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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
18 September 2008 (18.09.2008)

PCT

(10) International Publication Number
WO 2008/112894 A1

(51) International Patent Classification:
A61M 29/00 (2006.01) *A61B 1/00* (2006.01)

(21) International Application Number:
PCT/US2008/056858

(22) International Filing Date: 13 March 2008 (13.03.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/895,006 15 March 2007 (15.03.2007) US

(71) Applicant and
(72) Inventor: **LI, Jiayi** [US/US]; 754 Southampton Drive, Palo Alto, CA 94303 (US).

(74) Agents: **O'REGAN, Cecily, Anne** et al.; Wilson Sonsini Goodrich & Rosati, 650 Page Mill Road, Palo Alto, CA 94304-1050 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, 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, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, 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, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

(54) **Title:** DEVICES, SYSTEMS, KITS AND METHODS FOR TREATMENT OF OBESITY

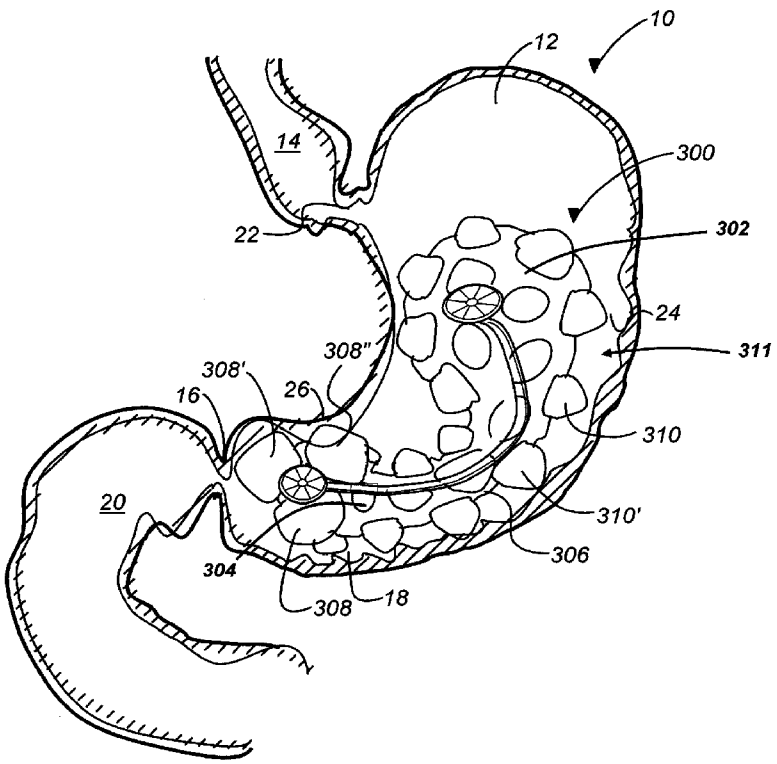

FIG. 4A

(57) **Abstract:** Methods, systems and kits are disclosed for devices suitable for use in the treatment of obesity in patients, either human or animal. The devices comprise an inflatable balloon having a proximal end and a distal end, the inflatable balloon further comprising an interior chamber adapted and configured to receive a filling material; a port in communication with the interior chamber of the inflatable balloon. The inflatable balloon can further be adapted and configured to achieve a deployment shape at least partially conformable to an interior dimensional shape of a stomach of the patient and further wherein the inflatable balloon is adapted and configured to have a distal diameter less than or equal to a proximal diameter.

WO 2008/112894 A1

DEVICES, SYSTEMS, KITS AND METHODS FOR TREATMENT OF OBESITY

CROSS-REFERENCE

[0001] This application claims the benefit of U.S. Provisional Application No. **60/895,006**, filed March 15, 2007, which application is incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] It is currently estimated that more than 50 million Americans are overweight; 40 million are obese; and anywhere from 3 million to 9 million are morbidly obese. Obesity is a concern that is not unique to the United States. In Asia, China's Ministry of Health found that the number of obese Chinese had doubled to 60 million between 1992 and 2004. There are an estimated 500 million overweight and 250 million obese people in the world. The World Health Organization (WHO) and American Centers for Disease Control (CDC) consider persons with a body mass index ("BMI") greater than 25 overweight, a BMI greater than 30 obese, and a BMI greater than 40 morbidly obese. BMI is expressed, for example, as weight/height^2 (kg/m^2).

[0003] Obesity is associated with many diseases including, for example, diabetes, cardiovascular disease, hypertension, stroke, dyslipidemia, sleep apnea, some forms of cancer (e.g., uterine, breast, colorectal, kidney, and gallbladder), and osteoarthritis. Many disease states and health risks can be significantly improved by weight loss. It is estimated that 80% of Type II Diabetes is related to obesity, while 70% of cardiovascular disease is related to obesity. The health impact from being overweight or obese has been estimated to cost $117 billion in the United States, with an estimated direct cost of $61 billion and indirect cost of $56 billion. *See, e.g.,* Finkelstein, E.A. et al. "National Medical Expenditures Attributable to Overweight and Obesity: How Much and Who's Paying?" *Health Affairs* (Web Exclusive): W3-219-W3-226 (May 14, 2003).

[0004] Many people spend years trying to lose weight to achieve a normal weight with little success. Diets range the gamut of starvation, to formula, to high protein, low protein, high fat, low fat, etc.

[0005] Various surgical approaches to weight loss have also been used or contemplated over the years. Adjustable gastric banding is a bariatric operation where a small pouch is created in the upper part of the stomach by wrapping an adjustable band around the stomach about 20 mm below the gastro-esophageal junction. The band leaves only a narrow passageway (stoma) from the newly created pouch into the larger lower section of the stomach. The reduced capacity of the pouch that is created results in patient's experiencing a rapid sense of fullness.

[0006] Stomach or gastric, bypass surgery is a malabsorptive bariatric surgical treatment or approach that involves two basic procedures. First, the size of the stomach is reduced (e.g., by partial removal of the stomach, using gastric staples or a gastric silastic ring). Second, the bypass surgery alters the anatomy of the digestive tract, so that food bypasses a first section of the small intestine, thus reducing the amount of calories (and nutrition) which can be absorbed. Some bypass surgeries (such as biliopancreatic diversion) bypass the duodenum and jejunum completely and connect the stomach directly to the ileum, the final section of the small intestine. Other operations (like Roux-en-Y) bypass less of the intestine thus permitting more calories and nutrients to be absorbed. These interventions have significant complications and several undesirable side-effects, including a death rate of approximately 1 in 50 patients.

[0007] Yet another alternative procedure employs deploying space-occupying structures into the stomach, often referred to as "gastric balloons." Gastric balloons, or intragastric devices, may be introduced through the esophagus and inflated in situ in order to occupy a significant volume within the stomach. The use of conventional gastric balloons has presented a number of problems. For example, in the event of a sudden or slow deflation of the gastric

balloon, it is possible for the balloon to pass through the pylorus in the stomach and enter the intestine. Such unintentional passage of the deflated balloon into the intestine can result in intestinal obstruction which can be life-threatening. The risk of deflation of the gastric balloon is further exacerbated by the fact that the patient may not immediately be aware that the balloon has deflated, delaying the patient from seeing a physician.

[0008] One problem with the balloons is that the weight of the balloons can cause them to induce gastric hypertrophy and create gastric erosions, ulcers, lesions, and abrasions within the stomach at the points where the balloon naturally rests due to the large surface area-to-surface area contact. Other problems include infections resulting from bacterial colonization of the gastric balloon and lack of adequate sizing of the balloon prior to deployment in a patient's stomach. Additionally, most gastric balloons have been filled with saline or other liquid, making them heavy and uncomfortable within a patient's stomach. Some gastric balloon designs were introduced in the 1980's, but ultimately were removed from the market.

[0009] Publications directed to treatment of obesity include, for example: U.S. Patents: **3,406,988** to Moreau et al. for Esophageal Nasogastric Tube; **3,055,371** to Kulick for Device for Regulation and Control of Esophago-Gastric Balloons; **4,133,315** to Berman et al. for Method and Apparatus for Reducing Obesity; **4,246,893** to Berson for Inflatable Gastric Device for Treating Obesity; **4,416,267** to Garren et al. for Method and Apparatus for Treating Obesity; **4,485,805** to Foster Jr. for Weight Loss Device and Method; **4,501,264** to Rockey, for Medical Sleeve; **4,607,618** to Angelchik for Method for Treatment of Morbid Obesity; **4,648,383** to Angelchik for Peroral Apparatus for Morbid Obesity Treatment; **4,694,827** to Weiner et al. for Inflatable Gastric Device for Treating Obesity and Method of Using the Same; **4,739,758** to Lai et al. for Apparatus for Stomach Cavity Reduction; **4,899,747** to Garren et al. for Method and Apparatus for Treating Obesity; **4,908,011** to Jacobsen et al. for Method and Device for Performing a Puncturing Work on an Inflated Balloon-Like Object Implanted in a Patient; **4,930,535** to Rinehold for Folding Leaf Valve and Method of Making; **5,084,061** to Gau et al. for Intragastric Balloon with Improved Valve Locating Means; **5,234,454** to Bangs et al. for Percutaneous Intragastric Balloon Catheter and Method for Controlling Body Weight Therewith; **5,259,399** to Brown for Device and Method of Causing Weigh Loss Using Removable Variable Volume Intragatric Bladder; **5,993,473** to Chan et al. for Expandable Body Device for the Gastric Cavity and Method; **6,454,785** to deHoyas Garza for Percutaneous Intragastric Balloon Catheter for the Treatment of Obesity; **6,579,301** to Bales et al. for Intragastric Balloon Device Adapted to be Repeatedly Wavied in Volume without External Assistance; **6,656,194** to Gannoe et al. for Magnetic Anchoring Device; **6,733,512** to McGhan for Self-Deflating Intragastric Balloon; **6,736,793** to Meyer et al. for Self-Sealing Detachable Balloon; **6,746,640** to Gannoe et al. for Intra-Gastric Fastening Devices; **6,916,307** to Willis et al. for Catheter with Distally Distending Balloon; **6,958,052** to Charlton for Esophageal Balloon Catheter; **7,112,186** to Shah for Gastro-Occlusive Device. Additionally, U.S. Patent Publication Nos. **US 2002/0055757** to Torre et al. for Method and Device for Use in Minimally Invasive Placement of Intragastric Devices; **US 2003/0158569** to Wazne for Intragastric Device for Treating Morbid Obesity; **US 2004/0059289** to Garza Alvarez for Intragastric Balloon Assembly; **US 2004/0106899** to McMichael et al for Gastric Balloon Catheter with Improved Balloon Orientation; **US 2004/0186502** to Sampson et al. for Self-Inflating Intragastric Volume-Occupying Device; **US 2004/0186503** to DeLegge for Intragastric Catheter; **US 2004/0267378** to Gazi et al. for Semi-Stationary Balloon in the Gastric Antrim Provided with Connecting an Anchoring Rod for Inducing Weight Reduction in Human Beings; **US 2005/0004430** to Lee et al. for Endoscopic Balloon Insertion Device for Treatment of Obesity and Insertion technique of the Same; **US 2005/0159769** to Alverdy for Balloon System and Methods for Treating Obesity; **US 2006/0129094** to Shah for Gastro-Occlusive Device; **US 2006/0155259** to MacLay for Stomach Balloon that can be

Inserted and Removed Via Mouth; **US 2005/0167595** to Chen et al. for Methods for Gastric Volume Control. *See, also,* BioEnterics Intragastric Balloon (BIB™ System), available at **www.bioenterics.com** and **www.bibasia.info.**

[0010] For these reasons, it would be desirable to provide improved devices and methods for their use in treating overweight and obese patients.

SUMMARY OF THE INVENTION

[0011] An aspect of the invention is directed to a device for treatment of obesity in a patient, including humans and animals. The device comprises an inflatable balloon having a proximal end and a distal end, the inflatable balloon further comprising an interior chamber adapted and configured to receive a filling material; a port in communication with the interior chamber of the inflatable balloon. Furthermore, the inflatable balloon is adapted and configured to assume a predetermined shape in situ and further wherein the inflatable balloon is adapted and configured to have a distal diameter less than or equal to a proximal diameter. Alternatively, in some embodiments, the distal diameter can be greater than or equal to the proximal diameter. The ends of the device can be formed into bulbs and can be connected by a bendable tubular joint.

[0012] Yet another aspect of the invention is direct to a device for treatment of obesity in a patient comprising: an inflatable balloon having a proximal end and a distal end, the inflatable balloon further comprising an interior chamber adapted and configured to receive a filling material; a port in communication with the interior chamber of the inflatable balloon wherein the inflatable balloon is adapted and configured to achieve a deployment shape at least partially conformable to an interior dimensional shape of a stomach of the patient and further wherein the inflatable balloon is adapted and configured to have a distal diameter less than or equal to a proximal diameter.

[0013] A method for treating obesity according to the invention comprises the steps of introducing a device comprising an inflatable balloon having a proximal end and a distal end, the inflatable balloon further comprising an interior chamber, and a port in communication with the interior chamber of the inflatable balloon wherein the inflatable balloon is adapted and configured to achieve a deployed shape at least partially conformable to an interior dimensional shape of a stomach of the patient; expanding the balloon to provide a conformable geometry; and at least partly filling the chamber of the balloon with a compressible air and/or incompressible fluid. A colored saline can then be used to inflate the balloon in case the balloon ruptures. A rupture can then be detected early from stool, urine or ejected stomach contents.

[0014] Yet another method of the invention is directed to a method for deploying a gastric balloon in a patient, the method comprising the steps of: introducing the gastric balloon into a stomach of the patient; and separately inflating a plurality of isolated chambers within the balloon, wherein the chambers have individual volumes such that the collective volume of the chambers remaining inflated after the deflation of any single chamber is such that the balloon is prevented from passing through the pylorus into the small intestine.

[0015] Still another method of the invention is directed to a method for selecting a gastric balloon for a patient, the method comprising the steps of: determining an internal volume of a stomach of the patient while the stomach is filled with a biocompatible filling medium; and selecting a balloon having a filling volume less than the determined volume by a preselected amount. Suitable biocompatible filling mediums could include solid, liquid or gaseous materials, or combinations thereof which, in the event of a breach of the system, would not cause harm to the patient.

[0016] Another method of the invention is directed to selecting a gastric balloon for a patient. In selecting a gastric balloon for a patient, the healthcare provider determines an internal volume of a stomach of the patient while the

stomach is filled with a biocompatible filling medium; and selecting a balloon having a filling volume less than the determined volume by a preselected amount.

[0017] Still another method of the invention provides for in vivo monitoring a condition of a gastric balloon. This method comprises the steps of introducing a device comprising an inflatable balloon having a proximal end and a distal end, the inflatable balloon further comprising an interior chamber, a port in communication with the interior chamber of the inflatable balloon wherein the inflatable balloon is adapted and configured to achieve a deployed shape at least partially conformable to an interior dimensional shape of a stomach of the patient, and one or more sensors adapted and configured to sense a condition; and sensing a condition of the device. Additionally, the port can be used to allow pressure within the balloon to be reduced in response to activation by the patient.

[0018] Another aspect of the invention is directed to a wireless device for treatment of obesity in a patient. The wireless device comprises: an inflatable balloon having a proximal end and a distal end, the inflatable balloon further comprising an interior chamber adapted and configured to receive a filling material; one or more sensors connected to the inflatable balloon adapted and configured to sense a parameter; and a port in communication with the interior chamber of the inflatable balloon.

[0019] Yet another aspect of the invention includes a kit for treatment of obesity in a patient. The kit comprises, for example, a device comprising an inflatable balloon having a proximal end and a distal end, the inflatable balloon further comprising an interior chamber adapted and configured to receive a filling material; one or more sensors connected to the inflatable balloon adapted and configured to sense a parameter; and a port in communication with the interior chamber of the inflatable balloon; an inflation tube adapted and configured to engage the inflatable balloon; one or more delivery materials; and a retrieval device.

[0020] An aspect of the invention is directed to an anatomically conformable elongated balloon having an enlarged distal and proximal end. In one embodiment, the distal end is adapted and configured to be smaller than the proximal end. In another embodiment, the distal end is filled with an amount of saline that will achieve comfortable positioning of the device in situ; for example about 100-500 ml saline. The saline filled, distal end is placed in the antrum of stomach. The proximal end is larger, and filled with gas, such as air. The proximal end of the device is positioned within the body of stomach where ingested food is stored, e.g. the upper part of stomach of a patient, where patients include humans and animals. The balloon can be adapted and configured to have one or more chambers. Thus, for example, the chamber of the proximal bulb and the distal bulb are connected and the fluid and gas can flow between the bulbs in response to the position of the patient in order to keep the liquid in the lower part of the stomach. The communication of gas and fluid between sections may reduce any intolerance the patient may have to the gastric balloon placement.

[0021] Another aspect of the invention features an elongate balloon adapted and configured to provide two or more prongs or protrusions that extend from the body of the balloon at the distal end. The prongs stabilize and position the balloon above the pylorus. The prongs are further adapted to prevent the balloon from migrating through the pylorus into the duodenum. Gaps or grooves between the prongs allow liquid and other materials to pass through the stomach and avoid obstruction. The proximal end is larger in order to prevent the migration of the balloon into the esophagus. Furthermore, the prongs, bumps or the balloon may be filled with a collapsible material that enables the device to achieve a low profile during delivery, and then assume a deployed configuration that prevents migration through the pylorus. A variety of materials are suitable to achieve this and would be known to persons of skill in the art.

[0022] In yet another aspect of the invention, the balloon is made with suitable biocompatible material, such as silicone, that is soft, elastic, and acid resistant. A joint section is provided that makes the overall device performance bendable and able to achieve a predetermined configuration.

[0023] In still another aspect of the invention, the surface of at least a portion of the device has bumps, bubbles or dimples, and protrusions extended from the surface. The bumps decrease the actual amount of surface area contact that the device has with the stomach and form grooves or channels there between. In further embodiments, one or two ports will be placed on the proximal end of the balloon for inflating or deflating it.

[0024] Another aspect of the invention includes using a biocompatible plastic or metal bar, joint or rod adapted and configured to connect each end of the device, e.g., balloons or bulbs positioned on either end. The bar, joint or rod can be used to support the shape of the device and bend the device at a joint part according to an angle between the gastric antrum and the body. The bar, joint or rod can also be adapted and configured to provide ports which are used to facilitate inflation or deflation of the balloon. In some embodiments, the pH and pressure sensors can be placed on or incorporated into the bar, joint or rod along with a power source, such as a battery. Optionally, the power source can be adapted and configured to be placed in communication with the sensor without necessarily being incorporated into the bar, joint or rod.

[0025] One or more sensors can be adapted and configured for use with the various designs of the invention including, for example, a pH sensor inside or outside the balloon that is adapted to detect an early rupture of the balloon; e.g. change of pH within the balloon indicating breach of the balloon and entry of stomach contents. The pH sensor can further be adapted and configured to detect pH in the stomach itself in order to correlate gastric pH and clinical symptoms so that delivery of regimens of antacid can be determined. Further, a pressure sensor can be provided inside the balloon to assist in determining how much to inflate the balloon. The pressure sensor can also be used to detect rupture of the balloon or to provide a guide to how much the patient eats after balloon placement, and whether symptoms of intolerance are caused by gastric spasm or contraction. Each of the sensors can also be adapted and configured to communicate with a device to provide feedback to the user or user's healthcare provider. For example a pager-like device, or a watch (similar to a heart rate monitor watch) can be configured to receive a signal from one or more sensors. The information from the sensor can then result in an alarm sounding, or a read-out display change. Additionally, in some instances, the sensor can communicate to the external device which in turn communicates with a health care provider when appropriate. Additionally, a release button, lever, switch, or toggle, can be used to allow the patient to release pressure in the device when needed. The release button is typically in communication with a sensor in proximity to the access valve. Once activated the release button sends a signal to the sensor in proximity to a two-way valve or an outflow valve. The sensor causes the valve to open thereby relieving pressure. The release button can be manually actuable and/or can be in wireless communication with the sensor.

[0026] To deploy the device, the balloon can be placed within the stomach during an outpatient upper endoscopy procedure with conscious sedation by a gastroenterologist. The procedure takes 15 to 30 minutes. First, a routine upper endoscopy is performed and an overtube is introduced through the endoscopy into the esophagus. The endoscopy is pulled out. A device containing the balloon is inserted into the stomach via the overtube and the balloon is deployed in the stomach.

[0027] The size of the balloon can be altered in situ if the goal of weight loss is not achieved. Altering the size of the device in situ can be achieved by, for example, activating a size controlling chamber. The balloon also can be removed if the ideal weight loss is met or complications develop.

[0028] In some embodiments, the size of the proximal balloon and the distal balloon can be altered according to the size of the patient's stomach. In still other embodiments, a third balloon may be attached to the proximal balloon to achieve a space occupying effect as well.

[0029] The balloon can be inflated with a mixture of gas and fluid in either one chamber, more than one chamber, or each of a plurality of chambers as appropriate based on the design of the device. The ratio of fluid and gas in any of the chambers can be altered according to the patient's symptoms and efficacy of weight loss.

[0030] Another aspect of the invention is directed to an intragastric balloon device comprising a hollow pliable sac defining an interior space, the sac further comprising a proximal end and a distal end and an exterior surface; at least one protrusion extending from the exterior surface of the sac; and an access port adapted to provide material access to the interior space. Additionally, the device may further comprise at least one prong extending from the exterior surface of the sac at the distal end. The interior space of the device may be divided into two isolated chamber adapted and configured to be filled with a material. In such a case, the device may further comprise an access port wherein the access port is configured to provide material access to the at least one of the isolated chambers. The device may further comprise a second access port. In such an embodiment, a first access port can provide material access to a first chamber in the interior space and the second access port provides material access to a second chamber in the interior space. The device may further comprise at least one prong extending from the exterior surface of the sac at the proximal end. In some embodiments, the device may further comprise one or more sensors that are adapted and configured to be positioned on the exterior surface of the sac. The sensor is typically adapted and configured to communicate wirelessly with a data receiver. In some aspects, the device the distal end of the device has a smaller diameter than the proximal end of the device. The diameter of the sac varies with the length of the sac. Typically, the diameter of the sac at the proximal end is greater than the diameter of the sac at the distal end.

[0031] In yet another aspect of the device, the device is an intragastric balloon device for positioning in the stomach comprising: a hollow pliable sac defining an interior space, the sac further comprising a proximal end and a distal end and an exterior surface; a series of protrusions extending from the exterior surface of the sac; an access port adapted to provide material access to the interior space; and a series of prongs located on the distal end of the sac, wherein the prongs are adapted to prevent migration of the sac. The interior space may further comprise at least two isolated chambers adapted and configured to be filled with a material. Additionally, the device may further include an access port wherein the access port is configured to provide material access to the at least one isolated chamber. Alternatively, the device may comprise a second access port. The first access port provides material access to a first chamber in the interior space and the second access port provides material access to a second chamber in the interior space. Typically, the distal end of the device has a smaller diameter than the proximal end of the device. In some embodiments, at least one prong may extend from the exterior surface of the sac at the proximal end. In a further aspect of the device, a sensor may be included with the device. Typically, the sensor is adapted and configured to be positioned on the exterior surface of the sac. The sensor can be further adapted and configured to communicate wirelessly with a data receiver. The diameter of the device varies with the length of the sac. Typically the diameter of the sac at the proximal end is greater than the diameter of the sac at the distal end.

[0032] An intragastric balloon device comprising: a hollow pliable sac, the sac further comprising a proximal end and a distal end and an exterior surface; an interior space defined within the sac wherein the interior space further comprises at least two isolated chambers wherein the isolated chambers are adapted to be filled with a media; and a controlling mechanism in communication with the exterior surface of the sac wherein the controlling mechanism is adapted to conform and maintain the device in a user defined configuration. In some aspects, the invention further

comprises at least one prong extending from the exterior surface of the sac at the distal end. The device may additionally comprise an access port wherein the access port is adapted and configured to provide material access to the at least one isolated chamber. In some embodiments, a second access port is included with the device. The first access port provides material access to a first chamber in the interior space and the second access port provides material access to a second chamber in the interior space. The distal end of the device has a smaller diameter than the proximal end of the device. The distal end may further comprise at least one prong extending from the exterior surface of the sac at the proximal end. In a further aspect of the device, a sensor is included with the device. The sensor is typically adapted and configured to be positioned on the exterior surface of the sac. Additionally, the sensor can be adapted and configured to communicate wirelessly with a data receiver. In some embodiments, the diameter of the sac varies along the length of the sac. In such an embodiment, the proximal diameter of the sac at the proximal end is greater than the diameter of the sac at the distal end.

[0033] An aspect of the device is directed to an intragastric balloon device comprising: a first inflatable chamber; a second inflatable chamber; and an elongate neck region connecting the first and second inflatable chambers wherein the neck region is adapted and configured to conform and maintain the device in a user defined configuration. The device may further comprise at least one prong extending from the exterior surface of the sac at the distal end. Additionally, the device may include an access port wherein the access port is configured to provide material access to the at least one chamber. In some aspects, a second access port is included with the device. The first access port provides material access to a first chamber in the interior space and the second access port provides material access to a second chamber in the interior space. Typically, the first inflatable chamber of the device has a smaller diameter than the second inflatable chamber of the device. In addition, at least one prong may extend from the second inflatable chamber wherein the second inflatable chamber is located proximal to the pylorus of a patient. In some embodiments, the device further comprises a sensor. The sensor is typically adapted and configured to be positioned on the exterior surface of the sac. Additionally, the sensor can be adapted and configured to communicate wirelessly with a data receiver.

[0034] Where desired, a diet and psychological counseling should be carried out before considering the gastric balloon placement. If patient can achieve some degree of weight loss in about 3 months, a gastric balloon can be placed. Typically, continued diet control and behavior monitoring during, and after the gastric balloon placement are performed to maintain long-term benefits.

INCORPORATION BY REFERENCE

[0035] All publications, patents and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0036] The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0037] **FIG. 1** illustrates a cross-sectional side view of the stomach of a human.

[0038] **FIG. 2** illustrates an embodiment of an intragastric balloon device having a single interior chamber and a shape that is at least partially conforming to the interior shape of the stomach comprising dimples and a pyloric prong.

[0039] FIGS. 3A-D illustrate an embodiment of an intragastric balloon device having two interior chambers and a shape that is at least partially conforming to the interior shape of the stomach comprising dimples and a pyloric prong;

[0040] FIGS. 4A-D illustrate another embodiment of an intragastric balloon device featuring a shape control mechanism;

[0041] FIG. 5 illustrates an embodiment of an intragastric balloon device comprising a proximal inflatable chamber, a distal inflatable chamber and a neck portion connecting the two chambers;

[0042] FIG. 6 illustrates an embodiment of an intragastric balloon device comprising a plurality of proximal inflation chambers;

[0043] FIG. 7 illustrates an embodiment of an intragastric balloon device having proximal prongs on the proximal end and distal prongs on the distal end;

[0044] FIG. 8 illustrates an embodiment of an intragastric balloon device having a proximal balloon and a distal balloon with a flexible neck region there between;

[0045] FIG. 9 illustrates a patient with a device implanted where the device is in wireless communication with a personal display and optionally in remote communication with a physician's office;

[0046] FIG. 10 illustrates a flow chart of a method for deploying the device; and

[0047] FIG. 11 illustrates a flow chart of a method for treating a patient with the device.

DETAILED DESCRIPTION OF THE INVENTION

[0048] A non-surgical, easy to perform, reversible, low cost procedure is contemplated under the invention as a way to treat moderately obese patients, patients who are contraindicated for surgery, or for use as a bridge procedure before bariatric surgery. With the rise of childhood obesity, gastric bypass surgeries are currently being performed in children. However, the long term benefits and complications, including malabsorption, are still unknown. As discussed above, placing a balloon in the stomach to induce satiety has been used in countries outside the United States. During these procedures, a round balloon with 500 ml of saline is placed in the stomach through an upper endoscopy. The procedure has been safe and has achieved weight loss for some moderate obesity patients. However, good clinical data is lacking and the balloon has failed to achieve a significant weight loss. Additionally, the devices and procedures may be suitable for use in animals.

[0049] In order to understand the context of the device, it is helpful to appreciate an anatomical framework for the device. Accordingly, FIG. 1 illustrates a cross-sectional side view of the stomach of a human. The stomach ***10*** is accessed via the esophagus ***14***. The stomach ***10*** is continuous with the esophagus ***14*** at the cardia ***22*** and with the duodenum ***20*** (part of the small intestinal tract) at the pylorus ***16***. The lesser curvature ***26*** lies on the posterior surface of the stomach and is the downward continuation of the posterior wall of the esophagus. Proximal the pylorus ***16*** the area of the stomach wall corresponding to the lesser curvature ***26*** curves upwards to complete a "J" shape. Where the esophagus joins the stomach, the interior region angles acutely upwards and curves downward to form the greater curvature ***28***. The wall then curves upwards slightly towards the pylorus ***16***.

[0050] The stomach ***10*** itself is divided into three regions: the fundus ***12***, the body ***24***, and the antrum ***18***. Typically, stomach size varies with the volume of the food it contains. The size of the stomach can be 1.5L or more in an adult. Typically the stomach can hold from 2L to 4L of food. When a meal is eaten, food accumulates in the stomach, with the last portion of the meal remaining in the fundus ***12***. Food is mixed with gastric juices while in the stomach and the gastric muscles contract which causes a churning movement. The stomach normally functions to

temporarily store food to allow digestive enzymes to act. During this time, chemical digestion and mechanical break down occurs.

I. DEVICES

[0051] Turning now to the embodiment of the invention, **FIG. 2** illustrates an embodiment of an intragastric device ***100*** suitably adapted and configured to be positioned within a stomach of a patient. The device is adapted and configured for treatment of obesity, weight loss, etc. The device ***100*** has a proximal end ***102*** and a distal end ***104***. The proximal end ***102*** is positioned nearest the cardia ***22*** while the distal end ***104*** is positioned near the pylorus ***16***. The device ***100*** has a single interior chamber and one or more discrete bumps, bubbles or dimples ***110, 110'*** on the exterior surface ***106***. The exterior bumps ***110, 110'*** are configured to extend away from the surface of the device ***100*** to reduce the total surface area of the device that contacts the interior wall of the stomach. Thus, a device having a total surface area of, for example, 800 cm^2, can be configured so that less than 50% of the surface area of the device can contact the walls of the stomach, preferably, less than 40%, and more preferably less than 30%. Additionally, the dimples allow food to pass along the length of the device, e.g. through grooves or valleys formed between the dimples, on all sides from the fundus to the antrum without being impeded by the device (e.g., where the device wall would otherwise completely engage the wall of the stomach). The prongs, bumps, or the balloon itself, may be formed from or filled with a collapsible material that enables the device to achieve a low profile during delivery, and then assume a deployed configuration that prevents migration through the pylorus. A variety of materials are suitable to achieve this function and would be known to persons of skill in the art. Furthermore, shape memory materials can be used to make the device such that after deployment the device assumes a shape that prevents it from traveling into the intestines in the event of a damage to the device.

[0052] A one way valve ***130*** can be incorporated that enables air and fluid to be placed within the chamber of the balloon. The one way valve can be used with a glue-like material that seals the port after access. In some embodiments, the one way valve can be configured such that it has a neck ***129*** and a cap ***131*** that facilitate capturing the device with a removal tool to remove the device after the treatment protocol is completed. Alternatively, a two way valve can be used. Additionally, the ability to capture the valve will also facilitate further inflating or deflating the device, during a treatment protocol, if necessary. In some embodiments, the port can function in communication with a release button, such that when a patient begins to feel uncomfortable, e.g., due to an increase in pressure within the balloon, an actuatable button is pressed which reduces the pressure within the balloon by releasing balloon contents. When a patient begins to feel discomfort due to a change in pressure in the device as caused by, e.g., change in pressure due to altitude, a release button can be pressed to relieve pressure. The release button is typically located on the monitoring device and can be pressed by the patient when desired. The release button is in communication with a receiver located in proximity to a release valve located on the surface of the device. Alternatively the receiver in communication with the device is located near the access valve. In such an embodiment, the access valve is typically a two-way valve. Furthermore, the receiver can be wirelessly connected to the device.

[0053] Additionally, as shown in the embodiment of **FIG. 2** a series of distal projections ***108, 108', 108''*** are provided that extend away from the exterior surface ***106*** of the device. The distal projections ***108*** serve to engage the stomach near the pylorus ***16*** such that the projections ***108*** prevent the device ***100*** from entering the small intestine ***20***, and simultaneously preventing the body of the device from engaging the pyloric channel to block off the pylorus or otherwise prevent food from passing from the stomach into the intestinal tract.

[0054] The device ***100*** is adapted and configured such that it is has a tendency to adopt an overall profile that conforms to at least a portion of a profile of an interior dimension of a stomach, as is apparent from the view of the

device in situ shown in FIG. 2. The device *100* can be adapted and configured such that the device has two bulbous ends *140, 140'*, one proximal one distal, such that the diameter *d1* of the proximal bulbous end *140* is greater than the diameter *d2* of the distal bulbous end *140'*. Further, the diameter *d3* of a neck region *142* positioned between two bulbous ends *140, 140'* can be smaller than the diameter of the other two regions at a midpoint along its length, or no larger than the diameter of the distal end. The length of the neck section can vary from 4 cm to greater than 10 cm.

[0055] Turning now to the embodiments of the invention, FIGS. 3A-D illustrate an embodiment of an intragastric device *200* suitably adapted and configured to be positioned within a stomach of a patient. The device is adapted and suitable for treatment of obesity, weight loss, etc. The device *200* has a proximal end *202* and a distal end *204*. The proximal end *202* is positioned nearest the cardia *22* while the distal end *204* is positioned near the pylorus *16*. The device *200* has one or more inflatable sections or chambers and one or more discrete bumps, bubbles or dimples *210, 210'* on the exterior surface *206*. The exterior bumps *210* are configured to extend away from the surface of the device *200* to reduce the total surface area of the device that contacts the interior wall of the stomach. A device similarly sized to the device of FIG. 3 is contemplated.

[0056] Additionally, as shown in the embodiment of FIG. 3A a series of distal projections *208, 208', 208''* are provided that extend away from the exterior surface *206* of the device. The distal projections *208* serve to engage the stomach near the pylorus *16* such that the projections *208* prevent the device *200* from entering the small intestine *20*, while preventing the body of the device from engaging the pyloric channel to block off the pylorus or otherwise prevent food from passing from the stomach into the intestinal tract.

[0057] Turning now to FIG. 3B, a cross-section of the device *200* is depicted. As illustrated in the cross-sectional view, the device is internally separated into two chambers *220, 222*. The interior chambers *220, 222* are accessed via an access port or inflation port *230* having a lumen that communicates with each of the chambers. As will be appreciated by those skilled in the art, the access port can be configured such that a first and second port is provided at a single location (as depicted). Alternatively, the device can be configured such that each chamber has a separate access port in direct communication with an exterior surface of the device. Turning back to the access port configuration depicted, an inner access port *232* with an elongated tubular section is provided that extends from an exterior surface *206* of the device *200* through the first chamber *220* and through an intermediate wall or divider *224* separating the two chambers and then into the second chamber *220*. The inner access port *232* enables the second chamber *222* to be filled partially or completely with suitable material. As shown in FIG. 3D, a second access port *234* is positioned around the inner access port *232* and has a tubular access lumen that enables fluid or material to be filled within the first chamber *220*. Each of the access ports is adapted and configured to provide a valve mechanism to allow fluid or material to be inserted into the chamber with which the access port communicates. Typically, the valve is a two way valve, allowing fluid or material to be placed within the chamber and removed from the chamber. As discussed above, a panic button feature can be provided that allows a patient to reduce the pressure within the device by allowing the filling material to pass out of the device. As will be appreciated by those skilled in the art, additional chambers can be provided without departing from the scope of the invention. Sensors *260, 260'* are provided to sense a change in condition in each of the chambers; or to sense a condition exterior the device, such as a patient condition or pH of the stomach contents. Sensors can be placed on the ends *220, 222* or in the middle *242*.

[0058] The device *200* is adapted and configured such that it is has a tendency to adopt an overall profile that conforms to at least a portion of a profile of an interior dimension of a stomach, as is apparent from the view of the device in situ shown in FIG. 3A. The device *200* can be adapted and configured such that the device has two bulbous

ends *240, 240'*, one proximal one distal, such that the diameter *d1* of the proximal end *240* is greater than the diameter *d2* of the distal end *240'*. Further, the diameter *d3* of a neck region *242* positioned between two bulbous ends *240, 240'* can be smaller than the diameter of the other two regions at a midpoint along its length, or no larger than the diameter of the distal end. The length of the neck section can vary from 4 cm to greater than 10 cm. FIG. 3C is a view of the device from a distal end illustrating an example of a relative diameter relationship in an embodiment between the distal end, the neck region and the proximal end. FIG. 3D is a view of the device from the proximal end. As the diameter of the neck region and the distal end is smaller than the proximal end, from the proximal view, the other sections of the device would not be seen in this view. A potential location for the access port is shown on a proximal surface of the device, which would be near the cardia. Additionally, separate access ports for each interior chamber are illustrated. Positioning the access port in this location facilitates accessing the device to either add additional material or remove material and deflate the device, e.g. for removal from the stomach through the esophagus.

[0059] FIGS. 4A-D illustrates yet another embodiment of an intragastric device *300* suitable for treatment of obesity and weight loss. The device *300* depicted in FIG. 4 features many of the same structural components as the devices of FIGS. 2-3.

[0060] The device *300* has a proximal end *302* and a distal end *304*. The proximal end *302* is positioned nearest the cardia *22* while the distal end *304* is positioned near the pylorus *16*. The device *300* has one or more inflatable sections or chambers and one or more discrete bumps, bubbles, dimples, or protrusions *310, 310'* on the exterior surface *306*. In between the bumps, grooves *311* or valleys are formed. The exterior bumps *310* are configured to extend away from the surface *306* of the device *300* to reduce the total surface area of the device that contacts the interior wall of the stomach. Additionally, as shown in the embodiment of FIG. 4A a series of distal projections *308, 308', 308''* are provided that extend away from the exterior surface *306* of the device. The distal projections *308* serve to engage the stomach near the pylorus *16* such that the projections *308* prevent the device *300* from entering the intestinal tract *20*, while preventing the body of the device from engaging the pylorus to block off the pyloric channel or otherwise prevent food from passing from the stomach into the intestinal tract.

[0061] Turning now to FIG. 4B a cross-section of the device *300* is depicted. As illustrated in the cross-sectional view, the device is internally separated into two chambers *320, 322*. The interior chambers *320, 322* are accessed via an access port or inflation port *330* having a lumen that communicates with each of the chambers. As will be appreciated by those skilled in the art, the access port can be configured such that a first and second port is provided at a single location (as depicted) or can be configured such that each chamber has a separate access port in direct communication with an interior surface of the device. Turning back to the access port configuration depicted, an inner access port *332* with an elongated tubular section is provided that extends from an exterior surface *306* of the device *300* through the first chamber *320* and through an intermediate wall or divider *324* separating the two chambers and then into the second chamber *322*. The inner access port *332* enables the second chamber *322* to be filled partially or completely with suitable material. A second access port *334* (shown in FIG. 4D) is positioned around the inner access port *332* and has a tubular access lumen that enables fluid or material to be filled within the first chamber *320*. Each of the access ports is adapted and configured to provide a valve mechanism to allow fluid or material to be inserted into the chamber with which the access port communicates. Typically, the valve is a two way valve, allowing fluid or material to be placed within the chamber and removed from the chamber. As discussed above, a panic button feature can be provided that allows a patient to reduce the pressure within the device. As will be appreciated by those skilled in the art, additional chambers can be provided without departing from the scope of the invention. Two separate access ports *332, 334* are depicted.

[0062] The device ***300*** additionally features a shape controlling mechanism ***350***. The shape controlling mechanism ***350*** facilitates deploying the device ***300*** into a shape that is maintained in situ. Additionally, the shape controlling mechanism helps to prevent rotation of the device within the stomach which, when combined with other features, can resist the tendency of the device to migrate proximally toward the pylorus, for example, when a patient is prone. The mechanism ***350*** has an elongated tube ***352*** that extends at least a portion of the length of the device ***300***. The elongate tube ***352*** can be hollow or solid, flexible, or made of shape memory material that achieves its shape after deployment, e.g. as a result of temperature. Additionally, the proximal and distal ends ***354, 354'*** of the shape controlling mechanism ***350*** can be further adapted to provide diameter control of one or both of the ends of the device. In another embodiment, the shape controlling mechanism ***350*** can be adapted and configured such that it is integral to the body of the device to form a spine. The integrally formed parts can be configured such that they act in a unified manner, or such that separate components are formed together into a single device. In yet another embodiment, the shape controlling mechanism can be adapted to also function partially as the access port. Radiopaque markers ***360*** can be provided in order to facilitate assessment of the positioning of the device in situ. The markers ***360*** can, for example, be incorporated into or associated with the wall of the device.

[0063] **FIG. 4C** is a view of the device from a distal end illustrating an example of a relative diameter relationship in an embodiment between the distal end, the neck region and the proximal end. **FIG. 4D** is a view of the device from the proximal end. As the diameter of the neck region and the distal end is smaller than the proximal end, from the proximal view, the other sections of the device would not be seen in this view. A potential location for the access port is shown on a proximal surface of the device, which would be near the cardia. Additionally, separate access ports for each interior chamber are illustrated. Positioning the access port in this location facilitates accessing the device to either add additional material or remove material and deflate the device, e.g. for removal from the stomach through the esophagus.

[0064] **FIG. 5** illustrates yet another embodiment of an intragastric device suitable for treatment of obesity and weight loss. The device ***400*** depicted in **FIG. 5** features many of the same structural components as the devices of **FIG. 2-4**.

[0065] As with the previous embodiments, the device ***400*** has a proximal end ***402*** and a distal end ***404***. The proximal end ***402*** is positioned nearest the cardia ***22*** while the distal end ***404*** is positioned near the pylorus ***16***. The device ***400*** has one or more inflatable sections or chambers and one or more discrete bumps, bubbles or dimples ***410***, ***410'*** on the exterior surface ***406***. The exterior bumps ***410*** are configured to extend away from the surface of the device ***400*** to reduce the total surface area of the device that contacts the interior wall of the stomach. Additionally, as shown in the embodiment of **FIG. 5**, a series of distal projections ***408, 408', 408''*** are provided that extend away from the exterior surface ***406*** of the device. The distal projections ***408*** serve to engage the stomach near the pylorus ***16*** such that the projections ***408*** prevent the device ***400*** from entering the intestinal tract ***20***, while preventing the body of the device from engaging the sphincter to block off the sphincter or otherwise prevent food from passing from the stomach into the intestinal tract.

[0066] In this embodiment, the device ***400*** is formed from a plurality of separate components each having its own interior chamber, e.g. balloons. A first chamber ***420*** and a second chamber ***422*** are provided. Each chamber is connected by a neck region ***442***. The distal end has radial projections ***408***. As will be appreciated by those skilled in the art, the one or more the pieces can be formed integrally with one or more other pieces, or can be formed from separate pieces in communication with an adjacent piece.

[0067] **FIG. 6** illustrates still another embodiment of an intragastric device ***500*** suitable for treatment of obesity and weight loss.

[0068] Again, the device ***500*** has a proximal end ***502*** and a distal end ***504***. The proximal end ***502*** is positioned nearest the cardia ***22*** while the distal end ***504*** is positioned near the pylorus ***16***. The device ***500*** has one or more inflatable sections or chambers and one or more discrete bumps, bubbles or dimples ***510, 510'*** on the exterior surface ***506***. The exterior bumps ***510*** are configured to extend away from the surface of the device ***500*** to reduce the total surface area of the device that contacts the interior wall of the stomach and to create grooves ***511*** or valleys in between the bumps. Additionally, as shown in the embodiment of **FIG. 6** a series of distal projections ***508, 508', 508''*** are provided that extend away from the exterior surface ***506*** of the device. The distal projections ***508*** serve to engage the stomach near the pylorus ***16*** such that the projections ***508*** prevent the device ***500*** from entering the intestinal tract ***20***, while preventing the body of the device from engaging the sphincter to block off the sphincter or otherwise prevent food from passing from the stomach into the intestinal tract.

[0069] As is further appreciate, the device ***500*** disclosed in **FIG. 6** has a proximal end ***540*** comprised of a plurality of inflatable sections ***540, 540', 540''***. This embodiment is illustrated with the inflatable sections being contained within each other in a first chamber ***520***. Each balloon can be separately engaged so that the inner balloon is inflated separately from an intermediate balloon and an exterior balloon. However, other configurations can be employed without departing from the scope of the invention. In the embodiment depicted in this figure, the plurality of proximal balloons can be separately engaged to provide incremental control over the size of the proximal end of the balloon. For example, a single balloon can be inflated. If the single balloon inflation does not achieve the desired results, then the device can be engaged and a second balloon can be inflated. This process can be repeated as often as desired to achieve the desired result. In some embodiments a plurality of inflatable sections may be located within the second chamber ***522.***

[0070] **FIG. 7** illustrates yet another embodiment of an intragastric device ***600*** suitable for treatment of obesity and weight loss. Again, the device ***600*** has a proximal end ***602*** and a distal end ***604***. The proximal end ***602*** is positioned nearest the cardia ***22*** while the distal end ***604*** is positioned near the pylorus ***16***. The device ***600*** has one or more inflatable sections or chambers and one or more discrete bumps, bubbles or dimples ***610, 610'*** on the exterior surface ***606***. The exterior bumps ***610*** are configured to extend away from the surface of the device ***600*** to reduce the total surface area of the device that contacts the interior wall of the stomach.

[0071] Additionally, as shown in the embodiment of **FIG. 7** a series of distal projections ***608, 608', 608''*** are provided that extend away from the exterior surface ***606*** of the device. The distal projections ***608*** serve to engage the stomach near the pylorus ***16*** such that the projections ***608*** prevent the device ***600*** from entering the intestinal tract ***20***, while preventing the body of the device from engaging the pylorus to block off the pyloric channel or otherwise prevent food from passing from the stomach into the intestinal tract.

[0072] In the embodiment depicted in **FIG. 7**, the proximal end is also configured to provide two or more projections ***670, 670', 670''*** in proximity to a sensor ***650*** adapted and configured to engage the side walls of the stomach in the antrum region and the fundus region. Providing fundus or proximal projections further assists in preventing the device from migrating toward the cardia when the patient changes position, e.g. to a prone position.

[0073] **FIG. 8** illustrates yet another embodiment of an intragastric device ***700*** suitable for treatment of obesity and weight loss. Again, the device ***700*** has a proximal end ***702*** and a distal end ***704***. The proximal end ***702*** is positioned nearest the cardia ***22*** while the distal end ***704*** is positioned near the pylorus ***16***. The device ***700*** can be configured to have a single inflatable chamber or a plurality of inflatable sections or chambers. This embodiment is depicted with an elongate, thin neck region ***742***. The thin neck region facilitates placement of the device while reducing the amount of area of the device that contacts the stomach wall, while providing a bendable, conformable section that facilitates adapting the shape of the device to the interior dimensions of a target patient's stomach chamber. This

embodiment may be further modified by providing any combination of one or more bumps or prongs as described with previous embodiments.

[0074] The various embodiments of the devices described above can also be provided with radiopaque markers on the wall of the balloons to facilitate assessment of the positioning of the device in situ using a variety of imaging techniques including but not limited to ultrasound, fluoroscopy and/or x-rays.

II. MATERIALS

[0075] Materials suitable for making the devices, or components of the devices, described herein would be apparent to those of skill in the art and include, but is not limited to biocompatible metals (such as cobalt chromium steel, surgical steels, titanium, titanium alloys, tantalum, tantalum alloys, aluminum, *etc.*), ceramics, polyethylene, biocompatible polymers, and other materials known in the orthopedic arts. Furthermore, surfaces may be formed from biocompatible metals such as cobalt chromium steel, surgical steel, titanium, titanium alloys (such as the nickel titanium alloy Nitinol), tantalum, tantalum alloys, aluminum, *etc.* Shape memory alloys, such as Nitinol, can also be used to facilitate deployment and flexibility of the device.

[0076] In some embodiments, portions of the device can also be formed from suitable polymers include polyesters, aromatic esters such as polyalkylene terephthalates, polyamides, polyalkenes, poly(vinyl) fluoride, PTFE, polyarylethyl ketone, and other materials that would be known to those of skill in the art. Various alternative embodiments of the devices and/or components could comprise a flexible polymer section (such as a biocompatible polymer) that is rigidly or semi rigidly fixed.

[0077] In each of the embodiments depicted, the device should be constructed from durable, biocompatible material. The proximal chamber of the device will be filled with material of lower density than the material in the distal chamber to facilitate placement of the device within the stomach. For example, the proximal chamber can be filled with air while the distal chamber is filled with fluid. Additionally, a third chamber can be provided in a middle region of the device which is configured to position the device while a patient is in a prone position such that the device will not migrate up toward the esophagus. The third chamber can extend radially away from the device and be weighted at its distal end (e.g., the end furthest away from the central body of the device).

[0078] Additionally, polymers can be employed that use polymer surface modification. For example, Oligomeric Surface-Modifying End Groups (SME) can be appended to the polymers used for the device. As would be appreciated by those skilled in the art, the SME are appended to base polymers during synthesis. The end groups are surface active and therefore migrate to the surfaces of formed articles, e.g. membranes, coatings and catheters. A wide range of inert (e.g., hydrocarbon, fluorocarbon, silicone, PEO, etc.) or bioactive groups can also be incorporated into polymers with little or no change in bulk physical properties or processability. Another feature of the SME-containing polymers is that it adds mobility of end groups relative to backbone groups which may facilitate self assembly of molecular overlayers by the surface-modifying groups.

[0079] In some components it may be useful to employ, for example, a family of dense (i.e. without permanent pore structure) selectively-permeable membranes which can be made permeable to high-molecular-weight solutes, such as proteins. With these materials, the permeability coefficient and molecular weight cutoff can be varied through changes in the composition and the molecular structure of the membrane polymer during synthesis. Suitable elastomeric, optically-transparent membranes and coatings may be used for the devices or components of the device that are cast from organic solvents or water-based dispersions, or they may be extruded from the melt. *In vivo* testing of a hybrid artificial pancreas by PTG resulted in virtually no fibrous tissue encapsulation around these very hydrophilic membranes. Rather the implants became surrounded by well-vascularized tissue with new capillaries forming within one or two cell layers of the membrane surface. The membranes have applications in cell culture as

gas and nutrient-permeable substrates and/or microbial barriers, in immunoisolation and in (protein-based) controlled released.

[0080] Suitable materials would be appreciated by those skilled in the art, and when reviewing, for example, U.S. Patent Publ. **2005/0282997** to Ward et al. for Control of Polymer Surface Molecular Architecture Via Amphiphathic Endgroups; **2004/0140264** to Ward et al. for Production of Potable Liquids. See also, U.S. Patent Nos. **7,157,528** to Ward for Permselective Structurally Robust Membrane Material; **6,692,528** to Ward et al. for Devices that Change Size/Shape Via Osmotic Pressure; **5,756,632** to Ward et al. for Systems for Permeating Molecules of Predetermined Molecular Weight Range; **5,589,563** to Ward et al. for Surface-Modifying Endgroups for Biomedical Polymers; **5,482,123** to Ward et al. for Copolymers and Non-porous, Semi-permeable Membrane Thereof and its Use for Permeating Molecules of Predetermined Molecular Weight Range; **5,190,546** to Jervis for Medical Devices Incorporating SIM Memory Alloy Elements; and **5,964,770** to Flomenblit for High Strength Medical Devices of Shape Memory Alloy.

III. DEVICE OPERATION

[0081] After a device of the invention, or its components, has been inflated and left in place within a patient, it may become desirable to adjust the size and/or buoyancy. Such adjustment may be desirable for patient comfort, efficacy, or other reasons. To perform such adjustments, the device is accessed, for example using an endoscope adapted to provide a suitable working tool. For example, the device may be grasped with graspers and an inflation tubes may be suitably attached or docked to the inflation port or ports accessible from the exterior of the device. As shown above, inflation ports may be located near the proximal end of the device which is positioned nearest the cardia in situ. After attachment with the device is assessed, an inflation medium can be introduced and/or extracted, depending on whether the particular structural component is to be enlarged, deflated, or have a buoyancy adjustment. Optionally, an incising instrument could be introduced through the endoscope to penetrate and deflate any filled compartment to reduce the overall volume of the device and improve accommodation of the device.

[0082] Additionally, the device can be adapted to allow a patient to detect leakage or impending leakage. In some current balloon embodiments, methylene blue dye or Indian ink, pH-sensitive markers, or any other biocompatible colored agent, can be added to the filling fluid, usually saline, prior to inflation in order to facilitate leakage detection. For example, if the methylene blue leaks into the stomach, a blue color will be present in the patient's excrement.

[0083] The wall of the device can be formed using suitable techniques known in the art. For example, an outermost layer and innermost layer can be used. Where there is more than one layer, the layers can be manufactured by either dipping a mold successively into solutions of different materials that dry and cure or preferably by successive precision injections of materials into a mold. Typically, the outermost layer is made of one or more materials, such as silicone rubber, selected primarily for their non-abrasiveness, biocompatibility in the stomach, and resistance to an acidic environment. The innermost layer is then made of materials selected primarily for their resistance to structural fatigue and impermeability to the filling fluid. The inner layer could have biocompatibility of a shorter duration than the outermost layer. The two layers are either bonded together to function as a single wall or left unbonded such that the layers could slide by each other except at certain attachment points. Other structural materials and elements can also be employed without departing from the scope of the invention. For example, the durability may be enhanced by incorporating other structural elements in the layers, such as a mesh made of metal, polymer, or high strength fibers, such as Kevlar.

[0084] The present invention further provides a wireless failure detection system for gastric balloons and methods for their deployment and use. The failure detection system can be configured from two probes, a transmitter, and a

detector, such as a wireless transmitter and wireless detector. The wireless detector can be adapted to use radio frequency as the signal transmission of choice. However, as will be appreciated by those skilled in the art, it does not exclude other carrier waves, such as light or acoustic, or via physical properties, such as magnetism or temperature. The probes are connected electronically to the wireless transmitter, which can emit a signal recognized by the detector. Upon detection of a change in condition, the detector can be adapted to notify the patient that the integrity of the balloon is compromised and to seek medical assistance. Change in condition can include, for example, change in pH of the contents of a chamber, change in humidity of a chamber, appearance of liquid in a chamber, change in pressure, etc. Alternatively, the device provides for a wireless manual release button or manual override failure system. The device can be configured with a wireless sensor located proximal to the access valve. When pressure changes cause the patient to feel discomfort, the panic button can be triggered on a wireless remote to open the valve to facilitate the release of pressure.

[0085] The system can be designed to function in a variety of algorithms to notify the patient in a simple, unequivocal fashion. For example, in a toggle algorithm, the transmitter is either on in the static state or preferably off in order to reduce the need for power. Upon direct contact with the stomach contents, the probe causes the transmitter to turn the signal off or preferably on to be able to send a wireless signal on a continuous basis. The wireless signal or lack thereof is recognized by the detector to notify the patient that the integrity of the balloon is compromised. Alternatively, the algorithm could be based on time, amplitude, frequency, or some other parameter. For example, the transmitter may send a wireless signal at a predetermined time interval in its static state. The detector recognizes the length of the interval as normal and the existence of the signal as the system in working order. Upon direct contact with the stomach contents by the probes, the transmitter is enabled to send the same signal at different time intervals or a different signal, which is recognized by the detector to notify the patient that the integrity of the balloon is compromised. The lack of a signal is recognized by the detector to notify the patient of a detection system malfunction and potential compromise of the integrity of the balloon.

[0086] Optionally, more than one probe or more than one type of probe may be placed internally in different parts or components in the device so that the particular part or component which failed may be identified based on which probe was activated. The transmitter would send different signals for the receiver to display the source of the failure. The internal probe could be of any shape and is disposed in the interior or preferably in the wall of the device.

[0087] The detection material could be any metal, polymer, fiber, or combination thereof, with or without any coating that can generate an electrical charge or enable flow of electric current when a change in condition occurs.

[0088] The transmitter can be a simple wireless signal generator triggered by an electric current or preferably a transponder using the well-established RFID technology, i.e., produces a wireless signal when triggered by an interrogating signal. The electric charge generated or the electric current enabled by the probe in contact with the stomach contents enables the transmitter to emit or causes it to emit a wireless signal. Typically, the transponder is powered by the interrogating radio frequency signal so that no power source of its own is required. Alternatively, the transmitter could be powered by a micro battery or by the electrical power generated by a chemical reaction. For protection from degradation by an acidic and electrolyte solution and become potentially toxic, the transmitter or transponder circuit is encased in a highly resistant material, such as silicon rubber or stainless steel. The transmitter or transponder circuit can be placed on the exterior, embedded in the wall, or preferably in the interior of the balloon for further shielding from chemical degradation and mechanical stress. It can be placed in any orientation, preferably in the plane where the antenna is most sensitive and the transmitter is most effective in sending and receiving signals through body tissue.

[0089] The wireless signal from the transmitter is recognized by a detector external to the body. The detector could be simply a receiver tuned to the transmitter's signal or, preferably, a combination of both a transmitter of a signal to interrogate the transponder and a receiver to distinguish the different signals from the transponder. The detector is preferably powered by batteries and portable enough to be worn on a wristband or belt or can be placed conveniently near a place where the patient spends most of his time. Upon receiving a signal that a breach has occurred, the detector will alert the patient to seek medical assistance or alert medical professionals directly through other devices, such as Bluetooth linked to an autodial telephone. The alarm could be auditory, such as beeping sounds, visual, such as flashing LED's or a LCD display, sensory, such as vibrations, or preferably a combination of any or all of the above.

[0090] Optionally, the detector could have different auditory, visual, sensory, or different combinations to identify the source of the detected breach, especially with more than one probe or more than one type of probe. For example, LED's of different colors or different sounds could be used. The alarm could further indicate the seriousness of the breach. For example, when multiple probes detect a breach, the volume of the alarm would increase to a higher level.

[0091] As a further option, at least a portion of the exterior of the device will be coated or impregnated with an anti-microbial and/or adhesion resistant agent. Preferably, the entire exposed surface of all components of the balloon will be so coated or impregnated to inhibit colonization of the balloon by bacteria or other microbes, and/or reduce possible accumulation of food particles on the device. Suitable anti-microbial agents include polyethylenetetrafluoride (PTFE), and antibiotics.

[0092] **FIG. 9** is a diagram showing a representative example logic device through which reviewing or analyzing data relating to the present invention can be achieved. Such data can be in relation to, for example, pH and pressure. A computer system (or digital device) ***1000*** that may be understood as a logical apparatus that can read instructions from either media ***1011*** and/or a network port ***1005***, which can optionally be connected to server ***1009*** having fixed media. The computer system ***1000*** can also be connected to the Internet or an intranet. The system includes CPU ***1001***, disk drives ***1003***, optional input devices, illustrated as keyboard ***1015*** and/or mouse ***1016*** and optional monitor ***1007***. Data communication can be achieved through the indicated communication medium to a server ***1009*** at a local or a remote location. The computer system ***1000*** can be at a patient's home, or in a remote location, such as a hospital or physician's office. The communication medium can include any means of transmitting and/or receiving data. For example, the communication medium can be a network connection, a wireless connection or an internet connection. It is envisioned that data relating to the present invention can be transmitted over such networks or connections. The computer system can be adapted to communicate with an participant parameter monitor and/or an apparatus on which a participant is engaged in exercise.

[0093] A patient ***1022*** is connected to the system ***1000*** using a wireless monitoring device ***1024*** that communicates with an implanted intragastric balloon *(*e.g., ***100-700)*** to assess the condition of the balloon and/or a patient treatment regimen. The monitoring device can be used to interact with the system. The monitoring device can be a handheld device for use in a point-of-care setting. As will be appreciated by those skilled in the art, the computer system, or digital device, ***1000*** can be any suitable device.

[0094] As discussed above, any of the embodiments of the intragastric device of **FIGS. 1-7** include, for example, one or more sensors to assess selected parameters. The sensors may be capable of measuring a biologic function from the participant, measuring a device condition or measuring a change in device environment. Communication from the sensors to the monitoring device could be achieved by any number of mechanisms, as would be appreciated by those skilled in the art. *See, for example,* **US 2005/0135039** entitled Electric Circuit and Transmission Method for

Telemetric Transmission (Klemetti), **US 2005/0130802** entitled Arrangement, Method and Computer Program for Determining Physical Activity Level of Human Beings (Kinnunen), **US 2005/0111307** entitled Electronic Wrist Device (Saaski et al.), **US 2005/0111306** entitled Portable Wrist-Worn Personal Electronic Device (Saaski et al.), **US 2005/0017850** entitled Mechanical Measuring Device and a Measuring Method (Nissala), **US 2005/0004436** entitled Method and Device for Weight Management of Humans (Nissala), **US 2004/0220738** entitled Portable Personal Data Processing Device (Nissala), and **US 2004/0220485** entitled Method and Device for Measuring Heart Rate, and for Manufacturing the Device (Rytky). U.S. Patent Nos. **6,832,109** entitled Wrist-Worn Device for Displaying and Setting Heart Rate Parameters (Nissala); **6,754,517** entitled Apparatus for Measuring Electrocardiograph Signal (Nissila); **6,714,812** entitled Method of Performing Operating Settings in Heart Rate Measurement Arrangement, and Heart Rate Measurement Arrangement (Karjalainen); **6,687,535** entitled Controlling of Fitness Exercise (Hautala et al.); **6,605,044** entitled Caloric Exercise Monitor (Bimbaum); **6,584,344** entitled Method and Apparatus for Measuring Heart Rate (Hannula); **6,553,247** entitled Electrode Belt of Heart Rate Monitor (Rytky); **6,540,686** entitled Measurement Relating to Human Body (Heikkila et al.); **6,954,661** entitled Blood Sugar Measuring Apparatus (Cho et al.).

IV. METHODS OF USE

[0095] The present invention further provides methods for treating obesity in a patient. The methods comprise introducing a device into the patient's stomach. The device is then filled with an incompressible fluid to provide a fixed support geometry. At least a portion of a separate space-filling compartment is then filled at least partly with a compressible fluid, and/or typically a gas such as air, nitrogen, or the like, within the remainder (if any) being filled with an incompressible material, such as a liquid, gel, slurry, or the like. In this way, the buoyancy of the balloon may be controlled within the limits described above. **FIG. 10** illustrates a flow chart of a method for deploying the device. The device is introduced into the stomach through the mouth without the need for surgery ***810***. The physician may optionally conduct an initial examination of the stomach by inserting an endoscope with an overtube into a patient's mouth and down into the esophagus. The overtube has a dimension known in the art, for example 1.6-2.0 cm in diameter. Thereafter an endoscope is advanced through the overtube ***820***. If no abnormalities are observed in the esophagus, stomach and duodenum, the physician removes the endoscope ***825*** and places the device containing a balloon through the overtube ***835***. The endoscope is reinserted into the mouth via the overtube. The use of an endoscope allows the physician to adjust the placement of the device as desired. Once the device is deployed into the stomach ***835***, the various chambers of the device are filled with material suitable material to achieve a first profile ***850***. As will be appreciated by those skilled in the art, a first chamber can be filled with fluid and then a second chamber can be filled with gas, or vice versa. The size of the deployed device can then be assessed to determine whether the device should be larger or smaller ***860.*** Later during the same procedure, or in a subsequent procedure, the profile of the device can be changed ***870***, either reduced or increased, if necessary. For example, it may be desirable to reduce the profile in order to reduce a patient's feeling of being overly full. Alternatively, it may be desirable to increase the profile if the patient is not experiencing any weight loss, or if the weight loss has plateaud. Thus, the device configuration within the stomach can be changed so that the device has a greater or lesser curvature along its length to either conform more or less to the curvature of the interior of the stomach.

V. METHODS OF TREATMENT

[0096] **FIG. 11** illustrates a flow chart of a method for treating a patient with the device. The device is indicated for treatment of pediatric obesity, as well as adult weight related issues. In initial physiological and psychological assessment is performed of the patient ***910*** to determine their suitability for the procedure and the likelihood that the patient will comply with behavioral modification requirements. A determination is made of the type of procedure

that the device is intended to achieve ***920***. For example, the device is suitable for weight loss ***922***, or use when a patient is contraindicated for surgical intervention ***924***, or as a bridge procedure for a gastric bypass ***926***. Once it is determined that the patient is suitable for the procedure, the device is deployed ***930***. After a period of time, the effectiveness of the treatment is evaluated ***940*** to determine whether weight loss is occurring and, if so, whether it is occurring at a safe and effective pace (generally considered to be 2 lbs per week). Once the effectiveness of the procedure is determined, the device inflation can be adjusted in situ (either increased or decreased). Thereafter, further evaluations occur at suitable time intervals, e.g., monthly, bimonthly, etc. with further adjustments as required.

[0097] A variety of protocols are described for the treatment of obesity. These protocols are provided for illustration purposes.

A. Patient Evaluation

[0098] At an initial examination can involve one or more of the following:

- The physician takes a complete history and administers a physical examination
- The patient is instructed to taper down, and stop NSAIDS (a common cause of peptic ulcer), 1-2 weeks before the gastric balloon placement
- A complete evaluation of blood chemistry is performed
- Helicobacter Pylori antibody is checked Helicobacter Pylori is a common causes of peptic ulcer)
- EKG is performed to exclude cardiac condition
- Chest x-ray and/or pulmonary function test is taken to assess pulmonary condition
- An upper gastrointestinal series (x-ray) are taken to exclude any abnormalities in the upper gastrointestinal tract, and also evaluate the anatomy and shape of stomach in order to place a right size of balloon for the patient.

[0099] At subsequent examinations:

- Patient consults a Dietitian to review dietary habits
- Patient is evaluated for underlying psychological conditions
- Patient engages in weight control program for 3 months to assess patient's suitability for protocol and likelihood of compliance with post-procedure instructions.

[00100] If the patient has no contraindications to the upper endoscopy or conscious sedation and patient has lost a prescribed amount of weight during the weight control program, then the upper endoscopy with balloon placement is scheduled at, for example, an outpatient endoscopy center.

B. Device Implantation Procedure

[00101] Once the patient has checked into the hospital or an outpatient endoscopy center, and has been prepared for the procedure, one or more of the following steps are performed:

- Start conscious sedation
- Insert endoscopy with an overtube: an overtube is used to avoid trauma, protect the airway, and because it makes it easier to pass the endoscope and balloon into the stomach
- Push the overtube into the esophagus when the endoscope is inside of the esophagus
- Complete the upper gastrointestinal examination with the upper endoscope
- Pull the scope out but leave the overtube in the esophagus
- A pre-packed balloon with a long shaft, and the diameter of the wrapped balloon is less than 1.5 cm. was inserted into the stomach through the overtube.

- The endoscope is re-insert into the stomach.
- The shaft of the balloon has a channel in the center. The shaft is made from metal, such as steel, or any other suitable biocompatible material. The distal end of the shaft engages the port at the balloon's proximal end and a thin needle or catheter device connecting the shaft is positioned inside the balloon. The proximal end of the shaft outside the human body has a port. The balloon is inflated via the proximal port with the needle by, for example, injecting liquid fist, then air.
- When the balloon is inflated at the pre-setting pressure. The shaft is disengaged from the balloon. The shaft and the endoscope are pulled out, followed by the overtube to complete the procedure.

C. Post-Implantation Protocol

[00102] Once the device has been implanted a variety of protocol steps can be employed, for example:

- Antacid medication is given daily with anti nausea medication as needed.
- Educate patient on techniques for monitoring pH and monitoring devices
- Nurse will call in 24 hours to check the patient
- Physician follow up in 1-2 weeks, with periodic re-checking thereafter

[00103] If there are no problems or complications within 3 months, but the patient is not loosing weight, the procedure at Section B can be performed again to replace the currently deployed device with another balloon. For example, the device can be replaced with another device that has a different ratio of liquid and air and different size of balloons (different in the proximal balloon or distal balloon). Alternatively, the deployed device can be left in place and reduced or increased in size, or the ratio of liquid and air can be changed to accommodate the patient.

[00104] The balloon should be replace every six months with different mixture of liquid and gas, different size of proximal balloon and distal balloon, or add the third balloon to the proximal balloon.

D. Identification of End of Treatment

[00105] The end point for overall treatment can be identified in a variety of ways. For example,

- the goal of weight loss is achieved by the patient
- the patient developed complications
- the patient achieved target initial weight loss before gastric bypass surgery

E. Removal of the Device

[00106] In one aspect of the method, the balloon is punctured, e.g. with a special knife like device to deflate the balloon. Thereafter, the port at the proximal balloon for inflation and deflation of the balloon is grasped and snared by a retrieval device, and then pulled out by the endoscope via the overtube.

[00107] While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention. It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that any claims that are presented by the inventors define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

WHAT IS CLAIMED IS:

1. A device for treatment of obesity in a patient comprising:

an inflatable balloon having a proximal end and a distal end, the inflatable balloon further comprising an interior chamber adapted and configured to receive a filling material;

a port in communication with the interior chamber of the inflatable balloon

wherein the inflatable balloon is adapted and configured to assume a predetermined shape in situ and further wherein the inflatable balloon is adapted and configured to have a distal diameter less than or equal to a proximal diameter.

2. The device of claim 1 wherein the device has a shape controller along a portion of its length.

3. The device of claim 2 wherein the shape controller is a bar, joint or rod.

4. The device of claim 2 wherein the shape controller is formed from a shape memory material.

5. The device of claim 1 further comprising a plurality of inflatable balloons.

6. The device of claim 1 further comprising two or more prongs extending outwardly from a body of the balloon positioned at the distal end.

7. The device of claim 1 further comprising two or more prongs extending outwardly from a body of the balloon positioned at the proximal end.

8. The device of claim 1 further comprising dimples on an exterior surface of the inflatable balloon.

9. The device of claim 1 further comprising a sensor.

10. The device of claim 9 wherein the sensor is adapted and configured to be positioned on an interior surface of the balloon.

11. The device of claim 9 wherein the sensor is adapted and configured to be positioned on an exterior surface of the balloon.

12. The device of claim 9 wherein the sensor is adapted and configured to detect a change in condition.

13. The device of claim 12 wherein the change in condition is at least one of pH or pressure.

14. The device of claim 9 wherein the sensor is adapted and configured to wirelessly communicate with the patient.

15. The device of claim 9 wherein the sensor is adapted and configured to wirelessly communicate with a patient's healthcare provider.

16. The device of claim 1 further comprising a manual release buttonwherein the manual release button is adapted and configured to facilitate the release of pressure from the device by the patient.

17. The device of claim 1 wherein the port is adapted and configured to engage a retrieval device.

18. The device of claim 1 wherein the device further comprises a proximal section, a distal section and an intermediate section, further wherein the diameter of the proximal section does not equal the diameter of the distal section and does not equal the diameter of the intermediate section.

19. The device of claim 1 wherein the port is further adapted and configured to communicate with a plurality of chambers.

20. The device of claim 1 wherein the device further comprises a plurality of ports and a plurality of chambers, the plurality of ports adapted and configured to communicate the plurality of chambers.

21. A device for treatment of obesity in a patient comprising:

an inflatable balloon having a proximal end and a distal end, the inflatable balloon further comprising an interior chamber adapted and configured to receive a filling material;

a port in communication with the interior chamber of the inflatable balloon

wherein the inflatable balloon is adapted and configured to achieve a deployment shape at least partially conformable to an interior dimensional shape of a stomach of the patient and further wherein the inflatable balloon is adapted and configured to have a distal diameter less than or equal to a proximal diameter.

22. The device of claim **21** wherein the device has a shape controller along a portion of its length.

23. The device of claim **22** wherein the shape controller is a bar, joint or rod.

24. The device of claim **22** wherein the shape controller is formed from a shape memory material.

25. The device of claim **21** further comprising a plurality of inflatable balloons.

26. The device of claim **21** further comprising two or more prongs extending outwardly from a body of the balloon positioned at the distal end.

27. The device of claim **21** further comprising two or more prongs extending outwardly from a body of the balloon positioned at the proximal end.

28. The device of claim **21** further comprising dimples on an exterior surface of the inflatable balloon.

29. The device of claim **21** further comprising a sensor.

30. The device of claim **21** wherein the sensor is adapted and configured to be positioned on an interior surface of the balloon.

31. The device of claim **30** wherein the sensor is adapted and configured to be positioned on an exterior surface of the balloon.

32. The device of claim **30** wherein the sensor is adapted and configured to detect a change in condition.

33. The device of claim **32** wherein the change in condition is at least one of pH or pressure.

34. The device of claim **30** wherein the sensor is adapted and configured to wirelessly communicate with the patient.

35. The device of claim **30** wherein the sensor is adapted and configured to wirelessly communicate with a patient's healthcare provider.

36. The device of claim **21** wherein the port is adapted and configured to engage a retrieval device.

37. The device of claim **21** further comprising a manual release buttonwherein the manual release button is adapted and configured to facilitate the release of pressure from the device by the patient.

38. The device of claim **21** wherein the device further comprises a proximal section, a distal section and an intermediate section, further wherein the diameter of the proximal section does not equal the diameter of the distal section and does not equal the diameter of the intermediate section.

39. The device of claim **21** wherein the port is further adapted and configured to communicate with a plurality of chambers.

40. The device of claim **21** wherein the device further comprises a plurality of ports and a plurality of chambers, the plurality of ports adapted and configured to communicate with the plurality of chambers.

41. A method for treating obesity in a patient, the method comprising:

introducing a device comprising an inflatable balloon having a proximal end and a distal end, the inflatable balloon further comprising an interior chamber, and a port in communication with the interior chamber of the inflatable balloon wherein the inflatable balloon is adapted and configured to achieve a deployed shape at least partially conformable to an interior dimensional shape of a stomach of the patient;

expanding the balloon to provide a conformable geometry; and

at least partly filling the chamber of the balloon with a compressible and/or incompressible fluid.

42. The method of claim **41**, further comprising the steps of determining a size of the stomach and selecting a balloon of a proper size.

43. The method of claim **42**, wherein the step of determining further comprises visually examining the gastric cavity of the stomach through a gastroscope, externally scanning with X-rays, or externally scanning with ultrasound.

44. The method of claim **42**, wherein the size is determined while the stomach is filled with a biocompatible medium.

45. The method of claim **44**, wherein the balloon size is selected to leave an unobstructed stomach volume surrounding the sides of the device in the range from 10 cm^3 to 100 cm^3 after the balloon is inflated.

46. The method of claim **41**, wherein the introducing step further comprises passing the device in a deflated configuration into the stomach through an endoscope.

47. The method of claim **41** wherein each chamber is inflated through the port with an inflation tube removably attached to the balloon.

48. The method of claim **47**, wherein the device has at least two interior chambers and further wherein the at least two chambers are inflated by the inflation tube.

49. The method of claim **41**, wherein the chambers are filled with a mixture of compressible and incompressible fluid to control the buoyancy of the gastric balloon in the stomach.

50. The method of claim **49**, wherein the mixture of compressible and incompressible fluids is selected to provide a generally neutral buoyancy in the stomach.

51. The method of claim **41**, further comprising the step of deflating the chambers and removing the deflated balloon from the stomach.

52. The method of claim **51**, wherein the step of deflating further comprises breaching one or more walls of each chamber.

53. The method of claim **41**, further comprising the step of adjusting a fill volume of at least one chamber after filling has been completed.

54. The method of claim **53** wherein the step of adjusting the fill volume further comprises reattaching an inflation tube to one or more space-filling compartments, and filling or removing inflation fluid through the reattached inflation tube.

55. A method for deploying a gastric balloon in a patient, the method comprising the steps of:

introducing the gastric balloon into a stomach of the patient; and

separately inflating a plurality of isolated chambers within the balloon, wherein the chambers have individual volumes such that the collective volume of the chambers remaining inflated after the deflation of any single chamber is such that the balloon is prevented from passing through the pylorus.

56. The method of claim **55**, further comprising the step of detecting a substance which is released into the stomach by a partially or fully ruptured balloon chamber wherein the detection is achieved by detecting excretion, secretion, exhalation, or regurgitation by the patient.

57. A method for selecting a gastric balloon for a patient, the method comprising the steps of:

determining an internal volume of a stomach of the patient while the stomach is filled with a biocompatible filling medium; and

selecting a balloon having a filling volume less than the determined volume by a preselected amount.

58. The method of claim **57**, wherein the preselected amount is in the range from 10 cm^3 to 100 cm^3.

59. The method of claim **58**, wherein the biocompatible filling medium comprises liquid or solid food.

60. The method of claim **58**, wherein the internal volume is measured by external X-ray, external ultrasound, or by internal endoscopic measurement.

61. A method of in vivo monitoring a condition of a gastric balloon comprising:

introducing a device comprising an inflatable balloon having a proximal end and a distal end, the inflatable balloon further comprising an interior chamber, a port in communication with the interior chamber of the inflatable balloon wherein the inflatable balloon is adapted and configured to achieve a deployed shape at least partially conformable to an interior dimensional shape of a stomach of the patient, and a sensor adapted and configured to sense a condition; and

sensing a condition of the device.

62. The method of claim **61** further comprising the step of performing a plurality of calibrations of the sensor.

63. The method of claim **61** wherein the step of sensing further comprises sensing a physiologic condition of a content of the stomach.

64. The method of claim **63** further comprising the step of instructing a patient to take an antacid.

65. The method of claim **63** further comprising the step of advising a healthcare provider of the results of the sensing step.

66. The method of claim **61** wherein the step of sensing further comprises sensing a condition of the device.

67. The method of claim **66** further comprising the step of alerting a patient of the condition of the device.

68. The method of claim **66** further comprising the step of instructing a patient to contact a healthcare provider.

69. The method of claim **66** further comprising alerting a healthcare provide of the condition of the device.

70. A wireless device for treatment of obesity in a patient comprising:

an inflatable balloon having a proximal end and a distal end, the inflatable balloon further comprising an interior chamber adapted and configured to receive a filling material;

a sensor connected to the inflatable balloon adapted and configured to sense a parameter; and

a port in communication with the interior chamber of the inflatable balloon.

71. The device of claim **70** wherein the device has a shape controller along a portion of its length.

72. The device of claim **71** wherein the shape controller is a bar, joint or rod.

73. The device of claim **71** wherein the shape controller is formed from a shape memory material.

74. The device of claim **70** further comprising a plurality of inflatable balloons.

75. The device of claim **70** further comprising two or more prongs extending outwardly from a body of the balloon positioned at the distal end.

76. The device of claim **70** further comprising two or more prongs extending outwardly from a body of the balloon positioned at the proximal end.

77. The device of claim **70** further comprising dimples on an exterior surface of the inflatable balloon.

78. The device of claim **70** wherein the sensor is adapted and configured to be positioned on an interior surface of the balloon.

79. The device of claim **70** wherein the sensor is adapted and configured to be positioned on an exterior surface of the balloon.

80. The device of claim **70** wherein the sensor is adapted and configured to detect a change in condition.

81. The device of claim **80** wherein the change in condition is at least one of pH or pressure.

82. The device of claim **70** wherein the sensor is adapted and configured to wirelessly communicate with the patient.

83. The device of claim **70** wherein the sensor is adapted and configured to wirelessly communicate with a patient's healthcare provider.

84. The device of claim **70** wherein the port is adapted and configured to engage a retrieval device.

85. The device of claim **70** wherein the device further comprises a proximal section, a distal section and an intermediate section, further wherein the diameter of the proximal section does not equal the diameter of the distal section and does not equal the diameter of the intermediate section.

86. The device of claim **70** wherein the port is further adapted and configured to communicate with a plurality of chambers.

87. The device of claim **70** wherein the device further comprises a plurality of ports and a plurality of chambers, the plurality of ports adapted and configured to communicate the plurality of chambers.

88. A kit for treatment of obesity in a patient comprising:

a device comprising an inflatable balloon having a proximal end and a distal end, the inflatable balloon further comprising an interior chamber adapted and configured to receive a filling material; a port in communication with the interior chamber of the inflatable balloon; wherein the inflatable balloon is adapted and configured to assume a predetermined shape in situ and further wherein the inflatable balloon is adapted and configured to have a distal diameter less than or equal to a proximal diameter;

one or more delivery materials; and

a retrieval device.

89. A kit for treatment of obesity in a patient comprising:

a device comprising an inflatable balloon having a proximal end and a distal end, the inflatable balloon further comprising an interior chamber adapted and configured to receive a filling material; a port in communication with the interior chamber of the inflatable balloon, wherein the inflatable balloon is adapted and configured to achieve a deployment shape at least partially conformable to an interior dimensional shape of a stomach of the patient and further wherein the inflatable balloon is adapted and configured to have a distal diameter less than or equal to a proximal diameter;

one or more delivery materials; and

a retrieval device.

90. A kit for treatment of obesity in a patient comprising:

a device comprising an inflatable balloon having a proximal end and a distal end, the inflatable balloon further comprising an interior chamber adapted and configured to receive a filling material; a sensor connected to the inflatable balloon adapted and configured to sense a parameter; and a port in communication with the interior chamber of the inflatable balloon;

one or more delivery materials; and

a retrieval device.

91. An intragastric balloon device comprising:

a hollow pliable sac defining an interior space, the sac further comprising a proximal end and a distal end and an exterior surface;

at least one protrusion extending from the exterior surface of the sac; and

an access port adapted to provide material access to the interior space.

92. The device of claim **89** further comprising at least one prong extending from the exterior surface of the sac at the distal end.

93. The device of claim **89** wherein the interior space further comprises at least two isolated chambers adapted and configured to be filled with a material.

94. The device of claim **93** wherein the access port is configured to provide material access to the at least one isolated chamber.

95. The device of claim **89** further comprising a second access port.

96. The device of claim **95** wherein a first access port provides material access to a first chamber in the interior space and the second access port provides material access to a second chamber in the interior space.

97. The device of claim **89** wherein the distal end of the device has a smaller diameter than the proximal end of the device.

98. The device of claim **89** further comprising at least one prong extending from the exterior surface of the sac at the proximal end.

99. The device of claim **89** further comprising a sensor.

100. The device of claim **99** wherein the sensor is adapted and configured to be positioned on the exterior surface of the sac.

101. The device of claim **99** wherein the sensor is adapted and configured to communicate wirelessly with a data receiver.

102. The device of claim **99** wherein the sensor is adapted and configured to detect a change in condition.

103. The device of claim **102** wherein the change in condition is at least one of pH or pressure.

104. The device of claim **102** wherein the diameter of the sac varies with the length of the sac.

105. The device of claim **104** wherein the diameter of the sac at the proximal end is greater than the diameter of the sac at the distal end.

106. The device of claim **105** further comprising a shape controller.

107. The device of claim **106** wherein the shape controller is a bar, joint or rod.

108. The device of claim **106** wherein the shape controller is formed from a shape memory material.

109. An intragastric balloon device for positioning in a stomach of a patient comprising

a hollow pliable sac defining an interior space, the sac further comprising a proximal end and a distal end and an exterior surface;

a series of protrusions extending from the exterior surface of the sac;

an access port adapted to provide material access to the interior space; and

a series of prongs located on the distal end of the sac, wherein the prongs are adapted to prevent migration of the sac.

110. The device of claim **109** wherein the interior space further comprises at least two isolated chambers adapted and configured to be filled with a material.

111. The device of claim **109** wherein the access port is configured to provide material access to the at least one isolated chamber.

112. The device of claim **109** further comprising a second access port.

113. The device of claim **112** wherein a first access port provides material access to a first chamber in the interior space and the second access port provides material access to a second chamber in the interior space.

114. The device of claim **109** wherein the distal end of the device has a smaller diameter than the proximal end of the device.

115. The device of claim **109** further comprising at least one prong extending from the exterior surface of the sac at the proximal end.

116. The device of claim **109** further comprising a sensor.

117. The device of claim **116** wherein the sensor is adapted and configured to be positioned on the exterior surface of the sac.

118. The device of claim **117** wherein the sensor is adapted and configured to communicate wirelessly with a data receiver.

119. The device of claim **116** wherein the sensor is adapted and configured to detect a change in condition.

120. The device of claim **119** wherein the change in condition is at least one of pH or pressure.

121. The device of claim **119** wherein the diameter of the sac varies with the length of the sac.

122. The device of claim **109** wherein the diameter of the sac varies with the length of the sac.

123. The device of claim **122** wherein the diameter of the sac at the proximal end is greater than the diameter of the sac at the distal end.

124. The device of claim **123** further comprising a shape controller.

125. The device of claim **124** wherein the shape controller is a bar, joint or rod.

126. The device of claim **124** wherein the shape controller is formed from a shape memory material.

127. An intragastric balloon device comprising

a hollow pliable sac, the sac further comprising a proximal end and a distal end and an exterior surface;

an interior space defined within the sac wherein the interior space further comprises at least two isolated chambers wherein the isolated chambers are adapted to be filled with a media; and

a controlling mechanism adapted to conform and maintain the device in a user defined configuration.

128. The device of claim **127** further comprising at least one prong extending from the exterior surface of the sac at the distal end.

129. The device of claim **127** further comprising an access port wherein the access port is adapted and configured to provide material access to the at least one isolated chamber.

130. The device of claim **127** further comprising a second access port.

131. The device of claim **130** wherein a first access port provides material access to a first chamber in the interior space and the second access port provides material access to a second chamber in the interior space.

132. The device of claim **127** wherein the distal end of the device has a smaller diameter than the proximal end of the device.

133. The device of claim **127** further comprising at least one prong extending from the exterior surface of the sac at the proximal end.

134. The device of claim **127** further comprising a sensor.

135. The device of claim **134** wherein the sensor is adapted and configured to detect a change in condition.

136. The device of claim **135** wherein the change in condition is at least one of pH or pressure.

137. The device of claim **134** wherein the sensor is adapted and configured to be positioned on the exterior surface of the sac.

138. The device of claim **134** wherein the sensor is adapted and configured to communicate wirelessly with a data receiver.

139. The device of claim **127** wherein the diameter of the sac varies with the length of the sac.

140. The device of claim **139** wherein the diameter of the sac at the proximal end is greater than the diameter of the sac at the distal end.

141. The device of claim **127** wherein the controlling mechanism is a bar, joint or rod.

142. The device of claim **127** wherein the controlling mechanism is formed from a shape memory material.

143. An intragastric balloon device comprising:

a first inflatable chamber;

a second inflatable chamber; and

an elongate neck region connecting the first and second inflatable chambers wherein the neck region is adapted and configured to conform and maintain the device in a user defined configuration.

144. The device of claim **143** further comprising at least one prong extending from the exterior surface of the sac at the distal end.

145. The device of claim **143** further comprising an access port wherein the access port is configured to provide material access to the at least one chamber.

146. The device of claim **143** further comprising a second access port.

147. The device of claim **146** wherein a first access port provides material access to a first chamber in the interior space and the second access port provides material access to a second chamber in the interior space.

148. The device of claim **143** wherein the first inflatable chamber of the device has a smaller diameter than the second inflatable chamber of the device.

149. The device of claim **143** further comprising at least one prong extending from the second inflatable chamber wherein the second inflatable chamber is located proximal to the pylorus.

150. The device of claim **143** further comprising a sensor.

151. The device of claim **150** wherein the sensor is adapted and configured to detect a change in condition.

152. The device of claim **151** wherein the change in condition is at least one of pH or pressure.

153. The device of claim **150** wherein the sensor is adapted and configured to be positioned on the exterior surface of the sac.

154. The device of claim **150** wherein the sensor is adapted and configured to communicate wirelessly with a data receiver.

155. The device of claim **143** wherein the elongate neck region is a bar, joint or rod.

156. The device of claim **143** wherein the elongate neck region is formed from a shape memory material.

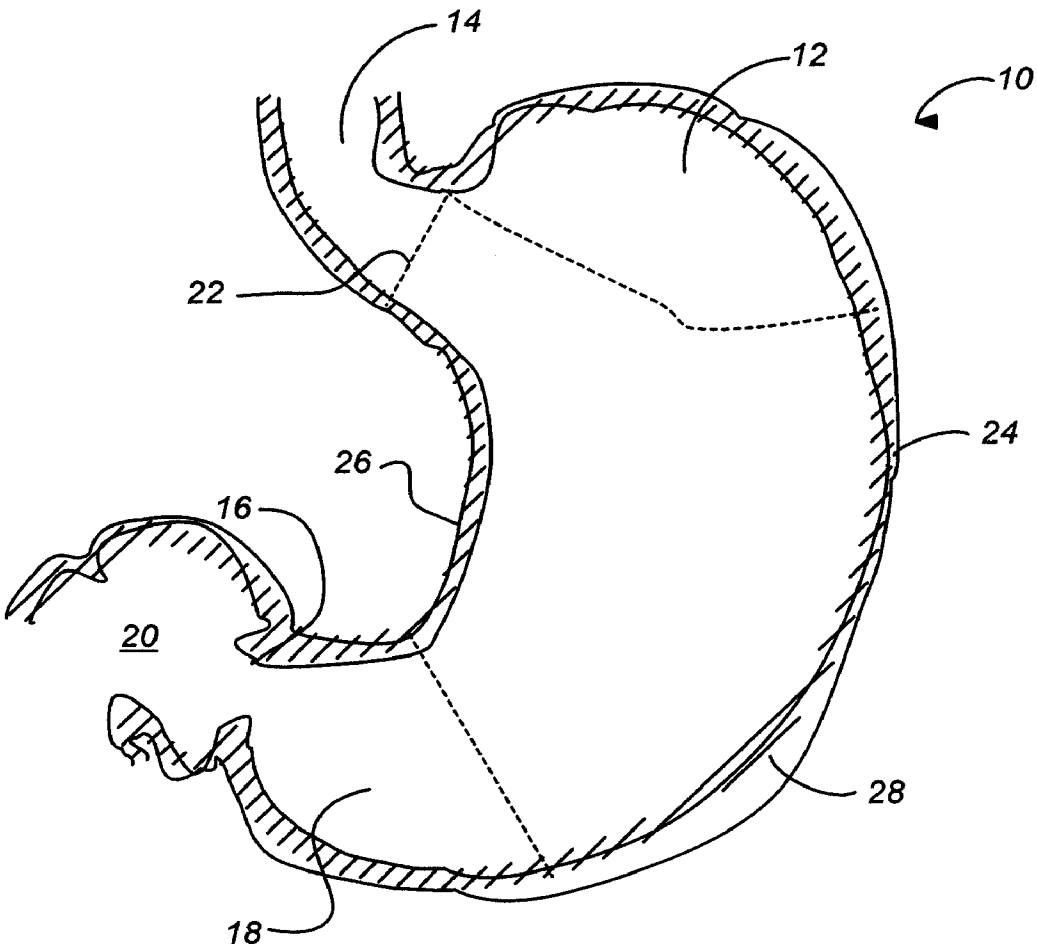

FIG. 1

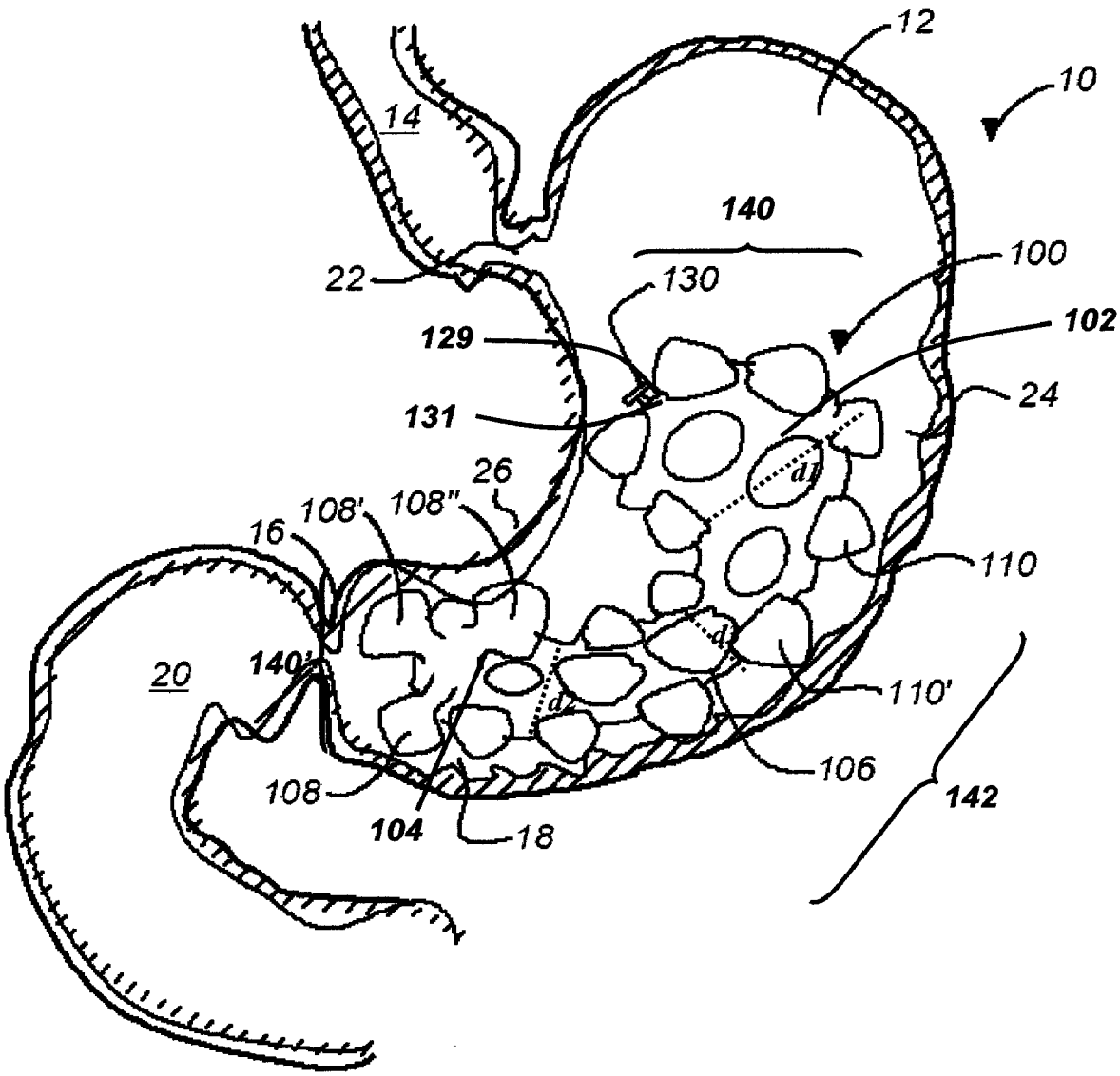
12
10
14
140
22
130
100
129
102
131
24
26
d1
108'
108"
16
110
d3
20
140'
d2
110'
106
108
142
104
18

FIG. 2

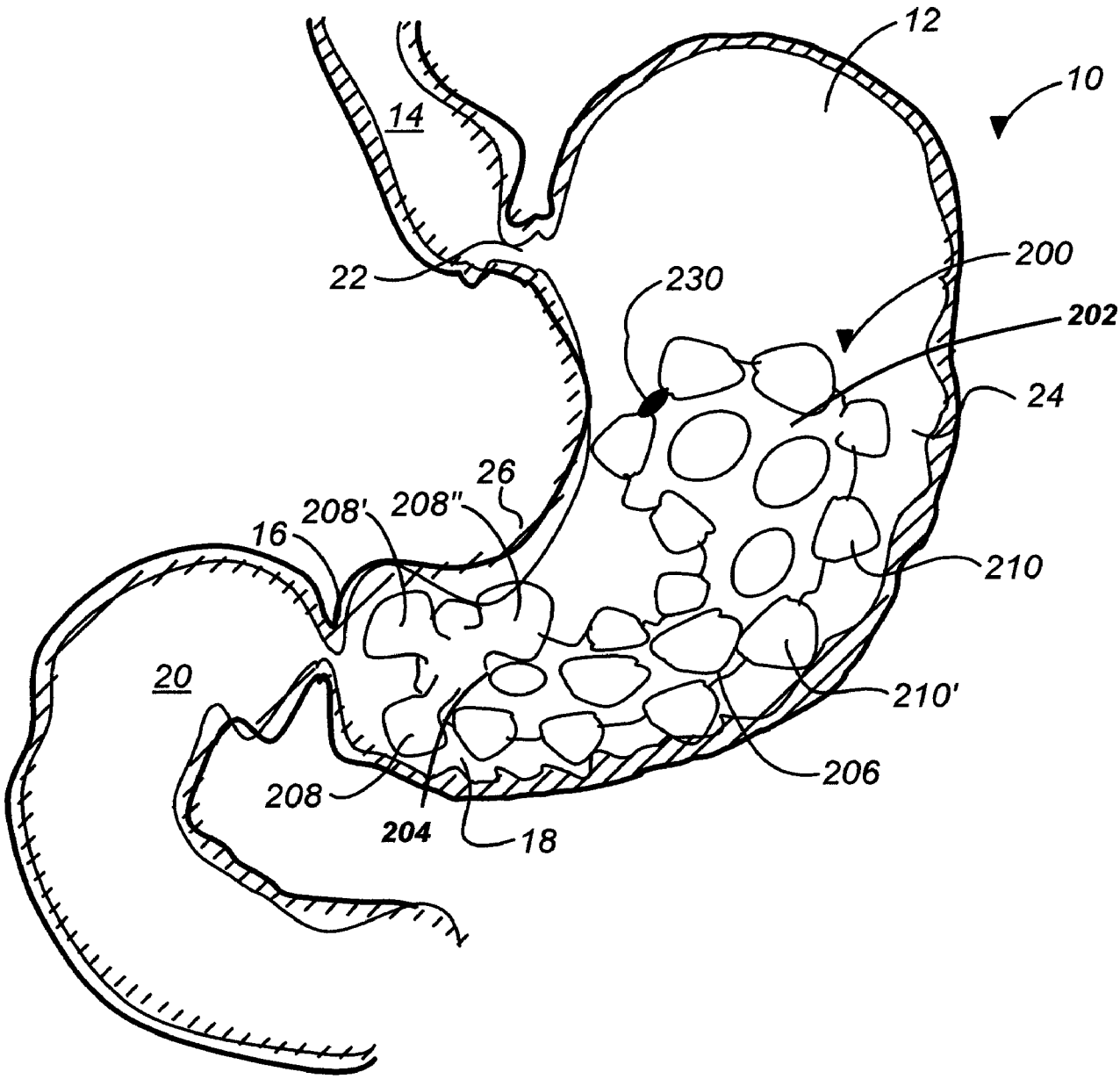

FIG. 3A

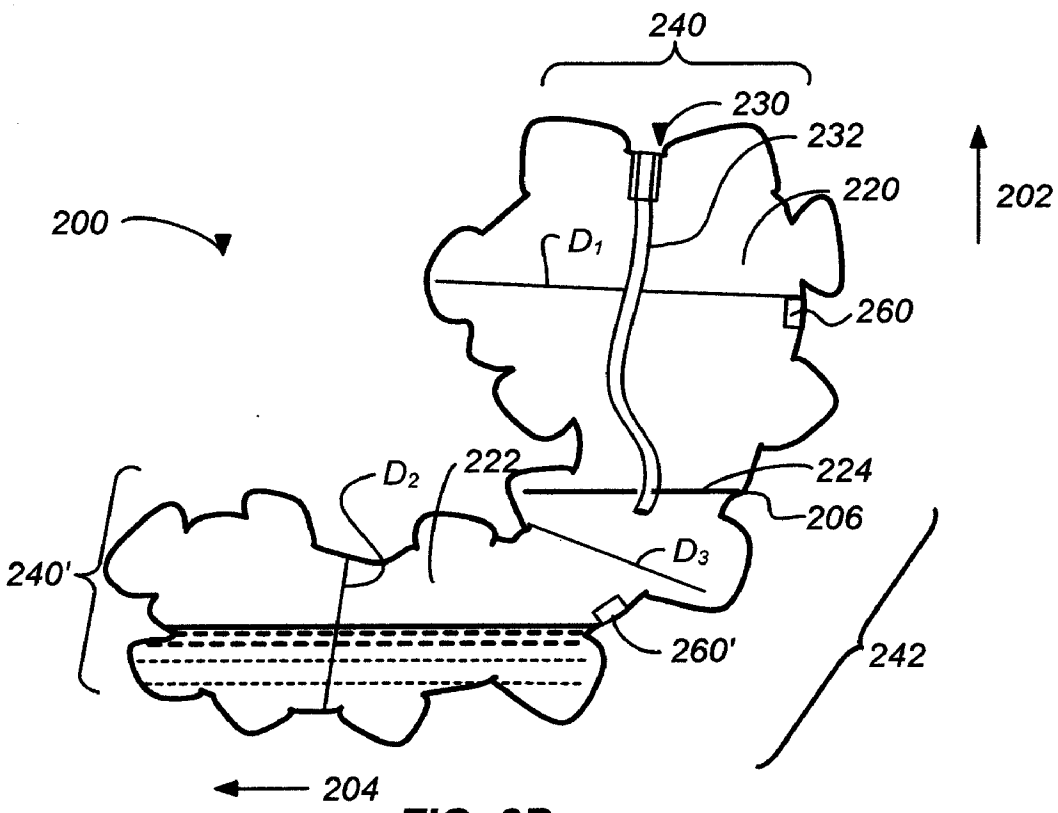

FIG. 3B

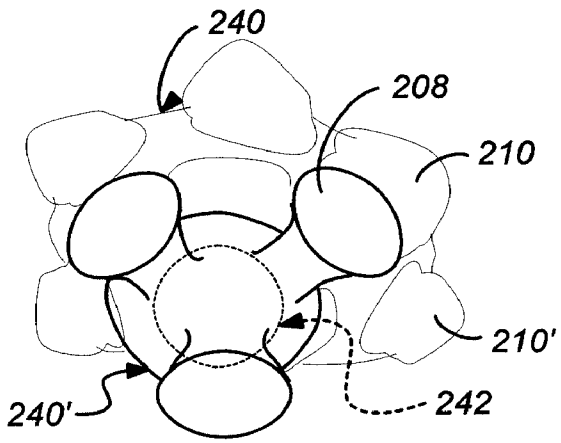

FIG. 3C

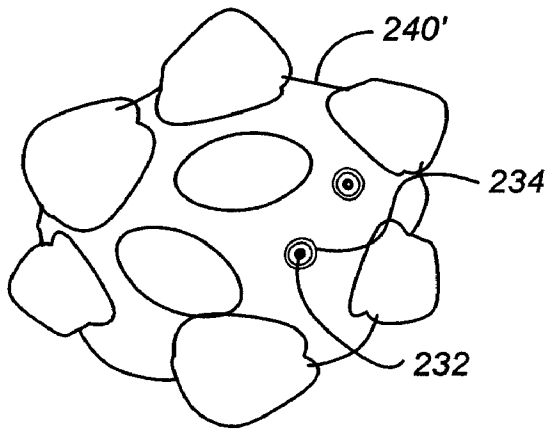

FIG. 3D

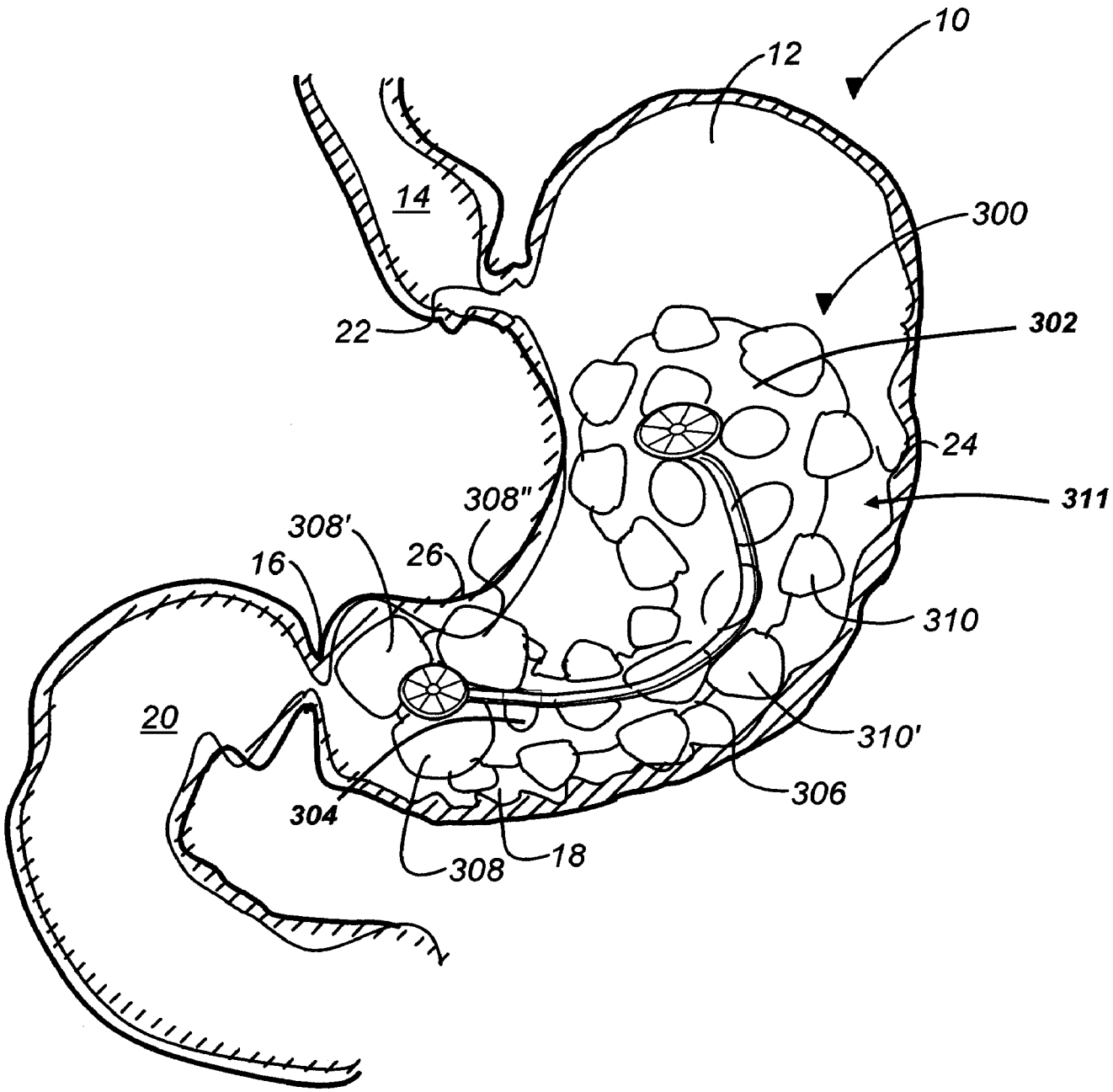

FIG. 4A

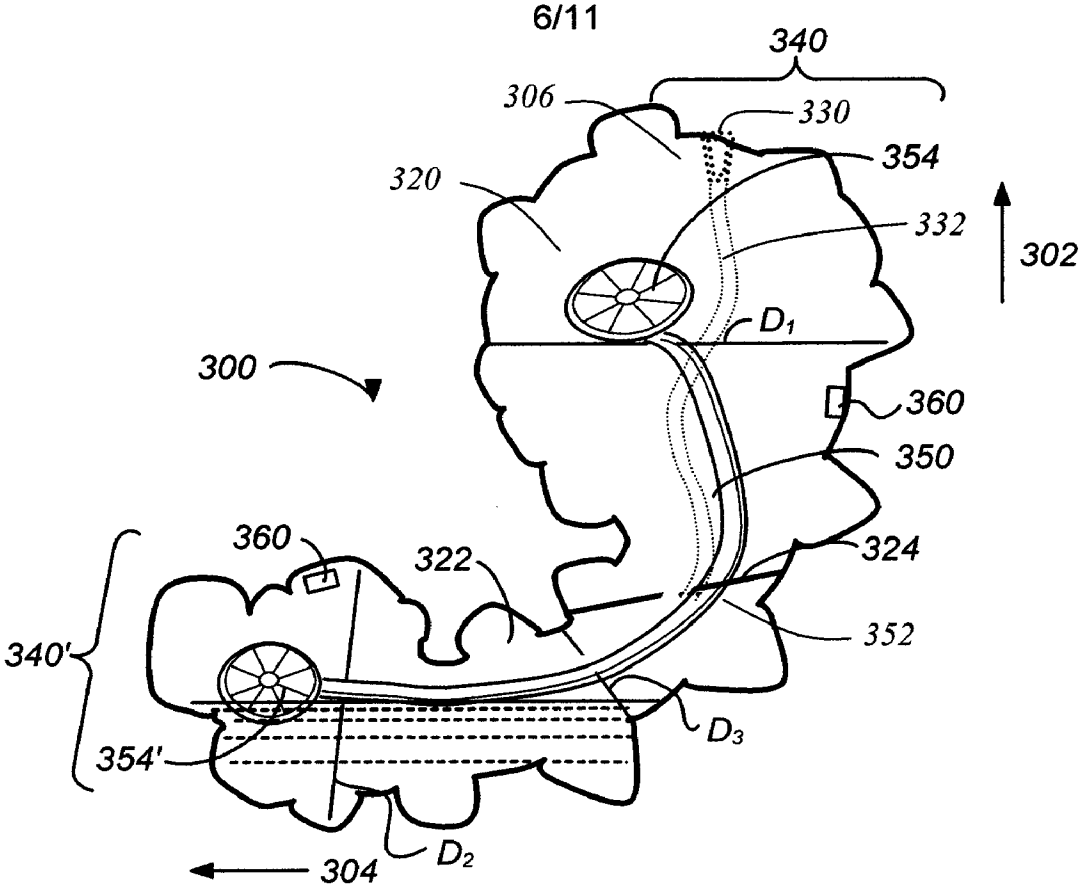

FIG. 4B

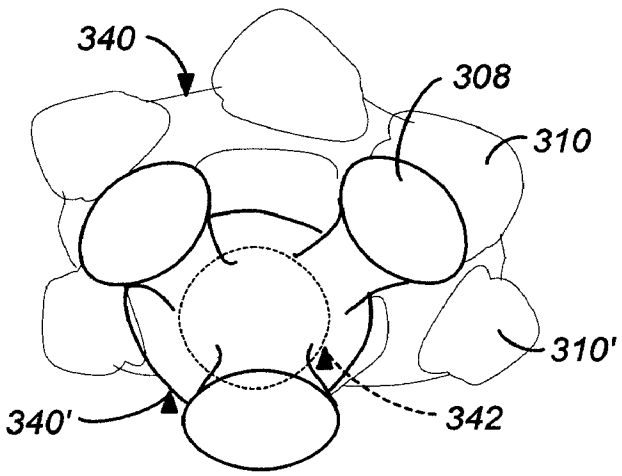

FIG. 4C

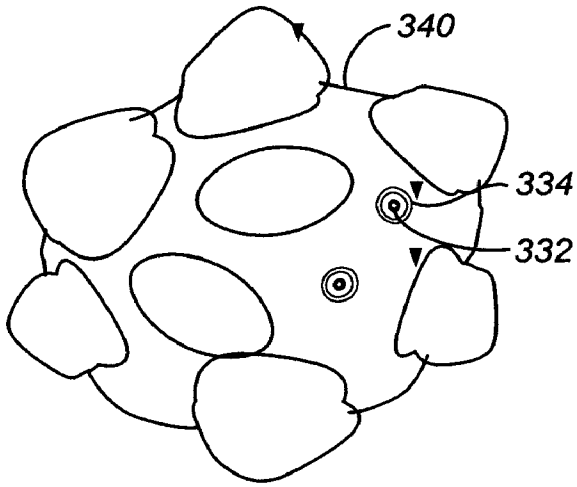

FIG. 4D

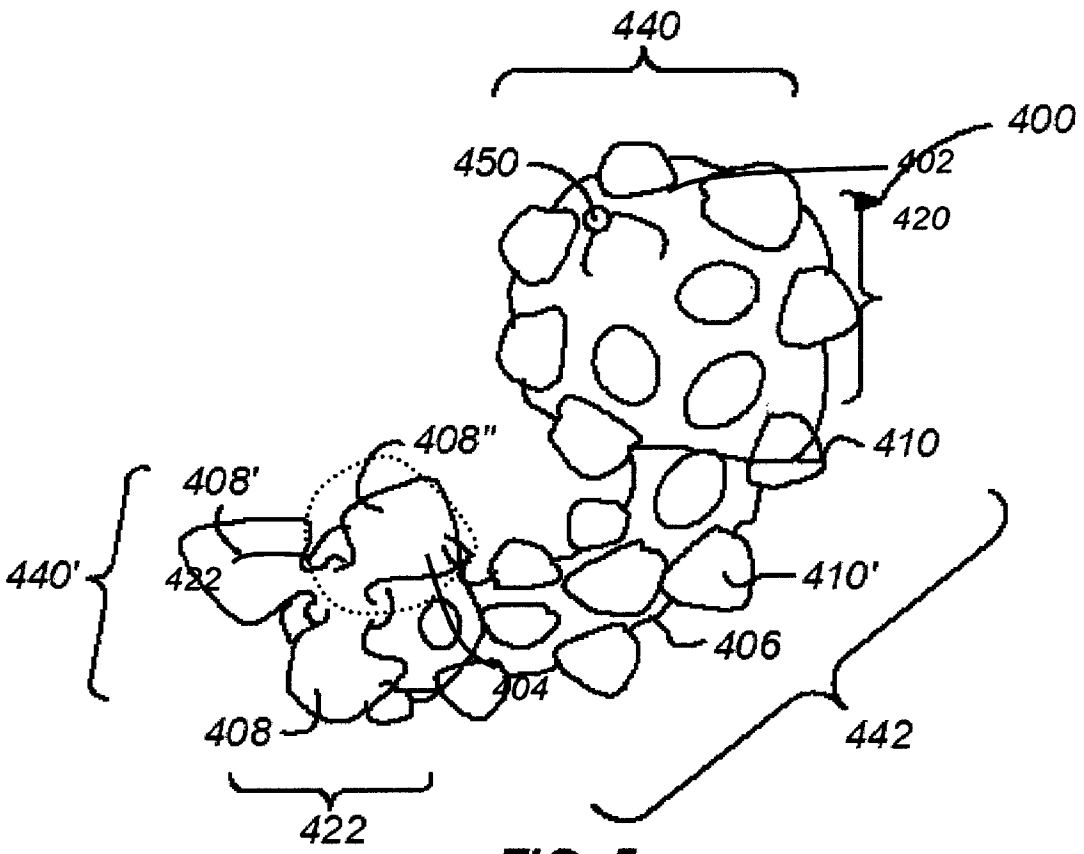
440
400
450
402
420
408"
410
408'
440'
422
410'
406
404
408
442
422

FIG. 5

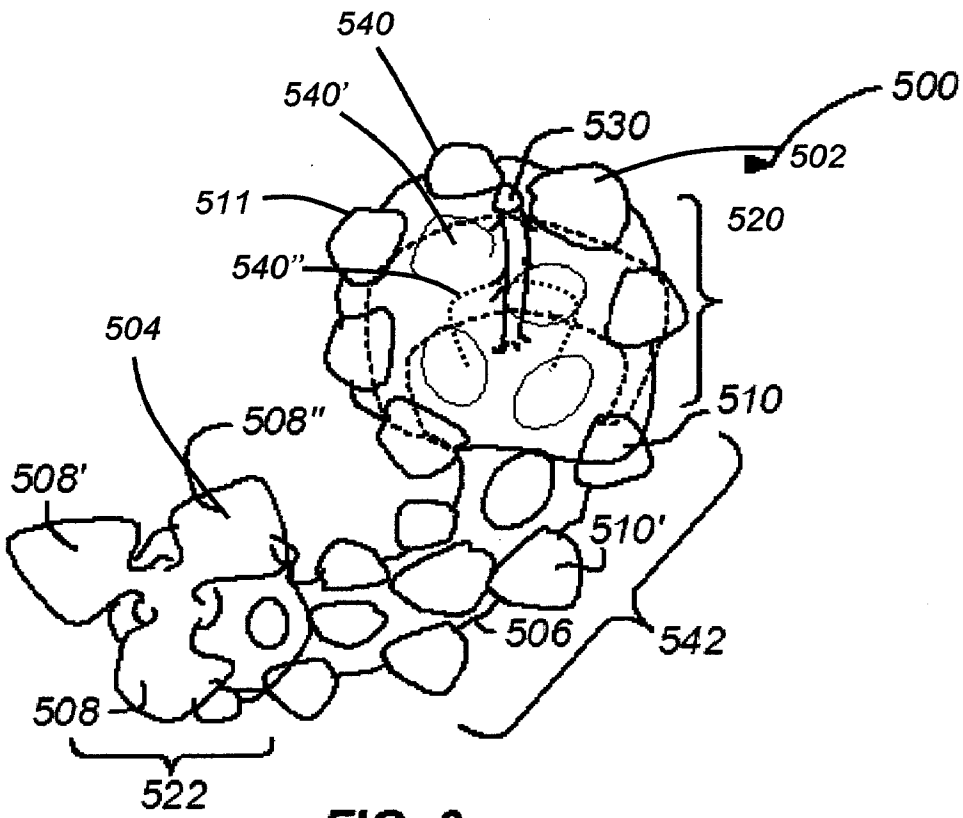
540
540'
500
530
502
511
520
540"
504
510
508"
508'
510'
506
542
508
522

FIG. 6

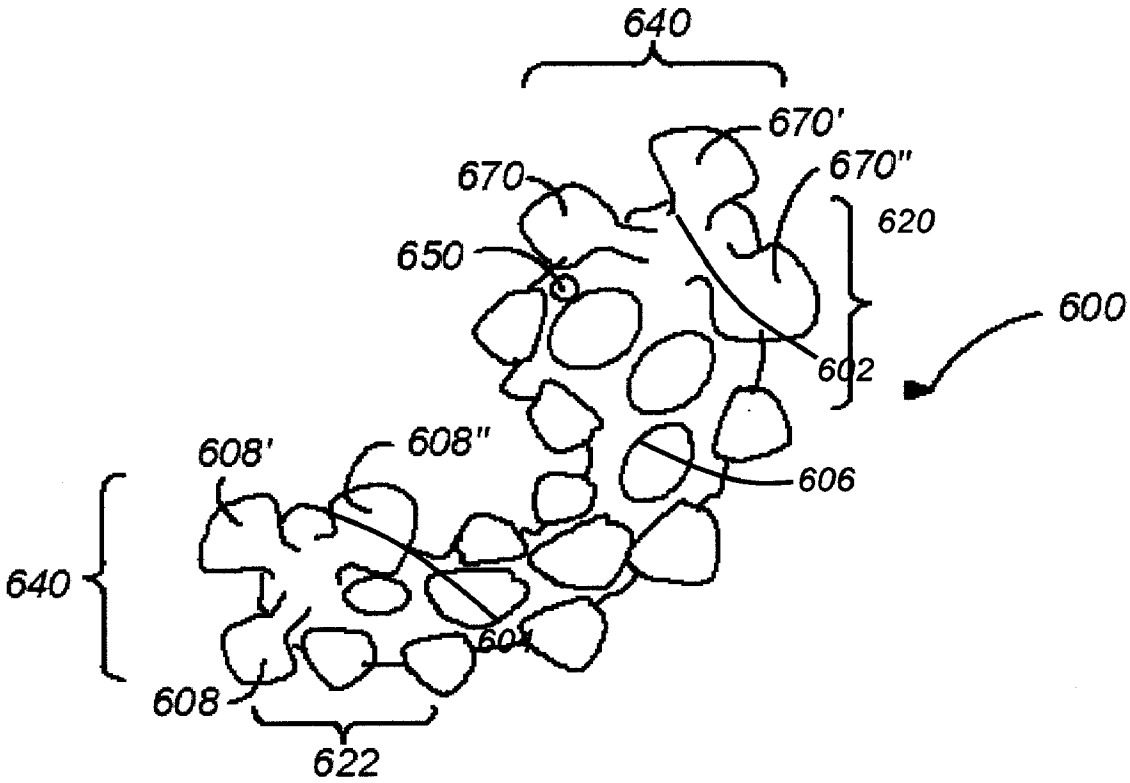
640
670'
670"
670
620
650
600
602
608'
608"
606
640
604
608
622

FIG. 7

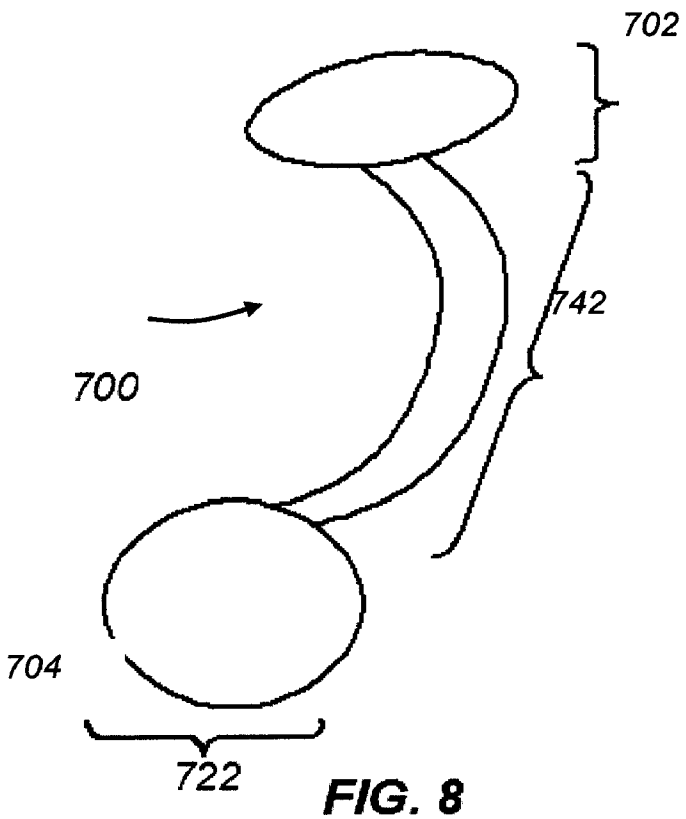
702
742
700
704
722

FIG. 8

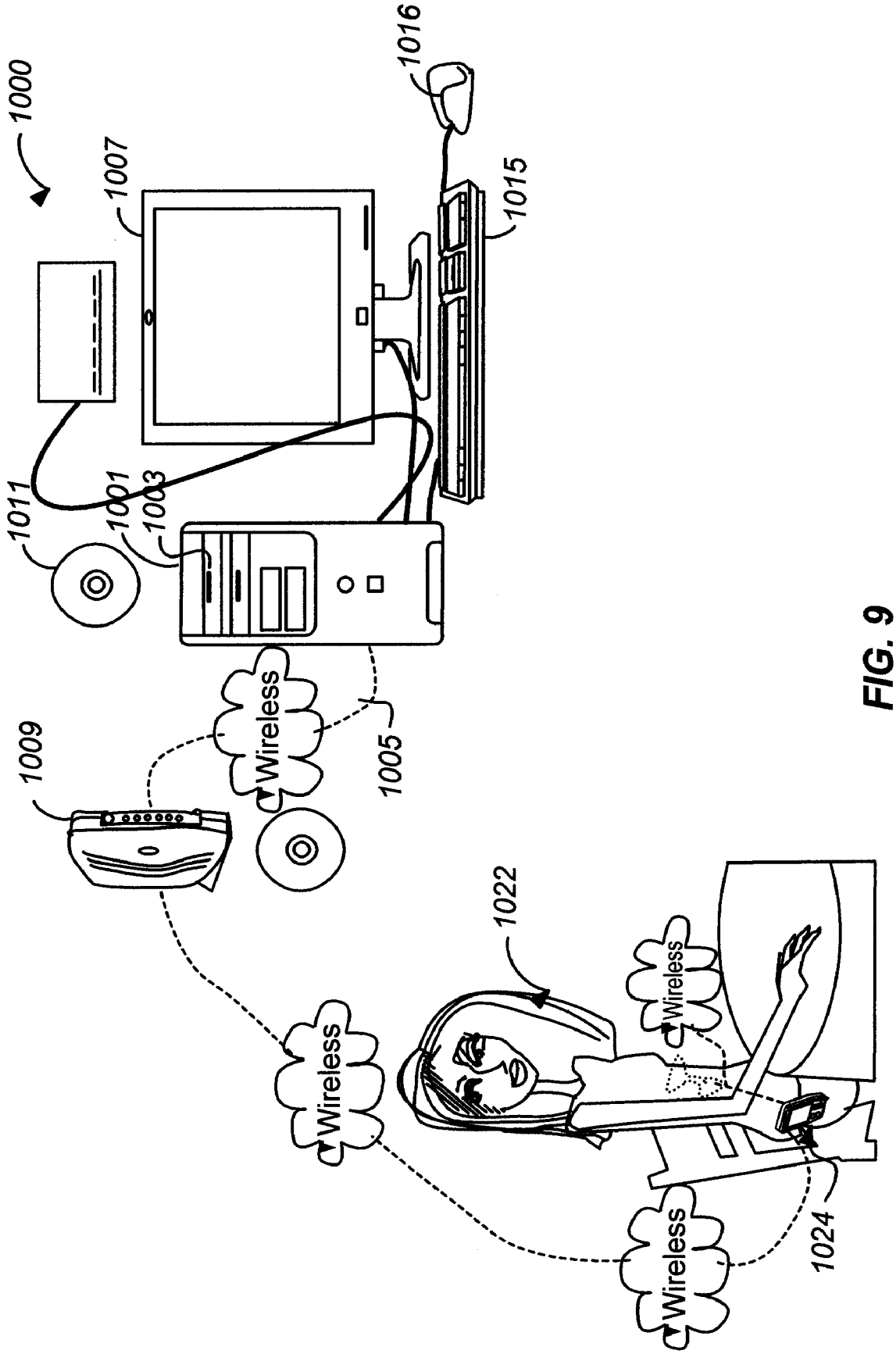
1000
1007
1016
1015
1011
1001
1003
1005
1009
1022
1024
Wireless
Wireless
Wireless
Wireless

FIG. 9

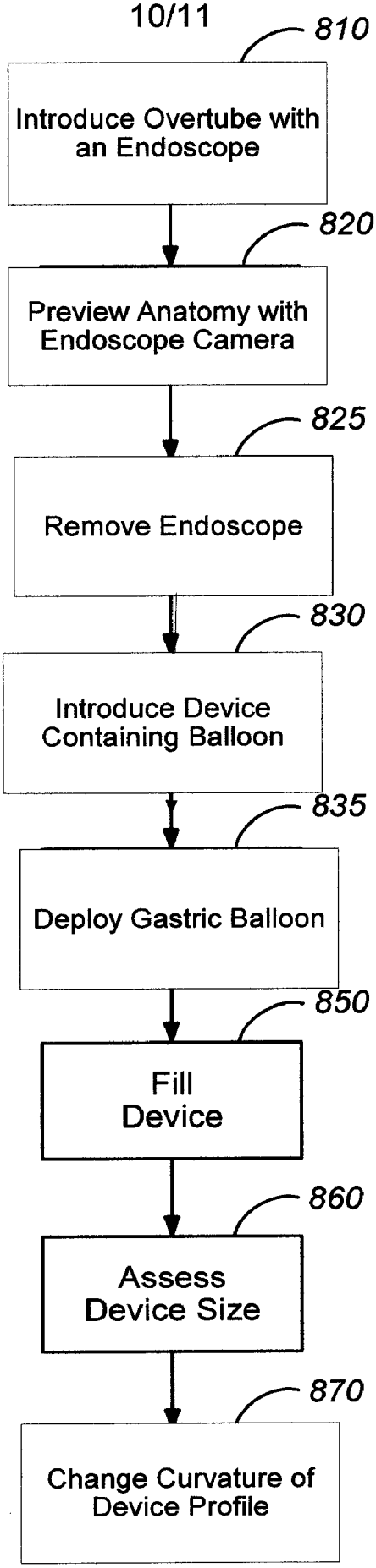
810
Introduce Overtube with an Endoscope
820
Preview Anatomy with Endoscope Camera
825
Remove Endoscope
830
Introduce Device Containing Balloon
835
Deploy Gastric Balloon
850
Fill Device
860
Assess Device Size
870
Change Curvature of Device Profile

FIG. 10

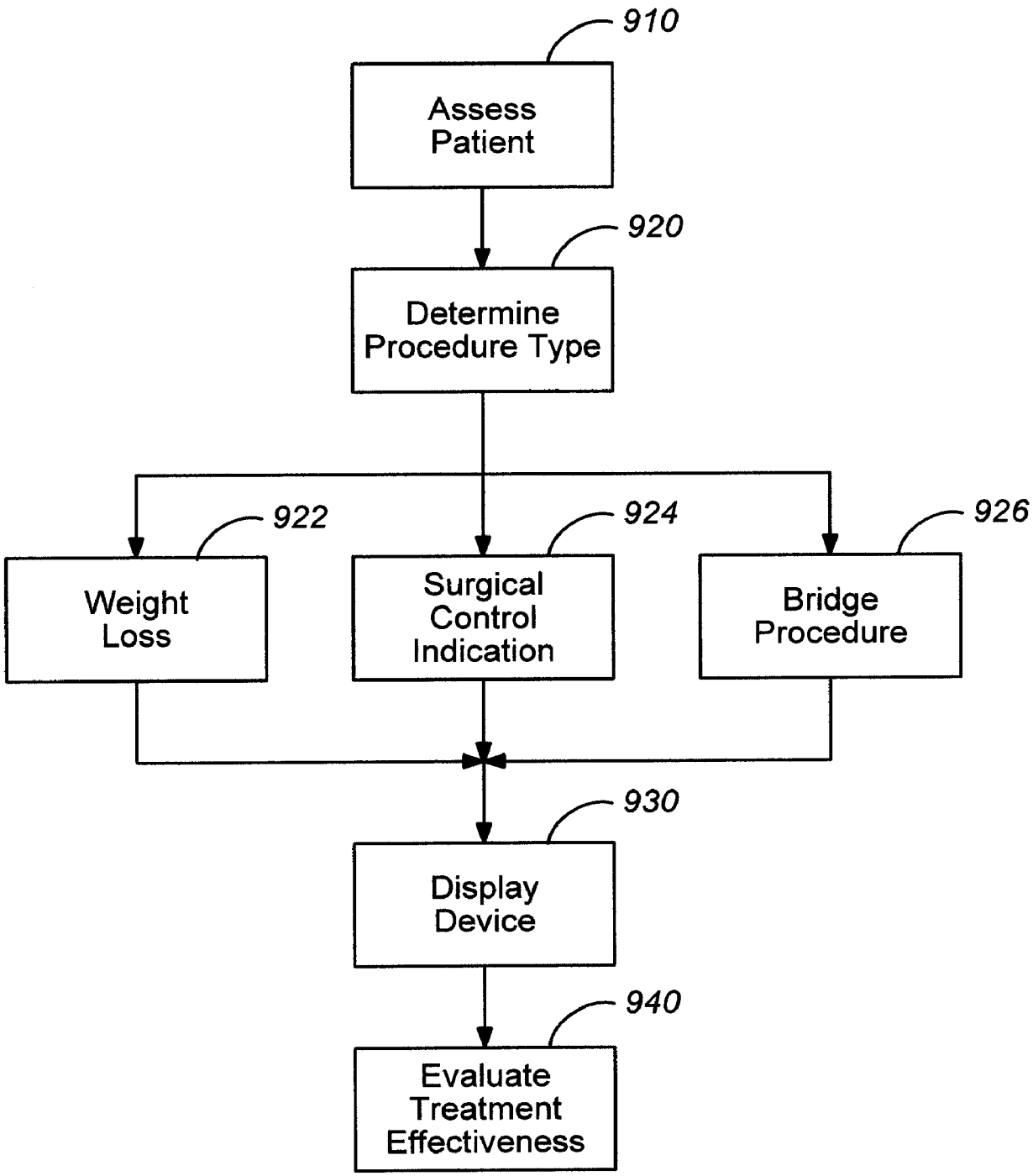
910
Assess Patient
920
Determine Procedure Type
922
Weight Loss
924
Surgical Control Indication
926
Bridge Procedure
930
Display Device
940
Evaluate Treatment Effectiveness

FIG. 11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/056858

A. CLASSIFICATION OF SUBJECT MATTER

A61M 29/00(2006.01)i, A61B 1/00(2006.01)i

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 8: A61M 29/00

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

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

eKIPASS, WPI, USPTO, PAJ "balloon, obesity, intragastric, shape memory, sensor, etc."

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2006-0020278 A1 (DANIEL R. BURNETT et al., US) 26 Jan. 2006 See figs. 15A-18B; paragraph 98.	1-4, 16-20, 21-24, 36-40, 88, 89
Y		5-15, 25-35, 71-73, 124-126
X	US 2005-0267595 A1 (RICHARD CHEN, US) 01 Dec. 2005 See figs. 1-3; paragraphs 44-48 and 78-85.	70, 74, 78-80, 82-87, 90
Y		5, 9-15, 25, 29-35, 71-73, 75-77, 81, 110-114, 116-156
X	US 4,694,827 (BRIAN C. WEINER; SARAH H. WEINER, US) 22 Sep. 1987 See figs. 1-5; claim 1; column 3 lines 17-22.	91, 109, 115
Y		6-8, 26-28, 75-77, 110-114, 116-126, 128, 133, 144, 149
Y	US 2005-0273060 A1 (MICHALE J. LEVY, et al., US) 08 Dec. 2005 See figs. 10-14; paragraphs 145-148.	9-15,29-35,81,120,127-156

☒ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents,such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 AUGUST 2008 (14.08.2008)	**14 AUGUST 2008 (14.08.2008)**

Name and mailing address of the ISA/KR
Korean Intellectual Property Office
Government Complex-Daejeon, 139 Seonsa-ro, Seo-gu, Daejeon 302-701, Republic of Korea
Facsimile No. 82-42-472-7140

Authorized officer
Heo, Joo-Hyung
Telephone No. 82-42-481-8150

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/056858

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 03-055420 A1 (COMPAGNI EUROPEENNE D'ETUDE ET DE RECHERCHE DE DISPOSITIFS POUR L'IMPLANTATION PAR LAPAROSCOPIE, FR) 10 Jul. 2003 See the whole document.	1-40, 70-91, 109-156
A	US 6,627,206 B2 (GREG A. LLOYD, US) 30 Sep. 2003 See the whole document.	1-40, 70-91, 109-156
A	KR 10-2005-0105284 A (KENYON & KENYON, US) 03 Dec. 2005 See the whole document.	1-40, 70-91, 109-156

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/056858

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

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

1. ☒ Claims Nos.: 41-69
because they relate to subject matter not required to be searched by this Authority, namely:

Claims 41-69 pertain to methods for treatment of the human or animal body by surgery methods and thus relate to a subject matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT, to search.

2. ☒ Claims Nos.: 92-108
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

Claims 92-108 are unclear, because it is described that they further define "the device of claim 89", but claim 89 is concerned with "a kit".

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

See Supplemental Box

1. ☐ As all required addtional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2008/056858

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2006-0020278 A1	26.01.2006	WO 2007-027812 A2	08.03.2007
		WO 2005-009288 A2	03.02.2005
		US 2007-0250132 A1	25.10.2007
		US 2005-0033332 A1	10.02.2005
		US 2005-0033331 A1	10.02.2005
		US 6,994,095 B2	07.02.2006
		JP 2007-500538 T2	18.01.2007
		EP 1919370 A2	14.05.2008
		EP 1659983 A2	31.05.2006
		CA 02534118 AA	03.02.2005
		AU 2006-284801 AA	08.03.2007
		AU 2004-258968 AA	03.02.2005
US 2005-0267595 A1	01.12.2005	WO 2006-055839 A2	26.05.2006
		WO 2005-107641 A2	17.11.2005
		US 2006-0111777 A1	25.05.2006
		US 2006-0111632 A1	25.05.2006
		US 2005-0267596 A1	01.12.2005
		JP 2007-535999 T2	13.12.2007
		EP 1811920 A2	01.08.2007
		EP 1744804 A2	24.01.2007
		AU 2005-306367 AA	26.05.2006
US 4,694,827	22.09.1987	None	
US 2005-0273060 A1	08.12.2005	WO 2005-120363 A1	22.12.2005
WO 03-055420 A1	10.07.2003	US 2007-0118168 A1	24.05.2007
		MX 04006313 A	10.11.2004
		FR 02834202 B1	19.03.2004
		FR 02834202 A1	04.07.2003
		EP 1458316 A1	22.09.2004
		CN 1911190 A	14.02.2007
		CA 2470455 AA	10.07.2003
		BR 0215432 A	06.06.2006
		AU 2002-364884 AA	15.07.2003
US 6,627,206 B2	30.09.2003	US 2003-0021822 A1	30.01.2003
KR 10-2005-0105284 A	03.12.2005	WO 2004-084763 A2	07.10.2004
		US 2006-0058829 A1	16.03.2006
		RU 5132225 A	10.05.2006
		NZ 0542854 A	30.03.2007
		MX 5009980 A	25.05.2006
		JP 2006-522643 T2	05.10.2006
		EP 1610737 A2	04.01.2006
		CN 1802181 A	13.07.2006
		CA 02519518 AA	07.10.2004
		BR 0408471 A	04.04.2006
		AU 2004-224409 AA	07.10.2004

- in continuation of Box No. III

This ISA found multiple inventions as follows:

Group I, claims 1-40, 88, and 89, drawn to a device (a kit) for treatment of obesity in a patient, the device comprising: an inflatable balloon; and a port in communication with the interior chamber of the inflatable balloon wherein the inflatable balloon is adapted and configured to have a distal diameter less than or equal to a proximal diameter.

Group II, claims 70-87 and 90, drawn to a wireless device (a kit) for treatment of obesity in a patient, the device comprising: an inflatable balloon; a sensor connected to the inflatable balloon; and a port in communication with the interior chamber of the inflatable balloon.

Group III, claims 91 and 109-126, drawn to an intragastric balloon device comprising: a hollow pliable sac; at least one protrusion extending from the exterior surface of the sac (and a series of prongs); and an access port adapted to provide material access to the interior space.

Group IV, claims 127-142 and 143-156 drawn to an intragastric balloon device comprising: a hollow pliable sac; an interior space (having at least two chambers); and a controlling mechanism (an elongated neck region) adapted to conform and maintain the device in a user defined configuration.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2 they lack the same or corresponding special technical features for the following reasons; they are separate inventions with distinct fields of search.