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Brian et al.

(54) **MULTI-METHOD AND MULTI-APPARATUS FOR TREATING OBESITY**

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A61B 1/32	(2006.01)
A61B 1/313	(2006.01)
A61B 17/34	(2006.01)
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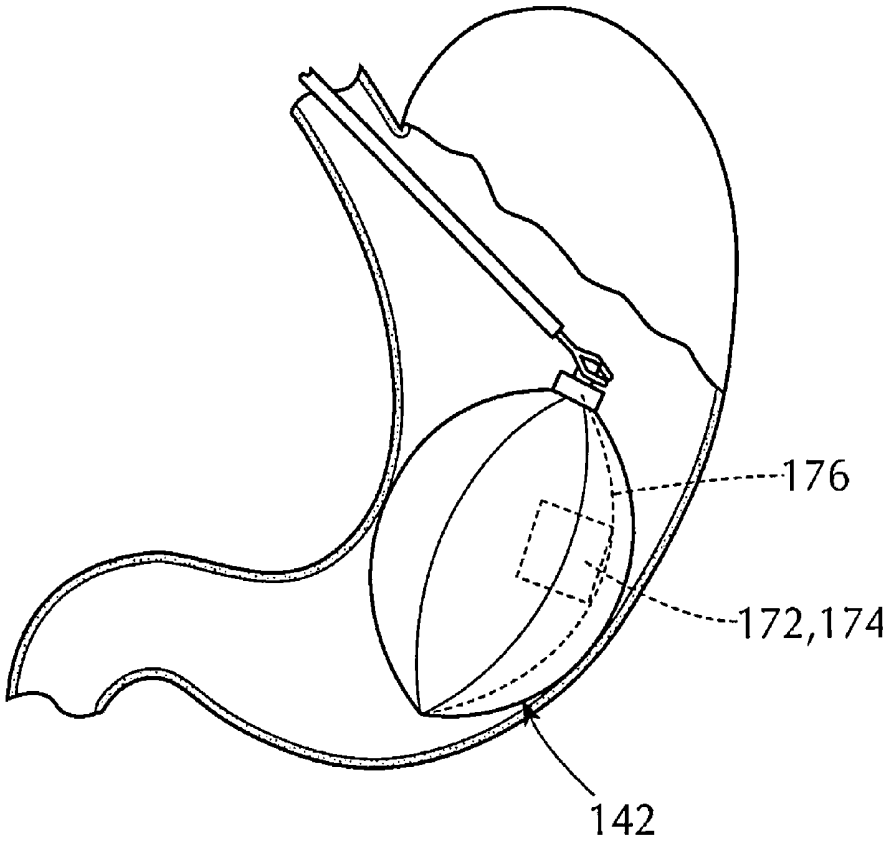
(57) **ABSTRACT**

A multi-method and multi-apparatus for treating obesity. The multi-method includes a method for estimating a volume of an intragastric balloon appropriate for an individual patient, a method for using an enterocutaneous fistula to inspect an intragastric balloon without sedation and endoscopic complications associated with an upper endoscopy, and a method for decreasing ability of the stomach of an individual patient to distend or expand after a meal increasing satiety and helping the individual patient to comply with a weight loss diet. The multi-apparatus includes an intragastric balloon for inflating without installation of a pressurized gas or liquid, an intragastric balloon for minimizing trauma of the intragastric balloon on the gastric mucosa, and an intragastric balloon for administering therapeutic medications.



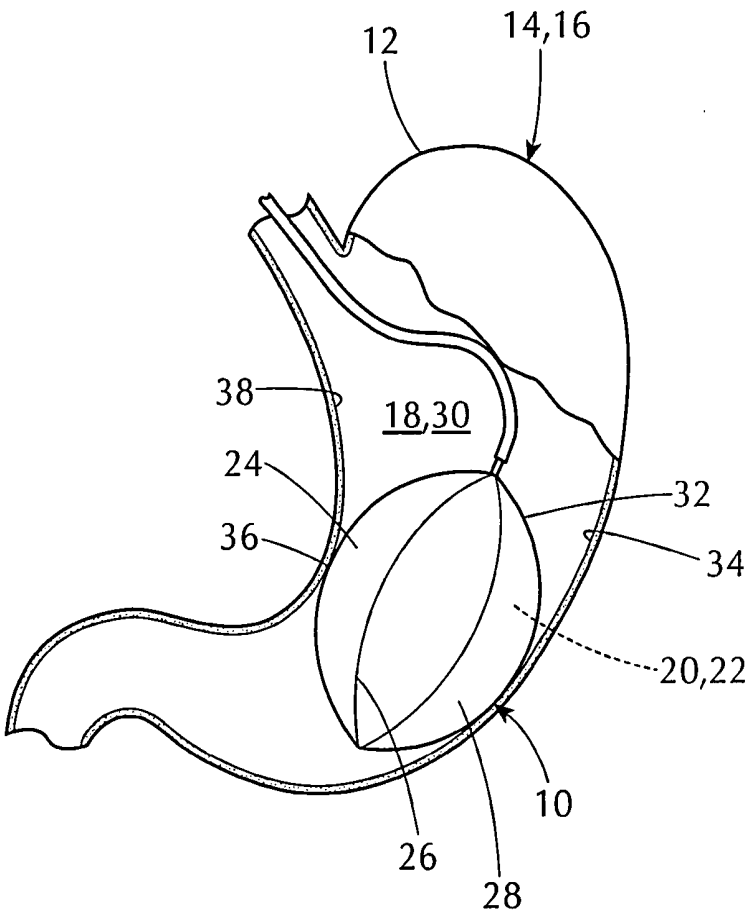


FIG. 1
PRIOR ART

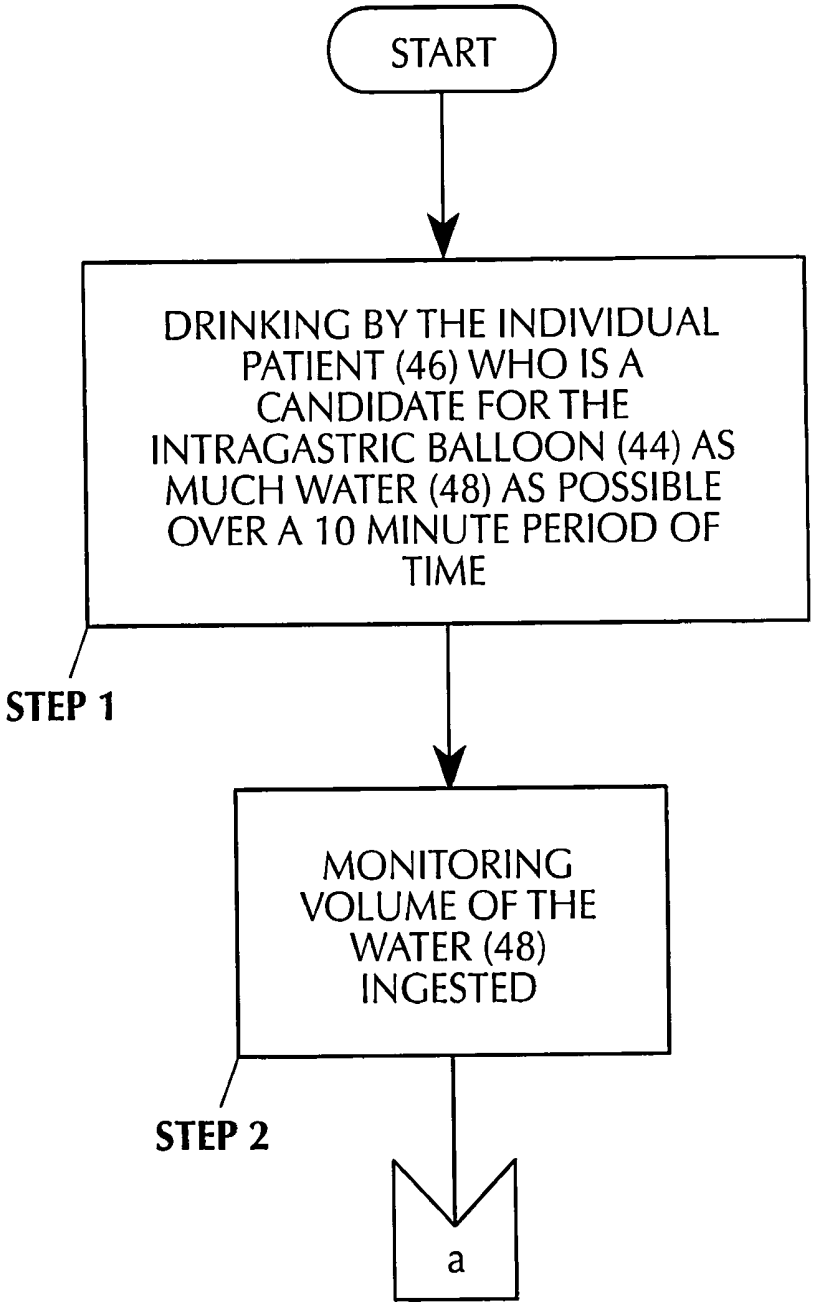

START
DRINKING BY THE INDIVIDUAL PATIENT (46) WHO IS A CANDIDATE FOR THE INTRAGASTRIC BALLOON (44) AS MUCH WATER (48) AS POSSIBLE OVER A 10 MINUTE PERIOD OF TIME
STEP 1
MONITORING VOLUME OF THE WATER (48) INGESTED
STEP 2
a

FIG. 2-A

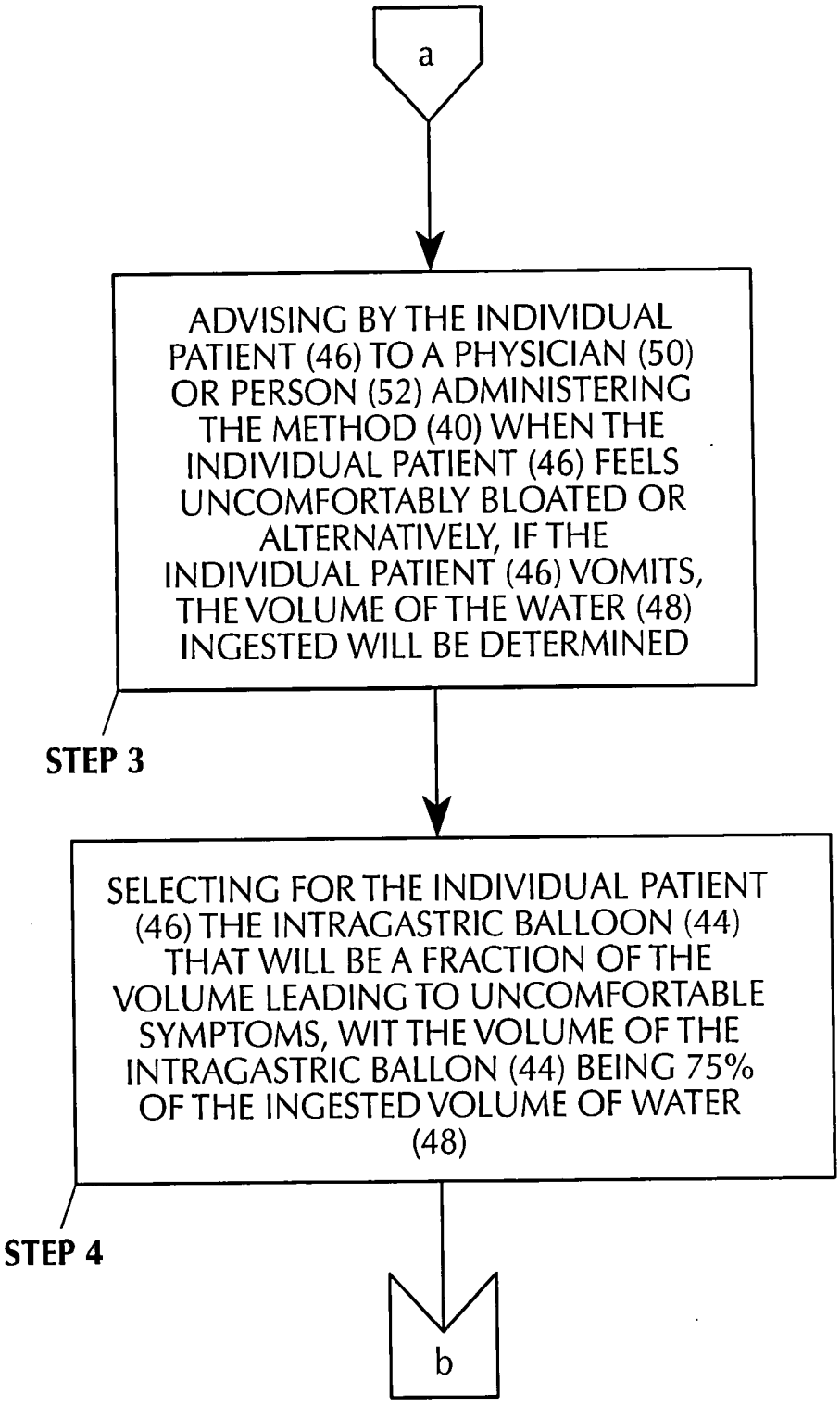

a
ADVISING BY THE INDIVIDUAL PATIENT (46) TO A PHYSICIAN (50) OR PERSON (52) ADMINISTERING THE METHOD (40) WHEN THE INDIVIDUAL PATIENT (46) FEELS UNCOMFORTABLY BLOATED OR ALTERNATIVELY, IF THE INDIVIDUAL PATIENT (46) VOMITS, THE VOLUME OF THE WATER (48) INGESTED WILL BE DETERMINED
STEP 3
SELECTING FOR THE INDIVIDUAL PATIENT (46) THE INTRAGASTRIC BALLOON (44) THAT WILL BE A FRACTION OF THE VOLUME LEADING TO UNCOMFORTABLE SYMPTOMS, WIT THE VOLUME OF THE INTRAGASTRIC BALLON (44) BEING 75% OF THE INGESTED VOLUME OF WATER (48)
STEP 4
b

FIG. 2-B

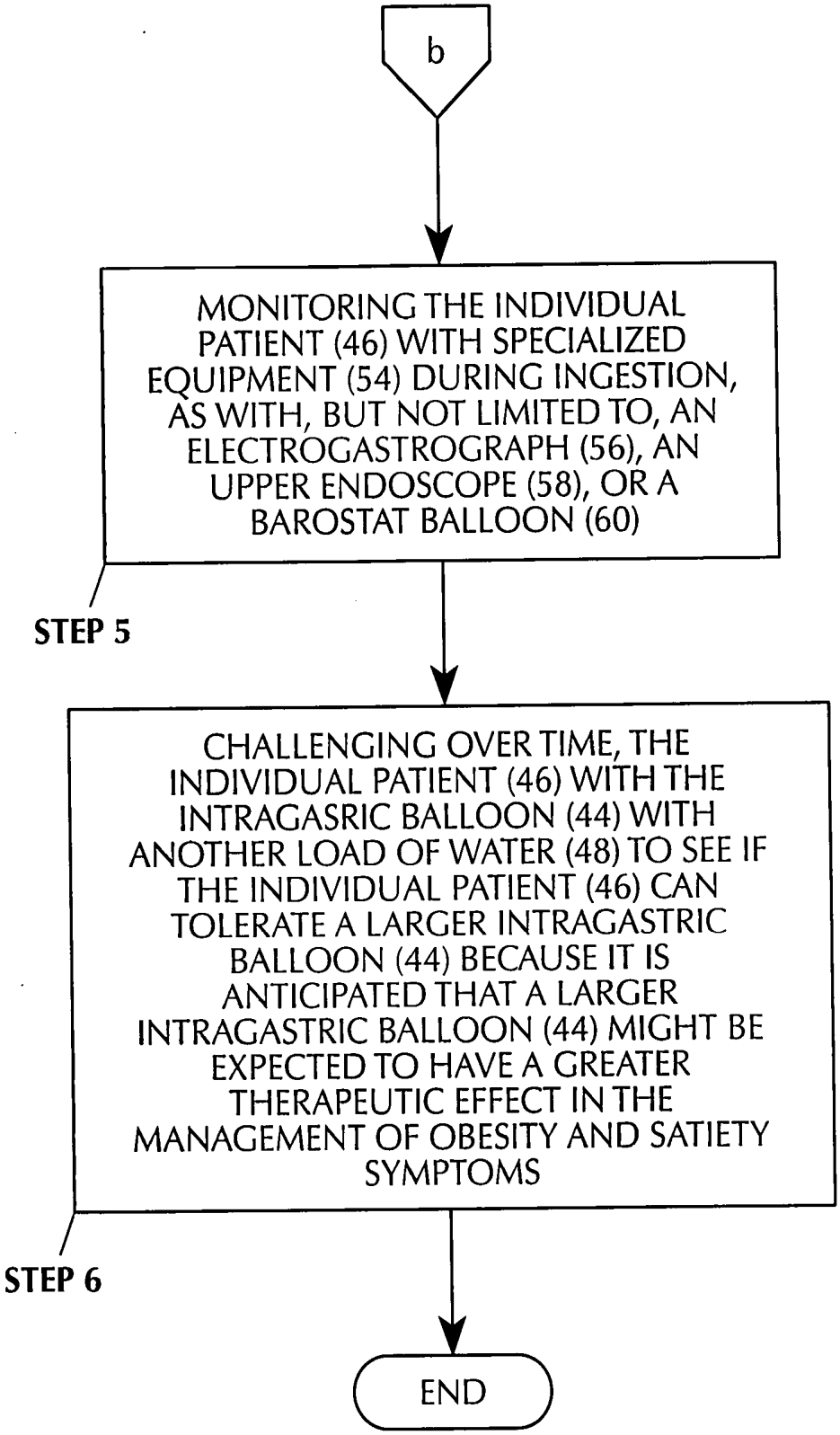

b
MONITORING THE INDIVIDUAL PATIENT (46) WITH SPECIALIZED EQUIPMENT (54) DURING INGESTION, AS WITH, BUT NOT LIMITED TO, AN ELECTROGASTROGRAPH (56), AN UPPER ENDOSCOPE (58), OR A BAROSTAT BALLOON (60)
STEP 5
CHALLENGING OVER TIME, THE INDIVIDUAL PATIENT (46) WITH THE INTRAGASRIC BALLOON (44) WITH ANOTHER LOAD OF WATER (48) TO SEE IF THE INDIVIDUAL PATIENT (46) CAN TOLERATE A LARGER INTRAGASTRIC BALLOON (44) BECAUSE IT IS ANTICIPATED THAT A LARGER INTRAGASTRIC BALLOON (44) MIGHT BE EXPECTED TO HAVE A GREATER THERAPEUTIC EFFECT IN THE MANAGEMENT OF OBESITY AND SATIETY SYMPTOMS
STEP 6
END

FIG. 2-C

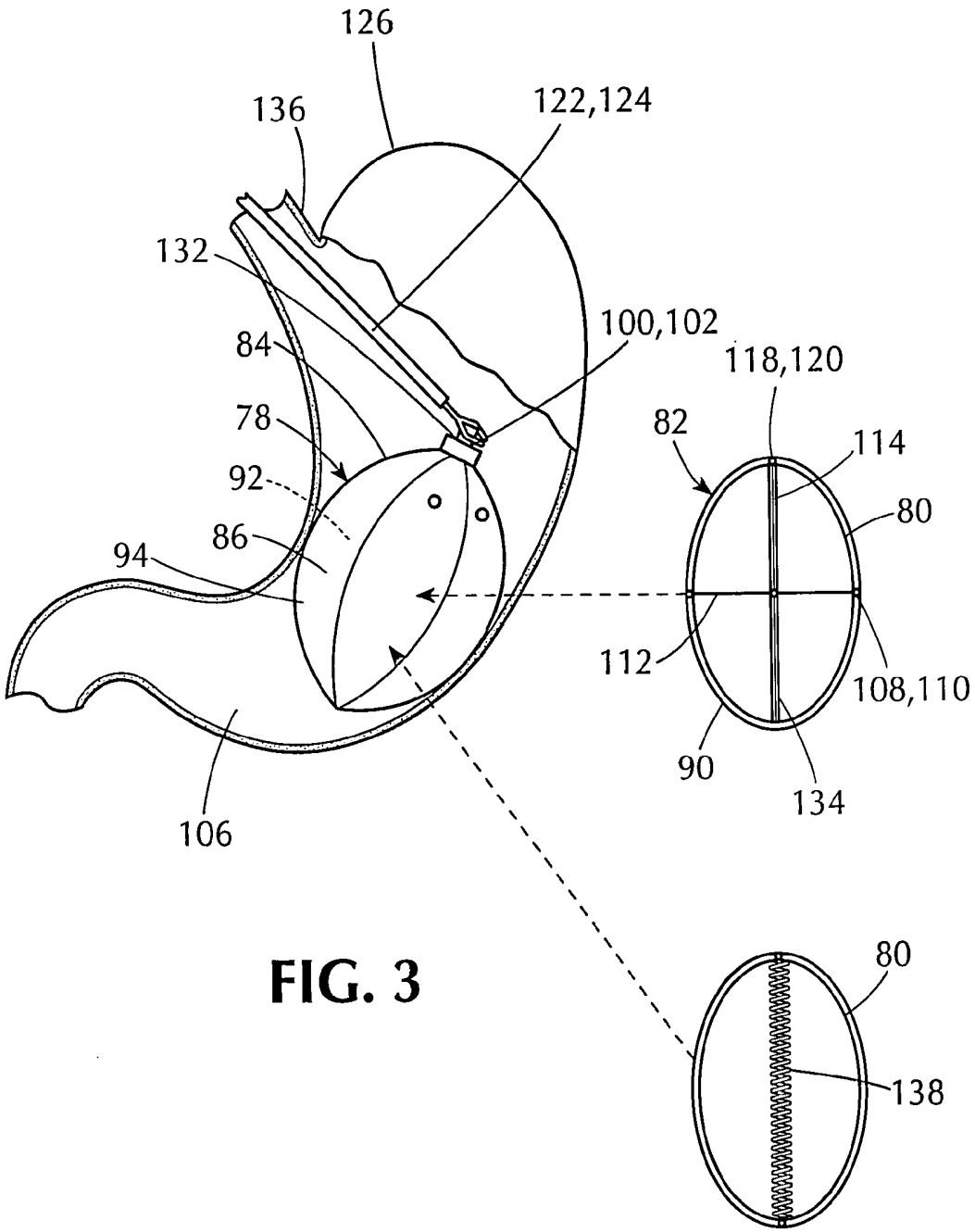

126
136
122,124
132
100,102
84
118,120
78
82
114
92
80
86
94
112
108,110
90
134
106
80
138

FIG. 3

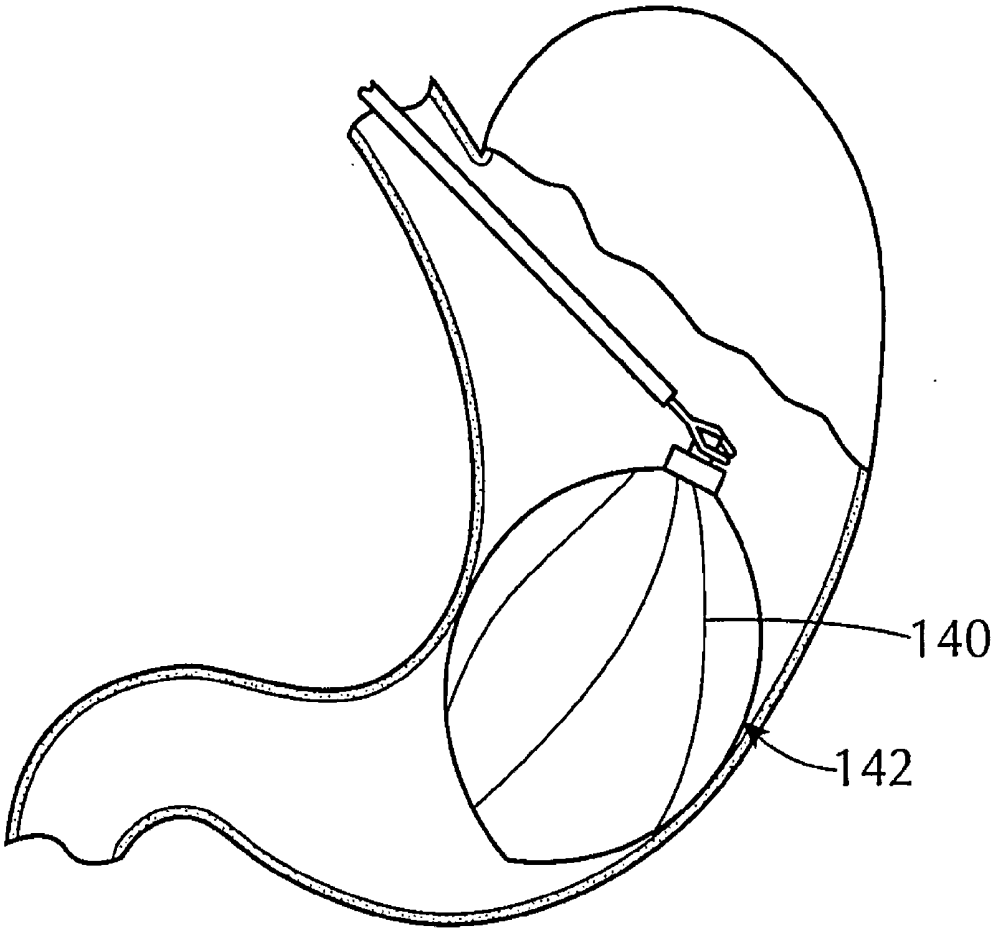


FIG. 4

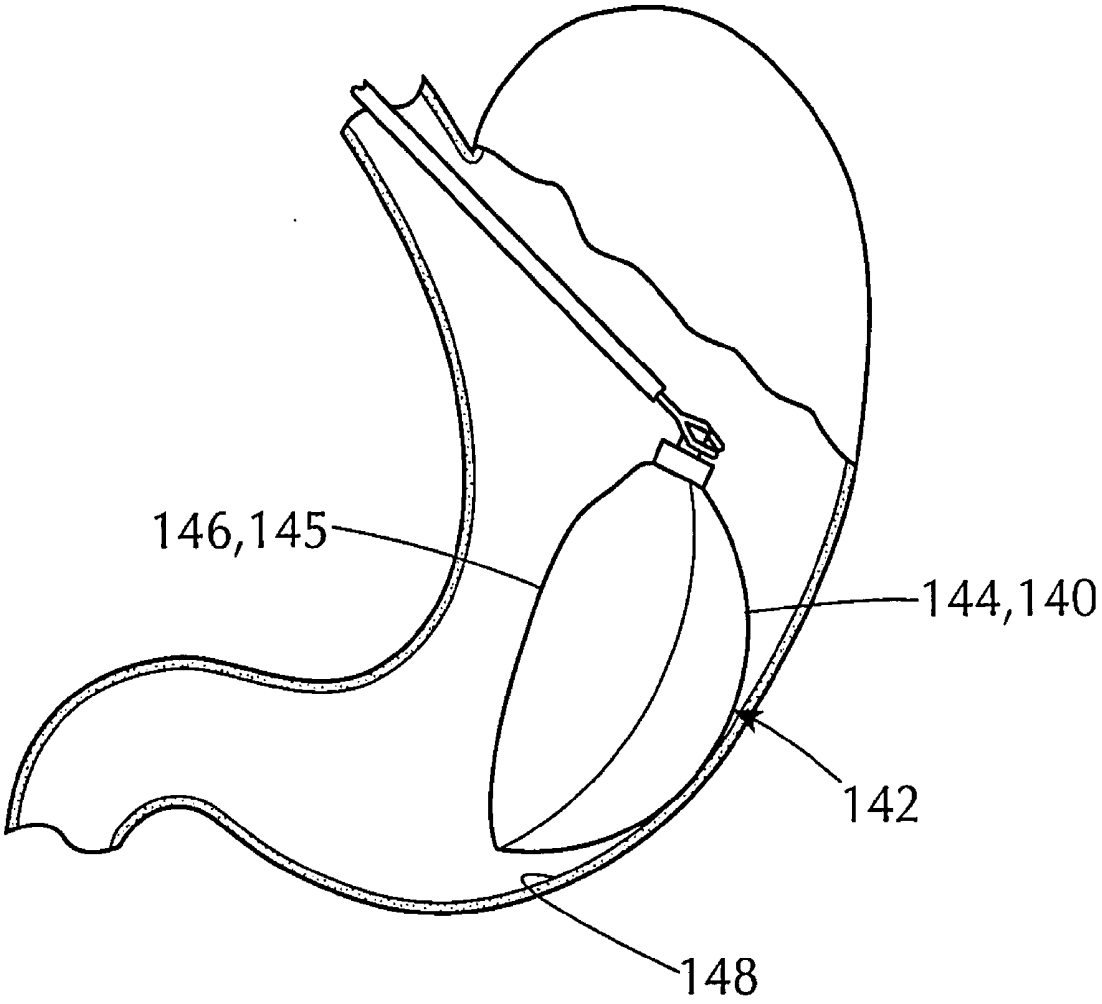


FIG. 5

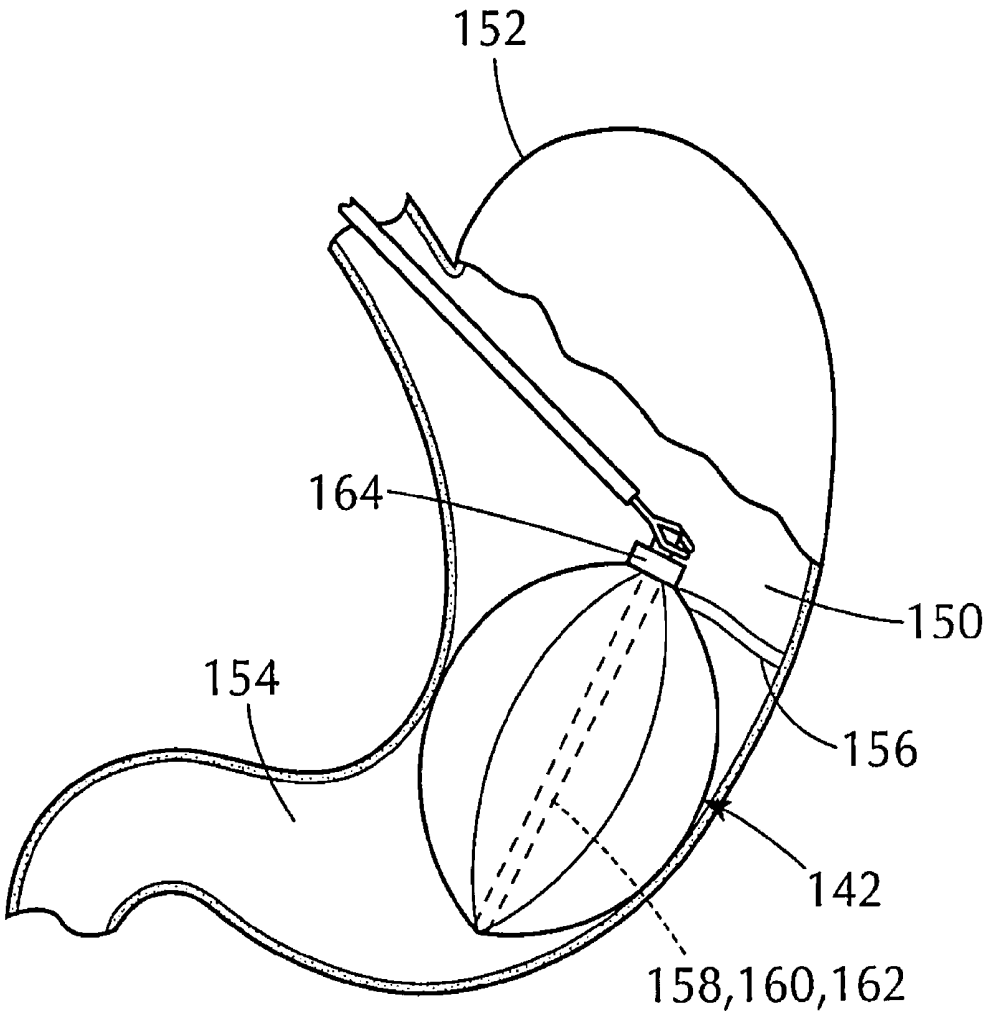


FIG. 6

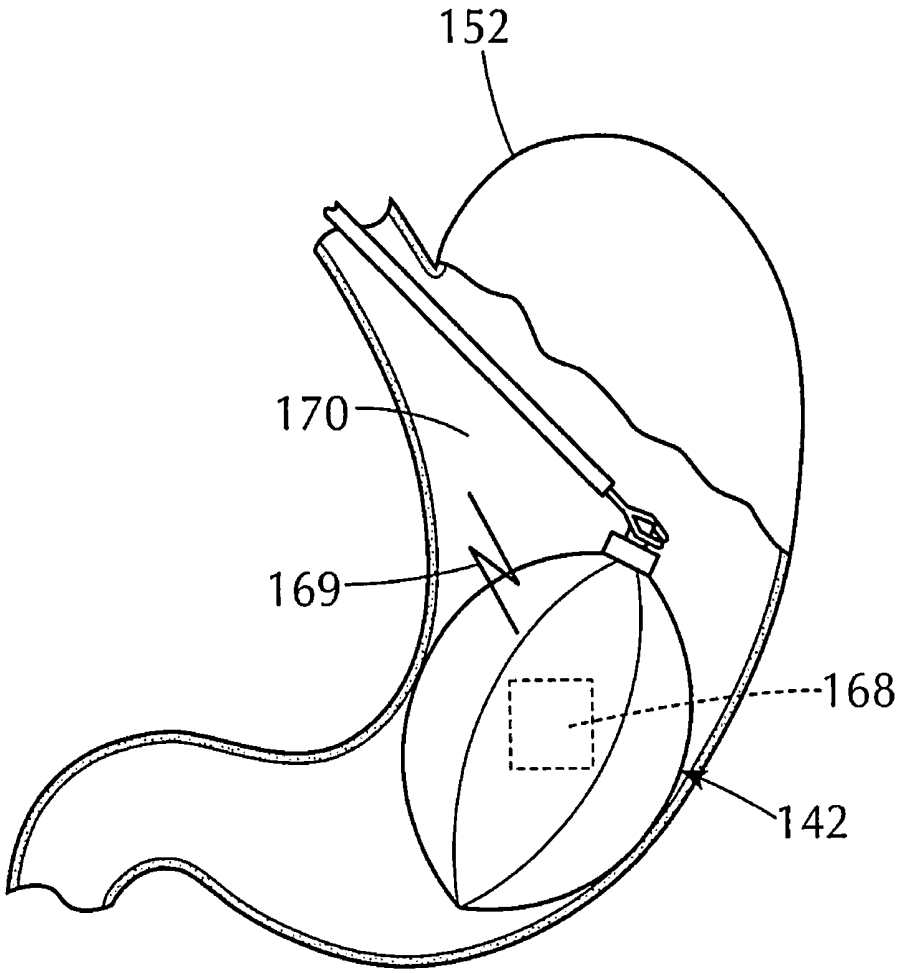


FIG. 7

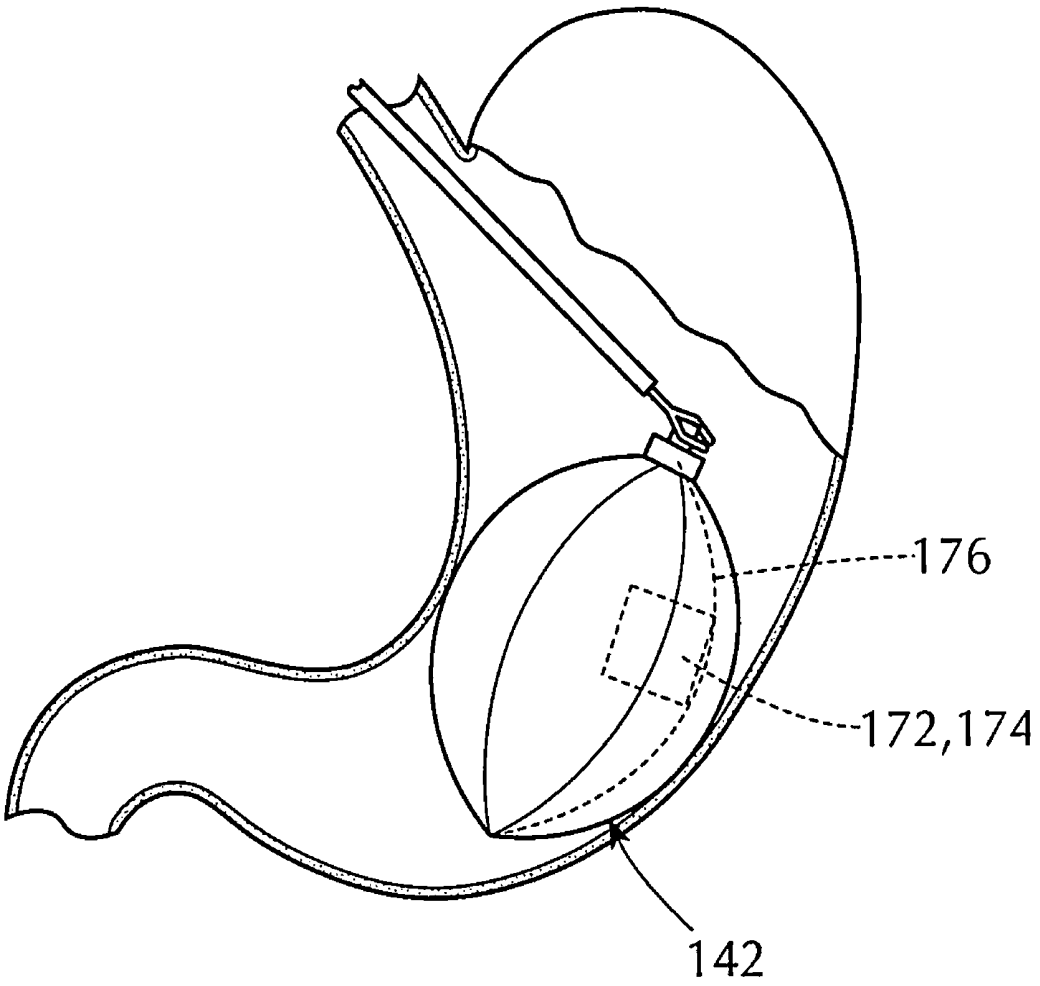


FIG. 8

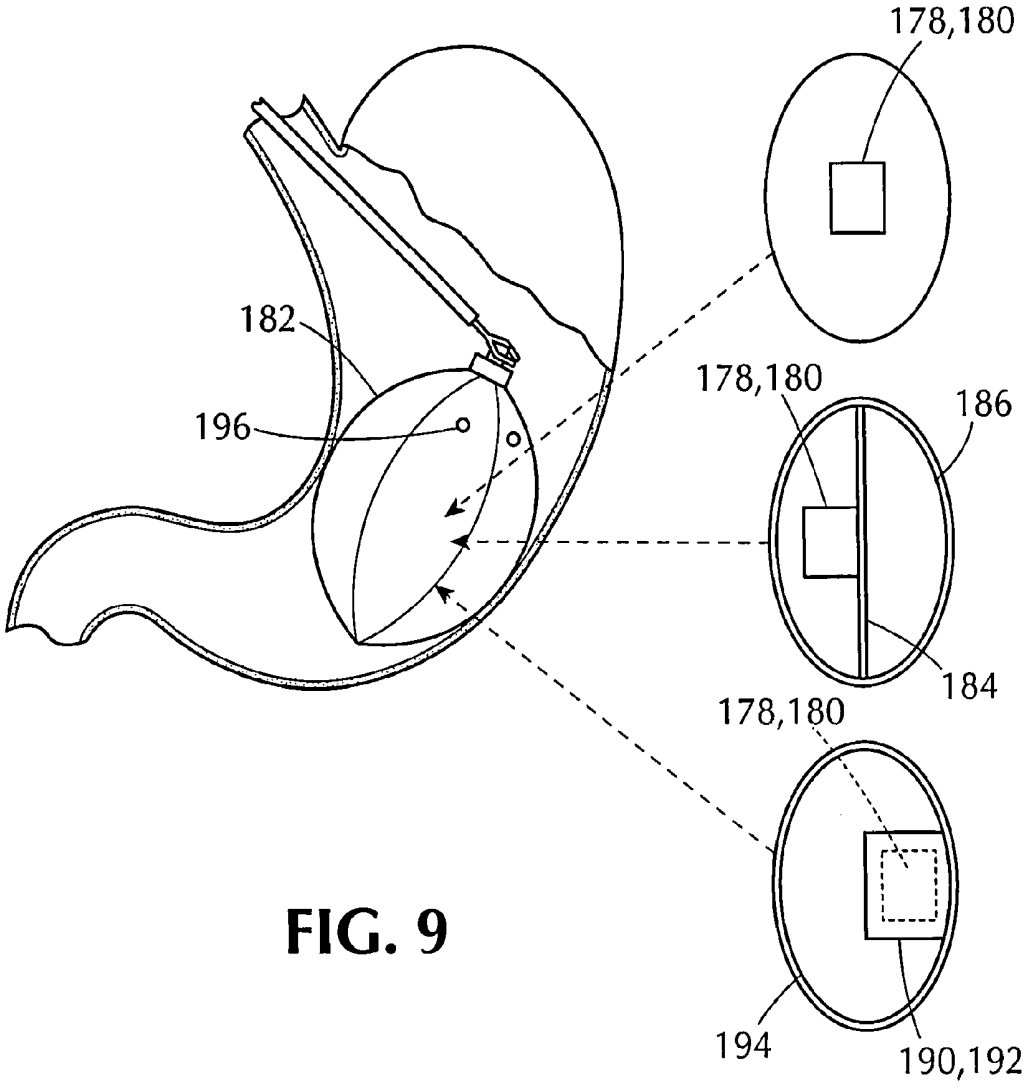


FIG. 9

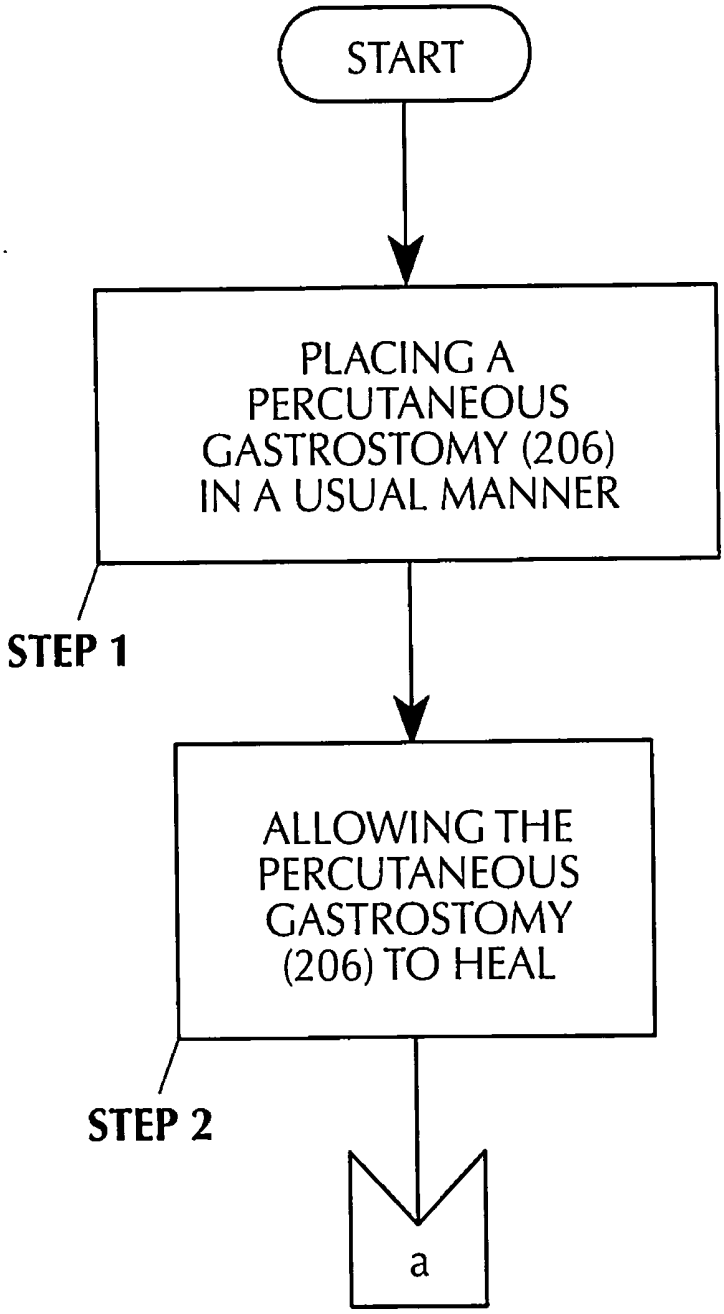

START
PLACING A PERCUTANEOUS GASTROSTOMY (206) IN A USUAL MANNER
STEP 1
ALLOWING THE PERCUTANEOUS GASTROSTOMY (206) TO HEAL
STEP 2
a

FIG. 10-A

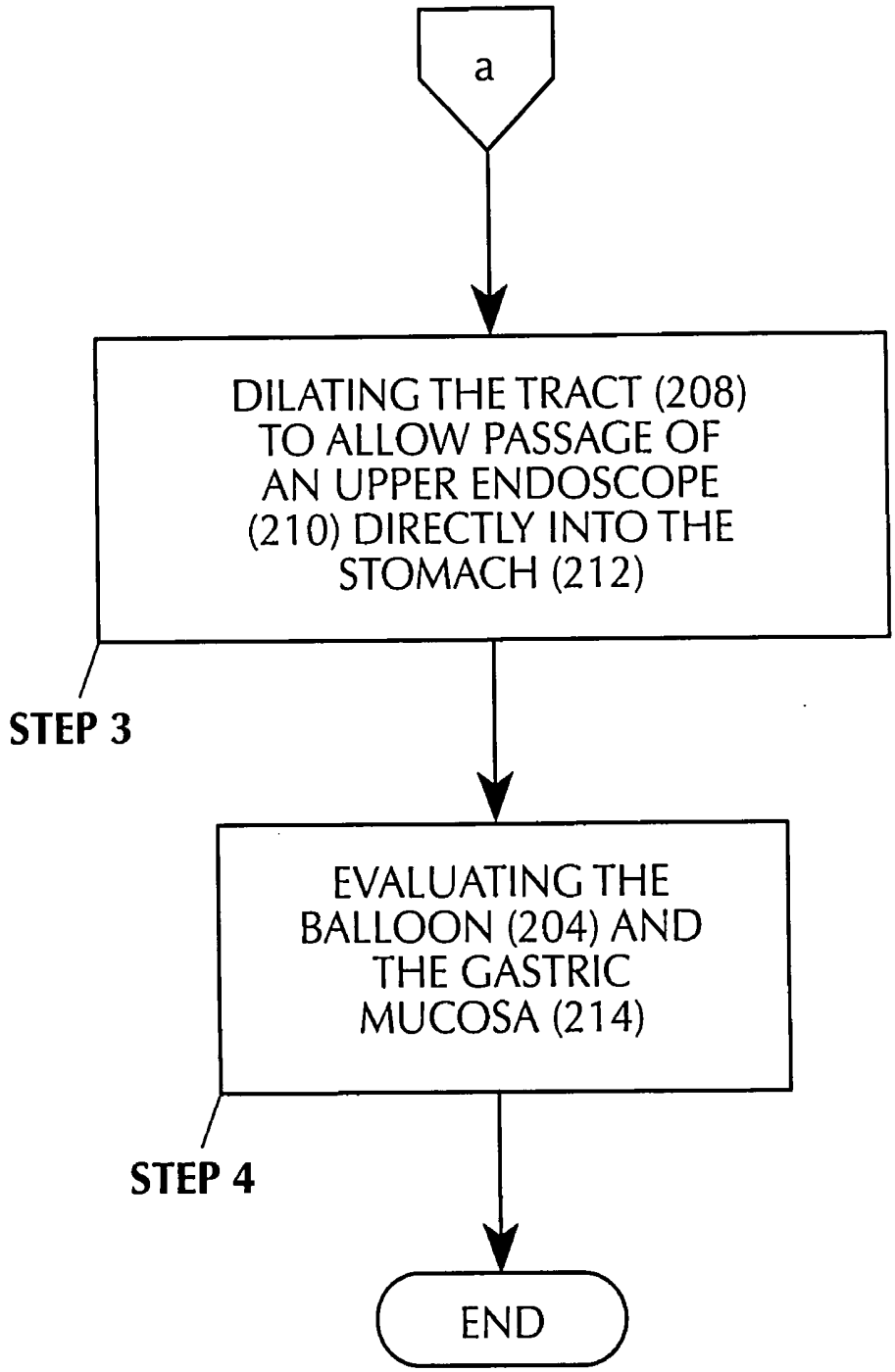

a
DILATING THE TRACT (208) TO ALLOW PASSAGE OF AN UPPER ENDOSCOPE (210) DIRECTLY INTO THE STOMACH (212)
STEP 3
EVALUATING THE BALLOON (204) AND THE GASTRIC MUCOSA (214)
STEP 4
END

FIG. 10-B

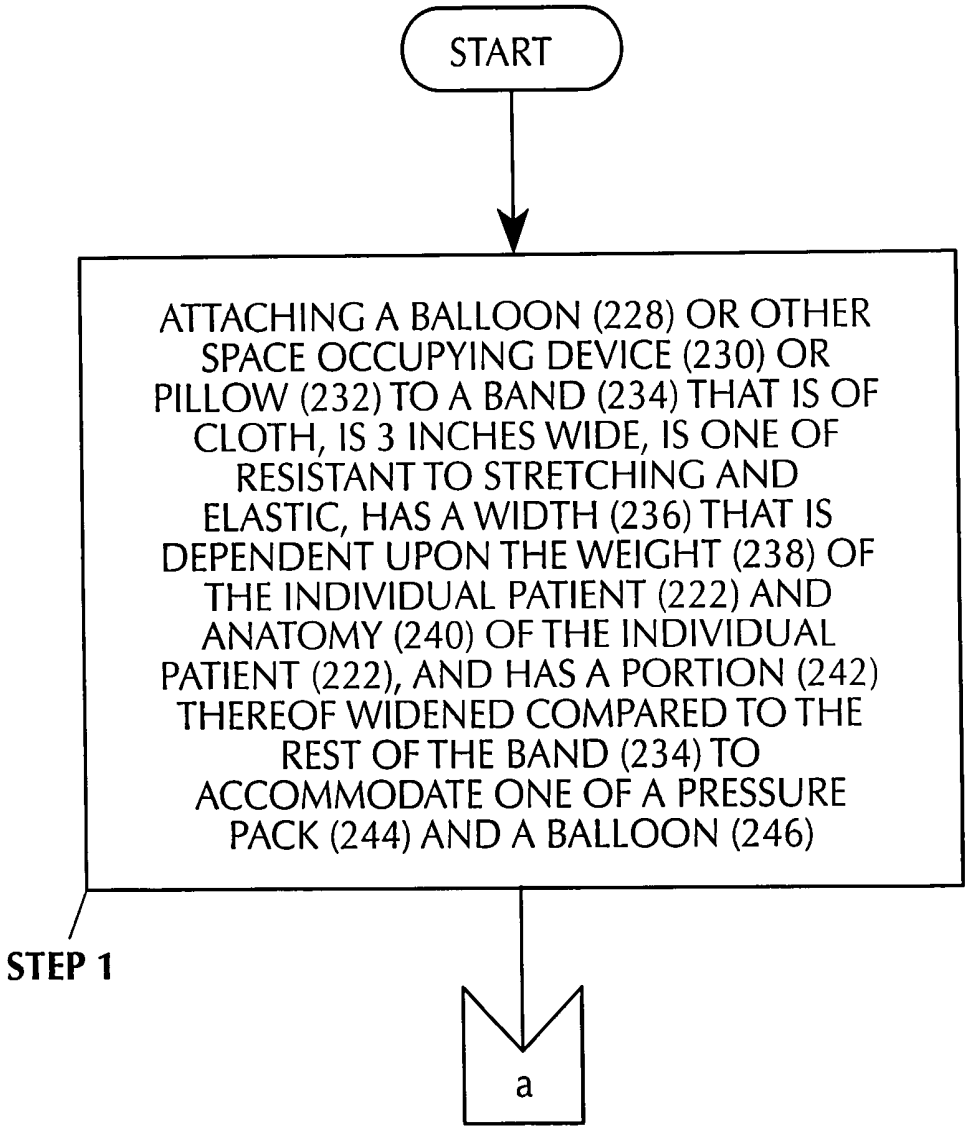

START
ATTACHING A BALLOON (228) OR OTHER SPACE OCCUPYING DEVICE (230) OR PILLOW (232) TO A BAND (234) THAT IS OF CLOTH, IS 3 INCHES WIDE, IS ONE OF RESISTANT TO STRETCHING AND ELASTIC, HAS A WIDTH (236) THAT IS DEPENDENT UPON THE WEIGHT (238) OF THE INDIVIDUAL PATIENT (222) AND ANATOMY (240) OF THE INDIVIDUAL PATIENT (222), AND HAS A PORTION (242) THEREOF WIDENED COMPARED TO THE REST OF THE BAND (234) TO ACCOMMODATE ONE OF A PRESSURE PACK (244) AND A BALLOON (246)
STEP 1
a

FIG. 11-A

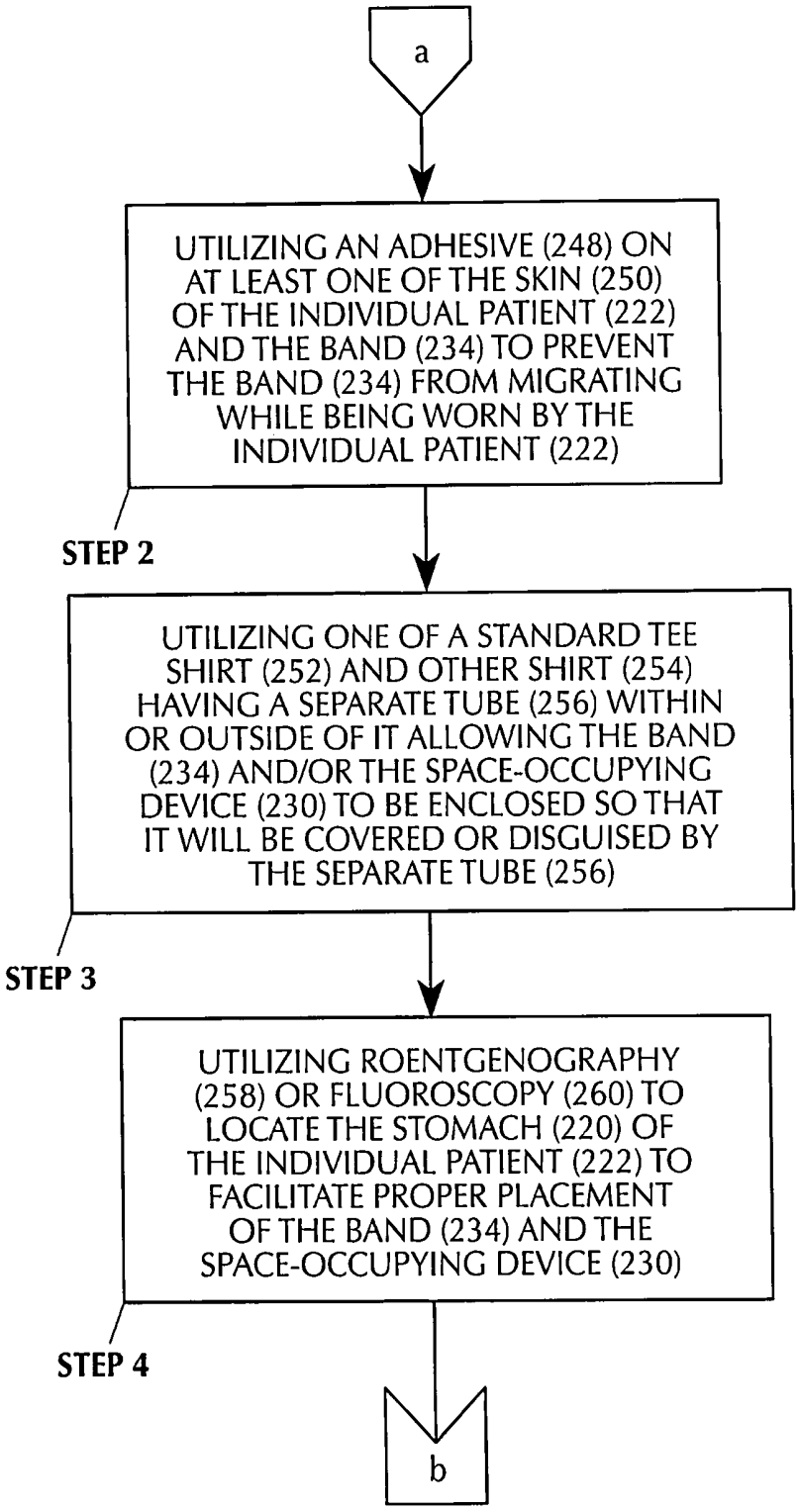

a
UTILIZING AN ADHESIVE (248) ON AT LEAST ONE OF THE SKIN (250) OF THE INDIVIDUAL PATIENT (222) AND THE BAND (234) TO PREVENT THE BAND (234) FROM MIGRATING WHILE BEING WORN BY THE INDIVIDUAL PATIENT (222)
STEP 2
UTILIZING ONE OF A STANDARD TEE SHIRT (252) AND OTHER SHIRT (254) HAVING A SEPARATE TUBE (256) WITHIN OR OUTSIDE OF IT ALLOWING THE BAND (234) AND/OR THE SPACE-OCCUPYING DEVICE (230) TO BE ENCLOSED SO THAT IT WILL BE COVERED OR DISGUISED BY THE SEPARATE TUBE (256)
STEP 3
UTILIZING ROENTGENOGRAPHY (258) OR FLUOROSCOPY (260) TO LOCATE THE STOMACH (220) OF THE INDIVIDUAL PATIENT (222) TO FACILITATE PROPER PLACEMENT OF THE BAND (234) AND THE SPACE-OCCUPYING DEVICE (230)
STEP 4
b

FIG. 11-B

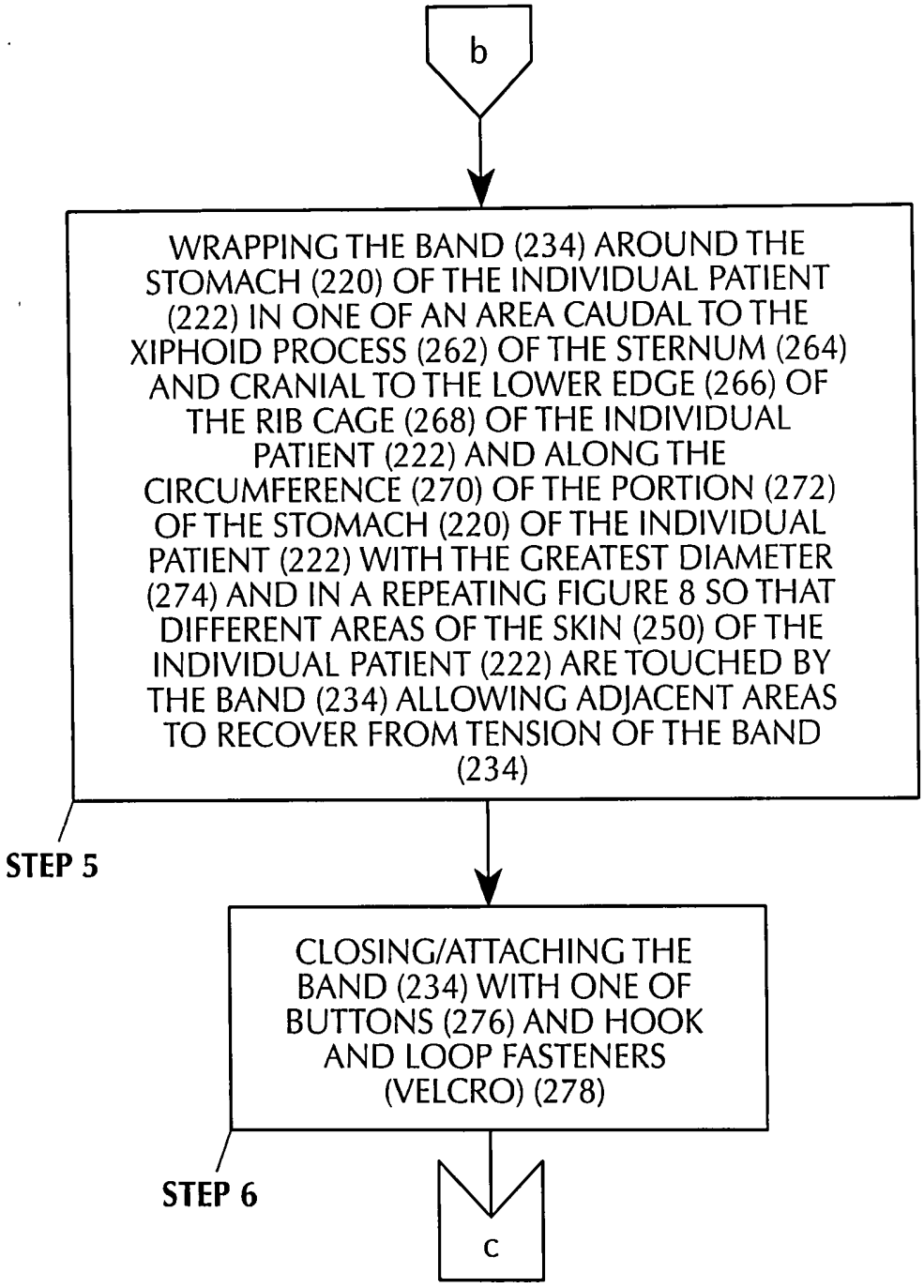

b
WRAPPING THE BAND (234) AROUND THE STOMACH (220) OF THE INDIVIDUAL PATIENT (222) IN ONE OF AN AREA CAUDAL TO THE XIPHOID PROCESS (262) OF THE STERNUM (264) AND CRANIAL TO THE LOWER EDGE (266) OF THE RIB CAGE (268) OF THE INDIVIDUAL PATIENT (222) AND ALONG THE CIRCUMFERENCE (270) OF THE PORTION (272) OF THE STOMACH (220) OF THE INDIVIDUAL PATIENT (222) WITH THE GREATEST DIAMETER (274) AND IN A REPEATING FIGURE 8 SO THAT DIFFERENT AREAS OF THE SKIN (250) OF THE INDIVIDUAL PATIENT (222) ARE TOUCHED BY THE BAND (234) ALLOWING ADJACENT AREAS TO RECOVER FROM TENSION OF THE BAND (234)
STEP 5
CLOSING/ATTACHING THE BAND (234) WITH ONE OF BUTTONS (276) AND HOOK AND LOOP FASTENERS (VELCRO) (278)
STEP 6
c

FIG. 11-C

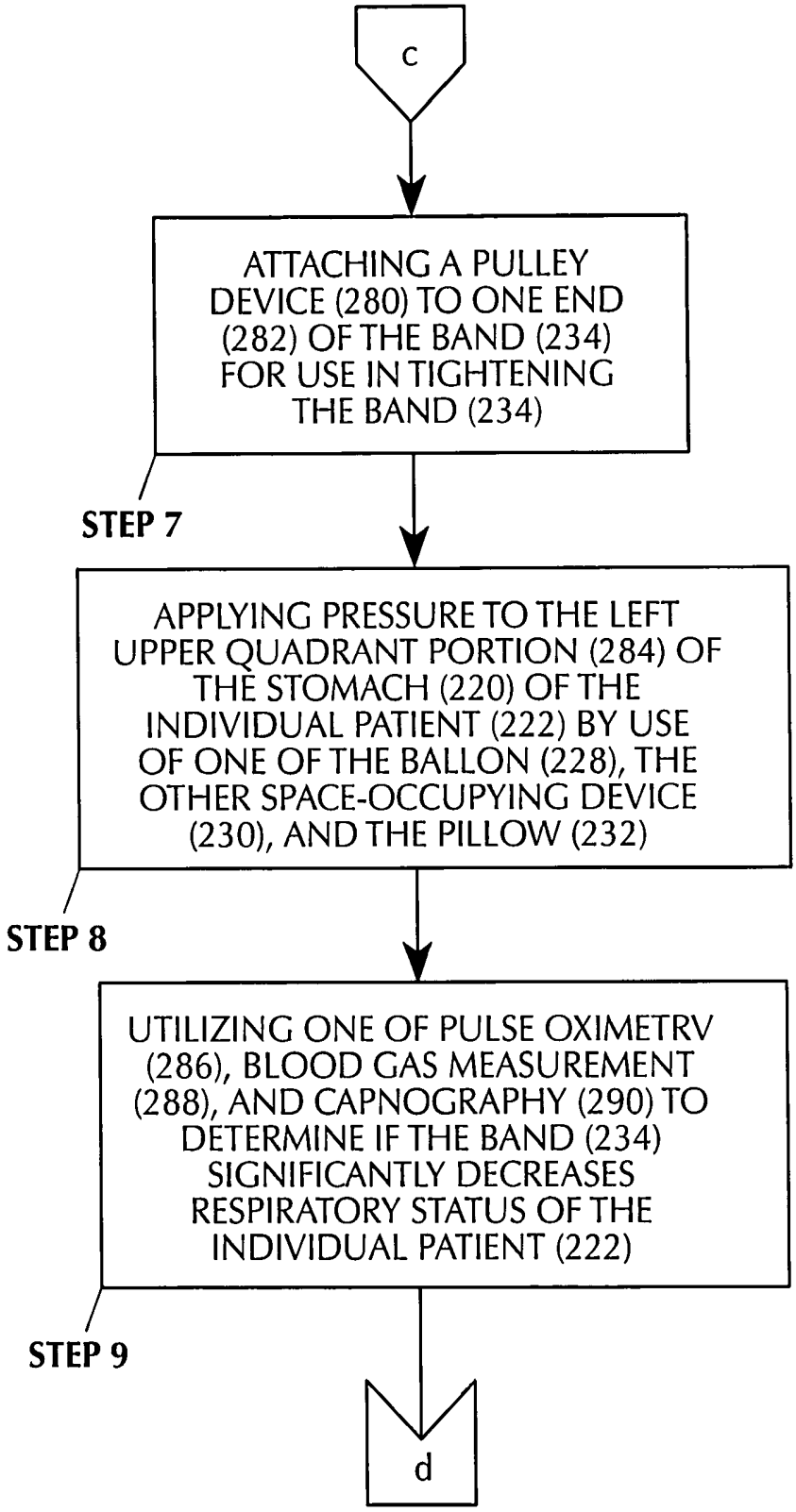

c
ATTACHING A PULLEY DEVICE (280) TO ONE END (282) OF THE BAND (234) FOR USE IN TIGHTENING THE BAND (234)
STEP 7
APPLYING PRESSURE TO THE LEFT UPPER QUADRANT PORTION (284) OF THE STOMACH (220) OF THE INDIVIDUAL PATIENT (222) BY USE OF ONE OF THE BALLON (228), THE OTHER SPACE-OCCUPYING DEVICE (230), AND THE PILLOW (232)
STEP 8
UTILIZING ONE OF PULSE OXIMETRV (286), BLOOD GAS MEASUREMENT (288), AND CAPNOGRAPHY (290) TO DETERMINE IF THE BAND (234) SIGNIFICANTLY DECREASES RESPIRATORY STATUS OF THE INDIVIDUAL PATIENT (222)
STEP 9
d

FIG. 11-D

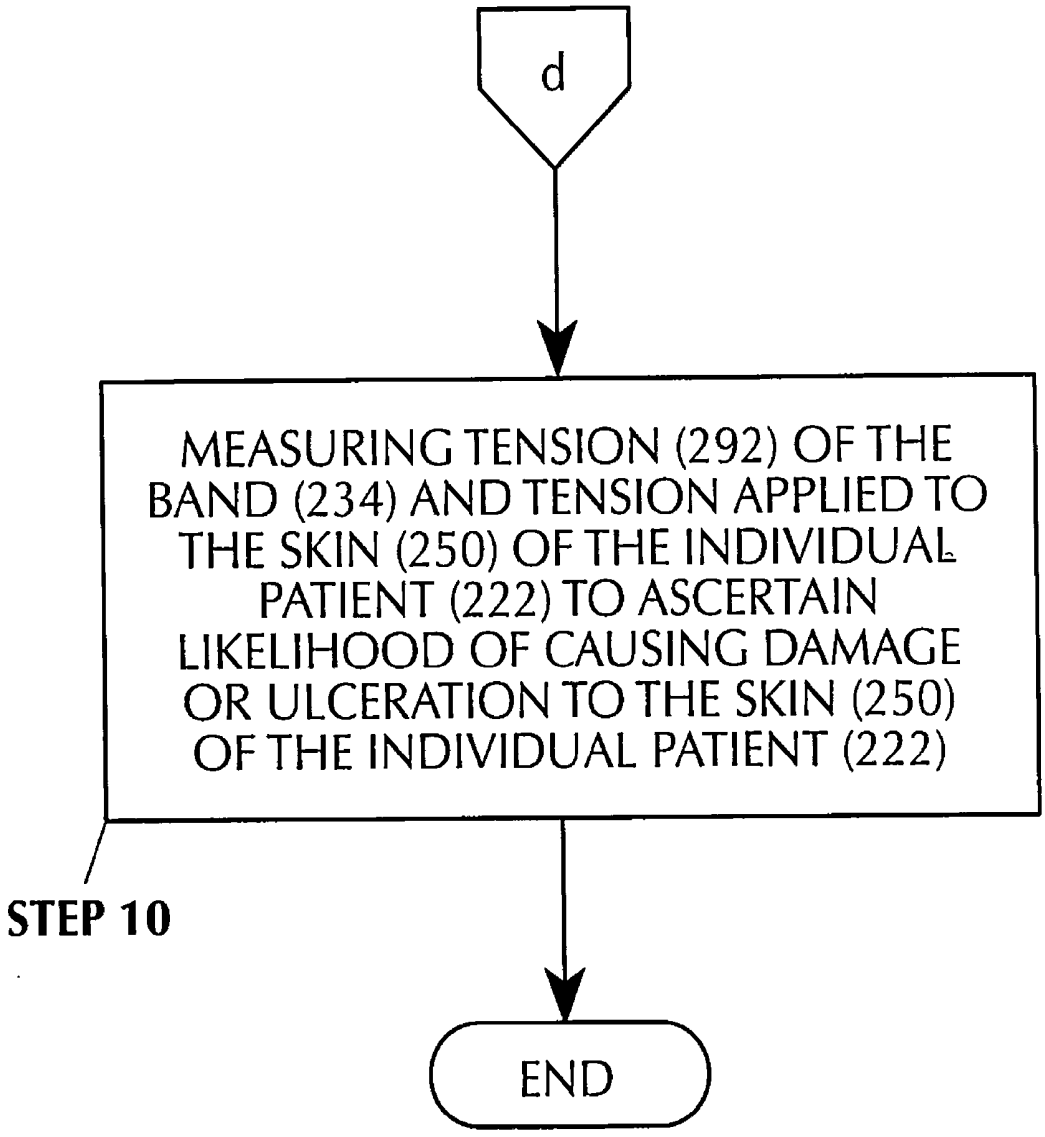

d
MEASURING TENSION (292) OF THE BAND (234) AND TENSION APPLIED TO THE SKIN (250) OF THE INDIVIDUAL PATIENT (222) TO ASCERTAIN LIKELIHOOD OF CAUSING DAMAGE OR ULCERATION TO THE SKIN (250) OF THE INDIVIDUAL PATIENT (222)
STEP 10
END

FIG. 11-E

MULTI-METHOD AND MULTI-APPARATUS FOR TREATING OBESITY

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. patent application Ser. No. 12/069,681, filed Feb. 12, 2008, entitled "Multi-method and multi-apparatus for treating obesity," and claims priority to U.S. provisional patent application Ser. No. 60/901,044, filed on Feb. 13, 2007, entitled "Methods for Treatment of Obesity," the disclosures of which are incorporated by reference herein in their entireties as if fully set forth herein.

BACKGROUND

[0002] 1. Field of the Invention

[0003] The embodiments of the present invention relate to a treatment for obesity, and more particularly, the embodiments of the present invention relate to a multi-method and multi-apparatus for treating obesity.

[0004] 2. Description of the Related Art

[0005] In the published medical literature, there are a significant number of patients who experience adverse gastrointestinal complaints in the period immediately after the deployment of an intragastric balloon. In this experience, all patients are treated with one specific model and size of balloon.

[0006] Thus, there exists a need for an intragastric balloon wherein both the geometry or shape of the balloon, as well as the volume of the balloon, are components that can be manipulated to enhance the therapeutic effect and to minimize complications.

[0007] In the published medical literature, intragastric balloons are placed in a deflated form and than inflated once in the stomach. The only material holding the balloons in their active shape is either air, liquid, or both. It is possible for these substances to leak out of the balloon causing the balloon to deflate and fail.

[0008] Thus, there exists a need for an intragastric balloons including a skeleton of metal struts that strengthen the balloon structure and prevent premature balloon failure, which could lead to a loss of therapeutic effect in obesity and can also lead to small bowel obstruction or gastric outlet obstruction.

[0009] In the published medical literature, intragastric balloons have been associated with the complication of irritation of the lining of the stomach (gastritis) and gastric ulceration. Considering the example of the intragastric balloon already patented by the instant inventors as U.S. Pat. No. 4,694,827, this complication was contemplated and a solution offered by using an intragastric balloon having protrusions and channels.

[0010] Non-compliance with therapeutic medications is a well known clinical problem interfering with good patient outcomes. Many different solutions have been attempted to deal with this problem, and to date, none have been completely satisfactory.

[0011] In the medical literature, damage to the lining of the stomach has been a major complication of intragastric balloon therapy. In many cases, severe damage, such as ulceration, may require removal of the balloon. Alternatively, there are many cases of patients with symptoms that might be related to the intragastric balloon, but might also be related to intercurrent viral illnesses, food poisoning, or milder complications of balloon therapy, not necessitating balloon extraction. In current practice, patients would undergo an upper endoscopy to assess the situation.

[0012] There are a multitude of methods purported to treat obesity in humans. Among the most effective of these methods are surgical techniques that alter the volume of the stomach available to receive food from the mouth and esophagus. The most popular of these surgical techniques is often referred to as a (Roux en Y) gastric bypass procedure. The gastric bypass is thought to work by limiting the amount of food that can be ingested at one time, although it may also alter gastrointestinal hormones and decrease the appetite.

[0013] Numerous innovations for inflatable medical devices have been provided in the prior art, which will be described below in chronological order to show advancement in the art, and which is incorporated herein by reference thereto. Even though these innovations may be suitable for the specific individual purposes to which they address, however, they differ from the present invention in that they do not teach a multi-method and multi-apparatus for treating obesity.

[0014] (1) U.S. Pat. No. 766,336 to Farrington.

[0015] U.S. Pat. No. 766,336 issued to Farrington on Aug. 2, 1904 teaches a device including a fluid-supply tube having a plurality of parallel slots and springs arranged within the tube and adapted to be partly projected through the slots. The springs have their inner ends secured to the tube. An adjustable member is secured to the outer ends of the springs. Elastic covers extend around that portion of the springs projecting through the slots.

[0016] (2) U.S. Pat. No. 797,676 to Flowers.

[0017] U.S. Pat. No. 797,676 issued to Flowers on Aug. 22, 1905 teaches a syringe including a nozzle having outlets and an expandable sack enveloping the nozzle, having outlets, and formed with longitudinal ribs stiffening and reinforcing the sack in the direction of its length and admitting of its diametrical expansion.

[0018] (3) U.S. Pat. No. 4,416,267 to Garren et al.

[0019] U.S. Pat. No. 4,416,267 issued to Garren et al. on Nov. 22, 1983 in class 128 and subclass 1 R teaches a stomach insert for treating obesity in humans by reducing the stomach volume, which includes a flexible torus-shaped inflatable balloon having a central opening extending therethrough. At least a portion of the balloon has a self-sealing substance to facilitate puncture thereof with a needle for inflating the balloon and sealing of the puncture upon removal of the needle. The method includes positioning the balloon inside the stomach of the person being treated for obesity so as to reduce the stomach volume.

[0020] (4) U.S. Pat. No. 4,694,827 to Weiner et al.

[0021] U.S. Pat. No. 4,694,827 issued to Weiner et al. on Sep. 22, 1987 in class 128 and subclass 303 R teaches generally, a balloon insertable and inflatable in the stomach to deter ingestion of food and having, when inflated, a plurality of smooth-surfaced convex protrusions disposed to permit engagement of the stomach wall by the balloon only at spaced localities for minimizing mechanical trauma of the stomach wall by the balloon.

[0022] Specifically, as shown in FIG. **1**, which is a diagrammatic side elevational view in partial section of a prior art balloon fully expanded within a stomach, a balloon **10** being flexible-walled, imperforate, air-inflatable, and insertable and inflatable within the stomach **12** of a human **14** or animal **16** to deter ingestion of food **18** by occupying a substantial

portion **20** of the volume **22** of the stomach **12** is taught. The balloon **10** has a plurality of wall portions **24** forming protrusions **26** that are smooth-surfaced, convex, and outward when inflated. The protrusions **26** are distributed around the balloon **10** and cooperatively define a plurality of channels **28** that are outwardly open for passage of fluent material **30** between the outer surface **32** of the balloon **10** and the wall **34** of the stomach **12**, and are shaped and disposed to permit engagement of the wall **34** of the stomach **12** by the balloon **10** only at spaced localities **36** so as to maintain a substantial portion **38** of the wall **34** of the stomach **12** away from contact with the balloon **10** for minimizing complications due to mechanical trauma of the balloon **10** against the wall **34** of the stomach **12**.

[0023] The protrusions **26** and the channels **28** minimize physical contact with the wall **34** of the stomach **12** and stimulate cytoprotection. Cytoprotection is an innate mechanism of preservation of the stomach **12** from adverse effects of a harsh environment of a gastric lumen.

[0024] It is apparent that numerous innovations for inflatable medical devices have been provided in the prior art that are adapted to be used. Furthermore, even though these innovations may be suitable for the specific individual purposes to which they address, however, they would not be suitable for the purposes of the embodiments of the present invention as heretofore described, namely, a multi-method and multi-apparatus for treating obesity.

SUMMARY

[0025] Thus, an object of the embodiments of the present invention is to provide a multi-method and multi-apparatus for treating obesity, which avoids the disadvantages of the prior art.

[0026] Briefly stated, another object of the embodiments of the present invention is to provide a multi-method and multi-apparatus for treating obesity. The multi-method includes a method for estimating a volume of an intragastric balloon appropriate for an individual patient, a method for using an enterocutaneous fistula to inspect an intragastric balloon without sedation and endoscopic complications associated with an upper endoscopy, and a method for decreasing ability of the stomach of an individual patient to distend or expand after a meal to increase satiety and help the individual patient to comply with a weight less diet. The multi-apparatus includes an intragastric balloon for inflating without installation of a pressurized gas or liquid, an intragastric balloon for minimizing trauma of the intragastric balloon on the gastric mucosa, and an intragastric balloon for administering therapeutic medications.

[0027] The novel features considered characteristic of the embodiments of the present invention are set forth in the appended claims. The embodiments of the present invention themselves, however, both as to their construction and their method of operation together with additional objects and advantages thereof will be best understood from the following description of the specific embodiments when read and understood in connection with the accompanying drawing.

BRIEF DESCRIPTION OF THE DRAWINGS

[0028] So the manner in which the above recited features of the present disclosure can be understood in detail, a more particular description of embodiments of the present disclosure, briefly summarized above, may be had by reference to embodiments, which are illustrated in the appended drawings. It is to be noted, however, the appended drawings illustrate only typical embodiments of embodiments encompassed within the scope of the present disclosure, and, therefore, are not to be considered limiting, for the present disclosure may admit to other equally effective embodiments, wherein:

[0029] FIG. **1** is a diagrammatic side elevational view in partial section of a prior art balloon fully expanded within a stomach;

[0030] FIGS. **2**A-**2**C are a flowchart of the method of an embodiment of the present invention for estimating volume of an intragastric balloon appropriate for an individual patient;

[0031] FIG. **3** is a diagrammatic side elevational view in partial section of a balloon of an embodiment of the present invention fully expanded within a stomach;

[0032] FIG. **4** is a diagrammatic side elevational view in partial section of a balloon of another embodiment of the present invention fully expanded within a stomach;

[0033] FIG. **5** is a diagrammatic side elevational view in partial section of a balloon of another embodiment of the present invention fully expanded within a stomach;

[0034] FIG. **6** is a diagrammatic side elevational view in partial section of a balloon of another embodiment of the present invention fully expanded within a stomach;

[0035] FIG. **7** is a diagrammatic side elevational view in partial section of a balloon of another embodiment of the present invention fully expanded within a stomach;

[0036] FIG. **8** is a diagrammatic side elevational view in partial section of a balloon of another embodiment of the present invention fully expanded within a stomach;

[0037] FIG. **9** is a diagrammatic side elevational view in partial section of a balloon of another embodiment of the present invention fully expanded within a stomach;

[0038] FIG. **10**A-**10**B are a flowchart of the method of another embodiment of the present invention for using an enterocutaneous fistula to inspect an intragastric balloon without sedation and endoscopic complications associated with an upper endoscopy; and

[0039] FIGS. **11**A-**11**E are a flowchart of the method of another embodiment of the present invention for decreasing ability of the stomach of an individual patient to distend or expand after a meal increasing satiety and helping the individual patient to comply with a weight loss diet.

[0040] The headings used herein are for organizational purposes only and are not meant to be used to limit the scope of the description or the claims. As used throughout this application, the word "may" is used in a permissive sense (i.e., meaning having the potential to), rather than the mandatory sense (i.e., meaning must). Similarly, the words "include", "including", and "includes" mean including but not limited to. To facilitate understanding, like reference numerals have been used, where possible, to designate like elements common to the figures.

LIST OF REFERENCE NUMERALS UTILIZED IN THE DRAWING

A. Prior Art

[0041] **10** balloon
[0042] **12** stomach of human **14** or animal **16**
[0043] **14** human
[0044] **16** animal

[0045] **18** food
[0046] **20** substantial portion of volume **22** of stomach **12**
[0047] **22** volume of stomach **12**
[0048] **24** plurality of wall portions
[0049] **26** protrusions
[0050] **28** plurality of channels
[0051] **30** fluent material
[0052] **32** outer surface of balloon **10**
[0053] **34** wall of stomach **12**
[0054] **36** spaced localities
[0055] **38** substantial portion of wall **34** of stomach **12**

B. Method of Embodiment of Present Invention for Estimating Volume of Intragastric Balloon Appropriate for Individual Patient

[0056] **40** method of embodiment of present invention for estimating volume **42** of intragastric balloon **44** appropriate for individual patient **46**
[0057] **42** volume of intragastric balloon **44** appropriate for individual patient **46**
[0058] **44** intragastric balloon appropriate for individual patient **46**
[0059] **46** individual patient
[0060] **48** water of material **62** ingested
[0061] **50** physician administering method **40**
[0062] **52** person administering method **40**
[0063] **54** specialized equipment
[0064] **56** electrogastrograph of specialized equipment **54**
[0065] **58** upper endoscope of specialized equipment **54**
[0066] **60** barostat balloon of specialized equipment **54**
[0067] **62** material ingested
[0068] **64** water solution suspension of material **62** ingested
[0069] **66** non-aqueous based material of material **62** ingested
[0070] **68** temperature
[0071] **70** room temperature of temperature **68**
[0072] **72** other temperature of temperature **68**
[0073] **74** 10 minutes time
[0074] **76** other interval of time

C. Intragastric Balloon for Inflating without Installation of Pressurized Gas or Liquid

[0075] **78** intragastric balloon
[0076] **80** plurality of struts
[0077] **82** skeleton of intragastric balloon **78**
[0078] **84** protrusions of intragastric balloon **78**
[0079] **86** channels of intragastric balloon **78**
[0080] **90** shape
[0081] **92** volume of intragastric balloon **78**
[0082] **100** valve of intragastric balloon **78**
[0083] **102** opening of intragastric balloon **78**
[0084] **106** gastric environment
[0085] **108** holes of plurality of struts **80**
[0086] **110** fastening points of plurality of struts **80**
[0087] **112** internal wires
[0088] **114** central longitudinal strut of plurality of struts **80**
[0089] **118** one end of central longitudinal strut **114** of plurality of struts **80**
[0090] **120** portion of central longitudinal strut **114** of plurality of struts **80**
[0091] **122** endoscopic device
[0092] **124** endoscopic forceps
[0093] **126** stomach
[0094] **132** grasping point
[0095] **134** two parallel layers of metals of plurality of struts **80**
[0096] **136** esophagus
[0097] **138** spring

D. Intragastric Balloon for Minimizing Trauma of Intragastric Balloon on Gastric

[0098] Mucosa
[0099] **140** plurality of protrusions
[0100] **142** balloon
[0101] **144** one of plurality of protrusions **140**
[0102] **145** opposite side of balloon **142**
[0103] **146** another one of plurality of protrusions **140**
[0104] **148** antral wall of stomach **152**
[0105] **150** proximal portion of stomach **152**
[0106] **152** stomach
[0107] **154** distal antrum of stomach **152**
[0108] **156** one tether
[0109] **158** long axis of central longitudinal strut **160** of plurality of struts **162**
[0110] **160** central longitudinal strut **160** of plurality of struts **162**
[0111] **162** plurality of struts
[0112] **164** ball and socket assembly
[0113] **168** electrical device
[0114] **169** electrical signals of electrical device **168**
[0115] **170** antrum of stomach **152**
[0116] **172** counterweight
[0117] **174** fixed counterweight of counterweight **172**
[0118] **176** plurality of struts of balloon **142**

E. Intragastric Balloon for Administering Therapeutic Medications

[0119] **178** therapeutic medication
[0120] **180** matrix of therapeutic medication **178**
[0121] **182** balloon
[0122] **184** one of struts **186** of balloon **182**
[0123] **186** struts of balloon **182**
[0124] **190** pocket
[0125] **192** attachment in wall **194** of balloon **188**
[0126] **196** holes of balloon **182**
[0127] **198** gastric contents

F. Method for Using Enterocutaneous Fistula to Inspect Intragastric Balloon without Sedation and Endoscopic Complications Associated with Upper Endoscopy

[0128] **200** method of embodiment of present invention for using enterocutaneous fistula **202** to inspect intragastric balloon **204** without sedation and endoscopic complications associated with upper endoscopy
[0129] **202** enterocutaneous fistula
[0130] **204** intragastric balloon
[0131] **206** percutaneous gastrostomy
[0132] **208** tract
[0133] **210** upper endoscope
[0134] **212** stomach
[0135] **214** gastric mucosa

G. Method for Restricting Expansion of Stomach for Individual Patient

[0136] **218** method of embodiment of present invention for decreasing ability of stomach **220** of individual patient **222** to distend or expand after meal **224** increasing satiety and helping individual patient **222** to comply with weight loss diet **226**

[0137] **220** stomach of individual patient **222**
[0138] **222** individual patient
[0139] **224** meal
[0140] **226** weight less diet
[0141] **228** balloon
[0142] **230** other space occupying device
[0143] **232** pillow
[0144] **234** band
[0145] **236** width of band **234**
[0146] **238** weight of individual patient **222**
[0147] **240** anatomy of individual patient **222**
[0148] **242** portion of band **234**
[0149] **244** pressure pack
[0150] **246** balloon
[0151] **248** adhesive
[0152] **250** skin of individual patient **222**
[0153] **252** standard tee shirt
[0154] **254** other shirt
[0155] **256** separate tube
[0156] **258** roentgenography
[0157] **260** fluoroscopy
[0158] **262** xiphoid process of sternum **264** of individual patient **222**
[0159] **264** sternum of individual patient **222**
[0160] **266** lower edge of rib cage **268** of individual patient **222**
[0161] **268** rib cage of individual patient **222**
[0162] **270** circumference of portion **272** of stomach **220** of individual patient **222**
[0163] **272** portion of stomach **220** of individual patient **222**
[0164] **274** greatest diameter
[0165] **276** buttons
[0166] **278** hook and loop fasteners
[0167] **280** pulley device
[0168] **282** one end of band **234**
[0169] **284** left upper quadrant portion of stomach **220** of individual patient **222**
[0170] **286** pulse oximetry
[0171] **288** blood gas measurement
[0172] **290** capnography
[0173] **292** tension of band **234**

DETAILED DESCRIPTION

A. A Method for Estimating Volume of an Intragastric Balloon Appropriate for an Individual Patient

[0174] Referring now to the figures, in which like numerals indicate like parts, and particularly to FIGS. **2**A-**2**C, which are a flowchart of the method of an embodiment of the present invention for estimating volume of an intragastric balloon appropriate for an individual patient, the method of an embodiment of the present invention is shown generally at **40** for estimating volume **42** of an intragastric balloon **44** appropriate for an individual patient **46**, and comprises the steps of:
[0175] STEP **1**: Drinking by the individual patient **46** who is a candidate for the intragastric balloon **44** as much water **48** as possible over a 10 minute period of time.
[0176] STEP **2**: Monitoring volume of the water **48** ingested.
[0177] STEP **3**: Advising by the individual patient **46** to a physician **50** or person **52** administering the method **40** when the individual patient **46** feels uncomfortably bloated or alternatively, if the individual patient **46** vomits, the volume of the water **48** ingested will be determined.
[0178] STEP **4**: Selecting for the individual patient **46** the intragastric balloon **44** that is a fraction of the volume leading to uncomfortable symptoms, with the volume of the intragastric balloon **44** being 75% of the ingested volume of water **48**.
[0179] STEP **5**: Monitoring the individual patient **46** with specialized equipment **54** during ingestion, as with, but not limited to, an electrogastrograph **56**, an upper endoscope **58**, or a barostat balloon **60**.
[0180] STEP **6**: Challenging over time, the individual patient **46** with the intragastric balloon **44** with another load of water **48** as in STEP **1** above to see if the individual patient **46** can tolerate a larger intragastric balloon **44** because it is anticipated that a larger intragastric balloon **44** might be expected to have a greater therapeutic effect in the management of obesity and satiety symptoms.
[0181] In the above embodiment, the water **48** is specified as material **62** ingested. The water **48** is only mentioned as a preferred example. The material **62** ingested may be a water solution suspension **64**, or other non-aqueous based material **66**. Temperature **68** is implied as room temperature **70**, but may be some other temperature **72**. Time **74** is specified as 10 minutes, but may be some other interval of time **76**.

B. An Intragastric Balloon for Inflating without Installation of a Pressurized Gas or Liquid

[0182] As shown in FIG. **3**, which is a diagrammatic side elevational view in partial section of a balloon of an embodiment of the present invention fully expanded within a stomach, an intragastric balloon **78** comprises a plurality of struts **80**. The plurality of struts **80** form a skeleton **82** of the intragastric balloon **78**, run longitudinally, are parallel to protrusions **84** and channels **86** of the intragastric balloon **78**, are fabricated out of a metal or a composite with a memory for its shape **90**, such as nitinol, and are shaped so that when released, they expand to fill out volume **92** of the intragastric balloon **78**, with this shape being the shape that would otherwise be created if the intragastric balloon **78** was inflated with air, water, or both.
[0183] The intragastric balloon **78** further comprises a valve **100** or opening **102** to allow air and gastric fluid into the intragastric balloon **78** as the intragastric balloon **78** is expanded in the gastric environment **106**.
[0184] In one embodiment, the plurality of struts **80** have holes **108** or other fastening points **110** midway. These fastening points **110** are connected by internal wires **112** to a central longitudinal strut **114** of the plurality of struts **80** running straight and longitudinally through the length of the balloon **78**. One end **118** or portion **120** of this central longitudinal strut **114** of the plurality of struts **80** is accessible by an endoscopic device **122**.
[0185] In another embodiment, with the balloon **78** held steadily in position with an endoscopic forceps **124** or an Ewald tube, an instrument can grasp the end **118** of the central longitudinal strut **114** of the plurality of struts **80** and pull it. This would collapse the balloon **78**, allowing it to be removed from the stomach **126** in its collapsed state.
[0186] In another embodiment, there is a shelf or ledge that allows the balloon **78** to be stabilized against a standard **36** French Ewald tube to facilitate traction on the central longitudinal strut **114** of the plurality of struts **80**.
[0187] In another embodiment, there would be a grasping point **132** for the endoscopic forceps **124** to grasp and stabilize the balloon **78** for removal from the stomach **126**.

[0188] In another embodiment, the plurality of struts **80** obtain their curved shapes by being configured of two parallel layers of metals **134** with different coefficients of thermal expansion. In this embodiment, the balloon **78** is chilled with ice before its deployment though the esophagus **136** into the stomach **126**. At body temperature, the plurality of struts **80** expand to their designed shapes. On removal, the stomach **126** is lavaged with ice water to allow the plurality of struts **80** of the balloon **78** to shrink.

[0189] In another embodiment, the central longitudinal strut **114** of the plurality of struts **80** is a spring **138**. The spring **138** is stretched when the balloon **78** is collapsed and ready to deploy in the stomach **126**. When released in the stomach **126**, the spring **138** retracts to its non-stretched length, expanding the balloon **78**. The spring **138** gives the balloon **78** more resilience, almost like a shock absorber, in the gastric environment **106**.

C. An Intragastric Balloon for Minimizing Trauma of the Intragastric Balloon on the Gastric Mucosa

[0190] As shown in FIG. **4**, which is a diagrammatic side elevational view in partial section of a balloon of another embodiment of the present invention fully expanded within a stomach, the plurality of protrusions **140** of the balloon **142** run diagonally rather than longitudinally.

[0191] As shown in FIG. **5**, which is a diagrammatic side elevational view in partial section of a balloon of another embodiment of the present invention fully expanded within a stomach, in another embodiment, one **144** of the plurality of protrusions **140** is made more prominent. On an opposite side **145** of the balloon **142**, another one **146** of the plurality of protrusions **140** is made less prominent. When a gastric peristaltic wave passes over the balloon **142**, more pressure is placed on the one **144** of the plurality of protrusions **140** that is more prominent and less on the one **146** of the plurality of protrusions **140** that is less prominent. As the balloon **142** impacts the antral wall **148** distally, there is a tendency for the balloon **142** to rotate along its long axis, which is repeated with every peristaltic wave, so that different points are presented to the gastric mucosa.

[0192] As shown in FIG. **6**, which is a diagrammatic side elevational view in partial section of a balloon of another embodiment of the present invention fully expanded within a stomach, in another embodiment, the balloon **142** is tethered by at least one tether **156** to a proximal portion **150** of the stomach **152** to prevent forward migration of the balloon **142** to impact in the distal antrum **154**. With the one tether **156** attached to long axis **158** of the central longitudinal strut **160** of the plurality of struts **162**, the balloon **142** is able to rotate freely with a ball and socket assembly **164**. With the at least one tether **156** attached to the balloon **142**, the balloon **142** twists on the at least one tether **156** and then is forced to turn backwards due to tension on the at least one tether **156**. The at least one tether **156** is attached to the balloon **142** and the proximal portion **150** of the stomach **152** to maximize stimulation of this area to maximize effects of ghrelin or other digestive hormones associated with the stomach **152**.

[0193] As shown in FIG. **7**, which is a diagrammatic side elevational view in partial section of a balloon of another embodiment of the present invention fully expanded within a stomach, in another embodiment, an electrical device **168** is incorporated into the balloon **142** to provide electrical signals **169** to the antrum **170** of the stomach **152** to maximize stimulating effects of ghrelin and other digestive hormones.

[0194] As shown in FIG. **8**, which is a diagrammatic side elevational view in partial section of a balloon of another embodiment of the present invention fully expanded within a stomach, in another embodiment, a counterweight **172** is built into the balloon **142** to accentuate eccentricity of the balloon **142** and allow it to spin. This can be a fixed counterweight **174** or attached to the plurality of struts **176** of the balloon **142**.

D. An Intragastric Balloon for Administering Therapeutic Medications

[0195] As shown in FIG. **9**, which is a diagrammatic side elevational view in partial section of a balloon of another embodiment of the present invention fully expanded within a stomach, a therapeutic medication **178** is placed in a matrix **180** that is slowly dissolving and inert. This matrix **180** is deployed loosely in the balloon **182** or fabricated to attach to one **184** of the struts **186** of the balloon **182** or inside a pocket **190** or attachment **192** in the wall **194** of the balloon **182**.

[0196] The balloon **182** is fabricated with holes **196** to freely allow the gastric contents **198** to enter the balloon **182**. The matrix **180** slowly dissolves, thereby releasing the therapeutic medication **178**.

E. A Method for Using an Enterocutaneous Fistula to Inspect an Intragastric Balloon without Sedation and Endoscopic Complications Associated with Upper Endoscopy

[0197] As shown in FIGS. **10**A-**10**B, which are a flowchart of the method of another embodiment of the present invention for using an enterocutaneous fistula to inspect an intragastric balloon without sedation and endoscopic complications associated with an upper endoscopy, the method of the embodiment of the present invention is shown generally at **200** for using an enterocutaneous fistula **202** to inspect an intragastric balloon **204** without sedation and endoscopic complications associated with an upper endoscopy, and comprises the steps of:

[0198] STEP **1**: Placing a percutaneous gastrostomy **206** in a usual manner.

[0199] STEP **2**: Allowing the percutaneous gastrostomy **206** to heal.

[0200] STEP **3**: Dilating the tract **208** to allow passage of an upper endoscope **210** directly into the stomach **212**.

[0201] STEP **4**: Evaluating the balloon **204** and the gastric mucosa **214**.

F. A Method for Restricting Expansion of the Stomach for an Individual Patient

[0202] As shown in FIGS. **11**A-**11**E, which are a flowchart of the method of another embodiments of the present invention for restricting expansion of the stomach for an individual patient, the method of the embodiment of the present invention is shown generally at **218** for decreasing ability of the stomach **220** of an individual patient **222** to distend or expand after a meal **224** increasing satiety and helping the individual patient **222** to comply with a weight loss diet **226**, and comprises the steps of:

[0203] STEP **1**: Attaching a balloon **228** or other space occupying device **230** or pillow **232** to a band **234** that is of cloth, is 3 inches wide, is one of resistant to stretching and elastic, has a width **236** that is dependent upon the weight **238** of the individual patient **222** and anatomy **240** of the individual patient **222**, and has a portion **242** thereof widened compared to the rest of the band **234** to accommodate one of a pressure pack **244** and a balloon **246**.

[0204] STEP **2**: Utilizing an adhesive **248** on at least one of the skin **250** of the individual patient **222** and the band **234** to prevent the band **234** from migrating while being worn by the individual patient **222**.

[0205] STEP **3**: Utilizing one of a standard tee shirt **252** and other shirt **254** having a separate tube **256** within or outside of it allowing the band **234** and/or the space-occupying device **230** to be enclosed so that it will be covered or disguised by the separate tube **256**.

[0206] STEP **4**: Utilizing roentgenography **258** or fluoroscopy **260** to locate the stomach **220** of the individual patient **222** to facilitate proper placement of the band **234** and the space-occupying device **230**.

[0207] STEP **5**: Wrapping the band **234** around the stomach **220** of the individual patient **222** in one of an area caudal to the xiphoid process **262** of the sternum **264** and cranial to the lower edge **266** of the rib cage **268** of the individual patient **222** and along the circumference **270** of the portion **272** of the stomach **220** of the individual patient **222** with the greatest diameter **274** and in a repeating FIG. **8** so that different areas of the skin **250** of the individual patient **222** are touched by the band **234** allowing adjacent areas to recover from tension of the band **234**.

[0208] STEP **6**: Closing/attaching the band **234** with one of buttons **276** and hook and loop fasteners (VELCRO®) **278**.

[0209] STEP **7**: Attaching a pulley device **280** to one end **282** of the band **234** for use in tightening the band **234**.

[0210] STEP **8**: Applying pressure to the left upper quadrant portion **284** of the stomach **220** of the individual patient **222** by use of one of the balloon **228**, the other space-occupying device **230**, and the pillow **232**.

[0211] STEP **9**: Utilizing one of pulse oximetry **286**, blood gas measurement **288**, and capnography **290** to determine if the band **234** significantly decreases respiratory status of the individual patient **222**.

[0212] STEP **10**: Measuring tension **292** of the band **234** and tension applied to the skin **250** of the individual patient **222** to ascertain likelihood of causing damage or ulceration to the skin **250** of the individual patient **222**.

[0213] In another embodiment, outside appearance of the shirt **254** appears normal to an observer, with the band **234** held in place by the cloth tube **256**. The cloth tube **256** is of such a volume that when the band **234** is activated, there would be sufficient space to allow the shirt **254** to hang freely.

[0214] In another embodiment, the band **234** is incorporated into the tee shirt **252** in such a way that it is obvious to a casual observer creating an obvious constriction.

[0215] In another embodiment, a device with the appearance of standard suspenders is attached to an adjustable belt around the waist of the individual patient **222** to hold the band **234** in a proper position as with one of hook and loop fasteners (Velcro), buttons, and snap devices.

G. The Conclusions

[0216] It will be understood that each of the elements described above or two or more together may also find a useful application in other types of constructions differing from the types described above.

[0217] While the embodiments of the present invention have been illustrated and described as embodied in a multi-method and multi-apparatus for treating obesity, however, they are not limited to the details shown, since it will be understood that various omissions, modifications, substitutions, and changes in the forms and details of the embodiments of the present invention illustrated and their operation can be made by those skilled in the art without departing in any way from the spirit of the embodiments of the present invention.

[0218] Without further analysis the foregoing will so fully reveal the gist of the embodiments of the present invention that others can by applying current knowledge readily adapt them for various applications without omitting features that from the standpoint of prior art fairly constitute characteristics of the generic or specific aspects of the embodiments of the present invention.

[0219] It should be emphasized that the above-described embodiments of the present disclosure are merely possible examples of implementations, merely set forth for a clear understanding of the principles of the disclosure. Many variations and modifications may be made to the above-described embodiment(s) of the disclosure without departing substantially from the spirit and principles of the disclosure. All such modifications and variations are intended to be included herein within the scope of this disclosure and the present disclosure and protected by the following claims.

[0220] While the foregoing is directed to embodiments of the present invention, other and further embodiments of the invention may be devised without departing from the basic scope thereof. For example, although numerous embodiments having various features have been described herein, combinations of such various features in other combinations not discussed herein are contemplated within the scope of embodiments of the present invention.

What is claimed is:

1. A method for estimating volume of an intragastric balloon appropriate for an individual patient, the method comprising:

drinking by the individual patient, who is a candidate for the intragastric balloon, as much of a fluid as possible over a given period of time;

monitoring volume of the fluid ingested;

advising, by the individual patient, to a physician or person administering the method when the individual patient feels uncomfortably bloated or if the individual patient vomits so that the volume of the fluid ingested is determined;

selecting for the individual patient the intragastric balloon that is a fraction of the volume leading to uncomfortable symptoms; and

monitoring the individual patient with specialized equipment during ingestion.

2. The method of claim **1**, wherein the drinking step includes drinking by the individual patient, who is a candidate for the intragastric balloon, as much fluid as possible over a 10 minute period of time.

3. The method of claim **1**, wherein the selecting step includes selecting for the individual patient the intragastric balloon that is 75% of the ingested volume of fluid.

4. The method of claim **1**, wherein the monitoring step includes monitoring the individual patient with one of an electrogastrograph, an upper endoscope, and a barostat balloon.

5. The method of claim **1**, further comprising the step of challenging over time the individual patient with the intragastric balloon with another load of the fluid to see if the individual patient can tolerate a larger intragastric balloon because a larger intragastric balloon has greater therapeutic effect in management of obesity and satiety symptoms.

6. The method of claim 1, wherein the drinking step includes drinking by the individual patient, who is a candidate for the intragastric balloon, as much of a fluid that is selected from the group consisting of water, a water solution suspension and a non-aqueous based material as possible over a given period of time.

7. The method of claim 1, wherein the selecting step includes selecting for the individual patient the intragastric balloon that will be a fraction of the volume leading to uncomfortable symptoms at room temperature.

8. A method for using an enterocutaneous fistula to inspect an intragastric balloon without sedation and endoscopic complications associated with an upper endoscopy, comprising:

placing a percutaneous gastrostomy in a usual manner;

allowing the percutaneous gastrostomy to heal;

dilating the tract to allow passage of an upper endoscope directly into the stomach; and

evaluating the balloon and the gastric mucosa.

9. A method for decreasing ability of the stomach of an individual patient to distend or expand after a meal to increase satiety and help the individual patient to comply with a weight loss diet, comprising:

locating the stomach of the individual patient to facilitate proper placement of a band;

wrapping the band around the stomach of the individual patient; and

closing/attaching the band to apply pressure to the stomach of the individual patient, thereby decreasing the ability of the stomach of the individual patient to distend or expand after the meal, thereby increasing the satiety and helping the individual patient to comply with the weight loss diet.

10. The method of claim 9, wherein the locating step includes locating the stomach of the individual patient to facilitate proper placement of a band by utilizing one of roentgenography and fluoroscopy.

11. The method of claim 9, wherein the wrapping step includes wrapping the band around the stomach of the individual patient in one of an area caudal to the xiphoid process of the sternum and cranial to the lower edge of the rib cage of the individual patient and along the circumference of the portion of the stomach of the individual patient.

12. The method of claim 9, wherein the closing/attaching step includes closing/attaching the band with one of buttons and hook and loop fasteners.

13. The method of claim 9, further comprising the step of attaching a pulley device to one end of the band to tighten the band.

14. The method of claim 9, wherein the closing/attaching step includes closing/attaching the band to apply pressure to the stomach of the individual patient at the left upper quadrant portion of the stomach of the individual patient by use of one of the balloon, other space-occupying device, and the pillow.

15. The method of claim 9, further comprising the step of utilizing one of pulse oximetry, blood gas measurement, and capnography to determine if the band significantly decreases respiratory status of the individual patient.

16. The method of claim 9, further comprising the step of measuring tension of the band and tension applied to skin of the individual patient to ascertain likelihood of causing damage or ulceration to the skin of the individual patient.

17. The method of claim 9, further comprising the step of attaching one of a balloon, another space occupying device, and a pillow to the band.

18. The method of claim 17, wherein the locating step includes locating the stomach of the individual patient to facilitate proper placement of a band that is of cloth, is 3 inches wide, is one of resistant to stretching and elastic, has a width that is dependent upon weight of the individual patient and anatomy of the individual patient, and has a portion thereof widened compared to the rest of the band to accommodate one of the balloon, the another space occupying device, and the pillow.

19. The method of claim 9, further comprising the step of utilizing an adhesive on at least one of the skin of the individual patient and the band to prevent the band from migrating while being worn by the individual patient.

20. The method of claim 9, further comprising the step of attaching a device with an appearance of standard suspenders to an adjustable belt around the waist of the individual patient to hold the band in a proper position by one of hook and loop fasteners, buttons, and snap devices.

* * * * *

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外部链接	Espacenet USPTO		

摘要(译)

一种治疗肥胖症的多方法和多器械。该多方法包括用于估计适合于个体患者的胃内气球的体积的方法，使用肠外瘘检查没有镇静的胃内气囊的方法和与上内窥镜检查相关的内窥镜并发症，以及用于降低能力的方法每个患者的胃在饭后扩张或扩张，增加饱腹感并帮助个体患者遵守减肥饮食。该多器械包括用于在不安装加压气体或液体的情况下进行充气的内置胃气球，用于最小化胃内粘膜上的胃内气囊的创伤的内置胃气球，以及用于施用治疗药物的内置胃气球。