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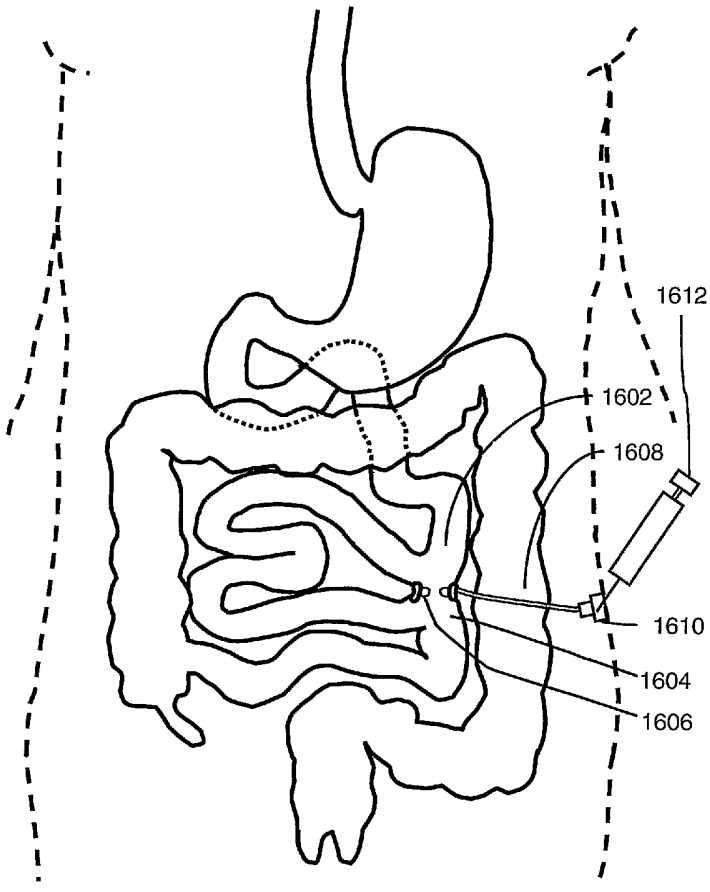

(57) Abstract: The present invention provides embodiments of devices for causing weight loss in obese patients that are used to create a gastrointestinal bypass between a first region of the gastrointestinal tract and a second region of the gastrointestinal tract. The devices comprise an adjustable opening to adjust the fraction of food material passing through the gastrointestinal bypass. Also disclosed are methods for causing weight loss in obese patients comprising the step of creating an adjustable gastrointestinal bypass between a first region of the gastrointestinal tract and a second region of the gastrointestinal tract.

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OBESITY TREATMENT DEVICES

This application claims the priority of U.S. Patent Application No. 10/885,209 filed July 6, 2004 titled "METHOD AND DEVICE FOR GASTROINTESTINAL TRACT BYPASS" and U.S. Provisional Patent Application No. 60/631,672 filed on Nov. 30, 2004 titled "METHODS AND DEVICES FOR GASTROINTESTINAL TRACT BYPASS", both of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

The present invention relates to surgical devices to treat obesity. More particularly, the present invention relates to implants for causing weight loss.

Obesity is a serious health problem especially in developed countries. Approximately 60 million adults in the U.S. are obese. Obesity leads to several health problems such as increased risk of illness and death due to coronary artery disease, diabetes and stroke.

Obesity has high medical costs due to the high prevalence of obesity and the various health problems associated with it. In a study conducted in 1998, the direct medical costs due to obesity were estimated to be $51.64 billion in the US (Source: Website of the American Obesity Association). These costs could increase in the future as the prevalence of obesity is steadily increasing. In the United States, the percentage of children and adolescents who are obese has doubled in the last 20 years. Thus, there is an urgent need to treat this serious health problem.

Obesity is treated by reducing the patient's weight. Weight loss methods can be broadly divided into diet modification, exercise therapy, pharmacological therapy and surgical procedures.

Surgical procedures are generally used for weight loss when diet modification, exercise therapy and pharmacological therapy fail to cause required weight loss. The most commonly used surgical procedures for weight loss are Roux-en-Y gastric bypass procedures, restrictive gastric operations, malabsorptive operations such as biliopancreatic diversion and intestinal bypass procedures. The Roux-en-Y gastric bypass procedure involves creating a stomach pouch out of a small portion of the stomach and attaching it directly to the small intestine, bypassing a large

small portion of the stomach and attaching it directly to the small intestine, bypassing a large part of the stomach and duodenum. The small stomach pouch holds much smaller amounts of food at a time, and hence the patient experiences a feeling of satiety even after eating a small quantity of food. Also, fat absorption from food is substantially reduced as the food bypasses a large portion of the duodenum.

Restrictive gastric operations cause weight loss by restricting the food intake by the patient. A portion of the stomach is surgically modified to form a small pouch. The food enters the pouch from the esophagus. The outlet from the pouch to the rest of the stomach is restricted. This restriction delays the emptying of food from the pouch, causing a feeling of fullness even after consuming small amounts of food.

Another type of restrictive procedure is called LAP-BAND.TM.. In this procedure, an inflatable silicone band is fastened around the upper stomach to create a new, stomach pouch. This limits the amount of food the patient can eat which in turn leads to weight loss.

Malabsorptive operations such as biliopancreatic diversion cause weight loss by restricting the food intake and also by reducing the fraction of calories absorbed by the body from the digested food. In a biliopancreatic diversion, portions of the stomach are removed along with the duodenum and the jejunum. This reduces the fraction of calories absorbed from the digested food, thereby causing weight loss.

Conventional intestinal bypass procedures cause weight loss by removing a section of the small intestine and reconnecting the remaining sections of the small intestine. In some cases, devices called anastomosis devices are used to reconnect the remaining sections of the small intestine. Removal of a section of the small intestine reduces the effective length of the intestine. As the intestine is the main site of absorption of nutrients from food material, reducing the effective length of the intestine reduces the amount of nutrients that are absorbed by the body from the food. This leads to weight loss.

Some of the abovementioned surgical procedures are invasive and require major modifications to the patient's anatomy. Further, the anatomical modifications due to some of these procedures cannot be frequently adjusted to adjust the rate of weight loss. For example, the anastomosis devices used during conventional intestinal bypass procedures cannot be frequently adjusted.

Further, procedures like LAP-BAND.TM. require significant behavior modifications by the patient. Also, if some of these surgical procedures cause severe side effects to the patient, the anatomical modifications cannot be easily reversed.

Thus, there is a need for an obesity treatment that does not need significant modifications to the patient's anatomy. Further, there is a need for an obesity treatment whose parameters can be adjusted frequently to adjust the rate of weight loss. Further, there is a need for an obesity treatment whose parameters can be adjusted with minimal discomfort to the patient. Further, there is a need for an obesity treatment that does not require significant behavior modification by the patient. Further, there is a need for an obesity treatment that can be reversed if the patient experiences significant side effects.

BRIEF SUMMARY OF THE INVENTION

An object of the present invention is to provide an obesity treatment whose parameters can be adjusted to adjust the rate of weight loss. Another object of the present invention is to provide an obesity treatment whose parameters can be adjusted with minimal discomfort to the patient. Another object of the present invention is to provide an obesity treatment that does not require significant behavior modification by the patient. Another object of the present invention is to provide an obesity treatment that does not cause significant permanent modifications to the patient's anatomy.

To achieve the foregoing objects, and in accordance with the purpose of the present invention, the present invention provides a device for causing weight loss in obese patients comprising an implant that creates a gastrointestinal bypass between a first region of the gastrointestinal tract and a second region of the gastrointestinal tract. A part of food material passing through the gastrointestinal tract from the first region of the gastrointestinal tract to the second region of the gastrointestinal tract is diverted through the gastrointestinal bypass. Diversion of a part of food material through the gastrointestinal bypass causes a reduction in the total nutrients absorbed by the body from the food material. This causes the patient to lose weight. In one embodiment, the implant comprises an adjustable opening to adjust the fraction of food material passing through the gastrointestinal bypass and hence adjust the rate of weight loss.

The present invention also provides a method for causing weight loss in obese patients comprising the steps of creating a gastrointestinal bypass between a first region of the gastrointestinal tract and a second region of the gastrointestinal tract. In one embodiment, the method for causing weight loss in obese patients comprises the steps of creating a gastrointestinal bypass between a first region of the gastrointestinal tract and a second region of the gastrointestinal tract with an adjustable opening and adjusting the size of the adjustable opening to adjust the patient's weight loss.

BRIEF DESCRIPTION OF THE DRAWINGS

The preferred embodiments of the invention will hereinafter be described in conjunction with the appended drawings provided to illustrate and not to limit the invention, where like designations denote like elements, and in which:

Figure 1 illustrates the general working principle of the invention;

Figure 2 illustrates an example of a method of treating a patient using the invention;

Figure 3 illustrates a second example of a method of treating a patient using the invention;

Figure 4 illustrates a third example of a method of treating a patient using the invention;

Figure 5 illustrates a fourth example of a method of treating a patient using the invention;

Figure 6 illustrates a fifth example of a method of treating a patient using the invention;

Figure 7 illustrates a sixth example of a method of treating a patient using the invention;

Figure 8 illustrates a seventh example of a method of treating a patient using the invention, the method being an improvement of the existing Roux-en-Y gastric bypass procedure;

Figures 9A and 9B illustrate an embodiment of the device of the invention;

Figures 10A and 10B illustrate a second embodiment of the device of the invention;

Figures 11A and 11B illustrate a sectional view of an adjustable connection made using the embodiment illustrated in Figures 9A and 9B;

Figures 12A and 12B illustrate a third embodiment of the device of the invention;

Figures 13A and 13B illustrate a sectional view of an adjustable connection made using the embodiment illustrated in Figures 12A and 12B;

Figures 14A and 14B illustrate a fourth embodiment of the device of the invention;

Figures 15A and 15B illustrate a sectional view of an adjustable connection made using the embodiment illustrated in Figures 14A and 14B;

Figure 16 illustrates an embodiment of a mechanism to adjust the device illustrated in Figures 14A and 14B;

Figure 17 illustrates a sectional view of a fifth embodiment of the device of the invention;

Figure 18 illustrates a sixth embodiment of the device of the invention;

Figure 19 illustrates a seventh embodiment of the device of the invention;

Figure 20 illustrates a sectional view of an eighth embodiment of the device of the invention;

Figure 21 illustrates a sectional view of a ninth embodiment of the device of the invention;

Figure 22 illustrates the steps of the present invention to achieve weight loss in patients.

Figure 23A shows a perspective view of an adjustable bypass band comprising an inflatable element. Figure 23B shows a perspective view of the adjustable bypass band of Figure 23A in a configuration in which the adjustable bypass band is implanted to enclose a region of the anatomy.

Figure 24 shows a perspective view of an embodiment of an adjustable bypass band comprising an inflatable element and a mechanism for non-invasively determining the degree of inflation of the inflatable element.

Figure 25 shows an embodiment of an adjustable bypass band comprising two inflatable regions.

Figure 26 shows a region of a human body showing an adjustable intestinal bypass in conjunction with an adjustable gastric banding.

Figure 27 shows an embodiment of an adjustable bypass device comprising an intra-luminal inflatable balloon.

Figures 28A and 28B show perspective views of two sides of an adjustable bypass device comprising a biofragmentable or bioabsorbable element.

DETAILED DESCRIPTION OF THE INVENTION

Figure 1 illustrates the general working principle of the invention. Food material 102 ingested through the mouth enters gastrointestinal tract 104. In gastrointestinal tract 104, food material 102 undergoes a process called digestion. In the digestion process, food material 102 is converted to a form that can be easily absorbed by the body. Food material 102 then undergoes a process known as absorption, wherein digested food material 102 is absorbed by the body. Ultimately, a fraction of food material 102 is absorbed by the body. Creation of a gastrointestinal bypass 106 between a first region 108 of the gastrointestinal tract and a second region 110 of the gastrointestinal tract causes a fraction of food material 102 to flow through gastrointestinal bypass 106. This changes the time food material 102 resides in gastrointestinal tract 104 which in turn leads to a decrease in digestion or absorption or both. Ultimately, this leads to a smaller fraction of food material 102 being absorbed by the body and hence leads to weight loss. The fraction of food material 102 flowing through gastrointestinal bypass 106 can be controlled by an adjustable opening 112. Enlarging adjustable opening 112 causes a greater portion of food material 102 to flow through gastrointestinal bypass 106. This reduces the

fraction of ingested food that is absorbed by the body which in turn increases the rate of weight loss. Similarly, reducing the size of adjustable opening 112 increases the fraction of ingested food that is absorbed by the body which in turn reduces the rate of weight loss. In this manner, the rate of weight loss can be adjusted to maintain it at a desired level.

In this document, unless specified, intestine can mean either small intestine or large intestine.

Figure 2 illustrates an example of a method of treating a patient using the invention. In this method, an implant 200 is provided that connects a first region 202 of the intestine to a second region 204 of the intestine to create an intestinal bypass. First region 202 is located on the small intestine. Second region 204 is located downstream from first region 202. Second region 204 can be located on the small intestine or the large intestine. This method achieves weight loss by reducing the amount of food material that is absorbed by the body. A portion of food material flowing through the intestine from the first region 202 to the second region 204 is diverted through implant 200. As the intestine is the main site for absorption of the food material, the portion of food material flowing through implant 200 is less absorbed by the body. This causes the patient to lose weight.

Figure 3 illustrates a second example of a method of treating a patient using the invention. The invention comprises a ring shaped implant 300 that connects a first region 302 of the intestine to a second region 304 of the intestine to create an intestinal bypass.

Figure 4 illustrates a third example of a method of treating a patient using the invention. The invention comprises a tubular implant 400 that connects a first region 402 of the intestine to a second region 404 of the intestine to create an intestinal bypass. Tubular implant 400 comprises an adjustable opening 406 to adjust the rate of weight loss. The rate of weight loss can be controlled by adjusting the size of adjustable opening 406. Increasing the size of adjustable opening 406 will cause a greater portion of the food material to pass through the intestinal bypass. This will reduce the amount of food material absorbed by the intestine and thus increase the rate of weight loss. Similarly, reducing the size of adjustable opening 406 will reduce the rate of weight loss.

Figure 5 illustrates a fourth example of a method of treating a patient using the invention. The invention comprises a ring shaped implant 500 that connects a first region 502 of the intestine to

a second region 504 of the intestine to create an intestinal bypass. Ring shaped implant 500 comprises an adjustable opening 506 to adjust the rate of weight loss. The rate of weight loss can be controlled by adjusting the size of adjustable opening 506. Increasing the size of adjustable opening 506 will cause a greater portion of the food material to pass through the intestinal bypass. This will reduce the amount of food material absorbed by the intestine and thus increase the rate of weight loss. Similarly, reducing the size of adjustable opening 506 will reduce the rate of weight loss.

Figure 6 illustrates a fifth example of a method of treating a patient using the invention. In the normal anatomy, stomach 600 is connected to duodenum 602 that continues as small intestine which ultimately continues as large intestine. In the method illustrated in Figure 6, the small intestine is cut between a first region 604 of small intestine and a second region 606 of small intestine. Second region 606 of small intestine is then anastomosed to a region of stomach 600 by an end-to-side anastomosis (or side-to-side anastomosis). An adjustable opening 608 is provided near the anastomosis of stomach 600 and second region 606 of small intestine. Thereafter, first region 604 of small intestine is anastomosed to a distal region 610 of small intestine by an end-to-side anastomosis. Distal region 610 is located distal to second region 606 of small intestine as illustrated in Figure 6. Food material flowing through stomach 600 is divided into two parts: first part flowing through duodenum 602 and second part flowing through adjustable opening 608. Thus, food material bypasses sections of the gastrointestinal tract. This reduces the total amount of food material that is absorbed by the body which in turn leads to weight loss. The rate of weight loss can be adjusted by adjusting the size of adjustable opening 608. As an optional step, the volume of stomach 600 can be reduced. One way to achieve this is by using staples 612 to isolate a volume of stomach 600.

Figure 7 illustrates a sixth example of a method of treating a patient using the invention. The illustrated method is similar to the method illustrated in Figure 6. In the normal anatomy, stomach 700 is connected to duodenum 702 that continues as small intestine which ultimately continues as large intestine. In the method illustrated in Figure 7, the small intestine is cut between a first region 704 of small intestine and a second region 706 of small intestine. Second region 706 of small intestine is then anastomosed to a region of stomach 700 by an end-to-side anastomosis. A first adjustable opening 708 is provided near the anastomosis of stomach 700 and second region 706 of small intestine. Thereafter, first region 704 of small intestine is anastomosed to a distal region 710 of small intestine by an end-to-side anastomosis. Distal

region 710 is located distal to second region 706 of small intestine as illustrated in Figure 7. Thereafter, a second adjustable opening 712 is provided near duodenum 702. Food material flowing through stomach 700 is divided into two parts: first part flowing through duodenum 702 and second part flowing through first adjustable opening 708. Thus, food material bypasses sections of the gastrointestinal tract. This reduces the total amount of food material that is absorbed by the body which in turn leads to weight loss. The rate of weight loss can be adjusted by adjusting the size of first adjustable opening 708 and second adjustable opening 712. As an optional step, the volume of stomach 700 can be reduced. One way to achieve this is by using staples 714 to isolate a volume of stomach 700.

Figure 8 illustrates a seventh example of a method of treating a patient using the invention, the method being an improvement of the existing Roux-en-Y gastric bypass procedure. In the Roux-en-Y procedure, a series of staples 802 divide the stomach into two regions: a first region 804 of stomach and a second region 806 of stomach. Thereafter, the small intestine is cut between a first region 808 of small intestine and a second region 810 of small intestine. Second region 810 of small intestine is then anastomosed to first region 804 of stomach by an end-to-side anastomosis. Thereafter, first region 808 of small intestine is anastomosed to a distal region 812 of small intestine by an end-to-side anastomosis. Distal region 812 is located distal to second region 810 of small intestine as illustrated in Figure 8. In the improved Roux-en-Y procedure of the invention, an adjustable opening 816 is provided between first region 804 of stomach and second region 806 of stomach. Thus, food material entering first region 804 of stomach is divided into two parts: a first part flowing out through second region 810 of small intestine and a second part flowing out through adjustable opening 816. The rate of weight loss can be adjusted by adjusting the size of adjustable opening 816.

Figures 9A and 9B illustrate an embodiment of a device to create an adjustable opening. In this embodiment, a deformable implant 900 is provided. Deformable implant 900 is substantially ring shaped and encloses a lumen 902. Deformable implant 900 comprises a deformable element 904. In one embodiment, deformable element 904 is in the form of a stiff metal loop of sufficient stiffness so that deformable implant 900 is substantially undeformable under the normal physiological forces acting on it after implantation. In another embodiment, deformable element 904 is in the form of a deformable stent of sufficient stiffness so that deformable implant 900 is substantially undeformable under the normal physiological forces acting on it after implantation. Size of lumen 902 can be adjusted by dilating or contracting deformable

implant 900. One example of a method to contract lumen 902 is laparoscopic compression of deformable implant 900 by a device inserted in the peritoneum through a small incision in the abdominal wall. One example of a method to dilate lumen 902 is endoscopic dilation of deformable implant 900 by a dilating device inserted endoscopically in the gastrointestinal tract. The dilating device may be inserted in the gastrointestinal tract through a trans-oral, trans-nasal or trans-anal approach. Deformable implant 900 further comprises apertures 906. Apertures 906 facilitate the creation of anastomosis between regions of the gastrointestinal tract that are being connected by deformable implant 900. In one embodiment, parts of deformable implant 900 except deformable element 904 are biofragmentable or bioabsorbable. Figure 9A illustrates deformable implant 900 in a contracted state. Figure 9B illustrates deformable implant 900 in a dilated state.

Figure 10A and Figure 10B illustrate a second embodiment of the invention. In this embodiment, a deformable implant 1000 is provided. Deformable implant 1000 encloses a lumen 1002. Lumen 1002 is substantially elongated in one direction. In one embodiment, deformable implant 1000 is substantially rectangular in cross-section. Deformable implant 1000 comprises a deformable element 1004. In one embodiment, deformable element 1004 is in the form of a stiff metal loop of sufficient stiffness so that deformable implant 1000 is substantially undeformable under the normal physiological forces acting on it after implantation. In another embodiment, deformable element 1004 is in the form of a deformable stent of sufficient stiffness so that deformable implant 1000 is substantially undeformable under the normal physiological forces acting on it after implantation. Size of lumen 1002 can be adjusted by dilating or contracting deformable implant 1000. One example of a method to contract lumen 1002 is laparoscopic compression of deformable implant 1000 by a device inserted in the peritoneum through a small incision in the abdominal wall. One example of a method to dilate lumen 1002 is endoscopic dilation of deformable implant 1000 by a dilating device inserted endoscopically in the gastrointestinal tract. The dilating device may be inserted in the gastrointestinal tract through a trans-oral, trans-nasal or trans-anal approach. Deformable implant 1000 further comprises apertures 1006. Apertures 1006 facilitate the creation of anastomosis between regions of the gastrointestinal tract that are being connected by deformable implant 1000. In one embodiment, parts of deformable implant 1000 except deformable element 1004 are biofragmentable or bioabsorbable. Figure 9A illustrates deformable implant 1000 in a contracted state. Figure 9B illustrates deformable implant 1000 in a dilated state. The lumen enclosed by

any of the devices disclosed herein may be elongated in one direction. For example, the lumen enclosed by any of the devices disclosed herein may be substantially oval, rectangular, etc.

Figures 11A and 11B illustrate a sectional view of an adjustable connection made using the embodiment illustrated in Figures 9A and 9B. The adjustable connection is created between a first region 1102 of the gastrointestinal tract and a second region 1104 of the gastrointestinal tract. The adjustable connection is created using a deformable implant 1106 that encloses a lumen 1108. The size of lumen 1108 is adjusted by deformation of deformable implant 1106. Deformable implant 1106 further comprises apertures 1110. Regions of first region 1102 of the gastrointestinal tract and second region 1104 of the gastrointestinal tract come into physical contact with each other through apertures 1110. This facilitates the two regions of the gastrointestinal tract to fuse with each other through apertures 1110. This enables the creation of a stable anastomosis 1112 between first region 1102 of the gastrointestinal tract and second region 1104 of the gastrointestinal tract. Figures 11A and 11B illustrate sectional views of the adjustable connection when deformable implant 1106 is in a dilated state and a contracted state respectively.

Figures 12A and 12B illustrate a third embodiment of a device to create an adjustable opening. In this embodiment, an adjustable implant 1200 is provided. Adjustable implant 1200 is substantially ring shaped and comprises an inflatable member 1202. Inflatable member 1202 encloses a lumen 1204. Inflatable member 1202 can be inflated or deflated to adjust the diameter of lumen 1204. Adjustable implant 1200 further comprises a first circular flange 1206 and a second circular flange 1208. First circular flange 1206 is located around the periphery of adjustable implant 1200 and second circular flange 1208 is located around lumen 1204. First circular flange 1206 and second circular flange 1208 are present on both sides of adjustable implant 1200. First circular flange 1206 and second circular flange 1208 are of a height sufficient to enclose an annular cavity of a depth sufficient to receive a region of the gastrointestinal tract. Adjustable implant 1200 further comprises apertures 1210. Apertures 1210 enable regions of the gastrointestinal tract to come into physical contact with each other. This facilitates the regions of the gastrointestinal tract to fuse with each other to create a stable anastomosis. Figure 12A illustrates adjustable implant 1200 in which inflatable member 1202 is deflated. Figure 12B illustrates adjustable implant 1200 in which inflatable member 1202 is inflated. Similarly, other designs of anastomosis rings comprising inflatable members may be created.

Figures 13A and 13B illustrate a sectional view of an adjustable connection made using the embodiment illustrated in Figures 12A and 12B. The adjustable connection is created between a first region 1302 of the gastrointestinal tract and a second region 1304 of the gastrointestinal tract using an adjustable implant 1306. First region 1302 of the gastrointestinal tract fits into an annular cavity located on one side of adjustable implant 1306. Similarly, second region 1304 of the gastrointestinal tract fits into an annular cavity located on the other side of adjustable implant 1306. Adjustable implant 1306 encloses a lumen 1308. The size of lumen 1308 is adjusted by inflation or deflation of an inflatable member 1310. Figure 13A illustrates a sectional view of the adjustable connection when inflatable member 1310 is in a deflated state. Figure 13B illustrates a sectional view of the adjustable connection when inflatable member 1310 is in an inflated state.

Figures 14A and 14B illustrate a fourth embodiment of a device to create an adjustable opening. Figures 14A and 14B illustrate two sides of an adjustable implant 1400. Adjustable implant 1400 is substantially ring shaped and comprises an inflatable member 1402. Inflatable member 1402 encloses a lumen 1404. A connection between a first region of the gastrointestinal tract and a second region of gastrointestinal tract is enclosed in lumen 1404. The diameter of the connection is adjusted by inflation or deflation of inflatable member 1402 through a port 1406. Adjustable implant 1400 further comprises a circular flange 1408. Circular flange 1408 is located around lumen 1404 and is present on both sides of adjustable implant 1400. Circular flange 1408 is of a height sufficient to enclose a region around the connection between the first region of the gastrointestinal tract and the second region of the gastrointestinal tract. In one embodiment, the first region of the gastrointestinal tract and the second region of the gastrointestinal tract are both sutured to circular flange 1408. Adjustable implant 1400 further comprises an annular region 1410 comprising apertures 1412. Apertures 1412 enable regions of the gastrointestinal tract to come into physical contact with each other. This facilitates the regions of the gastrointestinal tract to fuse with each other to create a stable anastomosis. In one embodiment, annular region 1410 is biofragmentable or bioabsorbable.

Figures 15A and 15B illustrate a sectional view of an adjustable connection made using the embodiment illustrated in Figures 14A and 14B. The adjustable connection is created between a first region 1502 of the gastrointestinal tract and a second region 1504 of the gastrointestinal to enclose a lumen 1506. The adjustable connection is enclosed by an adjustable implant 1508.

Adjustable implant comprises an inflatable member 1510. The size of lumen 1506 is adjusted by inflation or deflation of inflatable member 1510 through the introduction or removal of an inflating fluid through an inflation port 1512. Figure 15A illustrates a sectional view of the adjustable connection when inflatable member 1510 is in a deflated state. Figure 15B illustrates a sectional view of the adjustable connection when inflatable member 1510 is in an inflated state.

Figure 16 illustrates an embodiment of a mechanism to adjust the adjustable implant illustrated in Figure 14A and 14B. In this embodiment, a bypass is created between a first region 1602 of the intestine and a second region 1604 of the intestine using an implant 1606. Implant 1606 comprises an adjustable opening in the form of an inflatable member that is connected to a fluid introducing tube 1608. Fluid introducing tube 1608 is further connected to an injection port 1610. In one embodiment, injection post 1610 is located under the skin such as in the subcutaneous region. The adjustable opening of implant 1606 can be adjusted by introduction or removal of an inflating fluid through injection port 1610 by a syringe 1612.

Such inflatable members may be present on adjustable bypass devices including, but not limited to adjustable bypass bands, adjustable anastomosis rings, adjustable bypass tubular elements etc.

Figure 17 illustrates a sectional view of a fifth embodiment of the invention. An intestinal bypass graft 1700 used to create a bypass between a first region 1702 of the intestine and a second region 1704 of the intestine. Intestinal bypass graft 1700 comprises a tubular implant 1706. Tubular implant 1706 can be made of suitable biocompatible materials like silicone gel, polyurethane, ultra high molecular weight polyethylene, polyethylene terephthalate, polypropylene, polytetrafloroethylene and polyamides. In one embodiment, the walls of the tubular implant are hollow and are filled with a filler material. Examples of filler material that can be used are silicon gel, saline, soybean oil, hydro gel, polyvinylpyrrolidone, polyethylene glycol, and hyaluronic acid. The inner surface of tubular implant 1706 comprises a series of projections. The projections help the food material in the intestine to flow in a single direction. One end of tubular implant 1706 is connected to first region 1702 of intestine by one or more fasteners 1708 to create an end-to-side anastomosis. Fasteners 1708 are biocompatible. Examples of materials that can be used as fasteners 1708 are sutures, clips, staples, screws, tags and adhesives. The other end of tubular implant 1706 is connected to second region 1704 of intestine by one or more fasteners 1710 to create an end-to-side anastomosis. Fasteners 1710 are

biocompatible. Examples of materials that can be used as fasteners 1710 are sutures, clips, staples, screws, tags and adhesives. Tubular implant 1706 is provided with an adjustable opening 1712. Adjustable opening 1712 regulates the amount of food that passes through intestinal bypass graft 1700. Increasing the size of adjustable opening 1712 increases the amount of food passing through intestinal bypass graft 1700. This reduces the amount of consumed food that is absorbed by the patient's body and increases the rate of weight loss. Similarly, reducing the size of adjustable opening 1712 reduces the rate of weight loss. Thus the rate of weight loss can be regulated by changing the size of adjustable opening 1712. Tubular implant 1706 is further provided with an elastic mechanism 1714. Elastic mechanism 1714 provides elasticity to tubular implant 1706. The motion of the patient and the peristaltic motion of the patient's intestines cause various regions of tubular implant 1706 to move with respect to each other. This movement facilitates the flow of food material passing through tubular implant 1706. In one embodiment, elastic mechanism 1714 is in the form of a spring wound around tubular implant 1706. Several biocompatible materials like titanium alloys, stainless steel alloys or elastic biocompatible polymers can be used for constructing the spring. Tubular implant 1706 further comprises a valve 1716. Valve 1716 facilitates the flow of food material in a single direction by preventing backflow of the food material. Valve 1716 can be a mechanical valve or a bioprosthetic valve. Examples of mechanical valves that can be used are ball valves, single-leaflet (tilting disk) valves and bileaflet valves. They can be made of one or more biocompatible materials like collagen, stainless steel, titanium, pyrolytic carbon, Teflon.TM. or Dacron.TM.. Bioprosthetic valves can be made from animal or human tissues.

Figure 18 illustrates a sixth embodiment of the invention. In this embodiment, an adjustable implant 1800 is provided. Adjustable implant 1800 comprises an iris diaphragm. The iris diaphragm comprises a base plate 1802. Base plate 1802 is annular in shape. Adjustable implant 1800 further comprises a plurality of blades 1804. Each blade is attached to base plate 1802 by a pivot in such a way that blades 1804 enclose a lumen 1806. Adjustable implant 1800 further comprises a blade actuating ring 1808 attached coaxially to base plate 1802. Blade actuating ring 1808 can rotate around its axis. Blade actuating ring 1808 is provided with a plurality of slots 1810. The number of slots on blade actuating ring 1808 is equal to the number of blades attached to base plate 1802. Each blade is provided with a projection 1812. Projection 1812 of each blade slides within a slot on blade actuating ring 1808. Thus, each blade is pivoted on base plate 1802 and communicates with blade actuating ring 1808. Blade actuating ring 1808 is further provided with a plurality of gripping slots 1814. Gripping slots 1814 are used to grip and

rotate blade actuating ring 1808. Rotation of blade actuating ring 1808 changes the orientation of blades 1804. This changes the size of lumen 1806. Thus, the size of adjustable opening in the invention can be changed by rotating blade actuating ring 1808. In one embodiment, blade actuating ring 1808 is rotated using endoscopic means. Several biocompatible materials like titanium alloys, stainless steel alloys or elastic biocompatible polymers can be used for constructing adjustable implant 1800.

Figure 19 illustrates a seventh embodiment of the invention. In this embodiment, an adjustable implant 1900 is provided. Adjustable implant 1900 comprises an iris diaphragm that is adjusted using electromagnetic signals. Adjustable implant 1900 comprises a base plate 1902. Base plate 1902 is annular in shape. Adjustable implant 1900 further comprises a plurality of blades 1904. Each blade is attached to base plate 1902 by a pivot in such a way that blades 1904 enclose a lumen 1906. Adjustable implant 1900 further comprises a blade actuating ring 1908 attached coaxially to base plate 1902. Blade actuating ring 1908 can rotate around its axis and can act as a gear. Blade actuating ring 1908 is provided with a plurality of slots 1910. The number of slots on blade actuating ring 1908 is equal to the number of blades attached to base plate 1902. Each blade is provided with a projection 1912. Projection 1912 of each blade slides within a slot on blade actuating ring 1908. Thus, each blade is pivoted on base plate 1902 and communicates with blade actuating ring 1908. Blade actuating ring 1908 is geared to a driver gear 1914. Driver gear 1914 is connected to a control mechanism comprising a motor 1916 and a controller 1918 that supplies a controlled amount of electric current to motor 1916. Controller 1918 is connected to a receiver 1920. Receiver 1920 receives electromagnetic signals and converts the received electromagnetic signals to electric signals and transmits the electric signals to controller 1918. A battery 1922 supplies electric energy to controller 1918 and receiver 1920.

Receiver 1920 receives electromagnetic signals containing information about a required change in size of the adjustable opening. Receiver 1920 converts the electromagnetic signals to electric signals and transmits the electric signals to controller 1918. Controller 1918 calculates the required electric current to cause the required change in size of the adjustable opening. The required electric current is then delivered to motor 1916 causing driver gear 1914 to rotate. Rotation of driver gear 1914 causes blade actuating ring 1908 to rotate. Rotation of blade actuating ring 1908 changes orientation of blades 1904. This changes the size of lumen 1906. Thus, the size of adjustable opening in the invention can be changed. In one embodiment, controller 1918, receiver 1920 and battery 1922 are implanted in the patient's body. In another

embodiment, battery 1922 comprises a self-charging mechanism whereby motion of the patient is converted to electrical energy that charges battery 1922. The electromagnetic signals are generated out of the patient's body by an external remote controller. This enables the non-invasive adjustment of adjustable implant 1900. Several biocompatible materials like titanium alloys, stainless steel alloys or elastic biocompatible polymers can be used for constructing the adjustable implant 1900.

Figure 20 illustrates a sectional view of an eighth embodiment of the invention. In this embodiment, a gastrointestinal bypass with an adjustable opening is created between a first region 2002 of the gastrointestinal tract and a second region 2004 of the gastrointestinal tract. The adjustable opening is formed by an implant comprising three parts. First part 2006 of the implant is attached to first region 2002 of the gastrointestinal tract. Second part 2008 of the implant is attached to second region 2004 of the gastrointestinal tract. First part 2006 of the implant and second part 2008 of the implant can be attached to the gastrointestinal tract by several methods like suturing, clipping, stapling or using screws, tags or surgical adhesives. Third part 2010 of the implant is attached to first part 2006 of the implant and second part 2008 of the implant. Third part 2010 of the implant encloses a lumen 2012. Third part 2010 of the implant comprises an adjustable opening. In one embodiment, the adjustable opening is in the form of an inflatable member 2014 connected to an inflation port 2016. Inflation or deflation of inflatable member 2014 through inflation port 2016 changes the size of lumen 2012. In this way, the size of the adjustable opening can be adjusted. First part 2006 of the implant, second part 2008 of the implant and third part 2010 of the implant further comprise a locking mechanism 2018 to securely hold together the various parts of the implant. Similar bypass devices may be made such that the bypass devices comprise two parts that attach to each other. The first part is attached to a first region of the gastrointestinal tract and a second part is attached to a second region of the gastrointestinal tract. A bypass adjustable element e.g. an inflatable member may be located on the first part or the second part.

Figure 21 illustrates a sectional view of a ninth embodiment of the invention. In this embodiment, a side-to-side anastomosis with an adjustable opening is created between a first region 2102 of the gastrointestinal tract and a second region 2104 of the gastrointestinal tract using an adjustable implant 2106. Adjustable implant 2106 can be adjusted to adjust the size of anastomosis lumen 2108 enclosed by adjustable implant 2106. Adjustable implant 2106 further comprises stabilization means 2110 to stabilize the orientation of adjustable implant 2106 with

respect to the patient's anatomy. In one embodiment, stabilization means 2110 are in the form of baffles that stabilize the orientation of adjustable implant 2106 with respect to the patient's visceral organs like the intestine.

The described embodiments can be made of suitable biocompatible materials like silicone rubber, polyethylene terephthalate, ultra high molecular weight polyethylene, expanded polytetrafloroethylene, polypropylene, polycarbonate urethane, polyurethane, polyamides, stainless steel 316, titanium, nickel-titanium alloys and cobalt alloys. The described embodiments may comprise a suitable radio-opaque marker for radiographic determination of the position and the level of dilation or contraction of the adjustable implants. The described embodiments may be used as temporary or permanent implants. The embodiments can be used for end-to-end, end-to-side or side-to-side anastomosis. Although the invention is primarily described and illustrated as a gastrointestinal device, it is understood that it can also be used for other anastomosis procedures such as vascular anastomosis.

Figure 22 illustrates the method of the present invention to achieve weight loss in obese patients. The method of the present invention is based on periodically monitoring the patient's physiological parameters and adjusting the size of a gastrointestinal bypass. At step 2202, the patient's initial physiological parameters are measured. Some examples of the physiological parameters that are measured are total weight, body mass index, concentration of blood glucose and electrolyte balance. Electrolyte balance is the balance of physiologically crucial compounds like vitamins, and serum electrolytes such as calcium, magnesium, iron and phosphate. Based on these physiological parameters, at step 2204, a time is fixed for a followup of the patient after the creation of a gastrointestinal bypass. The aim of the followup is to monitor the patient's health status and the effectiveness of the weight loss method. At step 2206, a desired weight loss is calculated based on the patient's physiological parameters. The desired weight loss is in the form of a range of weight loss that is desired in the patient until the followup. Also, at step 2206, a desired electrolyte balance is calculated for the patient. A proper balance of electrolytes such as calcium, magnesium, iron and phosphate and of vitamin D is crucial for the normal functioning of the body. A poorly designed weight loss program can lead to an excessive loss of electrolytes from the body. At step 2210, an initial gastrointestinal bypass opening size is calculated based on the patient's physiological parameters, the desired weight loss and the desired electrolyte balance. At step 2212, a gastrointestinal bypass with an adjustable opening is created in the patient. The initial size of the adjustable opening is the initial gastrointestinal

bypass opening size determined at step 2210. Thereafter, the patient is asked to appear for followup at the time calculated at step 2204. During the followup, at step 2216, the patient's actual weight loss and actual electrolyte balance is measured. At step 2218, the desired weight loss and the actual weight loss are compared. Also, at step 2218, the desired electrolyte balance and the actual electrolyte balance are compared. If the desired weight loss and the actual weight loss are not comparable or if the desired electrolyte balance and the actual electrolyte balance are not comparable, the method proceeds to step 2220. At step 2220, a new gastrointestinal bypass opening size is calculated. The calculation is done by taking into consideration the desired weight loss, the actual weight loss, the desired electrolyte balance and the actual electrolyte balance. At step 2222, the intestinal bypass is adjusted to the new bypass opening size calculated at step 2220. At step 2224, a time is fixed for the followup of the patient. At step 2226, a desired weight loss is calculated. The desired weight loss is in the form of a range of weight loss that is desired in the patient until the followup calculated at step 2224. Also, at step 2226, a desired electrolyte balance is calculated for the patient. Thereafter, the method proceeds to step 2216.

Referring back to step 2218, if the desired weight loss and the actual weight loss are comparable and the desired electrolyte balance and the actual electrolyte balance are comparable, the method proceeds to step 2224.

Inflatable elements disclosed herein may be present on a band that goes around a region of the gastrointestinal tract. Such bands may be sized to be fitted around a region of the small intestine or around an intestinal bypass. For example, Figure 23A shows a perspective view of an adjustable bypass band comprising an inflatable element. Such adjustable bypass bands may be sutured to the anatomy or attached to the anatomy by a variety of attachment means know in the art. Bypass band 2300 comprises an elongate band 2302 made from suitable biocompatible materials including, but not limited to silicone rubber, polytetrafloroethylene, etc. Bypass band 2300 further comprises an inflatable region 2304 attached to elongate band 2302. Inflatable region 2304 may be made of suitable biocompatible materials including, but not limited to silicone rubber, PET, etc. Inflatable region 2304 can be inflated or deflated by a tube 2306 in fluid communication with inflatable region 2304. Inflatable elements disclosed herein may be inflated with a suitable inflating medium like a liquid (e.g. saline, water, contrast solution etc.) or a gas (e.g. nitrogen etc.). Bypass band 2300 further comprises an attachment mechanism to secure one region of bypass band 2300 to a second region of bypass band 2300 to create a ring-

like device enclosing a lumen. In one embodiment, the attachment mechanism is a buckle. In the embodiment shown in Figure 23A, the attachment mechanism comprises a spherical locking element 2308 located near one end of bypass band 2300 that fits into an locking slot 2310 located on the other end of bypass band 2300. Bypass band 2300 may also comprise a slot 2312 through which one end of the band can pass. Bypass band 2300 may be implanted by laparoscopic surgery, by open surgery, etc. Figure 23B shows a perspective view of the adjustable bypass band of Figure 23A in a configuration in which the adjustable bypass band is implanted to enclose a region of the anatomy. The adjustable bypass bands disclosed herein may be implanted around a region of the gastrointestinal tract or around a bypass of the gastrointestinal tract. The adjustable bypass bands disclosed herein may be designed to substantially occlude the lumen of the gastrointestinal tract or a gastrointestinal tract bypass when the inflatable element is fully inflated. For example, largest diameter of a lumen enclosed by an implanted adjustable bypass band may be less than 0.5 inches when the inflatable member is fully inflated.

Devices disclosed herein may comprise one or more mechanisms to non-invasively determine the position and/or the configuration of an adjustable bypass. For example, such mechanisms may be used to non-invasively determine the degree of inflation of an inflatable member. Figure 24 shows a perspective view of an embodiment of an adjustable bypass band comprising an inflatable element and a mechanism for non-invasively determining the degree of inflation of the inflatable element. The design of bypass band 2400 is similar to the design of bypass band 2300. Bypass band 2400 comprises an elongate band 2402 and an inflatable region 2404 attached to elongate band 2402. Inflatable region 2404 is in fluid communication with one end of an elongate tube 2406. The other end of elongate tube 2406 is in fluid communication with a port comprising a housing 2408 comprising a barrier 2410. In one embodiment, barrier 2410 is self-sealing. Fluid can be introduced to or removed from inflatable region 2404 by puncturing barrier 2410 with a needle connected to a syringe and introducing or removing fluid from the housing 2408. The port may be implanted in a subcutaneous location. Bypass band 2400 further comprises a radio-opaque marker located on inflatable region 2404. In one embodiment, radio-opaque marker comprises multiple radio-opaque elements 2412. In another embodiment, radio-opaque marker comprises an elongate radio-opaque element located parallel to inflatable region 2404. The location and relative positions of one or more radio-opaque markers located on inflatable region 2404 in a radiographic image may be used to non-invasively determine the

degree of inflation of inflatable region 2404. Similar markers may be used to non-invasively determine the lumen size of an adjustable bypass device.

The devices disclosed herein may comprise multiple inflatable regions. For example, Figure 25 shows an embodiment of an adjustable bypass band comprising two inflatable regions. The design of bypass band 2500 is similar to the design of bypass band 2300. Bypass band 2400 comprises a first inflatable region 2502 and a second inflatable region 2504. First inflatable region 2502 is in fluid communication with second inflatable region 2504 through a tube 2506. First inflatable region 2502 is further connected to an inflating tube 2508 that inflates first inflatable region 2502 and second inflatable region 2504. The inflatable elements disclosed herein may comprise one or more grooves or ridges.

The methods disclosed herein may be used in conjunction with other surgical methods for causing weight loss in obese patients. For example adjustable intestinal bypass methods disclosed herein may be used in conjunction with gastric surgeries including, but not limited to adjustable gastric banding surgery, sleeve gastrectomy, vertical banded gastroplasty, etc. Figure 26 shows a region of a human body showing an adjustable intestinal bypass in conjunction with an adjustable gastric banding. In Figure 26, adjustable bypass device 2600 comprising an adjustable inflatable member is used to adjust an intestinal bypass. The inflatable member is inflated or deflated through an elongate tube 2602 connected to a subcutaneous port 2604. An adjustable gastric band 2606 is also provided that is inflated or deflated through an elongate tube 2608 connected to a subcutaneous port 2610. Similarly, other methods and devices disclosed herein may be combined with existing techniques for causing weight loss.

The adjustable inflatable bypass devices may comprise an inflatable intra-luminal element that is located in the gastrointestinal lumen. Figure 27 shows an embodiment of an adjustable bypass device comprising an intra-luminal inflatable balloon. Inflatable implant 2700 comprises an inflatable balloon 2702 made of suitable biocompatible materials like silicone rubber. Inflatable balloon 2702 partially or completely occludes a lumen to create an adjustable resistance to the food material passing through the lumen. The lumen may be of a gastrointestinal lumen 2701 or a lumen of a bypass in the gastrointestinal tract. Such an inflatable balloon may also be used for other types of bypasses disclosed in this provisional patent application or in the patent applications incorporated herein by reference. The inflatable elements can be of a suitable dimension to partially or completely obstruct an intestinal lumen. For example, the inflated

diameter of inflatable balloon 2702 may range from 1 cm to 5 cm. In this way, the inflatable balloon 2702 is fundamentally different from the prior art since it creates an adjustable resistance for controlling a bypass rather than being a space occupying balloons in the stomach to reduce food intake. The inflatable elements thus have a smaller inflated volume than the gastric space occupying balloons which have an inflated volume typically in the range of 200 to 800 cc. The inflated volume of inflatable balloon 2702 is less than 50 ml. Inflatable balloon 2702 may be inflated through an inflating tube 2704 which may be connected to a subcutaneous port.

A biofragmentable or bioabsorbable material may be located on an adjustable bypass device such that the biofragmentable or bioabsorbable material is located in the lumen of the gastrointestinal tract. The biofragmentable or bioabsorbable material gradually fragments or dissolves thereby gradually opening the lumen of the gastrointestinal tract or a gastrointestinal tract bypass. For example, Figures 28A and 28B show perspective views of two sides of an adjustable bypass device comprising a biofragmentable or bioabsorbable element. In this example, adjustable bypass device is an adjustable anastomosis ring 2800 comprising an outer ring 2802. Outer ring 2802 may comprise one or more apertures 2804. Outer ring 2802 comprises an inflatable element 2806 that can be inflated or deflated through suitable inflating or deflating means. Anastomosis ring 2800 further comprises a biofragmentable or bioabsorbable element 2808 located on one side of inflatable element 2806. Biofragmentable or bioabsorbable element 2808 fully or partially obstructs the lumen of anastomosis ring 2800. Biofragmentable or bioabsorbable element 2808 may enclose a lumen.

The methods disclosed herein may be used with open surgical, laparoscopic, endoscopic or interventional procedures as appropriate. The anastomoses disclosed herein may be created by a variety of methods including, but not limited to conventional methods like suturing, stapling or by novel methods like using anastomosis clips, tissue glues, etc.

Typical examples of biofragmentable or bioabsorbable materials that can be used in the devices disclosed herein include, but are not limited to polyglycolic acid and other poly-hydroxy acids, polylactides, poly(dioxanone), poly(trimethylene carbonate) copolymers, poly (epsilon-caprolactone) homopolymers and copolymers, polydioxanone, polyanhydrides, polyorthoesters, poly-amino acids, polyesteramides, polyphosphazenes, polyhydroxybutyrate (PHB), polyhydroxyvalerate (PHV), modified cellulose, collagen, and other biodegradable polymers

and their combinations. Combinations of materials such as poly(glycolide-co-trimethylene carbonate), poly(l-lactide-co-glycolide), poly (dl-lactide-co-glycolide), poly (l-lactide-co-dl-lactide), poly(glycolide-co-trimethylene carbonate-co-dioxanone), polylactic acid-polyethylene oxide copolymers, etc. may also be used.

One or more devices disclosed herein may be attached to one or more anatomical regions by biocompatible fasteners including, but not limited to sutures, clips, staples, screws, tags and adhesives.

One or more devices disclosed herein may be coated or impregnated with substances such as antibiotics to reduce device infections.

Various intestinal methods disclosed herein may be used in addition to existing gastric surgeries for causing weight loss. Examples of such existing gastric surgeries include, but are not limited to adjustable gastric banding surgery, sleeve gastrectomy, vertical banded gastroplasty, etc.

It is to be appreciated that the invention has been described hereabove with reference to certain examples or embodiments of the invention but that various additions, deletions, alterations and modifications may be made to those examples and embodiments without departing from the intended spirit and scope of the invention. For example, any element or attribute of one embodiment or example may be incorporated into or used with another embodiment or example, unless to do so would render the embodiment or example unsuitable for its intended use. All reasonable additions, deletions, modifications and alterations are to be considered equivalents of the described examples and embodiments and are to be included within the scope of the following claims.

CLAIMS

What is claimed is:

1. An implant comprising: an inflatable member adapted to adjust a fraction of food material passing through an intestinal bypass.

2. The implant of claim 1, wherein the implant encloses an implant lumen such that food material passes through the region enclosed by the implant lumen.

3. The implant of claim 1, wherein the inflatable member is located substantially within the lumen of an intestinal region.

4. The implant of claim 3, wherein the maximum inflated volume of the inflatable member is less than 50 cc.

5. The implant of claim 3, wherein the maximum inflated diameter of the inflatable member is less than 5 cm.

6. The implant of claim 1, wherein the inflatable member is located substantially outside the lumen of an intestinal region.

7. The implant of claim 1, wherein the inflatable member is in fluid communication with a subcutaneous inflation port.

8. The implant of claim 1, wherein the implant further comprises a band adapted to encircle an intestinal region and wherein the inflatable member is located on the band.

9. The implant of claim 8, wherein the band further comprises an attachment mechanism to attach a first region of the band to a second region of the band to enable the band to enclose an anatomical region.

10. The implant of claim 9, wherein the inflatable member and the band enclose a lumen and wherein the largest diameter of the lumen is less than 0.5 inches when the inflatable member is fully inflated.

11. The implant of claim 1, wherein the inflatable member is inflated with a fluid comprising a radio-opaque agent.

12. The implant of claim 1, wherein the implant comprises a substantially tubular region.

13. The implant of claim 1, wherein the implant comprises a valve mechanism that facilitates flow of food material in one direction through the bypass.

14. The implant of claim 1, wherein the implant comprises an anastomosis ring and wherein the inflatable member is attached to the anastomosis ring.

15. The implant of claim 1, wherein the implant is connected to the gastrointestinal tract by biocompatible fasteners selected from the group consisting of sutures, clips, staples, screws, tags and adhesives.

16. The implant of claim 1, wherein the implant comprises: a. a first element that is attached to the first region of the gastrointestinal tract; and b. a second element that is attached to the second region of the gastrointestinal tract; wherein the first element and the second element can be attached to each other and wherein the inflatable member is located on the first element or the second element.

17. The implant of claim 1, wherein the implant comprises: a. a first element that is attached to the first region of the gastrointestinal tract; and b. a second element that is attached to the second region of the gastrointestinal tract; and c. a third element that connects the first element to the second element and wherein the inflatable member is located on the third element.

18. The implant of claim 1, wherein the implant comprises at least one aperture that enables direct physical contact between at least one portion of the first region of a gastrointestinal tract and at least one portion of the second region of a gastrointestinal tract.

19. The implant of claim 1, wherein the implant comprises a bioabsorbable or biofragmentable element.

20. The implant of claim 19, wherein the bioabsorbable or biofragmentable element comprises a material selected from the group consisting of polyglycolic acid and other poly-hydroxy acids, polylactides, poly(dioxanone), poly(trimethylene carbonate) copolymers, poly (epsilon-caprolactone) homopolymers and copolymers, polydioxanone, polyanhydrides, polyorthoesters, poly-amino acids, polyesteramides, polyphosphazenes, polyhydroxybutyrate (PHB), polyhydroxyvalerate (PHV), modified cellulose, collagen, poly(glycolide-co-trimethylene carbonate), poly(l-lactide-co-glycolide), poly (dl-lactide-co-glycolide), poly (l-lactide-co-dl-lactide), poly(glycolide-co-trimethylene carbonate-co-dioxanone), polylactic acid-polyethylene oxide copolymers, and combinations thereof.

21. The implant of claim 1, wherein the implant comprises a material selected from the group consisting of silicone rubber, polyethylene terephthalate, ultra high molecular weight polyethylene, expanded polytetrafloroethylene, polypropylene, polycarbonate urethane, polyurethane, polyamides, stainless steel, titanium, a nickel-titanium alloy and a cobalt alloy.

22. The implant of claim 1, wherein the implant comprises a coated or impregnated antibiotic.

23. The implant of claim 1, wherein the implant comprises a radio-opaque marker.

24. The implant of claim 23, wherein the radio-opaque marker is located on the inflatable member.

25. The implant of claim 2, wherein the cross-section of the implant lumen is elongated along one direction.

26. A device for causing weight loss comprising: an implant defining an implant lumen that creates a bypass between a first region of the intestine and a second region of the intestine such that a fraction of food material passing through the intestinal tract passes through the bypass, wherein the size of a cross-section of the implant lumen can be adjusted to adjust the fraction of the food material passing through the bypass.

27. The device in claim 26, wherein the implant comprises a deformable element, wherein the size of the implant lumen is adjusted by deformation of the deformable element.

28. The implant of claim 26, wherein the implant comprises an anastomosis ring.

29. The implant of claim 26, wherein the implant is connected to the gastrointestinal tract by biocompatible fasteners selected from the group consisting of sutures, clips, staples, screws, tags and adhesives.

30. The implant of claim 26, wherein the implant comprises at least one aperture that enables direct physical contact between at least one portion of a first region of the gastrointestinal tract and at least one portion of a second region of the gastrointestinal tract.

31. The implant of claim 26, wherein the implant comprises a bioabsorbable or biofragmentable element.

32. The implant of claim 26, wherein the bioabsorbable or biofragmentable element comprises a material selected from the group consisting of polyglycolic acid and other poly-hydroxy acids, polylactides, poly(dioxanone), poly(trimethylene carbonate) copolymers, poly (epsilon-caprolactone) homopolymers and copolymers, polydioxanone, polyanhydrides, polyorthoesters, poly-amino acids, polyesteramides, polyphosphazenes, polyhydroxybutyrate (PHB), polyhydroxyvalerate (PHV), modified cellulose, collagen, poly(glycolide-co-trimethylene carbonate), poly(l-lactide-co-glycolide), poly (dl-lactide-co-glycolide), poly (l-lactide-co-dl-lactide), poly(glycolide-co-trimethylene carbonate-co-dioxanone), polylactic acid-polyethylene oxide copolymers, and combinations thereof.

33. The implant of claim 26, wherein the implant comprises a material selected from the group consisting of silicone rubber, polyethylene terephthalate, ultra high molecular weight polyethylene, expanded polytetrafloroethylene, polypropylene, polycarbonate urethane, polyurethane, polyamides, stainless steel, titanium, a nickel-titanium alloy and a cobalt alloy.

34. The implant of claim 26, wherein the implant comprises a coated or impregnated antibiotic.

35. The implant of claim 26, wherein the implant comprises a radio-opaque marker.

36. The implant of claim 27, wherein the deformable element comprises a radio-opaque marker.

37. The implant of claim 26, wherein the cross-section of the implant lumen is elongated along one direction.

38. The device as recited in claim 54, wherein the size of a cross-section of the implant lumen can be adjusted by endoscopic means.

39. A method for treating obesity comprising the step of: creating an adjustable bypass between a first region of the intestine and a second region of the intestine, wherein a fraction of food material passing through the intestine passes through the adjustable bypass, and wherein the adjustable bypass is adjusted by an inflatable member.

40. The method as recited in claim 39, further comprising the step of inflating or deflating the inflatable member.

41. The method as recited in claim 40, wherein the step of inflating or deflating the inflatable member is performed after the creation of the adjustable bypass.

42. The method as recited in claim 40, wherein the step of inflating or deflating the inflatable member is performed by introducing or removing an inflating fluid through a subcutaneous port.

43. The method as recited in claim 39, wherein the method is used in conjunction with an existing gastric surgery for weight loss.

44. The method as recited in claim 43, wherein the gastric surgery is selected from the group consisting of: adjustable gastric banding surgery, sleeve gastrectomy, and vertical banded gastroplasty.

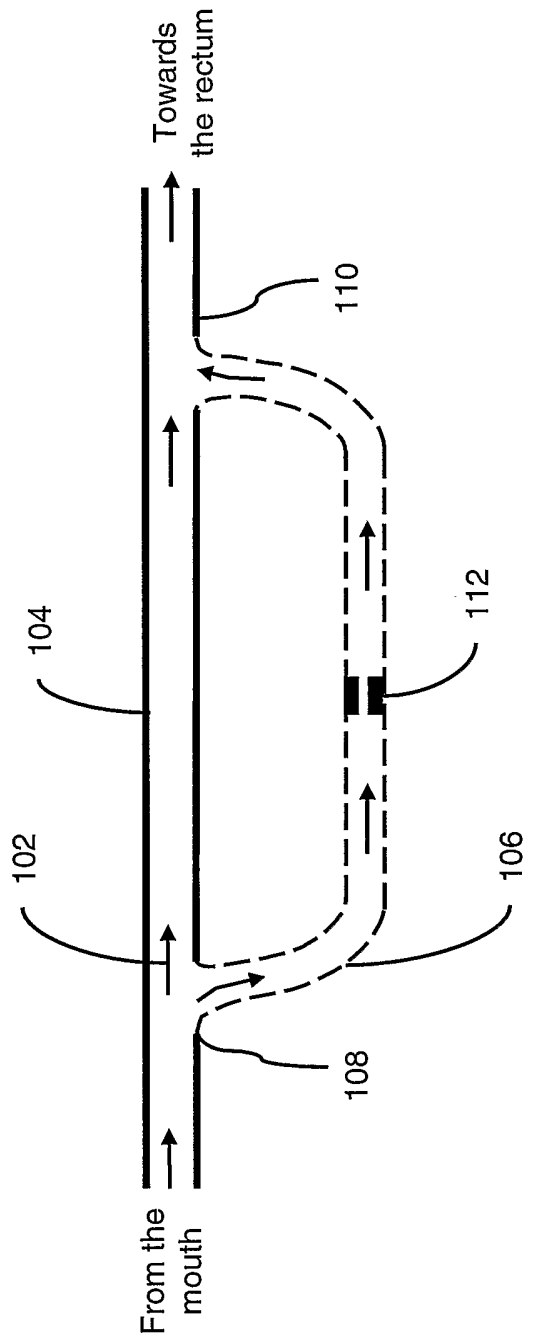

FIG. 1

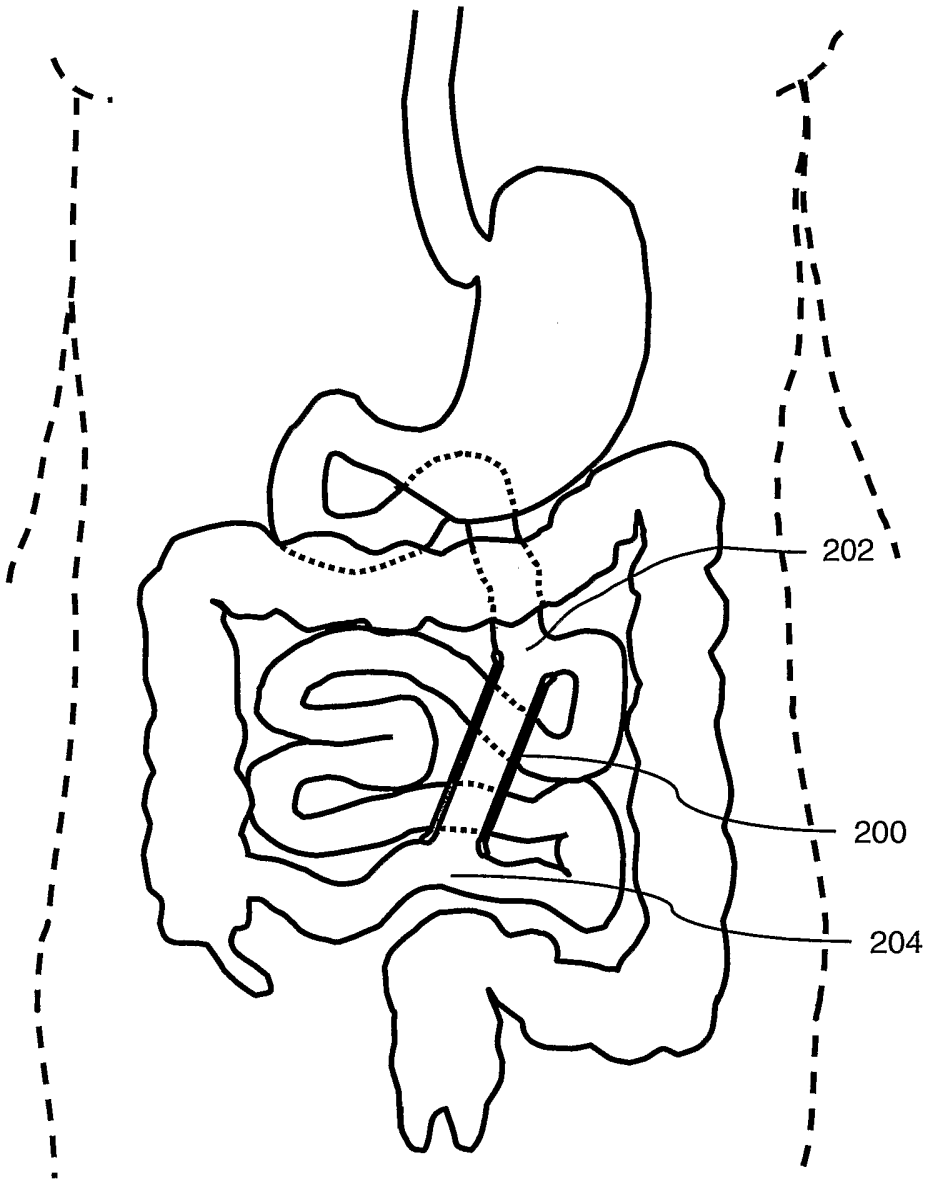

FIG. 2

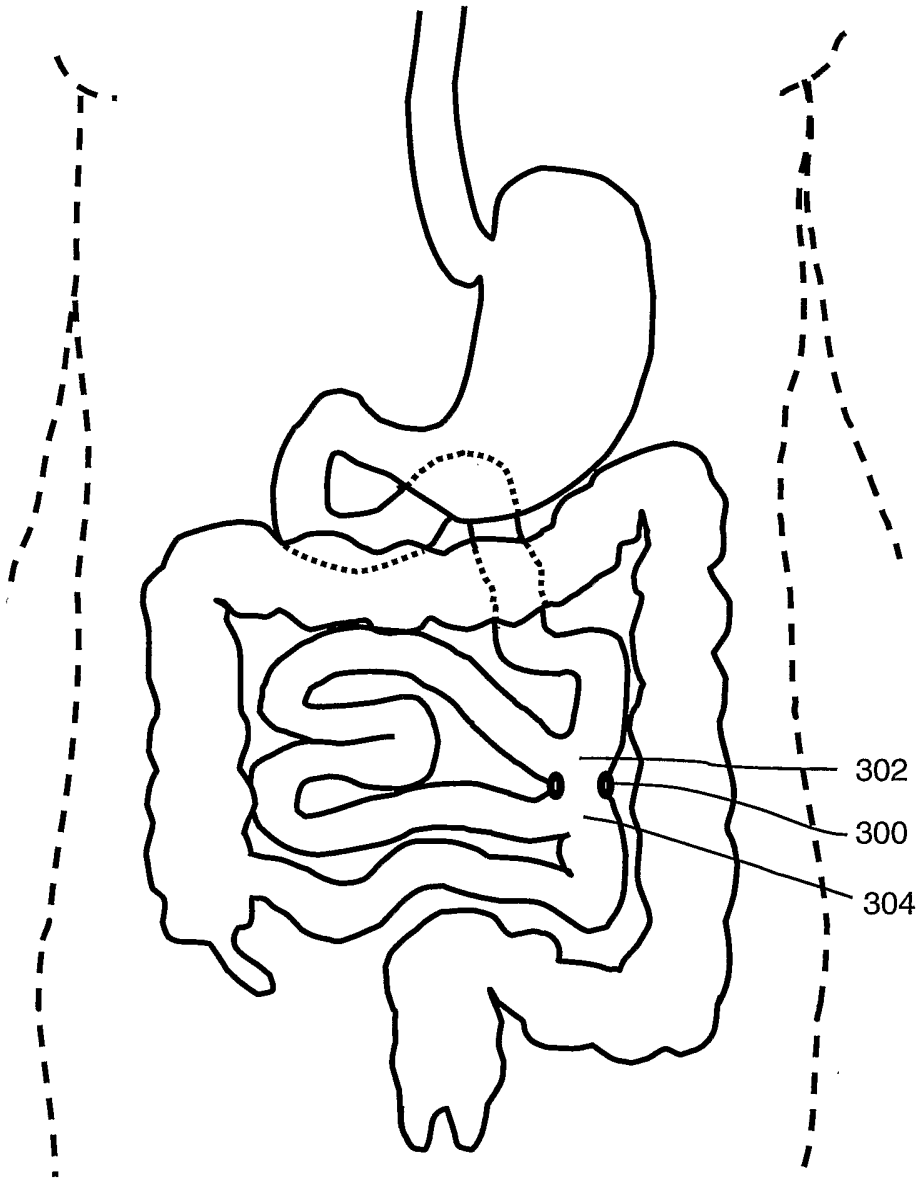

FIG. 3

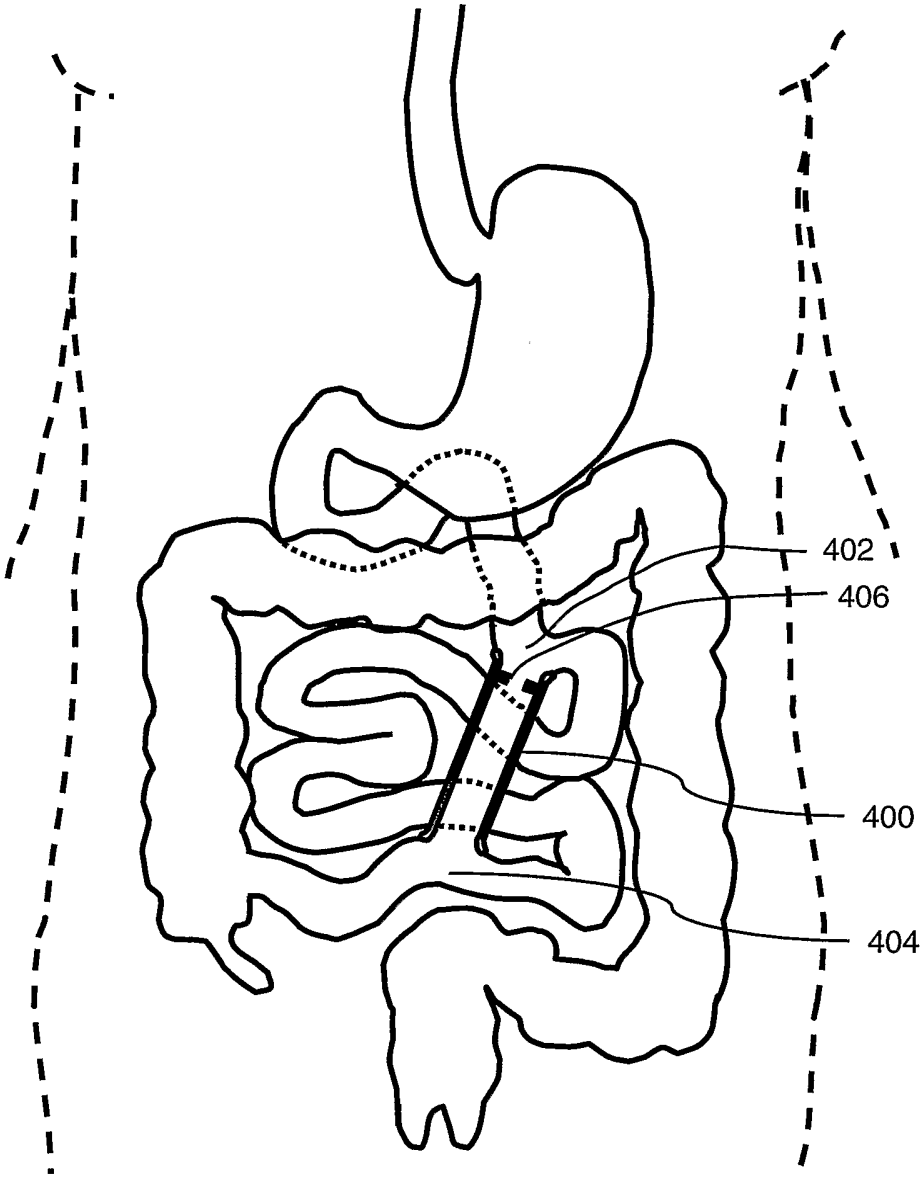

FIG. 4

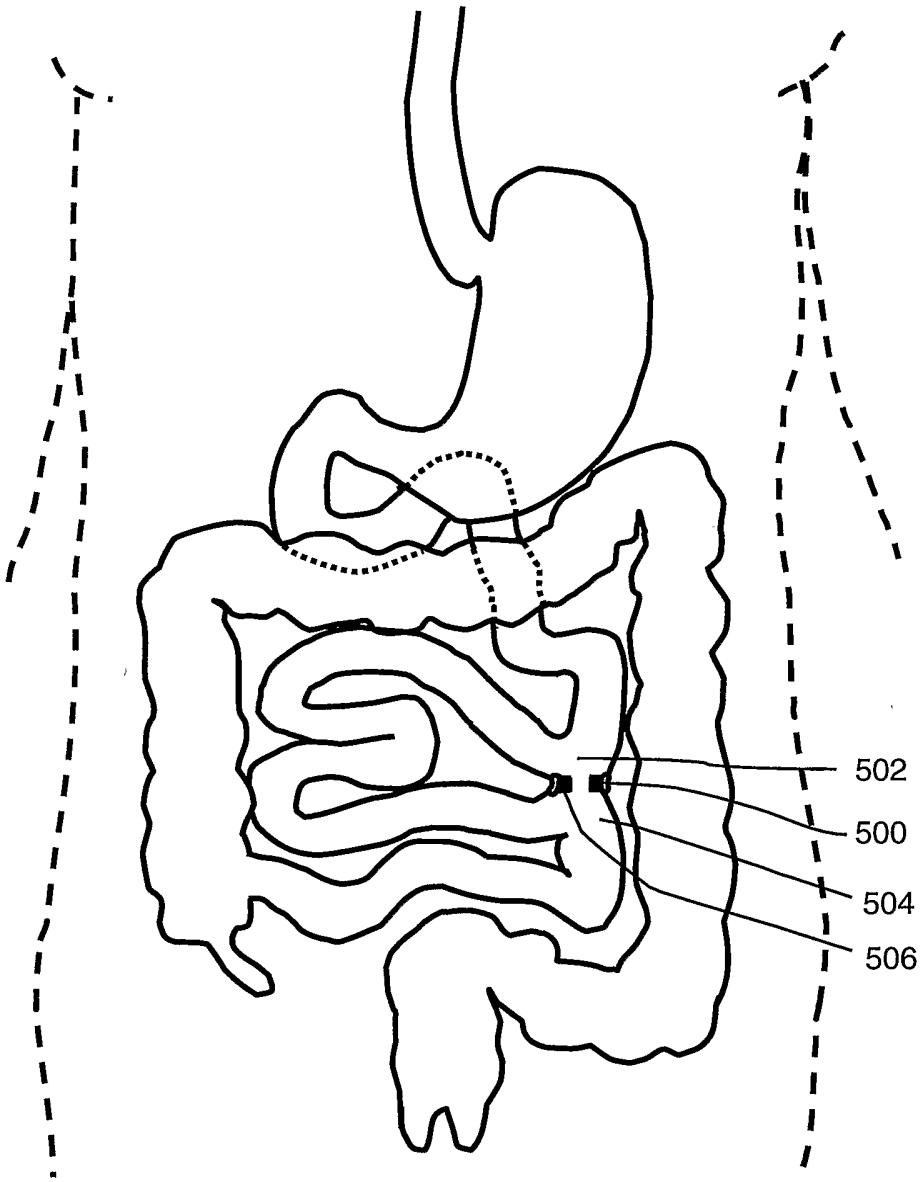

FIG. 5

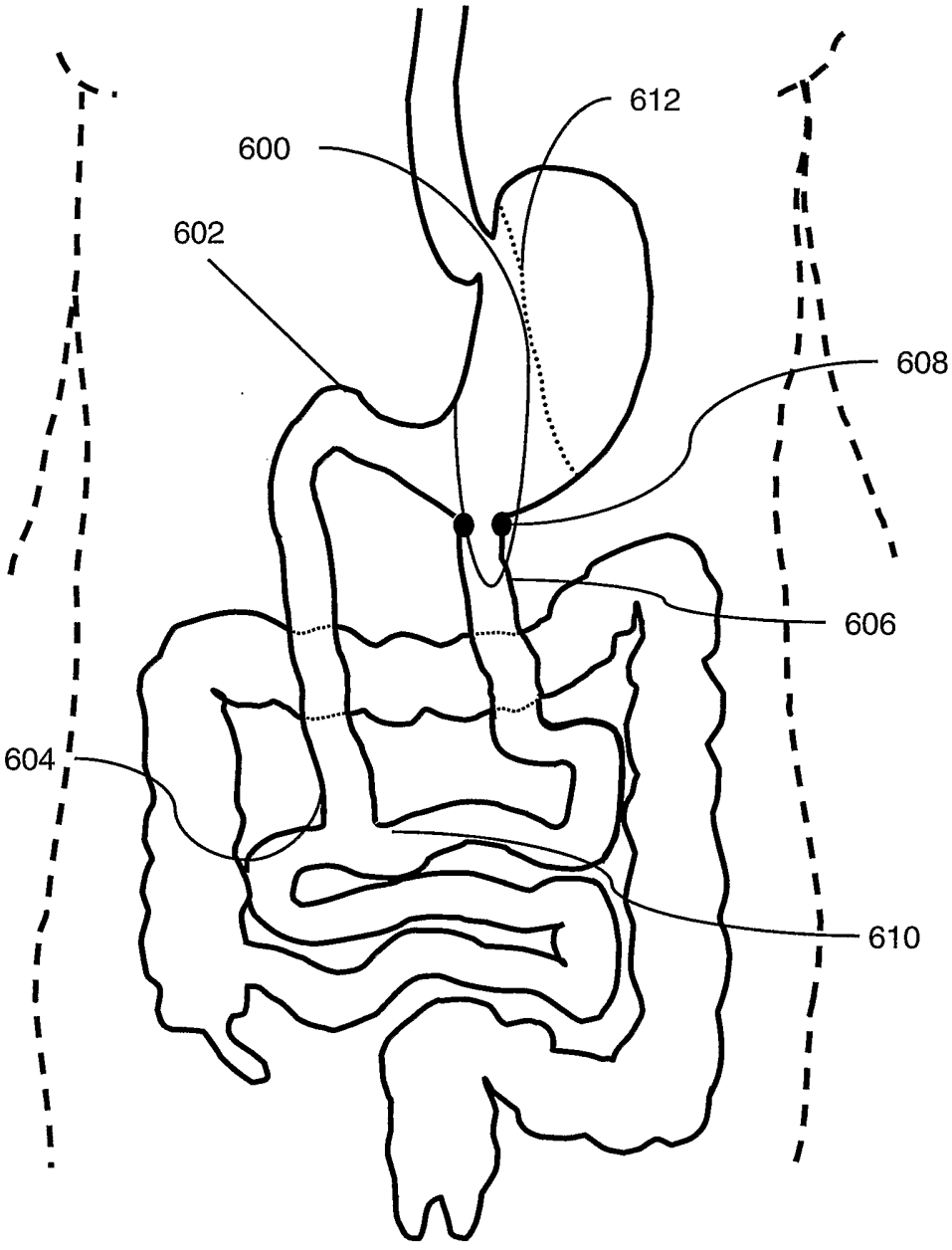

FIG. 6

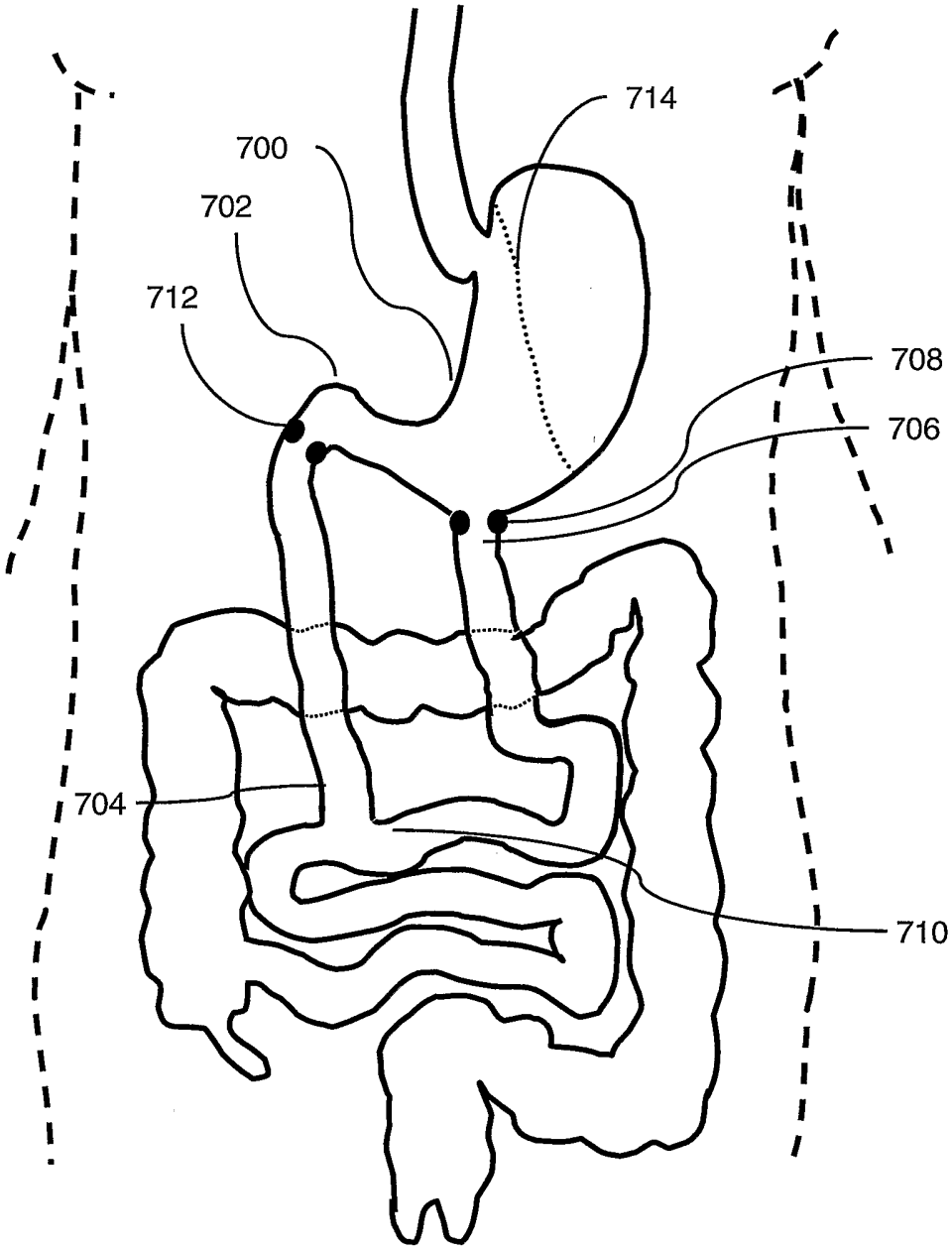

FIG. 7

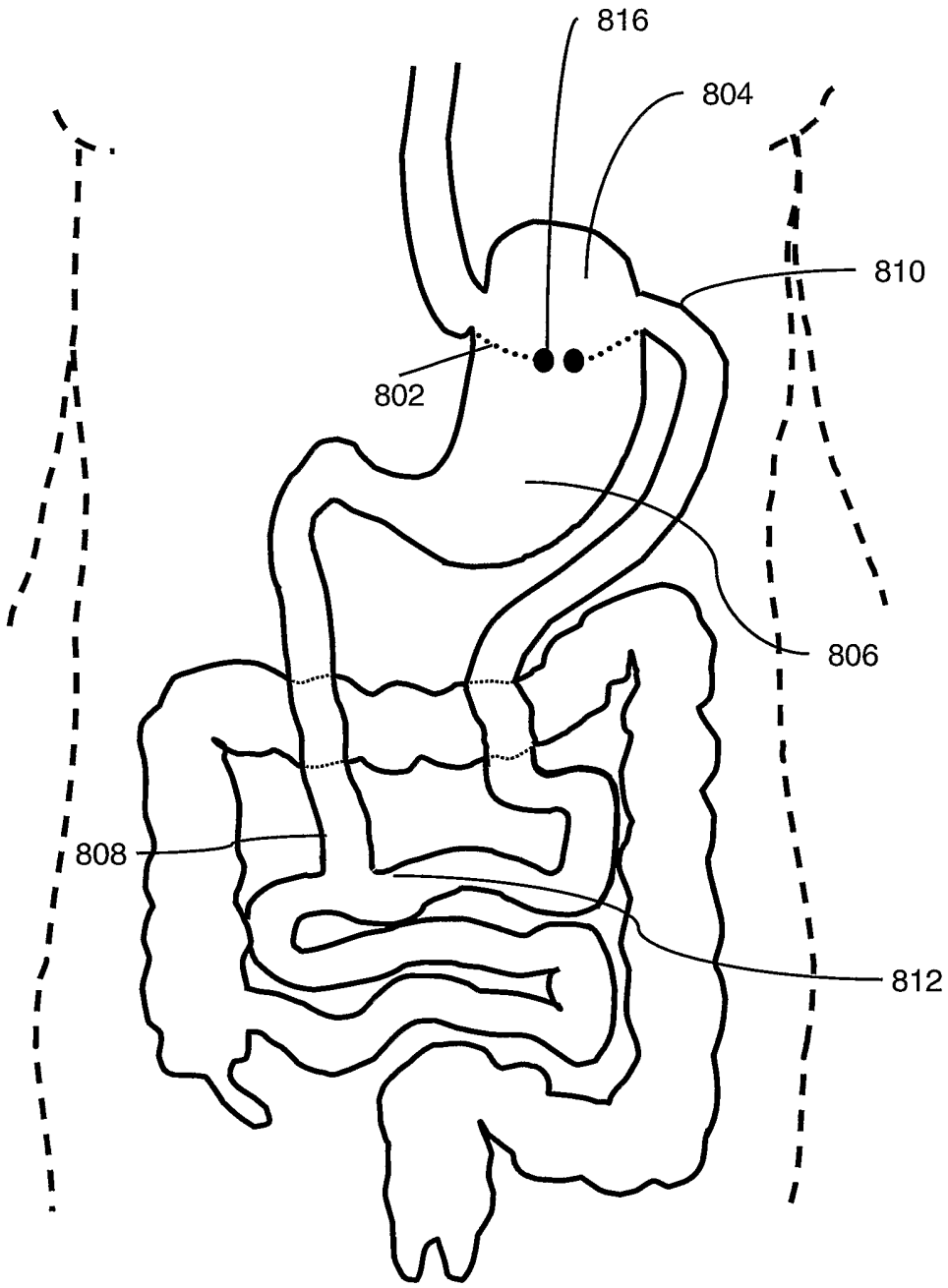

FIG. 8

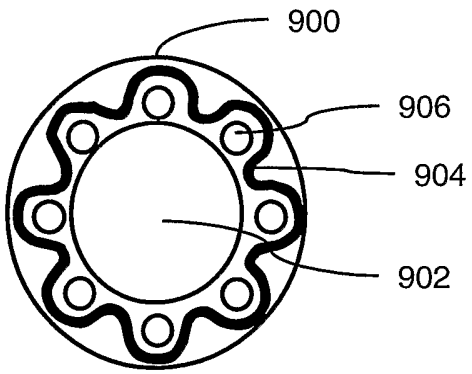

FIG. 9A

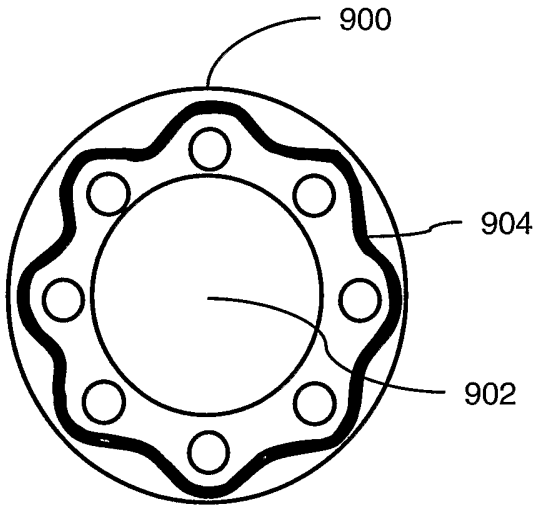

FIG. 9B

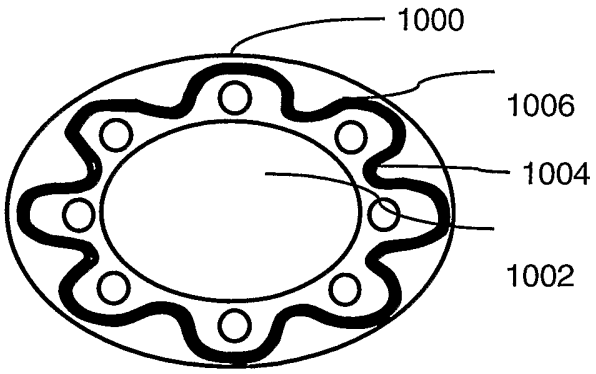

FIG. 10A

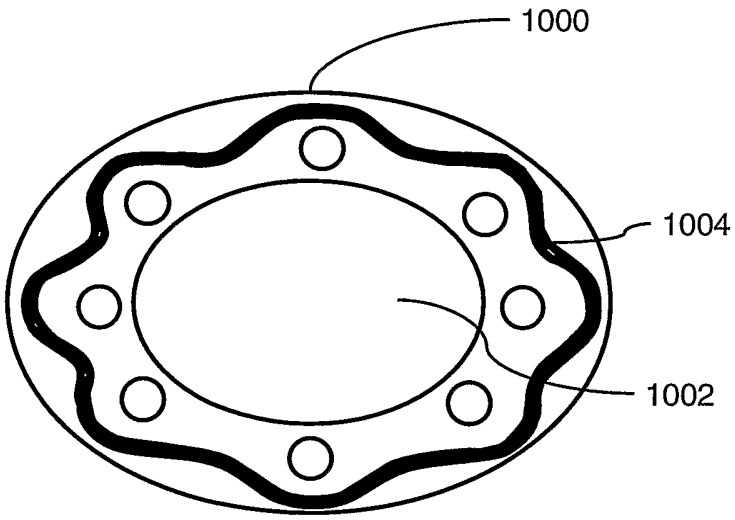

FIG. 10B

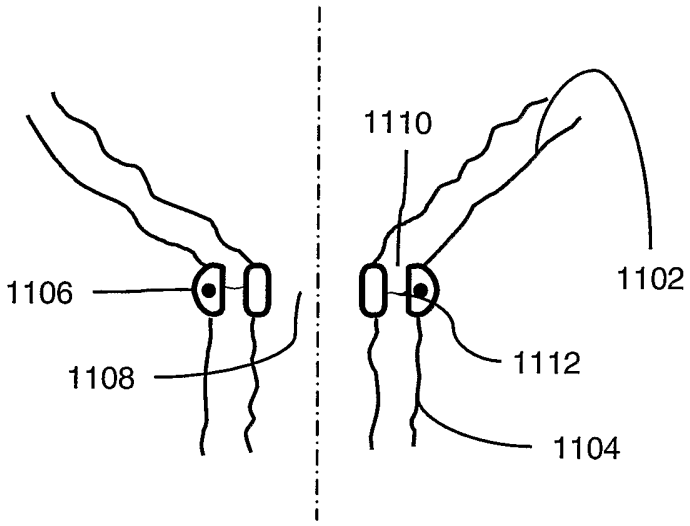

FIG. 11A

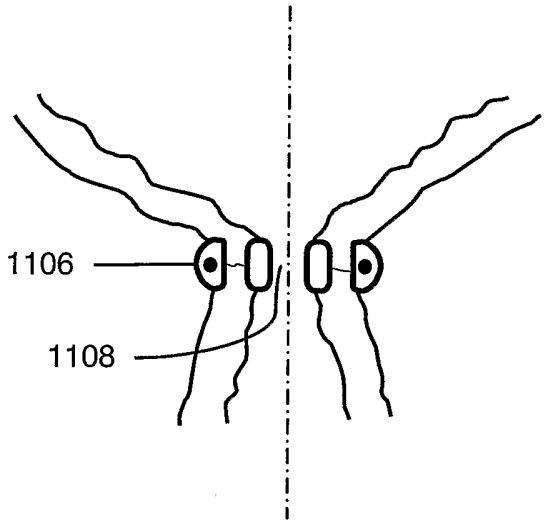

FIG. 11B

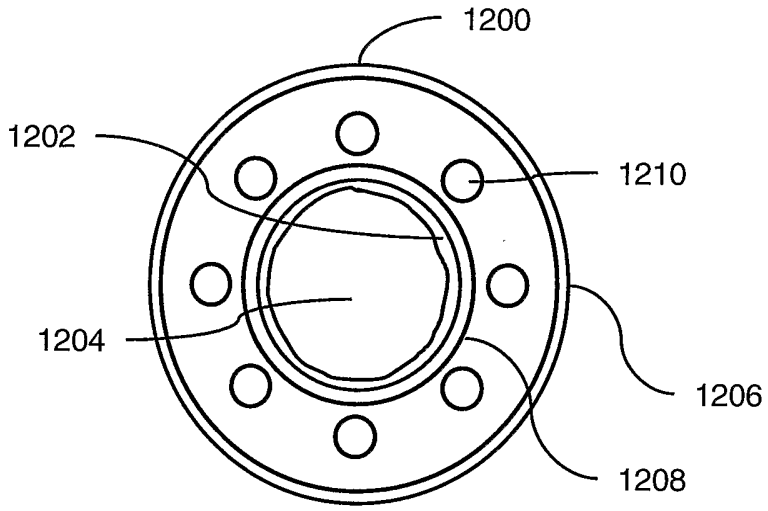

FIG. 12A

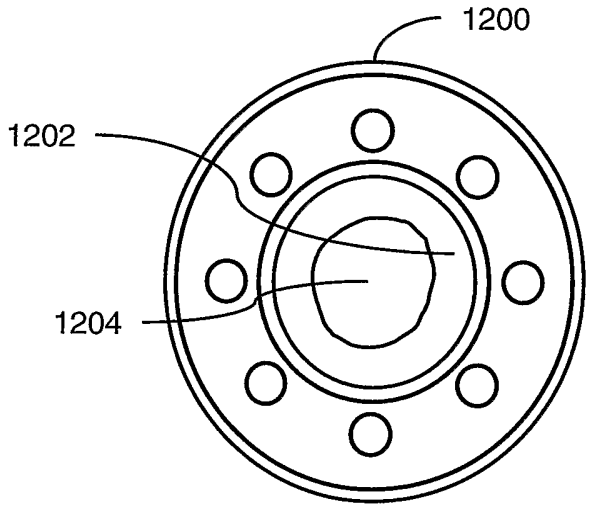

FIG. 12B

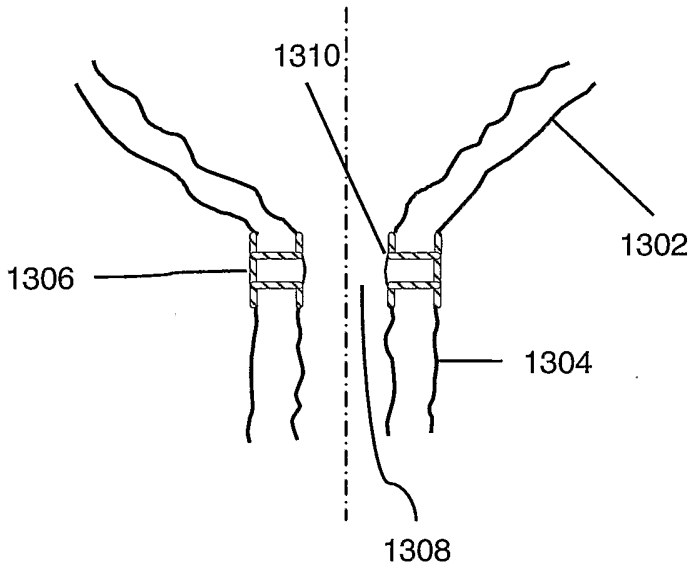

FIG. 13A

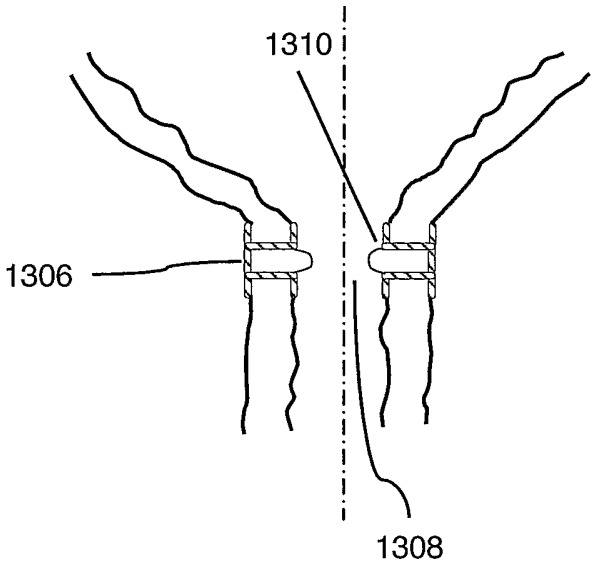

FIG. 13B

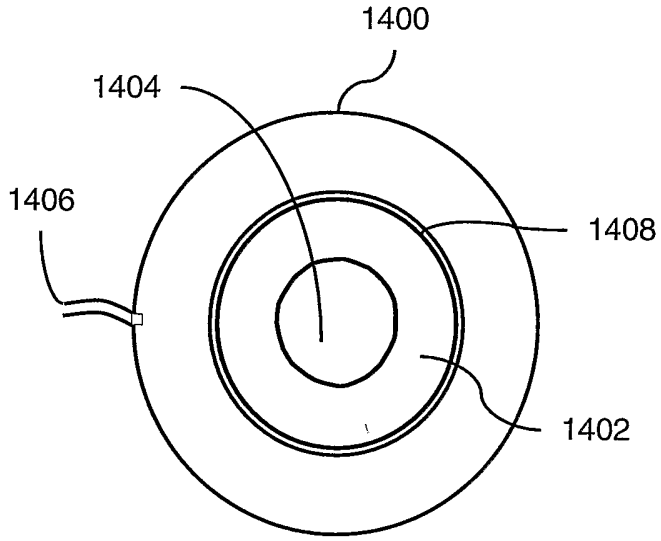

FIG. 14A

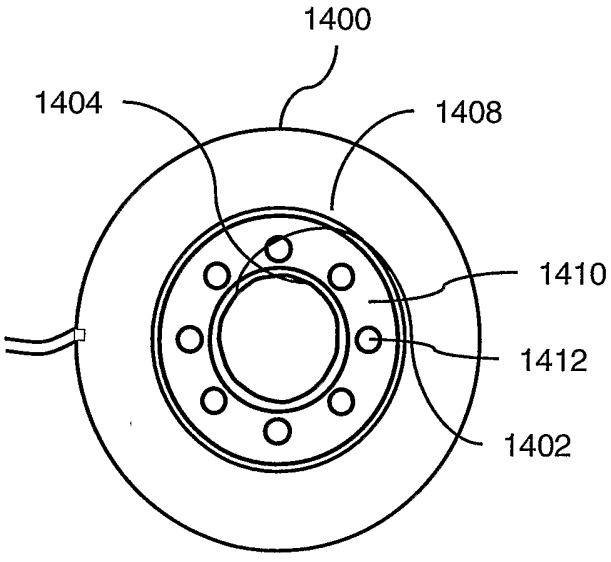

FIG. 14B

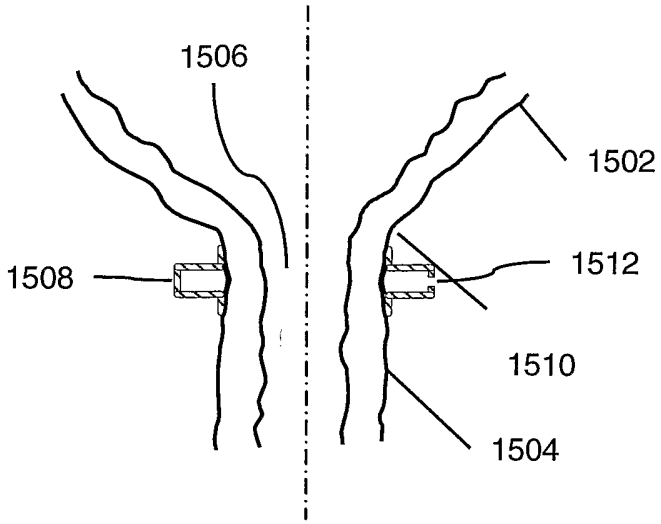

FIG. 15A

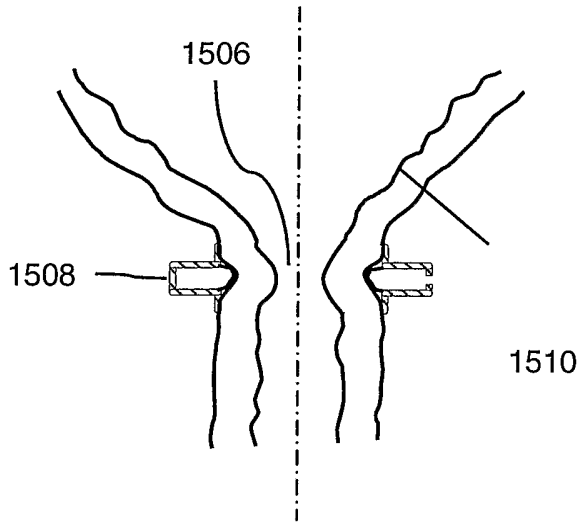

FIG. 15B

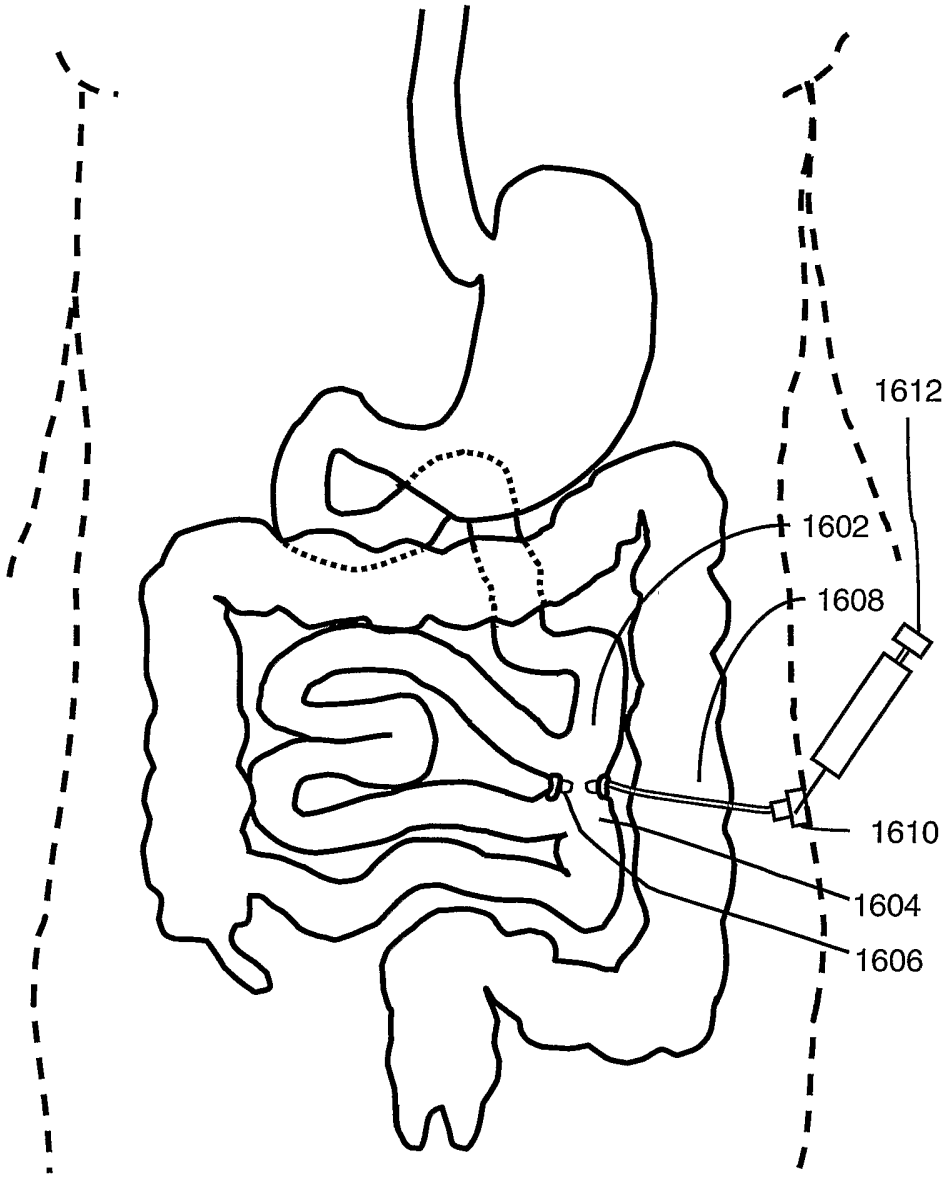

FIG. 16

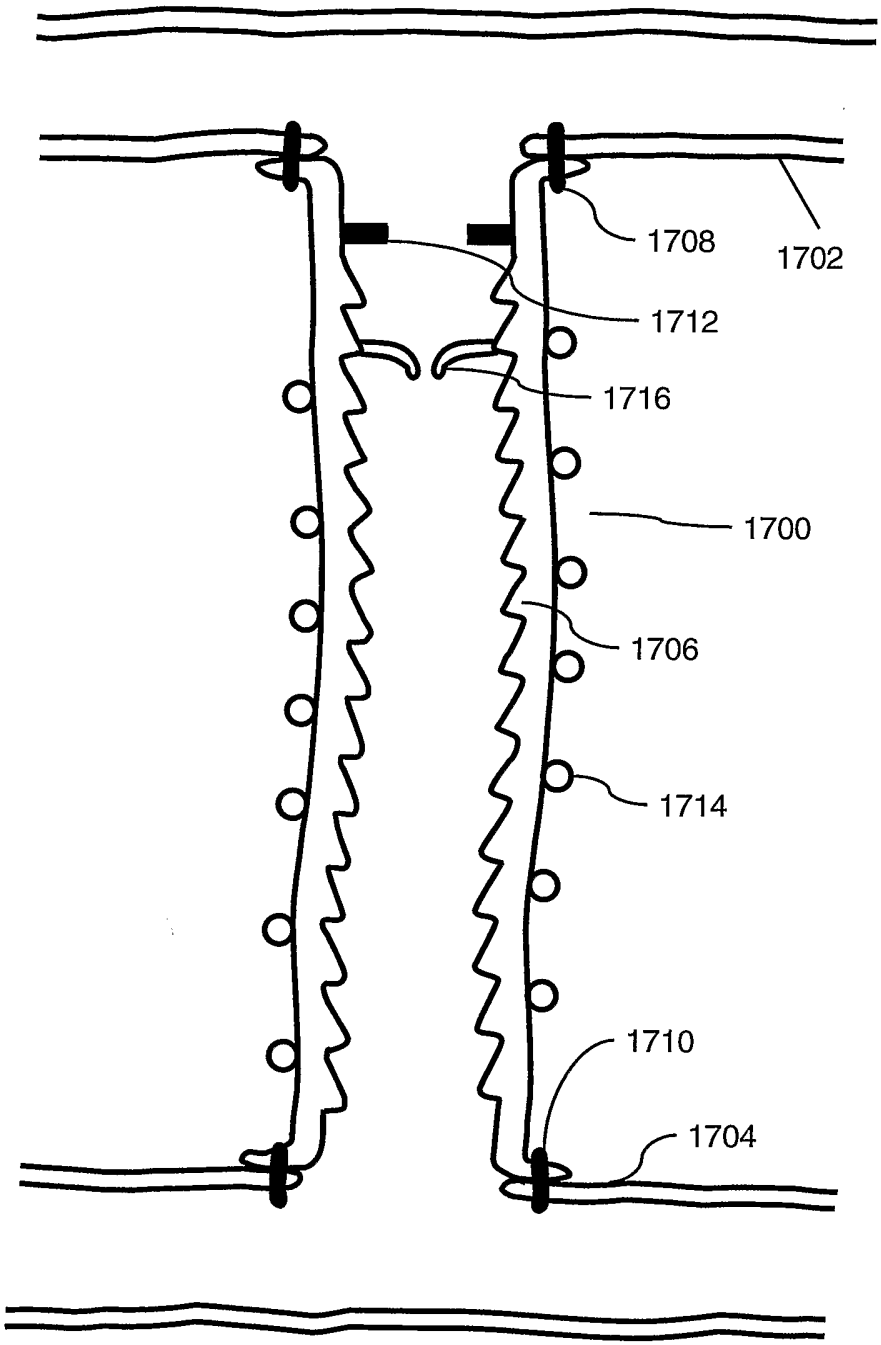

FIG. 17

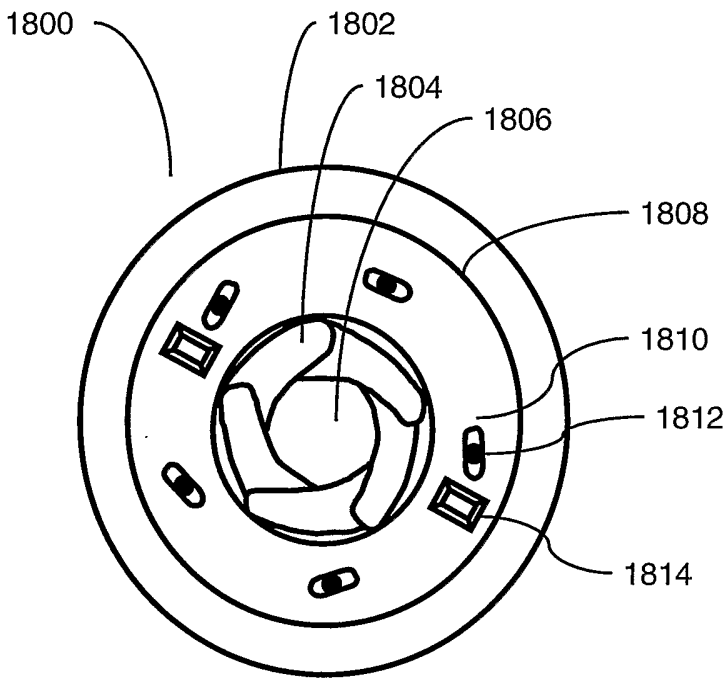

FIG. 18

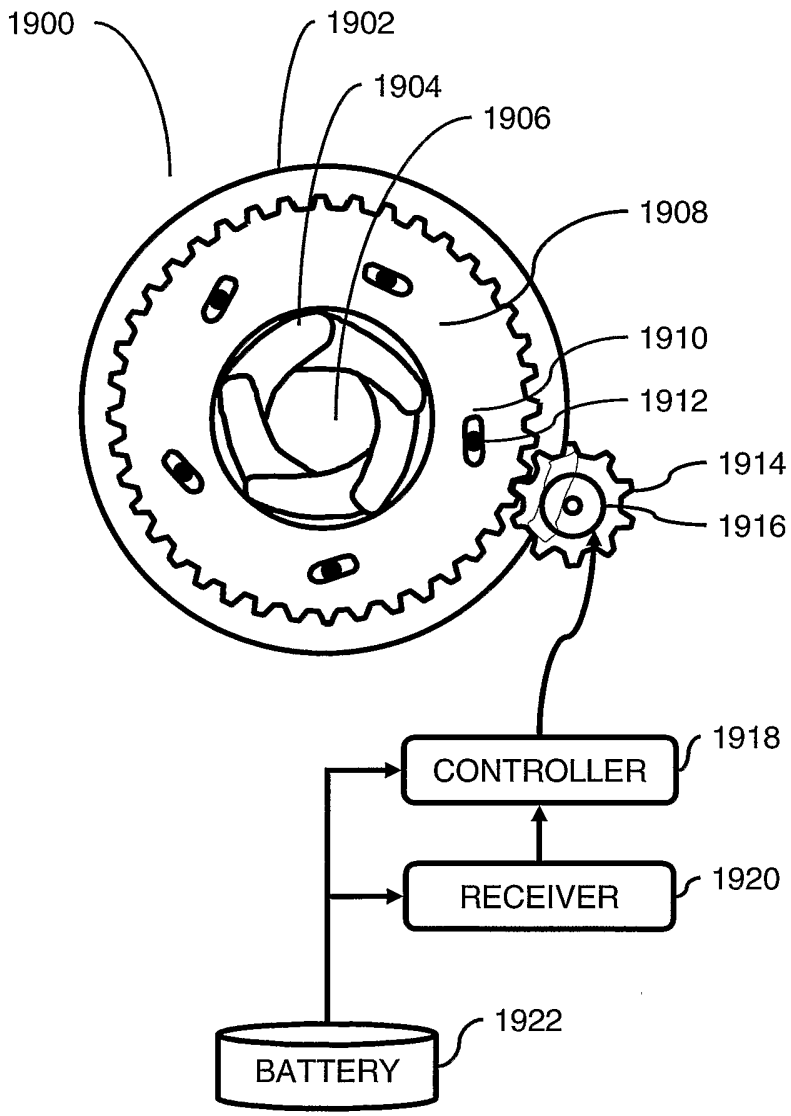
1900
1902
1904
1906
1908
1910
1912
1914
1916
CONTROLLER
1918
RECEIVER
1920
BATTERY
1922

FIG. 19

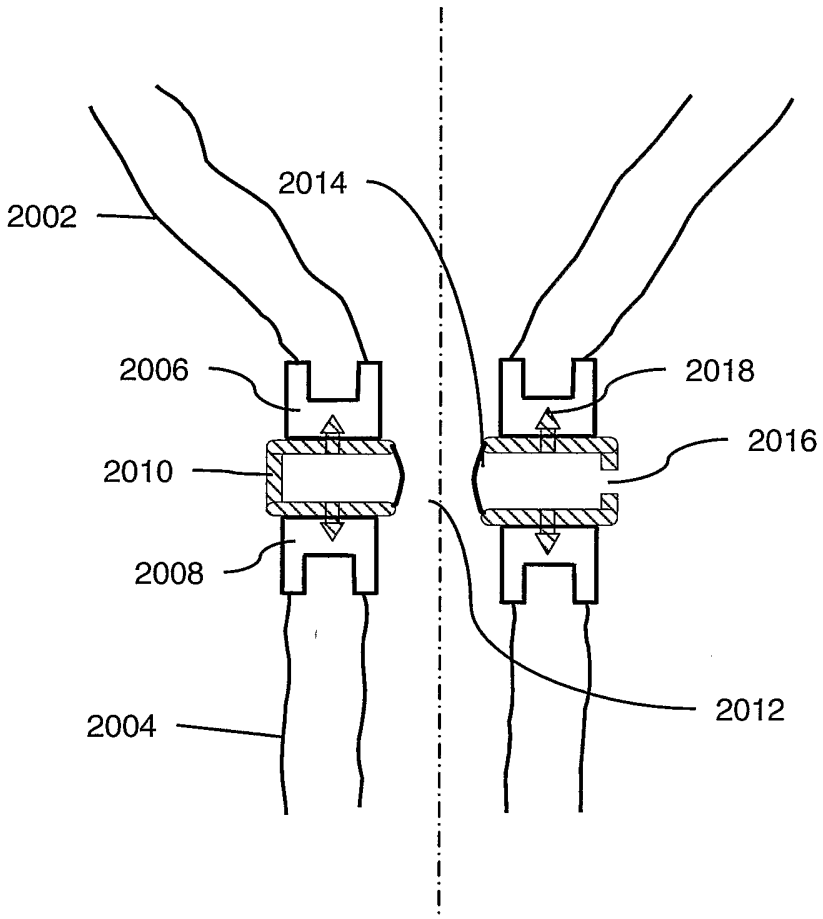

FIG. 20

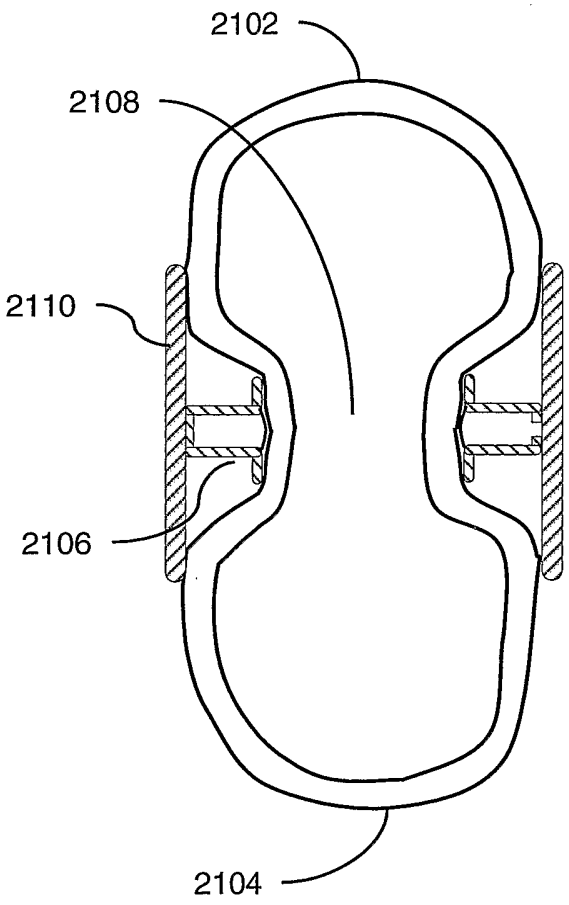

FIG. 21

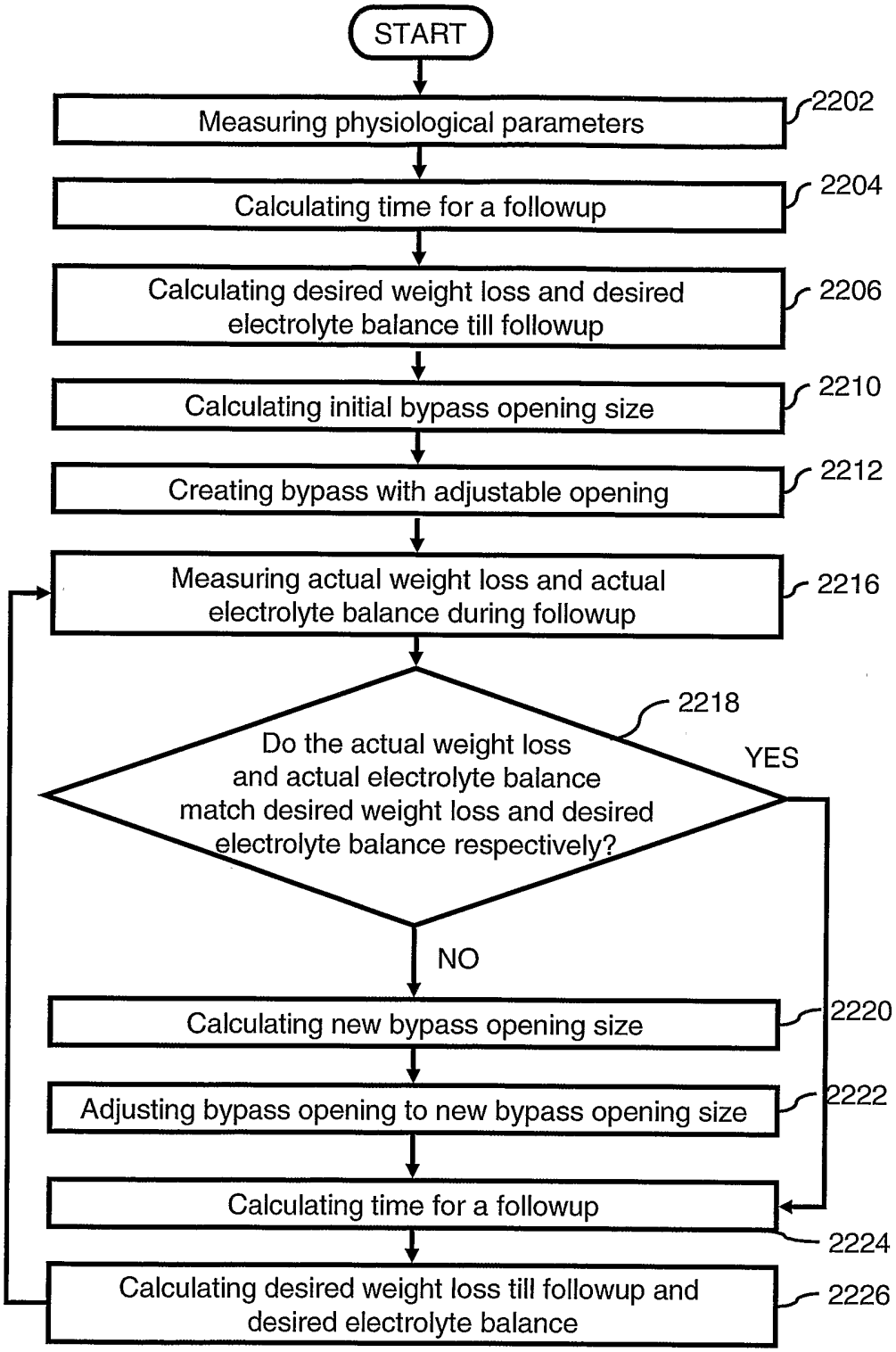
START
Measuring physiological parameters
2202
Calculating time for a followup
2204
Calculating desired weight loss and desired electrolyte balance till followup
2206
Calculating initial bypass opening size
2210
Creating bypass with adjustable opening
2212
Measuring actual weight loss and actual electrolyte balance during followup
2216
Do the actual weight loss and actual electrolyte balance match desired weight loss and desired electrolyte balance respectively?
2218
YES
NO
Calculating new bypass opening size
2220
Adjusting bypass opening to new bypass opening size
2222
Calculating time for a followup
2224
Calculating desired weight loss till followup and desired electrolyte balance
2226

FIG. 22

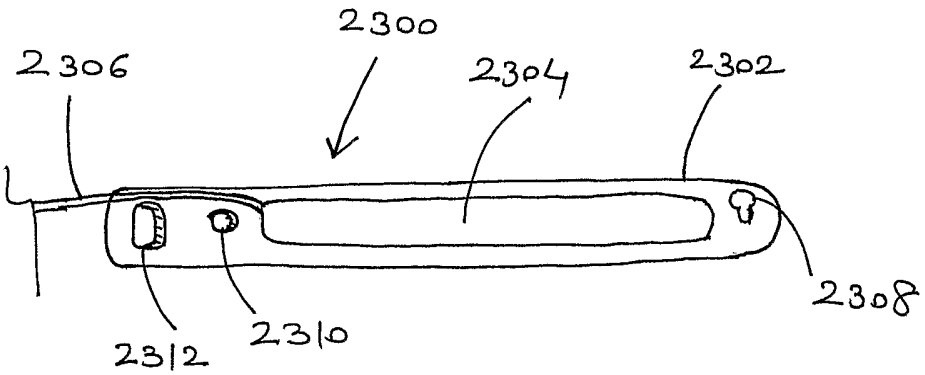

FIG. 23A

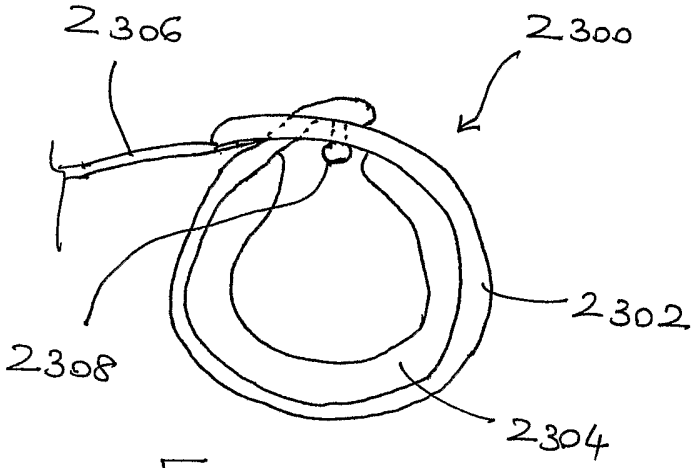

FIG. 23B

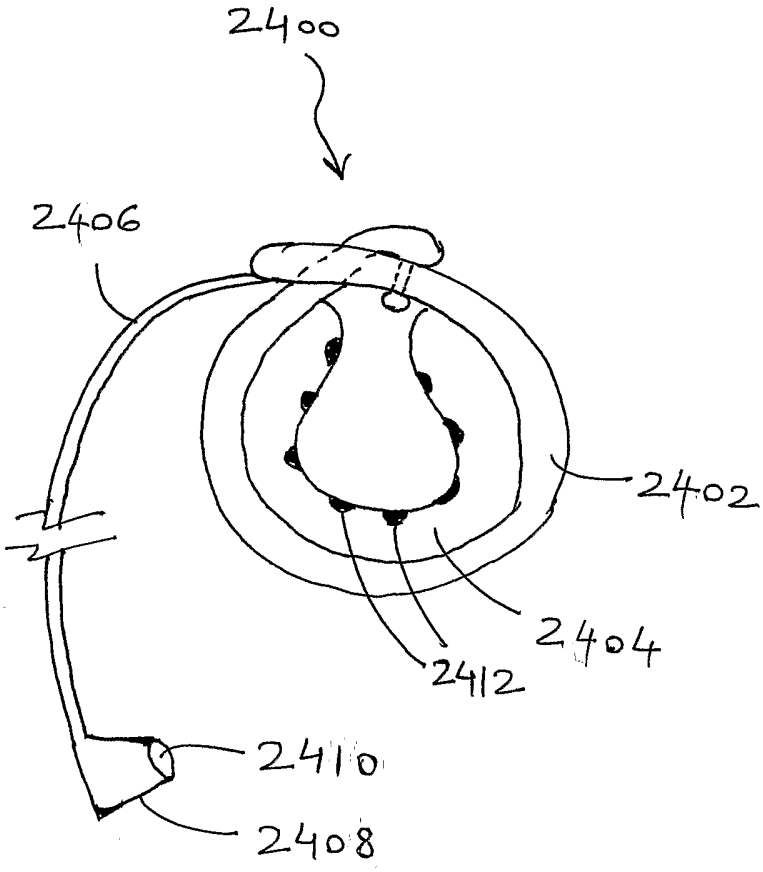

FIG. 24

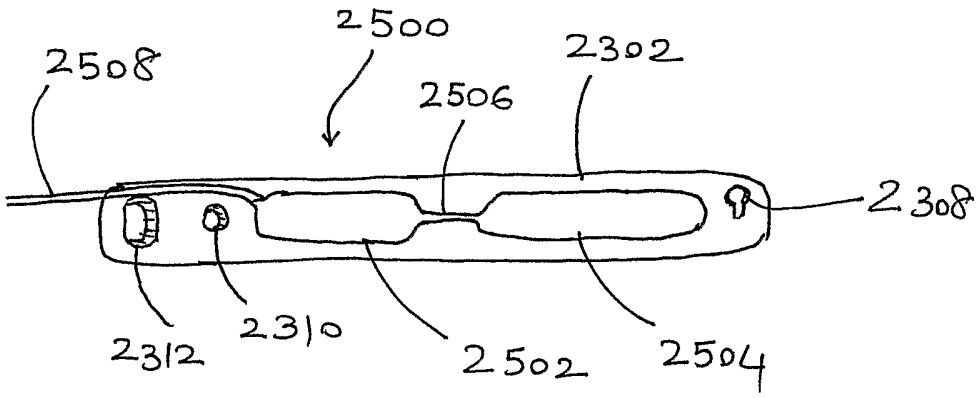

FIG. 25

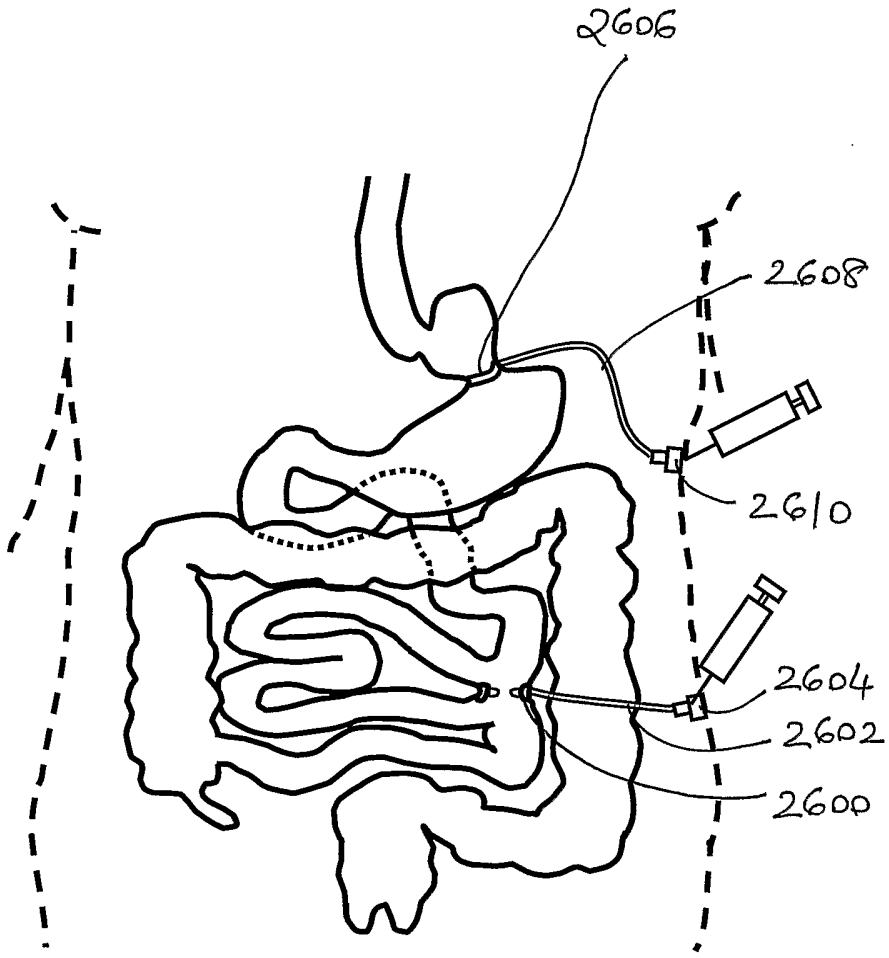

FIG. 26

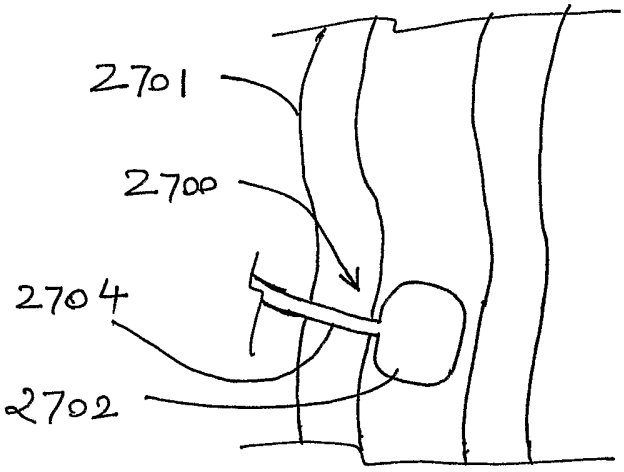

FIG. 27

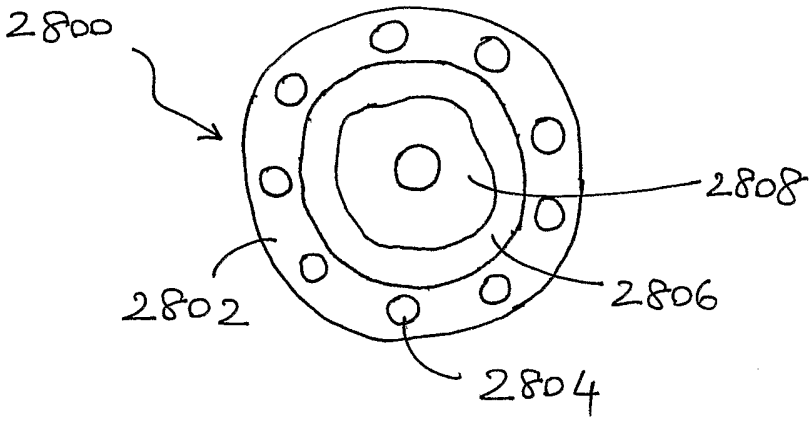

FIG. 28A

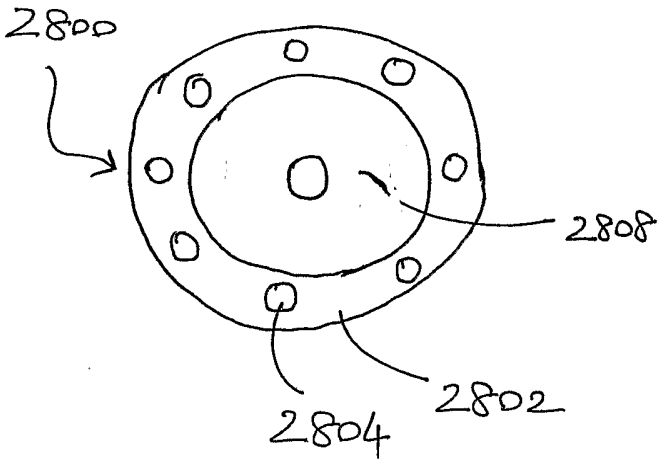

FIG. 28B