

(12) STANDARD PATENT
(19) AUSTRALIAN PATENT OFFICE

(11) Application No. **AU 2011213048 B2**

(54) Title
Bariatric device and method for recipient with altered anatomy

(51) International Patent Classification(s)
A61F 2/00 (2006.01)

(21) Application No: **2011213048** (22) Date of Filing: **2011.02.01**

(87) WIPO No: **WO11/097209**

(30) Priority Data

(31) Number	(32) Date	(33) Country
61/301,373	2010.02.04	US
61/300,674	2010.02.02	US

(43) Publication Date: **2011.08.11**

(44) Accepted Journal Date: **2015.05.28**

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(56) Related Art
US 2006/0142844 A1
US 2007/0293716 A1

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

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
11 August 2011 (11.08.2011)

(10) International Publication Number
WO 2011/097209 A1

PCT

- (51) **International Patent Classification:**
A61F 2/00 (2006.01)
- (21) **International Application Number:**
PCT/US2011/023306
- (22) **International Filing Date:**
1 February 2011 (01.02.2011)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**
61/300,674 2 February 2010 (02.02.2010) US
61/301,373 4 February 2010 (04.02.2010) 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, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

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

(54) **Title:** BARIATRIC DEVICE AND METHOD FOR RECIPIENT WITH ALTERED ANATOMY

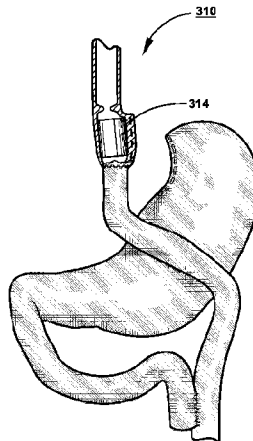


Fig. 4

(57) **Abstract:** A bariatric device and method of causing at least partial satiety in a recipient that either has or is presently undergoing a procedure that alters the anatomy of the recipient includes deploying a bariatric device to the recipient having an altered anatomy. The bariatric device includes a cardiac member having a cardiac surface that is configured to generally conform to the shape and size of a portion of the cardiac region of the stomach of the recipient. The cardiac member stimulates receptors with the cardiac surface in order to influence a neurohormonal mechanism in the recipient sufficient to cause at least partial satiety by augmenting fullness caused by food and simulating fullness in the absence of food.

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BARIATRIC DEVICE AND METHOD FOR RECIPIENT WITH ALTERED ANATOMY

The present invention is directed to a bariatric device and method of causing weight loss in a recipient.

Obesity is a large and increasing problem in the United States and worldwide. In round numbers, from the period encompassing the year 1990 to the period encompassing the year 2000, the prevalence of overweight people (BMI greater than 25) increased from 56 percent of United States adults to 65 percent and the prevalence of obese adults (BMI greater than 30) increased from 23 percent to 30 percent. Likewise, the prevalence of overweight children and adolescents (ages 6-19 years) increased from 11 percent in the period encompassing the year 1990 to 16 percent in the period encompassing the year 2000. The increasing prevalence of excess body mass among children and adolescents will make the problem even greater when they reach adulthood. The problem is not limited to the United States. Between 10 percent and 20 percent of European men are obese, and between 10 percent and 25 percent of European women are obese. Numerous medical conditions are made worse by obesity, including Type II diabetes, stroke, gallbladder disease, and various forms of cancer. Approximately 500,000 people in North America and Western Europe are estimated to die from obesity-related diseases every year and obesity is estimated to affect more than one billion adults worldwide. Therefore, there is a pressing and unmet need for a solution to the epidemic problem.

According to a first aspect of the present invention, there is provided a bariatric device, comprising: a cardiac member having a cardiac surface that is configured to generally conform to the shape and size of a stomach pouch that includes the cardiac region of the stomach of the recipient, the pouch being arranged to discharge contents through a stoma of the pouch, said cardiac member being adapted to stimulate receptors in order to influence a neurohormonal mechanism in the recipient sufficient to cause at least partial satiety by augmenting fullness caused by food and simulating fullness in the absence of food, and wherein said cardiac member is generally larger in shape than the stoma.

According to a second aspect of the present invention, there is provided a method of causing at least partial satiety in a recipient, comprising: deploying a bariatric device to a recipient having an altered anatomy, said bariatric device comprising a cardiac member having a cardiac surface that is configured to generally conform to the shape and size of a stomach pouch that includes

the cardiac region of the stomach of the recipient, the pouch being arranged to discharge contents through a stoma of the pouch, said cardiac member being generally larger in shape than the stoma, thereby stimulating receptors to influence a neurohormonal mechanism in the recipient sufficient to cause at least partial satiety by augmenting fullness caused by food and simulating fullness in the absence of food.

The device may be deployed to a recipient having undergone a bariatric procedure, such as (i) a gastric bypass procedure, (ii) a vertical banded gastroplasty, (iii) a sleeve gastrectomy, (iv) a duodenal switch, or (v) a laparoscopic gastric band, whether the procedure is performed laparoscopically, endoscopically, or the like.

The cardiac member may have a self-expanding surface. The self-expanding surface may be in the form of a scroll shaped to allow the self-expanding surface to be contracted in a roll, such as for deployment and unrolled to engage the walls of the stomach. The bariatric device may further include an esophageal member having an esophageal surface that is configured to generally conform to the shape and size of a portion of the esophagus and a connector connected with said esophageal member and said cardiac member.

The cardiac surface may be adjustable in order to adjust the amount of stimulus applied to the cardiac portion of the stomach. Adjustment may be made concurrently with deployment or subsequent to deployment. Adjustment may be performed endoscopically via a radio frequency link, or the like.

Anti-migration of the cardiac member may be provided. The anti-migration may include providing a surface having tissue adhesion and/or tissue ingrowth characteristics. The anti-migration may include mucosa capture. The anti-migration may include a projection from the cardiac member that is configured to extend to the esophagus or the intestine of the recipient to resist misorientation of the bariatric device.

The bariatric device and method may be applied to a recipient who had previously undergone bariatric surgery to produce the altered anatomy. Alternatively, the bariatric device and method may be applied concurrently with altering the anatomy of the recipient.

The present invention will now be described, by way of non-limiting example only, with reference to the accompanying drawings, in which:

FIG. 1 is a perspective view illustrating deployment of a bariatric device in a recipient who underwent or is undergoing a vertical banded gastroplasty;

FIG. 2 is a perspective view illustrating deployment of a bariatric device in a recipient who underwent or is undergoing a sleeve gastrectomy;

FIG. 3 is a perspective view illustrating deployment of a bariatric device in a recipient who underwent or is undergoing a duodenal switch;

FIG. 4 is a perspective view illustrating deployment of a bariatric device in a recipient who underwent or is undergoing a gastric bypass procedure;

FIG. 5 is a perspective view illustrating deployment of an alternative embodiment of a bariatric device in a recipient who underwent or is undergoing a vertical banded gastroplasty;

FIG. 6 is a perspective view illustrating deployment of another alternative embodiment of a bariatric device in a recipient who underwent or is undergoing a sleeve gastrectomy;

FIG. 7 is a perspective view illustrating deployment of another alternative embodiment of a bariatric device in a recipient who underwent or is undergoing a duodenal switch;

FIG. 8 is a perspective view illustrating deployment of another alternative embodiment of a bariatric device in a recipient who underwent or is undergoing a gastric bypass procedure;

FIG. 9 is a perspective view of the bariatric device in FIG. 1; and

FIG. 10 is the same view as FIG. 9 of an alternative embodiment thereof.

Referring now to the drawings and the illustrative embodiments depicted therein, a bariatric device of the various embodiments disclosed herein may be applied to a recipient that has an altered anatomy, such as from bariatric surgery. Such bariatric device stimulates receptors at least in the native stomach, or pouch, in order to influence a neurohormonal mechanism in the recipient sufficient to cause at least partial satiety by augmenting fullness caused by food and simulating fullness in the absence of food. Such bariatric device may be applied, for example, to a recipient who had previously

undergone bariatric surgery, but is now experiencing difficulty with lack of satiety including weight gain. Alternatively, such bariatric device may be deployed to a recipient who is presently undergoing bariatric surgery to enhance the effect of the surgery and avoid lack of satiety in the future. The altered anatomy may be a result of procedures other than bariatric procedures, such as stomach surgery for cancer, or the like. Also, the altered anatomy may be performed using open surgery, laparoscopic surgery, or endoscopic surgery.

Bariatric device 10 has a cardiac member 14 that is configured to the stomach component of the altered anatomy to provide a tension, such as an outward pressure. Cardiac member 14 has a wall 20 configured to the size and shape of the cardiac region of a stomach that has undergone vertical banded gastroplasty (FIG. 1). The outer surface of wall 20 applies a strain to the cardiac region of the stomach to stimulate receptors to influence the neurohormonal feedback mechanism in a manner that causes at least partial satiety by augmenting fullness caused by food and simulating fullness in the absence of food as disclosed in commonly assigned U.S. Patent No. 7,846,174, the disclosure of which is hereby incorporated herein reference. Cardiac member 14 may be partially or wholly the size of the stomach pouch. If cardiac member 14 is larger than the stoma of the pouch, the cardiac member will avoid distal migration through the stoma.

A bariatric device 110 is shown having a cardiac member 114 that is similar to cardiac member 14, except having a wall configured to the size and shape of the cardiac region of a stomach that has undergone a sleeve gastrectomy (FIG. 2). A bariatric device 210 is shown having a cardiac member 214 that is similar to cardiac members 14, 114, except having a wall configured to the size and shape of the cardiac region of a stomach that has undergone a duodenal switch (FIG. 3). A bariatric device 310 is shown having a cardiac member 314 that is similar to cardiac members 14, 114, 214, except having a wall configured to generally conform to the size and shape of the cardiac region of the proximal pouch of a recipient that has undergone a gastric bypass procedure, also known as a roux-en-y procedure (FIG. 4). Although not shown, the principles disclosed herein could be used with a recipient who received a laparoscopic gastric band. In order to avoid tissue erosion at the location of the band, the cardiac member of such device may be made having an especially soft outer surface.

Provisions may be made to resist migration of cardiac member 14, 114, 214 and 314. In the case of a vertical banded gastroplasty or a roux-en-y bariatric procedure, the cardiac member may be provided having an expanded configuration that is larger than the stoma emptying the stomach pouch. In this fashion, the cardiac member will have a tendency to be retained in the pouch. For a bariatric device applied, for example, to a sleeve gastrectomy or a duodenal switch, an anti-migration mechanism may be used to resist distal migration of the cardiac member in the pouch. Such anti-migration mechanism may be in the form of suturing of the cardiac member to the wall of the stomach pouch. Such suturing may be passed through the wall of the bariatric device, through the wall of the stomach, back in through the wall of the stomach and back in through the wall of the bariatric device. By selection of the surface characteristics of the suture material and/or the wall of the cardiac member, it may be possible to assist anti-migration by promotion of tissue adhesion and/or tissue ingrowth to the device and/or suture. Alternatively, it may be possible to provide capture of the mucosa and/or muscularis of the wall of the stomach pouch utilizing the principles set forth in International Patent Application Publication No. WO 2008/100984 A2, the disclosure of which is hereby incorporated herein by reference.

A bariatric device 410 is shown having an esophageal member 412 having a wall configured to the size and shape of a portion of the esophagus connected by a connector 416 with a cardiac member 414 having a wall configured to the size and shape of the cardiac region of a stomach that has undergone vertical banded gastroplasty (FIG. 5). Esophageal member 412 may be configured to reduce stenosis of the esophagus as disclosed in commonly assigned U.S. patent application Ser. No. 61/388,857 filed Oct. 1, 2010, by James A. Foote entitled INTRALUMINAL DEVICE AND METHOD, the disclosure of which is hereby incorporated herein by reference. Connector 416 may include a tension member 424 that passes through the gastroesophageal junction and a tether 426 that is applied *in situ* as disclosed in commonly assigned U.S. Patent Application Publication No. 2010/0030017 A1 entitled BARIATRIC DEVICE AND METHOD, the disclosure of which is hereby incorporated herein by reference.

A bariatric device 510 is shown having an esophageal member 512 that is similar to esophageal member 412 having a wall configured to the size and shape of a portion of

the esophagus connected by a connector 516 with a cardiac member 514 that is similar to cardiac member 414 and having a wall configured to the size and shape of the cardiac region of a stomach that has undergone a sleeve gastrectomy (FIG. 6). Connector 516 has a tension member 524 and tether 526.

A bariatric device 610 is shown having an esophageal member 612 that is similar to esophageal member 412 having a wall configured to the size and shape of a portion of the esophagus connected by a connector 616 with a cardiac member 614 that is similar to cardiac member 414 and having a wall configured to the size and shape of the cardiac region of a stomach that has undergone a duodenal switch (FIG. 7). Connector 616 has a tension member 624 and tether 626.

A bariatric device 710 is shown having an esophageal member 712 that is similar to esophageal member 412 having a wall configured to the size and shape of a portion of the esophagus connected by a connector 716 with a cardiac member 714 that is similar to cardiac member 414 and having a wall configured to generally conform to the size and shape of the cardiac region of the proximal pouch of a recipient that has undergone a gastric bypass procedure, also known as a roux-en-y procedure (FIG. 8). Connector 716 has a tension member 724 and tether 726. Other examples will become apparent to the skilled practitioner.

Esophageal members 412, 512, 612 and 712 may be provided according to the principles set forth in International Patent Application Publication No WO 2008/101048 A2, the disclosure of which is hereby incorporated herein by reference.

The strain exerted by the bariatric devices 410-710 stimulates receptors in the recipient to influence the neurohormonal feedback mechanism present at the esophagus and/or stomach pouch to cause weight loss. The strain that influences the neurohormonal feedback mechanism present at the abdominal portion of the esophagus and/or the cardiac portion of the stomach is intended to be relatively consistent over as large an area as reasonably possible.

In contrast to prior proposed devices, such as restriction devices, which require that the recipient ingest food in order to influence neurohormonal feedback mechanisms, the embodiments of the bariatric device disclosed herein are effective in the absence of food. It also augments fullness caused by food.

Cardiac member 14 (or any of the embodiments of a cardiac member disclosed herein) may be defined by a wall 20 having overlapping end portions 20a, 20b (FIG. 9). Wall 20 defines an outer surface 21 that applies a strain on the stomach wall. Wall 20 further defines an opening 22 that is configured to fit against the gastroesophageal junction to restrict the passage of food between the stomach wall and surface 21. Wall 20, which may be generally cylindrical in form, is self-expanding such that end portions 20a, 20b form a scroll shape that tends to unroll outwardly to expand to the shape of the stomach pouch. End portions 20a, 20b may be compressed into a further overlapping roll form in order to be deployed orally. The degree of overlap of end portions 20a, 20b configures the size of the cardiac member to the size of the stomach pouch. Wall 20 may be formed of Nitinol wire or a die cut Nitinol sheet covered with silicone, or the like.

Wall 20 may be provided with the ability to adjust the amount of strain or force applied to the cardiac region of the stomach. This may be accomplished, for example, by providing a bladder on outer surface 21, or by otherwise incorporating a bladder into wall 20. The bladder could be filled with saline either during deployment of cardiac member 14 or subsequent to deployment, such as by using an endoscopic needle. Also, an electronic/hydraulic control may be connected to the bladder and adjusted from a control external the patient via a radio frequency link. Adjustment of the bladder in either fashion may be as disclosed in the WO 2008/101048 publication.

Adjustability of wall 20 may, alternatively, be provided, such as by a ratcheting mechanism that either brings wall end portions 20a, 20b together or spreads them apart. Such ratcheting mechanism may be mounted to wall 20 at or before deployment and accessed endoscopically at or after deployment. Alternatively, a pattern of openings may be formed in end portions 20a, 20b that can be engaged by a ratcheting mechanism having features, such as feet, that engage the openings. Such ratcheting mechanism can be deployed and adjusted endoscopically, such as after deployment.

In the case of bariatric devices 410-710, adjustability may be provided by adjusting connector 416-716 including any tension member such as a tether forming a part of the connector.

One advantage of providing adjustability to the amount of strain or force applied by wall 20 is to facilitate removal of the device from the recipient. For example, as the

recipient experiences reduced excess body fat, the amount of strain or force could be reduced to acclimatize the recipient to reduced satiety provided by the device. Of course, adjustability allows the amount of satiety to be set or adjusted at the time of deployment or after deployment if the patient is experiencing too much or not enough satiety.

In an alternative embodiment shown in FIG. 10, bariatric device 10' includes a cardiac member 14' that is similar to cardiac member 14 except that wall 20 includes a projection 30 that is configured to extend either distally into the intestine or proximally into the esophagus. Projection 30 may be affixed, such as by suturing, stapling, mucosal capture, or the like. Projection 30 ensures proper orientation of cardiac member 10' with the openings at end portions 20a' and 20b' aligned with the respective openings at the GE junction and pylorus.

The bariatric devices disclosed herein may be made in whole or in part from bioabsorbable materials or from non-absorbable materials. The tissue attachment, tissue ingrowth and/or mucosal capture, which results from the tissue essentially at least partially incorporating certain embodiments of the bariatric device into the anatomy of the recipient, may provide resistance to the formation of microbial biofilm and thereby reduces the potential for infection, odor, and the like. As with all anti-migration fixation techniques described herein, these may be used in combination with other fixation techniques. These anchoring techniques may be used to promote long-term deployment by incorporating the device into the body of the recipient.

Thus, it is seen that the disclosed embodiment provides a new category of weight loss techniques. The embodiment advantageously utilizes mechanoreceptors, such as tension receptors, stretch receptors and/or baroreceptors, such as those located at the cardiac portion of the stomach of the recipient to cause weight loss. The disclosed embodiments facilitate burping and vomiting and do not substantially interfere with other functions of the GE junction pseudo-sphincter. Use with a recipient having undergone bariatric surgery in the past or concurrently with receiving the embodiments of the bariatric device disclosed herein augment the effect of the bariatric procedure which may utilize the presence of solid food to create satiety.

While various embodiments of the present invention have been described above, it should be understood that they have been presented by way of example only, and not by way of limitation. It will be apparent to a person skilled in the relevant art that various changes in form and detail can be made therein without departing from the spirit and scope of the invention.

Thus, the present invention should not be limited by any of the above described exemplary embodiments.

Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "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.

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 acknowledgment 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.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A bariatric device, comprising:
a cardiac member having a cardiac surface that is configured to generally conform to the shape and size of a stomach pouch that includes the cardiac region of the stomach of the recipient, the pouch being arranged to discharge contents through a stoma of the pouch,
said cardiac member being adapted to stimulate receptors in order to influence a neurohormonal mechanism in the recipient sufficient to cause at least partial satiety by augmenting fullness caused by food and simulating fullness in the absence of food,
and wherein said cardiac member is generally larger in shape than the stoma.
2. The bariatric device as claimed in claim 1, wherein said cardiac member is configured to the size and shape of the cardiac region of a recipient having undergone at least one chosen from (i) a gastric bypass procedure, (ii) a vertical banded gastroplasty, (iii) a sleeve gastrectomy, and (iv) a duodenal switch.
3. The bariatric device as claimed in claim 1 or claim 2, wherein said cardiac member has a self-expanding surface.
4. The bariatric device as claimed in claim 3, wherein said self-expanding surface is scroll-shaped to allow said self-expanding surface to be contracted in a roll.
5. The bariatric device as claimed in any one of the preceding claims, including an esophageal member having an esophageal surface that is configured to generally conform to the shape and size of a portion of the esophagus and a connector connected with said esophageal member and said cardiac member.

6. The bariatric device as claimed in any one of the preceding claims including an anti-migration mechanism.
7. The bariatric device as claimed in claim 6, wherein said anti-migration mechanism comprises at least one chosen from (i) a tissue adhesion surface and (ii) a tissue ingrowth surface.
8. The bariatric device as claimed in claim 6 or claim 7, wherein said anti-migration mechanism comprises a structure to capture at least the mucosa of the stomach wall.
9. The bariatric device as claimed in claim 6, wherein said anti-migration mechanism comprises a projection from said cardiac member, said projection configured to extend to the esophagus or the intestine of the recipient to resist misorientation of said bariatric device.
10. The bariatric device as claimed in any one of the preceding claims, wherein the altered anatomy comprises a gastric bypass procedure or a vertical banded gastroplasty.
11. A method of causing at least partial satiety in a recipient, comprising:
 - deploying a bariatric device to a recipient having an altered anatomy, said bariatric device comprising a cardiac member having a cardiac surface that is configured to generally conform to the shape and size of a stomach pouch that includes the cardiac region of the stomach of the recipient, the pouch being arranged to discharge contents through a stoma of the pouch, said cardiac member being generally larger in shape than the stoma,
 - thereby stimulating receptors to influence a neurohormonal mechanism in the recipient sufficient to cause at least partial satiety by augmenting fullness caused by food and simulating fullness in the absence of food.
12. The method as claimed in claim 11, including deploying said bariatric device to a recipient having undergone at least one chosen from (i) a gastric bypass procedure, (ii) a vertical banded gastroplasty, (iii) a sleeve gastrectomy, and (iv) a duodenal switch.

13. The method as claimed in claim 11, wherein said cardiac member has a surface which self-expands so as to stimulate the receptors.

14. The method as claimed in claim 13, wherein the self-expanding surface is scroll-shaped whereby it is contracted in a roll so as to self-expand.

15. The method as claimed in any one of claims 11 to 14, wherein said bariatric device has an esophageal member comprising an esophageal surface that is configured to generally conform to the shape and size of a portion of the esophagus and a connector connected with said esophageal member and said cardiac member.

16. The method as claimed in claim 15, including deploying said bariatric device to a recipient having undergone at least one chosen from (i) a gastric bypass procedure, (ii) a vertical banded gastroplasty, (iii) a sleeve gastrectomy, and (iv) a duodenal switch.

17. The method as claimed in any one of claims 11 to 16, wherein said bariatric device includes an anti-migration mechanism.

18. The method as claimed in claim 17, wherein said anti-migration mechanism is provided from at least one chosen from (i) a tissue adhesion surface and (ii) a tissue ingrowth surface.

19. The method as claimed in claim 17 or claim 18, comprising capturing at least mucosa of the stomach wall with said anti-migration mechanism.

20. The method as claimed in claim 17, wherein said anti-migration mechanism comprises a projection from said cardiac member, and said projection extends to the esophagus or the intestine of the recipient to resist misorientation of said bariatric device.

21. The method as claimed in any one of claims 11 to 20, applied to a recipient who had previously undergone bariatric surgery to produce the altered anatomy.
22. The method as claimed in any one of claims 11 to 21, applied concurrently with altering the anatomy of the recipient.
23. The method as claimed in any one of claims 11 to 22, including adjusting the amount of stimulating with said cardiac surface.
24. The bariatric device as claimed in any one of claims 1 to 10, wherein said bariatric device is adjustable.
25. The method as claimed in any of claims 11 to 23, when applied to a recipient having an altered anatomy comprising a gastric bypass procedure or a vertical banded gastroplasty.

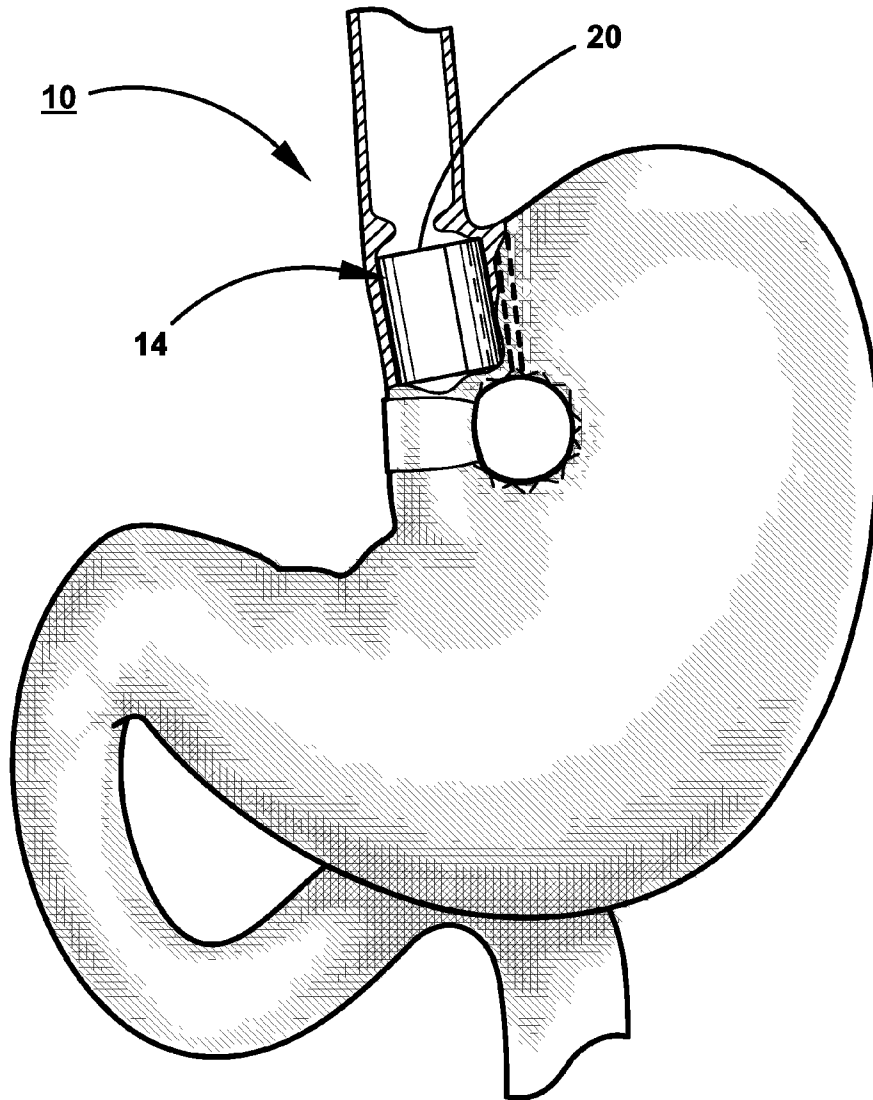


Fig. 1

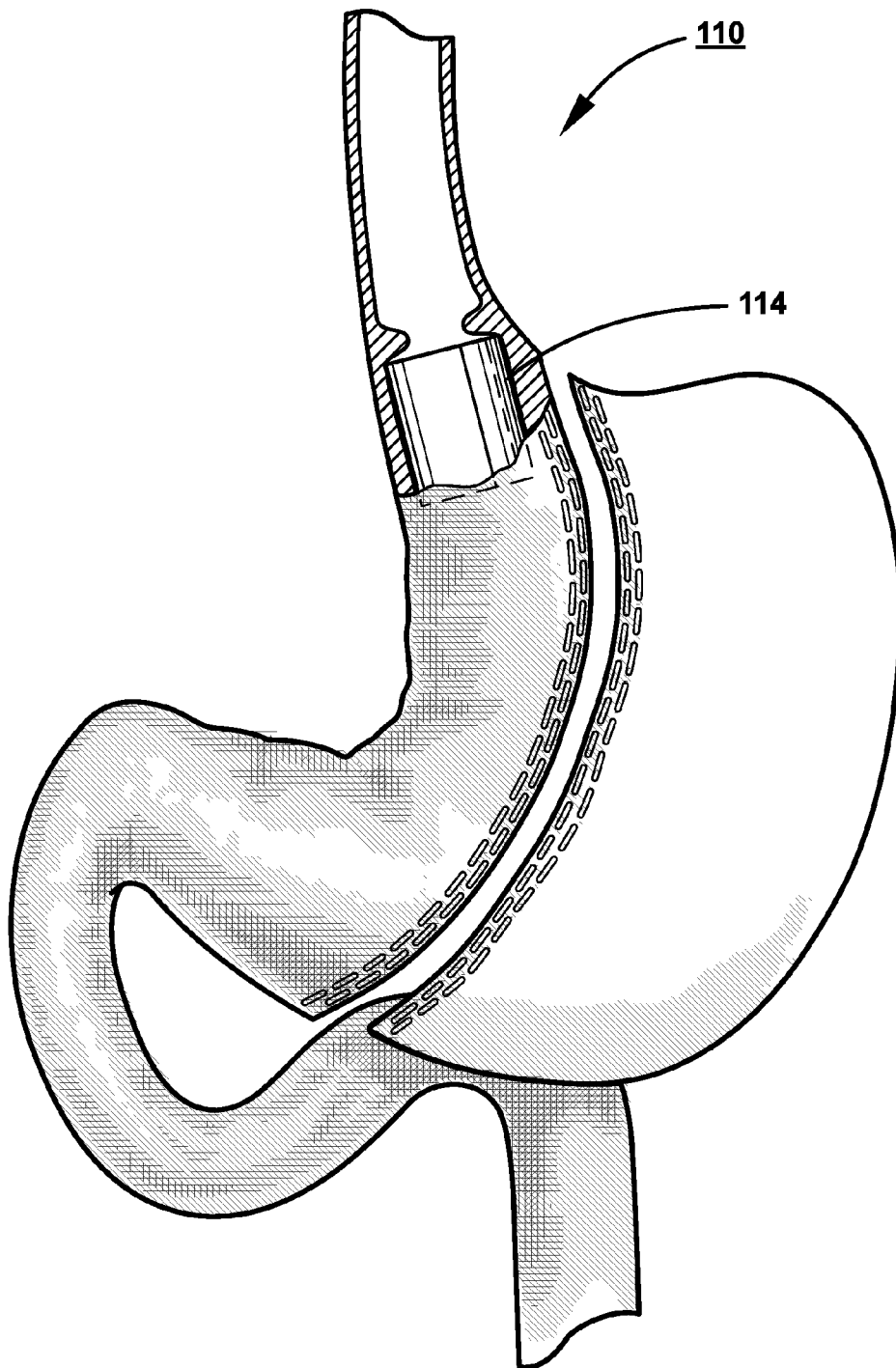


Fig. 2

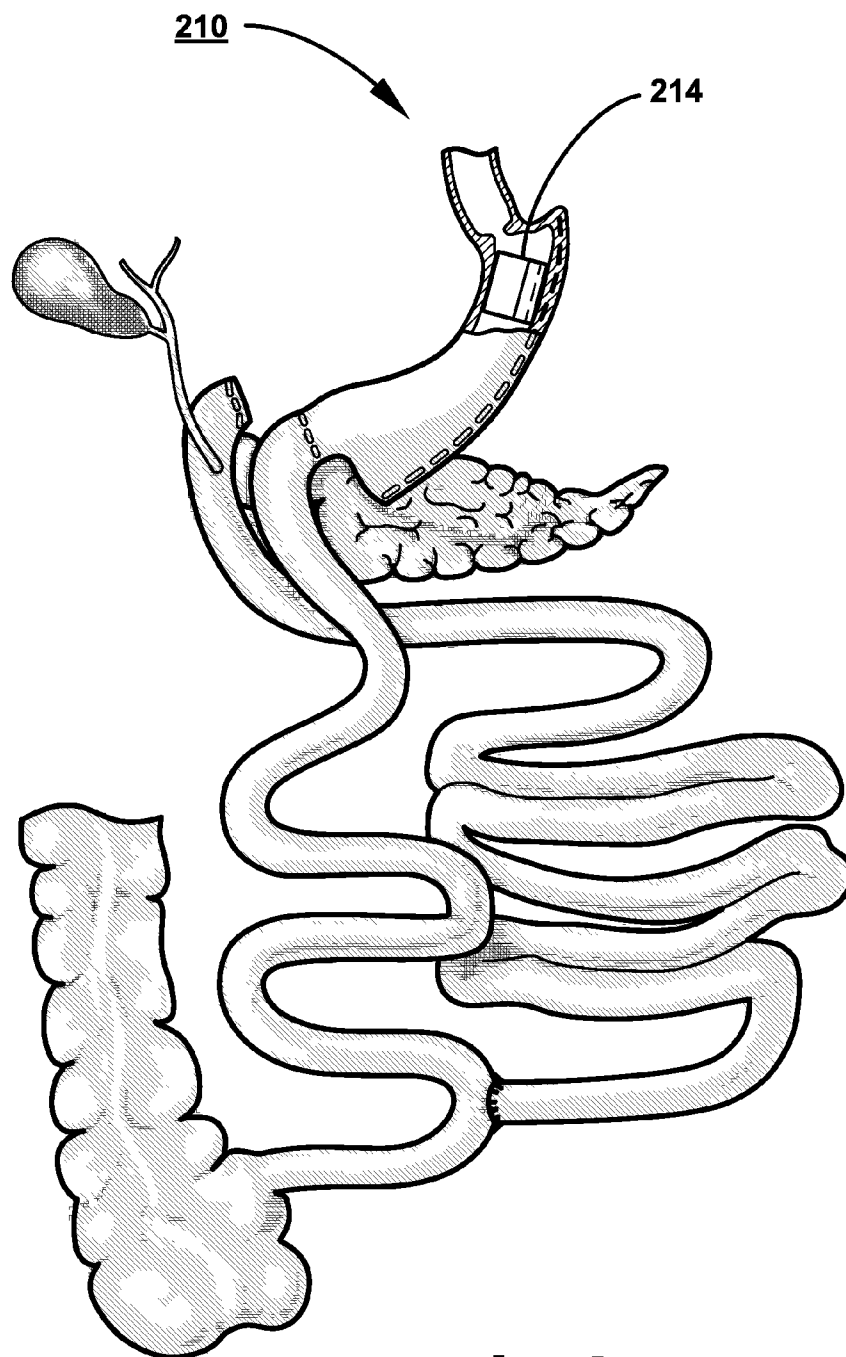


Fig. 3

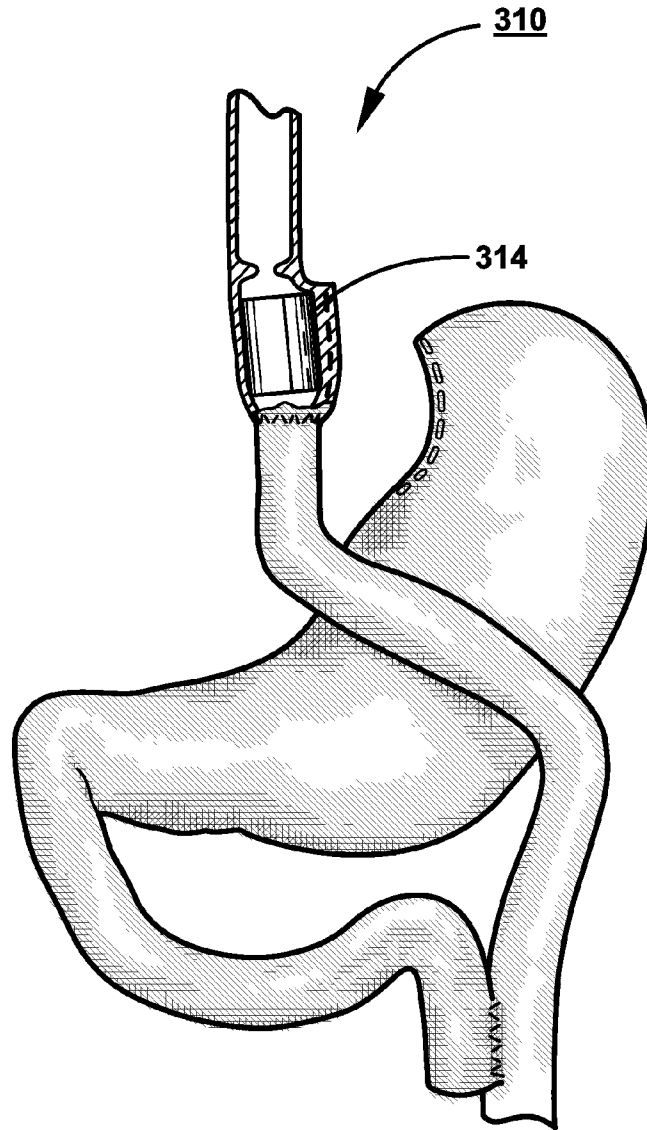


Fig. 4

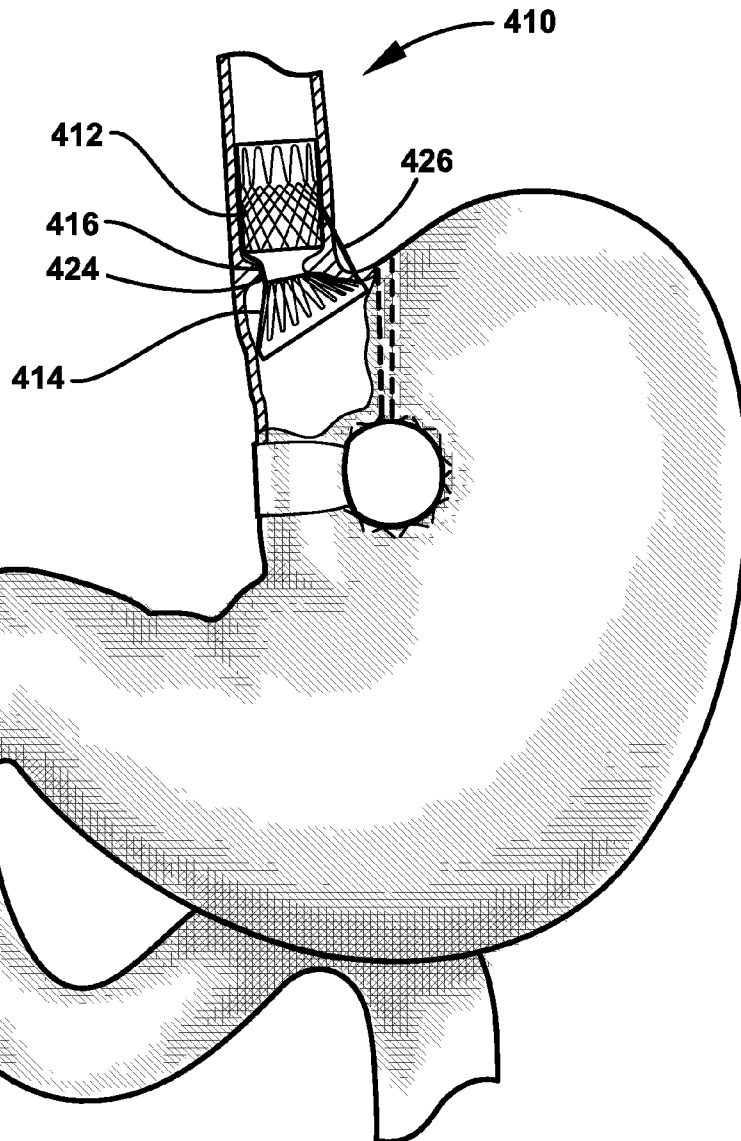


Fig. 5

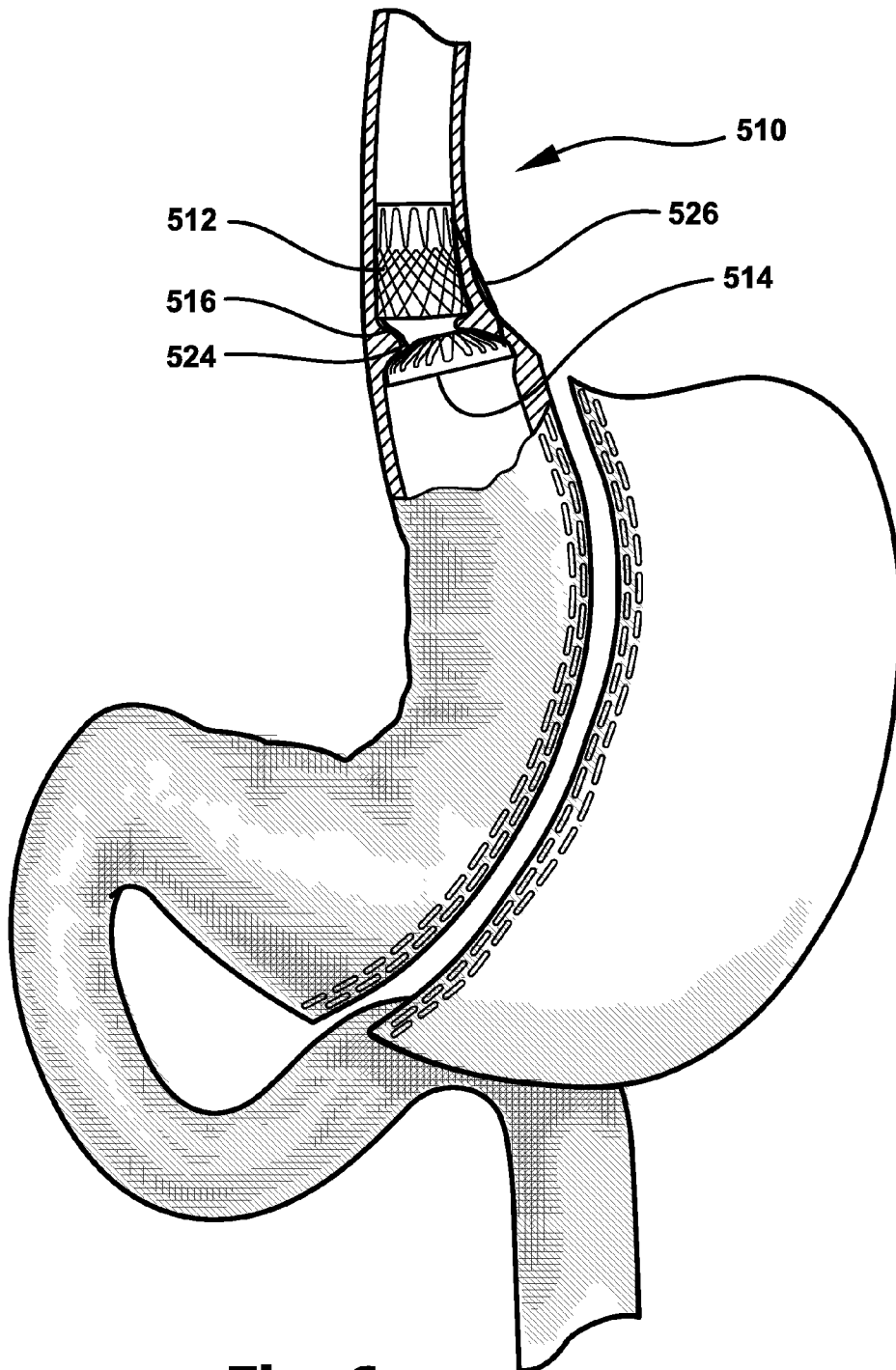


Fig. 6

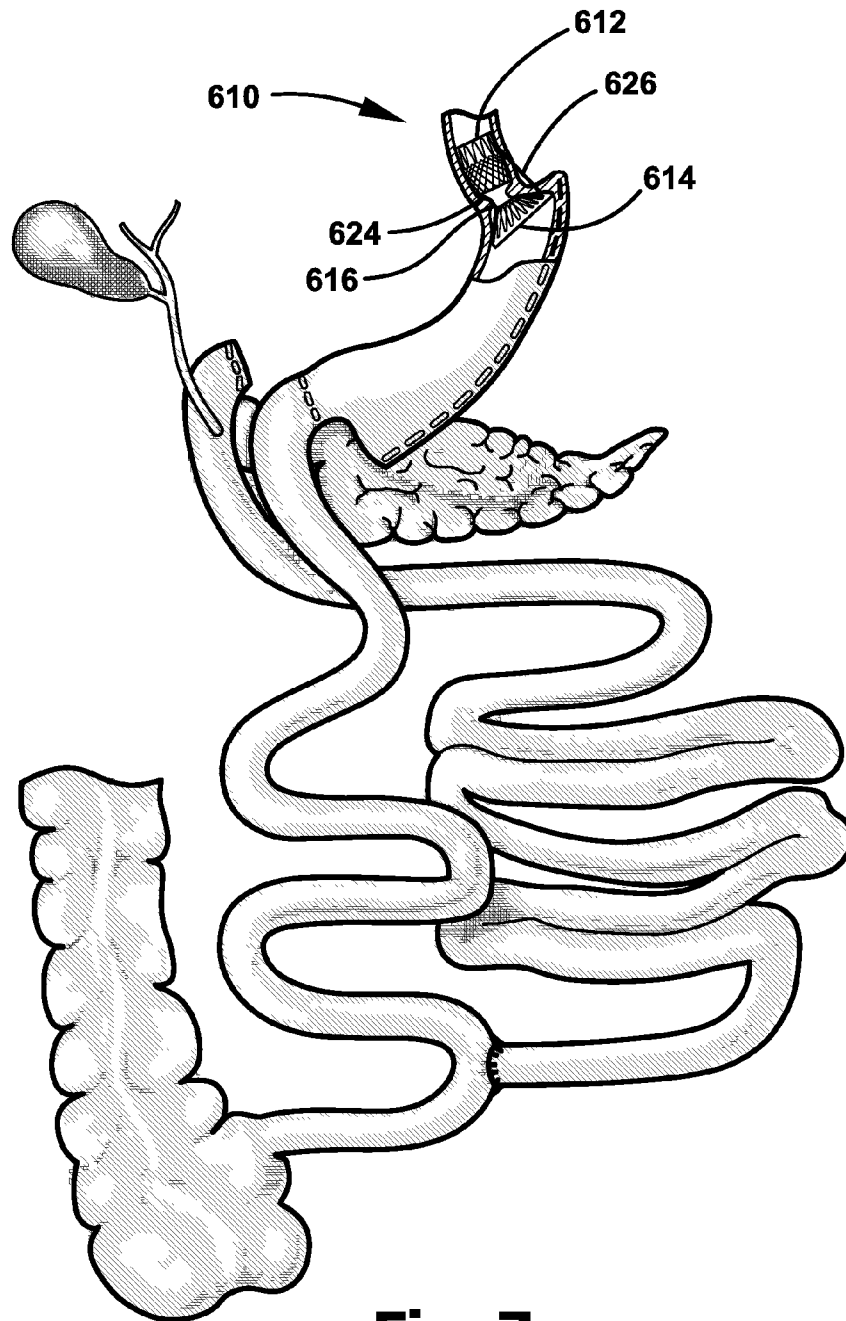


Fig. 7

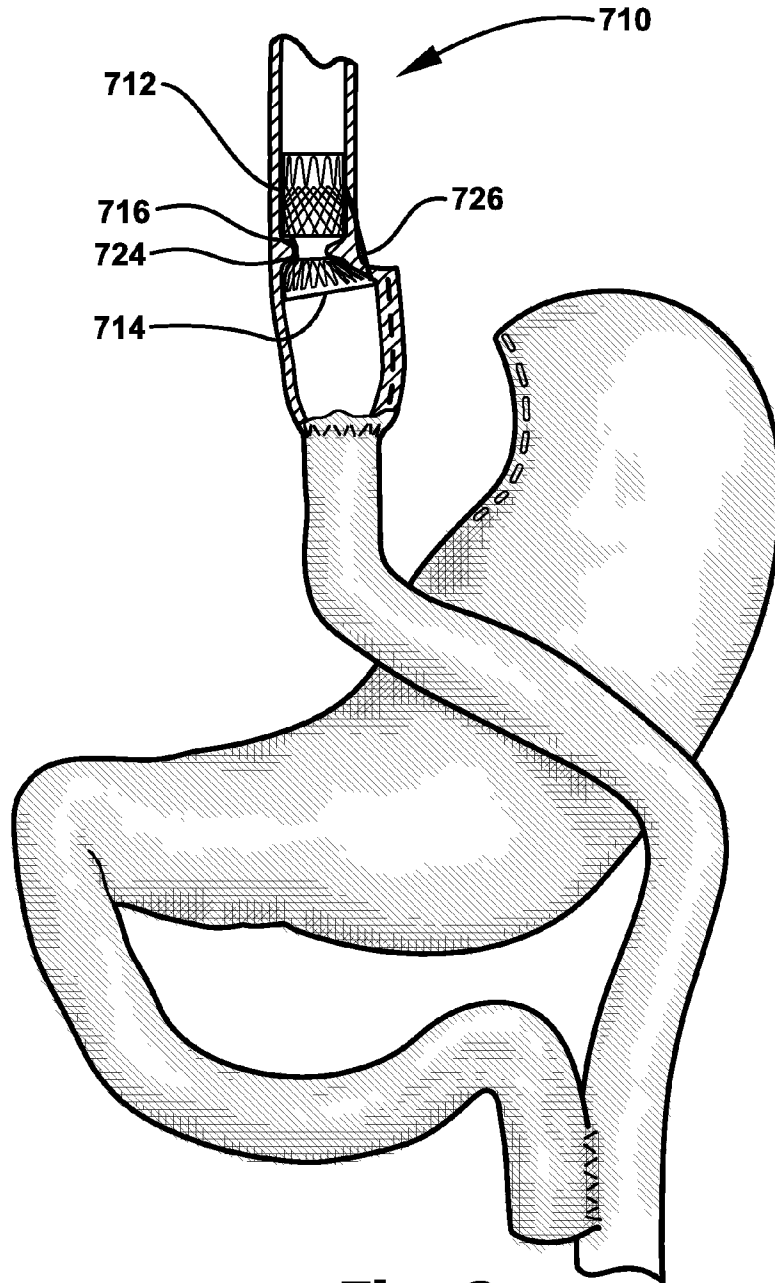


Fig. 8

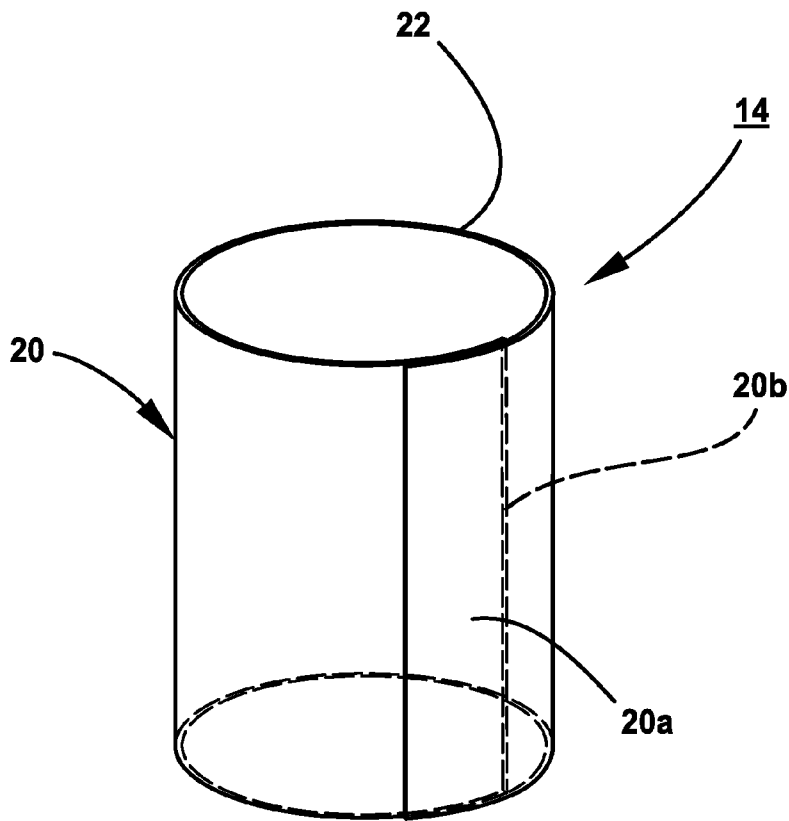


Fig. 9

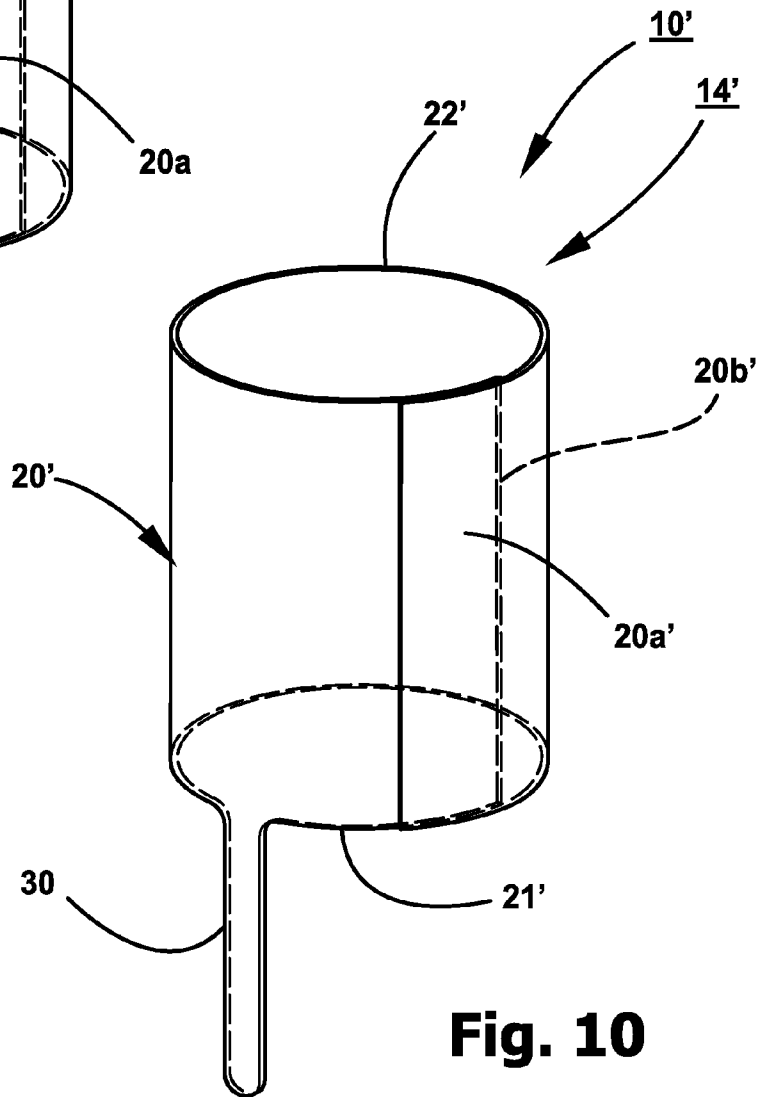


Fig. 10