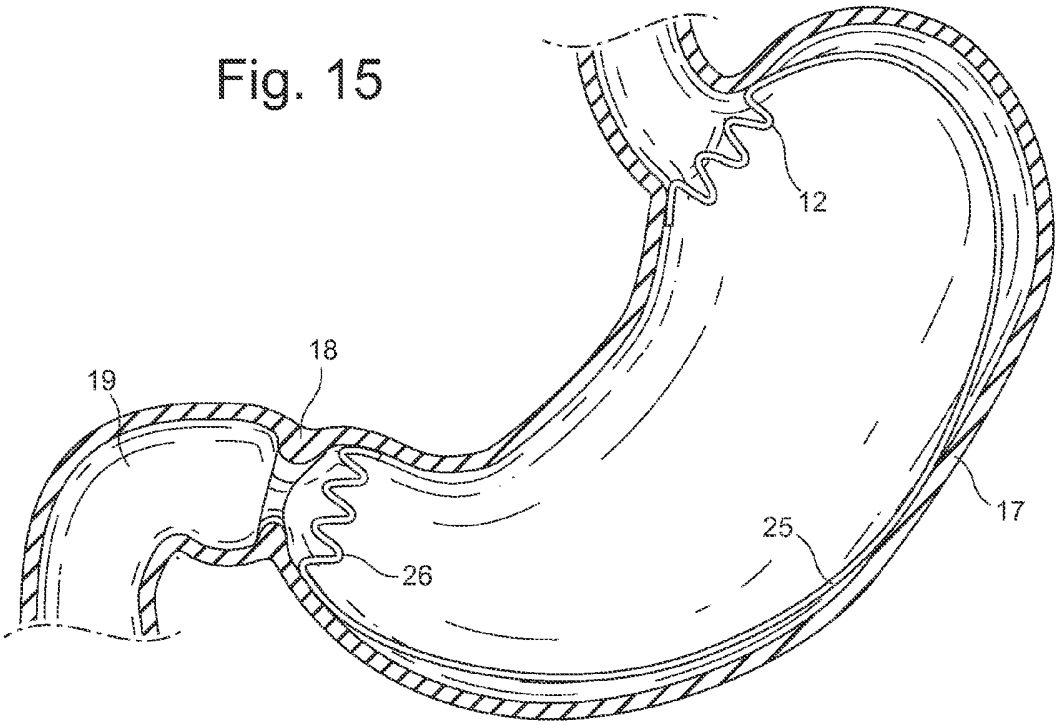


Fig. 16

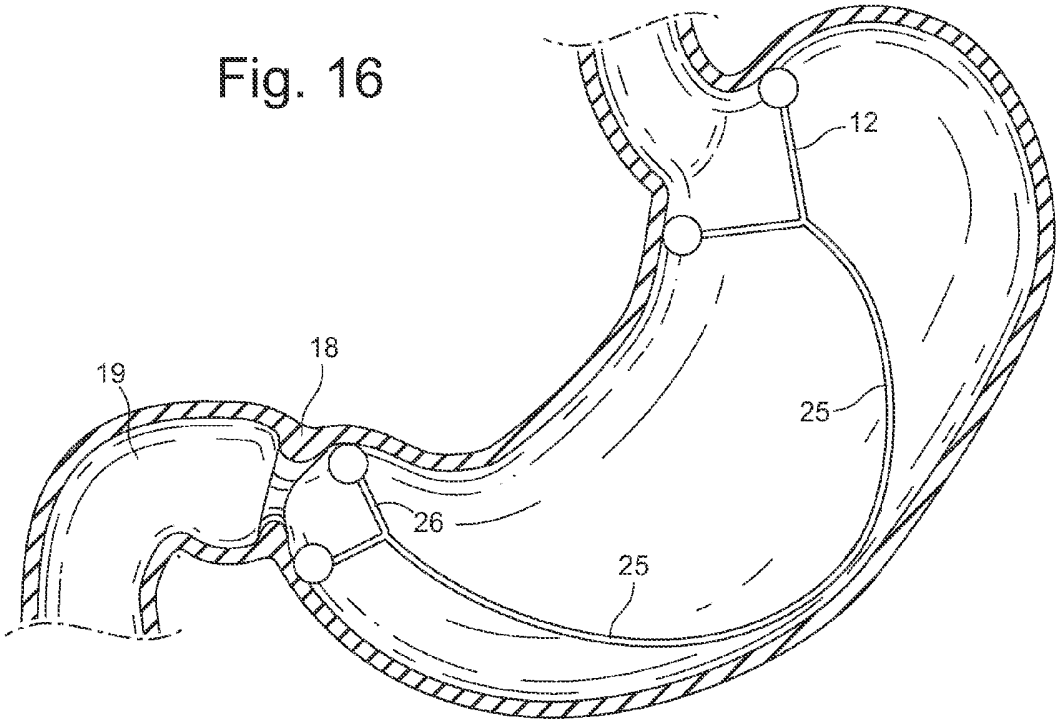


Fig. 17

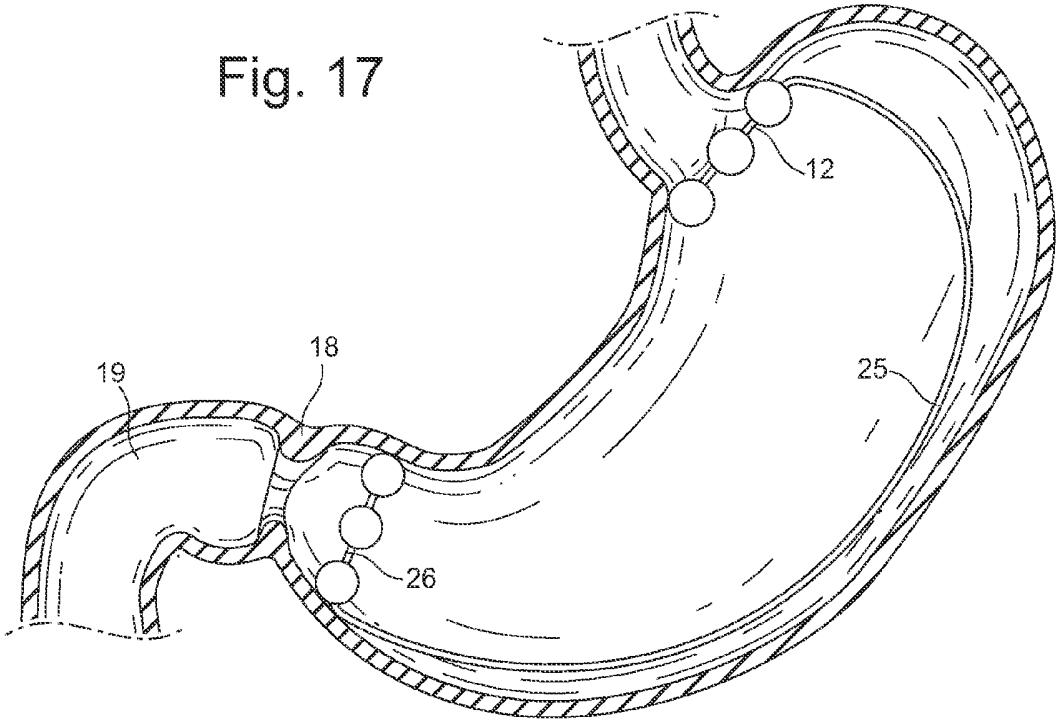


Fig. 18

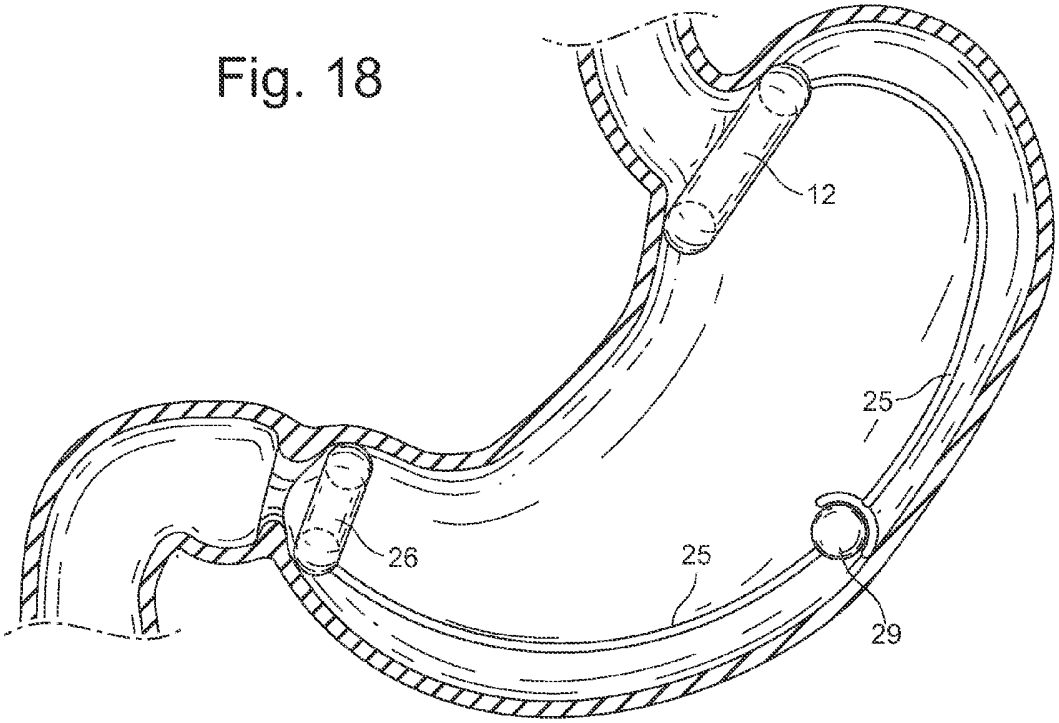


Fig. 19

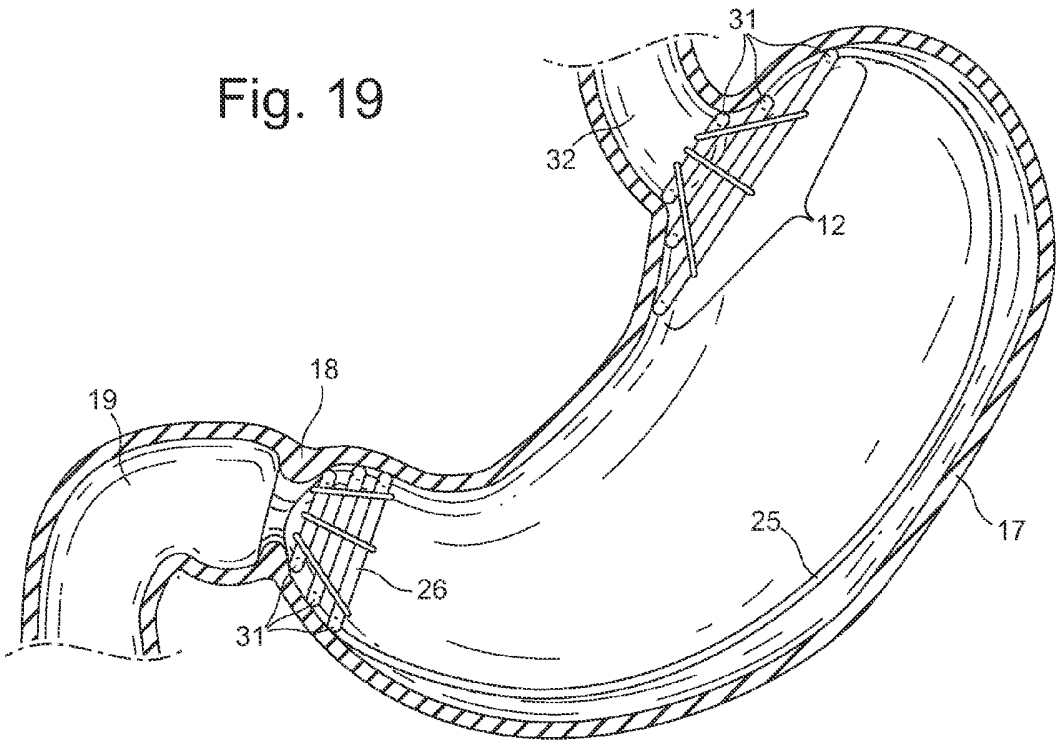


Fig. 20

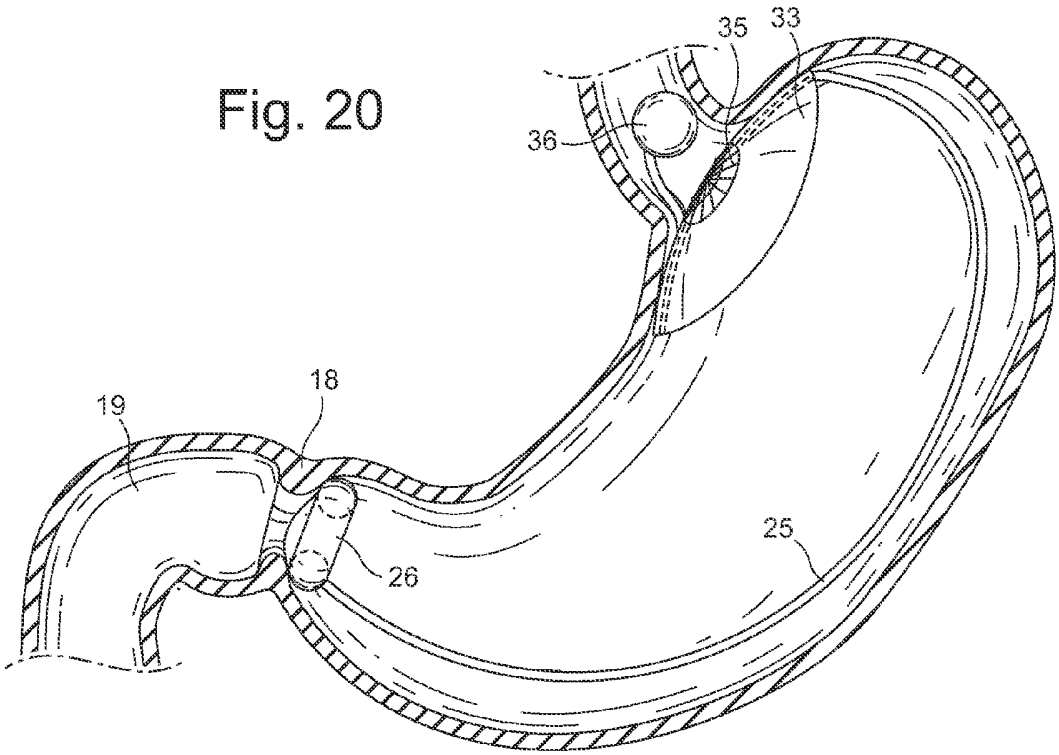


Fig. 21

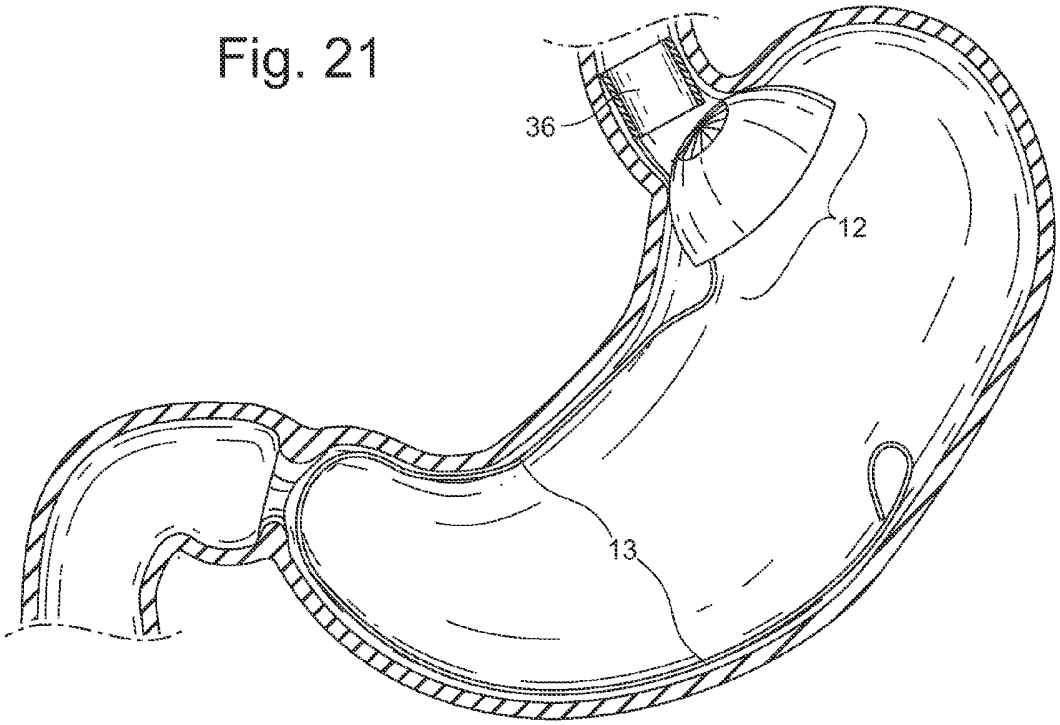


Fig. 22

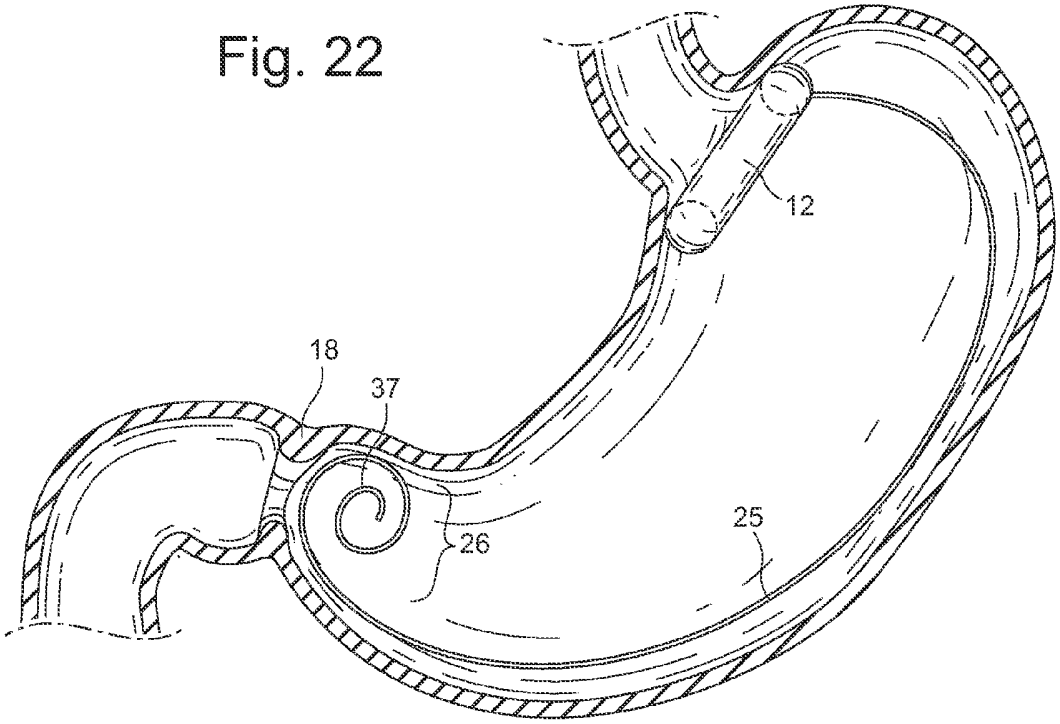


Fig. 23A

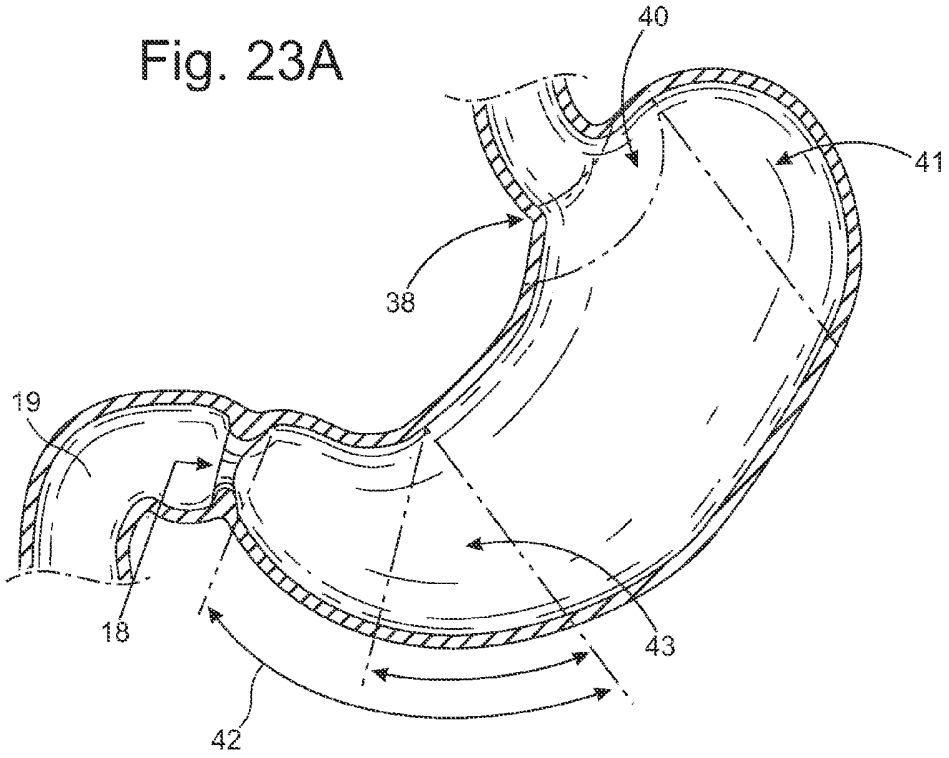


Fig. 23B

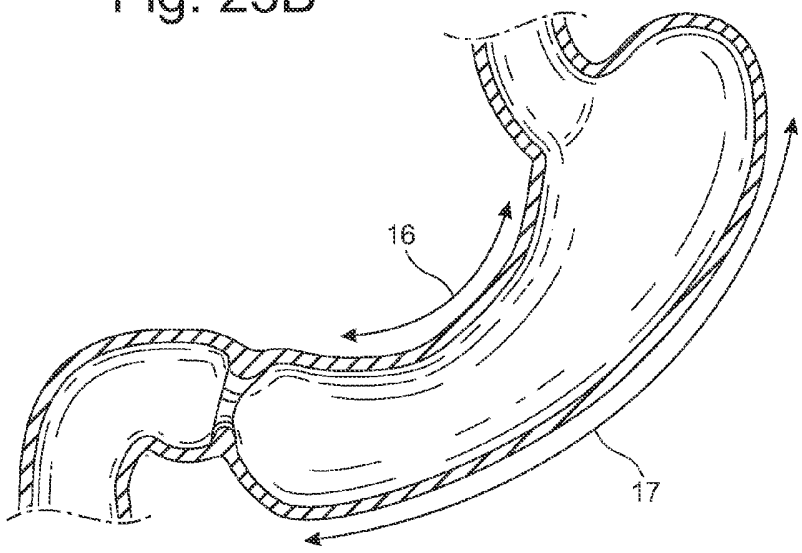


Fig. 24

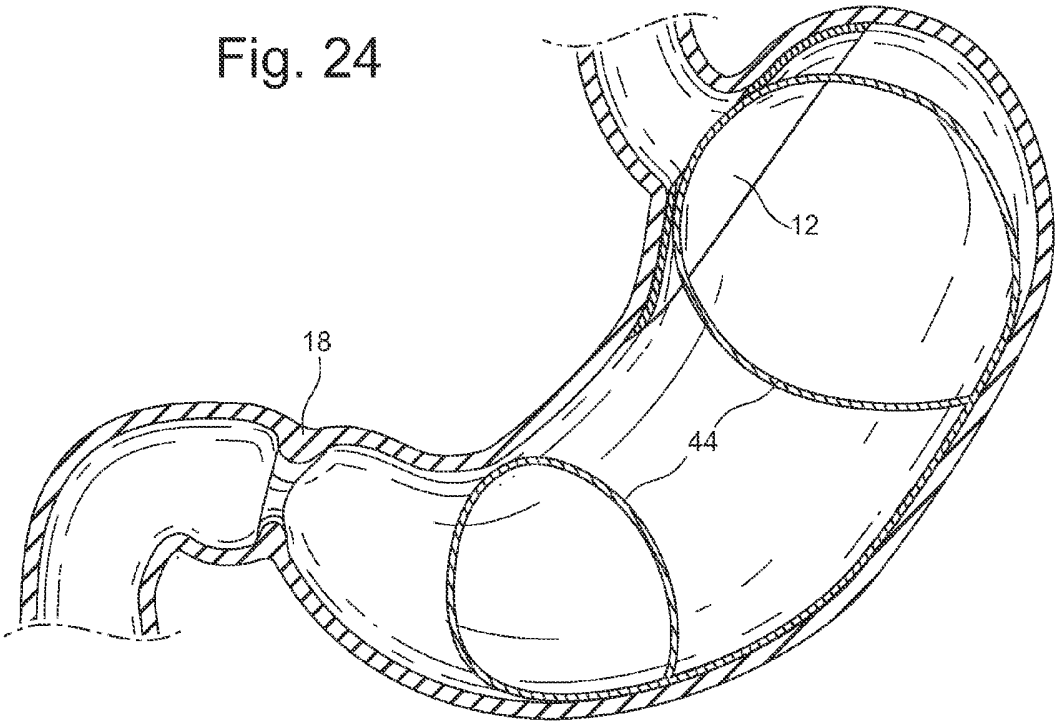


Fig. 25

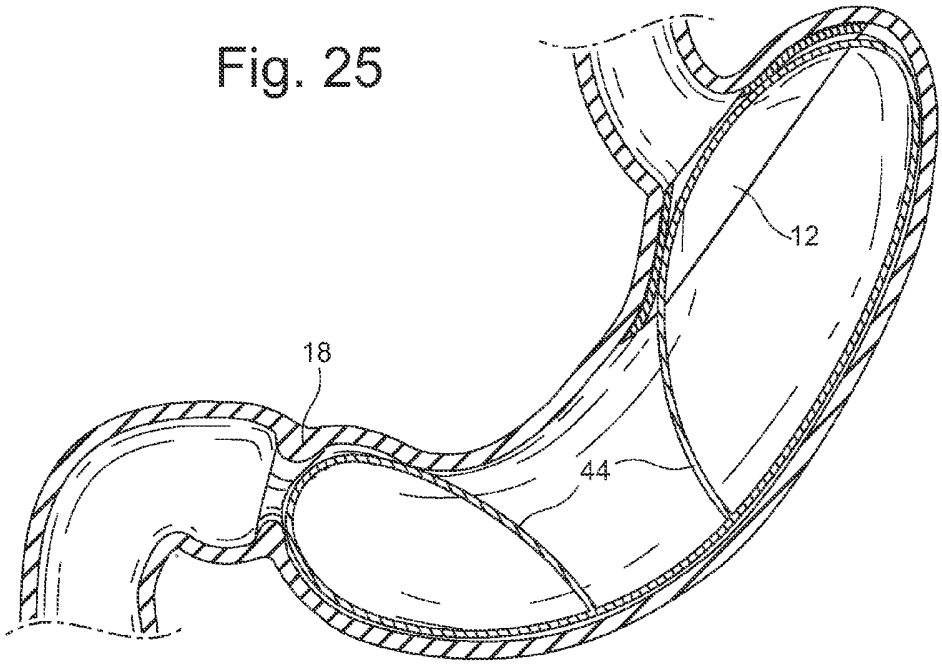


Fig. 26

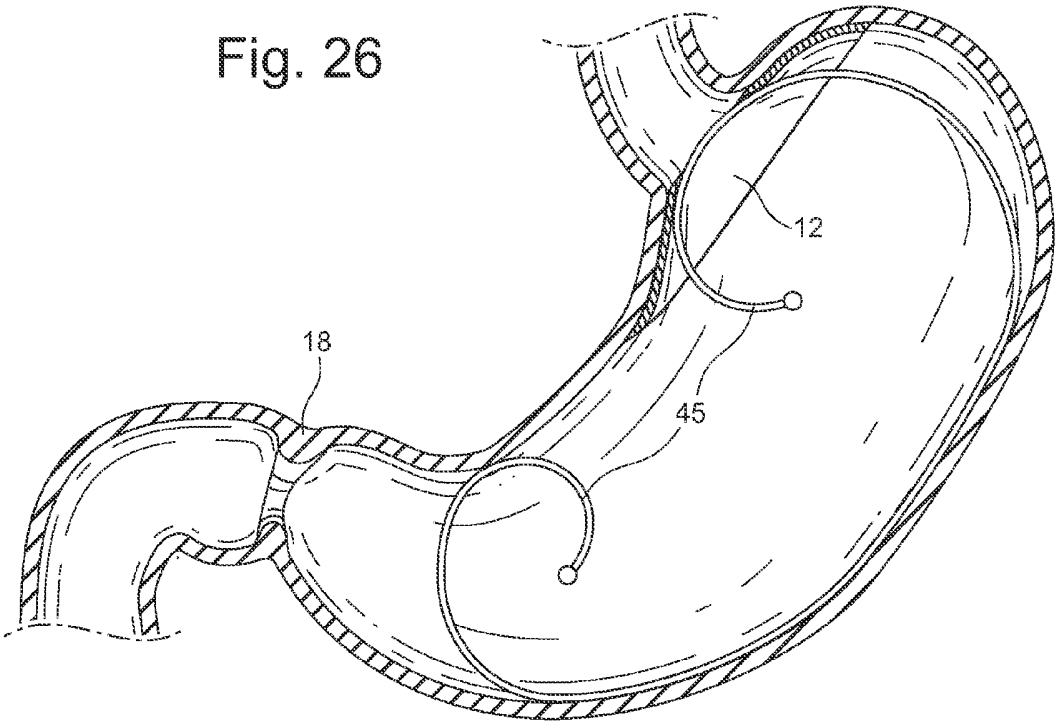


Fig. 27

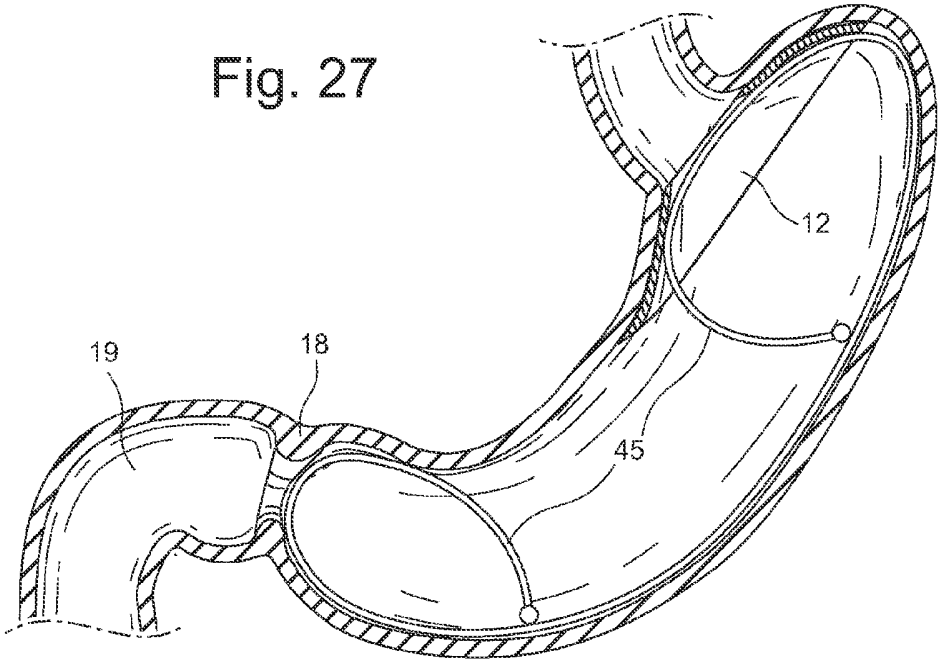


Fig. 28

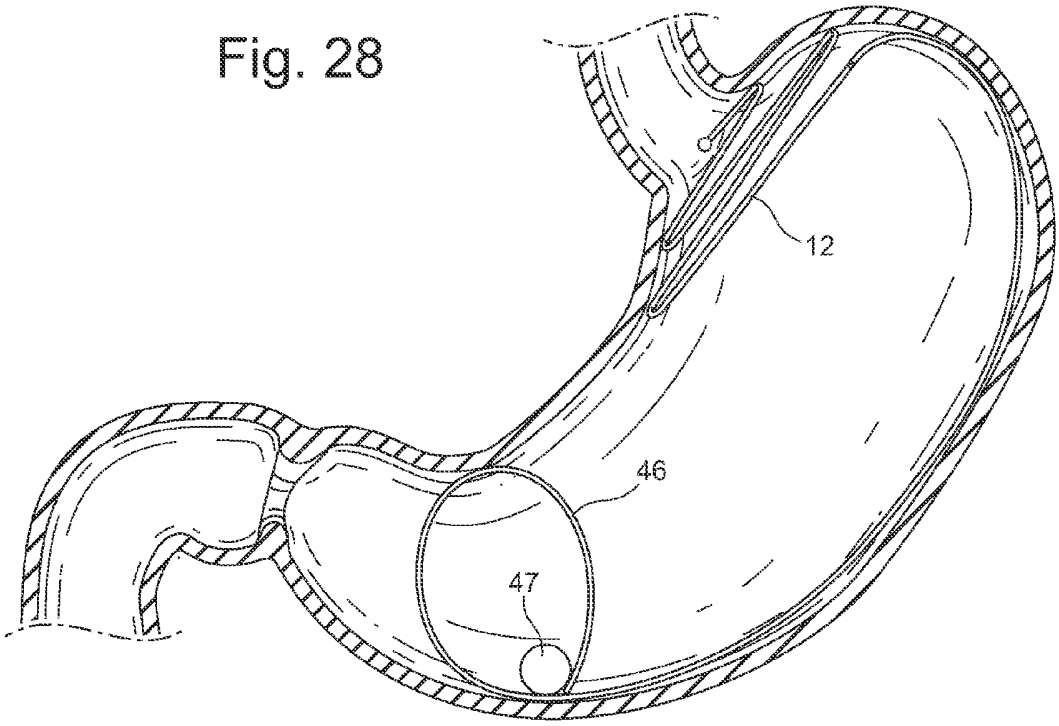


Fig. 29

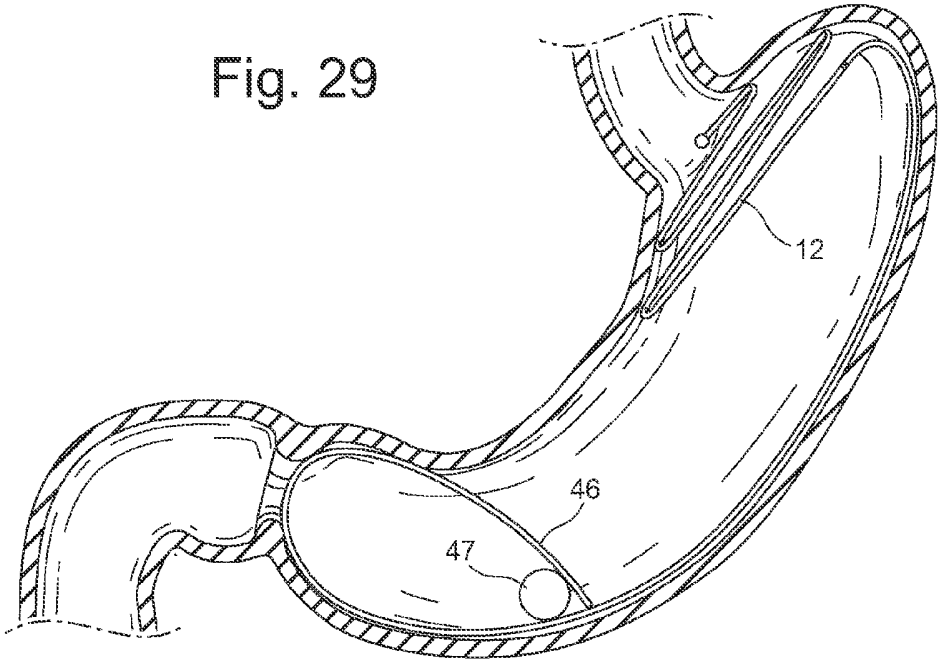


Fig. 30

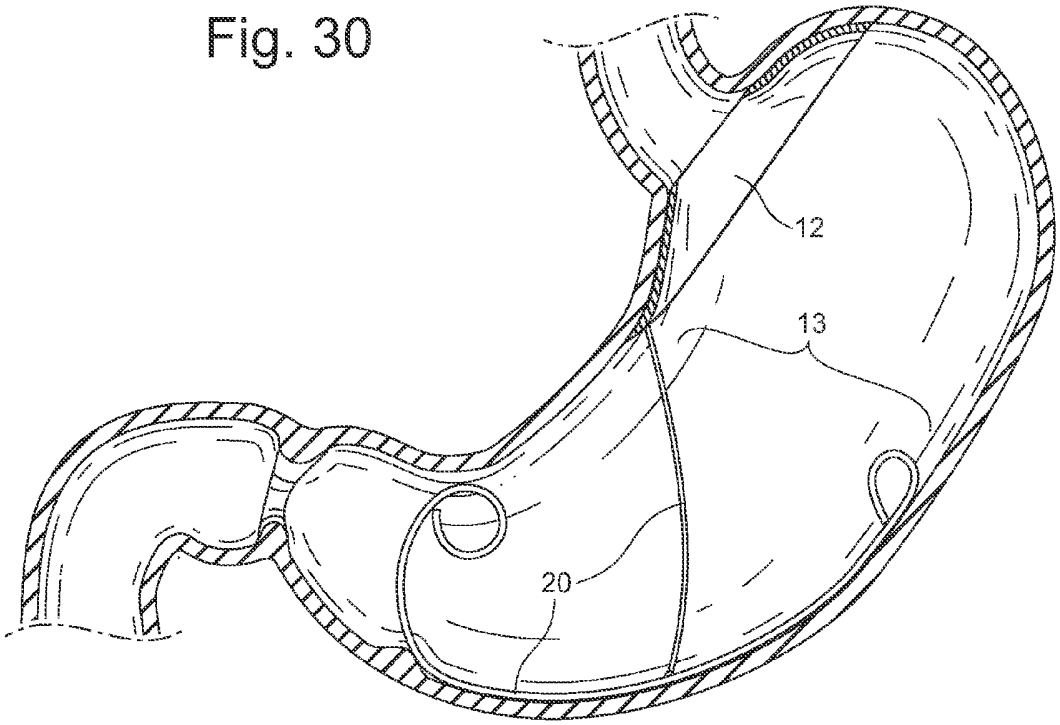


Fig. 31

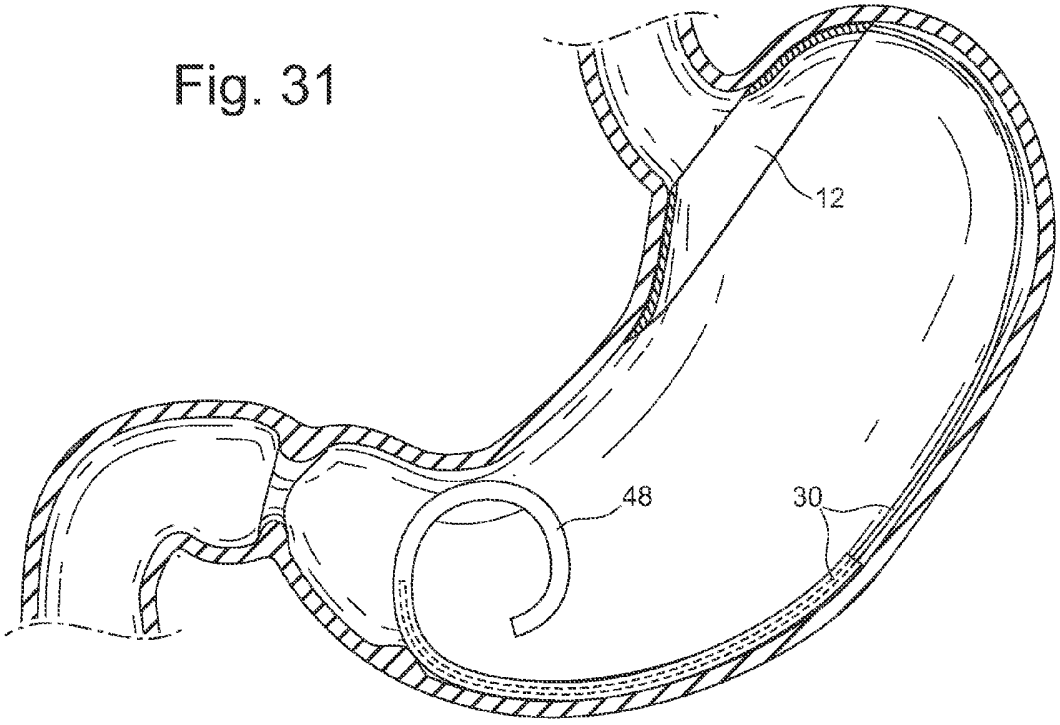


Fig. 32B

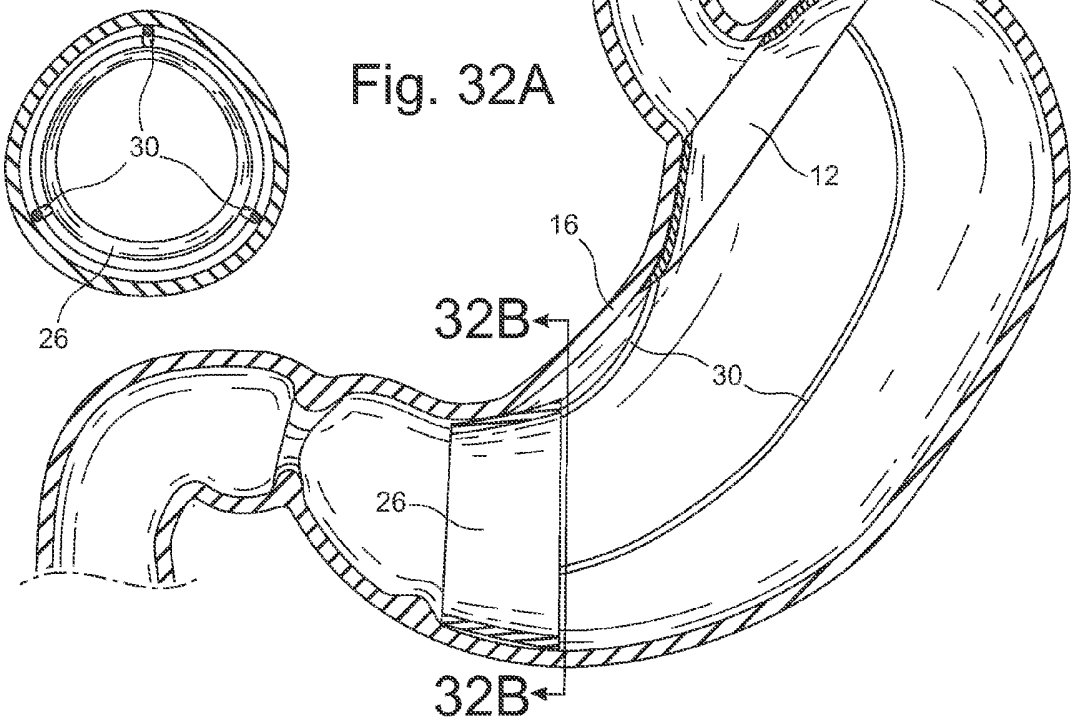


Fig. 33B

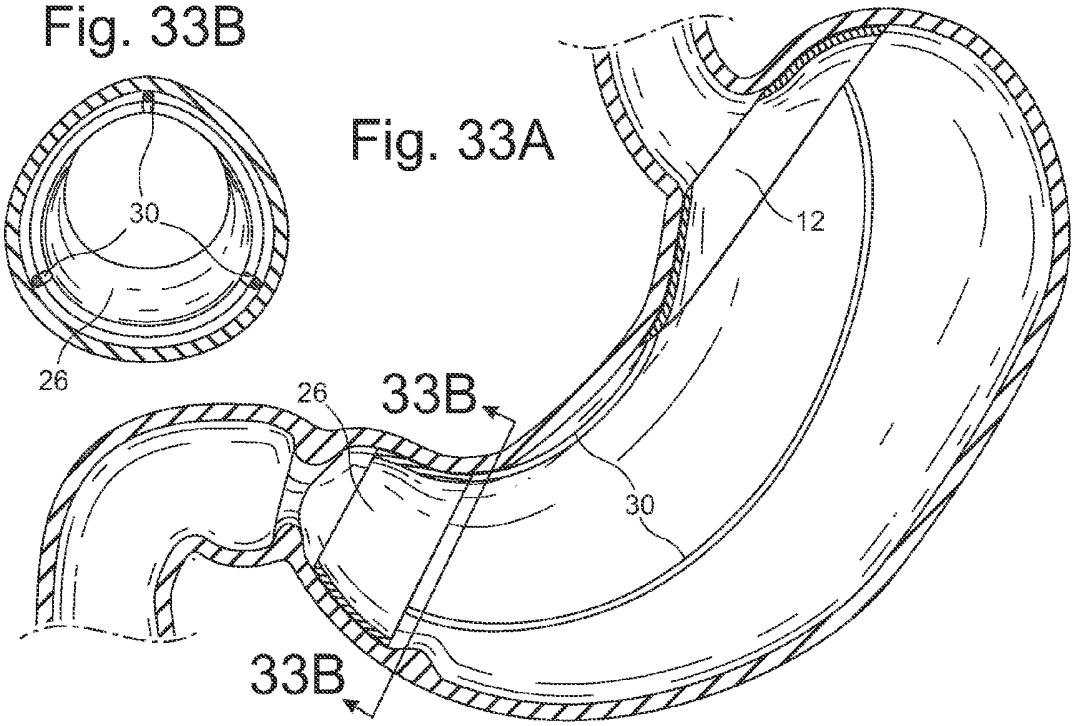


Fig. 34B

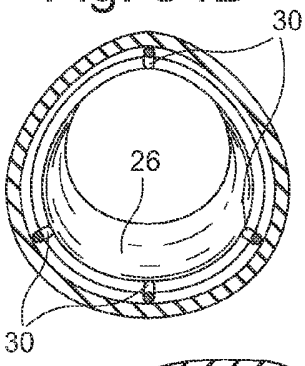


Fig. 34A

Fig. 35

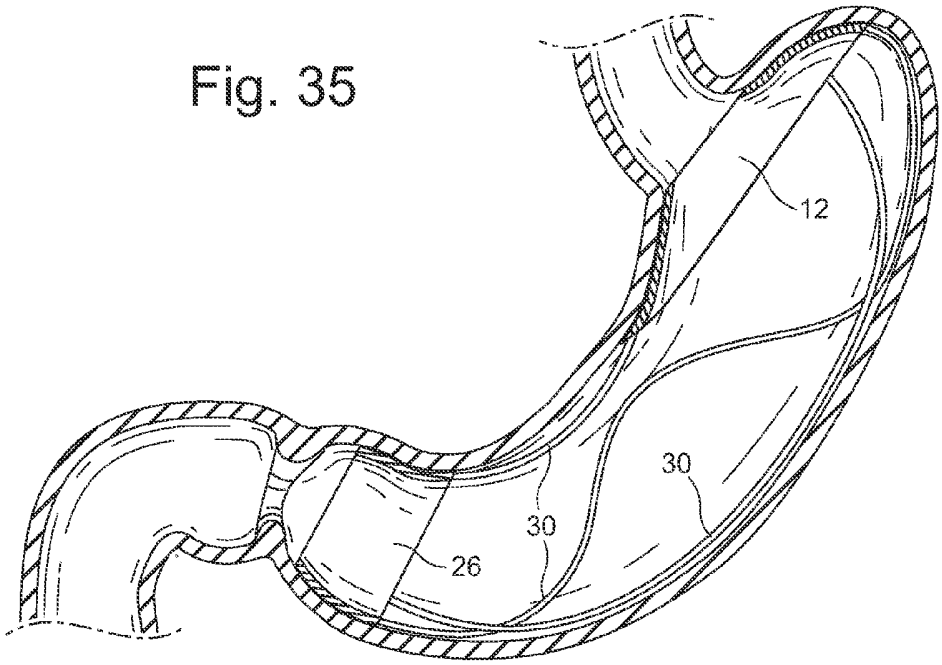


Fig. 36A

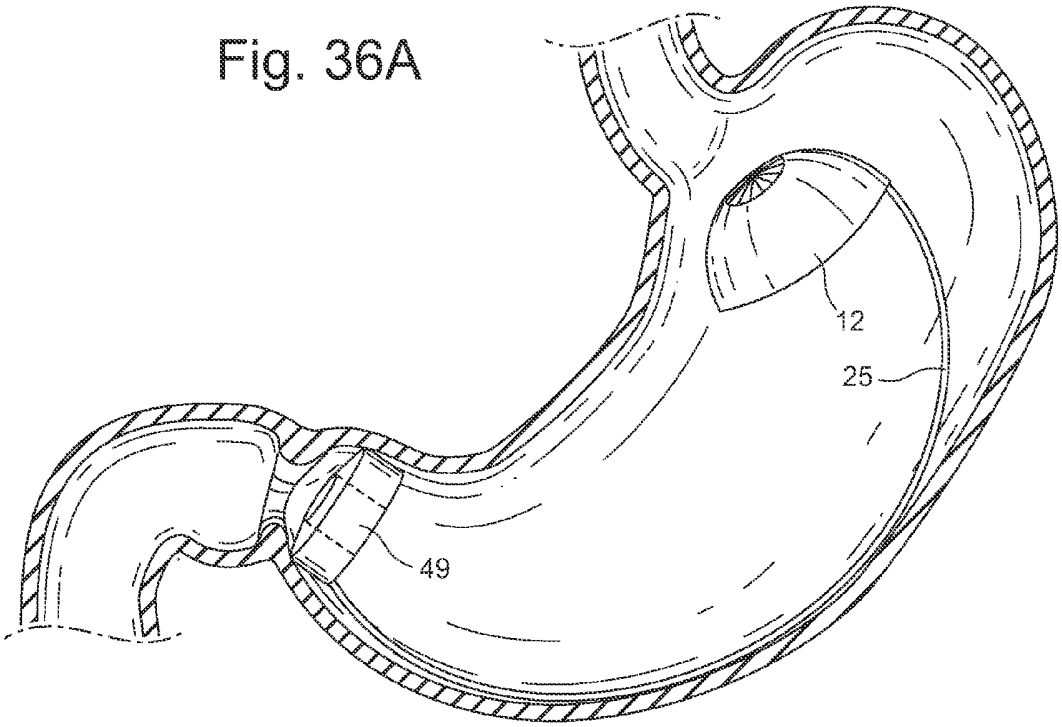


Fig. 36B

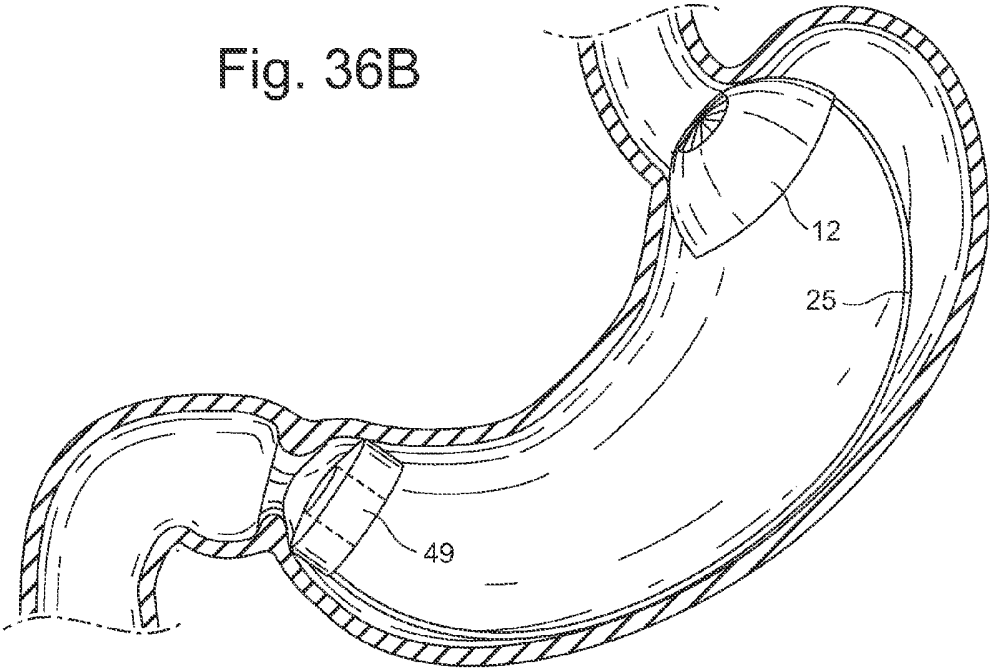


Fig. 37A

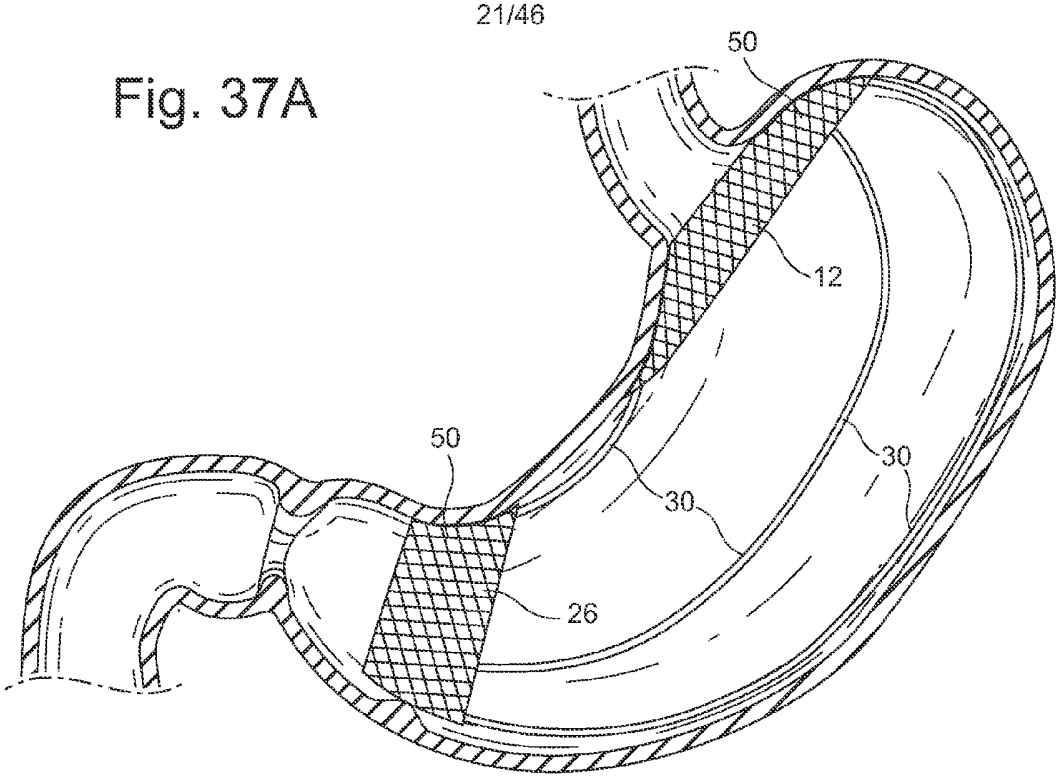
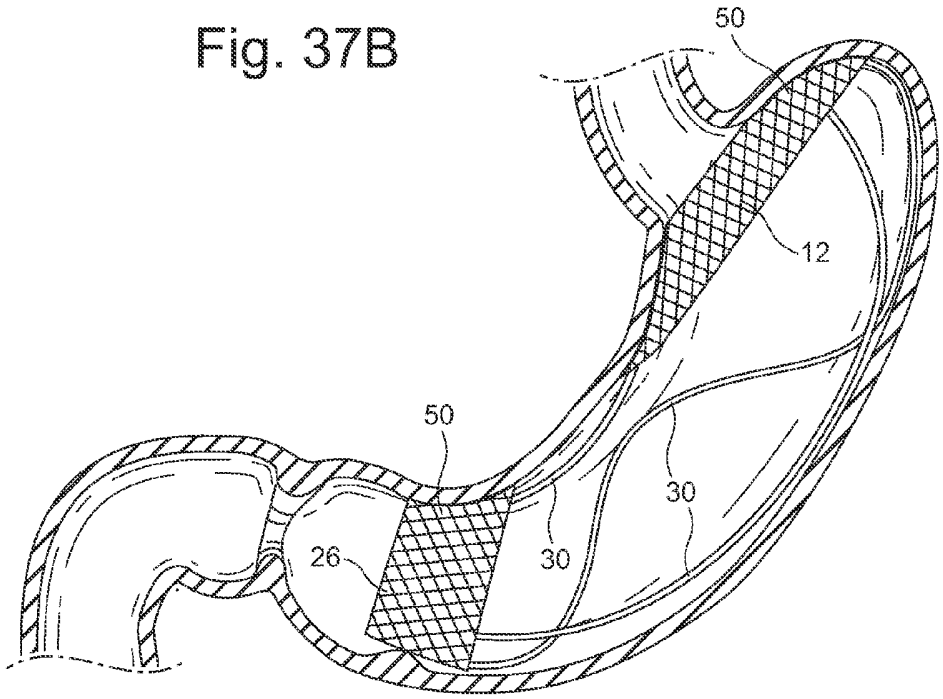


Fig. 37B



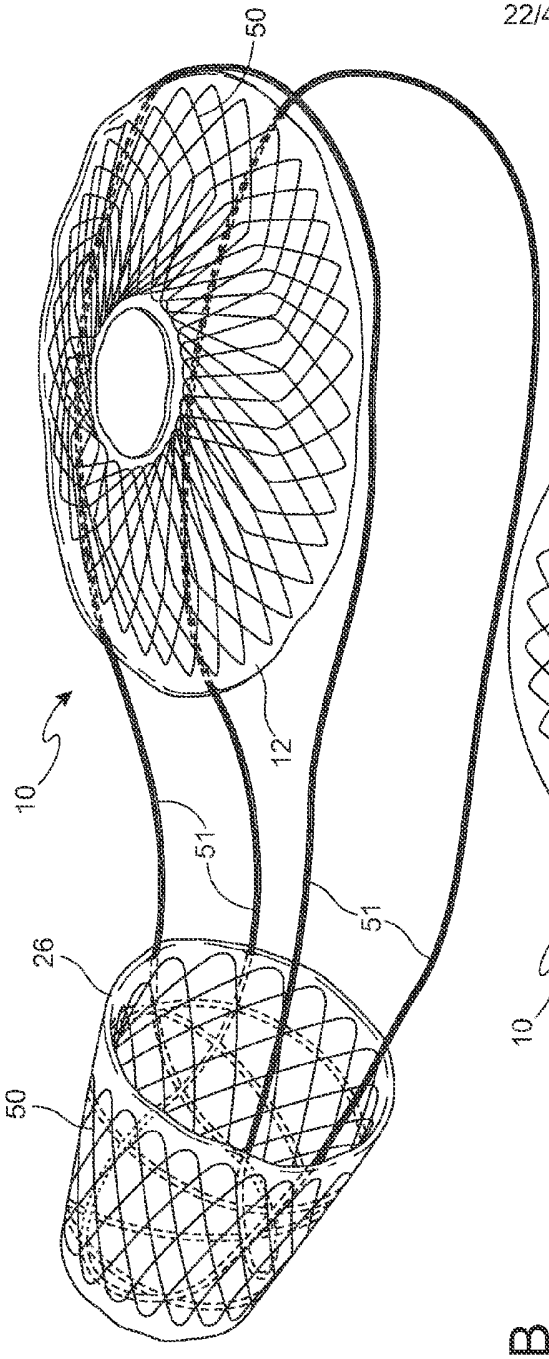


Fig. 38A

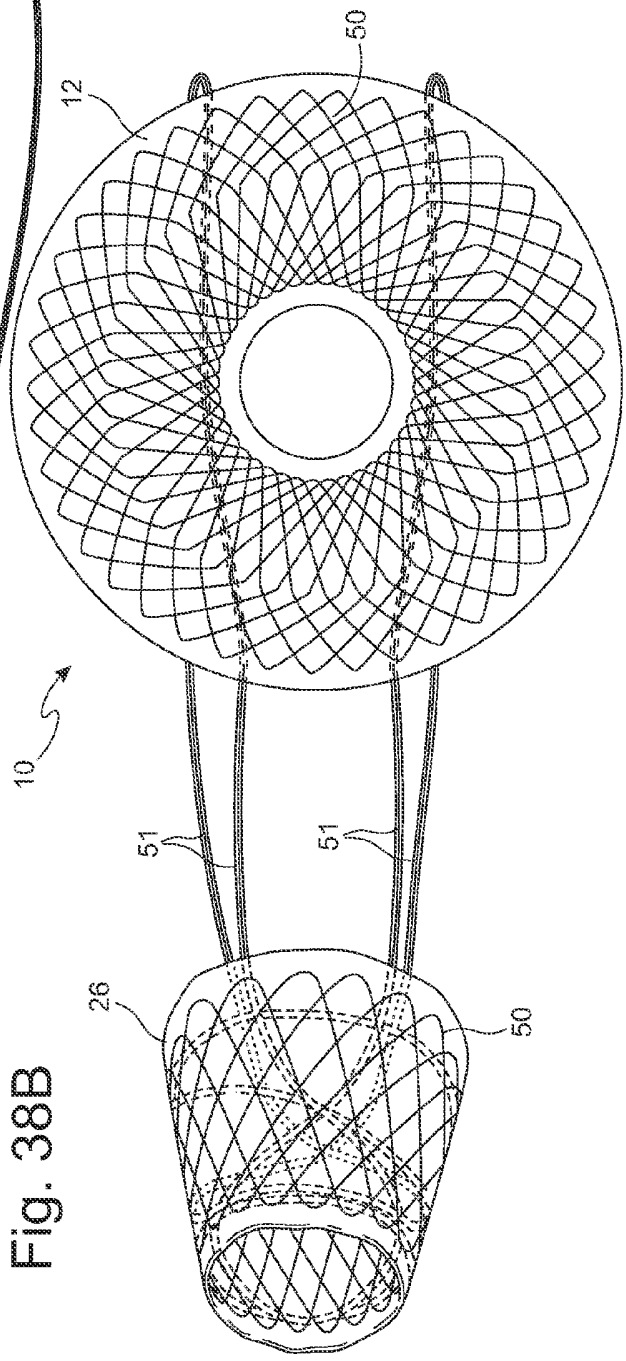


Fig. 38B

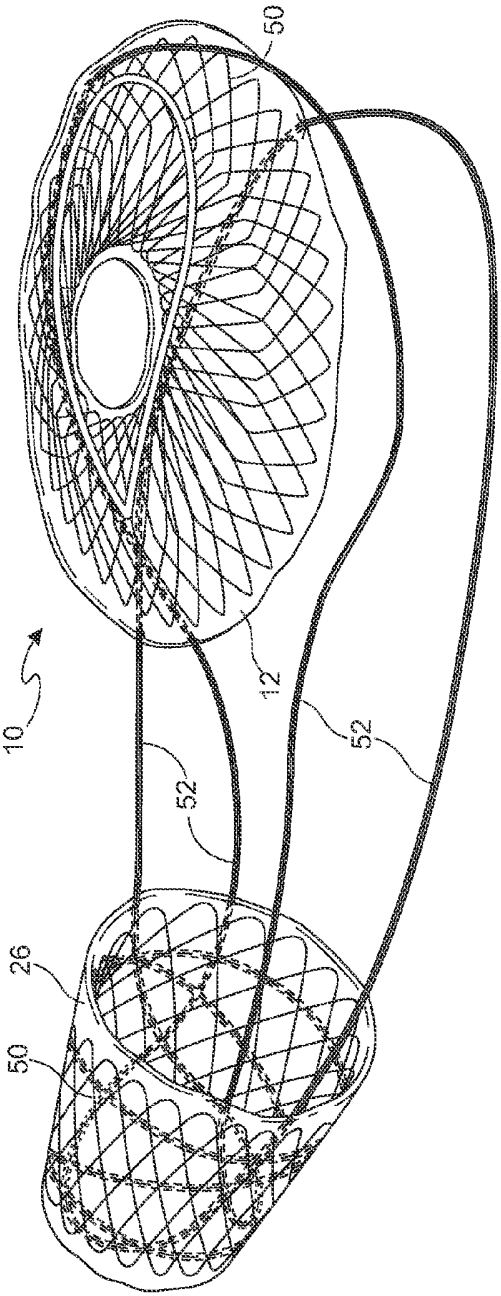


Fig. 39A

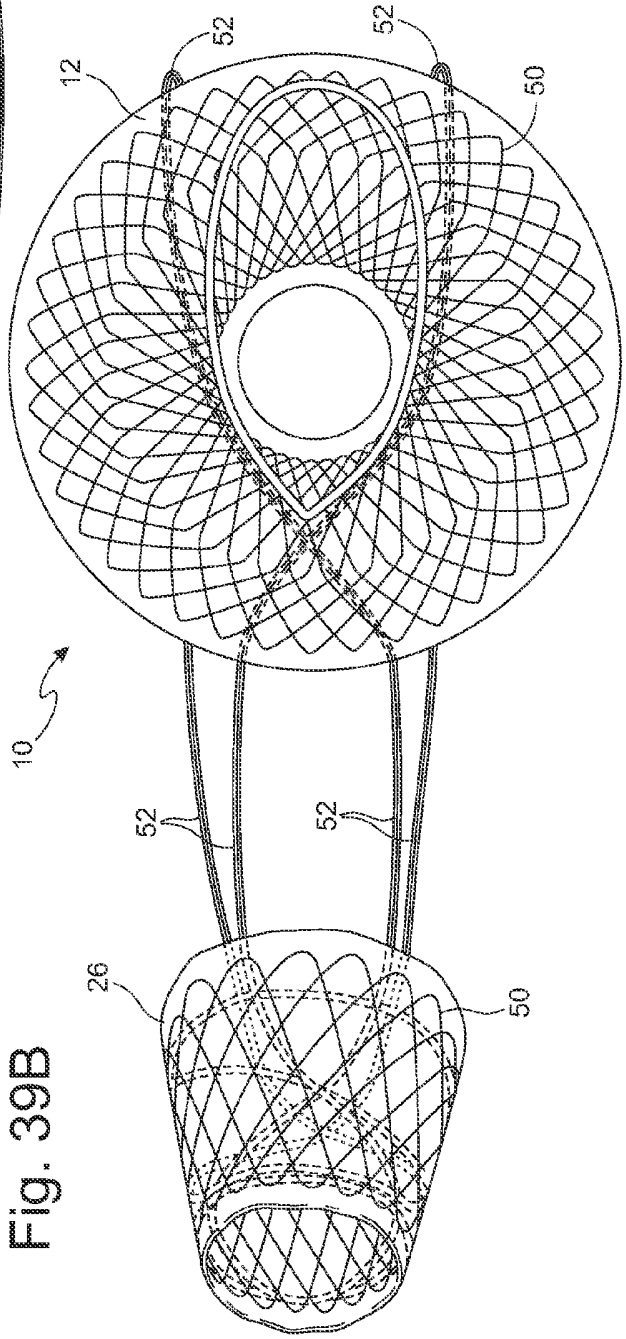


Fig. 39B

Fig. 40A

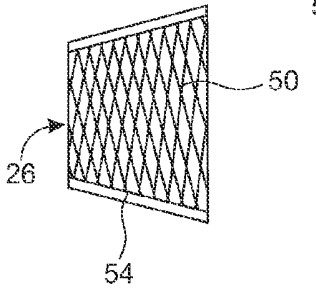


Fig. 40B

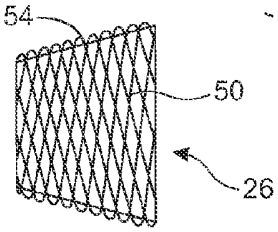


Fig. 41

Fig. 42A

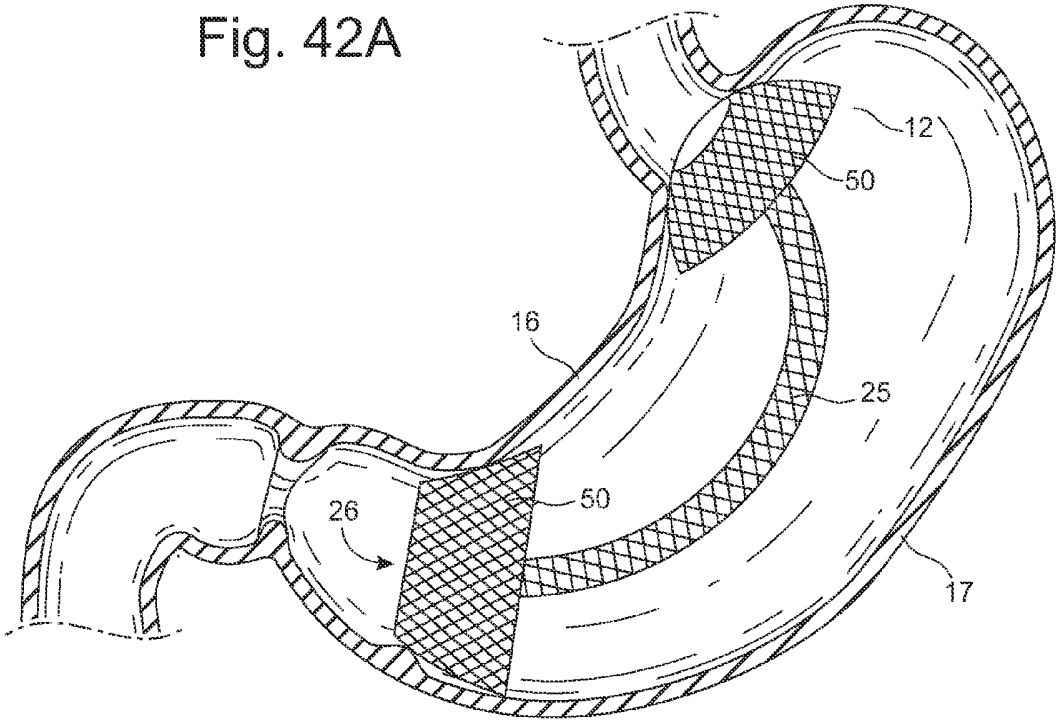


Fig. 42B

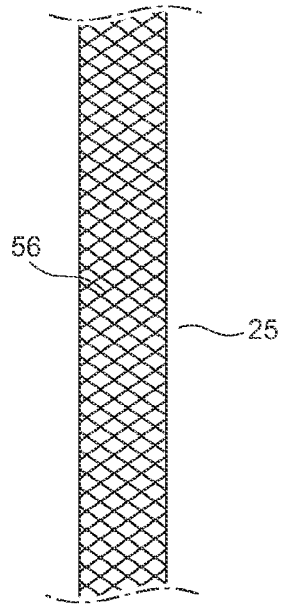


Fig. 42C

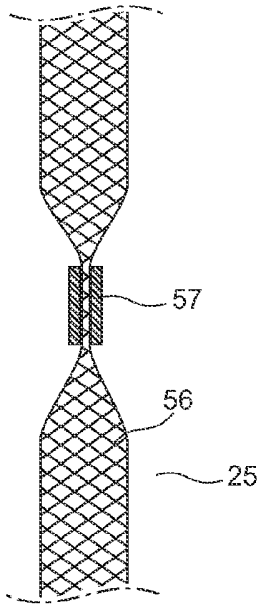


Fig. 42D

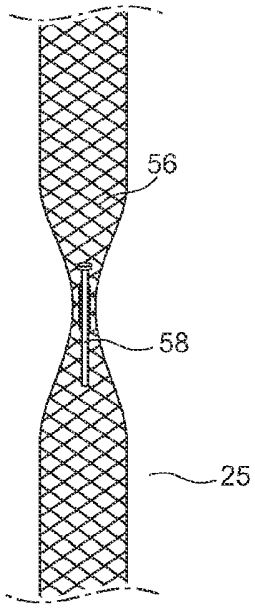


Fig. 43

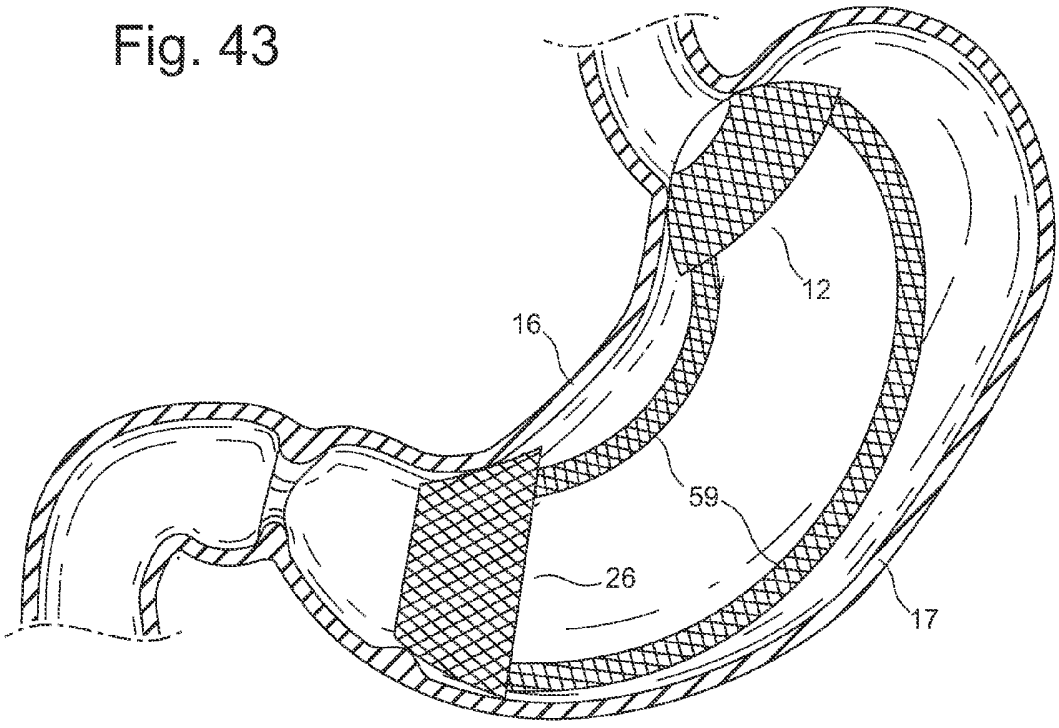


Fig. 44A

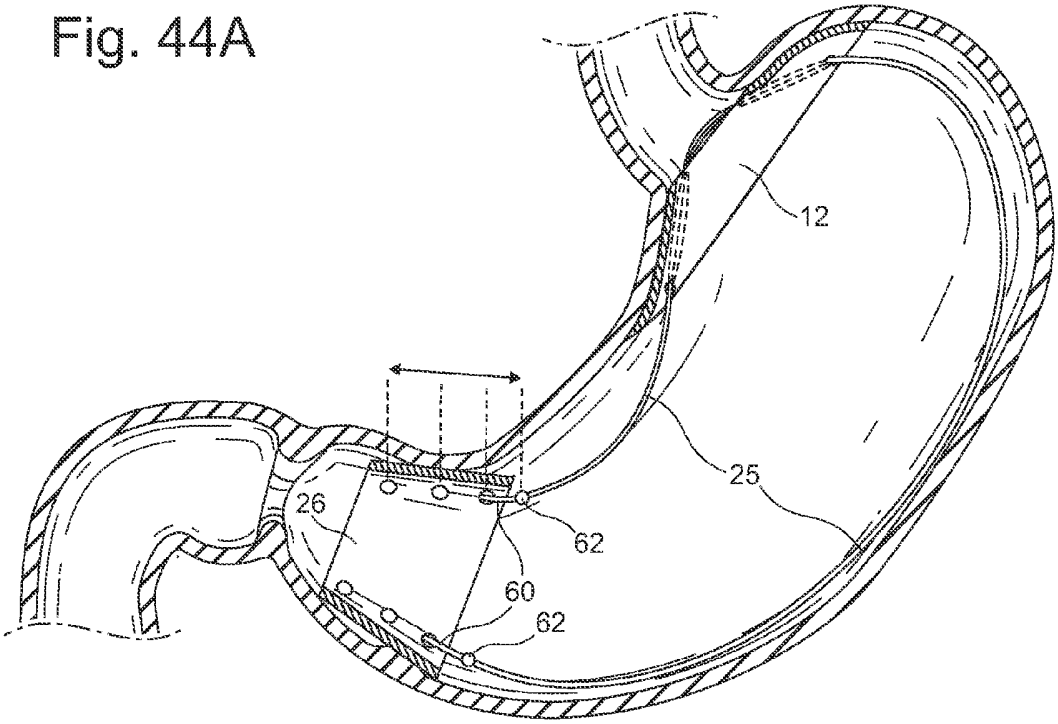


Fig. 44B

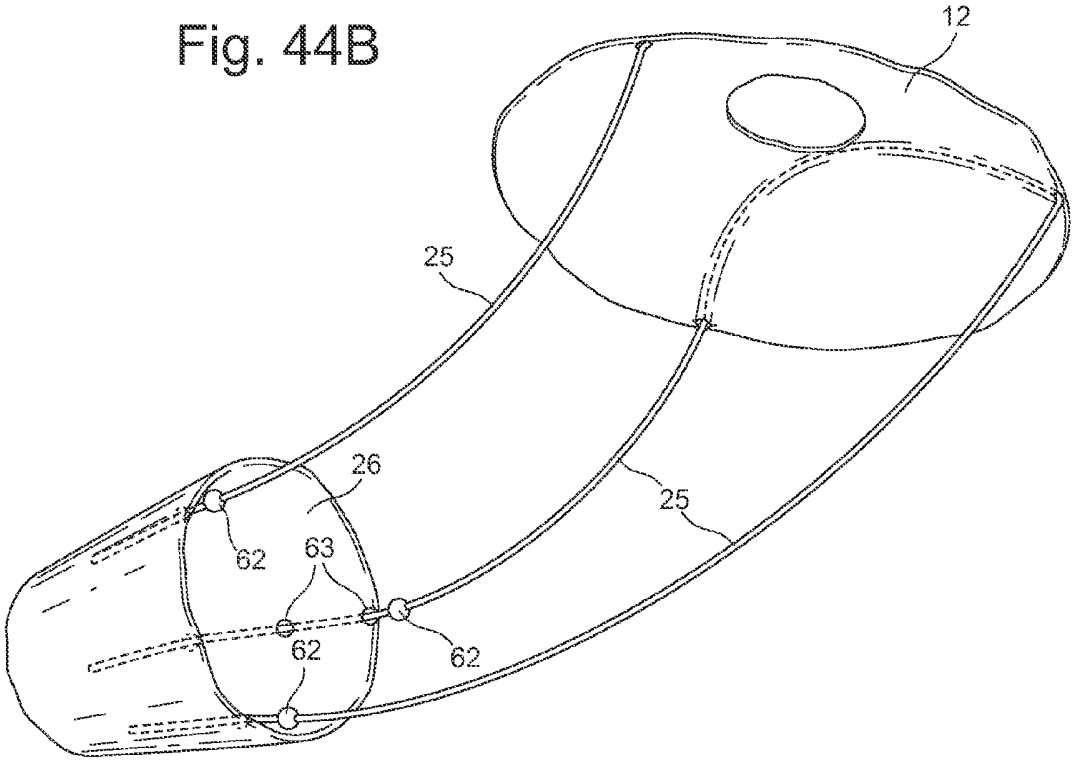


Fig. 45A

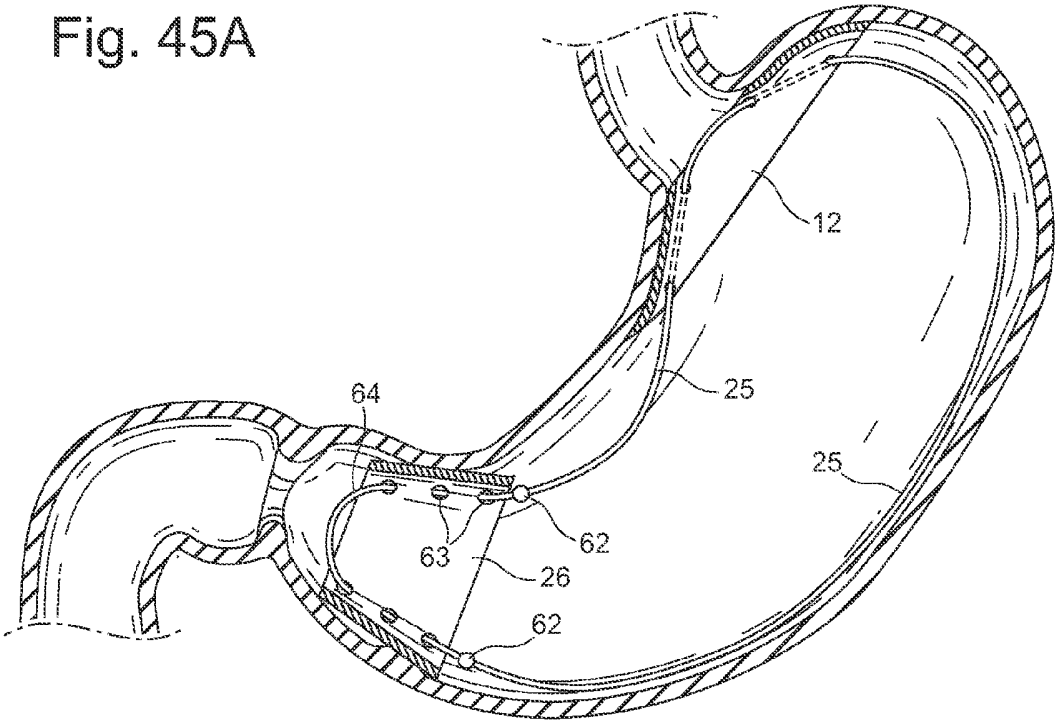


Fig. 45B

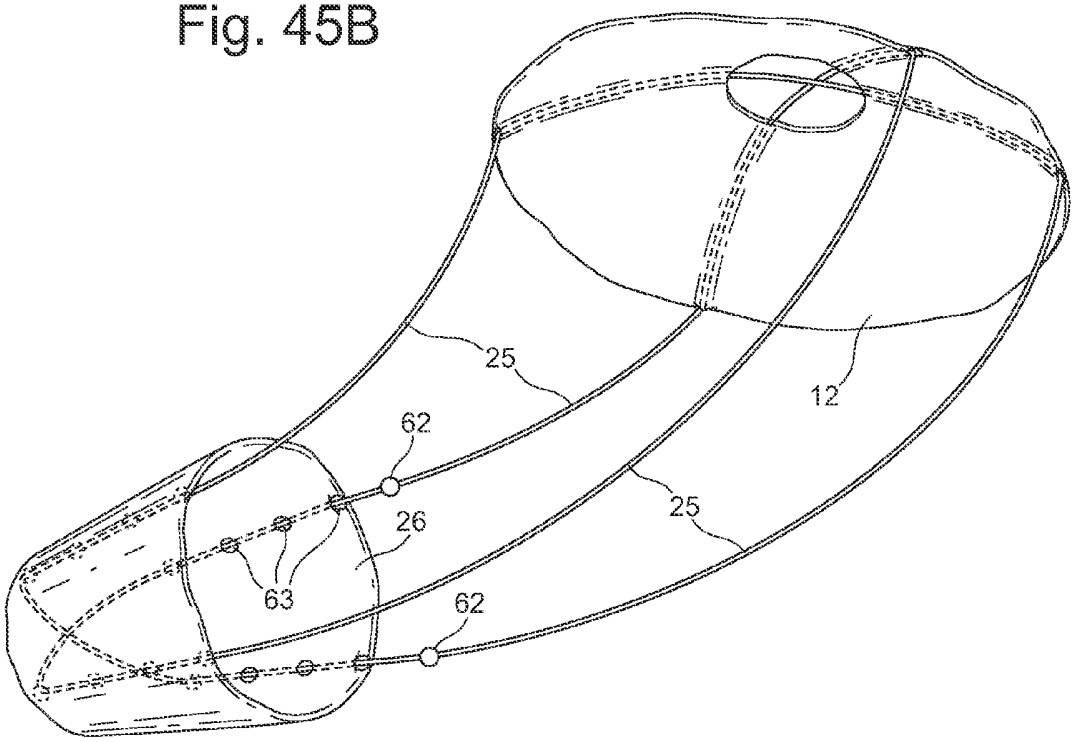


Fig. 46A

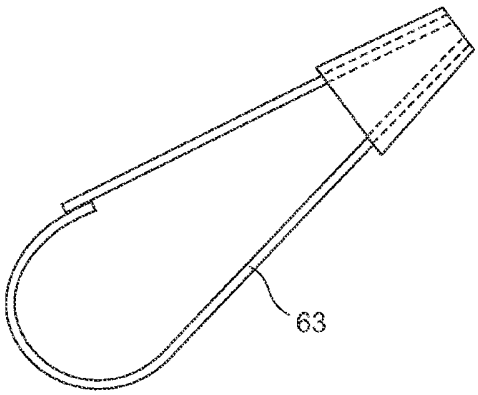


Fig. 46B

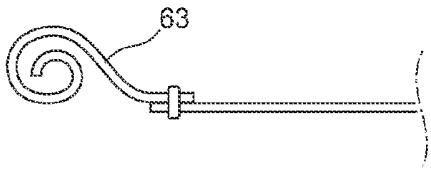


Fig. 46C

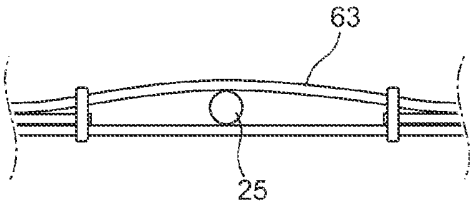


Fig. 46D

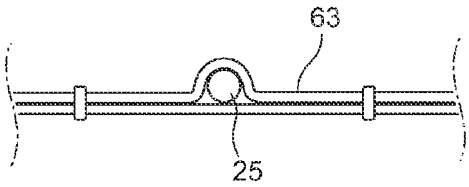


Fig. 46E

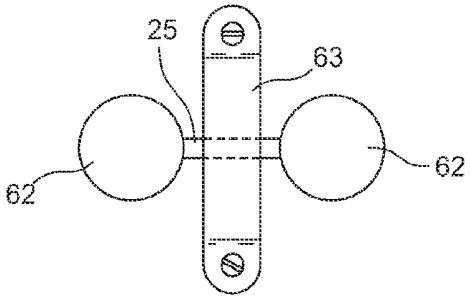


Fig. 47A

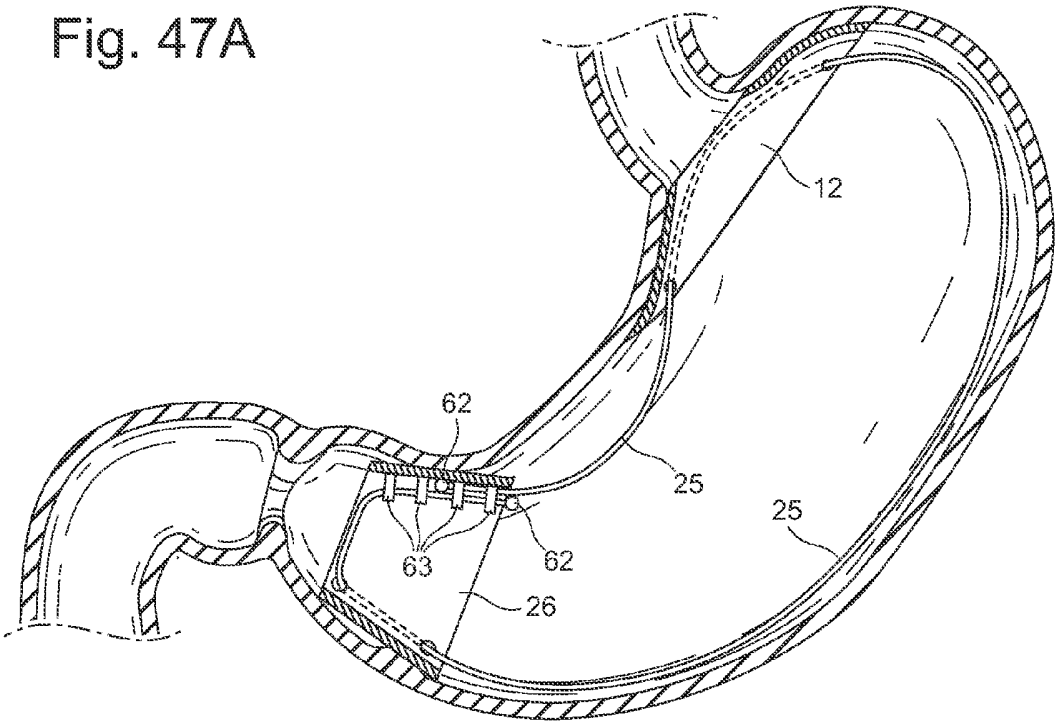


Fig. 47B

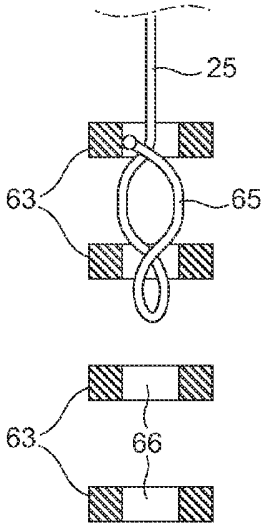


Fig. 47C

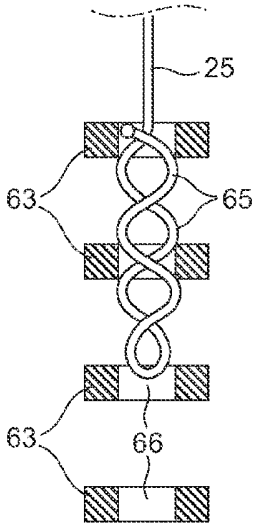


Fig. 47D

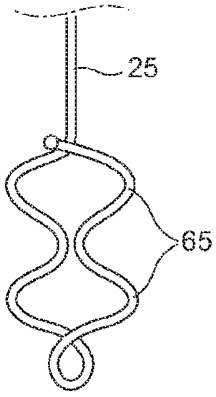


Fig. 48

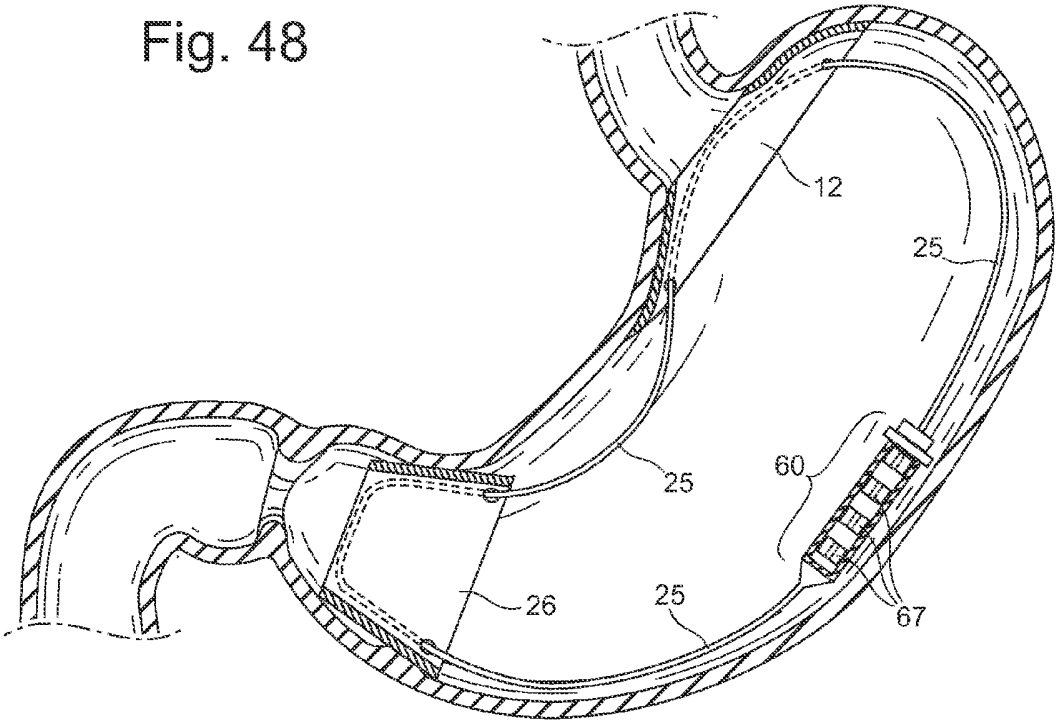


Fig. 49A

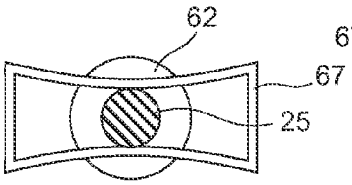


Fig. 50A

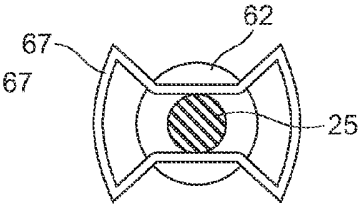


Fig. 51A

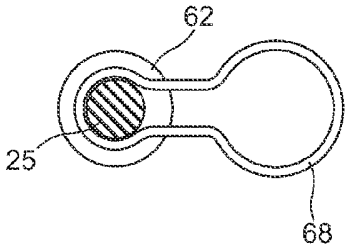


Fig. 49B

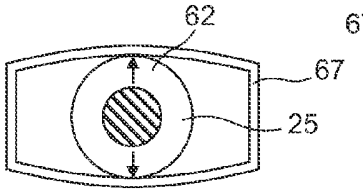


Fig. 50B

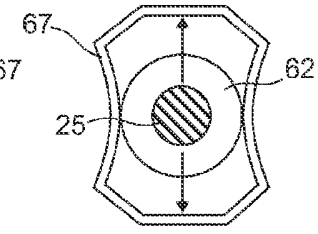


Fig. 51B

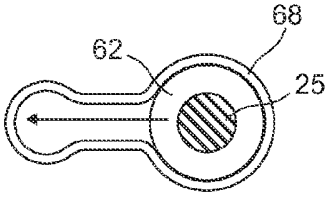


Fig. 52A

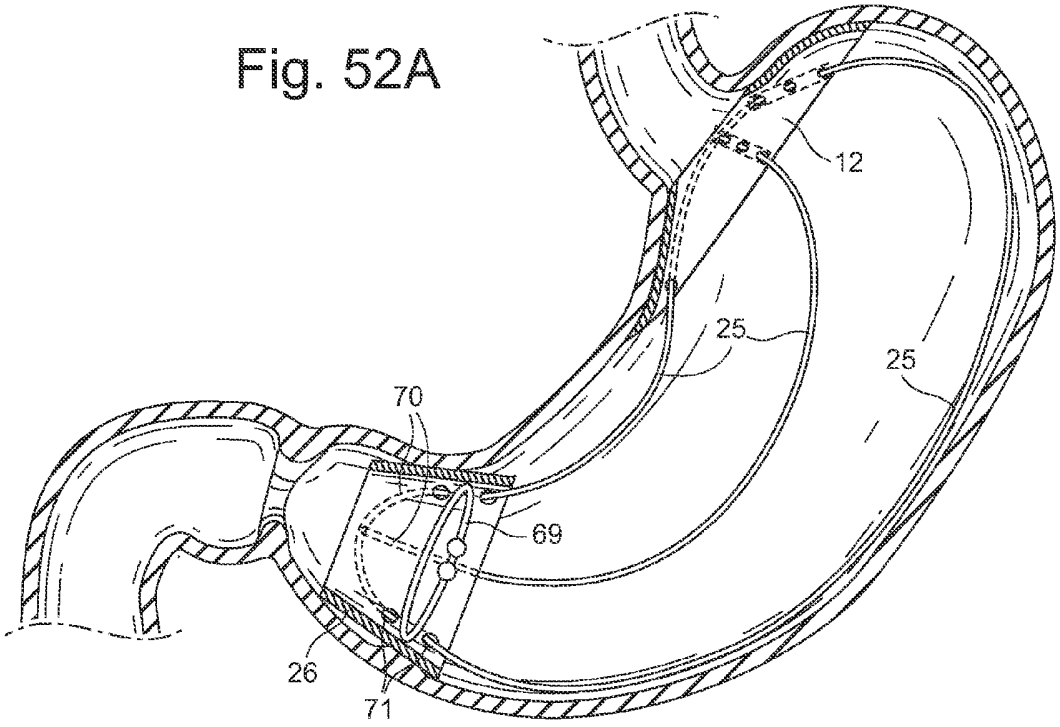


Fig. 52B

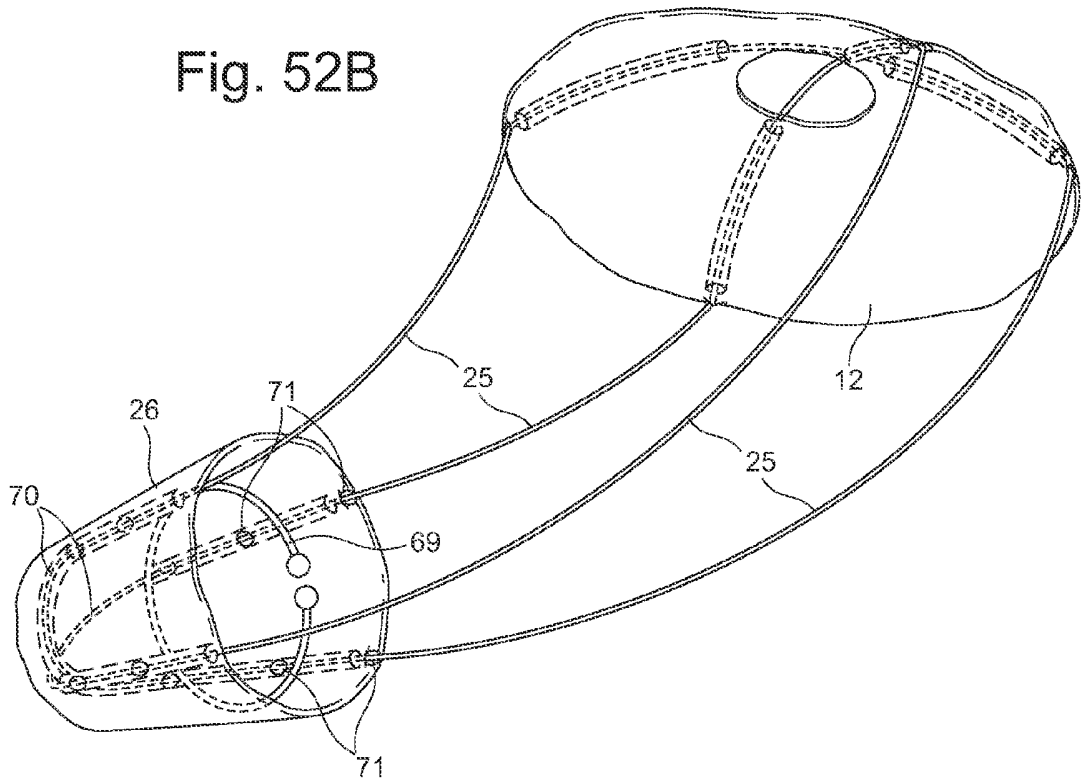


Fig. 54

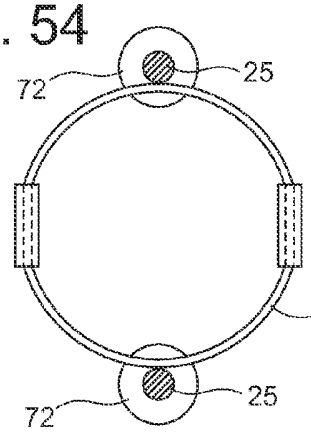


Fig. 53

Fig. 55

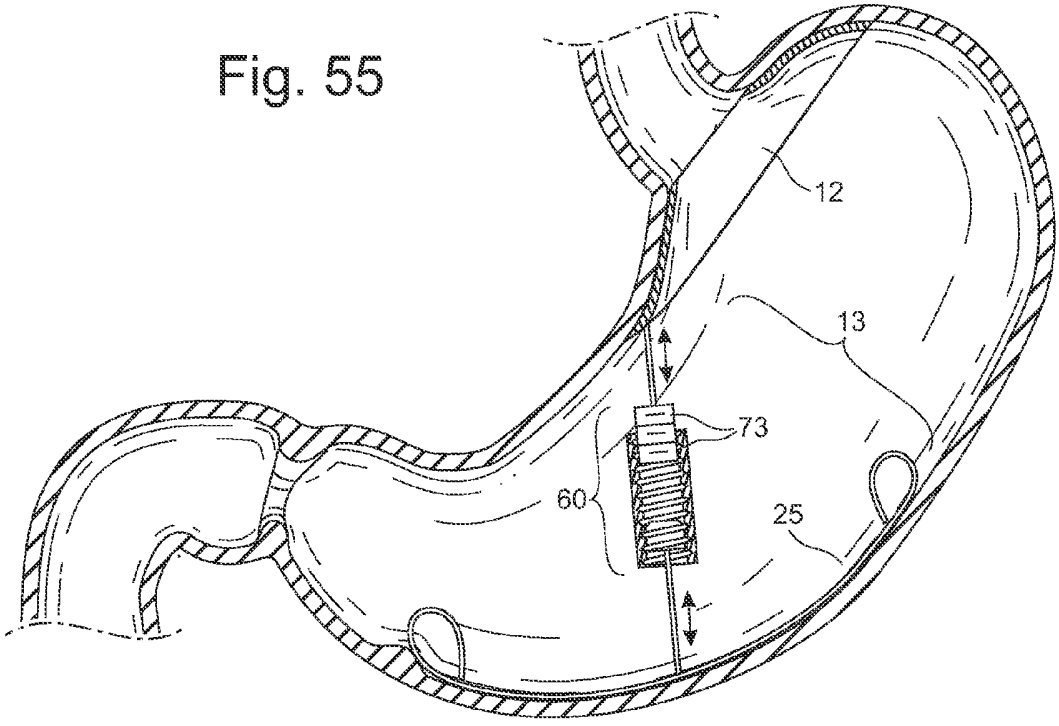


Fig. 56

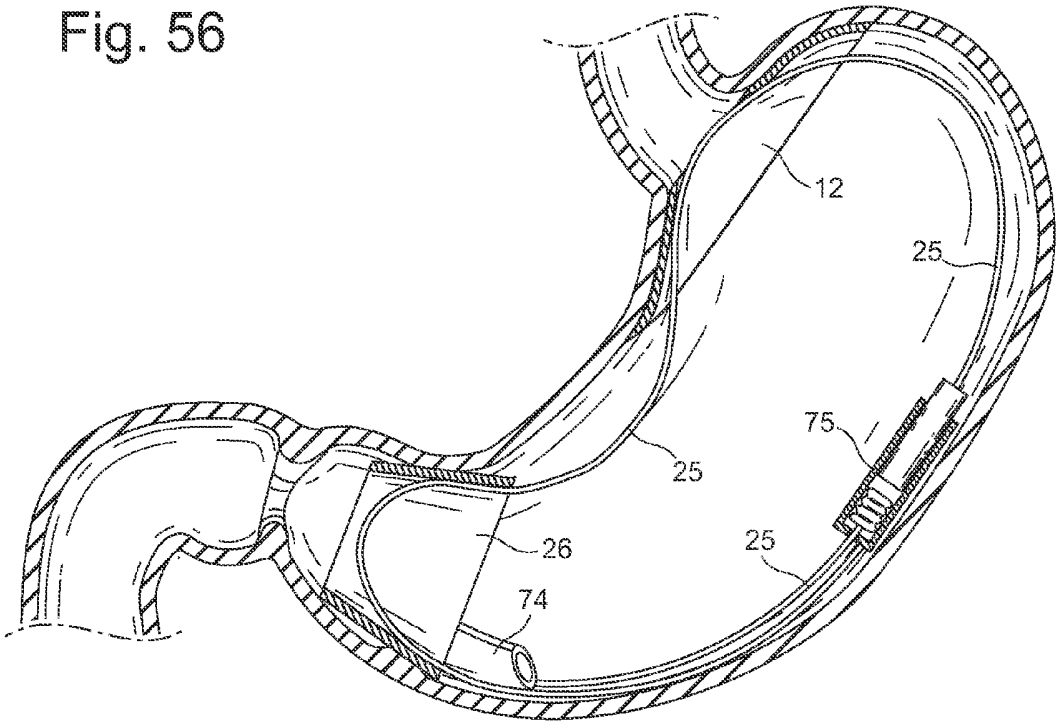


Fig. 57

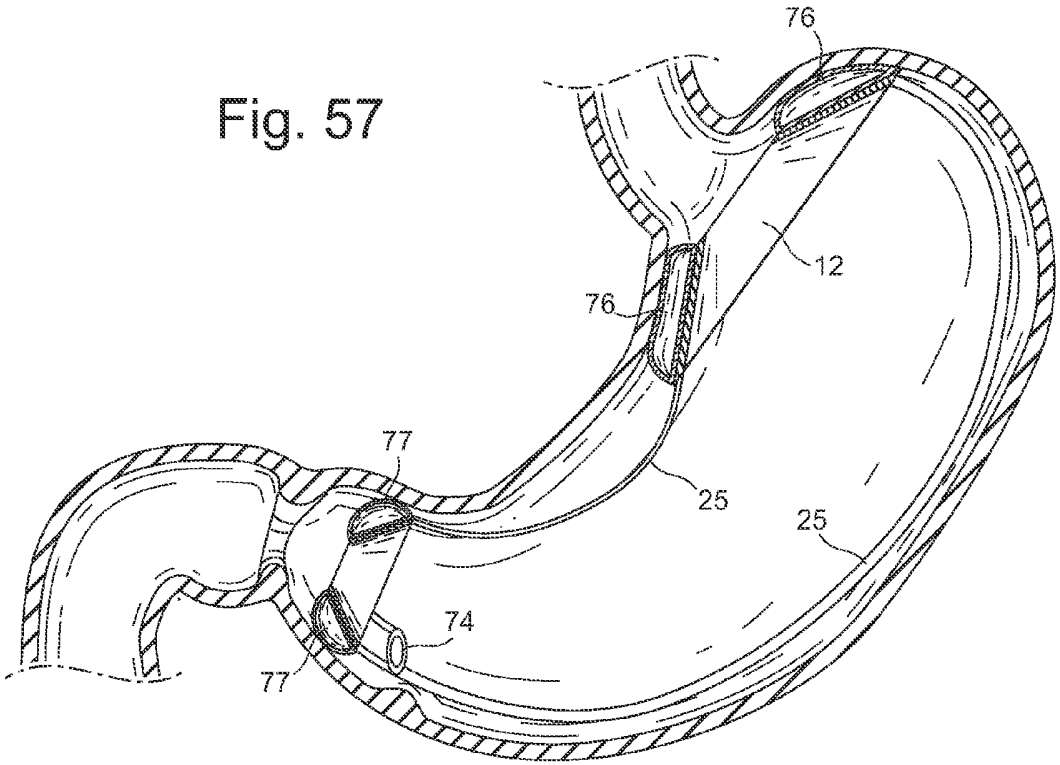


Fig. 58A

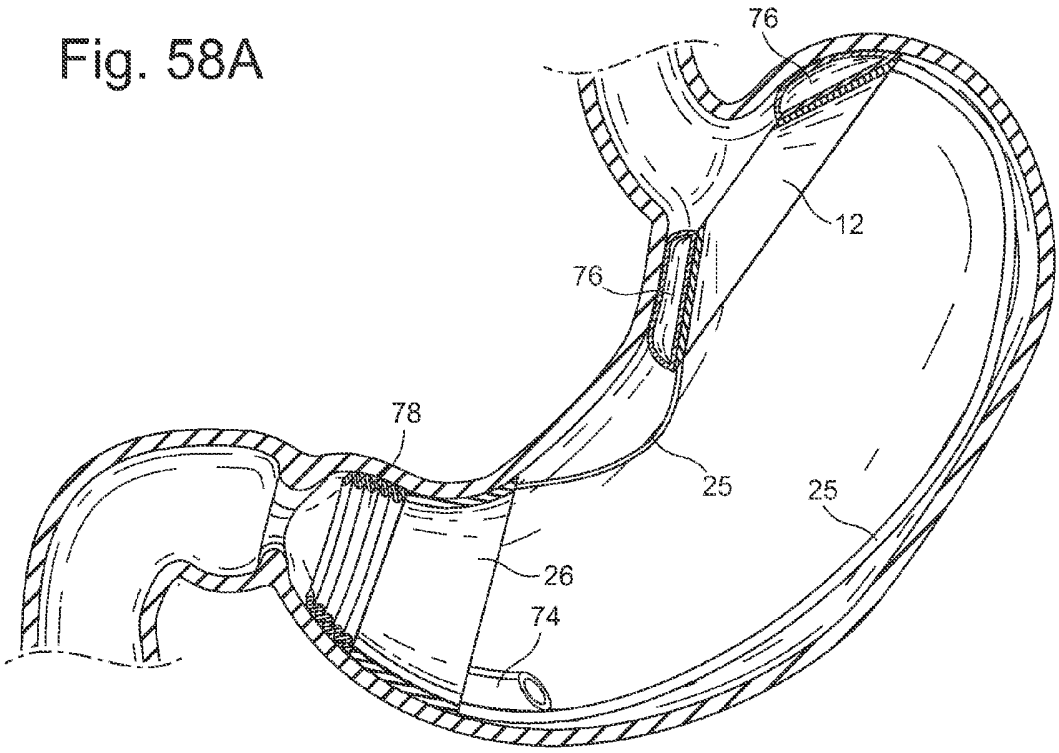


Fig. 58B

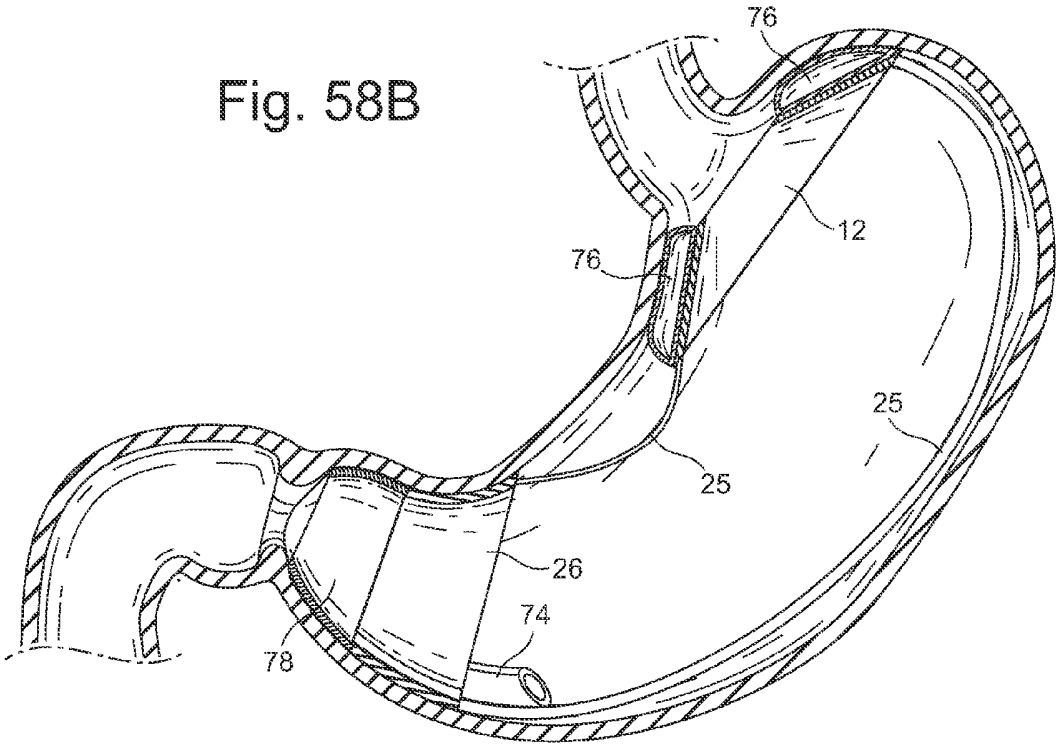


Fig. 59

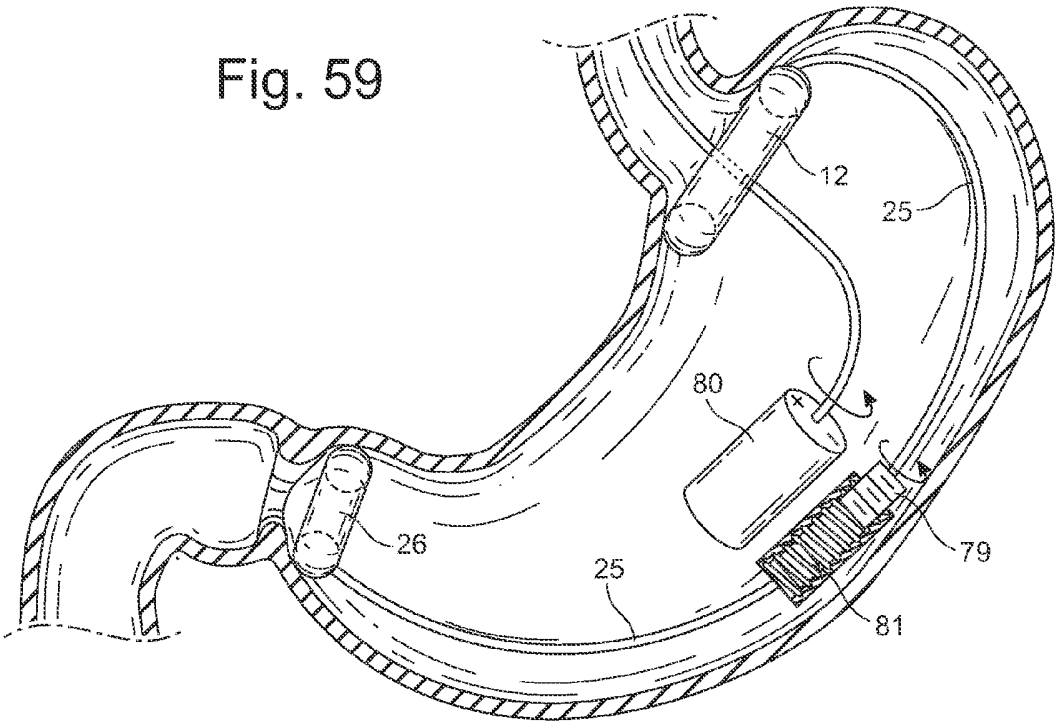


Fig. 60

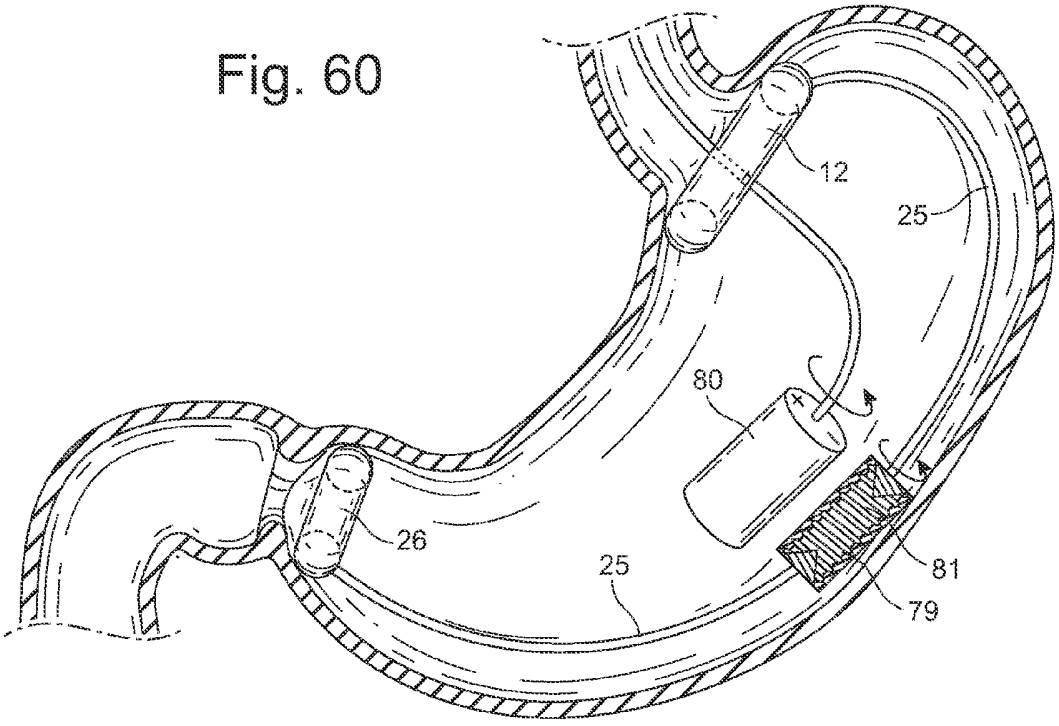


Fig. 61B

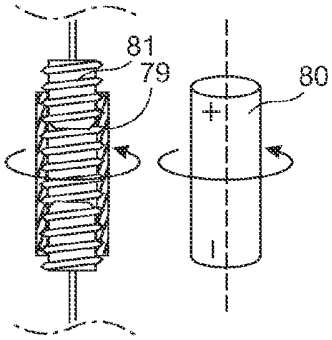


Fig. 61A

Fig. 62

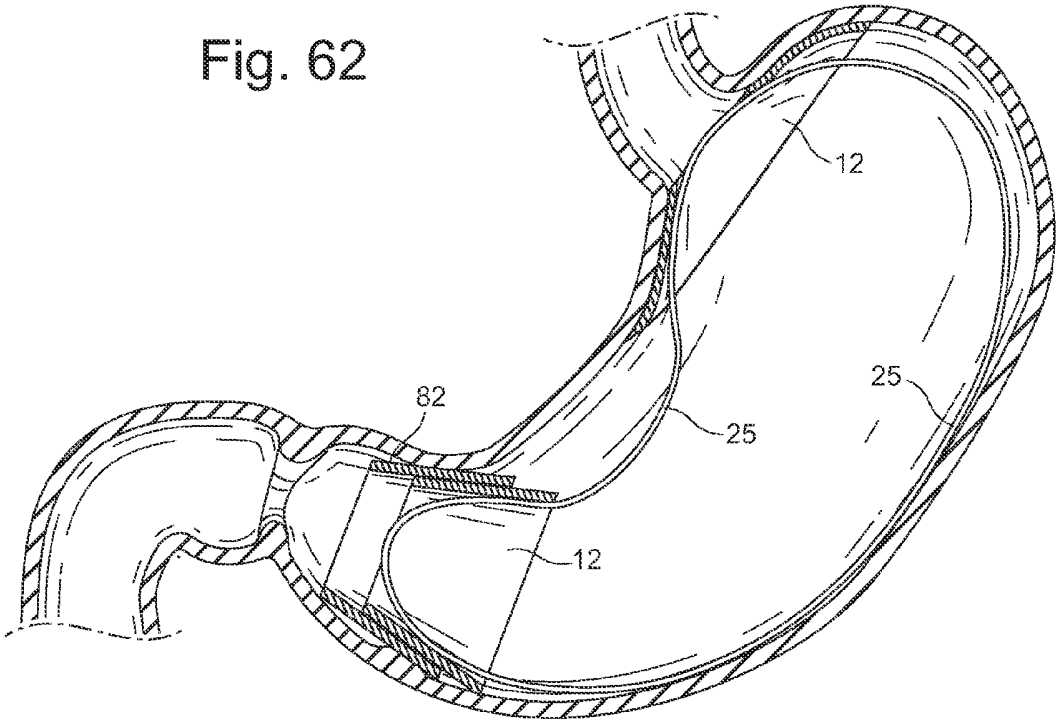


Fig. 63

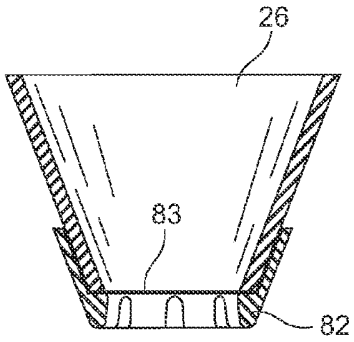


Fig. 64

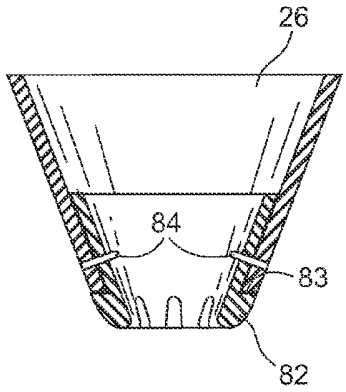


Fig. 65

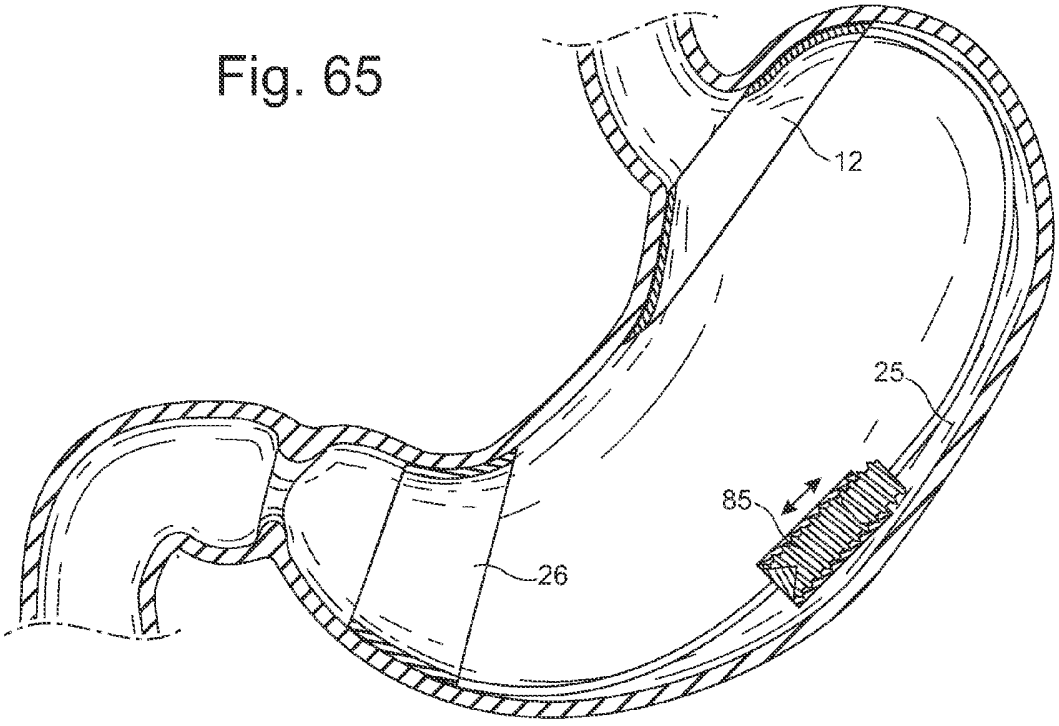


Fig. 66

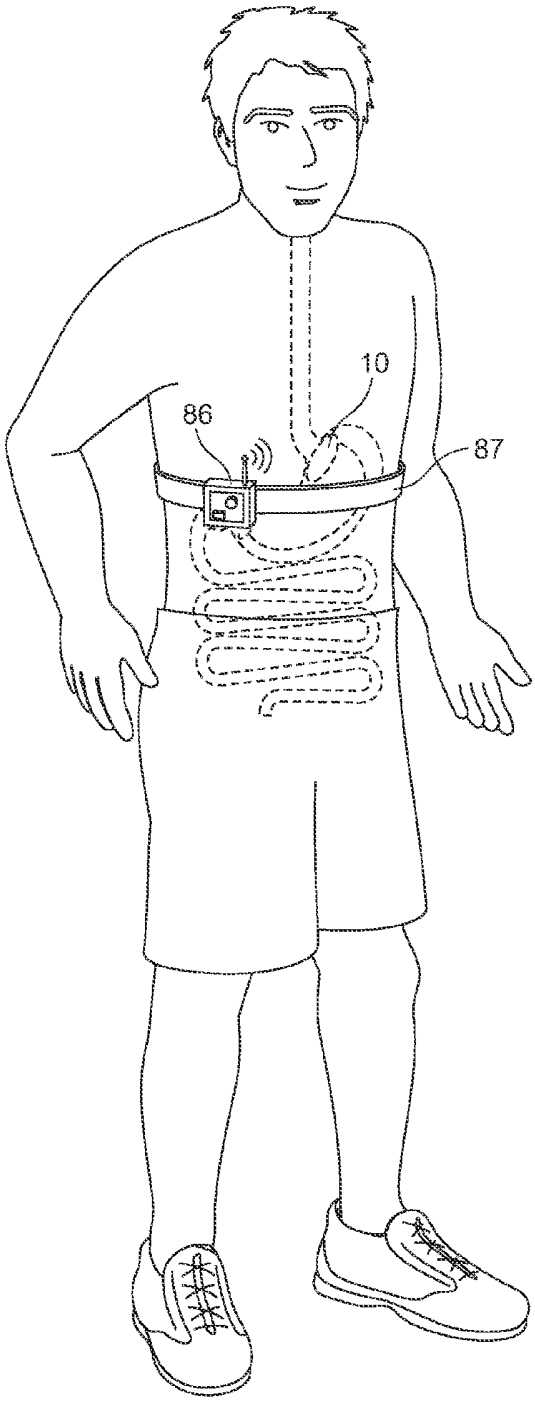


Fig. 67

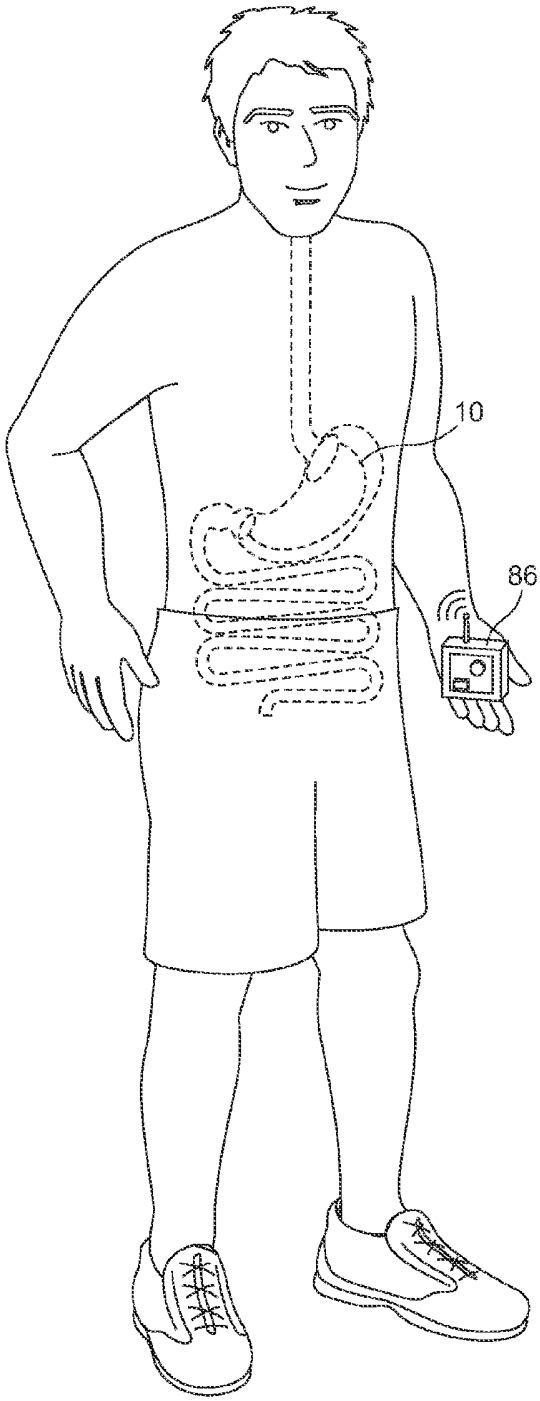


Fig. 68

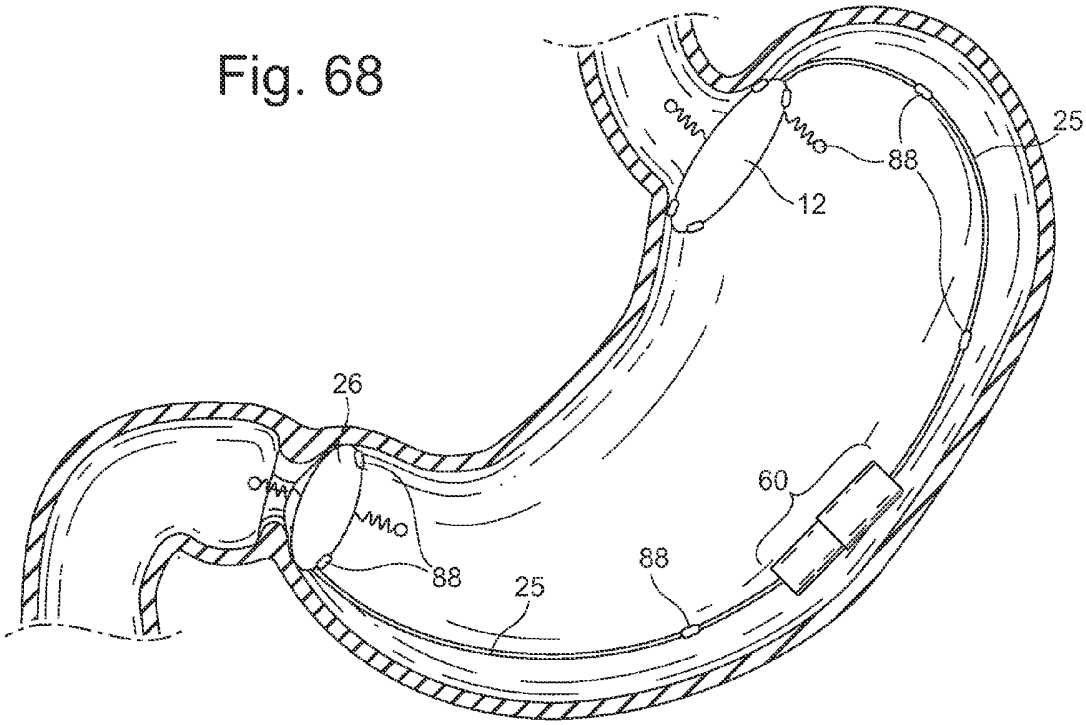


Fig. 69

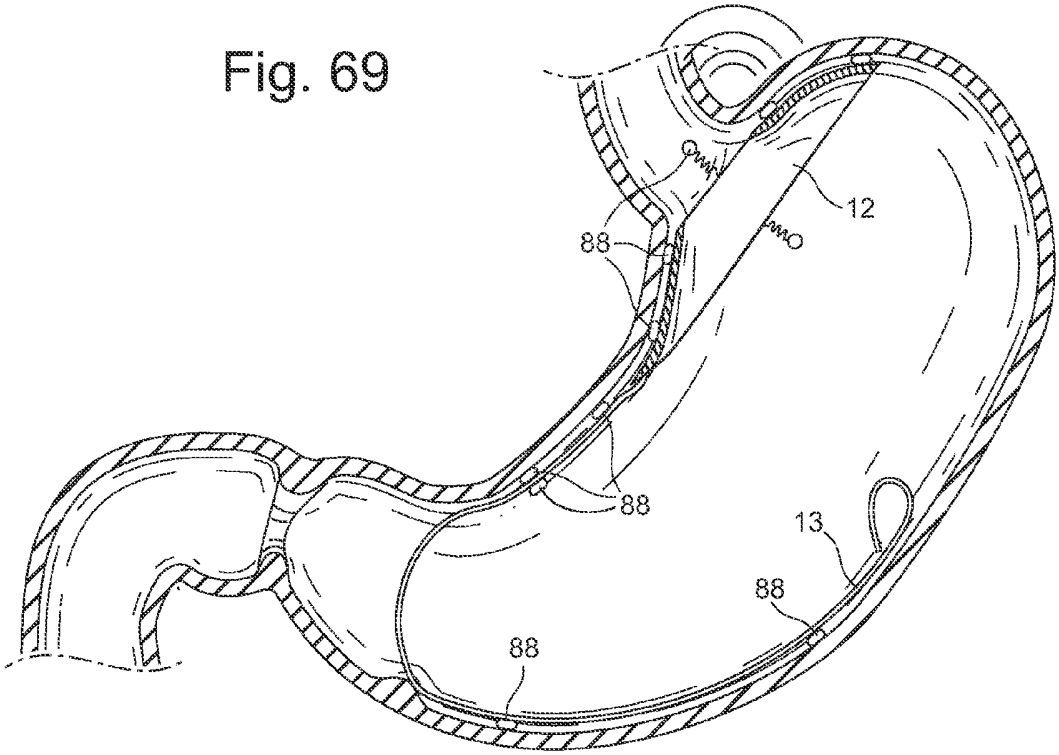


Fig. 70

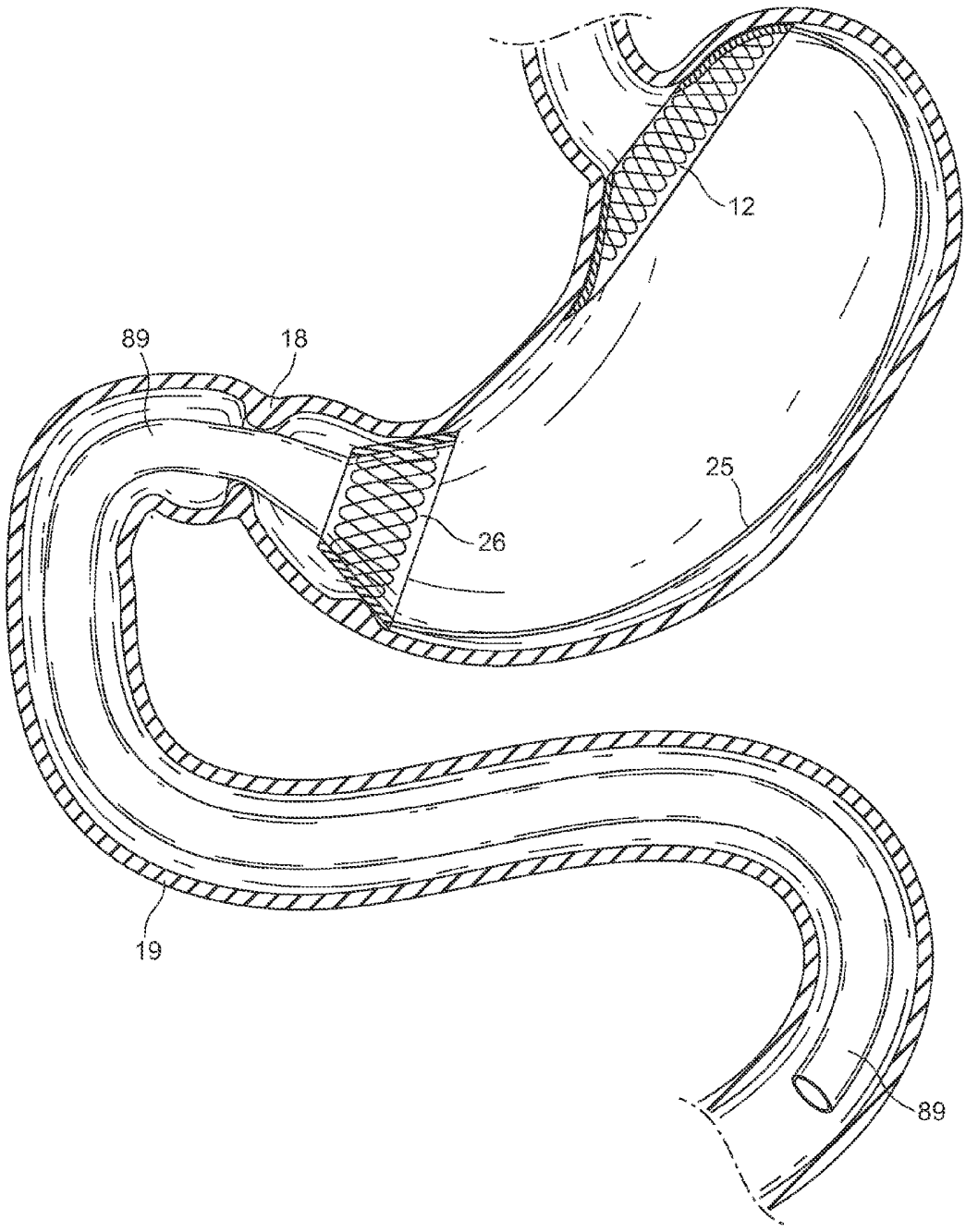


Fig. 71A

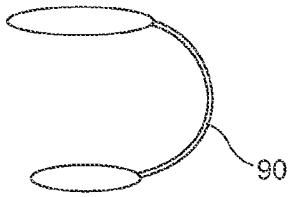


Fig. 71B

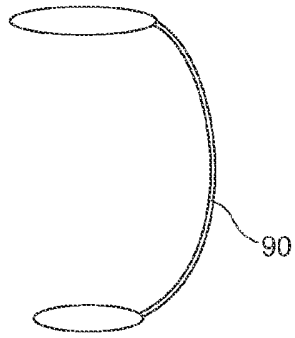


Fig. 72A

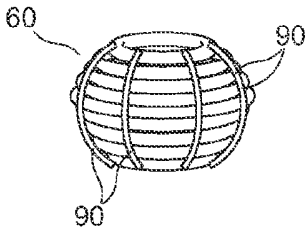


Fig. 72B

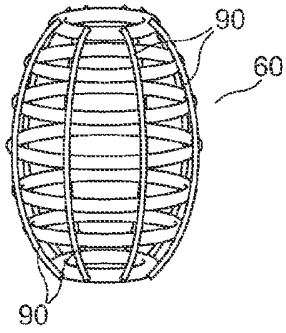


Fig. 73A

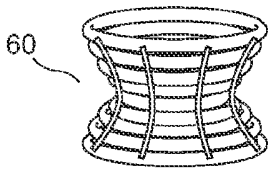
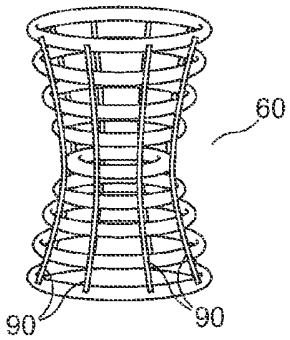


Fig. 73B



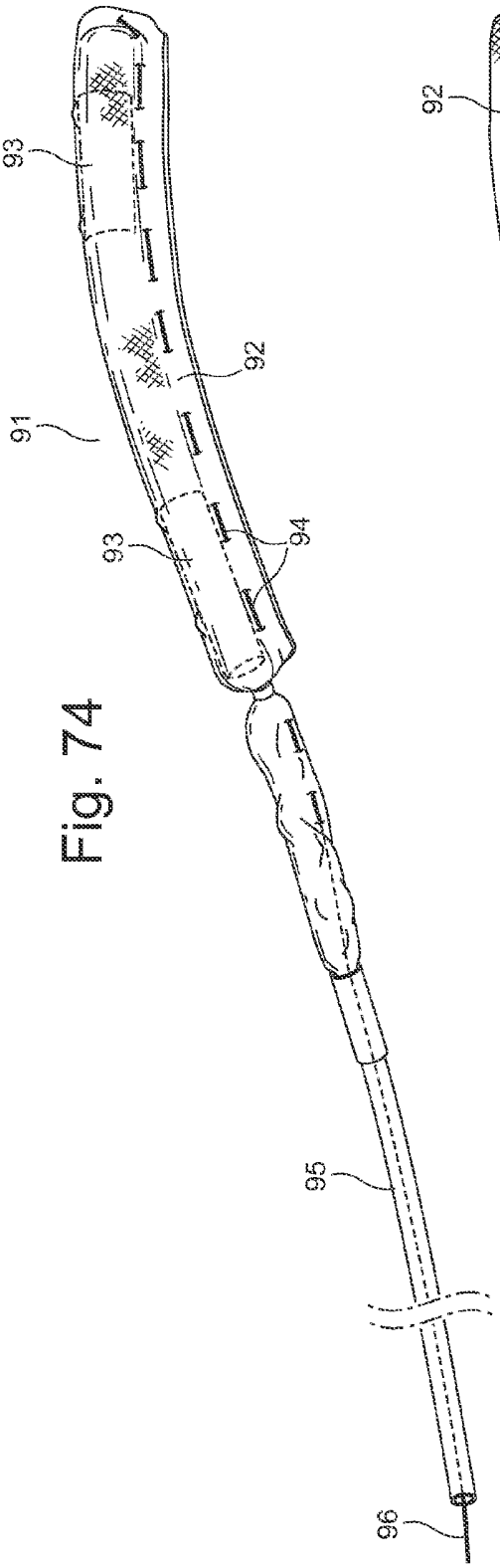


Fig. 74

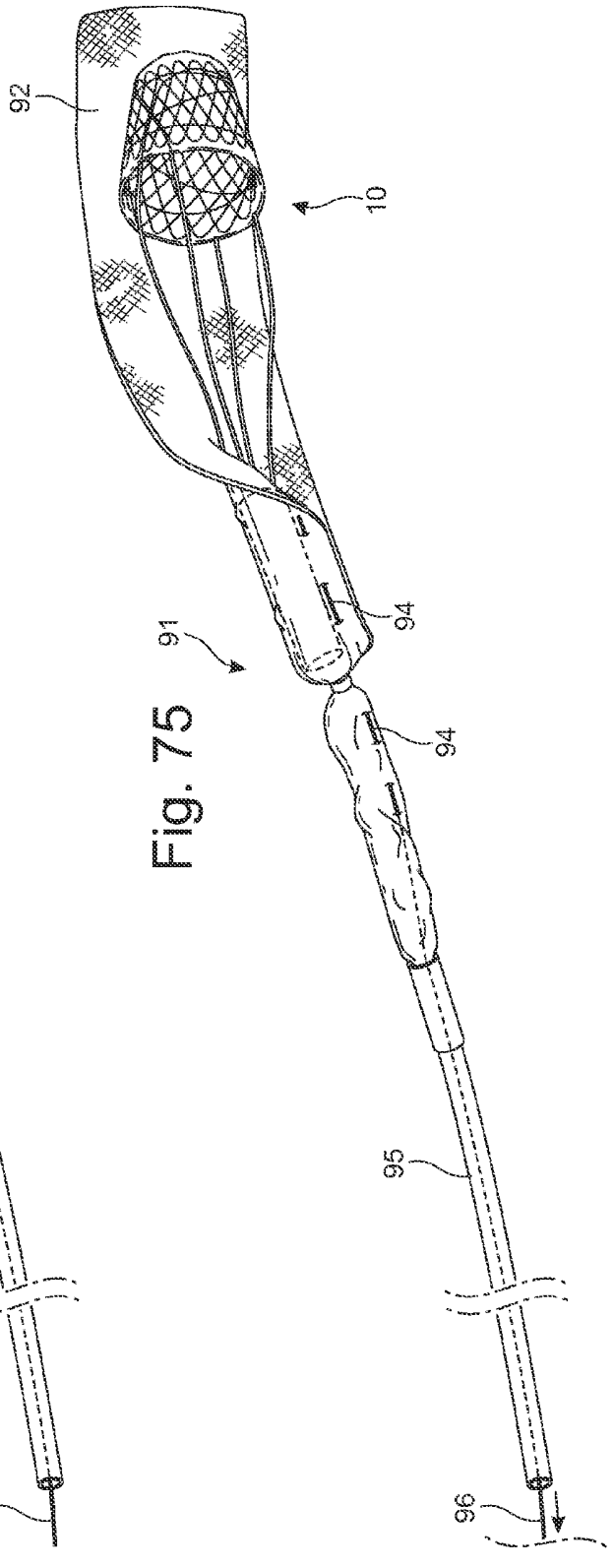


Fig. 75

Fig. 76

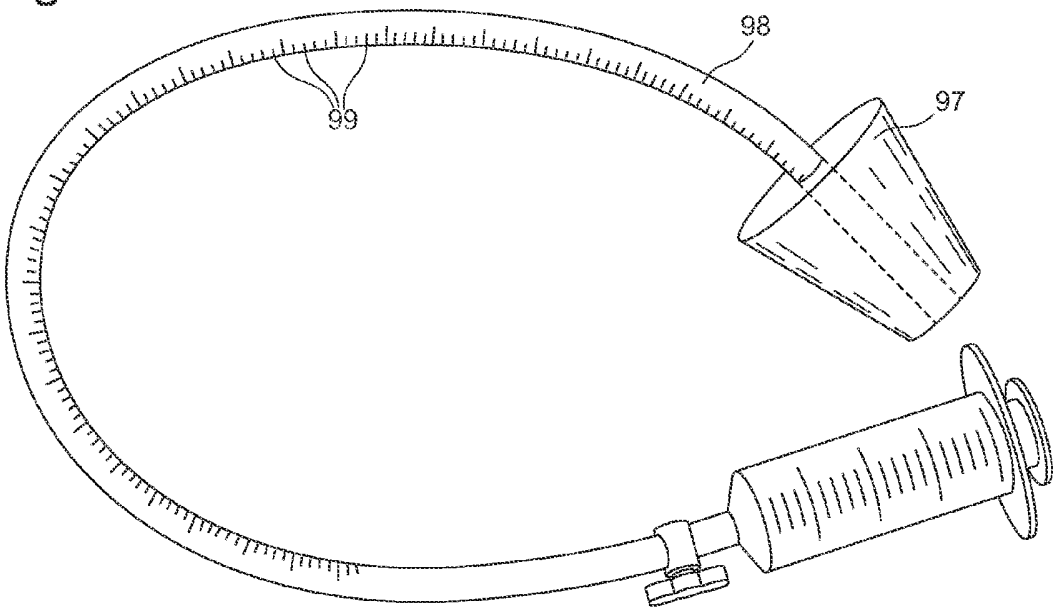


Fig. 77

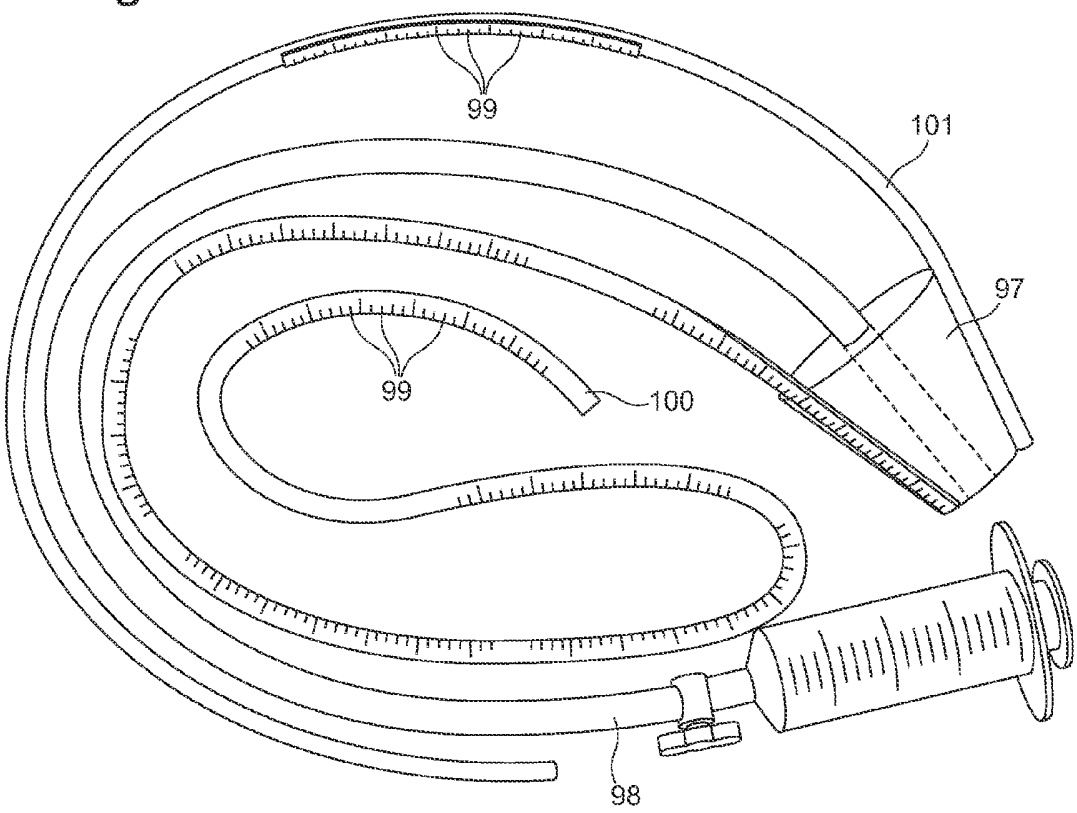


Fig. 78

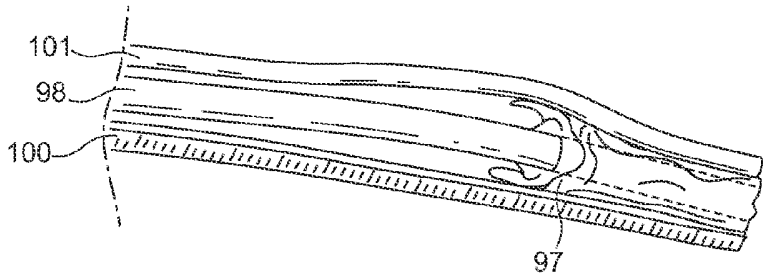


Fig. 79

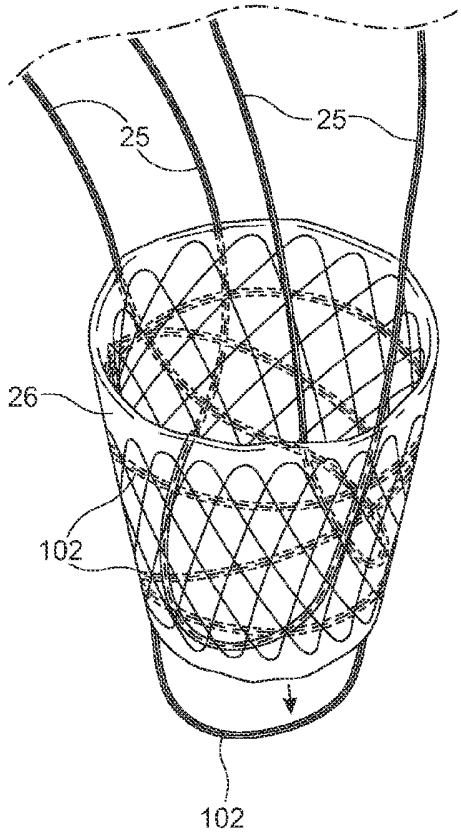


Fig. 80

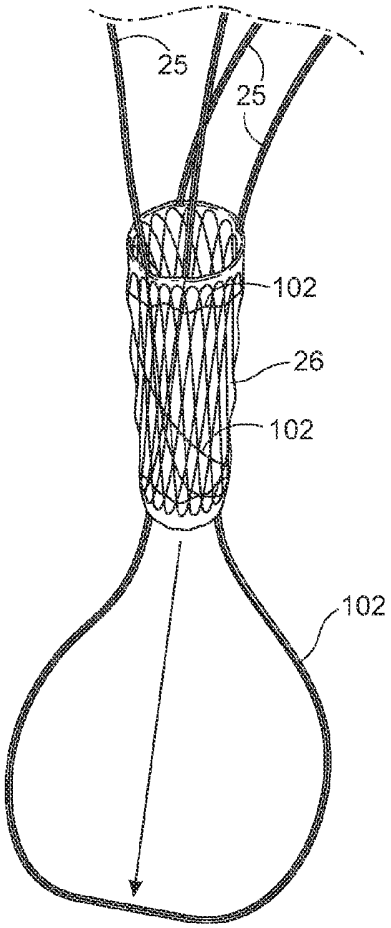


Fig. 81A

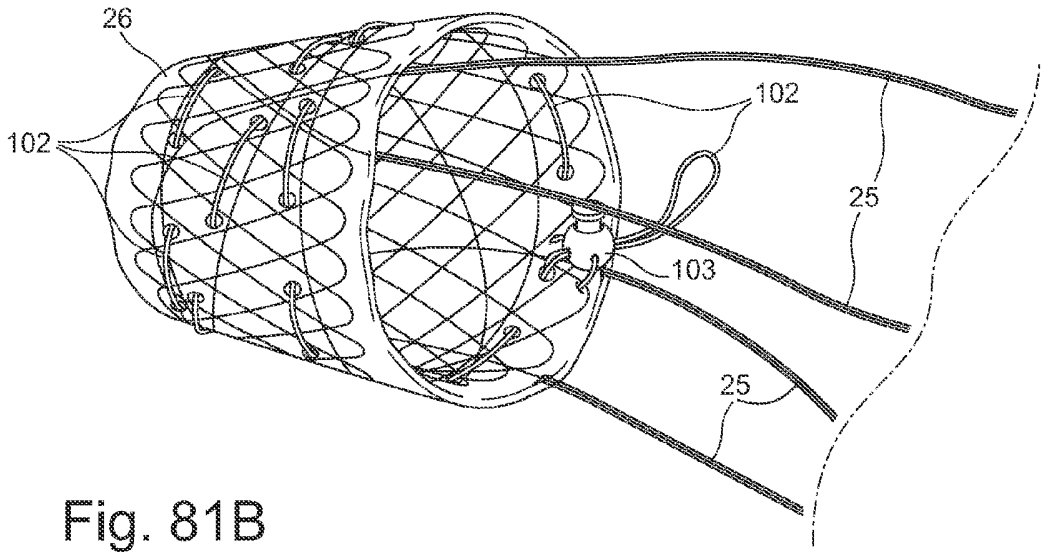


Fig. 81B

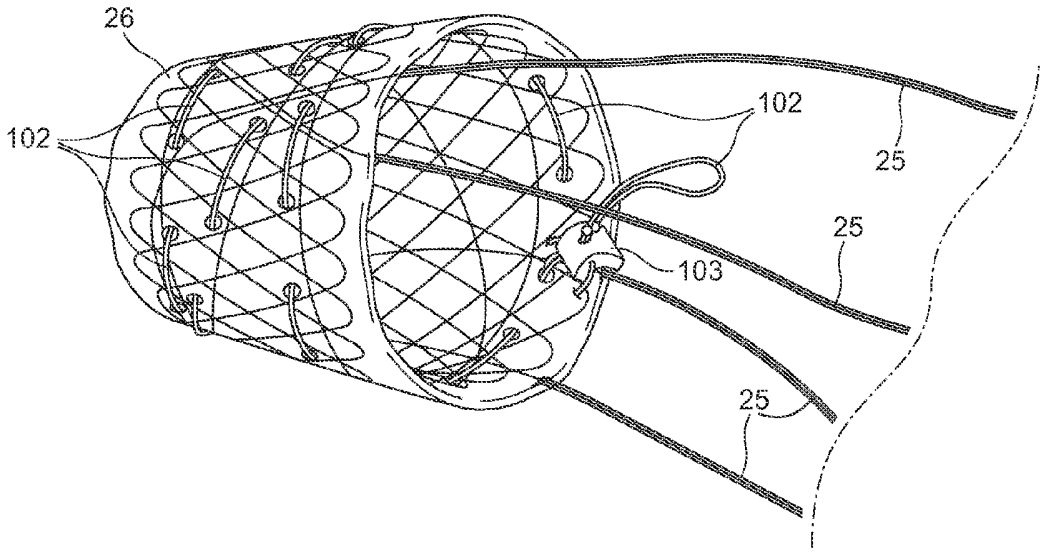


Fig. 82

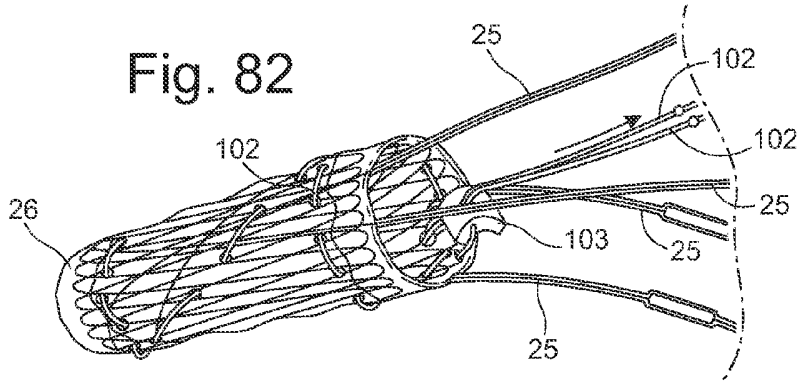


Fig. 83