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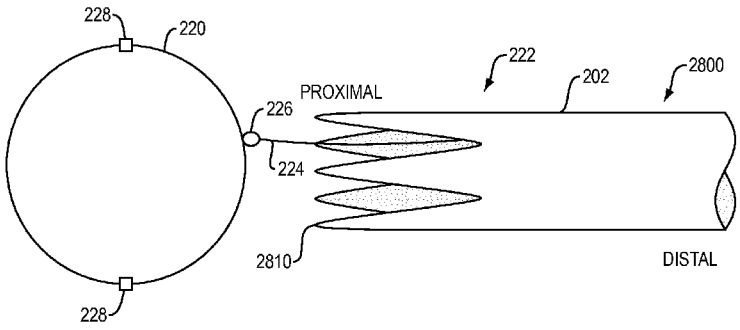

FIG. 2

(57) **Abstract**: A gastrointestinal implant device (2800) comprises a planar proximal element (220) configured to reside in a stomach to resist distal migration, a distal element (222) configured to reside in an intestine to resist proximal migration and one or more tethers (224) coupling the planar proximal element to the distal element.

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TRANSPYLORIC ANCHORING

RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Application No. 61/671,470, filed on July 13, 2012. The entire teachings of the above application are incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] There is an ongoing need to improve the duration of time over which gastrointestinal implants may safely be anchored in the gastrointestinal tract without occlusion, migration or other malfunction or drawbacks, particularly for implants that extend over at least a portion of the intestines.

[0003] Examples of such implants include those having flexible (floppy) sleeves extending into the intestine such as presented in U.S. patents 7,025,791; 7,122,058; 7,476,256; 7,608,114; 7,706,973; 7,771,382; 7,815,589; 7,837,643; 8,057,420; and those having restrictive orifices as presented in 7,771,382. All of those patents are incorporated by reference in their entirety.

SUMMARY OF THE INVENTION

[0004] In accordance with an embodiment of the invention, there is provided a gastrointestinal implant device. The device comprises a planar proximal element configured to reside in a stomach to resist distal migration; a distal element configured to reside in an intestine to resist proximal migration; and one or more tethers coupling the planar proximal element to the distal element. A single tether is generally preferred.

[0005] The distal element may be configured to seal to tissue of the intestine, thereby channeling chyme from the stomach into the intestine. The planar proximal element may comprise a hoop. The distal element may comprise a wave anchor. The planar proximal element may be significantly larger than a diameter of a pylorus of the stomach in a first dimension, and may be smaller than the diameter of the pylorus in a second dimension, orthogonal to the first dimension. The planar

proximal element may be between about 40 mm and about 100 mm in size in the first dimension; such as between about 50 mm and about 100 mm in size in the first dimension. The planar proximal element may be between about 1 mm and about 15 mm in size in the second dimension; for example, between about 1 mm and about 5 mm in size in the second dimension. The planar proximal element may comprise a hoop of between about 40 mm and about 60 mm diameter and of between about .5 mm and about 5 mm in thickness. The tether may comprise a flexible tether or a rigid tether. The planar proximal element may comprise a circular, polygon or an ellipsoid shape. The proximal element may be planar; for example, it may comprise at least one member of the group consisting of: a hoop, a polygon and an ellipsoid shape.

[0006] In further, related embodiments, the device may comprise no tissue penetrating features. The device may further comprise an unsupported, thin-walled sleeve coupled to the distal element. The sleeve may be floppy, flexible, conformable and collapsible. The planar proximal element may be without a seal to the stomach. In normal use of the implant device, a central longitudinal axis of the planar proximal element, perpendicular to a plane in which the planar proximal element lies, may be substantially perpendicular to a central longitudinal axis of a lumen of at least one of: a pyloric sphincter of the stomach; and the intestine. The distal element may comprise a three-dimensional object. The distal element may comprise a restrictor; and/or a fluid-filled chamber and/or a toroidal object. The distal element may comprise at least one of a catheter and a diagnostic device. The distal element may be between about 30 mm and about 40 mm in diameter. The distal element may comprise a wave anchor. The distal element may comprise a length to diameter ratio of at least about one. The distal element may comprise a length of between about 30mm and about 40 mm; such as a length of at most about 32 mm, and may comprise an anchor of about the same length as the duodenal bulb. The distal element may comprise a spring element.[A1].

[0007] In further related embodiments, at least one of the planar proximal element, the tether and the distal element may be covered in an atraumatic material, such as at least one of urethane and silicone. The tether may comprise a suture made of polymer or metal. The tether may be between about 10 mm and about 50 mm in

length, and may be between about .5 mm and about 5 mm in diameter, such as between about 1 mm and about 2 mm in diameter. The distal element may comprise a plurality of spokes, and the tether may be coupled to the plurality of spokes. The distal element may be configured to change shape upon transmission of force to the distal element by the tether. The distal element may comprise a wave anchor, the tether being coupled to at least one crown of the wave anchor; such as the tether being coupled to a distal crown of the wave anchor, where the wave anchor comprises a diameter of between about 30 mm and about 40 mm. The distal element may be configured to open radially outwards upon exertion of tension by the tether to resist proximal migration. The planar proximal element may be loosely attached to the tether, thereby permitting the planar proximal element to rotate independently of the tether. The planar proximal element may be coupled to a tie loop to which the tether is coupled.

[0008] In further related embodiments, at least one of the planar proximal element and the distal element may comprise a polymer. The polymer may comprise at least one material of the group consisting of: silicone, polytetrafluoroethylene, polyethylene and polypropylene. At least one of the planar proximal element and the distal element may comprise a metal. The metal may comprise at least one of nitinol and stainless steel. The planar proximal element, distal element and tether may be configured to be collapsible into a container for endoscopic delivery into a gastrointestinal tract. At least one of the proximal element and the distal element may further comprise a removal drawstring.

[0009] There is provided a method of treatment comprising: with a planar proximal element in a stomach, resisting distal migration of a proximal portion of a gastrointestinal implant device into an intestine; with a distal element in the intestine, resisting proximal migration of a distal portion of the gastrointestinal implant device into the stomach; and with one or more tethers, securing the planar proximal element to the distal element across a pylorus. A single tether is generally preferred.

[0010] The method may further comprise sealing the distal element to tissue of the intestine, thereby channeling chyme from the stomach through the duodenal element into the intestine. The method may comprise securing the gastrointestinal

implant device without penetrating tissue. The method may further comprise channeling chyme from the stomach into an unsupported, thin-walled sleeve extending into the intestine from the gastrointestinal implant device. The method may comprise resisting migration of the planar proximal element into the intestine without sealing the planar proximal element to the stomach. In the method, in normal use of the gastrointestinal implant device, a central longitudinal axis of the planar proximal element, perpendicular to a plane in which the planar proximal element lies, may be aligned to be substantially perpendicular to a central longitudinal axis of a lumen of at least one of: a pyloric sphincter of the stomach; and the intestine. The method may comprise restricting a flow of chyme from the stomach into the intestine using a restrictor coupled to the gastrointestinal implant device. The method may comprise retaining an anchor portion of the distal element within the duodenal bulb. The distal element may be configured to change shape upon transmission of force to the distal element by the tether; such as the distal element may be configured to open radially outwards upon exertion of tension by the tether. The planar proximal element may be loosely attached to the tether, thereby permitting the planar proximal element to rotate independently of the tether. The method may comprise delivering the planar proximal element, distal element and tether inside a container with an endoscope into a gastrointestinal tract.

[0011] There is provided a method of removing a gastrointestinal implant. The method comprises severing one or more tethers that couples a planar proximal element of the gastrointestinal implant in a stomach with a distal element of the gastrointestinal implant in an intestine; with a catheter, removing the planar proximal element proximally out of the stomach through a mouth; and with a grasper on a distal end of the catheter, grasping a drawstring to remove the distal element proximally out of the intestine, though the stomach and out of the mouth.

[0012] In further, related embodiments, removing the planar proximal element may comprise passing the planar proximal element through an overtube. Removing the distal element may comprise collapsing the distal element radially into a retrieval hood.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] The foregoing will be apparent from the following more particular description of example embodiments of the invention, as illustrated in the accompanying drawings in which like reference characters refer to the same parts throughout the different views. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating embodiments of the present invention.

[0014] FIG. 1 is a sectional view of a portion of the digestive tract in a body.

[0015] FIG. 2 is a perspective view of a gastrointestinal implant device with an embodiment of an anchoring device having a single tether and wave anchor distal element.

[0016] FIG. 3 is a sectional view of a body showing the gastrointestinal implant device of FIG. 2 implanted in the digestive system.

[0017] FIG. 4 is gastrointestinal implant devices in accordance with another embodiment of the invention having a single tether and stent distal element.

[0018] FIG. 5 is an implant device of the invention having plural tethers.

[0019] FIG. 6 is an implant device of the invention having a planar distal element.

[0020] FIG. 7 is an implant device of the invention in which the tether is coupled to spokes on the distal element.

DETAILED DESCRIPTION OF THE INVENTION

[0021] A description of example embodiments of the invention follows.

[0022] There is provided an anchor for a gastrointestinal implant device. The anchor spans the pylorus, and therefore is called a transpyloric anchor. It is an objective of certain embodiments to provide the same or similar functionality as is provided by existing anchoring techniques for gastrointestinal implant devices, while having fewer side effects (such as bleeding, discomfort, migration and/or infection), and while having few or no tissue penetrating features.

[0023] Among other things, certain embodiments provide a method and apparatus for the application of a barrier sleeve in the digestive tract to limit the contact of food products in specific parts of the digestive tract and to provide enhanced satiety to patients with morbid obesity, enabling them to reduce their food

intake. The sleeve may also be used for other treatments such as Type-2 diabetes through hormone triggers.

[0024] A rationale behind a transpyloric anchor in accordance with certain embodiments is that the antrum of the stomach is an advantageous location for a proximal element of the anchor; the duodenal bulb is an advantageous location for a distal element of the anchor; and the pylorus is a definite mechanical feature, which can be used for anchoring. The antrum of the stomach is adjacent to the pylorus and has tough tissue, while the duodenal bulb has minimal motion and permits the distal anchor to seal against tissue.

[0025] In a relaxed state, the stomach becomes flat, and thus a lightweight planar proximal element is able to orient itself in a plane within the relaxed stomach to cause as little trauma as possible to the stomach.

[0026] In accordance with certain embodiments, components of a transypyloric anchor include: (i) a planar proximal element in the stomach, which prevents distal migration; (ii) a distal element in the intestines, which both prevents proximal migration and may provide a seal; and (iii) one or more tethers, which connects the proximal and distal element.

[0027] FIG. 1 is a sectional view of a portion of the digestive tract in a body. Food to be digested enters the stomach 102 through the cardiac orifice 110 from the esophagus. Chyme, a semi-fluid, homogeneous creamy or gruel-like material produced by gastric digestion in the stomach exits the stomach through the pyloric orifice (pylorus) 108 and enters the small intestine 112. The pylorus 108 is a distal aperture of the stomach 102 surrounded by a strong band of circular muscle. The small intestine, about nine feet in length, is a convoluted tube, extending from the pylorus 108 to the ileo-caecal valve where it terminates in the large intestine. The small intestine has three sections, the duodenum 104, jejunum 106 and the ileum (not shown). The first eight to ten inch section of the small intestine 112, the duodenum 104, is the shortest, widest and most fixed part of the small intestine 112.

[0028] The duodenum 104 has four sections: superior, descending, transverse and ascending which typically form a U-shape. The superior section is about two inches long and ends at the neck of the gall bladder. The superior section also defines a feature referred to as the duodenal bulb 119 that begins just distal to the

pylorus 108 and extends for about 1 to 1.5 inches in an adult human. The duodenal bulb 119 defines a lumen therein that is slightly larger than the distal duodenum 104. Advantageously, the duodenal bulb 119 exhibits less motion than the pylorus 108 and even distal portions of the duodenum 104. Notably, the motion is substantially limited to contractions without having a significant linear component (*i.e.*, no movement along the central axis of the intestine). However, the tissue thins as one moves away from the pylorus 108.

[0029] The descending section of the duodenum 104 is about three to four inches long and includes a nipple shaped structure (papilla of Vater) 114 through which pancreatic juice from the pancreas and bile produced by the liver and stored by the gall bladder enter the duodenum from the pancreatic and bile ducts. The pancreatic juice contains enzymes essential to protein digestion and the bile dissolves the products of fat digestion. The ascending section is about two inches long and forms the duodenal-jejunal flexure 116 where it joins the jejunum 106, the next section of the small intestine. The duodenal-jejunal flexure 116 is fixed to the ligament of Treitz 118 (musculus supensionus duodeni). The juices secreted in the duodenum break the partially digested food down into particles small enough to be absorbed by the body. The digestive system is described in Gray's Anatomy ("Anatomy of the Human Body," by Henry Gray) and "Human Physiology," Vander, 3rd ed, McGraw Hill, 1980, the contents of which are incorporated herein by reference in their entirety.

[0030] FIG. 2 is a perspective view of a gastrointestinal implant device 2800 comprising an anchoring device in accordance with an embodiment of the invention. The device 2800 comprises a planar proximal element 220 configured to reside in a stomach to resist distal migration; a distal element 222 configured to reside in an intestine to resist proximal migration and to provide a seal; and a single tether 224 coupling the planar proximal element 220 to the distal element 222.

[0031] In accordance with an embodiment of the invention, the planar proximal element 220 prevents distal migration only by being large enough that it cannot fit through the pylorus 108. In addition, a lack of leading edges inherent in this geometry makes it hard for the proximal element to push through the pylorus. There is no need for the proximal element 220 to form a seal to the stomach wall, nor for it

to penetrate tissue of the stomach; and indeed, forces against the tissue required for sealing and members that penetrate tissue are undesirable in the proximal element 220 because the antrum of the stomach is a very active region that frequently undergoes contractions. The proximal element 220 can move relatively freely within the stomach (subject to the tether and contact with food and the walls of the stomach) without engaging tissue or forming a seal. By being planar, the proximal element 220 is atraumatic to the stomach tissue, since it orients in the plane of the stomach when the stomach is relaxed and without food and therefore typically the stomach is flat in this state. Likewise, the proximal element 220 should have as little mass as possible, in order to avoid trauma. The planar proximal element 220 may, for example, be a planar hoop or ring with an empty middle, as shown in FIG. 2. The hoop or ring may have a diameter between about 40 mm and about 100 mm. Using a diameter too small may risk the proximal element 220 migrating distally through the pylorus into the intestine; whereas using a diameter that is too large may risk producing trauma to the stomach. In one example, the proximal element may be a ring of about 60 mm diameter. The proximal element 220 should also be easy to deliver, which may be performed by bending the ring to fit within a container that can fit through the mouth and esophagus. The proximal element 220 is formed of a resilient material that can be deformed and return to its original shape. For example, the proximal element 220 may be formed of a metal such as stainless steel or Nitinol, or a polymer, such as polyethylene, polytetrafluoroethylene, polypropylene or silicone. The proximal element 220 may also be braided, such as a braided metal or polymer. In one example, the proximal element 220 is a ring of about 60 mm in diameter, formed of nitinol or stainless steel, coated with silicone or urethane. This could be a polymer coating or a tube that covers the element. A ring 220 may be formed by joining together nitinol components using one or more crimps 228 or by welding, and may then be covered with an atraumatic substance.

[0032] In accordance with an embodiment of the invention, the proximal element 220 may be normally oriented perpendicular to the lumen of the pyloric sphincter or the intestinal lumen, as shown in FIG. 3. More specifically, in normal use of the implant device, a central longitudinal axis of the planar proximal element, perpendicular to a plane in which the planar proximal element lies, is substantially

perpendicular to a central longitudinal axis of a lumen of pyloric sphincter of the stomach, or of the intestine. Because the proximal element 220 moves relatively freely, subject to tension from the tether and contact with chyme and the stomach walls, it will also be oriented at a variety of different angles in use.

[0033] While the planar proximal element 220 is described as "planar" it has some thickness in practice. The planar proximal element is significantly larger than a diameter of a pylorus of the stomach in a first dimension, and is smaller than the diameter of the pylorus in a second dimension, orthogonal to the first dimension. For example, the planar proximal element may be between about 40 mm and about 100 mm in size in the first dimension (e.g. ,diameter); such as between about 50 mm and about 100 mm in size in the first dimension (e.g., diameter); and between about .5mm and about 15 mm in size in the second dimension (e.g., thickness and bending), such as between about 1 mm and about 5 mm in size in the second dimension (e.g., thickness). In one example, the planar proximal element comprises a hoop of between about 40 mm and about 60 mm diameter and of between about 1 mm and about 5 mm in thickness. The planar proximal element may comprise other planar shapes in addition to a ring or hoop, such as a polygon or an ellipsoid shape.

[0034] In accordance with an embodiment of the invention, the distal element 222 has the purpose of both sealing to the tissue of the intestines, and preventing proximal migration. By forming a seal, the distal element 222 permits chyme to be channeled into the distal element without contacting the walls of the intestines, thereby forming an intestinal bypass. The distal element 222 may be a three dimensional object, such as a wave anchor 2810 (shown in FIG. 2), to which an unsupported, flexible sleeve 202 may be attached. The sleeve may be floppy, flexible, conformable and collapsible. For example, the sleeve may be one taught in U.S. Patent No. 7,981,163 B1, the entire disclosure of which is hereby incorporated herein by reference, or any of the previously cited U.S. patents. The distal element 222 may also be another three dimensional object, such as a balloon and/or a toroidal element, and may include a fluid-filled chamber. For example, the distal element may be a fluid-filled toroidal element such as those taught in U.S. Patent App. No. 2011/0004228 A1 of Priplata *et al.*, the entire disclosure of which is hereby incorporated herein by reference. The distal element 222 may support a

restrictive element, such as a plate resistor, which may be combined with a sleeve. The resistor extends across the anchor or a sleeve and has one or more restrictive apertures therein. Further, the distal element 222 may support a catheter or a diagnostic device, such as a pressure sensor. The diameter of the distal element 222, such as a wave anchor, may be between about 30 mm and 40 mm, in order to avoid trauma to the intestine. For example, the diameter may be about 35 mm. The length to diameter ratio of the distal element 222 may be about one. In length, the distal element 222 may be of about the same length as the duodenal bulb 119, in order to fit within that anatomical feature. The wave anchor may comprise a single wave of a few cycles, five being shown. The wave may be formed of collapsible wire, such as of metal such as Nitinol. The distal element 222 may include no tissue penetrating features, such as barbs, and may be coated or covered with an atraumatic substance such as silicone or urethane.

[0035] In another embodiment according to the invention, the distal element 222 may be planar. For example, the distal element may be a hoop, a polygon or an ellipsoid shape. This shape would not provide a seal, but would provide atraumatic anchoring.

[0036] In accordance with an embodiment of the invention, the purpose of the tether 224 is to couple the proximal element 220 to the distal element 222. Using a single tether 224 provides the advantage of avoiding tangling, as could occur if multiple tethers were to be used. The tether 224 may be flexible such as a suture or may be rigid, such as a rod. Regardless of whether flexible or rigid, the tether 224 may be attached at its proximal end to a tie loop 226, which permits the proximal element 220 to rotate independently of the tether 224 by sliding through loop 226. The tether 224 is between about 10 mm and about 50 mm in length. If the tether is too short, it may force the pylorus open, causing discomfort, but if it is too long, it may permit the distal element 222 to move too far into the intestine, such as out of the duodenal bulb. The tether has a diameter of between about .5 mm and about 5 mm, such as between about 1 mm and about 2 mm. A diameter that is too large may cause the pylorus to sense the tether. If too small, it could cause cutting of the tissues. In one example, the tether is a suture. The tether may be attached at its distal end to the center of a set of spokes, such as spokes made of sutures, which

extend to the inner periphery of the distal element 222. The tether may, for example, be formed of polypropylene braid, or polyethylene or ptfe; and may be either uncovered or covered, for example with silicone, ePTFE or urethane to prevent trauma.

[0037] In another embodiment, the tether 224 may be attached at its distal end to the distal element 222 in a way that causes the distal element 222 to change its shape. For example, where the distal element 222 is a wave anchor, the tether 224 may be coupled to a distal crown of the wave anchor, which tends to cause the wave anchor to open radially outwards at its proximal end when the tether 224 exerts tension on the distal element 222. In this way, the distal element 222 actively resists proximal migration. Other active elements may be used for the distal element 222.

[0038] In the embodiment of FIG. 2, the gastrointestinal implant device 2800 includes a sleeve 202 and an anchoring device 2810 for anchoring the gastrointestinal implant 2800 device in the duodenum 104. The anchoring device 2800 includes a wave anchor 2810 coupled to a proximal portion of the sleeve 202. The wave anchor 2810 includes a compliant, radial spring shaped into an annular wave pattern about a central axis, providing an outward radial force, while allowing substantial flexure about its perimeter. Such flexure is advantageous as it may be collapsed radially to allow for minimally-invasive delivery and ensures that the device will substantially conform to the surrounding anatomical structure when implanted and allowed to expand. The annular wave element can be formed from one or more elongated resilient members and defines a lumen along its central axis formed between two open ends.

[0039] When implanted, as shown in FIG. 3, the proximal element 220 moves substantially freely in the stomach, while the central axis of the distal element's anchor 2810 is substantially aligned with the central axis of the duodenum 104, allowing chyme to pass through the device 2800. Additionally, the compliant wave anchor 2810 minimizes trauma to the tissue by providing sufficient flexibility and compliance, while minimizing the likelihood of tissue erosion.

[0040] The compliant wave anchor 2810 can be manufactured from a resilient metal such as a heat-treated spring steel, stainless steel, or from an alloy such as

NiTi alloy commonly referred to as Nitinol. Other alloys include nickel-cobalt-chromium-molybdenum alloys possessing a unique combination of ultrahigh tensile strength, such as MP35N. Additionally, the wave anchor 2810 can be formed from a polymer and/or a composite having similar properties. The wave anchor 2810 can be manufactured from a single strand, such as a wire, contoured into the desired shape. Alternatively, the wave anchor 2810 can be manufactured from multi-strands of the same or different materials similarly contoured to the desired shape. In some embodiments, the wave anchor 2810 can be cut into the wave shape from tubular stock of the desired material, such as Nitinol.

[0041] When implanted, the anchor 2810 can enable a sleeve 202, or barrier to be securely implanted within the duodenum 104, preferably providing a fluid seal at the proximal end. To enhance a fluid seal, the proximal end of the sleeve can be contoured to the wave anchor as shown in FIG. 2. For a device 2800 using a sleeve 202 contoured to the wave anchor 2810, the proximal end appears tulip-shaped.

[0042] In an embodiment according to the invention, the proximal element 220 may prevent the device from migrating distally, but may be without a seal, whereas the distal element 222 is used to form a seal against tissue, such as the duodenal wall.

[0043] In one example, the distal element 222 is a 32-33 mm diameter wave anchor, with five peaks, formed from wire of 0.032-0.035 inches. The hoop 220 may, for example, be 0.034 inches thick, formed of two loops with two crimps; or 0.025 inches thick, formed of three loops with two crimps.

[0044] In another example, the proximal element 220 comprises 2 loops of 0.040" diameter wire, crimped together in two spots, 180 degrees opposed, with a 60 mm diameter overall loop; while the distal element 222 comprises a 35 mm diameter wave anchor, with a greater than one pound compliance and formed of 0.030" diameter wire. A wave anchor as large as 55 mm diameter may also be used, with no tissue engaging barbs. It will be appreciated that a variety of different diameters, wire thicknesses, compliances and number of crowns for a wave anchor may be used (for example, five or six crowns on the wave anchor).

[0045] In FIG. 4, the distal element 222 comprises a stent 442.

[0046] FIG. 5 shows an embodiment in which the wave anchor 2810 is tethered with two tethers. This is less preferred for reasons expressed above but may have some application.

[0047] FIG. 6 shows an embodiment in which the distal element 222 is also planar. The planar distal element serves to retain the device against proximal movement but does not provide fluid sealing against the intestine.

[0048] FIG. 7 shows an embodiment in which the tether is coupled to spokes 702 on the distal element.

[0049] The planar proximal element, distal element and tether are configured to be collapsible into a container for delivery through the mouth and esophagus into a gastrointestinal tract. For example, container delivery techniques may be used such as those taught in U.S. Patent No. 7,837,643 B2 of Levine *et al.*, the entire disclosure of which is hereby incorporated herein by reference.

[0050] In an embodiment according to the invention, the device may be removed by cutting the tether 224, and then pulling the proximal element 220 (such as a hoop) through the esophagus, for example through an esophageal overtube. The proximal element 220 (such as a hoop) can be cut or undone to assist in removal. Alternatively, suture material may be used in one or more components, which may be cut to assist in removal. The device may be able to be removed without an overtube. Further, the foregoing methods may be used to remove the proximal element 220, while another method of removal is used for the distal element 222, for instance using a drawstring 2810 (Fig. 3) technique as set forth in U.S. Patent No. 8,057,420, the entire disclosure of which is hereby incorporated herein by reference. The proximal element and/or the distal element further may comprise a removal drawstring.

[0051] In one embodiment, a method of removing a gastrointestinal implant comprises severing one or more tethers that couples a planar proximal element of the gastrointestinal implant in a stomach with a distal element of the gastrointestinal implant in an intestine; with a catheter, removing the planar proximal element proximally out of the stomach through a mouth; and with a grasper on a distal end of the catheter, grasping a drawstring to remove the distal element proximally out of the intestine, though the stomach and out of the mouth. The planar proximal

element may be removed through an overtube. The distal element may be collapsed radially into a retrieval hood. The proximal element may also be collapsed in a retrieval hood for removal.

[0052] In accordance with an embodiment of the invention, there is provided a method of treatment. The method comprises providing a gastrointestinal implant device set forth herein, and securing the device across the pylorus of a patient. Chyme may be channeled from the stomach into an unsupported, thin-walled sleeve extending into the intestine from the gastrointestinal implant device. For example, a sleeve such as those set forth in U.S. Patent No. 7,682,330 (the entire disclsoure of which is hereby incorporated herein by reference) may be used. Further, a flow of chyme from the stomach into the intestine may be restricted with a restrictor coupled to the gastrointestinal implant device. For example, a restrictor such as those set forth in U.S. Patent No. 7,771,382 (the entire disclsoure of which is hereby incorporated herein by reference) may be used.

[0053] The teachings of all patents, published applications and references cited herein are incorporated by reference in their entirety.

[0054] While this invention has been particularly shown and described with references to example embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the scope of the invention encompassed by the appended claims.

CLAIMS

What is claimed is:

1. A gastrointestinal implant device comprising:

a planar proximal element configured to reside in a stomach to resist distal migration;

a distal element configured to reside in an intestine to resist proximal migration; and

one or more tethers coupling the planar proximal element to the distal element.

2. The gastrointestinal device of claim 1, wherein only a single tether couples the planar proximal element to the distal element.

3. The gastrointestinal implant device of Claim 1 or 2, wherein the distal element is configured to seal to tissue of the intestine, thereby channeling chyme from the stomach into the intestine.

4. The gastrointestinal implant device of Claim 1, 2 or 3 wherein the planar proximal element comprises a hoop.

5. The gastrointestinal implant device of any preceding claim, wherein the distal element comprises a wave anchor.

6. The gastrointestinal implant device of any preceding claim, wherein the planar proximal element is significantly larger than a diameter of a pylorus of the stomach in a first dimension, and is smaller than the diameter of the pylorus in a second dimension, orthogonal to the first dimension.

7. The gastrointestinal implant device of Claim 6, wherein the planar proximal element is between about 40 mm and about 100 mm in size in the first dimension.

8. The gastrointestinal implant device of Claim 6, wherein the planar proximal element is between about 50 mm and about 100 mm in size in the first dimension.

9. The gastrointestinal implant device of Claim 6, 7 or 8, wherein the planar proximal element is between about .5 mm and about 15 mm in size in the second dimension.

10. The gastrointestinal implant device of Claim 6, 7, 8 or 9, wherein the planar proximal element is between about .5 mm and about 5 mm in size in the second dimension.

11. The gastrointestinal implant device of any preceding claim, wherein the planar proximal element comprises a hoop of between about 40 mm and about 60 mm diameter and of between about .5 mm and about 5 mm in thickness.

12. The gastrointestinal implant device of any preceding claim, wherein the tether comprises a flexible tether.

13. The gastrointestinal implant device of any preceding claim, wherein the tether comprises a rigid tether.

14. The gastrointestinal implant device of any preceding claim, wherein the planar proximal element comprises a polygon or an ellipsoid shape.

15. The gastrointestinal implant device of any preceding claim, wherein the distal element is planar.

16. The gastrointestinal implant device of Claim 15, wherein the distal element comprises at least one member of the group consisting of: a hoop, a polygon

and an ellipsoid shape.

17. The gastrointestinal implant device of any preceding claim, wherein the device comprises no tissue penetrating features.

18. The gastrointestinal implant device of any preceding claim, further comprising an unsupported, thin-walled sleeve coupled to the distal element.

19. The gastrointestinal implant device of Claim 18, wherein the sleeve is floppy, flexible, conformable and collapsible.

20. The gastrointestinal implant device of any preceding claim, wherein the planar proximal element is without a seal to the stomach.

21. The gastrointestinal implant device of any preceding claim, wherein, in normal use of the implant device, a central longitudinal axis of the planar proximal element, perpendicular to a plane in which the planar proximal element lies, is substantially perpendicular to a central longitudinal axis of a lumen of at least one of: a pyloric sphincter of the stomach; and the intestine.

22. The gastrointestinal implant device of any preceding claim, wherein the distal element comprises a three-dimensional object.

23. The gastrointestinal implant device of any preceding claim, wherein the distal element comprises a restrictor.

24. The gastrointestinal implant device of any preceding claim, wherein the distal element comprises a fluid-filled chamber.

25. The gastrointestinal implant device of any preceding claim, wherein the distal element comprises a toroidal object.

26. The gastrointestinal implant of any preceding claim, wherein the distal element comprises at least one of a catheter and a diagnostic device.

27. The gastrointestinal implant device of any preceding claim, wherein the distal element is between about 30 mm and about 40 mm in diameter.

28. The gastrointestinal implant device of any preceding claim, wherein the distal element comprises a wave anchor.

29. The gastrointestinal implant device of any preceding claim, wherein the distal element comprises a length to diameter ratio of at least about one.

30. The gastrointestinal implant device of any preceding claim, wherein the distal element comprises a length of between about 30mm and about 40 mm.

31. The gastrointestinal implant device of any preceding claim, wherein the distal element comprises a length of at most about 32 mm.

32. The gastrointestinal implant device of any preceding claim, wherein the distal element comprises an anchor of about the same length as the duodenal bulb.

33. The gastrointestinal implant device of any preceding claim, wherein the distal element comprises a spring.

34. The gastrointestinal implant device of any preceding claim, wherein at least one of the planar proximal element, the tether and the distal element is covered in an atraumatic material.

35. The gastrointestinal implant device of Claim 34, wherein the atraumatic material comprises a coating of at least one of urethane and silicone.

36. The gastrointestinal implant device of any preceding claim, wherein the tether comprises a suture.

37. The gastrointestinal implant device of any preceding claim, wherein the tether is between about 10 mm and about 50 mm in length.

38. The gastrointestinal implant device of any preceding claim, wherein the tether is between about .5 mm and about 5 mm in diameter.

39. The gastrointestinal implant device of any preceding claim, wherein the tether is between about 1 mm and about 2 mm in diameter.

40. The gastrointestinal implant device of any preceding claim, wherein the distal element comprises a plurality of spokes, and wherein the tether is coupled to the plurality of spokes.

41. The gastrointestinal implant device of any preceding claim, wherein the distal element is configured to change shape upon transmission of force to the distal element by the tether.

42. The gastrointestinal implant device of any preceding claim, wherein the distal element comprises a wave anchor, the tether being coupled to at least one crown of the wave anchor.

43. The gastrointestinal implant device of Claim 42, wherein the tether is coupled to a distal crown of the wave anchor, and wherein the wave anchor comprises a diameter of between about 30 mm and about 40 mm.

44. The gastrointestinal implant device of any preceding claim, wherein the distal element is configured to open radially outwards upon exertion of tension by the tether.

45. The gastrointestinal implant device of any preceding claim, wherein the planar proximal element is loosely attached to tether, thereby permitting the planar proximal element to rotate independently of the tether.

46. The gastrointestinal implant device of any preceding claim, wherein the planar proximal element is coupled to a tie loop to which the tether is coupled.

47. The gastrointestinal implant device of any preceding claim, wherein at least one of the planar proximal element and the distal element comprises a polymer.

48. The gastrointestinal implant device of Claim 47, wherein the polymer comprises at least one material of the group consisting of: silicone, polytetrafluoroethylene, polyethylene and polypropylene.

49. The gastrointestinal implant device of any preceding claim, wherein at least one of the planar proximal element and the distal element comprises a metal.

50. The gastrointestinal implant device of Claim 49, wherein the metal comprises at least one of nitinol and stainless steel.

51. The gastrointestinal implant device of any preceding claim, wherein the planar proximal element, distal element and tether are configured to be collapsible into a container for endoscopic delivery into a gastrointestinal tract.

52. The gastrointestinal implant device of any preceding claim, wherein at least one of the proximal element and the distal element further comprises a removal drawstring.

53. A method of treatment comprising:

with a planar proximal element in a stomach, resisting distal migration of a proximal portion of a gastrointestinal implant device into an intestine;

with a distal element in the intestine, resisting proximal migration of a distal portion of the gastrointestinal implant device into the stomach; and

with one or more tethers, securing the planar proximal element to the distal element across a pylorus.

54. The method of treatment of claim 53 wherein only a single tether secures the planar proximal element to the distal element.

55. The method of treatment of Claim 53 or 54, further comprising sealing the distal element to tissue of the intestine, thereby channeling chyme from the stomach into the intestine.

56. The method of treatment of Claim 53, 54 or 55, comprising securing the gastrointestinal implant device without penetrating tissue.

57. The method of treatment of any of Claims 53-56, further comprising channeling chyme from the stomach into an unsupported, thin-walled sleeve extending into the intestine from the gastrointestinal implant device.

58. The method of treatment of any of Claims 53-57, comprising resisting migration of the planar proximal element into the intestine without sealing the planar proximal element to the stomach.

59. The method of treatment of any of Claims 53-58, wherein, in normal use of the gastrointestinal implant device, a central longitudinal axis of the planar proximal element, perpendicular to a plane in which the planar proximal element lies, is aligned to be substantially perpendicular to a central longitudinal axis of a lumen of at least one of: a pyloric sphincter of the stomach; and the intestine.

60. The method of treatment of any of Claims 53-59, comprising restricting a flow of chyme from the stomach into the intestine using a restrictor coupled to the gastrointestinal implant device.

61. The method of treatment of any of Claims 53-60, comprising retaining an anchor portion of the distal element within the duodenal bulb.

62. The method of any of Claims 53-61, wherein the distal element is configured to change shape upon transmission of force to the distal element by the tether.

63. The method of any of Claims 53-62, wherein the distal element is configured to open radially outwards upon exertion of tension by the tether.

64. The method of any of Claims 53-63, wherein the planar proximal element is loosely attached to tether, thereby permitting the planar proximal element to rotate independently of the tether.

65. The method of any of Claims 53-64, comprising delivering the planar proximal element, distal element and tether inside a container with an endoscope into a gastrointestinal tract.

66. A method of removing a gastrointestinal implant, the method comprising:

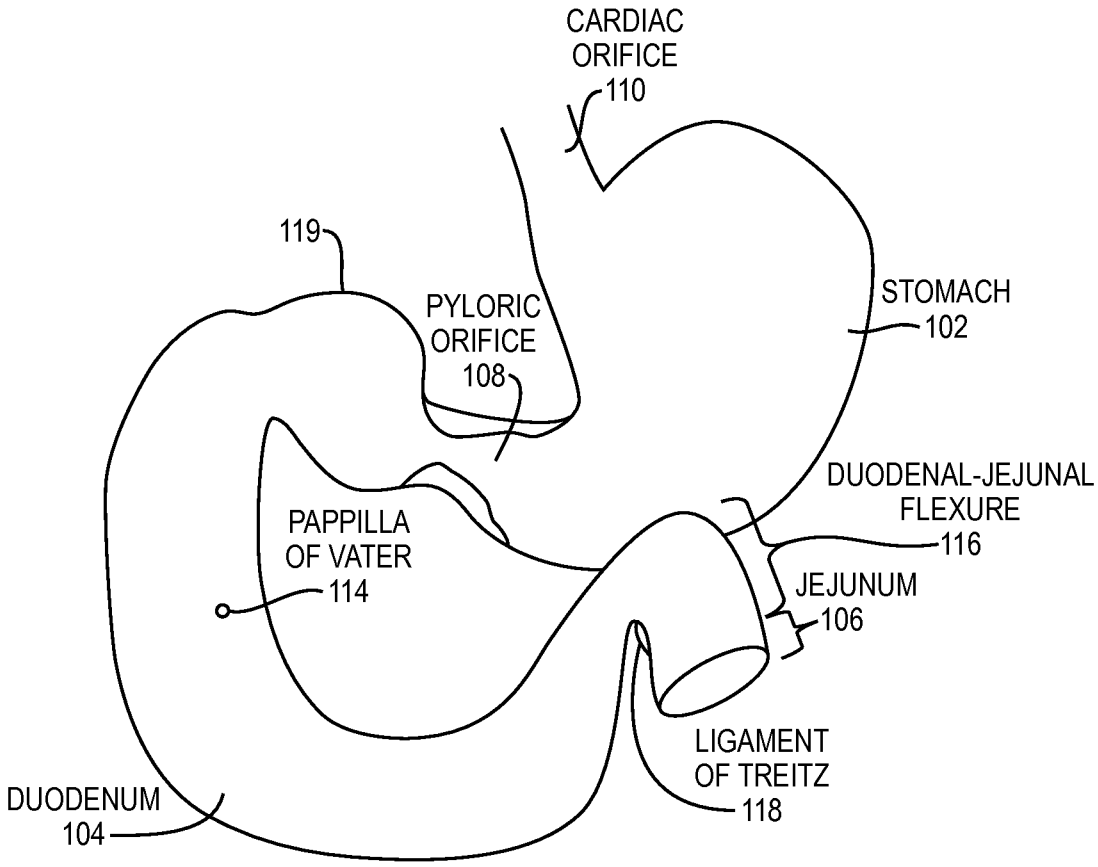
severing one or more tethers that couples a planar proximal element of the gastrointestinal implant in a stomach with a distal element of the gastrointestinal implant in an intestine;

with a catheter, removing the planar proximal element proximally out of the stomach through a mouth; and

with a grasper on a distal end of the catheter, grasping a drawstring to remove the distal element proximally out of the intestine, though the stomach and out of the mouth.

67. The method of Claim 66, wherein removing the planar proximal element comprises passing the planar proximal element through an overtube.

68. The method of Claim 66 or 67, wherein removing the distal element comprises collapsing the distal element radially into a retrieval hood.


CARDIAC
ORIFICE
110
119
PYLORIC
ORIFICE
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STOMACH
102
DUODENAL-JEJUNAL
FLEXURE
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PAPPILLA
OF VATER
114
JEJUNUM
106
LIGAMENT
OF TREITZ
118
DUODENUM
104

FIG. 1

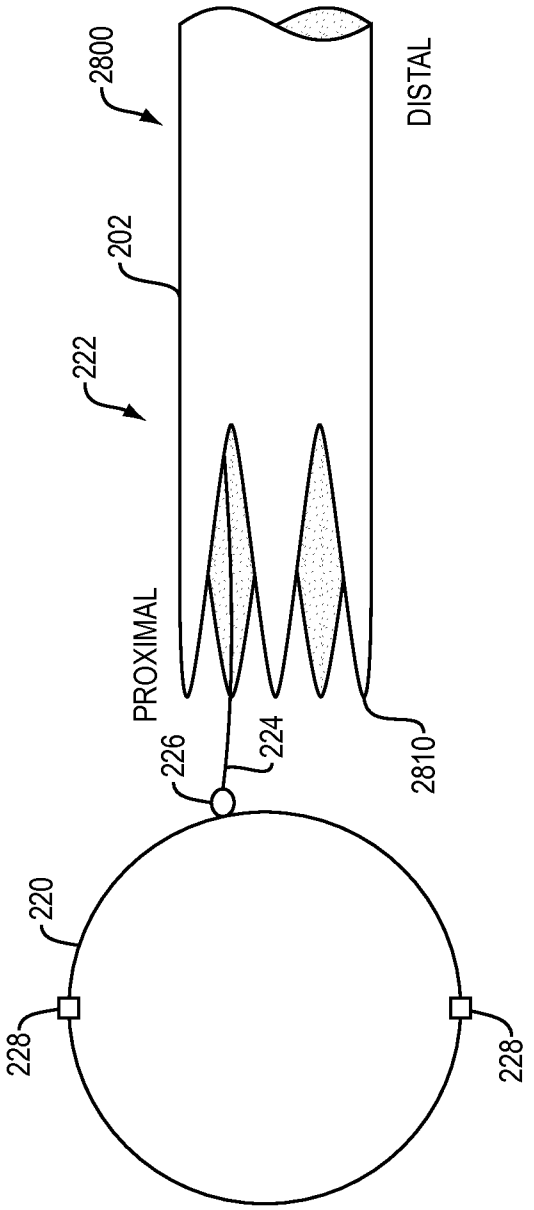

FIG. 2

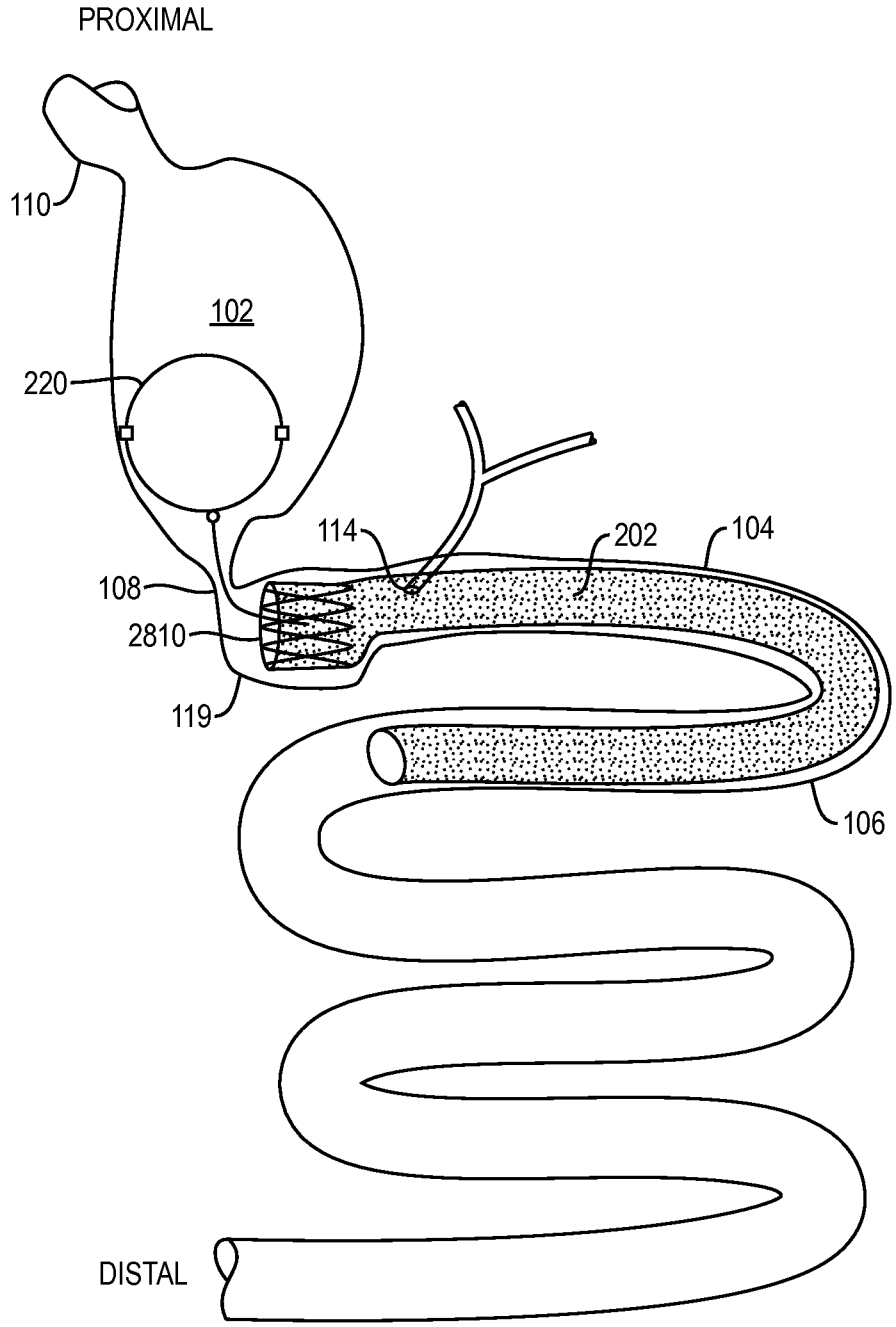

FIG. 3

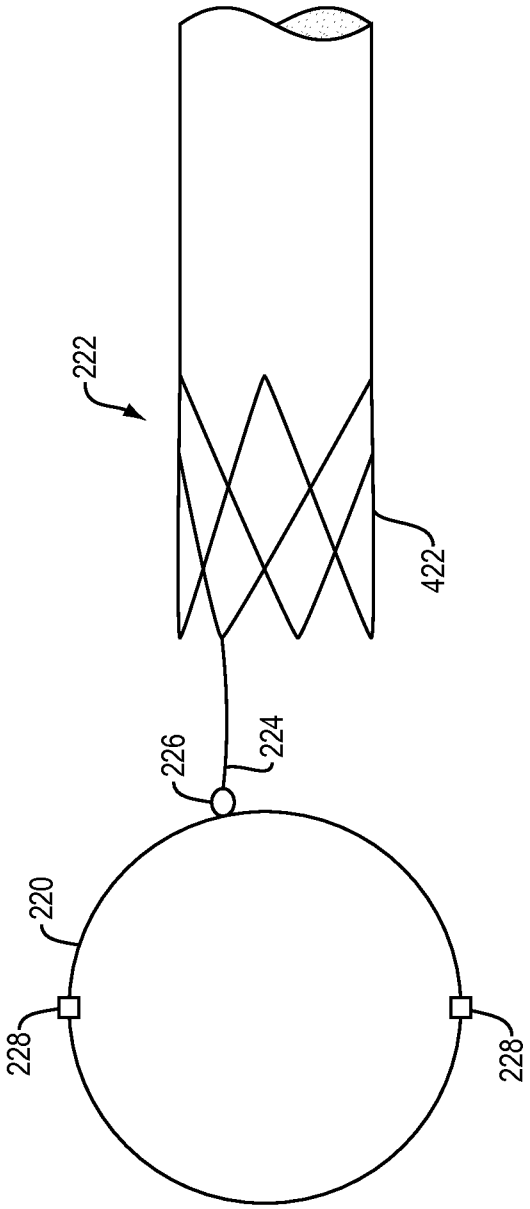

FIG. 4

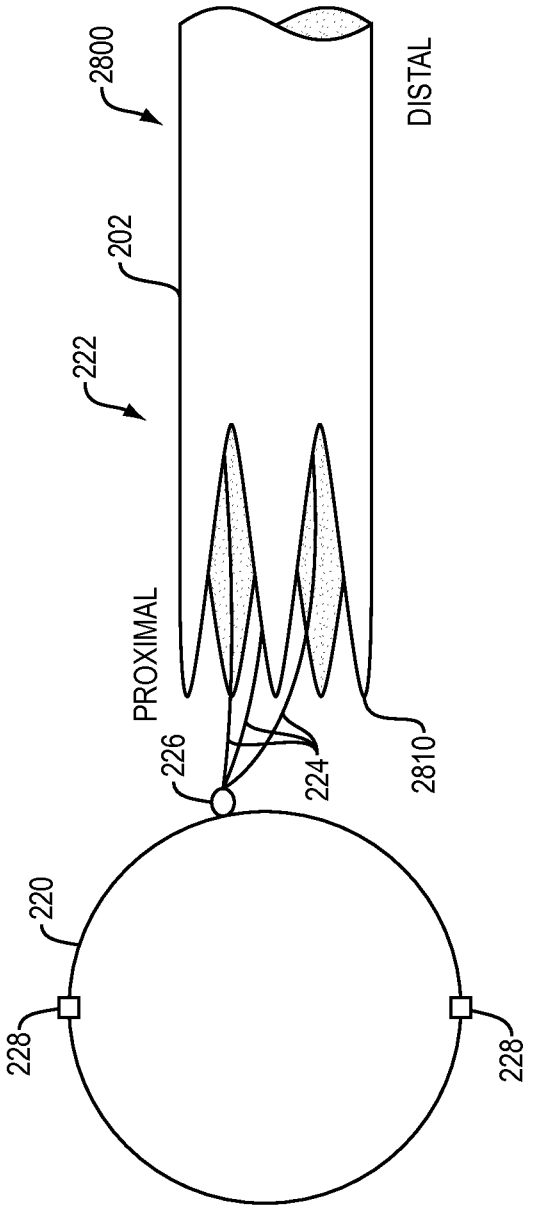

FIG. 5

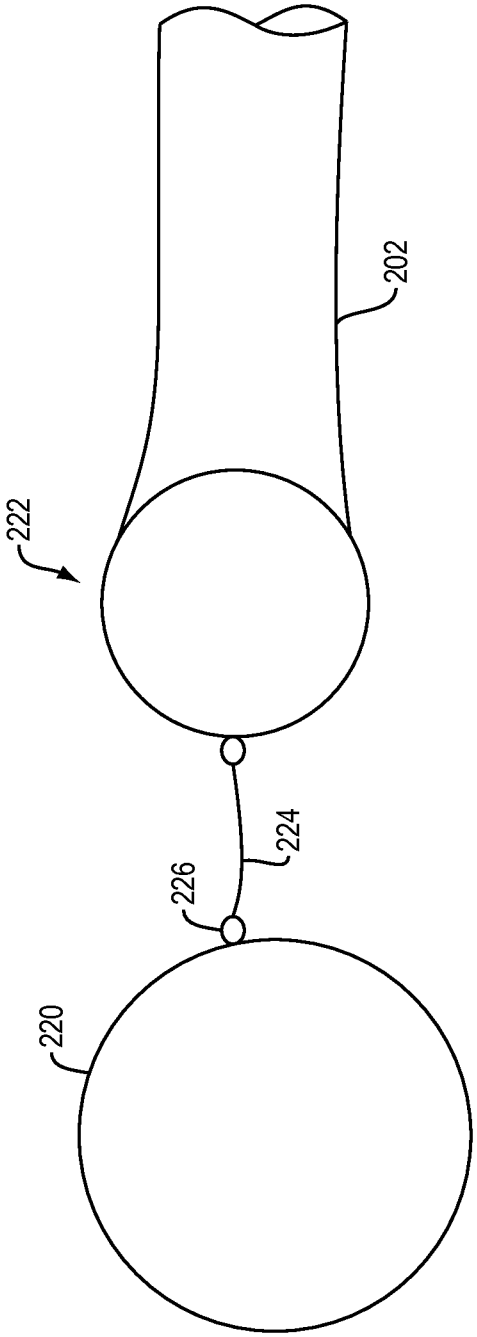

FIG. 6

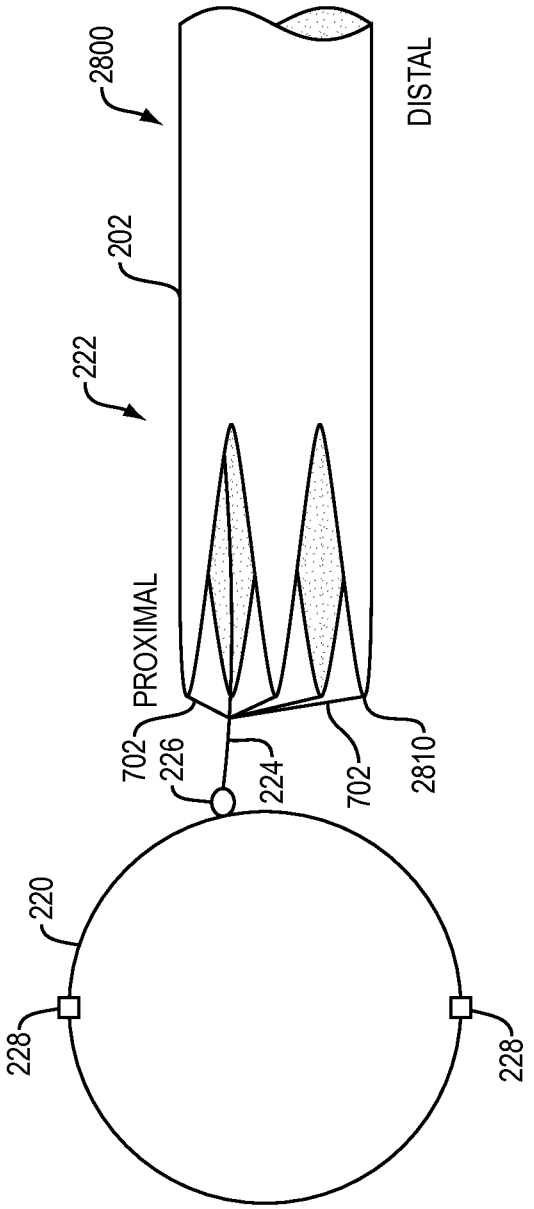

FIG. 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/050346

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F5/00
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011/004228 A1 (PRIPLATA ATTILA A [US] ET AL) 6 January 2011 (2011-01-06) cited in the application	1-4, 6-25,27, 29-32, 34-40, 45,47, 48,51
Y	paragraph [0012] paragraph [0086] paragraph [0099] - paragraph [0104]; figures 2,3	5,28,33, 49,50,52
Y	US 2005/125020 A1 (MEADE JOHN C [US] ET AL) 9 June 2005 (2005-06-09)	5,28,33, 49,50
A	paragraph [0014] - paragraph [0016] paragraph [0020] paragraph [0068]; figures 1A,1B,4,6	42,43

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 September 2013	10/10/2013

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Arjona López, G

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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/050346

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

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

1. [X] Claims Nos.: 53-68
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

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

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

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

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

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

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

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

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

Remark on Protest

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

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

[ ] No protest accompanied the payment of additional search fees.

Continuation of Box II.1

Claims Nos.: 53-68

Independent claim 53 defines a method of treatment. A method of treatment has an implicit therapeutical nature. Besides the method comprises the implantation of a planar proximal element and a distal element across a pylorus. Therefore, the subject-matter of claim 53 also relates to a surgical method. Consequently according to Rule 39.1(iv) and Article 17(2)(a)(i) PCT, the subject-matter of independent claim 53 is not patentable. Claims 54-68 are dependent on claim 53 and the same objection as to non-patentability applies.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/050346

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2009/130619 A1 (DUOCURE INC [IL]; MAGAL ELAD [IL]) 29 October 2009 (2009-10-29) page 30, line 10 - line 15; figure 2a	52
A	WO 2011/120047 A1 (IBIS MEDICAL INC [US]; VARGAS JAIME [US]) 29 September 2011 (2011-09-29) paragraph [0064] - paragraph [0067]; figure 1A	1

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2013/050346

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2011004228 A1	06-01-2011	US 2011000496 A1	06-01-2011
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		EP 2552350 A1	06-02-2013
		US 2012004676 A1	05-01-2012
		WO 2011120047 A1	29-09-2011

(19)中华人民共和国国家知识产权局

(12)发明专利申请

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(43)申请公布日 2015.04.29

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代理人 金鲜英 钟海胜
(51)Int.Cl.
A61F 5/00(2006.01)

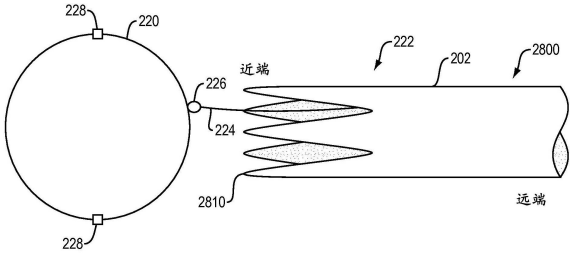
权利要求书4页 说明书7页 附图5页

(54)发明名称

经幽门的锚定

(57)摘要

本发明提供一种胃肠植入装置(2800),其包括平面型近端元件(220),其配置为位于胃中以抵抗远端迁移;远端元件(222),其配置为位于肠道中以抵抗近端迁移;和一根或多根系绳,其将所述平面型近端元件连接至所述远端元件。



CN 104582645 A

1.一种胃肠植入装置,包括 :

平面型近端元件,其配置为位于胃中以抵抗远端迁移 ;

远端元件,其配置为位于肠道中以抵抗近端迁移 ;和

一根或多根系绳,其连接所述平面型近端元件和所述远端元件。

2.权利要求 1 所述的胃肠装置,其中,仅单根系绳连接所述平面型近端元件和所述远端元件。

3.权利要求 1 或 2 所述的胃肠植入装置,其中,所述远端元件被配置为密封至所述肠道的组织,从而将食糜从所述胃引导至所述肠道。

4.权利要求 1、2 或 3 所述的胃肠植入装置,其中,所述平面型近端元件包括箍状物。

5.前述权利要求中任一项所述的胃肠植入装置,其中,所述远端元件包括波形锚。

6.前述权利要求中任一项所述的胃肠植入装置,其中,所述平面型近端元件在第一维度上明显大于所述胃的幽门的直径,并且在与所述第一维度垂直的第二维度上小于所述幽门的直径。

7.权利要求 6 所述的胃肠植入装置,其中,所述平面型近端元件在所述第一维度上的尺寸在约 40mm 和约 100mm 之间。

8.权利要求 6 所述的胃肠植入装置,其中,所述平面型近端元件在所述第一维度上的尺寸在约 50mm 和约 100mm 之间。

9.权利要求 6、7 或 8 所述的胃肠植入装置,其中,所述平面型近端元件在所述第二维度上的尺寸在约 0.5mm 和约 15mm 之间。

10.权利要求 6、7、8 或 9 所述的胃肠植入装置,其中,所述平面型近端元件在第二维度上的尺寸在约 0.5mm 和约 5mm 之间。

11.前述权利要求中任一项所述的胃肠植入装置,其中,所述平面型近端元件包括直径在约 40mm 和约 60mm 之间且厚度在约 0.5mm 和约 5mm 之间的箍状物。

12.前述权利要求中任一项所述的胃肠植入装置,其中,所述系绳包括柔性系绳。

13.前述权利要求中任一项所述的胃肠植入装置,其中,所述系绳包括刚性系绳。

14.前述权利要求中任一项所述的胃肠植入装置,其中,所述平面型近端元件包括多边形或椭圆形形状。

15.前述权利要求中任一项所述的胃肠植入装置,其中,所述远端元件是平面型的。

16.权利要求 15 所述的胃肠植入装置,其中,所述远端元件包括选自由箍状物、多边形和椭圆形形状所组成的组中的至少一种。

17.前述权利要求中任一项所述的胃肠植入装置,其中,所述装置不包括组织刺穿特征。

18.前述权利要求中任一项所述的胃肠植入装置,进一步包括与所述远端元件连接的无支撑薄壁套管。

19.权利要求 18 所述的胃肠植入装置,其中,所述套管是松软的、柔性的、贴合的和可折叠的。

20.前述权利要求中任一项所述的胃肠植入装置,其中,所述平面型近端元件没有密封至所述胃的密封件。

21.前述权利要求中任一项所述的胃肠植入装置,其中,在所述植入装置的正常使用

中，与所述平面型近端元件所处的平面垂直的、所述平面型近端元件的中心纵轴基本上垂直于所述胃的幽门括约肌和所述肠道中的至少一种的内腔的中心纵轴。

22. 前述权利要求中任一项所述的胃肠植入装置，其中，所述远端元件包括三维物体。

23. 前述权利要求中任一项所述的胃肠植入装置，其中，所述远端元件包括限流器。

24. 前述权利要求中任一项所述的胃肠植入装置，其中，所述远端元件包括填充流体的腔室。

25. 前述权利要求中任一项所述的胃肠植入装置，其中，所述远端元件包括环形物体。

26. 前述权利要求中任一项所述的胃肠植入，其中，所述远端元件包括导管和诊断装置中的至少一种。

27. 前述权利要求中任一项所述的胃肠植入装置，其中，所述远端元件的直径在约 30mm 和约 40mm 之间。

28. 前述权利要求中任一项所述的胃肠植入装置，其中，所述远端元件包括波形锚。

29. 前述权利要求中任一项所述的胃肠植入装置，其中，所述远端元件包括至少约 1 的长度与直径之比。

30. 前述权利要求中任一项所述的胃肠植入装置，其中，所述远端元件包括约 30mm 和约 40mm 之间的长度。

31. 前述权利要求中任一项所述的胃肠植入装置，其中，所述远端元件包括至多约 32mm 的长度。

32. 前述权利要求中任一项所述的胃肠植入装置，其中，所述远端元件包括与十二指肠球大约相同长度的锚。

33. 前述权利要求中任一项所述的胃肠植入装置，其中，所述远端元件包括弹簧。

34. 前述权利要求中任一项所述的胃肠植入装置，其中，所述平面型近端元件、所述系绳和所述远端元件中的至少一种被防止损伤的材料覆盖。

35. 权利要求 34 所述的胃肠植入装置，其中，所述防止损伤的材料包括聚氨酯和硅树脂中的至少一种的涂层。

36. 前述权利要求中任一项所述的胃肠植入装置，其中，所述系绳包括缝线。

37. 前述权利要求中任一项所述的胃肠植入装置，其中，所述系绳的长度在约 10mm 和约 50mm 之间。

38. 前述权利要求中任一项所述的胃肠植入装置，其中，所述系绳的直径在约 0.5mm 和约 5mm 之间。

39. 前述权利要求中任一项所述的胃肠植入装置，其中，所述系绳的直径在约 1mm 和约 2mm 之间。

40. 前述权利要求中任一项所述的胃肠植入装置，其中，所述远端元件包括多个辐条，并且其中所述系绳连接至所述多个辐条。

41. 前述权利要求中任一项所述的胃肠植入装置，其中，所述远端元件配置为当通过所述系绳向所述远端元件传递力时改变形状。

42. 前述权利要求中任一项所述的胃肠植入装置，其中，所述远端元件包括波形锚，所述系绳与所述波形锚的至少一个花冠连接。

43. 权利要求 42 所述的胃肠植入装置，其中，所述系绳与所述波形锚的远端花冠连接，

并且其中所述波形锚包括在约 30mm 和约 40mm 之间的直径。

44. 前述权利要求中任一项所述的胃肠植入装置，其中，所述远端元件被配置为当通过所述系绳施加张力时朝外放射状打开。

45. 前述权利要求中任一项所述的胃肠植入装置，其中，所述平面型近端元件松弛连接至系绳，从而允许所述平面型近端元件独立于所述系绳而旋转。

46. 前述权利要求中任一项所述的胃肠植入装置，其中，所述平面型近端元件连接至与所述系绳连接的系环。

47. 前述权利要求中任一项所述的胃肠植入装置，其中，所述平面型近端元件和所述远端元件中的至少一种包括聚合物。

48. 权利要求 47 所述的胃肠植入装置，其中，所述聚合物包括选自由硅树脂、聚四氟乙烯、聚乙烯和聚丙烯所组成的组中的至少一种材料。

49. 前述权利要求中任一项所述的胃肠植入装置，其中，所述平面型近端元件和所述远端元件中的至少一种包括金属。

50. 权利要求 49 所述的胃肠植入装置，其中，所述金属包括镍钛诺和不锈钢中的至少一种。

51. 前述权利要求中任一项所述的胃肠植入装置，其中，所述平面型近端元件、远端元件和系绳配置为可折叠地放入容器，用于内窥镜递送至胃肠道。

52. 前述权利要求中任一项所述的胃肠植入装置，其中，所述近端元件和远端元件中的至少一种进一步包括移除拉带。

53. 一种处理方法，包括：

利用胃中的平面型近端元件，抵抗胃肠植入装置的近端部分远端迁移至肠道；

利用肠道中的远端元件，抵抗所述胃肠植入装置的远端部分近端迁移至所述胃；以及

利用一根或多根系绳，横跨幽门将所述平面型近端元件固定至所述远端元件。

54. 权利要求 53 所述的处理方法，其中，仅单根系绳将上述平面型近端元件固定至所述远端元件。

55. 权利要求 53 或 54 所述的处理方法，进一步包括将所述远端元件密封至所述肠道的组织，从而使食糜从所述胃引导至所述肠道。

56. 权利要求 53、54 或 55 所述的处理方法，包括固定上述胃肠植入装置而没有刺穿组织。

57. 权利要求 53-56 中任一项所述的处理方法，进一步包括使食糜从所述胃引导至从上述胃肠植入装置延伸至所述肠道的无支撑薄壁套管。

58. 权利要求 53-57 中任一项所述的处理方法，包括在没有将所述平面型近端元件密封至所述胃的情况下，抵抗所述平面型近端元件迁移至所述肠道。

59. 权利要求 53-58 中任一项所述的处理方法，其中，在所述胃肠植入装置的正常使用中，与所述平面型近端元件所处的平面垂直的、所述平面型近端元件的中心纵轴被定位为基本上垂直于所述胃的幽门括约肌和所述肠道中的至少一种的内腔的中心纵轴。

60. 权利要求 53-59 中任一项所述的处理方法，包括：使用连接至所述胃肠植入装置的限流器，限制食糜从所述胃流入所述肠道。

61. 权利要求 53-60 中任一项所述的处理方法，包括：将所述远端元件的锚部分保留在

所述十二指肠球内。

62. 权利要求 53-61 中任一项所述的方法，其中，所述远端元件配置为当通过所述系绳向所述远端元件传递力时改变形状。

63. 权利要求 53-62 中任一项所述的方法，其中，所述远端元件配置为当通过所述系绳施加张力时朝外放射状打开。

64. 权利要求 53-63 中任一项所述的方法，其中，所述平面型近端元件松弛地连接至所述系绳，从而允许所述平面型近端元件独立于所述系绳而旋转。

65. 权利要求 53-64 中任一项所述的方法，包括用内窥镜将在容器内部的所述平面型近端元件、远端元件和系绳递送至胃肠道。

66. 一种移除胃肠植入物的方法，所述方法包括 ：

切断连接胃中的胃肠植入物的平面型近端元件与肠道中的所述胃肠植入物的远端元件的一根或多根系绳 ；

利用导管，通过口将所述平面型近端元件近端地移出所述胃 ；以及

利用导管的远端上的抓紧器，抓住拉带以将所述远端元件近端地移出所述所述肠道、通过所述胃、以及移出所述口。

67. 权利要求 66 所述的方法，其中，移除所述平面型近端元件包括使所述平面型近端元件穿过外套管。

68. 权利要求 66 或 67 所述的方法，其中，移除所述远端元件包括将所述远端元件径向折叠至取回罩。

经幽门的锚定

[0001] 相关申请

[0002] 本申请要求于 2012 年 7 月 13 日提交的美国临时申请号 61/671,470 的权益。上述申请的全部教导通过引用并入本文。

背景技术

[0003] 一直需要提高胃肠植入物可安全锚定在胃肠道中而没有闭塞、迁移或其他故障或缺点的持续时间，尤其对于沿着至少一部分肠道延伸的植入物。

[0004] 此类植入物的示例包括具有延伸进入肠道的柔性（松软）套管的植入物，例，如美国专利 7,025,791、7,122,058、7,476,256、7,608,114、7,706,973、7,771,382、7,815,589、7,837,643、8,057,420 中所呈现的植入物；和具有如 7,771,382 中所呈现的具有限流孔的植入物。所有那些专利通过参考以其全部内容引入本文。

发明内容

[0005] 根据本发明的实施方式，提供一种胃肠植入物装置。所述装置包括平面型号近端元件，其配置为位于胃中以抵抗远端迁移；远端元件，其配置为位于肠道中以抵抗近端迁移；和一根或多根系绳，其将平面型近端元件与远端元件连接。单根系绳一般是优选的。

[0006] 所述远端元件可配置为密封至肠道的组织，从而将食糜从胃引导至肠道。所述平面型近端元件可包括箍状物。所述远端元件可包括波形锚。所述平面型近端元件可在第一维度上明显大于胃的幽门的直径，并且可在与第一维度垂直的第二维度上小于幽门的直径。所述平面型近端元件在第一维度上的尺寸可在约 40mm 和约 100mm 之间；比如在第一维度上的尺寸在约 50mm 和约 100mm 之间。所述平面型近端元件在第二维度上的尺寸可在约 1mm 和约 15mm 之间；例如，在第二维度上的尺寸在约 1mm 和约 5mm 之间。所述平面型近端元件可包括箍状物，其直径在约 40mm 和约 60mm 之间且厚度在约 0.5mm 和约 5mm 之间。所述系绳可包括柔性系绳或刚性系绳。所述平面型近端元件可包括圆形、多边形或椭圆形形状。所述近端元件可以是平面形的；例如，其可包括由箍状物、多边形和椭圆形形状所组成的组中的至少一种。

[0007] 在进一步相关的实施方式中，所述装置可以不包括组织刺穿特征。所述装置可进一步包括与所述远端元件连接的无支撑薄壁套管。所述套管可以是松软的、柔性的、贴合的(conformable)和可折叠的。平面型近端元件可没有密封至胃。在植入装置的正常使用中，平面型近端元件的中心纵轴与平面型近端元件所处的平面垂直，其可基本上与下述中的至少一个的内腔的中心纵轴垂直：胃的幽门括约肌和肠道。所述远端元件可包括三维物体。所述远端元件可包括限流器和 / 或填充流体的腔室和 / 或环形物体。所述远端元件可包括导管和诊断装置中的至少一种。所述远端元件的直径可在约 30mm 和约 40mm 之间。所述远端元件可包括波形锚。所述远端元件可包括至少约 1 的长度与直径之比。所述远端元件可包括约 30mm 和约 40mm 之间的长度；比如至多约 32mm 的长度，并且可包括与十二指肠球约相同长度的锚。所述远端元件可包括弹簧元件。

[0008] 在进一步相关的实施方式中，平面型近端元件、系绳和远端元件中的至少一种可由防止损伤的材料覆盖，比如聚氨酯和硅树脂中的至少一种。系绳可包括由聚合物或金属制成的缝线。系绳的长度可在约 10mm 和约 50mm 之间，并且直径可在约 0.5mm 和约 5mm 之间，比如直径在约 1mm 和约 2mm 之间。远端元件可包括多个辐条，并且系绳可连接至所述多个辐条。远端元件可被配置为当通过系绳向远端元件传递力时改变形状。远端元件可包括波形锚，所述系绳与波形锚的至少一个花冠连接；比如所述系绳与波形锚的远端花冠连接，其中波形锚包括在约 30mm 和约 40mm 之间的直径。远端元件可被配置为当通过系绳施加张力时朝外放射状打开以阻止近端迁移。平面型近端元件可松弛地连接至系绳，从而允许平面型近端元件独立于系绳而旋转。平面型近端元件可连接至与系绳连接的系环。

[0009] 在进一步相关的实施方式中，平面型近端元件和远端元件的至少一种可包括聚合物。聚合物可包括选自下述中的至少一种材料：硅树脂、聚四氟乙烯、聚乙烯和聚丙烯。平面型近端元件和远端元件中的至少一种可包括金属。金属可包括镍钛诺和不锈钢中的至少一种。平面型近端元件、远端元件和系绳可被配置为可折叠地放入用于内窥镜递送至胃肠道的容器中。近端元件和远端元件的至少一种可进一步包括移除拉带。

[0010] 提供一种处理方法，其包括：利用胃中的平面型近端元件，抵抗胃肠植入装置的近端部分远端迁移进入肠道；利用肠道中的远端元件，抵抗胃肠植入装置的远端部分近端迁移进入胃；以及利用一根或多根系绳，横跨幽门将平面型近端元件固定至远端元件。单个系绳一般是优选的。

[0011] 所述方法可进一步包括将远端元件密封至肠道的组织，从而将食糜从胃经过十二指肠元件引导至肠道。所述方法可包括固定胃肠植入装置而不刺穿组织。所述方法可进一步包括将食糜从胃引导至从胃肠植入装置延伸至肠道的无支撑薄壁套管。所述方法可包括在没有将平面型近端元件密封至胃的情况下抵抗平面型近端元件迁移至肠道。在所述方法中，在胃肠植入装置的正常使用中，平面型近端元件的中心纵轴与平面型近端元件所处的平面垂直，其可被定位为基本上与下述中至少一种的内腔的中心纵轴垂直：胃的幽门括约肌和肠道。所述方法可包括使用连接至胃肠植入装置的限流器来限制食糜从胃流入肠道。所述方法可包括将远端元件的锚部分保留在十二指肠球内。远端元件可被配置为当通过系绳向远端元件传递力时改变形状；比如远端元件可被配置为当系绳施加张力时朝外放射状打开。平面型近端元件可松弛地连接至系绳，从而允许平面型近端元件独立于系绳而旋转。所述方法可包括用内窥镜将容器内的平面型近端元件、远端元件和系绳递送进入胃肠道。

[0012] 提供一种移除胃肠植入物的方法。所述方法包括：切断将胃中的胃肠植入物的平面型近端元件与肠道中的胃肠植入物的远端元件连接的一根或多根系绳；利用导管，通过口将平面型近端元件近端移出胃部；以及利用导管的远端上的抓紧器，抓住拉带以将远端元件移出肠道、经过胃且移出口。

[0013] 在进一步相关的实施方式中，移除平面型近端元件可包括使平面型近端元件穿过外套管。移除远端元件可包括将远端元件径向折叠至取回罩。

附图说明

[0014] 从下述本发明示例性实施方式更具体的描述中，前述内容将是显而易见的，如在附图中所阐释的，其中在所有不同的附图中，相同的附图标记表示相同的部分。附图没必要

按比例，而是强调图解本发明的实施方式。

[0015] 图 1 是体内一部分消化道的截面图。

[0016] 图 2 是其中锚定装置具有单根系绳和波形锚远端元件的实施方式的胃肠植入装置的透视图。

[0017] 图 3 是显示植入在消化系统中的图 2 的胃肠植入装置的身体的截面图。

[0018] 图 4 是具有单根系绳和支架远端元件的根据本发明另一实施方式的胃肠植入装置。

[0019] 图 5 是具有多根系绳的本发明植入装置。

[0020] 图 6 是具有平面型远端元件的本发明植入装置。

[0021] 图 7 是系绳连接至远端元件上的辐条的本发明植入装置。

具体实施方式

[0022] 本发明的示例性实施方式的描述如下。

[0023] 提供用于胃肠植入装置的锚。所述锚横跨幽门，所以称为经幽门的锚。某些实施方式的目的是为胃肠植入装置提供与现有锚定技术所提供的相同或类似的功能，同时具有更少的副作用（例如，出血、不适、迁移和 / 或感染），同时几乎没有或没有组织穿透特征。

[0024] 另外，某些实施方式提供如下方法和装置，用于在消化道中应用隔离套管，以限制在消化道的特定部位接触食品以及为具有病态肥胖的患者提供改善的饱腹感，能够使他们减少食品摄入。所述套管也可用于其他治疗如通过激素触发的 II- 型糖尿病。

[0025] 根据某些实施方式的经幽门的锚背后的基本原理是，胃窦是所述锚的近端元件的有利位置；十二指肠球是锚的远端元件的有利位置；以及幽门是可用于锚定的确定机械特征。胃窦临近幽门和强韧组织，而十二指肠球具有最小的运动且允许远端锚密封至组织。

[0026] 在松弛的状态下，胃变成平的，且因此轻量平面型近端元件能够使其本身定向在松弛胃的平面内，对胃造成尽可能少的创伤。

[0027] 根据某些实施方式，经幽门的锚的部件包括：(i) 胃中平面型近端元件，其抵抗远端迁移；(ii) 肠道中的远端元件，其抵抗近端迁移且可提供密封；和 (iii) 一根或多根系绳，其连接近端元件和远端元件。

[0028] 图 1 是体内一部分消化道的截面图。待消化的食品从食道经贲门口 110 进入胃 102。通过胃中胃消化产生的半流体均质乳脂状或稀粥样材料，食糜通过幽门口（幽门）108 离开胃且进入小肠 112。幽门 108 是胃 102 的末端口，其由强韧性圆形肌肉带围绕。长度约九英尺的小肠是盘绕的管，其从幽门 108 延伸至回盲肠瓣，其中其终止于大肠。小肠具有三部分：十二指肠 104、空肠 106 和回肠（未显示）。前八英寸至十英寸部分的小肠 112、十二指肠 104 是小肠 112 的最短、最宽和最固定的部分。

[0029] 十二指肠 104 具有通常形成为 U 形的四个部分：上部、降部、水平部和升部。上部是约两英寸长且终止于胆囊颈。上部也限定被称为十二指肠球 119 的特征，其在成人中始于幽门 108 的远端且延伸约 1 至 1.5 英寸。十二指肠球 119 在其中限定稍大于远端十二指肠 104 的内腔。有利地，十二指肠球 119 显示比幽门 108 和甚至十二指肠 104 的近端部分更少的运动。值得注意地，所述运动基本上限于收缩，而没有明显的直线分量（即没有沿着肠道中心轴的运动）。但是，随着组织远离幽门 108 移动而变薄。

[0030] 十二指肠 104 的降部是约三至四英寸长且包括乳头状结构（乳头）114，通过其由肝产生且由胆囊储存的来自胰腺和胆的胰液从胰腺和胆道进入十二指肠。胰液包含蛋白质消化所必需的酶，并且胆溶解脂肪消化的产物。升部约两英寸长且形成十二指肠－空肠弯曲部 116，此处其连接作为小肠的接下来部分的空肠 106。十二指肠－空肠弯曲部 116 固定至特赖茨氏韧带 118（十二指肠悬肌）。十二指肠中分泌的液汁使部分消化的食品降解成足够小的颗粒而被身体吸收。在以下文献中描述了消化系统：Gray's Anatomy（Henry Gray 的“人体解剖学（Anatomy of the Human Body）”）和“人生理学（Human physiology）”Vander，第 3 版，McGraw Hill，1980，其全部内容以它们的整体通过引用并入本文。

[0031] 图 2 是包括根据本发明实施方式的锚定装置的胃肠植入装置 2800 的透视图。装置 2800 包括平面型近端元件 220，其配置为位于胃中以抵抗远端迁移；远端元件 222，其配置为位于肠道中以抵抗近端迁移且提供密封；和单根系绳 224，其将平面型近端元件 220 连接至远端元件 222。

[0032] 根据本发明的实施方式，平面型近端元件 220 仅通过足够大使得其不适合穿过幽门 108 而防止远端迁移。另外，该几何学固有的缺少引导边缘，使得近端元件难以推过幽门。这不需要近端元件 220 形成与胃壁的密封，也不需要其刺穿胃的组织；的确，在近端元件 220 中，抵抗密封所需要的组织的力和刺穿组织的元件是不需要的，因为胃窦是非常活跃的区域，其经常进行收缩。近端元件 220 可在胃内相对自由移动（受制于系绳并且接触食品和胃壁）而不咬合组织或形成密封。通过为平面型，近端元件 220 对于胃组织是防止损伤的，因为其当胃松弛并且没有食品时，定向在胃的平面中，并且所以在该状态下胃通常是平的。同样地，近端元件 220 应具有尽可能少的质量，以便避免创伤。平面型近端元件 220 可以是例如平面型中空箍状物或环，如图 2 中所显示。箍状物或环的直径可在约 40mm 和约 100mm 之间。使用过小的直径可能具有近端元件 220 向远端迁移通过幽门进入肠道的风险；而使用过大的直径可能具有对胃产生创伤的风险。在一个实施例中，近端元件可以是直径约 60mm 的环。近端元件 220 也应该容易递送，其可通过使环弯曲以适合可适应通过口和食道的容器而进行递送。近端元件 220 由可变形且回到其初始形状的弹性材料形成。例如，近端元件 220 可由金属如不锈钢或镍钛诺，或聚合物如聚乙烯、聚四氟乙烯、聚丙烯或硅树脂形成。近端元件 220 也可以是编织的，比如编织的金属或聚合物。在一个实施例中，近端元件 220 是直径约 60mm 的环，由镍钛诺或不锈钢形成，涂布硅树脂或聚氨酯。这可以是覆盖该元件的聚合物涂层或管。环 220 可通过使用一个或多个折痕 228 或通过焊接将镍钛诺组件结合在一起，然后可以用防止损伤的物质覆盖。

[0033] 根据本发明的实施方式，近端元件 220 可通常垂直于幽门括约肌的内腔或肠道内腔定向，如图 3 中所显示。更具体而言，在植入装置的正常使用中，平面型近端元件的中心纵轴与平面型近端元件所处的平面垂直，基本上与胃的幽门括约肌或肠道的内腔的中心纵轴垂直。因为近端元件 220 相对自由移动，经受来自系绳的张力和接触食糜和胃壁，其在使用中也以各种不同的角度定向。

[0034] 尽管平面型近端元件 220 描述为“平面型”，但是其在实践中具有一些厚度。平面型近端元件在第一维度上明显大于胃的幽门的直径，并且在与第一维度垂直的第二维度上小于幽门的直径。例如，平面型近端元件在第一维度（例如，直径）上的尺寸可在约 40mm 和约 100mm 之间；比如在第一维度上的尺寸在约 50mm 和约 100mm 之间（例如，直径）；和在

第二维度上的尺寸在约 0.5mm 和约 15mm 之间（例如，厚度和弯曲），比如在第二维度上的尺寸在约 1mm 和约 5mm 之间（例如，厚度）。在一个实施例中，平面型近端元件包括箍状物，其直径在约 40mm 和约 60mm 之间和厚度在约 1mm 和约 5mm 之间。除了环或箍状物，平面型近端元件可包括其他平面型形状，比如多边形或椭圆形形状。

[0035] 根据本发明的实施方式，远端元件 222 的目的是密封至肠道的组织，和防止近端迁移。通过形成密封，远端元件 222 允许食糜经沟槽引导至远端元件而不接触肠道壁，从而形成肠道旁路。远端元件 222 可以是可附着无支撑的、柔性套管 202 的三维物体，比如波形锚 2810（如图 2 中所示的）。套管可以是松软、柔性、贴合的和可折叠的。例如，套管可以是美国专利号 7,981,163B1，其全部内容通过引用并入本文，或任何之前引用的美国专利中教导的一种。远端元件 222 也可以是另一种三维物体如球囊和 / 或环形元件，并且可包括填充流体的腔室。例如，远端元件可以是填充流体的环形元件如 Priplata 等的美国专利申请号 2011/0004228A1 中教导的那些，其全部内容通过引用并入本文。远端元件 222 可支撑限制性元件，比如板式限流器，其可与套管结合。该限流器延伸横跨锚或套管并且其中具有一个或多个限制性孔。此外，远端元件 222 可支撑导管或诊断装置，比如压力传感器。远端元件 222 如波形锚的直径可在约 30mm 和 40mm 之间，以便避免对肠道的创伤。例如，直径可以是约 35mm。远端元件 222 的长度与直径比可以是约 1。就长度而言，远端元件 222 可以具有与十二指肠球 119 大约相同的长度，以便适合于该解剖学特征内。波形锚可包括数个循环的单个波，显示了五个。波形锚可以由可折叠的金属丝形成，比如由金属如镍钛诺形成。远端元件 222 可以不包括组织穿透特征如倒勾，并且可由防止损伤的物质如硅树脂或聚氨酯涂布或覆盖。

[0036] 在根据本发明的另一实施方式中，远端元件 222 可以是平面型。例如，远端元件可以是箍状物、多边形或椭圆形形状。该形状不提供密封，但是提供防止损伤的锚定。

[0037] 根据本发明的实施方式，系绳 224 的目的将近端元件 220 连接至远端元件 222。使用单根系绳 224 提供避免如果使用多根系绳可能发生的缠绕的优势。系绳 224 可以是柔性的，比如缝线；或可以是刚性的，比如棒。无论是柔性的或刚性的，系绳 224 可在其近端附接至系环 226，其允许近端元件 220 通过滑过圈 226 而不受系绳 224 的约束旋转。系绳 224 的长度在约 10mm 和约 50mm 之间。如果系绳过短，其可迫使幽门打开，造成不适，但是如果其过长，其可允许远端元件 222 移动太远而进入肠道，比如离开十二指肠球。系绳的直径在约 0.5mm 和约 5mm 之间，比如在约 1mm 和约 2mm 之间。过大的直径可造成幽门感觉到系绳。如果太小，其可造成组织的切割。在一个实施例中，系绳是缝线。系绳可在其远端附接至一组辐条的中心，比如由缝线制作的辐条，其延伸至远端元件 222 的内边缘。例如，系绳可以由聚丙烯编织物，或聚乙烯或 PTFE 形成；并且可以是未覆盖的；或例如用硅氧烷、EPTFE 或氨基甲酸乙酯覆盖的，从而防止创伤。

[0038] 在另一实施方式中，系绳 224 可在其远端以使得远端元件 222 改变其形状的方式附接至远端元件 222。例如，当远端元件 222 是波形锚时，系绳 224 可连接至波形锚的远端花冠，其当系绳 224 在远端元件 222 施加张力时，容易使得波形锚在其近端朝外放射状打开。这样，远端元件 222 积极抵抗近端迁移。其他活性元件可用于远端元件 222。

[0039] 在图 2 的实施方式中，胃肠植入装置 2800 包括套管 202 和锚定装置 2810，用于将胃肠植入物 2800 装置锚定在十二指肠 104 中。锚定装置 2800 包括连接至套管 202 的近端

部分的波形锚 2810。波形锚 2810 包括贴合的径向弹簧，其围绕中心轴形成环形波图案形状，提供向外的径向力，同时允许围绕其周长大量弯曲。这种弯曲是有利的，因为其可径向收缩以允许微创递送，并且确保装置在移植时基本上符合周围解剖学结构并且允许扩张。环形波元件可由一个或多个伸长的弹性元件形成并且沿着其在两个开口端形成的中心轴限定内腔。

[0040] 当移植时，如图 3 中所显示，近端元件 220 在胃中基本上自由移动，而远端元件的锚 2810 的中心轴基本上与十二指肠 104 的中心轴对齐，允许食糜穿过装置 2800。另外，贴合的波形锚 2810 通过提供足够的挠性和贴合性使对组织的创伤最小化，同时使组织腐蚀最小化。

[0041] 贴合的波形锚 2810 可由弹性金属如热处理的弹簧钢、不锈钢制造，或由合金如通常称为镍钛诺的 NiTi 合金制造。其他合金包括具有独特的组合超高拉伸强度的镍－钴－铬－钼合金，比如 MP35N。另外，波形锚 2810 可由具有类似特性的聚合物和 / 或复合材料形成。波形锚 2810 可由轮廓形成为所期望的形状的单条线，比如金属丝制造。可选地，波形锚 2810 可由多股相同的或不同的、类似地轮廓形成为所期望的形状的材料制造。在一些实施方式中，波形锚 2810 可由所期望的材料如镍钛诺的管状原料切割成波形状。

[0042] 当移植时，锚 2810 可使得套管 202、或屏障安全地移植在十二指肠 104 内，优选地在近端提供流体密封。为了增强流体密封，套管的近端轮廓可形成为波形锚，如图 2 中所显示的。对于使用轮廓形成为波形锚 2810 的套管 202 的装置 2800，近端好像是郁金香形状的。

[0043] 在根据本发明的实施方式中，近端元件 220 可防止装置向远端迁移，但是可以没有密封，而远端元件 222 被用于靠着组织如十二指肠壁形成密封。

[0044] 在一个实施例中，远端元件 222 是 32 ～ 33mm 直径波形锚，具有五个峰，由 0.032 ～ 0.035 英寸的金属丝形成。箍状物 220 可以是 0.034 英寸厚，由具有两个折痕的两个环形成；或 0.025 英寸厚，由具有两个折痕的三个环形成。

[0045] 在另一个实施例中，近端元件 220 包括直径为 0.040”、在两个地方折叠在一起、180 度相对的金属丝的 2 个环，总体环直径为 60mm；而远端元件 222 包括 35mm 直径波形锚，贴合性大于一磅并且由 0.030”直径金属丝形成。也可使用直径大至 55mm 的波形锚，没有组织咬合倒勾。认识到可以使用各种不同直径、金属丝厚度、贴合性和花冠数量的波形锚（例如，波形锚上五个或六个花冠）。

[0046] 图 4 中，远端元件 222 包括支架 442。

[0047] 图 5 显示其中波形锚 2810 由两个系绳系住的实施方式。由于上述原因这是较不优选的，但是也可具有一些应用。

[0048] 图 6 显示其中远端元件 222 也是平面型的实施方式。平面型远端元件用于保持装置抵抗近端移动，但是不提供靠着肠道的流体密封。

[0049] 图 7 显示其中系绳在远端元件连接至辐条 702 的实施方式。

[0050] 平面型近端元件、远端元件和系绳被配置为可折叠的进入容器，用于通过口和食道递送进入胃肠道。例如，可使用容器递送技术如 Levine 等的美国专利号 7,837,643B2 教导的那些，其全部内容通过引用并入本文。

[0051] 在根据本发明的实施方式中，可通过切割系绳 224，然后将近端元件 220（比如箍

状物）通过食道，例如，通过食道外套管拉出而移除装置。可切割或解开近端元件 220（比如箍状物）以帮助移除。可选地，缝合材料可用在一个或多个组件中，其可被切割以帮助移除。装置可以能够被移除而不需要外套管。此外，前述方法可以用于移除近端元件 220，而移除的另一方法是用于远端元件 222，例如，使用美国专利号 8,057,420 中所阐释的拉带 2810（图 3）技术，其全部内容通过引用并入本文。近端元件和 / 或远端元件进一步可包括移除拉带。

[0052] 在一种实施方式中，移除胃肠植入物的方法包括：切断连接胃中的胃肠植入物的平面型近端元件与肠道中的胃肠植入物的远端元件的一根或多根系绳；利用导管，通过口近端移出胃的平面型近端元件；以及利用导管的远端上的抓紧器，抓住拉带以将远端元件移出肠道、通过胃且移出所述口。平面型近端元件可以通过外套管被移除。远端元件可径向折叠至取回罩。近端元件也可折叠在取回罩中用于移除。

[0053] 根据本发明的实施方式，提供一种处理方法。所述方法包括提供本文阐释的胃肠植入装置，和使装置横跨患者的幽门固定。食糜可以从胃经沟槽进入从胃肠植入装置延伸进入肠道的无支撑薄壁套管。例如，可使用如美国专利号 7,682,330 中所阐释的那些套管（其全部公开通过引用并入本文）。此外，可用连接至胃肠植入装置的限流器限制食糜从胃流入肠道。例如，可使用如美国专利号 7,771,382 中所阐释的那些限流器（其全部公开通过引用并入本文）。

[0054] 所专利、公开的申请和本文所引用的参考文献的教导都通过参考以它们的整体并入本文。

[0055] 尽管已经参考其示例性实施方式具体显示和描述了本发明，但是本领域技术人员理解，在不背离由所附的权利要求书所包括的本发明的范围情况下，可在形式和细节上作出各种改变。

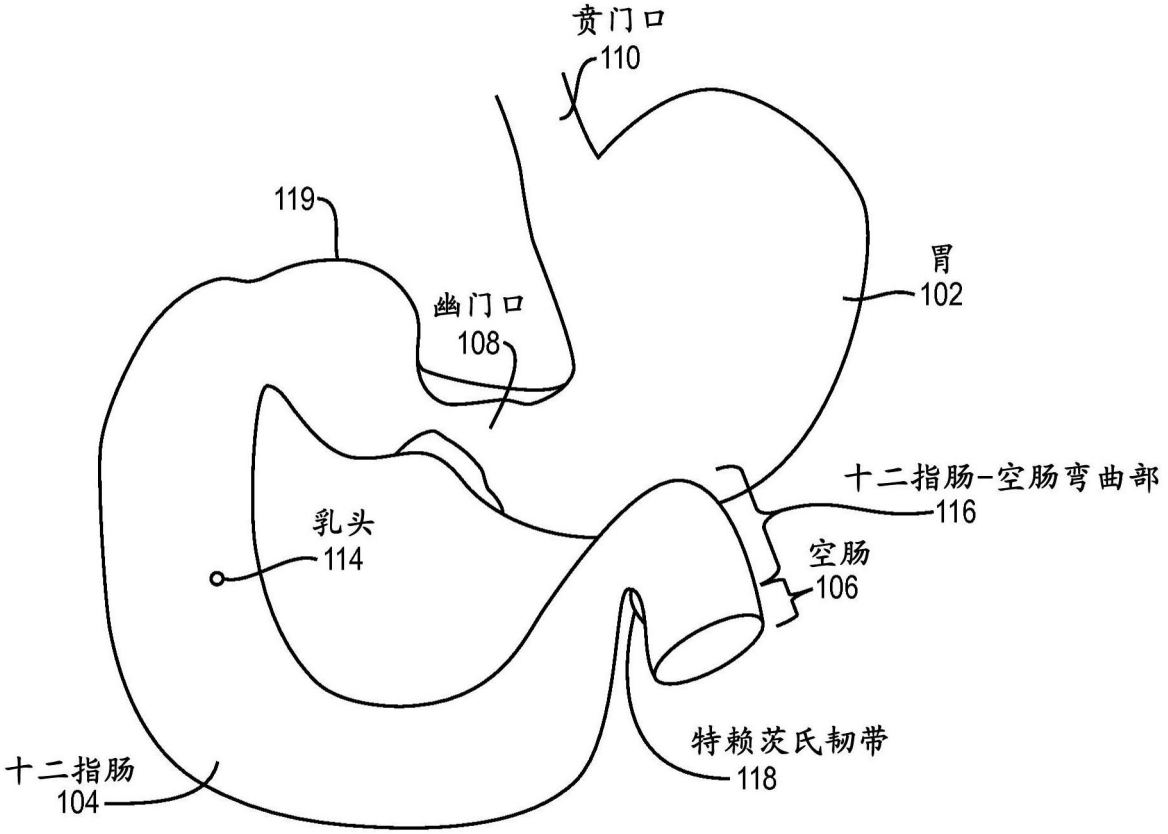

贲门口
110
119
胃
102
幽门口
108
十二指肠-空肠弯曲部
116
乳头
114
空肠
106
特赖茨氏韧带
118
十二指肠
104

图 1

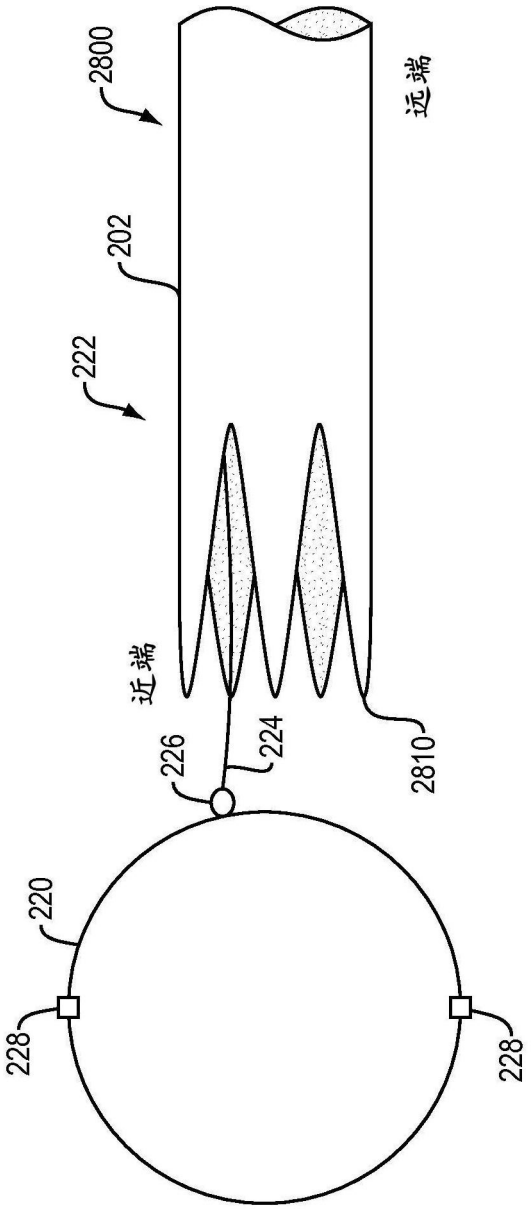


图 2

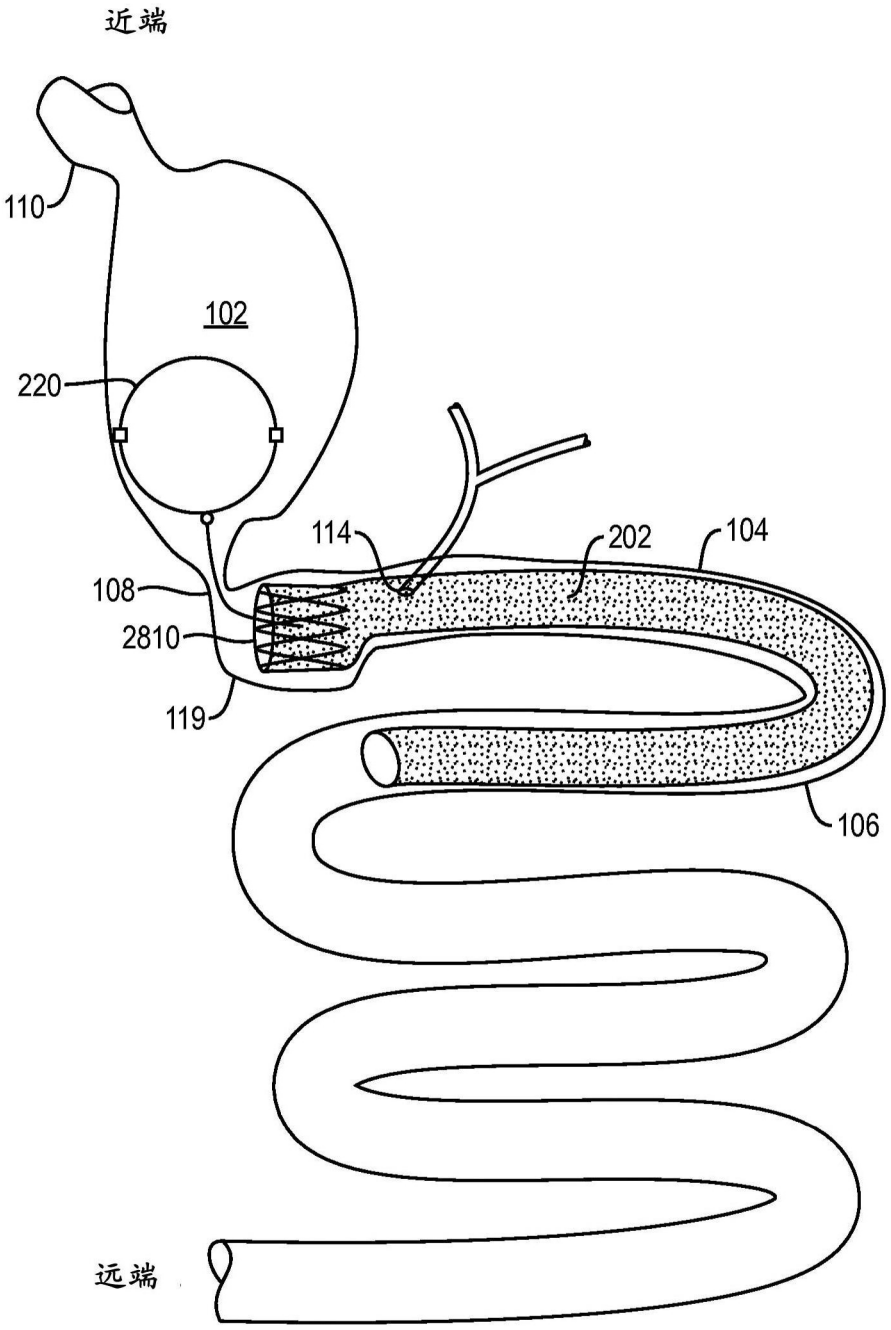
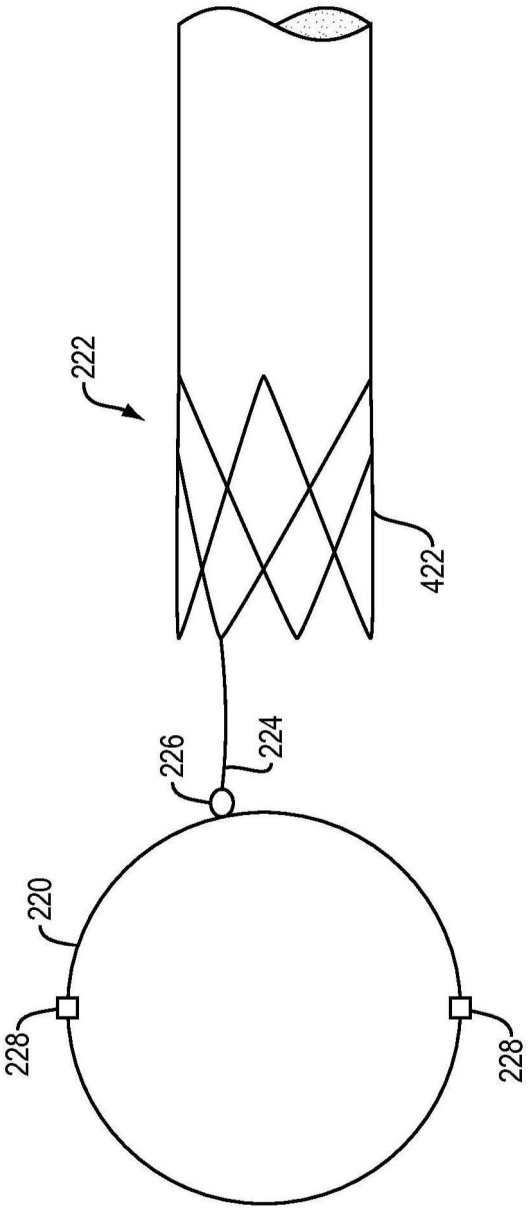


图 3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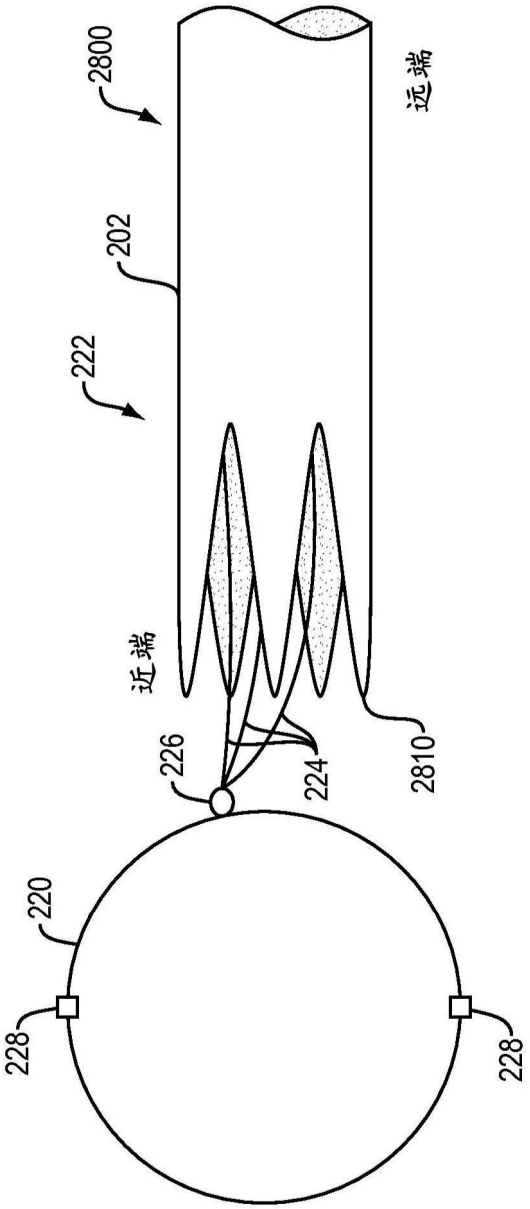
228

图 4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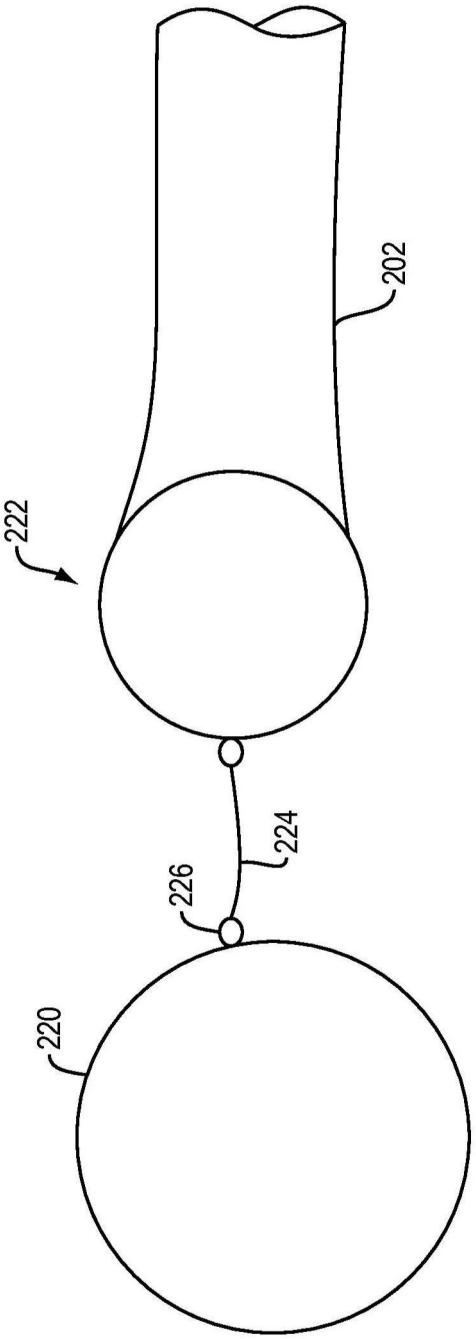
222
近端
226
224
2810
220
228
228

图 5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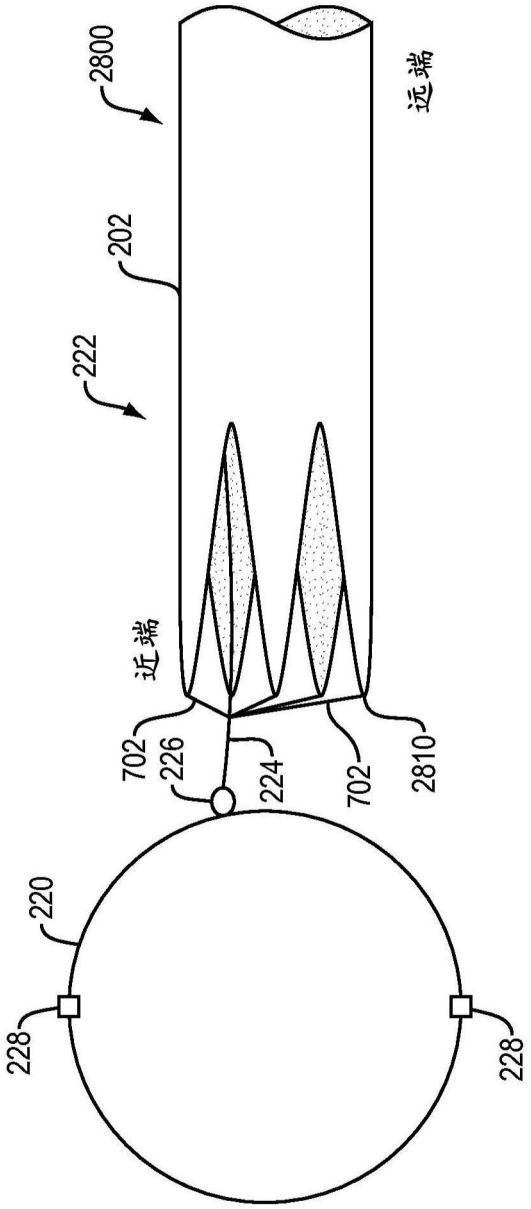
226
220

图 6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远端
202
222
近端
702
226
224
702
2810
220
228
228

图 7