Note: Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).
According to the Center for Disease Control (CDC), over sixty percent of the United States population is overweight, and almost twenty percent are obese. This translates into about 38.8 million adults in the United States with a Body Mass Index (BMI) of 30 or above. The BMI is generally defined as the weight (e.g., in kilograms) of an individual divided by the height (e.g., in meters) of the individual, squared. To be considered clinically, morbidly obese, one must meet one of three criteria: BMI over 35, 100 lbs. overweight, or 100% above ideal body weight. There is also a category for the super-obese for those weighing over 350 lbs.

Obesity is thus an overwhelming health problem in the U.S. Moreover, because of the enormous strain associated with carrying this excess weight, organs are affected, as are the nervous and circulatory systems in an individual who is overweight or obese. In 2000, the National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK) estimated that there were 280,000 deaths directly related to obesity. The NIDDK further estimated that the direct cost of healthcare in the US associated with obesity is $51 billion. In addition, Americans spend approximately $33 billion per year on weight loss products. In spite of this economic cost and consumer commitment, the prevalence of obesity continues to rise at alarming rates. From 1991 to 2000, obesity in the US grew by about 61%. Not exclusively a US problem, worldwide obesity percentages are also increasing dramatically.

There have been many attempts in the past to surgically modify anatomies of a patient to address the consumption problem by reducing the desire to eat. Stomach staplings, or gastroplasties, in order to reduce the volumetric size of the stomach, therein achieving faster satiety, were initially performed in the 1980’s and early 1990’s. Although able to achieve early weight loss, sustained reduction in connection with gastroplasties was not obtained. The reasons are not all known, but are believed to be related to several factors. One of which is that the stomach stretches over time, thereby increasing volume, while psychological drivers motivate patients to find creative approaches to literally eat around the smaller pouch.

Space-occupying gastric balloons have also been used to treat obesity since the 1980’s. One such balloon is described by Garren et al. (4,899,747 Method and apparatus for treating obesity). Gastric balloons are generally designed to decrease the functional volume of the stomach.

Similarly, intestinal sleeves are also being used for obesity treatment (Levine et al., 7,347,875 Methods of treatment using a bariatric sleeve; Levine et al. 7,025,791 Bariatric sleeve). These sleeves consist of an anchoring mechanism that attaches at one end of a thin walled plastic sleeve and extends from the pylorus to allow the sleeve to extend past the Ligament of Treitz. Intestinal sleeves function to decrease absorption from the portion of bowel covered by the sleeve. Presently, a guidewire is advanced into the patient’s jejunum under fluoroscopic guidance (Gersin KS, Keller JE, Stefanidis D, et al. Duodenal jeuna bypass sleeve: A totally endoscopic device for the treatment of morbid obesity. Surg Innov 2007:14:275). A gastroscope is then used to deploy the stent-like anchor in the pylorus, and gastroscopic instruments; e.g., graspers, are used to hold the sheath and advance it along the intestine to the Ligament of Treitz. However, complications often associate with delivery of intestinal sleeves. In addition, the sleeves are difficult to manipulate, and especially the current methods for advancing the sleeves along the intestine are time consuming and inefficient.

In another approach, an open bariatric surgical procedure known as the “Roux-en-Y” procedure, a small stomach pouch is created by stapling part of the stomach together. This small pouch can limit how much food an individual can eat. In addition, a Y-shaped section of the small intestine is attached to the pouch to allow food to bypass the duodenum as well as the first portion of the jejunum. This causes reduced calorie and nutrient absorption. Common problems associated with Roux-en-Y include pouch stretching, where the stomach gets bigger overtime and can stretch back to its original size over time; a breakdown of staple lines where the staples fall apart and reverse the procedure; and a leakage of stomach contents into the abdomen (this is dangerous because the acid can eat away other organs. In addition, as the Roux-en-Y procedure requires open surgery, it is a painful, time-consuming operation and requires relatively long recovery time.

Accordingly, it would be desirable to have an effective system for bariatric therapy, reducing the harmful side effects such as painful surgical operations. In particular, there is a need for effective systems and delivery mechanisms for bariatric therapy that can minimize complications and recovery time, reduce operation time and resources, and improve therapy efficiency, success rate, and safety.

US 2011/0046537 provides systems and methods for treating and controlling obesity and/or type II diabetes. It discloses a device comprising a hollow sleeve sized and shaped for positioning within a duodenum of the patient, an anchor coupled to the proximal end of the sleeve and being sized and shaped to inhibit distal migration of the sleeve and a plurality of elastomeric objects coupled to the distal end of the sleeve and being sized and shaped to inhibit proximal migration of the sleeve through a pylorus of the patient. The bypass device can be placed and removed endoscopically through the patient’s esophagus in a minimally invasive outpatient procedure. It is “self-anchoring” and does not require invasive tissue fixation within the patient’s GI tract, thereby reducing collateral tissue damage and minimizing its im-
The present invention provides, in an embodiment, a gastrointestinal implant device according to claim 1. The sleeve, in an embodiment, may be made from a sufficiently flexible material to permit the sleeve to move between an inverted position and an everted position. In certain embodiments, the sleeve may be made from a material having substantially low permeability, so as to minimize absorption of nutrients from the digested food by the wall of the small intestine. The gastrointestinal implant device, includes an anchoring mechanism coupled to a proximal end of the sleeve and designed to be secured within a stomach, so as to allow the sleeve to securely extend into the small intestine. In some embodiments, the anchoring mechanism is designed to reduce functional volume of the stomach. The anchoring mechanism, in one example, can be an inflatable balloon sufficiently large to prevent the inflatable balloon from entry into the small intestine. To that end, the anchoring mechanism may include a port for inflating the anchoring mechanism. The anchoring mechanism may alternatively be a self-expanding frame which, upon expansion, can be substantially frustoconical in shape for securing against a wall of the stomach, while allowing the stomach to maintain a substantially full functional volume. The gastrointestinal implant device, in an embodiment, can further include a passageway extending through the anchoring mechanism and the sleeve, and along which digested food can be directed from the stomach into the small intestine.

In an exemplary embodiment not forming part of the invention, a bariatric therapy system. The system can include a gastrointestinal implant device. The device, in an embodiment, can include a sleeve for placement into a small intestine and to minimize absorption of nutrients by a wall of the small intestine. The device can also include an anchoring mechanism coupled to a proximal end of the sleeve and designed to be secured within

SUMMARY OF THE INVENTION

The present invention provides, in an embodiment, a gastrointestinal implant device according to claim 1. The sleeve, in an embodiment, may be made from a sufficiently flexible material to permit the sleeve to move between an inverted position and an everted position. In certain embodiments, the sleeve may be made from a material having substantially low permeability, so as to minimize absorption of nutrients from the digested food by the wall of the small intestine. The gastrointestinal implant device, includes an anchoring mechanism coupled to a proximal end of the sleeve and designed to be secured within a stomach, so as to allow the sleeve to securely extend into the small intestine. In some embodiments, the anchoring mechanism is designed to reduce functional volume of the stomach. The anchoring mechanism, in one example, can be an inflatable balloon sufficiently large to prevent the inflatable balloon from entry into the small intestine. To that end, the anchoring mechanism may include a port for inflating the anchoring mechanism. The anchoring mechanism may alternatively be a self-expanding frame which, upon expansion, can be substantially frustoconical in shape for securing against a wall of the stomach, while allowing the stomach to maintain a substantially full functional volume. The gastrointestinal implant device, in an embodiment, can further include a passageway extending through the anchoring mechanism and the sleeve, and along which digested food can be directed from the stomach into the small intestine.
a stomach so as to allow the sleeve to securely extend into the small intestine. In some embodiments, the anchoring mechanism can be an inflatable balloon designed to reduce functional volume of the stomach upon inflation and may be designed to include a port for inflating the anchoring mechanism. The anchoring mechanism, in certain embodiments, can also be a self-expanding frame which, upon expansion, can be substantially frustoconical in shape for securing against a wall of the stomach while allowing the stomach to maintain a substantially full functional volume. The device can further include a passageway extending through the anchoring mechanism and the sleeve, and along which digested food can be directed from the stomach to the small intestine. In addition to the device, the system can further include a delivery mechanism for directing the device to a site of implantation. The delivery mechanism, in an embodiment, can include a housing for accommodating the device. The housing can be provided with a delivery end, an opposing proximal end, and a passageway therebetween. In certain embodiments, the housing can be substantially tubular in shape and/or made from a sufficiently flexible material for accommodating the device. The delivery mechanism, in an embodiment, can also include a deploying balloon, situated within the passageway of the housing, for accommodating the sleeve of the device. The balloon may be provided with an open end attached to the delivery end of the housing and a closed end situated within the housing, such that in the presence of positive pressure within the passageway of the housing, the balloon can be everted from within the housing to direct the sleeve of the device into the small intestine. A port, in an example, can be provided on the housing through which positive pressure can be introduced into the passageway of the housing to evert the balloon from within the passageway. To that end, the delivery mechanism may further include an inflation device detachably connected to the port and designed to introduce positive pressure into the housing via the port to deploy the implant device. In addition, a gastroscope for guiding the delivery mechanism to the site of implantation can also be provided for use in connection with the delivery mechanism of the present invention.

In an embodiment not forming part of the invention, there is provided, a method for providing bariatric therapy. The method can include evertting a sleeve from an inverted position into a small intestine. In an embodiment, positive pressure can be used to cause eversion of the sleeve. The method can further include anchoring the sleeve at its proximal end adjacent a pyloric junction between stomach and small intestine. The anchoring mechanism, in an embodiment, can include securing an anchoring mechanism coupled to a proximal end of the sleeve within the stomach so as to allow the sleeve to securely extend into the small intestine. The method, in some embodiments, can further include allowing digested food to be directed from the stomach through the anchoring mechanism into the sleeve, while minimizing absorption of nutrients from the digested food by a wall of the small intestine. In addition, to the extend desired, the method can further include guiding the sleeve to a site of implantation with a gastroscope.

The present invention further provides, in an embodiment, another gastrointestinal implant device. The device includes a plurality of struts that are interconnected to define an expandable body. In some embodiments, the expandable body is sufficiently elastic and capable of contracting and expanding along with stomach peristalsis without being expelled therefrom. The expandable body may also be designed to exert a pressure against a wall of the stomach to distend the stomach and provide a feeling of satiety upon expansion. In addition, the expandable body may include an expandable mechanism which, upon expansion, reduces a functional volume of the stomach. The device additionally includes a plurality of openings situated between the struts, the openings designed to allow food to enter into the expandable body through a first opening and to exit from the expandable body through a second opening. The device further includes a sleeve having an entrance that is coupled to the expandable body, such that the entrance is in alignment with the second opening to direct the food into the sleeve. In certain embodiments, the sleeve is designed for placement into a small intestine and to minimize absorption of nutrients by a wall of the small intestine.

The present invention also provides, in a further embodiment, yet another gastrointestinal implant device. The device includes a first anchoring mechanism designed to be secured along a gastrointestinal tract and within a stomach. The first anchoring mechanism, in an embodiment, is expandable to reduce a functional vol-
ume of the stomach. The device further includes a second anchoring mechanism coupled to and spaced from the first anchoring mechanism, the second anchoring mechanism being designed to be secured further along the gastrointestinal tract and beyond the stomach. In an embodiment, the second anchoring mechanism is designed to be secured within a duodenum by exerting a radial force against a wall of the duodenum. The second anchoring mechanism may be coupled to the first anchoring mechanism via a tethering mechanism. For example, the tethering mechanism may be a proximal portion of the sleeve, or one or more tethers. The tethering mechanism, in an embodiment, may be sufficiently elastic to allow the first and/or second anchoring mechanism to exert a compressive force on a pylorus, so as to maximize anchoring of the first and second anchoring mechanisms adjacent the pylorus. The tethering mechanism may also be sufficiently elastic to allow axial movement of the second anchoring mechanism in relation to the first anchoring mechanism. The device additionally includes a sleeve coupled to and positioned outside the second anchoring mechanism, the sleeve being designed for placement into a small intestine and to minimize absorption of nutrients by a wall of the small intestine. In an embodiment, the sleeve is circumferentially situated about an outer surface of the second anchoring mechanism. In some embodiments, the second anchoring mechanism may be designed to expand to contact the wall of the duodenum, so as to seal the sleeve against the wall of the duodenum.

[0019] In an embodiment not forming part of the invention, there is provided another method for providing bariatric therapy. The method includes first securing a first anchoring mechanism along a gastrointestinal tract and within a stomach. In an embodiment not forming part of the invention, the securing step includes expanding the first anchoring mechanism to contact a wall of the stomach. The method also includes positioning a second anchoring mechanism further along the gastrointestinal tract and beyond the stomach, the second anchoring mechanism being coupled to and spaced from the first anchoring mechanism. The positioning step, in an embodiment not forming part of the invention, includes expanding the second anchoring mechanism within a duodenum so as to contact a wall of the duodenum. The method further includes placing a sleeve about an outer surface of the second anchoring mechanism to permit the sleeve to extend further downstream, and to minimize leakage of fluid from within the sleeve. The placing step may, for example, include situating the sleeve circumferentially about the outer surface of the second anchoring mechanism. In an embodiment not forming part of the invention, the placing step includes everting the sleeve from an inverted position and allowing the sleeve to extend further downstream along the pathway. The sleeve may be sealed against the wall of the pathway, for example, by act of the second anchoring mechanism.

DESCRIPTION OF SPECIFIC EMBODIMENTS

[0021] In accordance with one embodiment of the present invention, a system is provided herein for bariatric therapy. One system, as described hereinafter, may be used to employ volume restriction within the stomach and/or enhance malabsorption within the small intestine. Such a system of the present invention includes, in one embodiment, a gastrointestinal implant device having an anchoring mechanism designed to be positioned within the stomach to anchor the device, and an intestinal sleeve attached at one end to the anchoring mechanism. The sleeve can be designed to extend along a portion of the small intestine to minimize or prevent nutrient absorption by the small intestine. In one embodiment, the anchoring mechanism may be a space occupying ring, an inflatable balloon, a self-expanding anchor or frame, or any combination thereof. As will be seen hereinafter, the system can also include a delivery mechanism for delivering or placing the device at a site of implantation.

[0022] Generally, food to be digested enters the stomach through the cardiac orifice from the esophagus. Once in the stomach, food is at least partially digested to produce chyme, a semi-fluid substance that can be homogenous, creamy or gruel-like. Once produced, the chyme can then exit the stomach through the pylorus or pyloric junction and enter the small intestine. The pylorus is a distal aperture of the stomach surrounded by a strong band of circular muscle. The small intestine, about nine feet in length, is a convoluted tube, extending from the pylorus to the ileo-caecal valve where it terminates in the...
The duodenum has four sections including the duodenum, jejunum and the ileum. The small intestine has three sections including the duodenal-jejunal flexure which typically form a U-shape. The superior section is about two inches long and ends at the neck of the gall bladder. The descending section is about three to four inches long and includes a nipple shaped structure (papilla of vater) through which pancreatic juice from the pancreas and bile produced by the liver and stored by the gall bladder can enter the duodenum from the pancreatic duct. The pancreatic juice typically contains enzymes essential to protein digestion and bile that can be used to dissolve the products of fat digestion. The ascending section, on the other hand, is about two inches long and forms the duodenal-jejunal flexure where it joins the jejunum, the next section of the small intestine. The duodenal-jejunal flexure is fixed to the ligament of Treitz (musculus suspensiorius duodeni). The juices secreted in the duodenum can break the partially digested food down into particles small enough to be absorbed by the body.

Referring now to Fig. 1A, a system 100 for providing bariatric therapy is shown. System 100 may include a gastrointestinal implant device 105 for facilitating weight loss. In one embodiment, the device 105 can be used to reduce the size of the stomach while simultaneously reducing absorption of food nutrients within the small intestine. The device 105 may include an intestinal sleeve 130 designed to extend from within the stomach and along a portion of the intestine below the pylorus, to minimize absorption of nutrients by the intestinal walls.

As illustrated, the sleeve 130 may include a proximal end 132 that may be designed for placement adjacent the pyloric junction, an area around the pylorus where the stomach and the small intestine meet. The sleeve 130 may further include a passageway 136 extending from the proximal end 132 to allow passage of food and other food material through sleeve 130. As used herein, “food” or “other food material” can be used interchangeably; “food” can also include undigested, partially digested, and completely digested food. The sleeve 130 may further include a distal end 134. The distal end 134, in an embodiment, can be open-ended to provide an opening through which food and other food material can exit sleeve 130.

The sleeve 130, in an embodiment, can be designed to reduce absorption and digestion of food by the intestinal walls. In particular, sleeve 130 can line and cover the intestinal wall, and act to reduce absorption and digestion of food by delaying the mixing of food with bile and pancreatic juices until after the food exits the distal end 134 of sleeve 130. In other words, by preventing the mixing of bile and pancreatic juices with food in the duodenum, digested (partially or completely) food material is not broken down into particles small enough to be absorbed by the body. As a result, the absorption of nutrients (e.g., fats and carbohydrates) is reduced.

To that end, the sleeve 130 can be made from any material that can aid in the passage of food through the sleeve 130. In one embodiment, the sleeve 130 can be made from a material that minimizes resistance and friction so as to allow food to slide more easily through the sleeve. For instance, the sleeve 130 can be made from a material that is substantially smooth and/or has a relatively low coefficient of friction. The sleeve 130 material may further have substantially low permeability to fluids to minimize the occurrence of digested food leaking through the sleeve 130 and coming into contact with the intestinal wall where it can be absorbed. The sleeve 130 can also be made from any material that helps to minimize or prevent tissue in-growth, as well as a material that can be non-irritating to the bowel, so as to aid in the removal of the sleeve 130, once removal is desired. Since the sleeve 130 can be designed to be implanted within an intestine of a human or animal body, the sleeve 130 should also be made from a material that is biocompatible. The biocompatibility of the material may help minimize occurrence of adverse reactions due to constant contact of the sleeve 130 with the gastrointestinal tract. In an embodiment, the sleeve 130 can be made from any material that can be obtained commercially.

Should it be desired, sleeve 130 may further include a coating that can aid in reducing absorption of nutrients, minimize resistance to provide a smooth passageway for food, minimizing porosity, preventing tissue in-growth, allowing subsequent removal of the device from the intestinal tract, or any other characteristic that may be desirable for the sleeve 130. The coating may be applied to the sleeve 130 on an inner surface, an outer surface, or a combination thereof to minimize any porous characteristics of the sleeve material.

In one embodiment, the sleeve 130 can also be made from any material that allows the sleeve 130 to expand and collapse in accordance with the digestive process. When food enters and passes through the sleeve 130, the sleeve material can be such that it may allow the sleeve 130 to expand sufficiently to accommodate the digested food. Once the food from the stomach has passed through the sleeve 130, however, the sleeve material can be such that may allow the sleeve 130 to become flexible or floppy, permitting the sleeve 130 to contour toward one side of the intestine. In this floppy state, the sleeve 130 may permit the pancreatic juice to flow with minimal resistance into the duodenum through the papilla of vater. Of course, in some instances, it may be desirable for the sleeve 130 to maintain a substantially constant form throughout the digestive process. In these instances, the sleeve 130 may be made from a material that can maintain such a substantially constant form.

The length of the sleeve 130 may, in an embodiment, vary depending on a variety of characteristics. In certain instances, the length of the sleeve 130 may be dependent on the patient’s Body Mass Index (BMI). In other instances, the length of the sleeve 130 may be selected based on the amount of absorption desired. A longer sleeve 130, for example, may minimize absorption of
nutrients by the intestinal walls over a longer distance than a shorter sleeve 130. In some instances, the length of the sleeve 130 may be selected based on the distance necessary to bypass the duodenum and allow the sleeve 130 to couple with the jejunum. It should be noted that the length of the sleeve 130 should also permit the sleeve 130 to fit within the delivery mechanism 115 as well as within the intestine.

[0031] The sleeve 130 may have any shape desirable, so long as the shape allows the sleeve 130 to fit within the intestine. In one embodiment, the sleeve 130 may have a substantially tubular shape to allow the sleeve 130 to substantially conform to the intestine. Of course, other geometric shapes may be possible.

[0032] The sleeve 130 may further have any diameter desirable so long as the diameter allows food to travel through the sleeve 130 without substantial hindrance. In one embodiment, the sleeve 130 may have a diameter to allow the sleeve 130 to substantially conform to the intestinal walls when in an expanded state. By substantially conforming to the intestinal walls in an expanded state, the sleeve 130 can maximize the amount of food traveling through. Of course, smaller diameters may also be possible.

[0033] The gastrointestinal implant device 105 may further include, an anchoring mechanism 140, coupled to the proximal end 132 of the sleeve 130. The anchoring mechanism 140 may be designed to be positioned, in certain instances, in the stomach to anchor the device 105 thereat. In an embodiment, the anchoring mechanism 140 can be an anchor that acts to reduce the functional volume of the stomach. An example of such an anchoring mechanism 140 can be a space occupying inflatable ring or balloon, or any other anchoring mechanism 140 adapted to adequately engage and secure the proximal end 132 of the sleeve 130 at the pyloric junction, while reducing the volume of the stomach. In an embodiment, the anchoring mechanism 140 can be integral with the sleeve 130 at the proximal end 132, so that the anchoring mechanism 140 and sleeve 130 are formed from one piece of material. Alternatively, the anchoring mechanism 140 can be separate and independent from the sleeve so that the anchoring mechanism and sleeve 130 are formed from two pieces of material and are coupled to one another.

[0034] Fig. 1B shows the gastrointestinal implant device 105 in a deployed position. In particular, the anchoring mechanism 140 is positioned at a point within the stomach 145 just above the pylorus 149. The proximal end 134 of the sleeve 130, on the other hand, can extend from the anchoring mechanism 140 within the stomach 145, across the pylorus 149, and into the small intestine 147. It should be appreciated that anchoring mechanism 140 can also extend into the pylorus 149 and proximal end 134 of the sleeve 130 can be situated adjacent the pylorus 149. A passageway 150, in an embodiment, can extend through the anchoring mechanism 140 and the sleeve 130, so that food can be directed from the stomach 145, into the device 105 and moved along the passageway 150, and into the small intestine 147.

[0035] As noted, the anchoring mechanism 140 can be designed, in certain instances, to facilitate weight loss by reducing the functional volume of the stomach 145. In other words, by occupying a portion of the stomach 145, the anchoring mechanism 140 can act to decrease the functional volume of the stomach 145, and thus, the amount of food intake by the patient. To that end, The anchoring mechanism 140, in an embodiment, may have any size desirable, depending on the particular application, as the size of the anchoring mechanism 140 may affect the functional volume by which the stomach 145 is reduced. For instance, a larger anchoring mechanism 140 may occupy a larger space within the stomach and may, accordingly, reduce the functional volume of the stomach by a larger amount than a smaller anchoring mechanism. It should be noted that the size of the anchoring mechanism 140 needs to permit the anchoring mechanism 140 to be securely positioned within the stomach at a site of implantation. That is, the anchoring mechanism 140 can be sufficiently large to prevent it from entry into the small intestine.

[0036] The anchoring mechanism 140, as illustrated in Figs. 1A-1B, may have a donut shape. A donut shape may allow the anchoring mechanism 140 to be positioned within the stomach, such that the anchoring mechanism 140 can substantially conform to the shape of the stomach and may, simultaneously, provide an exit for food to leave the stomach. Of course, other shapes for the anchoring mechanism 140 may be possible.

[0037] To adequately secure the anchoring mechanism 140 within the stomach, the anchoring mechanism 140 can be made from a material that can radially expand to exert a sufficient radial force to push the anchoring mechanism 140 against the walls of the stomach at the site of implantation. It should be appreciated that the material used should permit the anchoring mechanism 140 to conform to the dimensions of the stomach at the implantation site, even when the dimensions of the stomach vary. In one embodiment, an anti-inflammatory agent such as dexamethasone, prednisolone, corticosterone, budesonide, estrogen, sulfasalazine, mesalamine, or any suitable combination or mixture thereof may be applied to the anchoring mechanism 140 to prevent inflammation or any other adverse reaction caused by the engagement of the anchoring mechanism 140 within the stomach.

[0038] As illustrated in Figs. 1A-1B, the anchoring mechanism 140 may be provided with a port or valve 142 to which an inflation mechanism may be detachably connected for inflation purposes. To that end, the valve can be a one-way valve designed to prevent premature and unintentional deflation and removal of the device 105 from the intestinal tract. The one-way valve may be an elastomeric plug, a spring loaded valve, or any other valve known in the art as the present invention is not intended to be limited in this manner.
[0039] An inflation mechanism (not shown) for inflating the anchoring mechanism 140 can include, for instance, an inflation catheter or any other inflation device capable of inflating the anchoring mechanism 140. As the inflation mechanism can be detachably coupled to port or valve 142 of the anchoring mechanism 140, the inflation mechanism can be disconnected and detached from the port or valve 142 of anchoring mechanism 140 following inflation. It should be appreciated that the anchoring mechanism 140 can be deflated when removal of the device 105 is desired.

[0040] Connection of the inflation mechanism to port or valve 142 of the anchoring mechanism 140 may occur, in certain embodiments, through the use of a connector (not shown). The connector can act to couple the inflation mechanism to the anchoring mechanism 140 allowing the inflation mechanism to inflate the anchoring mechanism 140. In an embodiment, the connector may be situated on either the inflation mechanism or the anchoring mechanism 140. Alternatively, the connector may include a two-piece design having two complimentary pieces to permit coupling between the inflation mechanism and the anchoring mechanism 140. Examples of connectors include a mating luer connector, a metal tube, or any other connectors known in the art.

[0041] Although an inflation mechanism is described herein, it should be appreciated that the anchoring mechanism 140 can be self-expanding to allow expansion of anchoring mechanism 140 without the aid of additional inflation mechanisms. Such self-expanding mechanism, similar to a life vest, are known in the art.

[0042] Still referring to Fig. 1A, system 100 for providing bariatric therapy may further include, in an embodiment not forming part of the invention, a delivery mechanism 115 for delivering the gastrointestinal implant device 105 to a site of implantation. In an embodiment not forming part of the invention, the delivery mechanism 115 can include a housing 110 having a delivery end 112, an opposing end 114, and a passageway 116 therebetween. In one embodiment not forming part of the invention, the delivery mechanism 115 can include a housing 110 having a delivery end 112, an opposing end 114, and a passageway 116 therebetween. In one embodiment not forming part of the invention, the delivery end 112 can be designed to permit sleeve 130 of device 105 to be inserted (e.g., in an inverted position) into delivery mechanism 115. In addition, the delivery end 112 may be sufficiently sized to permit anchoring mechanism 140 to be securely positioned about delivery end 112.

[0043] In one embodiment not forming part of the invention, the housing 110 can be made from any material capable of passing through the intestine and delivering device 105 to a site of implantation. To that end, housing 110 may be formed from a substantially hard material, so as to minimize deformation of the housing 110 during delivery. Examples of materials that are substantially hard include metals, plastics, ceramics, or any other materials that can maintain a substantially consistent shape. Housing 110 can also be made from a sufficiently flexible material to permit compression of the housing 110. For example, housing 110 may be formed from a thin-walled membrane such as nylon laminated with polyurethane.

[0044] Since the housing 110 is designed to be inserted into an intestine of a human or animal body, the housing 110, in an embodiment, can be made from a material that is biocompatible. The biocompatibility of the material may help minimize occurrence of adverse reactions due to use of the housing 110 within an intestine. The housing 110 may further include a coating on an outer surface to reduce friction between the housing 110 and the intestinal wall upon insertion into the intestine. Likewise, the housing 110 may include a coating on an inner surface to reduce friction during deployment of the sleeve 130 situated within the housing 110.

[0045] It should be appreciated that the housing 110 may be provided with any shape desirable, depending on the particular application, as the shape of the housing 110 may affect ability of the housing 110 to deliver the device 105 to a site for implantation. For instance, housing 110 may be tubular in shape. Housing 110, in other embodiments not forming part of the invention, may be triangular in shape. Of course, other shapes can be used as the present invention is not intended to be limited in this manner.

[0046] The delivery mechanism 115, as shown in Fig. 1A, can also include a deploying balloon 120 for use in advancing the sleeve 130 of device 105 from within housing 110 to the site of implantation (e.g., stomach and/or small intestine). The deploying balloon 120, in an embodiment, may include an open end 122 and a closed end 124, and may be provided with a length sufficient to accommodate sleeve 130. In an embodiment, open end 122 of deploying balloon 120 can be provided with a tight fitting seal with the delivery end 112 of housing 110. By providing such a seal at the delivery end 112 of housing 110 and by providing the deploying balloon 120 with closed end 124, positive pressure can be introduced into the housing 110 to evert the deploying balloon 120 from within the housing 110, and to aid in deployment of the sleeve 130 from the deploying balloon 120. Of course, deploying balloon 120 and housing 110 can be integral to each other (e.g., as a one-piece design) where additional seal may not be necessary to keep positive pressure in the housing 110.

[0047] To deploy device 105 to a site of implantation, deploying balloon 120 can be made from a material capable of withstanding a sufficient force, so as to permit eversion of the deploying balloon 120, and thus advancement of the sleeve 130 from within the housing 110. In an embodiment, the deploying balloon 120 may be made from a thin-walled membrane. For example, the deploying balloon 120 may be made from nylon laminated with polyurethane or any similar materials. In an embodiment not forming part of the invention, the deploying balloon 120 may have a thickness ranging from about 0.05 mm to about 0.09 mm. In an embodiment, the thickness of the deploying balloon 120 may be about 0.076 mm or 0.003 inches. The material of the deploying balloon 120 may also be impermeable to fluids in order to allow the
deploying balloon 120 to withstand sufficient positive pressure. Since the deploying balloon 120 is designed to be inserted within an intestine of a human or animal body, the deploying balloon 120 can be made from a material that is biocompatible. The biocompatibility of the material may help minimize occurrence of adverse reactions due to use of the deploying balloon 120 within an intestine.

As shown in Figs. 2A-2B, the housing 110 and the deploying balloon 120 can be integral with one another (Fig. 2A) or may be provided as two separated components (Fig. 2B). In the embodiment not forming part of the invention, where housing 110 and deploying balloon 120 can be integral with one another, housing 110 and deploying balloon 120 can be made of the same material, e.g., a continuous sheet of the same sufficiently flexible material. This way, no attachment or connection mechanism is required for connecting housing 110 and deploying balloon 120. Suitable materials include without limitation, plastics, rubber, polymers, resin, cloth, and so on. Alternatively, in the embodiment where housing 110 and deploying balloon 120 can be two separate components, housing 110 and deploying balloon 120 can be made of different materials. For example, housing 110 can be made of a sufficiently rigid material, while the deploying balloon 120 being made of a sufficiently flexible material. Of course, the same material can be used for both the housing 110 and the deploying balloon 120. Suitable attachment or connection mechanism known in the art may also be provided, to the extent desired, so as to connect housing 110 and deploying balloon 120.

As shown in Fig. 2A, the housing 110 can have a diameter substantially smaller than that of the deploying balloon 120. In one example, the diameter of the housing 110 can be about half of the deploying balloon 120 while still able to accommodate the deploying balloon 120. In other examples (e.g., Fig. 2B), the housing 110 can have a diameter that is larger than that of the deploying balloon 120. It should be noted that Figs. 2A-2B illustrate the deploying balloon 120 in its everted or deployed position, and that before eversion or deployment, the deploying balloon 120 can be inverted for placement within the housing 110. Of course, the diameter of the housing 110 and deploying balloon 120 may remain substantially constant throughout.

It should be appreciated that regardless of the size of the housing 110 relative to that of the deploying balloon 120, the diameter of each should be sufficient to accommodate the sleeve 130. It should be appreciated that the length of the housing 110 should permit the delivery mechanism 115 to be inserted into an intestine and advanced along the intestine to a site for implantation.

The housing 110, in an embodiment not forming part of the invention, may have any shape desirable, depending on the particular application, as the shape of housing 110 can facilitate delivery of the device 105 to a site for implantation. For instance, housing 110 may be tubular in shape. Of course, other shapes can be used as the present invention is not intended to be limited in this manner.

In accordance with one embodiment not forming part of the invention, the delivery mechanism 115 can further include an inflation mechanism (such as inflation device 250 shown in Fig. 4) for introducing positive pressure into the housing 110, so as to cause eversion of the deploying balloon 120 from within the housing 110. Suitable inflation mechanism can include, for instance, an inflation catheter, a pump, or any other inflation device capable of introducing positive pressure the housing 110. As the inflation mechanism can be detachably coupled to the housing 110, the inflation mechanism can be disconnected and detached from the housing 110 following inflation. Connection of the inflation mechanism to the housing 110 may be achieved using any method known in the art.

In order to introduce positive pressure into housing 110 through the use of an inflatable mechanism, the system 100 may be provided with an inflation port 170 in the housing 110 through which fluids (e.g., air, liquids, gas or other substances) can enter with sufficient positive pressure to evert deploying balloon 120 and subsequently deploy the gastrointestinal implant device 105. In one embodiment, inflation port 170 can be situated at end 114 of housing 110. Of course, other locations for the inflation port 170 may be possible, as long as fluids can enter with a sufficient force to deploy the device 105.

Now referring to Figs. 3A-3B, the system 100 can be used in connection with a gastroscope 160, 160’. The gastroscope 160, 160’ may help guide the system 100 through the gastrointestinal tract. In an embodiment not forming part of the invention, the gastroscope 160 in Fig. 3A may be provided with a body designed to be situated about or adjacent the housing 110. The gastroscope 160 may also be provided with tip 162 to be positioned against a surface of the anchoring mechanism 140. In such an embodiment, the anchoring mechanism 140 may be constructed of transparent material to allow visualization out the end of the gastroscope 160 as shown in Fig. 3A. No X-ray exposure or any other mechanism may be needed to help deploy the gastrointestinal implant device 105 of the present invention. Should it be desired, delivery mechanism 115 and device 105 may include an opaque substance to permit visualization by a user during implantation.

In certain embodiments not forming part of the invention, the system 100 may be designed to allow a gastroscope 160’ to help guide the system 100 through the intestinal tract. As shown in Fig. 3B, gastroscope 160’ may be used with the deploying balloon 120’ and sleeve 130’ in their everted or deployed position to help guide the sleeve 130’ to its desired location (e.g., to further extend along the small intestine). The gastroscope 160’, as shown, may be positioned through the housing 110 and beyond and designed to maintain the stability of the system 100 as the system 100 is advanced along the gastrointestinal tract. It should be noted that while the
gastroscope 160 can be positioned in any manner to allow guidance of the system 100, its design should minimize any obstructions of the deploying balloon 120 and sleeve 130 from evertion. In an embodiment not forming part of the invention, the gastroscope 160 may be any guidewire that is commercially available.

Looking now at Figs. 4-6, there are illustrated alternative system. As illustrated, system 200 can be used to provide bariatric therapy. System 200, in an embodiment, can include a delivery mechanism 215 and an implant device 205. In accordance with the embodiments shown in Figs. 4-6, delivery mechanism 215 may be substantially similar to the delivery mechanism 115 described above, but the housing 110 delivery mechanism 215 may be a reservoir 210 for use in connection with the deployment of the device 205. Such a housing 210 can allow the delivery mechanism 215 to reside in different organs, such as the stomach in a patient, in addition to being inserted into the intestine. The delivery mechanism 215, in accordance with one embodiment, may include a reservoir 210 for use in connection with implantation of device 205. In one embodiment not forming part of the invention, the reservoir 210 may serve substantially the same functions as housing 110 in that the reservoir 210 can be used to accommodate at least a part of the device 205 and deliver the device 205 to a site for implantation. Reservoir 210, if desired, may be designed to accommodate sleeve 230 in reservoir 210 and may be designed to facilitate eversion of sleeve 230.

In an embodiment not forming part of the invention, the reservoir 210 can be made from a material that can be sufficiently strong to allow the reservoir 210 to be directed within the body of a patient without rupturing. The material can also be sufficiently flexible to allow the reservoir 210 to expand and collapse during deployment of the device 205.

The reservoir 210 may have any shape, as long as the shape can fit within the intestine or esophagus for delivery. In an embodiment not forming part of the invention, the reservoir 210 can be substantially circular in shape and can be expanded to any shape desired. In another embodiment, the reservoir 210 can be tubular in shape. Of course, other shapes are possible. The reservoir 210, in another embodiment not forming part of the invention, may have a size and/or length sufficient to accommodate balloon 220 and/or sleeve 230. As shown in Fig. 5A, the size and/or length of the reservoir 210 may be such that it may accommodate balloon 220 and/or sleeve 230 in a folded or rolled up manner.

The reservoir 210 may also be provided with any size desirable, as the size the reservoir 210 may facilitate delivery of device 205 and sleeve 230. For example, a smaller sized reservoir 210 may be used to deliver device 205 through an individual’s esophagus, while a larger one may be able to fit through an esophagus.

The delivery mechanism 215 may further include a deploying balloon 220, similar to deploying balloon 120, for use in placement of the device 205 at the site of implantation within the gastrointestinal tract. It should be noted that the length and shape of the deploying balloon 220 should be such that the balloon 220 can fit (e.g., in a folded or rolled up manner), at least partially within the reservoir 210. In an embodiment not forming part of the invention, the balloon 220 can be attached to or positioned about an end of the reservoir 210 at its open end 222.

A sleeve 230 may be stored (e.g., in an inverted state) within deploying balloon 220 similar to the manner in which the sleeve 130 can be stored within deploying balloon 120 and housing 110, as described above. In an embodiment, the sleeve 230 may be stored in a folded state such as shown in Fig. 5A or may be stored in a rolled up state. Of course, the sleeve 230 may be stored in other manners so long as it fits, at least partially within the reservoir 210. An anchoring mechanism 240 for anchoring and securing device 205 to a site of implantation, similar to the one described above, may be situated at the proximal end 232 of sleeve 230, as shown in Fig. 4.

To deploy the gastrointestinal implant device 205, an inflation device 250 may be connected to the reservoir 210. The inflation device 250 may be designed so as to permit insertion of the gastrointestinal implant device 205 through the esophagus of a patient. The inflation device 250 can be sufficiently thin and narrow. A seal 280, can be provided at the end of the inflation device 250, as desired, to minimize leakage of fluid being introduced by inflation device 250.

Figs. 5A, 5B, and 6 show the use of a gastroscope 260 to help guide the system 200 through the intestinal tract to a site of interest. The gastroscope 260, as shown in Fig. 5A, can be positioned through the inflation device 250 and the reservoir 210. In Fig. 6, gastroscope 260’ can extend to reservoir 210 without going through the inflation device 250. It should be noted that Fig. 5B and 6 show the system 200’ in a fully deployed state, with the deploying balloon 220’ and sleeve 230’ in their everted position.

To prepare the system 100 for insertion in the body, a user can initially position a deploying balloon 120 within housing 110 of delivery mechanism 115. The open end 122 of the deploying balloon 120 can be situated adjacent or attached to the delivery end 112 of the housing 110, and the closed end 124 of the deploying balloon 120 can be situated adjacent the opposing end 114 of the housing 110. An open ended sleeve 130 may then be placed within cavity 126 of deploying balloon 120 with the open ended distal end 134 of the sleeve 130 situated adjacent the closed end 124 of the deploying balloon 120, while the proximal end 132 of the sleeve 130 situated adjacent the open end 122 of the deploying balloon 120. Additionally, anchoring mechanism 140, being coupled to the proximal end 132 of the sleeve 130, can be positioned about the delivery end 112 of the housing 110.

Once loaded, the system 100 may be inserted into the body, and advanced along the intestine within the body to a site of interest for implantation. A gastro-
scope 160 may be used to help guide the system 100 through the intestinal tract to a site of implantation. A guidewire (not shown) may be used to maintain the stability of the system 100 as the system 100 advances through the tract. Once at the site of implantation, the system 100 can be prepared for deploying the device 105. Implantation may first require the anchoring mechanism 140, attached to the proximal end 132 of the sleeve 130, to be inflated using an inflation mechanism. Inflation of the anchoring mechanism 140 can act to hold the gastrointestinal implant device 105 in a desired position during the eversion process. For example, the anchoring mechanism 140 can be placed within the stomach or in the small intestine adjacent the pyloric junction. After the anchoring mechanism 140 is anchored at the site of interest, the sleeve 130 may be everted. Eversion may require the direction of pressurized or unpressurized fluid (e.g., gas, liquid, or a combination thereof) into housing 110 via inflation port 170. As fluid is directed into housing 110, the fluid acts to evert and advance deploying balloon 120 from within housing 110, while pushing sleeve 130 from housing 110 along with deploying balloon 120, as shown in Fig. 3B. The sleeve 130 is a shorter length than the deploying balloon 120, which can allow complete delivery of the sleeve 130 upon full eversion of deploying balloon 120.

[0066] Fig. 7-8 show the deploying balloon 120 and sleeve 130 of the system 100 in partial eversion and subsequent deployment upon full eversion. In Fig. 7, gastrointestinal implant device 105 is in the process of being everted from within the passageway 116 of the housing 110, where evertidng deploying balloon 120' pushes and everts the sleeve 130' from therewithin. The evertidng deploying balloon 120', thereafter, can distend the intestine as it is deploying the evertidng sleeve 130', and can automatically follow the course of the bowel. Fig. 8 shows the implant device 105" in a fully deployed state, with everted deploying balloon 120" extending beyond the everted sleeve 130". With the gastrointestinal implant device 105" deployed and engaged within the intestinal wall, food and other food material can be passed from the stomach through the everted sleeve 130".

[0067] In accordance with the embodiments depicted in Figs. 4-6, the method of deploying device 205 using a reservoir 210 may be substantially similar to the method described above with several changes to reflect the use of a reservoir 210. Once loaded into the reservoir 210, system 200 may be inserted into the body, and advanced along the intestine within the body to a site of implantation. A gastroscope 260 may be used to guide the system 200 through the gastrointestinal tract. Implantation may first require the anchoring mechanism 240, attached to the proximal end 232 of the sleeve 230, to be inflated using an inflation mechanism. After the anchoring mechanism 240 is anchored to the stomach or small intestine at the site of implantation, the device 205 may be everted. Eversion may require activation of the inflation device 250, which can result in the reservoir 210 being inflated, as shown in Fig. 5A. Inflation of the reservoir 210 can cause the reservoir 210 to enlarge and/or become pressurized, allowing the balloon 220 to evert and deploy the device 205. Figs. 5B and 6 show embodiments of the system 200 in a fully deployed state. The reservoir 210 can provide a low friction compartment for everting the balloon 220 and sleeve 230.

[0068] Following deployment of the sleeve 130, the deploying balloon 120 can be deflated and a vacuum can be drawn to constrict the deploying balloon 120. Constriction of the deploying balloon 120 can allow the deploying balloon 120 to be pulled out of the sleeve 130, leaving the sleeve 130 in position within the intestine. Since the diameter of the deploying balloon 120 can be less than the diameter of the sleeve 130, deploying balloon 120 withdrawal is performed upon deflation and formation of a vacuum in the deploying balloon 120. As previously stated, a coating or lubrication may be placed between the sleeve 130 and the deploying balloon 120 during manufacture, to ensure easy deploying balloon 120 removal.

[0069] With reference now to Figs. 9-13, there are illustrated another bariatric therapy system 300. System 300, in an embodiment, can include a delivery mechanism 315 and an implant device 305. As shown in Figs. 9-13, the delivery mechanism 315 may be substantially similar to the delivery mechanism 115, 215 described above, but no separate housing may be necessary to deploy the device 305. The delivery mechanism 315, in an embodiment, may include a deploying balloon 320, similar to deploying balloon 120 and housing 110 described above, for use in the placement of device 305 at the site of implantation within the gastrointestinal tract. It should be noted that the length and shape of the deploying balloon 320 should be such that the balloon 320 can fit within the intestinal track. The deploying balloon 320 may be formed from a continuous piece of material as shown in Fig. 9A. The deploying balloon 320 may also be formed from a soft and flexible material such that upon inflation of the balloon 320, the pressure therein can allow the device 305 to be advanced through the intestinal track. The material from which deploying balloon 320 can be made can also be inelastic to withstand a sufficient pressure for deploying the device 305. The deploying balloon 320 may be made from a single thin-walled membrane. For example, the deploying balloon 320 may be made from nylon laminated with polyurethane. The deploying balloon 320 may have a thickness ranging from about 0.05 mm to about 0.09 mm. In an embodiment, the thickness of the deploying balloon 320 may be about 0.076 mm or 0.003 inches.

[0070] Referring still to Fig. 9A, the delivery mechanism 315, in an embodiment, may further include a sleeve 330 that may be positioned within deploying balloon 320, similar to the manner in which the sleeve 230 can be stored within deploying balloon 220, as described above. The sleeve 330, in one embodiment, may be formed from a membrane that can be less thick than the thickness of...
the membrane used to form the deploying balloon 320. In an example, the sleeve 330 may be approximately 0.025 mm (0.001”) in thickness. The materials from which sleeve 330 may be formed includes without limitation, polyethylene, polyvinyl chloride, nylon, polyethylene terephthalate, or other polymer. The relative thickness of the intestinal sleeve 330 compared to the deploying balloon 320 can be important, as such thickness can provide less friction during eversion of the sleeve 330 and the deploying balloon 320. In one example, when a sleeve material has a thickness less than the thickness of the balloon material, air eversion may be possible and the evertion structure may be sufficiently soft to advance through tortuous bowel. In one embodiment, a sleeve material can have a thickness that is about one-third of the thickness of the balloon material. In other examples, when a sleeve material has a substantially similar thickness to that of the balloon material, friction between the membrane layers may cause inflation pressure to rise to a sufficiently high level, such that an incompressible fluid (water or saline) may be required to deploy the sleeve 330. This may, in turn, cause increased rigidity of the evertion closed ended balloon 320.

[0071] The device 305 may further include an anchoring mechanism 340 for anchoring and securing device 305 to a site of implantation. In an embodiment, anchoring mechanism 340 may be situated at proximal end 332 of sleeve 330. Anchoring mechanism 340 may be designed to be self-expanding and/or with a minimal profile so that when it is positioned within the stomach, the anchoring mechanism 340 can allow the stomach to retain substantially its full functional volume. In accordance with the embodiments shown in Figs. 9-13, the anchoring mechanism 340 may be a self-expanding anchor or frame, for securing against the stomach wall. The anchoring mechanism 340, as shown in Fig. 10, may be a thin structure that can be designed to expand immediately proximal to the pylorus, and remains in the stomach, to allow the intestinal sleeve 330 to extend into the small intestine (e.g., into the duodenum and jejunum). The proximal end 332 of sleeve 330, in some embodiments, may be situated within the stomach just above the pylorus.

[0072] The anchoring mechanism 340, in one embodiment, may be constructed of spring metal, such as stainless steel, or it may be formed of a rigid plastic, such as polyurethane or polyethylene terephthalate. The anchoring mechanism 340 may be processed to have shape memory properties. The anchoring mechanism 340 may also be designed to present a smaller packing profile, as a thin frame can occupy less space than multiple layers of membrane in an inflatable anchor, and may present less obstruction to outflow of stomach contents.

[0073] The system 300 may also be designed to accommodate a gastroscope 360. The gastroscope 360 may be used to provide or enhance columnal strength for advancement of the device into the duodenum in preparation for deployment of the intestinal sleeve in the bowel. The gastroscope 360 can be a part of the system 300. The gastroscope 360 may be constructed from a plastic material such as polyethylene, polyethylene terephthalate, polyvinyl chloride, polyurethane, polytetrafluoroethylene (Teflon), or any other known strong material. The gastroscope 360 may contain fiber or wire strands or braid for reinforcement. Fig. 11 shows a system 300 having gastroscope tube 380, gastroscope 360, anchor 340, and inverted deploying balloon 320 and sleeve 330.

[0074] The gastroscope 360 may be provided within a gastroscope tube 380. The gastroscope 360 and/or tube 380 may be coupled to the deploying balloon 320, for example, through the use of a coupling mechanism 335, so as secure the device 305 thereto. The deploying balloon 320 may also be bonded to the gastroscope 360 and/or tube 380 to form a compact unit. The bonding can be along one line axially. The gastroscope 360 and/or tube 380 may be coupled to the deploying balloon 320 through the use of an adhesive, such as glue or tape. In other embodiments, the gastroscope tube 360 and/or tube 380 may be coupled to the deploying balloon 320 through the use of a nail, screw, clip or other coupling mechanism 335 capable of bonding the gastroscope tube 360 and/or 380 to the balloon 320. Of course, those skilled in the art may appreciate that other coupling mechanisms 335 may also be possible.

[0075] The gastroscope 360 may also contain a connecting mechanism 342, as shown in Figs. 13A and 13B, for holding the anchoring mechanism 340 in position during deployment of the intestinal sleeve. The connecting mechanism 342 may be designed to couple the deploying balloon 320 to the gastroscope 360. The connecting mechanism 342 may include a suture 343 to couple the deploying balloon 320 to the gastroscope 360. An opening in the side of the gastroscope 360 may be provided to allow the suture 343 to pass therethrough. As shown in Fig. 13B, the suture 343 may run the length of the gastroscope 360, out the side opening, through a loop in the anchoring mechanism 340, and end at a proximal port, to secure the anchoring mechanism 340 to the gastroscope 360. The suture 343 may be designed so that it can be severed and removed so as to release the anchoring mechanism 340 and sleeve 330 following deployment. The connecting mechanism 342 may further be designed to provide reference positioning for intestinal sleeve deployment.

[0076] The system 300 of the present embodiment may further include a sheath 310, as shown in Figs. 12A-12C, designed to for placement over the anchoring mechanism 340, the proximal end of deploying balloon 320, and the proximal end of the sleeve 330. The sheath 310 may be made from a semi-flexible material with a length sufficient to cover substantially the entire length of the anchoring mechanism 340. Of course, the length of sheath 310 can be varied according to specific designs. In an embodiment, sheath 310 can be sufficiently long so as to cover substantially the entire length of the de-
To deploy the gastrointestinal implant device 305, as shown in Fig. 9B, delivery mechanism 315 of system 300 may be provided with an inflation port 370. The inflation port 370 may be designed to allow fluids (e.g., air, liquids, gas or other substances) to enter with sufficient pressure to evert deploying balloon 320 and deploy the gastrointestinal implant device 305. Inflation port 370 can be coupled to deploying balloon 320. Of course, other locations for the inflation port 370 are possible as long as fluids can enter delivery mechanism 315 with a sufficient force to deploy the device 305.

To prepare the delivery mechanism 315 for insertion in the body, a user can initially position an open ended sleeve 330 within deploying balloon 320. In an embodiment, the proximal end 332 of the sleeve 330 may be situated adjacent the open end 322 of the deploying balloon 320, while the distal end 334 of the sleeve 330 may be situated adjacent the closed end 324 of the deploying balloon 320. Additionally, anchoring mechanism 340, can be coupled to the proximal end 332 of the sleeve 330. The open ended sleeve 330, deploying balloon 320 and anchoring mechanism 340 may be compressed and encased within sheath 310.

Once loaded, the delivery mechanism 315 may be inserted into the body, and advanced along the intestine within the body to a site of interest for implantation. The gastroscope 360 may be used to help guide the delivery mechanism 315 through the intestinal tract to a site of implantation. A guidewire (not shown) may be used to maintain the stability of the delivery mechanism 315, as the delivery mechanism 315 advances through the tract. Once at the site of implantation, the delivery mechanism 315 can be prepared for deploying the device 305. Deployment may first require removal of the sheath 310 by pulling wire 365 to withdraw the sheath 310, prior to deployment of the sleeve 330, which may act to cause subsequent expansion of the anchoring mechanism 340. Expansion of the anchoring mechanism 340 can act to hold the gastrointestinal implant device 305 in a desired position during the eversion process. After the anchoring mechanism 340 is anchored to the stomach wall or intestinal wall at the site of interest, the sleeve 330 may be everted from within the deploying balloon 320. Eversion may require activation of the inflation port 370, which can result in the deploying balloon 320 being inflated. Inflation of the deploying balloon 320 can cause the deploying balloon 320 to enlarge and/or become pressurized, allowing the deploying balloon 320 to evert and deploy the device 305. The deploying balloon 320 can provide a low friction compartment for evertting the sleeve 330. With the gastrointestinal implant device 305 deployed and engaged within the intestinal wall, food and other food material can be passed through the sleeve 330.

Following deployment of the sleeve 330, the gastroscope 360, deploying balloon 320 and sheath 310 can be removed from the body. For example, the suture 343 may be severed and removed so as to release the anchoring mechanism 340 and sleeve 330 following deployment. The deploying balloon 320 may be constricted to allow the deploying balloon 320 to be pulled out of the sleeve 330, leaving the sleeve 330 in position within the intestine. Since the diameter of the deploying balloon 320 can be less than the diameter of the sleeve 330, deploying balloon 320 withdrawal may be performed upon deflation and formation of a vacuum in the deploying balloon 320. As previously stated, a coating or layer of lubrication may be placed between the sleeve 330 and the deploying balloon 320 during manufacture, to ensure easy deploying balloon 320 removal.

Turning now to Fig. 14, there is illustrated an expandable body 400 for use, for example, as an anchor in connection with the gastrointestinal implant devices of the present invention. In an embodiment, expandable body 400 can be used to secure placement of the sleeve in the gastrointestinal tract (e.g., from within the stomach, the duodenum, adjacent the pylorus, or within the small intestine). Expandable body 400 may include a geometric array of struts that may form a three-dimensional structure, such as a geodesic sphere, a system of interconnected loops or hoops 410, an ellipsoid structure, or other elastic forms that may define a three-dimensional structure.

Expandable body 400, in an embodiment, may be constructed from any suitable elastic or shape-memory materials described herein, such as spring metal (e.g., stainless steel) and/or spring plastic (e.g., polyurethane, polyethylene, or polyethylene terephthalate). The materials used, in an embodiment, should provide sufficient elasticity may be provided by such materials, such that expandable body 400 may collapse, for instance, by compression and expand, for instance, after deployment as desired.

Expandable body 400, in an embodiment, may also include one or more expandable mechanism (not shown). For example, expandable body 400 may be an expandable array of struts or loops that form an elastic structure which, upon expansion, may occupy a greater degree of volume to provide a space occupying effect. Such space occupying effect in the stomach may act to reduce the functional volume of the stomach and/or provide a feeling of satiety. In another embodiment, expandable body 400 may also be a metal or plastic frame (e.g., formed by struts 410) with one or more secondary expandable structures attached thereeto. In some instance, the expandable mechanism may be inflatable.

Expandable body 400 may contain at least two openings 420, through which undigested, partially digested, or completely digested food can be directed from the stomach into the intestinal sleeve, such as sleeve 130.
shown in Fig. 1B. In particular, one opening may be sufficiently large and in alignment with the entrance, such as the proximal end of the intestinal sleeve, so as to hold the intestinal sleeve open to allow entry of food.

[0085] In certain embodiments, expandable body 400 may be provided with sufficient elasticity. This may be advantageous for use as an anchoring mechanism in the stomach. Without wishing to be bound by any theory, advantages of a sufficiently elastic expandable body 400 for use in the stomach may be explained as follows: The stomach undergoes contraction and peristalsis, as it moves food out into the duodenum. A sufficiently elastic expandable body 400 placed inside the stomach may contract and expand as the stomach contracts and relaxes. This way, expandable body 400 may be prevented from being expelled out of the stomach as may occur to a substantially rigid anchor.

[0086] Expandable body 400 may be configured with a diameter as large as needed to achieve anchoring, for example, from approximately 6 cm to 12 cm or greater. Both the elasticity and geometric structure, as described, may help anchor expandable body 400 within the stomach, and prevent it from being expelled by the stomach. As such, while stomach peristalsis tends to move food towards the pylorus, and expandable body 400 tends to move down to the antrum, an intestinal sleeve that is coupled to expandable body 400 may remain anchored in the desired position (e.g., within the antrum). The anchoring effect of the elastic expandable body 400 to stay within the stomach may be analogized to the physiologic mechanism of a gas embolus in the arterial system: Gas is compressible, and a volume of gas residing in an artery while compressing and expanding along with the arterial pulse, does not significantly move down the artery.

[0087] In addition to the anchoring and space occupying potential of expandable body 400 described above, expandable body 400 may also be designed to expand in circle to contact the stomach wall, distend the stomach, and/or act to provide a feeling of satiety to the patient implanted with such a framework. In an embodiment, stomach distention may result in neural feedback of fullness, adding to the therapeutic bariatric effects of the implant device, which may include volume restriction or reduction by the anchoring mechanism and nutrient malabsorption by the intestinal sleeve.

[0088] With reference now to Figs. 15-16, there is illustrated a gastrointestinal implant device 500 having two anchoring mechanisms 510 and 520. A first anchoring mechanism 510 may be designed for secure placement within the stomach, as discussed above. A second anchoring mechanism 520 may be coupled to and spaced from the first anchoring mechanism 510. The second anchoring mechanism 520 may be designed to be secured within a gastrointestinal tract and outside the stomach. In an embodiment, the second anchoring mechanism 520 may be placed within the duodenum just past the pylorus, or anywhere in the small intestine. It should be noted that the spacing between the two anchoring mechanisms 510 and 520 may be chosen according to their desired placement in the gastrointestinal tract. In an embodiment, sufficient spacing may be provided to allow lateral movement and/or axial rotation, such that relative movement between the two anchoring mechanisms 510 and 520 can be accommodated.

[0089] As illustrated in Figs. 15A-15C, the first anchoring mechanism 510 may or may not be coupled to sleeve 530, while the second anchoring mechanism 520 may be coupled to and at least partially positioned within sleeve 530. That is, sleeve 530 may be circumferentially situated and attached on an outer surface of the second anchoring mechanism 520 to partially or substantially completely cover the second anchoring mechanism 520.

In certain embodiments, sleeve 530 may extend from the second anchoring mechanism 520 into the small intestine, after eversion and deployment. Sleeve 530 may also be expanded outwardly by the second anchoring mechanism 520 to provide a passageway 540 therethrough. In addition, sleeve 530 may be anchored by the second anchoring mechanism 520 against retrograde movement that may be caused by a back force, for example, during patient vomiting.

[0090] It should be noted that Figs. 15A-15C show sectional views of gastrointestinal implant device 500, with the first and second anchoring mechanisms 510 and 520 being shown as disk-like structures, for illustration purposes only. While the corresponding three-dimensional view may be substantially spherical, the first and second anchoring mechanisms 510 and 520 may independently have any other suitable geometry such as a geodesic sphere, a truncated icosahedron, an ellipsoid structure, or a half or partial structure thereof.

[0091] In certain embodiments, the second anchoring mechanism 520 may have a smaller diameter than the first anchoring mechanism 510, so as to fit within the duodenum or along other parts in the small intestine. The second anchoring mechanism 520 may also have a substantially similar or larger diameter than the first anchoring mechanism 510, depending on the relative anatomical size of the duodenum, small intestine, and stomach of the patient requiring the implant. Regardless of their relative size, anchoring mechanisms 510 and 520 may expand outwardly against the stomach, duodenum, or small intestine, without significantly overstretching the respective tissue.

[0092] The first and second anchoring mechanisms 510 and 520, in an embodiment, may be connected to each other via any suitable coupling mechanisms known in the art. Exemplary coupling mechanisms include, without limitation, threading, tethering, and tying. Suitable coupling mechanisms may be connected to anchoring mechanisms via methods known in the art such as gluing, bonding, interlocking, fastening, molding, welding, clamping, etc.

[0093] For example, the first and second anchoring mechanisms 510 and 520 may be connected by a portion 535 of the sleeve 530, as shown in Fig. 15A. To the extent
desired, sleeve portion 535 (or a portion thereof) may have a diameter that fits in the pylorus in its closed position. Alternatively, sleeve portion 535 may be substantially elastic while holding anchoring mechanisms 510 and 520 in a substantially fixed relative position (e.g., at either side of the pylorus). For example, a substantially elastic sleeve portion 535 may be in a stretched state which may exert a contracting or pulling force to anchoring mechanisms 510 and 520 toward one another. This way, a compressive force may be exerted on the pylorus by anchoring mechanisms 510 and 520, thereby increasing the anchoring function of the implant device 500, with minimal relative movement of anchoring mechanisms 510, 520 and sleeve 530. It should be noted that while sleeve portion 535 may have various degree of elasticity depending on the specific device design, it should be sufficiently flexible to bend or move according to the patient’s body movement. In addition, such flexibility of sleeve portion 535 and/or other portions of sleeve 530 may be desirable, for example, to allow the portion extending distally from the second anchoring mechanism 520 to move between an inverted position and an everted position.

In the embodiments illustrated in Figs. 15B and 15C, the first and second anchoring mechanisms 510 and 520 may be connected by one or more tethering mechanism 550 or 560. In this case, sleeve 530 is attached to the second anchoring mechanism 520 only. As discussed above, the second anchoring mechanism 520 may be designed to expand to contact the inner wall of the duodenum, or other parts of the small intestine. This design may help seal sleeve 530 against the duodenal or intestinal wall to ensure that food exiting the stomach passes into sleeve 530, without leaking into the small intestine. Such a design may also help securely anchor sleeve 530 at its point of contact with the duodenal or intestinal wall.

Where the second anchoring mechanism 520 is connected to the first anchoring mechanism 510 by multiple tethering mechanisms 550, as shown in Fig. 15B, the multiple tethering mechanisms 550 may be configured in such a way that they do not substantially interfere with the opening or closing of the pylorus as it occurs in accordance with the digestive process. For example, the multiple tethering mechanisms 550 may attach, at either end, adjacent the respective central axis of anchoring mechanisms 510 and 520, such that the multiple tethering mechanisms 550 may be arranged in proximity to one another. In addition, spacing between adjacent tethering mechanisms should be designed in a way such that even upon twisting of the multiple tethering mechanisms 550, food passageway between anchoring mechanisms 510 and 520 is neither blocked nor occluded. That is, food should still be able to pass through the spaces between adjacent tethering mechanisms to enter sleeve 530.

A single tethering mechanism 560 may also be used, as shown in Fig. 15C. This design may be preferred, in some embodiments, allowing more space for the passageway between anchoring mechanisms 510 and 520.

Tethering mechanisms 550, 560 may be made from any suitable structure or material known in the art. In an embodiment, tethering mechanisms 550, 560 may be a connecting cords, wires, strings, cables, rods, ropes, and the like. The diameter of tethering mechanisms 550, 560 may be sufficient small so as to not substantially occlude the passageway between anchoring mechanisms 510 and 520 when food passes therethrough. The length of tethering mechanisms 550, 560 may also be chosen (e.g., a few centimeters or longer) such that different anatomical pyloric lengths may be accommodated by one or few versions of implant device 500. Alternatively, the length of tethering mechanisms 550, 560 may be custom made for the patient.

Tethering mechanisms 550, 560 may have sufficient flexibility to bend or move along with movement of the patient’s body. In an embodiment, tethering mechanisms 550, 560 may be made of spring metal or plastic. In some embodiments, tethering mechanisms 550, 560 may be sufficiently elastic while holding anchoring mechanisms 510 and 520 in a substantially fixed relative position at either side of the pylorus. As discussed above, such design may impart a compressive force on the pylorus to enhance anchoring of the anchoring mechanisms 510 and 520 adjacent the pylorus. Tethering mechanisms 550, 560, in another embodiment, may be substantially inelastic, such that no significant compression is exerted on the pylorus. When substantially inelastic tethering mechanism(s) are used, a limited degree of movement may be experienced by the implant device 500 relative to the pylorus, to the extent that the respective anchoring mechanism 510 or 520 contacts either side of the pylorus.

To the extent desired, anchoring mechanisms 510, 520 and the tethering mechanism(s) therebetween may be molded or formed as a one-piece design. Alternatively, these parts can be formed separately and then attached together. Various suitable attaching/connecting methods known in the art can be used to attach the tethering mechanism and the anchoring mechanism. For instance, suitable methods include glue, key-lock structures or the like, sucking disks, clamps, hooks, screws, latches, and so on.

Other suitable tethering mechanisms for connecting anchoring mechanisms 510 and 520 may also be used. For example, an expandable metal or plastic frame (e.g., having shape memory property) may be used, which may expand or collapse along with the opening or closing movement of the pylorus. Upon expansion, a passageway may extend between anchoring mechanisms 510 and 520 to allow food to pass through and enter sleeve 530.

Fig. 16A illustrates a perspective view of a gastrointestinal implant device 500 having two anchoring mechanisms 510 and 520. In an embodiment, anchoring
mechanisms 510 and 520 may each include a plurality of struts 515 to form a framework. One or more of struts 515 may be expandable, as discussed above. Multiple tethering mechanisms 550 may be provided to connect anchoring mechanisms 510 and 520. Figs. 16B and 16C are side views of anchoring mechanisms 510, 520 and tethering mechanisms 550 therebetween. Fig. 16C being turned 90 degrees relative to Fig. 16B.

[0102] In addition to the structural configurations for the anchoring mechanisms discussed above, suitable shapes that offer sufficiently small strut profile, desired structural integrity, and sufficient spacing between struts for food passage may also be used. Suitable shapes include spherical or non-spherical truncated icosahedrons as shown in Figs. 17A and 17B, geodesic spheres as shown in Figs. 17C and 17D, and full or partial spheres as shown in Fig. 17E.

[0103] With reference now to Figs. 18-19, there is illustrated another two-anchor device 505 for use in connection with an intestinal sleeve (not shown) to form a gastrointestinal implant device, as discussed herein. In an embodiment, the two anchoring mechanisms 510 and 520 may be partial spheres (Fig. 18) or partial geodesic spheres (Fig. 19). Anchoring mechanisms 510 and 520 have substantially the same diameter as illustrated, or different diameters in accordance with the relative anatomical size of the stomach and duodenum.

[0104] Anchoring mechanisms 510 and 520 may each include a plurality of interconnected members 515 such as loops (Fig. 18) or struts (Fig. 19). Both anchoring mechanisms 510 and 520, in an embodiment, may be constructed from suitable expandable materials described herein, such as spring metal (e.g., stainless steel) and/or spring plastic (e.g., polyurethane, polyethylene, or polyethylene terephthalate). As discussed above, one or more of the interconnected members 515 may be expandable. For example, the first anchoring mechanism 510 may be provided with one or more expandable mechanism which, upon inflation, may occupy a greater degree of volume to reduce the functional volume of the stomach. Such inflated mechanism may also exert an additional pressure to the stomach wall, enhancing the secured placement of the first anchoring mechanism 510 within the stomach. Similarly, the second anchoring mechanism 520 may also include one or more expandable mechanism which, upon inflation, may exert a radial force against the duodenal wall, for securing the second anchoring mechanism 520 within the duodenum. It should also be appreciated that where sleeve 530 is attached to the outer surface of the second anchoring mechanism 520, such radial force may also act to secure and anchor sleeve 530 against the duodenal wall.

[0105] A single tethering mechanism 560 may be provided between anchoring mechanisms 510 and 520 to connect them. More than one tethering mechanisms may also be used, as discussed above. For ease of construction, tethering mechanism 560 may be molded as one piece together with anchoring mechanisms 510 and 520 (e.g., as a metal or plastic structure). Alternatively, these parts can be formed separately and then assembled into the two-anchor device 505. In this case, tethering mechanism 560 may be connected at either end to anchoring mechanisms 510 and 520 by designs 562 and 564 shown in Fig. 18. Other suitable designs or connecting mechanisms known in the art may also be used. For example, tethering mechanism 560 may be mounted on, bonded to, glued to, molded with, assembled into, or interlocked with anchoring mechanisms 510 and 520.

[0106] In a preferred embodiment, Figs. 19A-19C illustrate a two-anchor device 505 in side view (Fig. 19A), perspective view (Fig. 19B), and top view (Fig. 19C). In an example, the major diameter (a) and height (b) of anchoring mechanisms 510, 520, as well as the length (c) of tethering mechanism 560, may be chosen according to average anatomical size of the gastrointestinal system. Alternatively, these measurements may be custom made for each patient or patient group.

[0107] In operation, the first and second anchoring mechanism 510 and 520 may first be secured along a gastrointestinal tract of a patient. For example, the first anchoring mechanism 510 may be secured within a stomach, and the second anchoring mechanism 520 may be secured beyond the stomach, such as in a duodenum. Next, sleeve 530 may be placed about an outer surface of the second anchoring mechanism 520 and extend therefrom into a small intestine. In an embodiment, sleeve 530 may be situated circumferentially about the outer surface of the second anchoring mechanism 520. The second anchoring mechanism 520 may also expand and act to seal sleeve 530 against the wall of the duodenum. This way, food can be directed through first anchoring mechanism 510, second anchoring mechanism 520, and sleeve 530, sequentially, without leaking into the small intestine.

[0108] While the invention has been described in connection with the specific embodiments thereof, it will be understood that it is capable of further modification. For instance, it should be appreciated that any of the anchors or anchoring mechanisms described above may be modified, for use in connection with gastrointestinal implant devices and/or intestinal sleeve delivery systems described herein. Furthermore, this application is intended to cover any variations, uses, or adaptations of the invention, including such departures from the present disclosure as come within known or customary practice in the art to which the invention pertains, and as fall within the scope of the appended claims.

Claims

1. A gastrointestinal implant device (500) comprising:

   a first anchoring mechanism (510) designed to be secured along a gastrointestinal tract and within a stomach;
a second anchoring mechanism (520) coupled to and spaced from the first anchoring mechanism (510), the second anchoring mechanism (520) designed to be secured further along the gastrointestinal tract and beyond the stomach; and

a sleeve (530) coupled to and positioned circumferentially about the outer surface of the second anchoring mechanism (520), the sleeve (530) designed to extend from the second anchoring mechanism (520) into a small intestine and to minimize absorption of nutrients by a wall of the small intestine;

wherein the second anchoring mechanism (520) includes a plurality of struts (515) to form a framework, the framework being expandable to contact a duodenal or an intestinal wall a coupling mechanism (535) coupling the first anchoring mechanism to the second anchoring mechanism, the coupling mechanism is configured to allow rotational movement of the second anchoring mechanism relative to the first anchoring mechanism following implantation of the gastrointestinal implant device characterised at least in that the second anchoring mechanism (520) has a spherical or a partially spherical shape.

2. The gastrointestinal implant device of claim 1, wherein the first anchoring mechanism (510) is expandable to reduce a functional volume of the stomach.

3. The gastrointestinal implant device of claim 1 or claim 2, wherein the second anchoring mechanism (520) is designed to be secured within a duodenum by exerting a radial force against a wall of the duodenum.

4. The gastrointestinal implant device of claim 3, wherein the second anchoring mechanism (520) is designed to expand to contact the wall of the duodenum, so as to seal the sleeve against the wall of the duodenum.

5. The gastrointestinal implant device of one of claims 1 through 4, wherein the second anchoring mechanism (520) is coupled to the first anchoring mechanism (510) via a tethering mechanism (535, 550, 560).

6. The gastrointestinal implant device of claim 5, wherein the tethering mechanism is a proximal portion of the sleeve (535) or one or more tethers (550, 560).

7. The gastrointestinal implant device of claim 5, wherein the tethering mechanism (535, 550, 560) is sufficiently elastic to allow the first and/or second anchoring mechanism (510, 520) to exert a compressive force on a pylorus, so as to maximize anchoring of the first and second anchoring mechanisms adjacent the pylorus.

8. The gastrointestinal implant device of claim 5, wherein the tethering mechanism (535, 550, 560) is sufficiently elastic to allow axial movement of the second anchoring mechanism (520) in relation to the first anchoring mechanism.

9. The gastrointestinal implant device of one of claims 1 through 8 wherein the sleeve (530) is made from a sufficiently flexible material to permit the sleeve to move between an inverted position and an everted position, and wherein the sleeve (530) is designed to securely extend into the small intestine in the everted position.

10. The gastrointestinal implant device of one of claims 1 through 9 wherein the first anchoring mechanism (510) and the second anchoring mechanism (520) are connected by a portion of the sleeve (535), wherein the sleeve portion (535) is substantially elastic while the first anchoring mechanism (510) and the second anchoring mechanism (520) are held in a substantially fixed relative position of the second anchoring mechanism (520) along the gastrointestinal track away from the first anchoring mechanism (510).

11. The gastrointestinal implant device of one of claims 1 through 10, wherein the second anchoring mechanism (520) is configured to maintain a seal between the sleeve (530) and the duodenal or intestinal wall to ensure that food from the stomach passes into the sleeve (530) while minimizing leaking into the small intestine.

Patentansprüche

1. Gastrointestinal Implantatvorrichtung (500), umfassend:

   einen ersten Verankerungsmechanismus (510), der konzipiert ist, entlang eines Gastrointestinaltrakts und innerhalb eines Magens befestigt zu werden;

   einen zweiten Verankerungsmechanismus (520), der an den ersten Verankerungsmechanismus (510) gekoppelt und von diesem beabstandet ist, wobei der zweite Verankerungsmechanismus (520) konzipiert ist, weiter entlang des Gastrointestinaltrakts und jenseits des Magens befestigt zu werden; und

   eine Hülse (530), die an die äußere Oberfläche des zweiten Verankerungsmechanismus (520)
gekoppelt und zirkumferenziell um diese positioniert ist, wobei die Hülse (530) konzipiert ist, sich ab dem zweiten Verankerungsmechanismus (520) in den Dünndarm zu erstrecken und die Absorption von Nährstoffen durch eine Wand des Dünnarms zu minimieren;

wobei der zweite Verankerungsmechanismus (520) eine Vielzahl von Streben (515) einschließt, um ein Rahmenwerk zu bilden, wobei das Rahmenwerk expandierbar ist, um eine Zwölffingerdarmwand oder eine intestinale Wand zu kontaktieren, wobei ein Kopplungsmechanismus (535) den ersten Verankerungsmechanismus an den zweiten Verankerungsmechanismus im Anschluss an die Implantation der gastrointestinalen Implantatvorrichtung zu zulassen,
dadurch gekennzeichnet, dass wenigstens der zweite Verankerungsmechanismus (520) eine sphärische oder eine teilweise sphärische Form aufweist.

2. Gastrointestinale Implantatvorrichtung nach Anspruch 1, wobei der erste Verankerungsmechanismus (510) expandierbar ist, um ein Funktionsvolumen des Magens zu reduzieren.

3. Gastrointestinale Implantatvorrichtung nach Anspruch 1 oder Anspruch 2, wobei der zweite Verankerungsmechanismus (520) konzipiert ist, innerhalb eines Zwölffingerdarms durch Ausübung einer radialen Kraft gegen eine Wand des Zwölffingerdarms befestigt zu werden.

4. Gastrointestinale Implantatvorrichtung nach Anspruch 3, wobei der zweite Verankerungsmechanismus (520) konzipiert ist, sich zu expandieren, um die Wand des Zwölffingerdarms zu kontaktieren, um die Hülse gegen die Wand des Zwölffingerdarms abzudichten.

5. Gastrointestinale Implantatvorrichtung nach einem der Ansprüche 1 bis 4, wobei der zweite Verankerungsmechanismus (520) über einen anbindenden Mechanismus (535, 550, 560) an den ersten Verankerungsmechanismus (510) gekoppelt ist.


9. Gastrointestinale Implantatvorrichtung nach einem der Ansprüche 1 bis 8, wobei die Hülse (530) aus einem ausreichend flexiblen Material hergestellt ist, um zuzulassen, dass sich die Hülse zwischen einer invertierten Position und einer evertierten Position bewegt, und wobei die Hülse (530) konzipiert ist, sich in der evertierten Position sicher in den Dünnarm zu erstrecken.


11. Gastrointestinale Implantatvorrichtung nach einem der Ansprüche 1 bis 10, wobei der zweite Verankerungsmechanismus (520) konfiguriert ist, eine Dichtung zwischen der Hülse (530) und der Duodenalwander beizubehalten, um sicherzustellen, dass Nahrung aus dem Magen in die Hülse (530) gelangt, während Sickern in den Dünnarm minimiert wird.

Revendications

1. Dispositif d’implant gastro-intestinal (500) comprenant :

   un premier mécanisme d’ancrage (510) conçu pour être fixé le long d’un tractus gastro-intestinal et dans l’estomac ;
   un deuxième mécanisme d’ancrage (520) accouplé au et espacé du premier mécanisme d’ancrage (510), le deuxième mécanisme d’ancrage (520) conçu pour être fixé plus loin le long d’un tractus gastro-intestinal et au-delà de l’estomac ; et
un manchon (530) accouplé à et positionné à la circonférence de la surface extérieure du deuxième mécanisme d’ancrage (520), le manchon (530) étant conçu pour s’étendre du deuxième mécanisme d’ancrage (520) dans l’intestin grêle et pour minimiser l’absorption des aliments par une paroi de l’intestin grêle ; où le deuxième mécanisme d’ancrage (520) inclut une pluralité d’entretoises (515) pour former un châssis, le châssis étant extensible pour mettre en contact une paroi duodénale ou une paroi intestinale avec un dispositif d’accouplement (535) accouplant le premier mécanisme d’ancrage au deuxième mécanisme d’ancrage par rapport au premier mécanisme d’ancrage après l’implantation du dispositif d’implant gastro-intestinal caractérisé au moins en ce que le deuxième mécanisme d’ancrage (520) est de forme sphérique ou partiellement sphérique.

2. Dispositif d’implant gastro-intestinal selon la revendication 1, où le premier mécanisme d’ancrage (510) est extensible pour réduire un volume fonctionnel de l’estomac.

3. Dispositif d’implant gastro-intestinal selon la revendication 1 ou la revendication 2, où le deuxième mécanisme d’ancrage (520) est conçu pour être fixé dans un duodénum en exerçant une force radiale contre une paroi du duodénum.

4. Dispositif d’implant gastro-intestinal selon la revendication 3, où le deuxième mécanisme d’ancrage (520) est conçu pour se dilater et venir au contact de la paroi du duodénum, pour sceller le manchon contre la paroi du duodénum.


9. Dispositif d’implant gastro-intestinal selon l’une des revendications 1 à 8, où le manchon (530) est constitué d’un matériau suffisamment souple pour permettre au manchon de se déplacer entre une position inversée et une position évasée, et où le manchon (530) est conçu pour se déployer en toute sécurité dans l’intestin grêle dans la position évasée.

10. Dispositif d’implant gastro-intestinal selon l’une des revendications 1 à 9, où le premier mécanisme d’ancrage (510) et le deuxième mécanisme d’ancrage (520) sont reliés par une partie du manchon (535), où la partie manchon (535) est plus ou moins élastique tandis que le premier mécanisme d’ancrage (510) et le deuxième mécanisme d’ancrage (520) sont maintenus dans une position relative plus ou moins du deuxième mécanisme d’ancrage (520) le long du tractus gastro-intestinal, à l’écart du premier mécanisme d’ancrage (510).

11. Dispositif d’implant gastro-intestinal selon l’une des revendications 1 à 10, où le deuxième mécanisme d’ancrage (520) est configuré pour maintenir un joint entre le manchon (530) et la paroi duodénale ou la paroi intestinale pour veiller à ce que la nourriture dans l’estomac passe dans le manchon (530) tout en minimisant les fuites dans l’intestin grêle.
REFERENCES CITED IN THE DESCRIPTION

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