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(54) **RESTRICTIVE AND/OR OBSTRUCTIVE IMPLANT FOR INDUCING WEIGHT LOSS**

RESTRIKTIVES UND/ODER OBSTRUKTIVES IMPLANTAT ZUR INDUKTION VON GEWICHTSVERLUST

IMPLANT RESTRICTIF ET/OU OBSTRUCTIF DESTINE A INDUIRE UNE PERTE DE POIDS

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Description

[0001] The present invention relates generally to the field of implants for inducing weight loss in patients, and specifically to devices for reducing the effective volume of a patient's stomach and or creating restrictions to slow passage of food into the stomach.

[0002] An anatomical view of a human stomach S and associated features is shown in Fig. 1A. The esophagus E delivers food from the mouth to the proximal portion of the stomach S. The z-line or gastro-esophageal junction Z is the irregularly-shaped border between the thin tissue of the esophagus and the thicker tissue of the stomach wall. The gastro-esophageal junction region G is the region encompassing the distal portion of the esophagus E, the z-line, and the proximal portion of the stomach S.

[0003] Stomach S includes a fundus F at its proximal end and an antrum A at its distal end. Antrum A feeds into the pylorus P which attaches to the duodenum D, the proximal region of the small intestine. Within the pylorus P is a sphincter that prevents backflow of food from the duodenum D into the stomach. The middle region of the small intestine, positioned distally of the duodenum D, is the jejunum J.

[0004] Fig. 1B illustrates the tissue layers forming the stomach wall. The outermost layer is the serosal layer or "serosa" S and the innermost layer, lining the stomach interior, is the mucosal layer or "mucosa" MUC. The submucosa SM and the multi-layer muscularis M lie between the mucosa and the serosa.

[0005] Prior art treatments for obesity range from diet and medication to highly invasive surgical procedures. Some of the more successful surgical procedures are the vertical banded gastroplexy or the proximal gastric pouch with a Roux-en-Y anastomosis. However, known complications are present with each of these procedures. More successful and less invasive options are desired.

[0006] A less invasive prior art treatment for obesity includes implantation of a gastric balloon delivered into the stomach via the esophagus. The balloon is an obstructive device - it prevents overeating by occupying volume within the stomach. Although implantation of a gastric balloon is less invasive than other surgical procedures, gastric balloons can migrate down the GI tract, causing obstruction and thus necessitating removal.

[0007] WO 2004/019765 A2 discloses methods and devices for maintaining a space-occupying device in a fixed relationship relative to a patient's stomach by manipulation of the stomach. In one variation, two or more regions of the stomach wall are brought into approximation with one another and secured together in a manner that secures a space-occupying device within the stomach of the patient. In another variation, two or more regions of the stomach wall are wrapped around a space-occupying device to maintain the position of the space-occupying device relative to the stomach wall. In another variation, a system having a space-occupying member and a locking member capable holding the space-occupying member against the inner wall of the stomach are provided. In a further variation, a pouch is created within the stomach that receives and retains a space-occupying device.

[0008] The present invention relates to a system for inducing weight loss in a patient according to claim 1. Preferred embodiments of the present invention are described in the dependent claims.

Fig. 1A is a schematic illustration of a human stomach and a portion of the small intestine.

Fig. 1B is a cross-sectional perspective view of a portion of a stomach wall, illustrating the layers of tissue forming the wall.

Fig. 2 is a cross-section view of a stomach illustrating positioning of an obstructive implant.

Fig. 3. is a cross-section view of a stomach illustrating positioning of two obstructive implants.

Fig. 4 is a cross-section view of a stomach illustrating positioning of an obstructive implant in the antral region of the stomach.

Fig. 5 is a cross-section view of a stomach illustrating positioning of an obstructive implant in the fundal region of the stomach.

Fig. 6 is a cross-section view of a stomach illustrating alternative positioning of two obstructive implants

Fig. 7 is a cross-section view of a stomach illustrating positioning of an irregularly-shaped obstructive implant.

Fig. 8 is a cross-section view of a stomach illustrating positioning of an elongate obstructive implant.

Fig. 9. is a cross-section view of a stomach illustrating positioning of an obstructive implant having an alternative shape.

Figs. 10 - 12A are perspective views of alternative configurations for obstructive implants. Fig. 12B illustrates the implant of Fig. 12A positioned in the stomach.

Figs. 13A through 13F are a sequence of drawings illustrating endoscopic implantation of an obstructive implant. Fig. 13G is an implantation step that is an alternative to the step shown in Fig. 13F.

Fig. 14 is a cross-section view of a stomach illustrating use of a force-distributing retention band with an obstructive implant.

Fig. 15 is a cross-section view of a stomach illustrating use of an alternative force-distributing retention band with an obstructive implant.

Figs. 16 through 18 are cross-section views of a stomach illustrating alternate retention methods for obstructive implants.

Fig. 19 illustrates an obstructive implant having a subcutaneous inflation port.

Figs. 20 and 21 illustrate use of obstructive implants to facilitate retention of other obesity-controlling devices within the stomach.

[0009] Referring to Fig. 2, an obstructive implant 10

includes a body positioned against the exterior of the stomach wall W. The implant occupies stomach volume by causing a portion of the stomach wall W to bulge into the interior volume of the stomach, thus reducing the effective volume of the stomach interior and reducing stomach capacity. Because the implant 10 is positioned outside the stomach, it cannot migrate into the intestinal tract creating obstructions. A retention band 12 is positioned within the stomach encircling a portion of the wall W so as to retain the implant 10 within pocket 2 as shown. The retention band 12 may be a ring that is elastic or inelastic, flexible or fairly rigid. The diameter of the retention band 12 may be adjustable if desired. The retention band 12 is preferably proportioned such that in the event the band becomes free within the stomach, it can pass through the intestinal system without incident. Thus, the retention device is preferably of a size that will not on its own to occupy sufficient space within the stomach to create feelings of satiety, but that relies on the extragastric implant 10 to reduce stomach capacity. Nonetheless, in alternate embodiments the retention band 12 may also perform a space-occupying function, and/or a restrictive and/or obstructive function.

[0010] Various positions for the implant are illustrated in the drawings. Depending on the size and positioning of the implant, it may function as an obstructive device, a restrictive device, or both. In some embodiments, the implant may have an expanded volume in the range of approximately 200 - 700 cc, sufficient to cause the inwardly-protruding to fill a portion of the stomach, thereby causing the patient to feel full and thus limiting food intake. In Fig. 2, the implant is positioned to function as an obstructive device (i.e. to occupy space so as to reduce effective stomach volume), but also to create a restriction 14 in the stomach. The restriction 14 is a narrowed region of the stomach, which slows the rate at which food can descend from the esophagus into the stomach. Food may accumulate in the region above the restriction, causing the patient to experience feelings of satiety and thus limiting food intake, and/or limiting the amount of food a patient can consume at one time.

[0011] Fig. 3 shows a pair of implants 10 and a pair of retention bands 12 positioned in the proximal stomach to create a restriction 14a. This restriction 14a may also minimize reflux and thus function as treatment for patients suffering from gastro-intestinal reflux disease (GERD).

[0012] Fig. 4 illustrates that the implant 10 may be positioned in the antrum A. It may similarly be positioned at the pylorus P (see Fig. 1A). Alternatively, the implant 10 may be positioned in the fundus F as shown in Fig. 5 again creating an obstruction as well as an (optional) restriction 14b in the proximal stomach. The original position of the wall of the fundus F is illustrated in dashed lines.

[0013] Fig. 6 illustrates that a pair of implants 10 may be positioned against regions of stomach wall W1, W2 on opposite sides of the stomach. These implants are retained in their respective pockets 2 using a single retention band 12 encircling both regions of wall W1, W2 to create an obstruction within the stomach and which creates restricted flow paths on opposite sides of the obstruction.

[0014] The configuration illustrated in Fig. 6 is particularly advantageous in that it relies in part on adhesion of the serosal tissue lining the outer surface of the stomach. It has been found that serosal tissue layers can adhere to form relatively strong bonds when held in apposition to one another. Other embodiments including, but not limited to, the Fig. 2-5, 7 and 8 embodiments may be modified to allow the retention band to retain regions of serosal tissue into contact with one another such that over time the serosal tissue will adhere as a permanent means for retaining the implant 10. For example, if such a modification was made to the Fig. 2 embodiment, the regions R1, R2 of stomach wall would be drawn into contact with one other, and retention band 12 would retain that contact until the serosal layers adhered to one another. At that time, the retention band (or other retention devices such as sutures, staples, etc.) could be removed from the stomach, such that no device remained in the stomach interior, and the implant remained in the protrusion formed against the exterior stomach wall. It may be further desirable in such embodiments to inflate the implant during a later procedure performed after the serosal layers have adhered to one another. In such embodiments, inflation may be carried out using a needle introduced into the stomach, used to pierce the stomach wall, and then passed into an inflation port (e.g. such as port 26 of Fig. 2 or valve 48 of Fig. 13G). Alternatively, the balloon may be self-sealing (similar to self-sealing tires), also allowing inflation/deflation of the balloon using a needle that pierces the stomach wall and the balloon.

[0015] A section of reinforcing and/or ingrowth-promoting material 15 (Fig. 6) may be optionally placed between serosal and/or mucosal tissue layers that are positioned in contact with one another. The material may be a synthetic or non-synthetic mesh, porous material, slotted material, or any other material through which adhesions will form or onto which tissue will grow. Examples include, but are not limited to, polypropylene, materials sold under the trade names Goretex or Dacron, or tissue graft material such as the Surgisis material sold by Wilson Cook Medical, Inc. The material may be treated with tissue-ingrowth promoting substances such as biologics. If such material is used, the adhesions that form between the serosal tissue layers will pass through and/or onto the interstices of the material and serve to reinforce the bond between the tissue layers. The material may further cause some mechanical abrasion of the adjacent tissue, creating additional scar tissue that would further reinforce the strength of the opposed tissue.

[0016] If adhesion of adjacent mucosal tissue surfaces is desired, modification of the interior tissue surface may further be needed in order to optimize adhesion of opposed regions of internal stomach tissue. In particular, it

is believed that better adhesion of the interior wall surfaces may be achieved when a portion of the mucosal layer of tissue lining the stomach interior is removed, such that the tissue surfaces sutured in apposition to one another are serosal, sub-mucosal or muscularis layers. It is believed that opposed layers of mucosal tissue do not adhere together as well as opposed layers of serosal, sub-mucosal, or muscularis tissue. Surface modification methods for promoting such tissue adhesion include cutting, ablating (using RF, laser, or chemical ablation) or abrading the mucosal surface within the stomach as indicated by dashed lines. This modification is ideally performed before the folds are placed in apposition. Depending on the depth to which cutting, ablation or abrasion is performed, the sub-mucosal, musclaris, or serosal layer beneath the mucosal layer is exposed. This allows the exposed regions of tissue to be placed in apposition and causes the opposed surfaces to tightly adhere over time.

[0017] Although the implants shown in Figs. 2 - 6 are illustrated as being spherical, various other configurations may be used. For example, an alternate implant 10a shown in Fig. 7 may include a recess 16 along its surface such that the portion of the stomach wall W following the contour of recess 16 creates a form of pouch or reservoir 18 in the stomach within which food may accumulate. An elongate implant 10b of the type shown in Fig. 8 may be used to form an elongate restriction 20 while greatly reducing the effective volume of the stomach. Fig. 9 shows an implant 10c having a modified hourglass configuration including an obstructive portion 22 that functions to bulge the stomach wall inwardly as described in connection with earlier embodiments. A neck 24 extending from the obstructive portion 22 connects with a base portion 26 that helps to distribute forces imparted against the stomach W and prevents tissue erosion and/or migration of the implant. As shown in the figure, the retention band 12 preferably seats against the stomach tissue surrounding the neck 24.

[0018] Many other shapes beyond those shown in this application may be used for the implant (such as for accommodating the shape of the anatomy, or for creating a restriction or obstruction of a particular size/shape), without departing from the scope of the present invention.

[0019] There are likewise many suitable structures and materials useful for the implant. Some structures and materials are shown and described herein, although again many others may be used without exceeding the scope of the present invention.

[0020] For example, the implant may be an elastic or inelastic balloon that is implantable in a deflated state and then inflated within the body using a gas or liquid. A balloon of this type may include a port such as port 26 shown in Fig. 2. During use an inflation needle may be introduced into the stomach, used to pierce the stomach wall, and then passed into the port 26. The needle may be used to introduce inflation medium into the balloon, or to deflate the balloon if adjustments in balloon size are needed. Alternatively, the balloon may be self-sealing (along the lines of puncture-proof or self-sealing tires), also allowing inflation/deflation of the balloon using a needle that pierces the stomach wall and the balloon. This latter embodiment is advantageous in that it does not necessitate a particular orientation for the balloon as would be needed to orient an inflation port for receipt of an inflation needle.

[0021] Other configurations besides balloons are also suitable for the implant. The implant 10d may have fluted walls 28 as shown in Fig. 10, or it may be formed of a mesh 30 as shown in Fig. 11. These implants 10d, 10e may be self-expanding or they may be provided in a fully expanded form. The implant 10f of Fig. 12A includes a pair of plates 32 separated by a neck 34. When positioned as shown in Fig. 12B, a portion of the stomach wall W caves into the gap 36 between the plates 32, creating a flow path for food moving from the esophagus E into the stomach. The amount of restriction provided by the implant 10f may be selected by selecting a suitable length or width for the neck 34.

[0022] The implant need not be a hollow structure, but could instead be entirely solid.

[0023] The implant may be implanted endoscopically using tools passed into the stomach via the esophagus. According to the endoscopic approach, the implant is inserted into the stomach and then passed through an opening formed in the stomach wall. Alternatively, a laparoscopic method may be used to pass the implant into the abdominal cavity through incisions or trocar punctures in the skin. The implant may also be introduced using an open surgical approach. In both the laparoscopic and surgical procedures, the retention band 12 is preferably introduced endoscopically into the stomach.

[0024] Figs. 13A through 13F illustrate one method of positioning an inflatable implant using an endoscopic approach. Referring to Fig. 13A, retention band 12 is inserted down the esophagus into the stomach using an endoscopic instrument 38. Next, the implant 10 is passed into the stomach and through the retention band 12 as shown in Fig. 13B. Implant 10 is preferably compressed within a tubular instrument 40 having a tissue-piercing distal end. The instrument 40 may be telescopically disposed within a tubular sheath 42 to prevent the instrument from inadvertently nicking surrounding tissue. Although not shown, an inflation tube extends through the instrument 40 and sheath 42 and is coupled to an inflation port of the implant. An endoscope 44 is used to monitor the procedure.

[0025] Referring to Fig. 13C, the tissue-piercing instrument 40 is extended from its sheath and used to pierce through the stomach wall W at a desired implant location. The implant 10 is released from the instrument 40 and partially inflated by passing inflation medium through the inflation tube. The tissue-piercing instrument 40 and its sheath 42 may be removed from the stomach, leaving the inflation tube 46 (Fig. 13D) behind.

[0026] Next, tension is applied to the inflation tube 46 to pull the implant 10 towards the stomach so as to create

the pocket 2. This step draws the implant 10 and the surrounding stomach wall through the retention band 12 as shown in Fig. 13D. Once a sufficient amount of tissue has been drawn through the retention band, the implant is inflated to the desired size as shown in Fig. 13E. The inflation tube 46 is detached from the implant 10 and the endoscopic instrument 38 is detached from the retention band 12, leaving the implant in place as shown in Fig. 13F. The hole formed in the stomach wall may be closed using sutures or a sealable gel that solidifies when placed into contact with the tissue.

[0027] Referring to Fig. 13G, it should be noted that the implant may include an inflation valve 48 that is left extending through the stomach wall. The valve 48 allows for post-implant size adjustments by allowing inflation medium to be added to or removed from the balloon using an inflation tube passed through the esophagus and attached to the valve. If removal of the balloon is required, the valve may be grasped using endoscopic instruments to draw the balloon back into the stomach and out the esophagus. The valve may be surrounded by a seal to prevent movement of stomach contents into the abdominal space outside the stomach. A gel of a type that will solidify when placed into contact with the stomach surface may be used for this purpose.

[0028] The retention band 12 may take alternate forms or be replaced altogether using other types of structures that help to capture the implant 10 in the pocket 2 at the implant site. Fig. 14 illustrates that the cross-sectional area of the restrictive band 12a may be large relative to the size of the implant so as to diffuse the forces imparted on the region of stomach wall captured between the band 12a and the implant 10 and to thereby prevent erosion of, or damage to, the stomach tissue. Fig. 15 illustrates that a large surface-area retention liner 12b may alternatively be used so as to distribute forces over a broader surface. Referring to Fig. 16, the restriction ring 12c and implant 10 may be coupled together by an inflation tube 50 extending through the stomach wall. A valve 52 is fluidly coupled to the tube 50 and allows for introduction/removal of inflation medium using an inflation needed passed into the stomach. The valve 52 and tube 50 facilitate explantation of the implant using a grasping instrument inserted through the esophagus and into the stomach.

[0029] The retention band itself may be inflatable. Referring to Fig. 17B, the retention band may include separate inflatable chambers 54a, 54b each having an inflation port 56a, 56b. The chambers 54a, 54b are joined together to form an annular band. The upper chamber 54a may be shaped to form a channel 58 for passage of food, as shown in Fig. 17B.

[0030] Fig. 18 illustrates that the retention band may be eliminated entirely. As shown, after the implant 10 is pulled against the stomach wall W, stomach tissue adjacent to the pocket 2 can be fastened together using pledgets 60 (or sutures, staples, clips or other means). Over time, a physiological response will cause the regions of serosal tissue held in contact with one another to bond together, thereby retaining the implant in the pocket 2.

[0031] Referring to Fig. 19, inflatable implant 10 may be tethered to an inflation port 62 positioned within a subcutaneous pocket in the body. If needed following implantation, an inflation needle may be inserted through the patient's skin and into the inflation port 62 to increase or decrease the amount of inflation medium within the implant.

[0032] Referring to Figs. 20 and 21, it should be noted that while the implant 10 may itself provide restriction and/or obstruction, the implant 10 may also be used to prevent migration of a restrictive and/or obstructive device positioned inside the stomach. For example, device 64 of Fig. 20 or device 66 of Fig. 21 may be positioned in the proximal stomach and seat against the portion of the stomach wall that protrudes inwardly as a result of implant 10.

[0033] Components of the type described herein may be supplied individually or as systems which may include various combinations of components such as implants (e.g. implant 10) retention devices (e.g. band 12), implantation instruments and/or instructions for use. If included, instructions for use may include instructions instructing a user to implant the implant using methods such as any of those described above. For example, the instructions may instruct the user to create an inward protrusion in the stomach wall such as by positioning an instrument or the implant against an exterior surface of the stomach wall. The instructions may further instruct the user to position the retention device in a manner that at least partially retains the protrusion in the wall and that thus captures implant within the protrusion, externally of the stomach. In some embodiments where a retention band is provided, the instructions for use may instruct the user to encircle a portion of the protrusion in the wall with the retention band. The instructions may instruct the user as to laparoscopic, endoscopic, and/or open surgical approaches such as those described above.

[0034] It should be appreciated that the various features of the embodiments that have been described might be combined in various ways to produce numerous additional embodiments.

[0035] The methods defined by the following numbered paragraphs have been described hereinbefore:

1. A method of assisting weight loss in a patient, comprising the steps of: positioning an extragastric space occupier into contact with an exterior surface of a stomach wall to form an inward protrusion of wall into the stomach; and
placing a retention device in contact with the wall to retain the inward protrusion and to thereby capture the extragastric space occupier within the protrusion.

2. The method of paragraph 1, wherein the placing step places the retention device into contact with an

interior surface of the wall.

3. The method of paragraph 2, wherein the retention device comprises a band wherein the placing step includes encircling the protrusion using the band.

4. The method of paragraph 1, wherein the placing step includes the step of drawing proportions of the wall into contact with one another and attaching a retention device to the wall to retain the protrusion.

5. The method of paragraph 4, wherein the retention device comprises at least one suture or staple.

6. The method of paragraph 1, wherein the extragastric space occupier is expandable, and wherein the method includes the step of expanding the space occupier to a volume sufficient to cause the protrusion to fill a portion of the stomach, thereby causing the patient to feel full.

7. The method of paragraph 6, wherein the expanding step includes expanding the space occupier to a volume in the range of 200 - 800 cc.

8. The method of paragraph 1, wherein the space occupier is expandable, and wherein the method includes the step of expanding the space occupier to cause the protrusion to create a restriction in the stomach that will slow the rate at which food can descend from the esophagus into the stomach.

9. The method of paragraph 1, wherein the space occupier includes an inflation port, and wherein the method includes the step of passing an inflation needle extendable through the esophagus into the stomach, engaging inflation port with the inflation needle, and inflating the space occupier using the inflation needle.

10. The method of paragraph 9, wherein the positioning step includes positioning the inflation port to extend an opening in the stomach wall.

11. The method of paragraph 9, wherein the inflation port includes a resealable portion of the space occupier, and engaging step includes passing the needle through the stomach wall into engagement with the inflation port.

12. The method of paragraph 1, wherein the positioning step includes passing the extragastric space occupier through the esophagus into the stomach, and then passing the extragastric space occupier through an opening formed in the wall of the stomach and into contact with the exterior of the wall.

13. The method of paragraph 1, wherein the positioning step includes passing the extragastric space occupier laparoscopically into an abdominal cavity and into contact with the exterior of the wall.

Claims

1. A system for inducing weight loss in a patient, the system comprising:

an extragastric space occupier (10c; 10f) positionable in contact with an exterior surface of a stomach wall to form an inward protrusion of the wall into the stomach; and
a retention device (12) positionable in contact with the wall to retain the inward protrusion and to thereby capture the extragastric space occupier within the protrusion, the system **characterized in that** the extragastric space occupier (10c; 10f) has a first portion (22; 32) to form the inward protrusion, a second portion (26; 32), and a neck portion (24; 34) between and narrower than the first and second portions.

2. The system according to claim 1, wherein the extragastric space occupier is proportioned to cause the protrusion to fill a portion of the stomach, thereby causing the patient to feel full.

3. The system according to claim 1, wherein the extragastric space occupier is expandable to an expanded volume in the range of 200-800 cc.

4. The system according to claim 1, wherein the extragastric space occupier is proportioned to cause the protrusion to create a restriction in the stomach that will slow the rate at which food can descend from the esophagus into the stomach.

5. The system according to claim 1, wherein the retention device comprises at least one of a suture and a staple.

6. The system according to claim 1, wherein the retention device comprises at least one band to seat adjacent stomach tissue surrounding the neck portion.

7. The system according to claim 6, wherein the band is positionable to encircle at least a portion of the protrusion.

8. The system according to claim 6, wherein the band is inflatable.

9. The system according to claim 1, wherein the extragastric space occupier is inflatable.

10. The system according to claim 1, wherein the extra-

gastric space occupier includes an inflation port, and wherein the system includes an inflation needle extendable through the esophagus into the stomach, the inflation needle engageable with the inflation port.

11. The system according to claim 10, wherein the inflation port is extendable through an opening in the stomach wall.

12. The system according to claim 10, wherein the inflation port includes a resealable portion of the extragastric space occupier, and wherein the needle is extendable through the stomach wall into engagement with the inflation port.

13. The system according to claim 1, further including instructions setting forth a method for implanting the system, including the steps of:

positioning the extragastric space occupier into contact with an exterior of a wall of the stomach, causing the wall to protrude inwardly into the stomach; and
coupling a retention device to the stomach so as to retain the inward protrusion and to thereby capture the extragastric space occupier within the protrusion.

14. The system according to claim 13, wherein the instructions set forth that the positioning step includes the step of passing the extragastric space occupier through the esophagus into the stomach, and then passing the extragastric space occupier through an opening formed in the wall of the stomach and into contact with the exterior of the wall.

15. The system according to claim 13, wherein the instructions set forth that the positioning step includes the step of passing the extragastric space occupier laparoscopically into an abnormal cavity and into contact with the exterior of the wall.

Patentansprüche

1. System zum Herbeiführen eines Gewichtsverlusts bei einem Patienten, wobei das System aufweist:

eine den extragastrischen Raum einnehmende Vorrichtung (10c; 10f), die in Kontakt mit einer Außenfläche einer Magenwand positionierbar ist, um einen nach innen gerichteten Vorsprung der Wand in den Magen zu bilden; und
eine Haltevorrichtung (12), die in Kontakt mit der Wand positionierbar ist, um den nach innen gerichteten Vorsprung zu halten und dadurch die den extragastrischen Raum einnehmende Vorrichtung im Vorsprung zu erfassen,
wobei das System **dadurch gekennzeichnet ist, dass** die den extragastrischen Raum einnehmende Vorrichtung (10c; 10f) einen ersten Abschnitt (22; 32), um den nach innen gerichteten Vorsprung zu bilden, einen zweiten Abschnitt (26; 32) und einen Verengungsabschnitt (24; 34) aufweist, der zwischen dem ersten und zweiten Abschnitt liegt und enger als diese ist.

2. System nach Anspruch 1, wobei die den extragastrischen Raum einnehmende Vorrichtung so proportioniert ist, dass sie bewirkt, dass der Vorsprung einen Abschnitt des Magens füllt, wodurch bewirkt wird, dass sich der Patient satt fühlt.

3. System nach Anspruch 1, wobei die den extragastrischen Raum einnehmende Vorrichtung auf ein expandiertes Volumen im Bereich von 200-800 cm^3 expandierbar ist.

4. System nach Anspruch 1, wobei die den extragastrischen Raum einnehmende Vorrichtung so proportioniert ist, dass sie bewirkt, dass der Vorsprung eine Einengung im Magen erzeugt, der die Geschwindigkeit verlangsamen wird, mit der Nahrung vom Ösophagus in den Magen absinken kann.

5. System nach Anspruch 1, wobei die Haltevorrichtung eine Naht und/oder eine Klammer aufweist.

6. System nach Anspruch 1, wobei die Haltevorrichtung mindestens ein Band aufweist, um benachbartes Magengewebe einzupassen, das den Verengungsabschnitt umgibt.

7. System nach Anspruch 6, wobei das Band positionierbar ist, so dass es mindestens einen Abschnitt des Vorsprungs umgibt.

8. System nach Anspruch 6, wobei das Band aufblasbar ist.

9. System nach Anspruch 1, wobei die den extragastrischen Raum einnehmende Vorrichtung aufblasbar ist.

10. System nach Anspruch 1, wobei die den extragastrischen Raum einnehmende Vorrichtung einen Aufblasanschluss aufweist, und wobei das System eine Aufblasnadel aufweist, die durch den Ösophagus in den Magen ausfahrbar ist, wobei die Aufblasnadel mit dem Aufblasanschluss in Eingriff bringbar ist.

11. System nach Anspruch 10, wobei der Aufblasanschluss durch eine Öffnung in der Magenwand ausfahrbar ist.

12. System nach Anspruch 10, wobei der Aufblasanschluss einen wiederverschließbaren Abschnitt der den extragastrischen Raum einnehmende Vorrichtung aufweist, und wobei die Nadel durch die Magenwand in einen Eingriff mit dem Aufblasanschluss ausfahrbar ist.

13. System nach Anspruch 1, das ferner Anweisungen aufweist, die ein Verfahren zum Implantieren des Systems darlegen, das die Schritte aufweist:

Positionieren der den extragastrischen Raum einnehmenden Vorrichtung in Kontakt mit einem Äußeren einer Wand des Magens, die bewirkt, dass die Wand nach innen in den Magen vorsteht; und
Koppeln einer Haltevorrichtung am Magen, um den nach innen gerichteten Vorsprung zu halten und dadurch die den extragastrischen Raum einnehmende Vorrichtung im Vorsprung zu erfassen.

14. System nach Anspruch 13, wobei die Anweisungen darlegen, dass der Positionierungsschritt den Schritt des Schiebens der den extragastrischen Raum einnehmenden Vorrichtung durch den Ösophagus in den Magen, und dann das Schieben der den extragastrischen Raum einnehmenden Vorrichtung durch eine Öffnung, die in der Wand des Magens ausgebildet ist, und in Kontakt mit dem Äußeren der Wand aufweist.

15. System nach Anspruch 13, wobei die Anweisungen darlegen, dass der Positionierungsschritt den Schritt des laparoskopischen Schiebens der den extragastrischen Raum einnehmenden Vorrichtung in einen abnormen Raum und in Kontakt mit dem Äußeren der Wand aufweist.

Revendications

1. Système destiné à provoquer une perte de poids chez un patient, ledit système comprenant :

un élément d'occupation d'un espace extra-gastrique (10c ; 10f) positionnable en contact avec une surface extérieure de la paroi de l'estomac pour former une saillie de la paroi vers l'intérieur de l'estomac ; et
un dispositif de maintien (12) positionnable en contact avec la paroi pour maintenir la saillie rentrante et pour retenir l'élément d'occupation d'un espace extra-gastrique à l'intérieur de la saillie, ledit système étant **caractérisé en ce que** l'élément d'occupation d'un espace extra-gastrique (10c ; 10f) présente une première partie (22 ; 32) pour former la saillie rentrante, une deuxième partie (26 ; 32), et une partie de col (24 ; 34) entre la première et la deuxième parties, étroite par rapport à celles-ci.

2. Système selon la revendication 1, où l'élément d'occupation d'un espace extra-gastrique est dimensionné de telle manière que la saillie occupe une partie de l'estomac, en causant une sensation de satiété chez le patient.

3. Système selon la revendication 1, où l'élément d'occupation d'un espace extra-gastrique est expansible vers un volume d'expansion compris entre 200 et 800 cm^3.

4. Système selon la revendication 1, où l'élément d'occupation d'un espace extra-gastrique est dimensionné de telle manière que la saillie provoque une constriction de l'estomac qui ralentit la descente des aliments de l'oesophage dans l'estomac.

5. Système selon la revendication 1, où le dispositif de maintien comprend au moins soit une suture, soit une agrafe.

6. Système selon la revendication 1, où le dispositif de maintien comprend au moins une bande pour fixer le tissu d'estomac adjacent entourant la partie de col.

7. Système selon la revendication 6, où la bande est positionnable pour encercler au moins une partie de la saillie.

8. Système selon la revendication 6, où la bande est gonflable.

9. Système selon la revendication 1, où l'élément d'occupation d'un espace extra-gastrique est gonflable.

10. Système selon la revendication 1, où l'élément d'occupation d'un espace extra-gastrique comporte un orifice de gonflage, et où ledit système comporte une aiguille de gonflage pouvant s'étendre dans l'oesophage vers l'estomac, ladite aiguille de gonflage étant ajustable dans l'orifice de gonflage.

11. Système selon la revendication 10, où l'orifice de gonflage peut s'étendre dans une ouverture de la paroi de l'estomac.

12. Système selon la revendication 10, où l'orifice de gonflage comporte une partie rescellable de l'élément d'occupation d'un espace extra-gastrique, et où l'aiguille peut traverser la paroi d'estomac paroi pour s'ajuster dans l'orifice de gonflage.

13. Système selon la revendication 1, comportant en outre des instructions relatives à un procédé d'im-

plantation dudit système comprenant les étapes suivantes :

positionnement de l'élément d'occupation d'un espace extra-gastrique en contact avec l'extérieur de la paroi de l'estomac, de telle manière que la paroi fait saillie vers l'intérieur de l'estomac ; et
fixation sur l'estomac d'un dispositif de maintien de manière à maintenir la saillie rentrante et retenir ainsi l'élément d'occupation d'un espace extra-gastrique à l'intérieur de la saillie.

14. Système selon la revendication 13, où les instructions spécifient que l'étape de positionnement comprend l'étape d'insertion de l'élément d'occupation d'un espace extra-gastrique dans l'oesophage vers l'estomac, puis d'insertion de l'élément d'occupation d'un espace extra-gastrique dans une ouverture formée dans la paroi de l'estomac, et de mise en contact avec l'extérieur de la paroi.

15. Système selon la revendication 13, où les instructions spécifient que l'étape de positionnement comprend l'étape d'insertion laparoscopique de l'élément d'occupation d'un espace extra-gastrique dans une cavité anormale, et de mise en contact avec l'extérieur de la paroi.

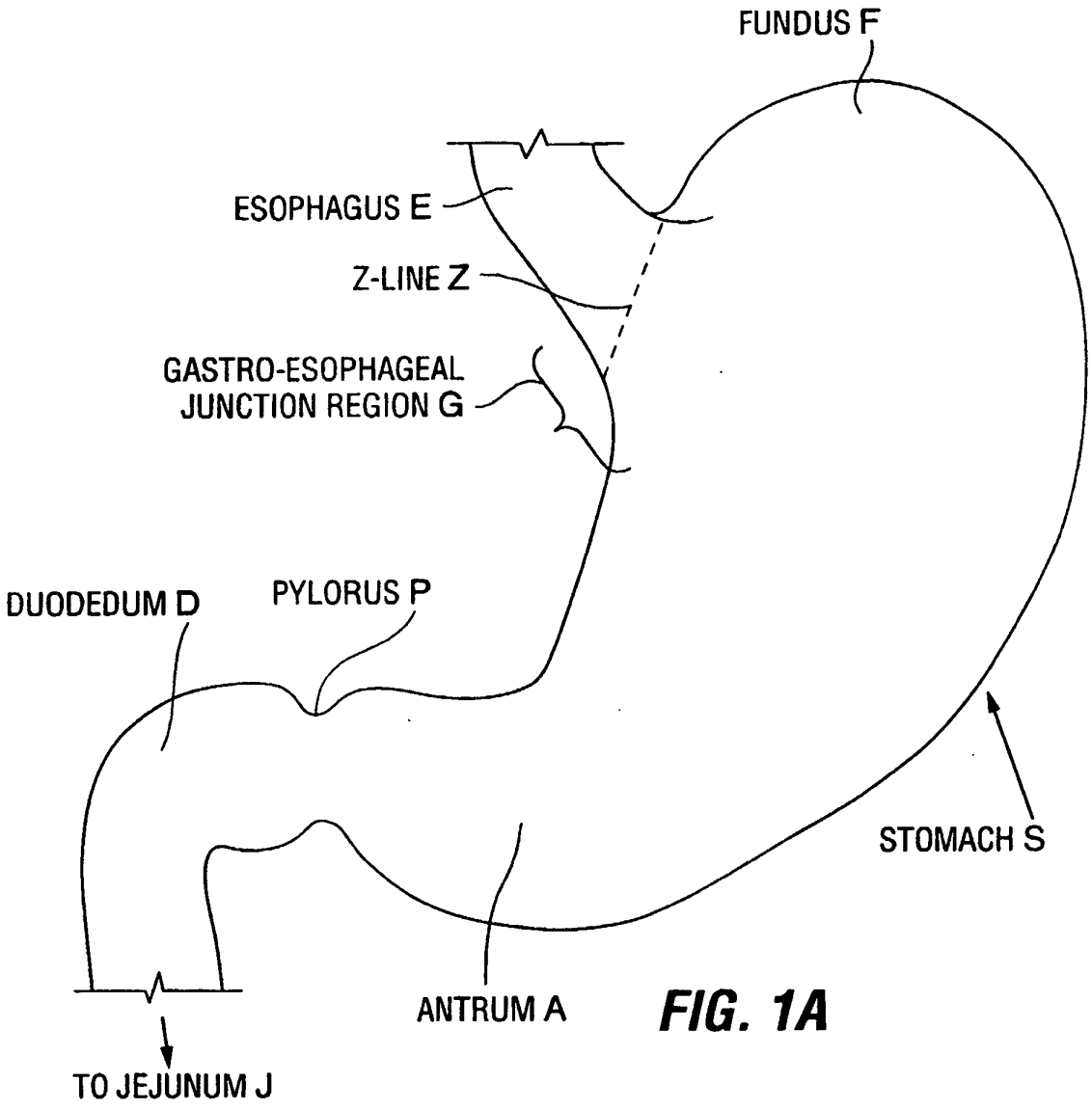
FUNDUS F
ESOPHAGUS E
Z-LINE Z
GASTRO-ESOPHAGEAL
JUNCTION REGION G
DUODEDUM D
PYLORUS P
STOMACH S
ANTRUM A
TO JEJUNUM J

FIG. 1A

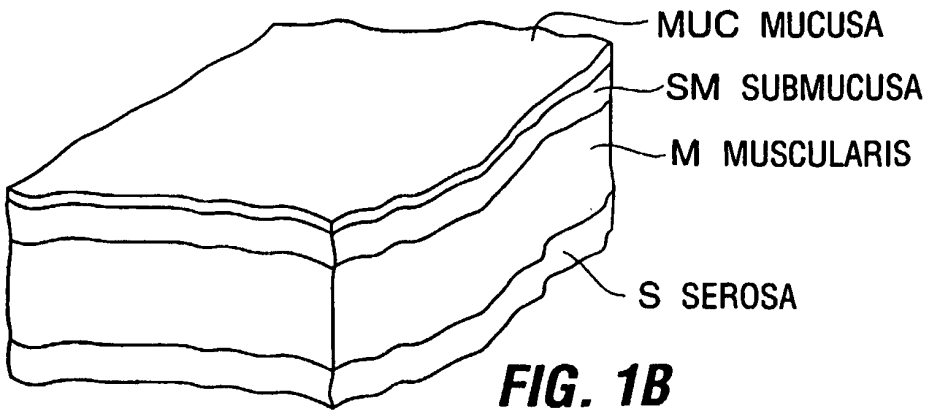
MUC MUCUSA
SM SUBMUCUSA
M MUSCULARIS
S SEROSA

FIG. 1B

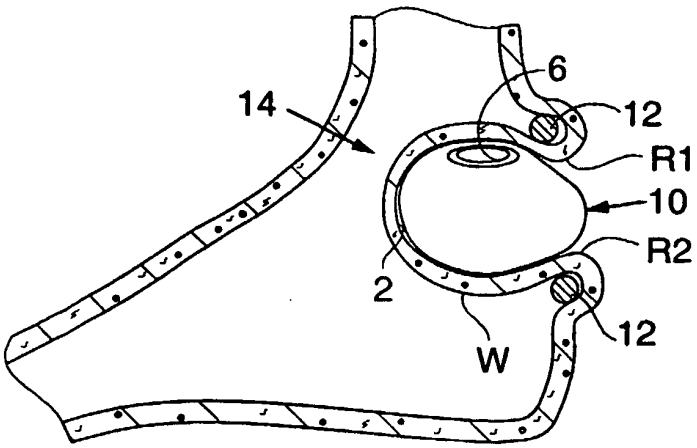

FIG. 2

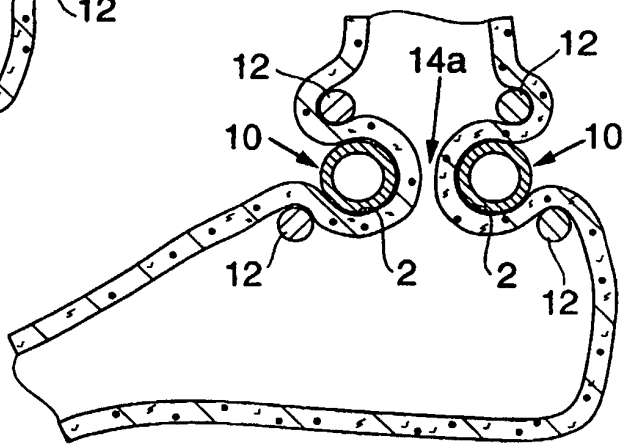

FIG. 3

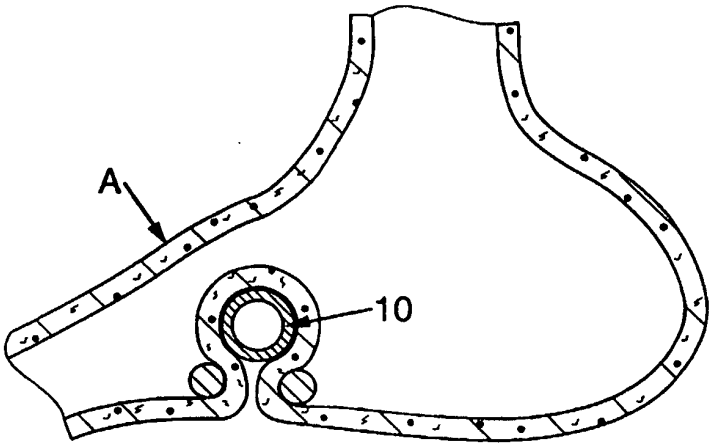

FIG. 4

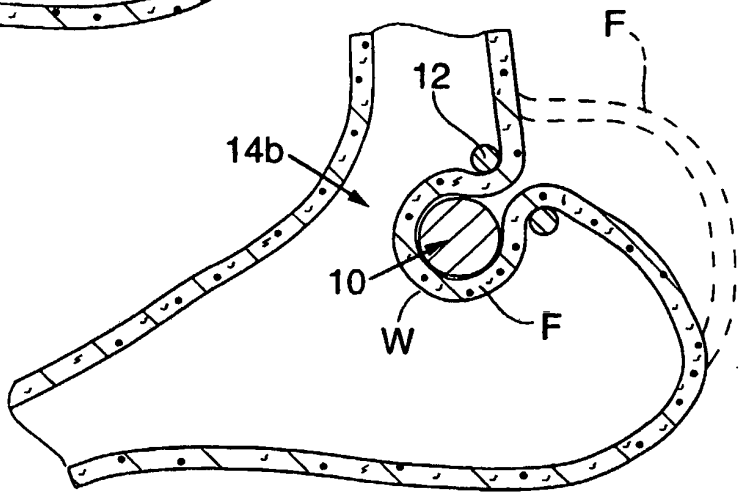

FIG. 5

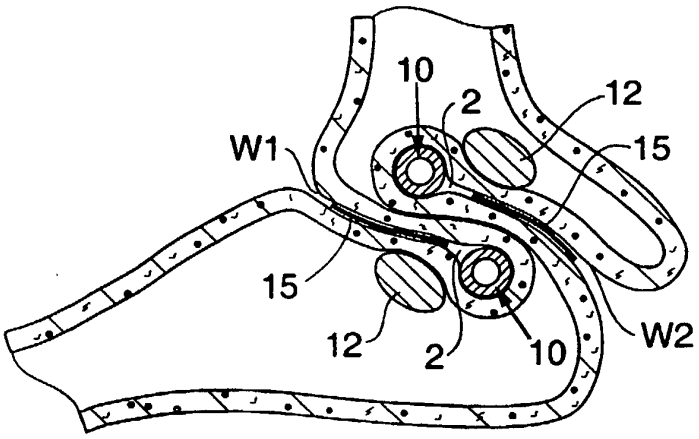

FIG. 6

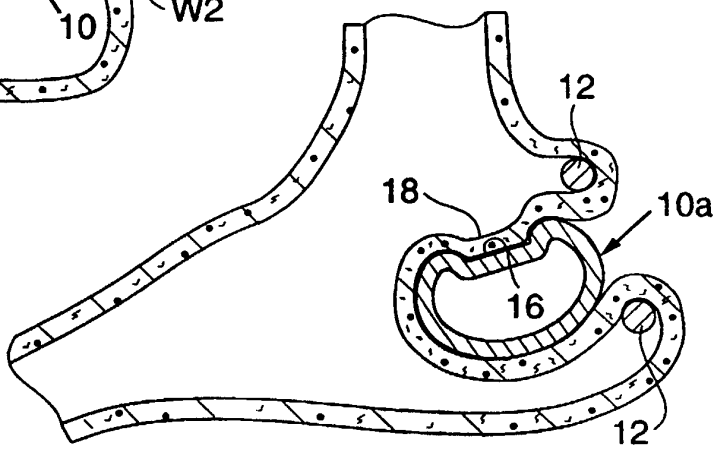

FIG. 7

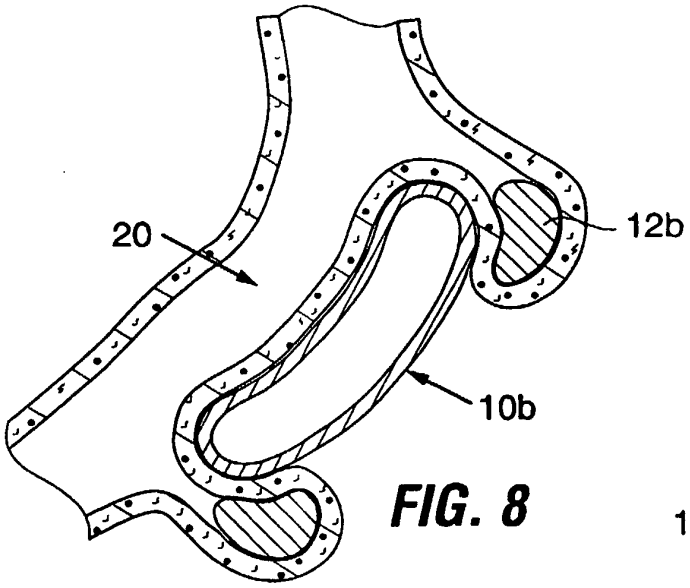

FIG. 8

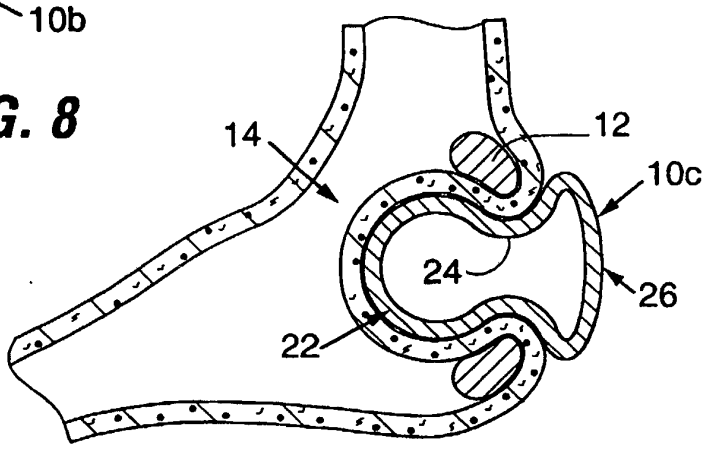

FIG. 9

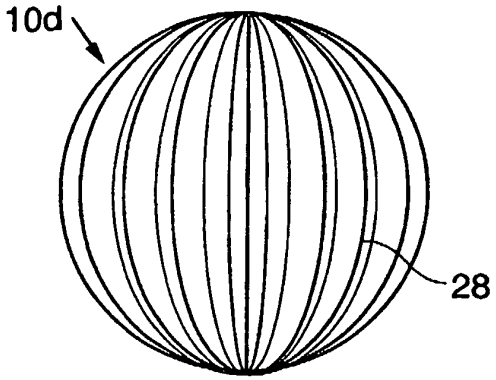

FIG. 10

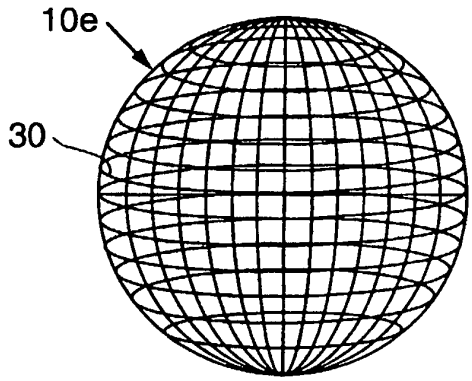

FIG. 11

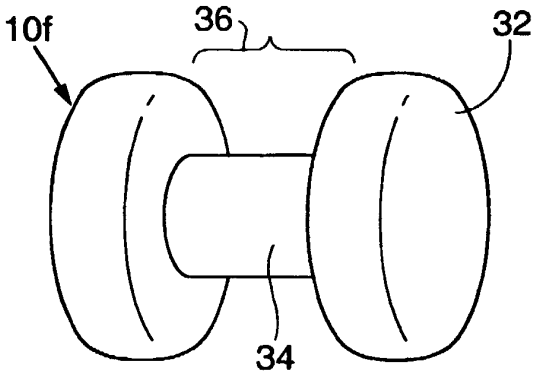

FIG. 12A

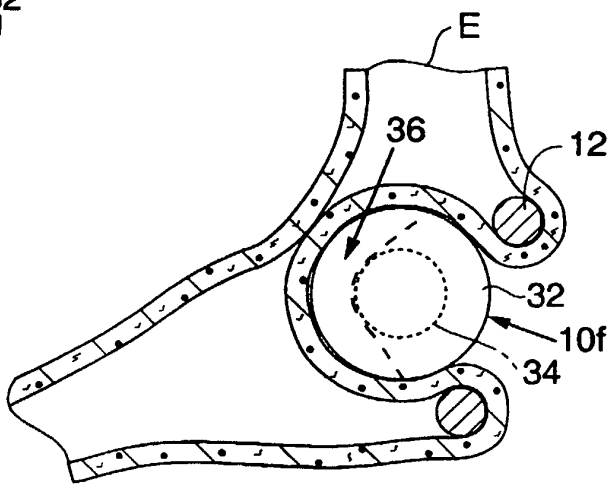

FIG. 12B

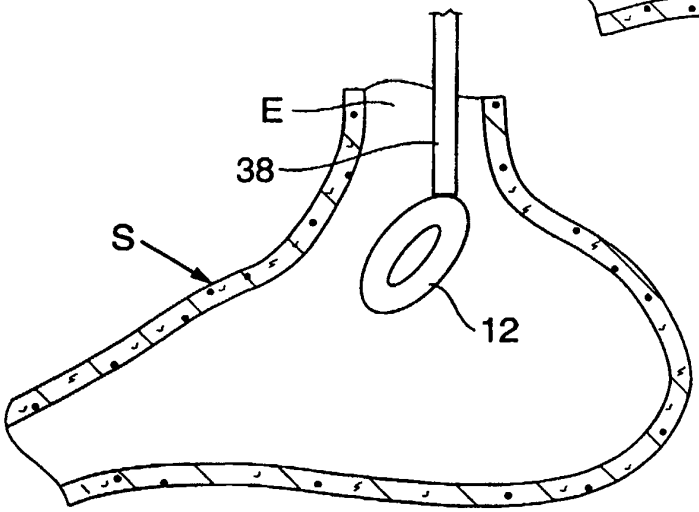

FIG. 13A

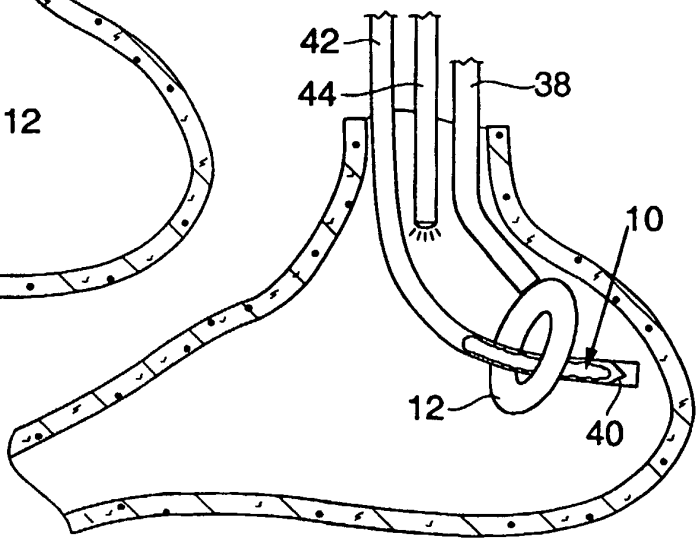

FIG. 13B

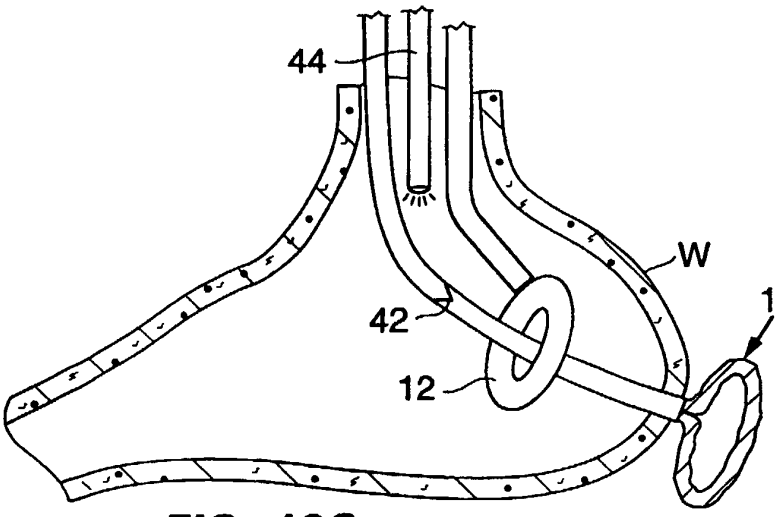

FIG. 13C

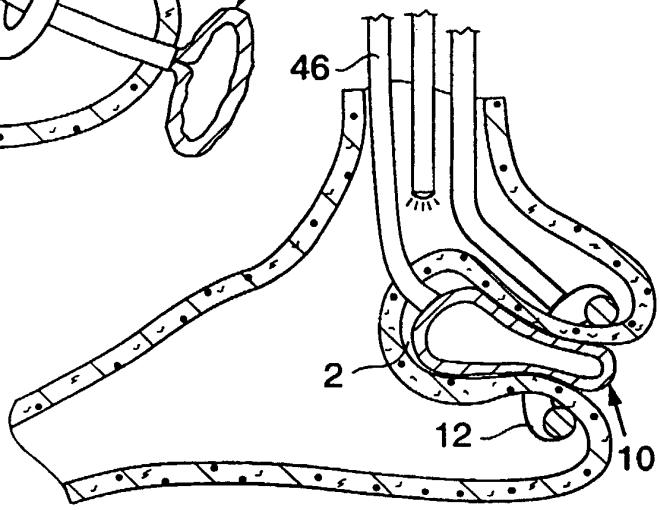

FIG. 13D

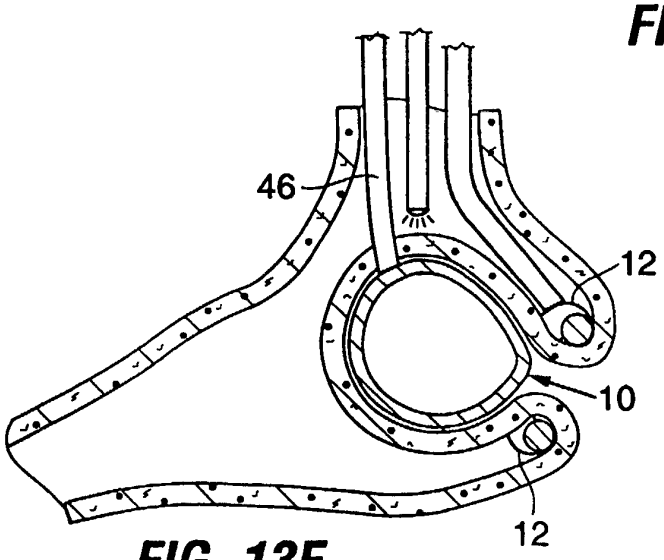

FIG. 13E

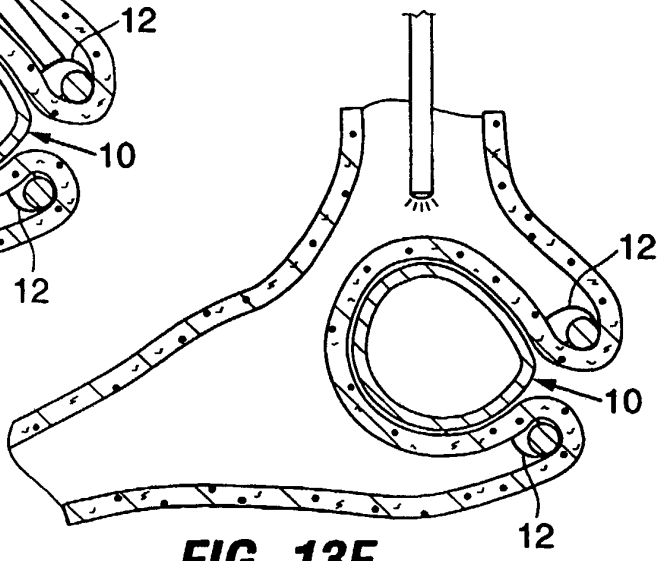

FIG. 13F

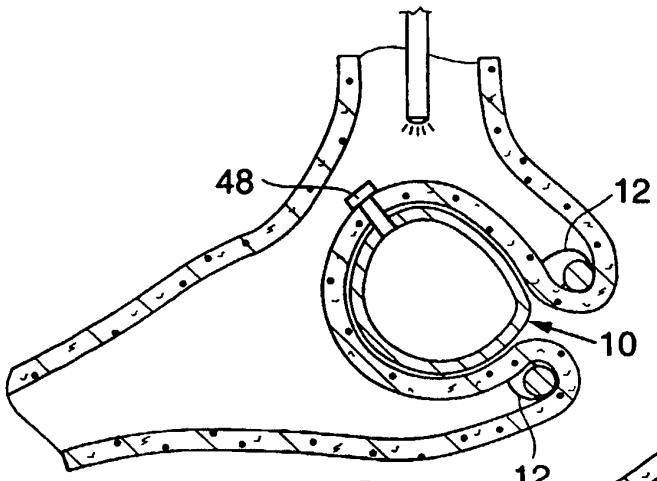

FIG. 13G

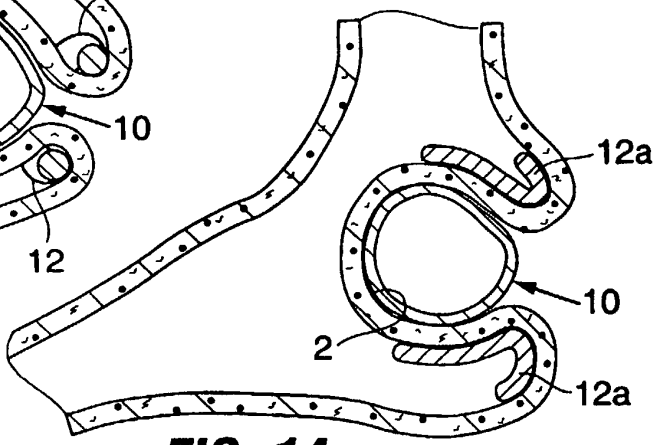

FIG. 14

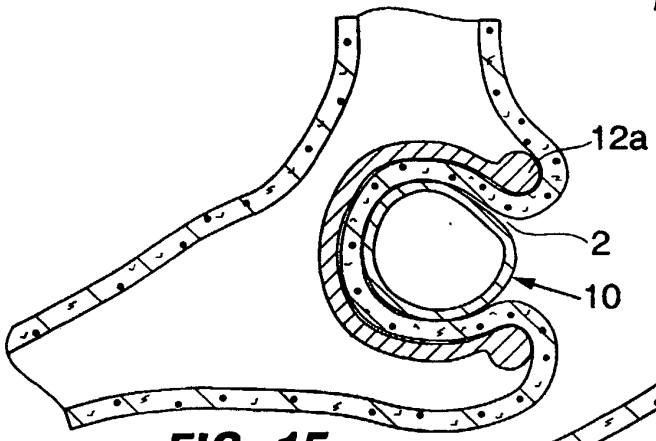

FIG. 15

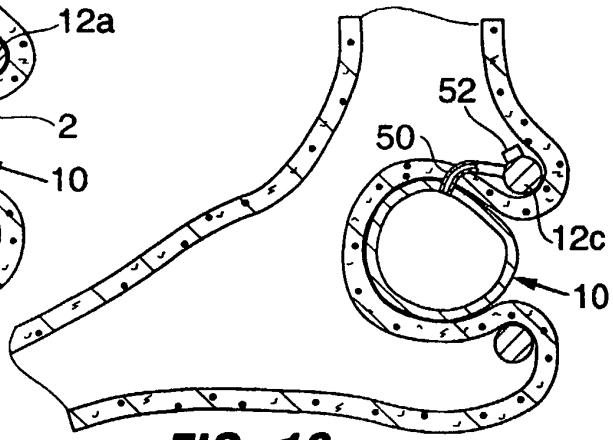

FIG. 16

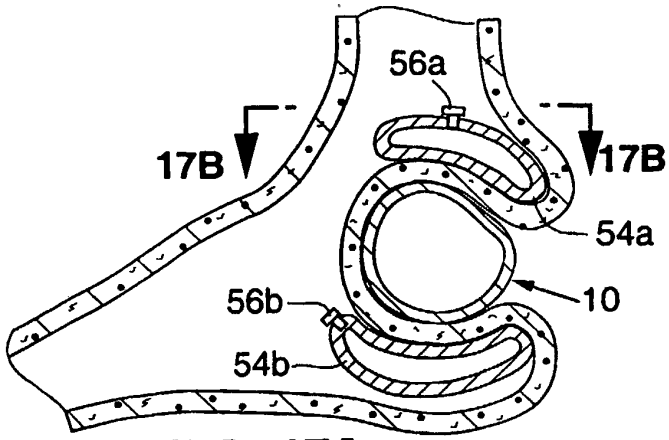

FIG. 17A

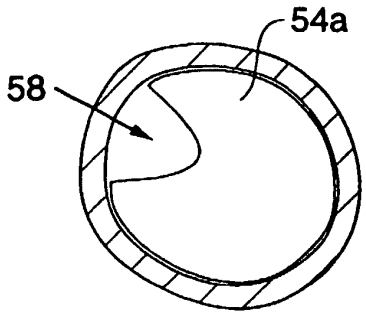

FIG. 17B

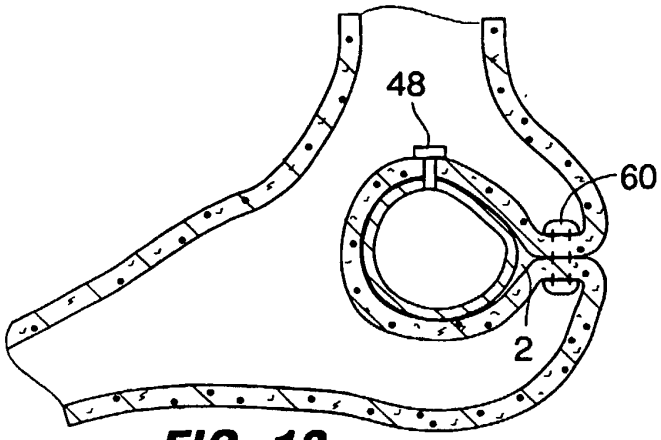

FIG. 18

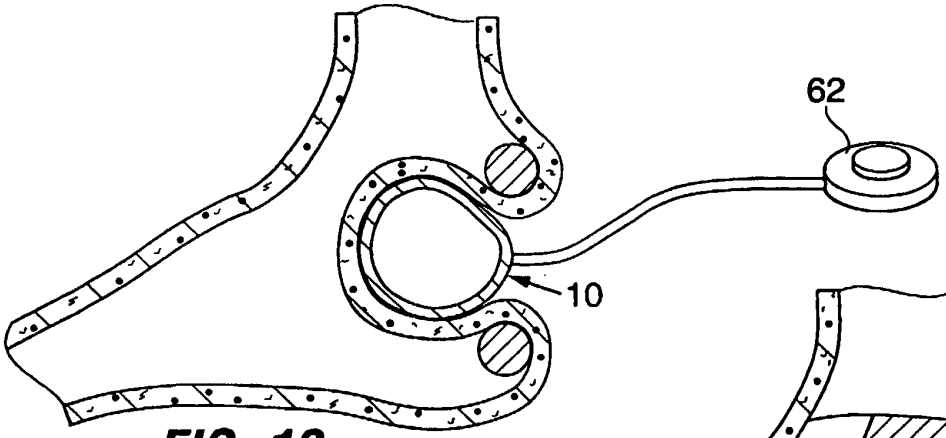

FIG. 19

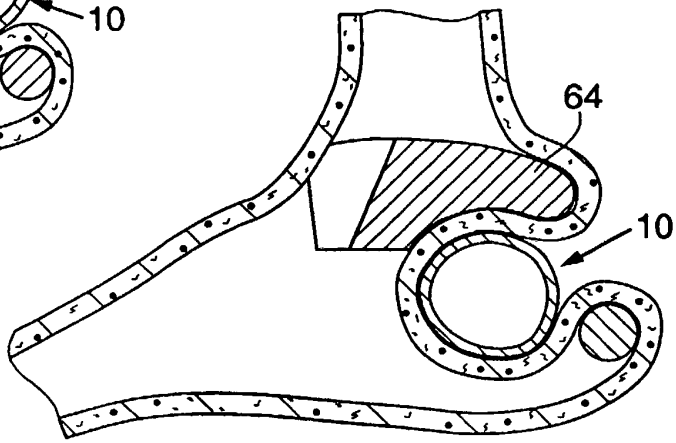

FIG. 20

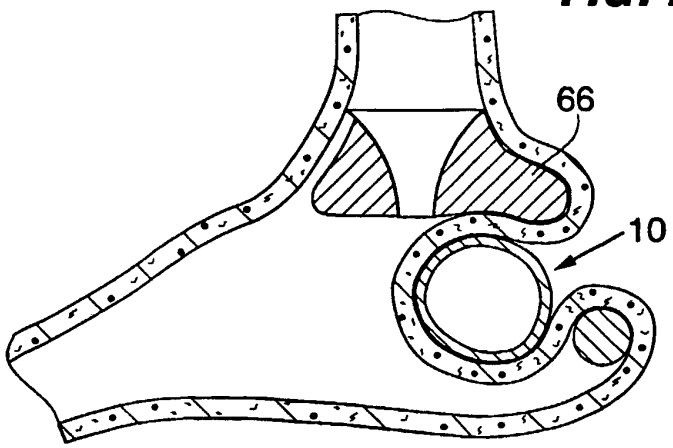

FIG. 21

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- WO 2004019765 A2 **[0007]**

专利名称(译)	用于引起体重减轻的限制性和/或阻塞性植入物		
公开(公告)号	EP1740132B1	公开(公告)日	2014-12-31
申请号	EP2005744737	申请日	2005-04-26
[标]申请(专利权)人(译)	辛尼科有限责任公司		
申请(专利权)人(译)	SYNECOR，LLC		
当前申请(专利权)人(译)	SYNECOR，LLC		
[标]发明人	BALBIERZ DANIEL J ATHAS WILLIAM L LUNSFORD JOHN EUBANKS WILLIAM S VAN BLADEL KEVIN		
发明人	BALBIERZ, DANIEL, J. ATHAS, WILLIAM, L. LUNSFORD, JOHN EUBANKS, WILLIAM, S. VAN BLADEL, KEVIN		
IPC分类号	A61B17/12 A61F5/00 A61B17/08		
CPC分类号	A61F5/0086 A61B17/12009 A61B2017/12018 A61F5/003 A61F5/0036		
代理机构(译)	法思博事务所		
优先权	60/565378 2004-04-26 US		
其他公开文献	EP1740132A1		
外部链接	Espacenet		

摘要(译)

本文描述了一种用于在患者体内引起体重减轻的系统，其包括可定位成与胃壁的外表面接触以形成向内进入胃壁的突出物的胃外空间占用者，以及可定位成与胃接触的保持装置。壁保持向内突出，从而捕获突出内的额外空间占据者。

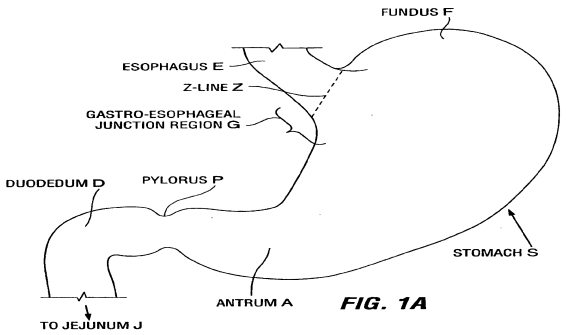

FIG. 1A

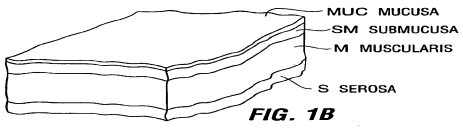

FIG. 1B