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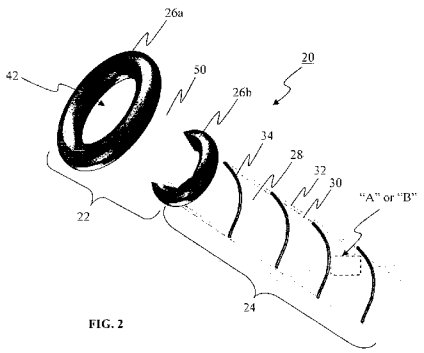

FIG. 2

(57) Abstract: A device that can be placed, retained, and/or anchored within a gastrointestinal tract. The device includes an anchor portion and a chute that is couplable to the anchor portion. The anchor portion includes at least one retention unit. The anchor portion can be shaped, dimensioned, and/or configured for retention in a trans-pyloric configuration. The chute includes a channel disposed along a wall of the chute. The channel includes a passage. Flow of fluid through the passage of the channel effectuates longitudinal extension of the chute. A process for deploying, expanding, and retaining the device within the gastrointestinal tract is also provided, as well as a process for re-inflating the chute of the device.

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SYSTEM, DEVICE, AND PROCESS FOR MODIFYING ABSORPTION OF MATTER BY A GASTROINTESTINAL WALL

Technical Field

The present disclosure relates generally to gastrointestinal implants and devices. More specifically, the present disclosure relates to systems, devices, and processes for modifying the absorption of matter or material (e.g., ingested food matter) by a gastrointestinal wall.

Background

Obesity is increasing at an alarming rate throughout the world. The World Health Organization (WHO) has projected that by 2015, there will be more than two billion overweight adults and more than 700 million obese adults globally. Researchers have discovered that being overweight, and particularly being obese, can lead to serious health consequences, including cardiovascular diseases (e.g., heart disease and stroke), diabetes, musculoskeletal disorders (e.g., Osteoarthritis), and some types of cancers (e.g., colon and endometrial cancers).

There are numerous conventional medical devices, methods, and techniques for preventing, treating, or managing obesity. Examples of such conventional techniques include dieting, medication, and surgical procedures. Surgical procedures for combating obesity are commonly classified as being either gastric (i.e., stomach) restrictive procedures or gastrointestinal (i.e., stomach, small intestinal, and large intestinal) bypass procedures. However, there are numerous potential health risks and complications associated with surgical procedures. Such potential risks and complications include mortality, infection, hemorrhage, venous thromboembolism, bowel obstruction, anastomotic leakage, and anastomotic ulcers. For instance, some gastrointestinal bypass procedures have been reported to have a mortality rate of between 1% - 2%, a recovery period of up to 6 months, and a relatively high potential for subsequent development of digestive problems.

There exist various devices and apparatuses that are implantable within the gastrointestinal tract for modifying absorption of food material by gastrointestinal walls. For instance, there exist numerous devices that are implantable within the gastrointestinal tract for reducing or limiting the absorption of food material through the gastrointestinal walls. Such devices generally include an anchor portion or structure for anchoring the device within the gastrointestinal tract and a chute or tube extending from the anchor portion. Digested, or partially digested, food material that is traveling through the gastrointestinal tract can enter into, and travel through, the chute of the device. Food material travelling within the chute is at least substantially prevented from coming into direct physical contact with gastrointestinal walls, thereby facilitating or effectuating a reduction in absorption of food material by the gastrointestinal walls.

An example of a device that is implantable within the gastrointestinal tract for inhibiting the absorption of food material through the gastrointestinal walls is described in United States published patent application number US 2009/0248171 A1. The gastrointestinal implant device of US 2009/0248171 A1 includes an anchor for anchoring the device within the stomach and a flexible sleeve that extends from the anchor. When the gastrointestinal implant device is implanted within the stomach, the sleeve limits the absorption of nutrients by the gastrointestinal walls. However, the anchor of US 2009/0248171 A1 includes at least one external barb that is adapted to penetrate bodily tissue (e.g., the gastrointestinal walls). The penetration of the external barb into the gastrointestinal walls when the gastrointestinal implant device of US 2009/0248171 A1 is anchored within the body can cause damage to bodily tissue (e.g., the gastrointestinal walls), and may result in internal bleeding and infection.

United States published patent application number US 2006/0064120 A1 discloses a gastrointestinal implant device that includes an anchor adapted for providing variable radial force along its length for anchoring the device within the gastrointestinal tract of a patient. The gastrointestinal implant device of US 2006/0064120 A1 also includes a tube or sleeve that inhibits nutrient outflow therefrom, hence reducing the absorption of the nutrients by the gastrointestinal walls. However, similar to the device of US

2009/0248171 A1, the gastrointestinal implant device of US 2006/0064120 A1 also includes external barbs used for facilitating anchoring of said gastrointestinal implant device to the gastrointestinal walls. Therefore, use of the gastrointestinal implant device of US 2006/0064120 A1 is also associated with damage to bodily tissue (e.g., the gastrointestinal walls), internal bleeding, and/or infection.

A gastrointestinal implant device having atraumatic surfaces is disclosed in United States published patent US 5,820,584. US 5,820,584 describes a duodenal insert with an elongated tube for reducing intermixing of digestive fluids with partially digested food materials. More specifically, the duodenal insert of US 5,820,584 reduces intermixing of food materials traveling within the elongated tube with digestive fluids present external the elongated tube. The duodenal insert of US 5,820,584 is anchored within the pylorus through the use of a pair of spaced apart rings or cuffs, which attach to the pylorus in a trans-pyloric manner. While the duodenal insert of US 5,820,584 may have atraumatic surfaces, it can be considered to include various structural, functional, and/or operational limitations, which can hinder the insertion, deployment, use, and/or removal of the duodenal insert of US 5,820,584.

The high prevalence and incidence of obesity globally, together with the existence of the various health risks, problems, and/or limitations associated with existing devices, methods, and techniques used for combating obesity results in a continuing need for new, improved, safer, cheaper, more efficient, and/or more effective devices, methods, and techniques for combating obesity.

Summary

In accordance with a first aspect of the present disclosure, there is disclosed a device including an anchor portion that is shaped and configured for placement at, or across, a pyloric valve. The device also includes a chute coupled to the anchor portion, the chute including a first passage formed therethrough. The device further includes a channel carried by chute. The channel is disposed along a wall of chute and includes a second

passage formed therewithin, the second passage being shaped and configured to allow flow of fluid therewithin to thereby effectuate longitudinal extension of the chute.

In accordance with a second aspect of the present disclosure, there is disclosed a method for increasing a length of a device. The method includes providing the device, the device including an anchor portion and a chute coupled to the anchor portion. The chute of the device includes a first passage formed therethrough and a channel carried by a wall of the chute. The channel includes a second passage with a diameter that is substantially smaller than a diameter of the first passage. The channel includes a first end that is proximal the anchor portion and a second end that is distal the anchor portion. The method also includes introducing fluid into the channel at the first end of the channel, the introduced fluid flowing from the first end towards the second opening to effectuate longitudinal extension of the chute.

In accordance with a third aspect of the present disclosure, there is disclosed a system for facilitating implantation of a device at a pyloric valve. The device includes an anchor portion and a chute coupled to the anchor portion. The chute includes a first passage formed therethrough and a channel disposed along a wall thereof, the channel including a second passage with a diameter that is substantially smaller than a diameter of the first passage, the first and second passages being shaped and dimensioned to communicate fluid therewithin. The system further includes a delivery sheath shaped and dimensioned for at least substantially carrying the device during displacement of the device towards the pyloric valve and a fluid delivery tube, the fluid delivery tube being reversibly couplable to the device for introducing or removing fluid into or from the second passage of the channel.

In accordance with a fourth aspect of the present disclosure, there is disclosed a device including an anchor portion shaped and dimensioned for trans-pyloric placement or retention. The anchor portion includes a first inflation unit shaped and dimensioned for placement at a first side of a pyloric valve, the first side being proximal a stomach. The anchor portion also includes a second inflation unit shaped and dimensioned for

placement at a second side of the pyloric valve, the second side being proximal a duodenum. In addition, the device includes a chute coupled to the anchor portion and comprising a first passage formed therethrough. The chute includes a channel carried by a wall thereof, the channel including a second passage with a first end proximal the anchor portion and a second end distal the anchor portion. Fluid communication from the first end to the second end of the channel effectuates longitudinal extension of the chute.

In accordance with a fifth aspect of the present disclosure, there is disclosed a method for modifying matter absorption by an intestinal wall. The method includes placing or retaining a device at or across a pylorus. The device includes an anchor portion and a chute coupled to the anchor portion. The chute of the device includes a first passage formed therethrough and a channel carried by a wall of the chute. The channel includes a second passage with a diameter that is substantially smaller than a diameter of the first passage. The second passage includes a first end that is proximal the anchor portion and a second end that is distal the anchor portion. The method also includes introducing fluid into the channel at the first end of the channel, the introduced fluid flowing from the first end towards the second end to thereby effectuate longitudinal extension of the chute.

Brief Description of the Drawings

A description of embodiments of the present disclosure is provided hereinafter with reference to the figures, in which:

FIG. 1. shows a device provided that is by an embodiment of the present disclosure, the device including an anchor portion that is positioned in a trans-pyloric configuration;

FIG. 2 shows a partial isometric view of a device in accordance with an embodiment of the present disclosure;

FIG. 3A is an expanded view of area "A" as marked in FIG. 2;

FIG. 3B is an expanded view of area "B" as marked in FIG. 2;

FIG. 4A is a schematic illustration of a channel carried by a chute of a device in accordance with an embodiment of the present disclosure;

FIG. 4B is a schematic illustration of an open second end of a channel in accordance with an embodiment of the present disclosure;

FIG. 4C is a schematic illustration of a closed second end of a channel in accordance with an embodiment of the present disclosure;

FIG. 4D is a schematic illustration of a second end of a channel that includes a perforated seal in accordance with an embodiment of the present disclosure;

FIG. 5A shows a length of a chute at a compressed state;

FIG. 5B shows a length of a chute at an extended or expanded state;

FIG. 6A to FIG. 6D are partial isometric views of various retention units that are provided by various embodiments of the present disclosure;

FIG. 7 illustrates the trans-pyloric placement or retention of a particular anchor portion in accordance with an embodiment of the present disclosure;

FIG. 8A illustrates the transpyloric placement or retention of a particular anchor portion of a flower shape in accordance with an embodiment of the present disclosure;

FIG. 8B shows a top view of the anchor portion of FIG. 8A;

FIG. 9A shows a cross-sectional view of a retention unit in accordance with an embodiment of the present disclosure;

FIG. 9B shows a retention unit that includes an inlet coupled thereto as provided by an embodiment of the present disclosure;

FIG. 10A to FIG. 10E show partial line drawings of a front view of the anchor portion of several devices in accordance with several embodiments of the present disclosure;

FIG. 11A, FIG. 11B, and FIG. 11C show partial line drawings of a side, a top, and an isometric view respectively of an anchor portion of a device according to an embodiment of the present disclosure, wherein the anchor portion includes a network of struts;

FIG. 12 shows a partial isometric view respectively of an anchor portion of a device according to an embodiment of the present disclosure, wherein the anchor portion includes a corrugated portion;

FIG. 13 shows a partial isometric view of a device provided by an embodiment of the present disclosure;

FIG. 14A to FIG. 14E show partial line drawings of a front view of the chute of several devices in accordance with several embodiments of the present disclosure;

FIG. 15A and FIG. 15B provide representative illustrations of the docking between a fluid delivery tube and an inlet of a device in accordance with an embodiment of the present disclosure;

FIG. 16 provides a representative illustration of the docking between a fluid delivery tube and an inlet of a device via electromagnetic forces of attraction in accordance with an embodiment of the present disclosure;

FIG. 17A to FIG. 17D illustrates various connection configurations between fluid delivery tube(s) and an inlet(s) in accordance with various embodiments of the present disclosure;

FIG. 18A shows a partial schematic diagram of a system for positioning and retaining a particular device of the present disclosure within the gastrointestinal tract in accordance with an embodiment of the present disclosure;

FIG. 18B shows a partial schematic diagram of a system for positioning and retaining a particular device of the present disclosure within the gastrointestinal tract, the system including a wire, in accordance with an embodiment of the present disclosure;

FIG. 18C shows a partial schematic diagram of the system of FIG. 18B with a partial cross-sectional view of a sheath of the system;

FIG. 19A and FIG. 19B is a flowchart of a process for positioning and retaining a particular device of the present disclosure within the gastrointestinal tract in accordance with an embodiment of the present disclosure;

FIG. 19C is a flowchart of a process for positioning a device of the present disclosure within the gastrointestinal tract with the use of a wire in accordance with an embodiment of the present disclosure;

FIG. 20A to FIG. 20C is a representative set of figures illustrating various process portions, or aspects, of the process of FIG. 19A and FIG. 19B;

FIG. 21A to FIG. 21C is a representative set of figures showing a particular device of the present disclosure at various durations, or at various process portions, of the process of FIG. 19A and FIG. 19B;

FIG. 22 is a flowchart of a process for re-inflating a chute in accordance with an embodiment of the present disclosure;

FIG. 23A to FIG. 23C is a representative set of figures illustrating various process portions, or aspects, of the process of FIG. 22;

FIG. 24 is a flowchart of a process for retrieving or removing a particular device of the present disclosure from the gastrointestinal tract in accordance with an embodiment of the present disclosure; and

FIG. 25A to FIG. 25C is a set of representative set of figures illustrating various process portions, or aspects, of the process of FIG. 24.

Detailed Description

Many conventional surgical methods, processes, and techniques for preventing, treating, or managing, obesity, for example gastrointestinal bypass surgery, have been associated with serious medical risks including mortality, infection, and hemorrhage. The medical risks associated with many surgical methods for combating obesity have contributed to the development and use of gastrointestinal implants (also known as gastrointestinal implant devices) for combating obesity. A gastrointestinal implant typically include an attachment or anchor portion for attaching or anchoring the gastrointestinal implant to a gastrointestinal wall, and a chute (also known as a sleeve or tube) that is connected to the attachment portion. Ingested matter, for example partially digested and/or digested food matter, is communicated through the chute. Said food matter communicated through the chute is generally at least substantially prevented from contacting the gastrointestinal walls (e.g., intestinal walls), and is hence prevented from being absorbed thereby.

The attachment portions of many existing gastrointestinal implants have traumatic surfaces and/or structures, for example barbs, spikes, and/or hooks, for effectuating the attachment of the gastrointestinal implants to the gastrointestinal wall. Generally, said traumatic surfaces and/or structures have been known to cause infection, ulceration, and internal bleeding within the gastrointestinal tract. In addition, the use of numerous existing gastrointestinal implants has been associated with limitations and/or problems, for example difficulty in accurately deploying or inflating the chute after placement of

the gastrointestinal implant at a target site within the gastrointestinal tract, as well as maintaining structure, shape, and/or configuration of the gastrointestinal implant, and/or various parts thereof, during retention of the gastrointestinal implant within the body.

Embodiments of the present disclosure relate to systems, devices, apparatuses, processes, methods, and/or techniques for addressing at least one aspect, limitation, disadvantage, and/or problem associated with existing gastrointestinal implants.

Most embodiments of the present disclosure relate to systems, devices, apparatuses, processes, methods, and/or techniques for modifying the absorption, or absorption pattern, of ingested matter by a wall of the gastrointestinal tract (i.e., gastrointestinal wall).

For purposes of the present disclosure, absorption pattern includes at least one of rate, quantity, type, and size of the ingested material being absorbed. In addition, for purposes of the present disclosure, ingested matter can include any matter that is introduced into the gastrointestinal tract, for example solid, semi-solid, and/or liquid food matter.

Most embodiments of the present disclosure relate to systems, devices, apparatuses, processes, methods, and/or techniques for facilitating or effectuating the modification of the absorption pattern of ingested matter by an intestinal wall, more specifically a wall of the small intestine (e.g., duodenal wall, jejunum wall, and ileum wall) or a wall of the large intestine (e.g., cecum wall and colon wall). More specifically, many embodiments relate to systems, devices, apparatuses, processes, methods, and/or for facilitating or effectuating a reduction in the quantity of ingested matter being absorbed by the intestinal wall.

The systems, devices, apparatuses, processes, and/or methods of many embodiments of the present disclosure facilitate or effectuate the prevention, cure, control, alleviation, management, and/or treatment of a physiological condition, more specifically a condition of the digestive system, gastrointestinal system and/or metabolic system. More

specifically, the systems, devices, apparatuses, processes, and/or methods of many embodiments of the present disclosure facilitate or effectuate the prevention, cure, control, alleviation, management, and/or treatment of obesity. Alternatively, or in addition, the systems, devices, apparatuses, processes, and/or methods of many embodiments of the present disclosure facilitate or effectuate the prevention, cure, control, alleviation, management, and/or treatment of metabolic conditions, for example Type II diabetes.

Representative embodiments of the present disclosure, and aspects of said embodiments, are described in detail hereinafter with reference to FIG. 1 to FIG. 25C, in which like or analogous elements or features are shown numbered with like or analogous reference numerals. Relative to descriptive material corresponding to one or more of FIG. 1 to FIG. 25C, the recitation of a given reference numeral can indicate the simultaneous consideration of a FIG. in which such reference numeral is also shown. The embodiments provided by the present disclosure are not precluded from other applications (e.g., patient care or patient treatment applications), or medical indications, in which particular fundamental principles present among the various embodiments described herein, such as structural and/or functional characteristics, are desired.

Aspects of Particular Gastrointestinal Device Embodiments

FIG. 1 and FIG. 2A show a device 20 (also known as an implant, gastrointestinal device, or gastrointestinal implant) provided by an embodiment of the present disclosure, which can be configured for insertion and deployment in a human or animal body.

In most embodiments of the present disclosure, the device 20 includes an anchor portion 22 and a chute 24 (also known as a sleeve, tube, or tubing) that is coupled to the anchor portion 22.

In many embodiments of the present disclosure, for instance with the device 20 as shown in FIG. 1, the anchor portion 22 is shaped, dimensioned, and/or configured to be positioned, anchored, retained, and/or secured at the pyloric valve, or pylorus, of a body.

In numerous embodiments, the anchor portion 22 is shaped, dimensioned, and/or configured to be positioned, anchored, retained, and/or secured in a trans-pyloric configuration.

FIG. 1 also illustrates that the chute 24 can be shaped, dimensioned, and/or configured for extending into the small intestine, more specifically the duodenum and/or jejunum, of the body when the anchor portion 22 is retained in the trans-pyloric configuration.

The anchor portion 22 and the chute 24 can be constructed or made of various materials or material compositions, for instance depending upon properties and/or characteristics of the devices 20 as provided by various embodiments of the present disclosure. In some embodiments, each of the anchor portion 22 and the chute 24 is made of an identical, or substantially similar, material (or group of materials). In other embodiments, each of the anchor portion 22 and the chute 24 is made of a different material (or group of materials).

In most embodiments, the anchor portion 22 and/or the chute 24 can be made using a polymeric compound (i.e., a polymer). In many embodiments, the anchor portion 22 and/or the chute 24 can be made using a biocompatible, soft, and/or flexible polymer. Representative examples of polymers that can be used for manufacturing the anchor portion and/or the chute of the device include polyurethane (PU), silicone, polytetrafluoroethylene (PTFE), and polyvinyl chloride (PVC).

In some embodiments, the anchor portion 22 and/or the chute 24 are made of a combination or mixture of at least two different materials. For example, in several embodiments, the anchor portion 22 and/or the chute 24 is made of silicone polyether, urethane (PurSil), or silicone polycarbonate urethane (CarboSil).

Although examples of materials or material compositions from which the anchor portion 22 and/or the chute 24 can be manufactured are provided above, a person of ordinary skill in the art will appreciate that other natural or synthetic material(s) can also be used for manufacturing the anchor portion 22 and/or chute 24.

As shown in FIG. 2, in most embodiments, the anchor portion 22 includes at least one retention unit 26 that is shaped and dimensioned for facilitating or effectuating the retention or anchoring of the anchor portion 22 at the pylorus. The retention unit 26 can alternatively be referred to as a securing unit, anchoring unit, and/or placement unit. In addition, the retention unit 26 can be referred to as a retention cuff, securing cuff, anchoring cuff, and/or placement cuff.

In many embodiments, the anchor portion 22 includes at least two retention units 26, namely, a first or proximal retention unit 26a and a second or distal retention unit 26b. Each of the first and second retention units 26a, 26b is shaped, dimensioned, and/or configured for facilitating or effectuating anchoring or retention of the anchor portion 22 at, or across, the pylorus. More specifically, in many embodiments, the first and second retention units 26a, 26b are shaped, dimensioned, and configured for facilitating or effectuating trans-pyloric retention of the anchor portion 22.

In many embodiments, the second retention unit 26b is disposed between the first retention unit 26a and the chute 24. In many embodiments, the first retention unit 26a is placed at a first side of the pylorus or pyloric valve, for example at a side of the pylorus proximal the antrum or the stomach, and the second retention unit 26b is placed at a second side of the pylorus or pyloric valve, for example at a side of the pylorus proximal the duodenum. The placement of each retention unit 26a, 26b on either side of the pylorus enables trans-pyloric placement, anchoring, retention, and/or securing of the anchor portion 22.

For purposes of the present disclosure, the description provided hereinafter relates to devices that include two retention units 26 (i.e., the first and second retention units 26a, 26b). However, a person of ordinary skill in the art, with the present disclosure, will understand that devices that include other numbers of retention units 26, for example one, two, three, four, or more, retention units are also included within the scope of the present disclosure.

Aspects of Particular Chute Embodiments

In many embodiments, the chute 24 of the device 20 is coupled to the anchor portion 22, and more specifically to the second retention unit 26b. The chute 24 can be directly coupled or attached to the second retention unit 26b. Alternatively, the chute 24 is indirectly coupled or attached to the second retention unit 26b, for instance by way of interconnecting structures, mechanisms, and/or means, such as adhesives, hooks, and/or clasps (not shown). In certain embodiments, the chute 24 can be directly or indirectly coupled to the first retention unit 26a, inclusive or exclusive of any coupling to the second retention unit 26b depending upon embodiment details.

In particular embodiments, the chute 24 is coupled to the anchor portion 22, for example the second retention unit 26b of the anchor portion 22, by using bio-compatible thread(s). Bio-compatible threads can be used to attach (e.g., sew) the chute to the anchor portion 22, for example the second retention unit 26b of the anchor portion 22, using techniques (e.g., sewing techniques) known in the art. In most embodiments, the chute 24 is coupled or attached to the anchor portion 22 before insertion of the device 20 into the gastrointestinal tract. In particular embodiments, the chute 24 can be coupled or attached to the anchor portion 22 subsequent insertion of the device 20 into the gastrointestinal tract.

In most embodiments, the chute 24 includes a passage or lumen 28 (also known as a passageway or channel) formed therethrough. In many embodiments, the passage or lumen 28 of the chute 24 is shaped and dimensioned to allow the flow or displacement of ingested matter (e.g., solid, semi-solid, or liquid food) therethrough.

In most embodiments, the diameter of the lumen 28 of the chute 24 can be selected and varied depending upon an expected diameter of the gastrointestinal tract (e.g., duodenum) and/or type of ingested matter being communicated or displaced through the lumen 28 of the chute 24.

In most embodiments, the diameter of the lumen 28 of the chute 24 is between approximately 10 millimeters (mm) and 100mm. In some embodiments, the diameter of the lumen 28 of the chute 24 is between approximately 15mm and 75mm. In selected embodiments, the diameter of the passage of the chute is approximately 20mm, 25mm, 30mm, 35mm, 40mm, 45mm, or 50mm, 55mm, or 60mm.

The length of the chute 24 can also be determined and varied, for instance depending upon desired extent of modification of absorption pattern of ingested food matter by the gastrointestinal walls (e.g., duodenal walls) and/or length of a specified portion along the gastrointestinal tract (e.g., length of the duodenum).

For example, in most embodiments, the chute 24 is at least approximately 5 centimeters (cm) in length. In many embodiments, the chute 24 is at least approximately 10cm in length. In numerous embodiments, the chute 24 is at least approximately 15cm in length. In selected embodiments, the chute 24 is approximately 20cm, 25cm, 30cm, 35cm, 40cm, 45cm, 50cm, 60cm, 70cm, 80cm, 90cm, or even 1 meter (m) in length.

In most embodiments, the chute 24 is a thin, or substantially thin, walled chute 24. In many embodiments, the chute 24 includes an inner wall 30 and an outer wall 32 formed around the inner wall 30 such that a circumference of the outer wall 32 is larger than a circumference of the inner wall 30. For purposes of the present disclosure, the diameter of the lumen 28 of the chute 24 as described above can be defined as a diameter of, or between, the inner wall(s) 30 of the chute 24.

In addition, for purposes of the present disclosure, a thickness of the wall(s) of the chute 24 is defined as the distance between the inner and outer walls 30, 32 of the chute 24. In many embodiments, the thickness of the wall(s) of the chute 24 is between approximately 0.01 millimeter (mm) and 5mm. In some embodiments, the thickness of the wall(s) of the chute 24 is between approximately 0.05mm and 2.5mm. In several embodiments, the thickness of the wall(s) of the chute 24 is between approximately 0.1mm and 1mm. In

selected embodiments, the thickness of the wall(s) of the chute 24 is approximately 0.1mm, 0.2mm, 0.3mm, 0.4mm, or 0.5mm.

In most embodiments, the wall(s) of the chute 24 are of a uniform, or substantially uniform, thickness along the entire length of the chute 24. In some embodiments, the wall(s) of the chute 24 are of a non-uniform, or substantially non-uniform, thickness along one or more portions of the length of the chute 24. In many embodiments, the thickness of the wall(s) of the chute 24 at a selected length thereof (e.g., at a specific position along the chute 24) can be determined and varied, for instance depending upon a desired torque resistance at the said selected length of the chute 24.

Representative Porus Portions of the Chute

In most embodiments, the chute 24 includes a number of pores 33 formed through or within the walls 30,32 of one or more portions along the length of the chute 24. Alternatively, the walls 30, 32 of the chute 24 can be impermeable (i.e., do not include pores 33).

FIG. 3A and FIG. 3B show expanded views of selected portions the chute walls 30, 32 that include pores 33 as provided by various embodiments of the present disclosure.

The pores 33 can be uniformly disposed or positioned along the entire length of the chute 24. Alternatively, the pores 33 can be non-uniformly disposed or positioned along the entire length of the chute 24. For example, the pores 33 may be disposed only along a length of the chute 24 that is between approximately 0cm and 10cm, between approximately 0cm and 15cm, or between approximately 5cm and 15cm, from the second securing unit 26b.

In several embodiments of the present disclosure, the pores 33 can be shaped and dimensioned to allow a one-way (i.e., unidirectional) flow or movement of material therethrough. For example, the pores 33 can be shaped and dimensioned to allow inflow of bile and pancreatic juices normally present within the intestine (e.g., the duodenum)

into the lumen 28 of the chute 24, without allowing outflow of the ingested material (e.g., partially, or substantially, digested food material) from the lumen 28 of the chute 24. In other embodiments, the pores 33 are shaped and dimensioned to allow two-way (i.e., bi-directional) flow or movement of material thereacross.

In many embodiments, the porosity, more specifically the pore size and pore density of the chute 24, can be determined and varied in order to facilitate or effectuate the control of movement or transport of substances or material across the walls 30,32 of the chute. For instance, the porosity of the chute 24 can be determined and varied for facilitating or effectuating the control of movement of digestive fluids and/or ingested matter across the walls 30,32 of the chute 24.

In several embodiments, the porosity of the chute 24, more specifically the pore size and/or pore density of the chute 24, can influence and/or determine at least one of rate, quantity, size, and/or type of the ingested matter being absorbed by the gastrointestinal walls (e.g., duodenal walls).

In some embodiments, for example as shown in FIG. 3A, the pores 33 of the chute 24 are of a uniform or similar size. In other embodiments, for example as shown in FIG. 3B, the pores 33 of the chute 24 are of non-uniform or dissimilar sizes.

In most embodiments, the diameter of the pores 33 of the chute 24 is between approximately 5microns and 750microns. In many embodiments, the diameter of the pores 33 of the chute 24 is between approximately 10microns and 500microns. In several embodiments, the diameter of the pores 33 of the chute 24 is between approximately 50mircons and 250microns. In selected embodiments, the diameter of the pores 33 of the chute 24 is approximately 50microns, 75mircons, 100microns, 125 microns, or 150microns.

In some embodiments, the size of the pores 33 is different at different lengths of the chute 24. For instance, in selected embodiments, the pores 33 along a certain portion of the

chute 24 (e.g., at a length between approximately 5cm and 10cm from the anchor portion 22) can be smaller than the pores 33 along a different portion of the chute 24 (e.g., at a length between approximately 10cm and 15cm from the anchor portion 22).

In many embodiments, the pore density of the chute 24 (i.e., total surface area of pores / total surface area of chute 24) is between approximately 1% and 50%. In some embodiments, the pore density of the chute 24 is between approximately 10% and 40%. In specific embodiments, the pore density of the chute 24 is approximately 15%, 20%, 25%, or 30%.

In some embodiments, pore density at a specific length of the chute 24 can be selected and/or varied, for instance in order to control the rate and/or quantity of ingested matter moving across the walls 30,32 of the chute 24 at said specific length.

Although specific aspects of the porosity of the chute 24 are described above, a person skilled in the art, having the present disclosure, will understand that the porosity of the chute 24, more specifically the size, density, and/or distribution of pores 33 along the chute 24, can be alternatively determined or varied within the scope of the present disclosure.

Representative Channel(s) Carried by the Chute

In addition, as shown in FIG. 2, the device 20 includes at least channel 34 that is carried by the chute 24. The channel 34 can also be referred to as a fluid channel, column, passage, or tube. In most embodiments, the channel 34 is carried by or disposed along the walls 30,32 of the chute 24 along at least a portion of the chute's length.

In many embodiments, the channel 34 is disposed or formed alongside or proximate to at least one of the inner and outer walls 30,32 of the chute 24. In some embodiments, the channel 34 is disposed or formed at least substantially between the inner wall 30 and the outer wall 32 of the chute 24. In several embodiments, the channel 34 is shaped,

dimensioned, and/or configured to provide at least some structural support or structural integrity to the chute 24.

FIG. 4A is a schematic illustration of the channel 34 carried by the chute 24 in accordance with embodiments of the present disclosure.

In most embodiments, the channel 34 includes a passage 36 (also known as a passageway or lumen) formed therewithin. The passage 36 of the channel 34 is shaped and dimensioned to allow fluid communication therewithin.

In most embodiments, the passage 34 includes a first end 37 that is proximal the anchor portion 22 and a second end 38 that is distal the anchor portion 22. In many embodiments, the first and second ends 37, 38 of the channel 34 are positioned at opposite ends or terminals of the channel 24.

In many embodiments, fluid is introduced into the passage 36 of the channel 34 at the first end 37. Fluid introduced into the passage 36 of the channel 34 at the first end 37 flows towards the second end 38. For purposes of the present disclosure, fluid includes one or more of liquids (e.g., water and saline solution) and/or gases (e.g., air, oxygen, and nitrogen).

FIG. 4B shows an open second end 38 of the channel 34 associated with many embodiments of the present disclosure.

In many embodiments, the first and second ends 37, 38 of the channel 34 are open ends, and hence can be known as first and second openings 37, 38 respectively. Fluid can be introduced into the passage 36 of the channel 34 via the first end or opening 37, and expelled from the passage 36 of the channel 24 via the second end or opening 38.

FIG. 4C shows a closed second end 38 of the channel 34 associated with various embodiments of the present disclosure.

In various embodiments, the second end 38 of the channel 34 is a closed or sealed end 38. In such embodiments, fluid introduced into the passage 36 of the channel 34 at the first end 37 cannot be expelled from the passage 36 at the second end 38, and therefore is stored within the passage 36 of the channel 34. The stored fluid within the passage 36 of the channel 34 facilitates or effectuates inflation, extensions, and/or expansion of the channel 34.

FIG. 4D shows a second end 38 of the channel 34 with a partially sealed end, which in several embodiments includes a perforated seal 39 (and can hence be referred to as a perforated end 38).

In several embodiments, the perforated seal 39 controls fluid expulsion from the passage 36 of the channel 34. For instance, in various embodiments, the perforated seal 39 prevents expulsion of fluid from the passage 36 of the channel when fluid pressure within the passage 36 is below a predetermined pressure, for instance 0.5psi, 1.0psi, 2.0psi, 5.0psi, 10psi, or more, and/or a predetermined volume, for instance 10ml, 20ml, 50ml, 100ml, or more. In some embodiments, the perforated seal 39 is broken when the pressure and/or volume of fluid within the passage 36 of the channel 34 exceed a predetermined quantity, to thereby allow fluid expulsion from the passage 36 of the channel 34 at the second end 38.

FIG. 5A and FIG. 5B show the chute 24 at a compressed state and an extended or expanded state respectively.

In most embodiments, the length of the chute 24 is shorter at the compressed state as compared to the extended state. In many embodiments, the length of the chute 24 is at least approximately 50% shorter at the compressed state as compared to the extended state. In several embodiments, the length of the chute 24 is at least approximately 75% shorter at the compressed state as compared to the extended state. For instance, in

selected embodiments, the length of the chute is at least approximately 80%, 85%, 90%, or 95% shorter at the compressed state as compared to the extended state.

In most embodiments, a cross-sectional diameter of the chute 24 is smaller at the compressed state as compared to the extended state. In many embodiments, the cross-sectional diameter of the chute 24 is at least approximately10% smaller at the compressed state as compared to the extended state. In several embodiments, the cross-sectional diameter of the chute 24 is at least approximately 25% smaller at the compressed state as compared to the extended state. In various embodiments, the cross-sectional diameter of the chute 24 is at least approximately 50% smaller at the compressed state as compared to the extended state. For instance, in selected embodiments, the cross-sectional diameter of the chute 24 is at least approximately 60%, 65%, 70%, 75%, or 80% smaller at the compressed state as compared to the extended state.

In most embodiments, presence or storage of fluid within the passage 36 of the channel 34 causes longitudinal extension or expansion of the chute 24. More specifically, in many embodiments, fluid communication or flow within the passage 36 of the channel 34 from the first end or opening 37 towards the second end or opening 38 effectuates longitudinal extension or expansion of the chute 24.

In many embodiments, the presence or storage of fluid within the passage 36 of the channel 34 causes deployment of the chute 24 from the compressed state (as shown in FIG. 5A) to an extended state (as shown in FIG. 5B). More specifically, in numerous embodiments, the communication or flow of fluid from the first end 37 towards the second end 38 of the passage 38 effectuates a deployment of the chute 24 from the compressed state (as shown in FIG. 5A) to the extended state (as shown in FIG. 5B) thereby extending the chute 24 into or along a portion of the gastrointestinal tract. The longitudinal extension or expansion of the chute 24, or the deployment of the chute 24 from the compressed state to the extended state, is also known as an inflation of the chute 24.

Aspects of Particular Anchor Portion Embodiments

In many embodiments of the present disclosure, the anchor portion 22 of the device 20 has atraumatic surfaces for reducing, or at least substantially eliminating, damage to body tissue (e.g., pyloric tissue) caused by placement, retention, and/or anchoring of the anchor portion 22 at the pylorus. More specifically, in numerous embodiments, the first and second retention units 26a, 26b have atraumatic surfaces for reducing, or at least substantially eliminating, damage to pyloric tissue during trans-pyloric placement, retention, and/or anchoring of the anchor portion 22.

In many embodiments of the present disclosure, the anchor portion 22 omits or excludes penetrating attachment or anchoring structures, for instance barbs, spikes, hooks, needles, or a like attachment or anchoring instrument, for facilitating or effectuating retention of anchor portion 22 at the pylorus. In addition, in several embodiments, external or exterior surfaces of the anchor portions 22 are at least substantially smooth. Accordingly, the anchor portion 22 of many embodiments of the present disclosure can be considered to be at least substantially atraumatic.

Although the anchor portion 22 provided by many embodiments of the present disclosure has atraumatic surfaces, or is at least substantially atraumatic, anchor portions 22 that include attachment or anchoring structure(s), for instance barbs, spikes, hooks, needles, or a like anchoring instrument, are not precluded by the present disclosure. In selected embodiments, the anchor portion 22 can include a number of attachment structures. The attachment structure(s) facilitate attachment, retention, and/or anchoring of the anchor portion 22 within the gastrointestinal tract (e.g., at the pylorus). More specifically, the attachment structure(s) mediate attachment or anchoring of the anchor portion 22 to the gastrointestinal walls (e.g., pyloric walls). In specific embodiments, the attachment structure(s) extend or project from the surfaces of the anchor portion 22 (e.g., first retention unit and/or second retention unit) for facilitating attachment, anchoring, and/or fastening of the anchor portion 22 to the gastrointestinal walls.

FIG. 6A to FIG. 9B show various aspects of representative anchor portions 22, more specifically representative retention unit(s) 26 of anchor portions 22, in accordance with various embodiments of the present disclosure.

For purposes of the present disclosure, a reference to "retention unit" can be understood to be a reference to either of the first retention unit 26a and the second retention unit 26b. In addition, retention units 26 shown in FIG. 6A to FIG. 9B can be illustrations of either of the first retention unit 26a and the second retention unit 26b.

The retention unit 26 of the present disclosure can be of various shapes, sizes, and/or configurations, for instance depending upon properties and/or characteristics of the retention unit 26 and/or device 20 as provided by various embodiments of the present disclosure.

As shown in FIG. 6A to FIG. 7, the retention unit 26 of several embodiments of the present disclosure can be of a toroidal, donut, or ring, shape. It will, however, be understood by a person of ordinary skill in the art, in view of the present disclosure, that the retention unit 26 can have an alternative shape or configuration, for example an oval, a square, a rectangular, or an irregular shape. For instance, the anchor portion 22 can include a retention unit 26 with a petal-shape or contour, or with a petal-shaped protruding structure, such as that shown in FIG. 8A and FIG. 8B.

In most embodiments, the retention unit 26 includes an opening 42 (also referable to as an aperture, hole or lumen) formed in the middle of the retention unit 26. The opening 42 defined by the retention unit 26 is shaped and dimensioned for allowing fluid communication therethrough.

For purposes of the present disclosure, a diameter of the retention unit 26 can be defined as a diameter of the opening 42 defined by, or formed within, the retention unit 26 (or a distance between the inner walls of the retention unit 26). The diameter of the retention unit 26 can be selected and varied, for instance in order to facilitate or effectuate

placement or retention of the retention unit 26 at a desired side (i.e., the first side or second side) of the pylorus. In some embodiments, the diameter of the retention unit 26 can be selected for facilitating or effectuating trans-pyloric retention of the anchor portion 22 as provided by particular embodiments of the present disclosure.

In embodiments of the present disclosure wherein the anchor portion 22 has multiple retention units 26, the diameter of each retention unit 26 can be one of similar or dissimilar to each other. For instance, in some embodiments, the diameters of the first and second retention units 26a, 26b are similar, or substantially similar. In several embodiments, the diameters of the first and second retention units 26a, 26b are different. For instance, in numerous embodiments, the diameter of the first retention unit 26a is larger or bigger than the diameter of the second retention unit 26b.

In many embodiments, the diameter of the first retention unit 26a is between approximately 20mm and 150mm. In numerous embodiments, the diameter of the first retention unit 26a is between approximately 30mm and 100mm. In several embodiments, the diameter of the first retention unit 26a is between approximately 40mm and 75mm. In selected embodiments, the diameter of the first retention unit 26a is approximately 45mm, 50mm, 55mm, 60mm, 65mm, or 70mm.

In many embodiments, the diameter of the second retention unit 26b is between approximately 5mm and 100mm. In numerous embodiments, the diameter of the second retention unit 26b is between approximately 10mm and 70mm. In several embodiments, the diameter of the second retention unit 26b is between approximately 15mm and 50mm. In selected embodiments, the maximum inner diameter of the second retention unit 26b is approximately 20mm, 25mm, 30mm, or 35mm.

Aspects of Representative Retention Unit Surface Topography

In many embodiments, the retention unit 26 has a surface or structural topography that facilitates or effectuates a reduction in a total surface area of contact between the retention unit 26 and the gastrointestinal wall (e.g., a portion of the stomach wall or the

wall of the pylorus). In several embodiments, reduction in a total surface area of contact between the retention unit 26 and the gastrointestinal wall helps to reduce risk, and/or occurrence, of erosion or ulceration of the gastrointestinal mucosa.

As shown in FIG. 6B to FIG. 6D, in various embodiments, the retention unit 26 carries or includes a number of structural features 44 that are shaped, dimensioned, and/or configured for reducing the total surface area of contact between the retention unit 26 and the gastrointestinal wall. In some embodiments, the structural features 44 carried by the retention unit 26 allows at least some flow of material or fluid around an outer periphery thereof.

In several embodiments, the structural features 44 include a number of protruding structures 44 (also known protrusions or protruding features) that protrude, extend, or project from a surface of the retention unit 26. In most embodiments, the protruding structures 44 are shaped, dimensioned and/or configured for reducing the total surface area of contact between the retention unit 26 and the gastrointestinal wall. The reduction in the total surface area of contact between the retention unit 26 and the gastrointestinal wall can help to reduce contact abrasion, cuts, irritancies, and/or related damage to body tissue (e.g., pyloric tissue). In addition, in some embodiments, the protruding structures 44 can be shaped and dimensioned to enhance retention (e.g., provide a securer or tighter fit) of the retention unit 26 at the pylorus as provided by particular embodiments of the present disclosure.

In some embodiments of the present disclosure, the protruding structures 44 include a number of podia pods 44 (also known as podia feet or bulbs) that protrude, extend, or project from the surface thereof. The number, size, shape, and/or configuration of the podia pods 44 can be varied, for instance depending upon particular properties and/or characteristics of the retention unit 26 as provided by the present disclosure.

In many embodiments, the protruding structures 44, for instance the podia pods 44, have a height of between approximately 1.0mm and 10mm. In numerous embodiments, the

protruding structures 44, for instance the podia pods 44, have a height of between approximately 2.5mm and 7.5mm. In various embodiments, the protruding structures 44, for instance the podia pods 44, have a height of between approximately 4.0mm and 6.0mm, for instance approximately 4.5mm, 5.0mm, and 5.5mm.

In many embodiments, distances between adjacent protruding structures 44, for instance podia pods 44, are between approximately 1mm and 100mm. In numerous embodiments, distances between adjacent protruding structures 44, for instance podia pods 44, are between approximately 5mm and 50mm. In various embodiments, distances between adjacent protruding structures 44, for instance podia pods 44, are between approximately 10mm and 40mm, for instance approximately 15mm, 20mm, 25mm, 30mm, and 35mm.

As illustrated in FIG. 6D, in other embodiments of the present disclosure, the retention unit 26 includes a tapered or scalloped surface structure or formation, which is shaped and dimensioned for reducing the total surface area of contact between the retention unit 26 and the gastrointestinal wall.

As shown in FIG. 7, in many embodiments, the protruding structures 44 are disposed between the retention unit 26 and the gastrointestinal wall. For instance, in many embodiments, the protruding structures 44 on the first retention unit 26a (hereinafter referred to as a first set of protruding structures 44a) are disposed between the first retention unit 26a and the walls of the first side of the pylorus or pyloric valve, and the protruding structures 44 on the second retention unit 26b (hereinafter referred to as a second set of protruding structures 44b) are disposed between the second retention unit 26b and the walls of the second side of the pylorus. This is to say, in several embodiments featuring trans-pyloric retention of the anchor portion 22, the first set of protruding structures 44a is disposed between the surface of the first retention unit 26a and the wall of the pylorus that is proximal the stomach or antrum, and the second set of protruding structures 44b is disposed between the surface of the second retention unit 26b and the wall of the pylorus that is proximal the duodenum.

In many embodiments, the first set of protruding structures 44a extends towards, or generally towards, the chute 24 of the device 20. In many embodiments, the second set of protruding structures 44b extends away, or generally away, from the chute 24 of the device 20, for instance towards, or generally towards, the first retention unit 26a.

In many embodiments, the first and second sets of protruding structures 44a, 44b extend substantially toward each other. In numerous embodiments, the extension of the first and second sets of protruding structures 44a, 44b towards each other facilitates or effectuates enhanced (e.g., more secure) trans-pyloric retention of the anchor portion 22. In specific embodiments, the first and second sets of protruding structures 44a, 44b apply at least some pressure against the walls of the pylorus (e.g., the walls of the pylorus proximal the stomach and the duodenum respectively) for facilitating or effectuating a more secure grip or hold of the anchor portion 22 onto said walls of the pylorus to thereby enable a securer trans-pyloric retention of the anchor portion 22.

In several embodiments, the first and second sets of protruding structures 44a, 44b create at least some space between the first and second retention units 26a, 26b and the walls of the pylorus (e.g., the walls of the pylorus proximal the stomach and the duodenum respectively) as shown in FIG. 7. Accordingly, in several embodiments, the presence of the first and second sets of protrusions 44a, 44b enables at least some material or substance transfer or leakage (e.g., fluid leakage) across said space between the first and second retention units 26a, 26b and the walls of the pylorus (e.g., the walls of the pylorus proximal the stomach and the duodenum, respectively). In some various embodiments, the presence of the first and second sets of protruding structures 44a, 44b allows at least some fluid communication between the first and second sets of protruding structures 44a, 44b.

Although representative types of structural features 44 (or types of protruding structures 44 such as podia pods 44) are described above, a person of ordinary skill in the art, with the present disclosure, will understand that the retention unit 26 can include alternative surface topographical features, shapes, configurations, and/or structures for reducing the

total surface area of contact between the retention unit 26 and the gastrointestinal wall. For instance, the retention unit 26 can include a wave-like or contoured surface, or a wave-like or contoured protrusion or projection, for reducing the total surface area of contact between the retention unit 26 and the gastrointestinal wall.

In some embodiments, the design, configuration, shape, and/or size of the anchor portion 22 can be selected for enhancing (e.g., enabling a more secure) the retention of the anchor portion 22 at, or across, the pylorus. For instance, in various embodiments the anchor portion 22 can further include an extension 45 that extends from a surface of a retention unit 26 (e.g., the first retention unit 26a).

FIG. 8A and FIG 8B show an anchor portion 22 that includes an extension 45 that extends or protrudes from a retention unit 26, more specifically the first retention unit 26a.

As shown in FIG. 8A and FIG. 8B, in several embodiments, the extension 45 has a petal-shape, or a generally petal-shaped profile. Accordingly, the anchor portion 22 shown in FIG. 8A and FIG. 8B can also be said to be of a flower (e.g., a tulip) shape or design. In various embodiments, the extension 45 includes a rim 47 and an interconnecting web 49 (also known as an interconnecting sheath 49) disposed between the rim 47 and the first retention unit 26a. In several embodiments, the interconnecting web 49 carries a support or stiffening structure (not shown), for example support wires, for supporting the shape, structure, and/or form of the extension 45.

As shown in FIG. 8A, in some embodiments, the petal-shaped extension 45 extends or protrudes into the antrum or the stomach. More specifically, in several embodiments, portions of the petal-shaped extension 45 are disposed against the walls of the antrum or stomach. In various embodiments, the petal-shaped extension 45 presses against, grips, or holds onto the walls of the stomach for enhancing retention of the first retention unit 26a at the first side of the pylorus (i.e., at the side of the pylorus proximal the stomach).

In some embodiments, portions of the extension 45, for example the rim 47, can be an inflatable, extendible, or expansible structure, for example in a manner analogous to inflatable, extendible, or expansible structures described below with reference to FIG. 9A and 9B, FIG. 13, and FIG. 17A to 17D.

In some embodiments, portions of the extension 45, for example the rim 47, include, or are made of, a shape memory or superelastic alloy. Generally, a shape memory alloy is an alloy that "remembers" its original, cold, or forged shape, and which when deformed returns to said original shape after heating. For instance, in various embodiments, portions of the extension 45, for example the rim 47, include, or are made of, nitinol (an acronym for Nickel Titanium Naval Ordnance Laboratories). Nitinol has shape memory and superelasticity (also known as pseudoelasticity) properties. Accordingly, in various embodiments, portions of the extension 45, for example the rim 47, "remember" their original, cold, or forged shape. In several embodiments, the original shape of the rim 47 is a flower shape (e.g., an expanded tulip).

In certain embodiments, the extension 45 includes gripping structures or mechanisms (e.g., suction pads and hook-type structures such as curved fingers) (not shown) disposed between a surface thereof and the walls of the antrum or stomach for enhancing the retention of the first retention unit 26a at the first side of the pylorus. In several embodiments, the extension 45, and/or the gripping structures thereof, facilitates or effectuates an enhanced (e.g., more secure) retention of the anchor portion 22 at, or across, the pylorus. More specifically, in various embodiments, the extension 45, and/or the gripping structures thereof, facilitates or effectuates an enhanced (e.g., more secure) retention of the first retention unit 26a at the first side of the pylorus (i.e., at the side of the pylorus proximal or facing the stomach).

Aspects of Inflatable or Expandable Retention Unit Embodiments

FIG. 9A shows a horizontal cross-sectional view of a retention unit 26 according to an embodiment of the present disclosure.

In many embodiments of the present disclosure, for instance in the embodiment shown in FIG. 9A, the retention unit 26 includes an internal or inner cavity 46 (also known as a chamber, a lumen, or an internal or inner circumferential passage) that is encased or defined by the walls of the retention unit 26.

In many embodiments, the internal cavity 46 of the retention unit 26 is shaped and dimensioned for allowing fluid flow and/or storage therewithin. In numerous embodiments, the internal cavity 46 of the retention unit 26 has a substantially circular or toroidal shape, which at least generally corresponds to the shape of the retention unit 26. In some embodiments, the internal cavity 46 of the retention unit 26 is disposed or orientated such that fluid flow within the internal cavity 46 of the retention unit 26 is at an angle to the fluid flow within the passage 36 of the channel 34. In several embodiments, the internal cavity 46 of the retention unit 26 is disposed or orientated such that fluid flow and/or storage therewithin is in a direction that is substantially perpendicular to a length of the chute 24.

In many embodiments, the internal cavity 46 of the retention unit 26 has a diameter of between approximately 1mm and 50mm. In some embodiments, the internal cavity 46 of the retention unit 26 has a diameter of between approximately 5mm and 25mm. In selected embodiments, the internal cavity 46 of the retention unit 26 has a diameter of approximately 7mm, 8mm, 9mm, 10mm, 11mm, 12mm, 13mm, 14mm, 15mm, or 20mm.

In many embodiments, the introduction of fluid into the internal cavity 46 of the retention unit 26 facilitates or effectuates inflation or expansion of the retention unit 26 from a compressed state to an inflated or expanded state. This is to say, in many embodiments, the retention unit 26 can be known as an inflatable or expandable retention unit 26. In most embodiments, the inflation of the retention unit 26 from the compressed state to the inflated state increases the diameter of the retention unit 26 (i.e., increases the diameter of the opening as defined in the middle of the retention unit 26).

In several embodiments, the internal cavity 46 of the retention unit 26 includes or carries biocompatible hydrophilic polymers (not shown), which have a capacity for swelling (i.e., size increment). Examples of such hydrophilic polymers include hydrogels and superabsorbants such as polyethylene oxide (PEO), polyethylene glycol (PEG), methylacrylate (MAA), maleic anhydride (MAH), polyacrylamide, poly-hydroxyethyl methacrylate, poly-N-vinyl pyrrolidone (PVP), and poly-vinyl alcohol. In some embodiments, the introduction of fluid within the internal cavity 46 of the retention unit 26 causes swelling, or a size increment, of the hydrophilic polymers and thereby a corresponding inflation of the retention unit 26.

In many embodiments, the inflation of the retention unit 26 facilitates or effectuates retention and/or anchoring of the anchor portion 22 at the pylorus. In numerous embodiments, for instance with embodiments wherein the anchor portion 22 of the device 20 includes the first and second retention units 26a, 26b, the inflation of the first and second retention units 26a, 26b can facilitate or effectuate trans-pyloric retention of the anchor portion 22.

In most embodiments, the shape, dimensions, and/or configuration of, as well as the contents within, the internal cavity 46 of the retention unit 26 can be selected and varied, for example, in order to achieve a particular diameter or size of the retention unit 26, a particular pressure within the retention unit 26, and/or to facilitate the trans-pyloric retention of the anchor portion 22, as according to particular embodiments of the present disclosure.

FIG. 9B shows a retention unit 26 that includes an inlet 48 as provided by an embodiment of the present disclosure.

In most embodiments, the inlet 48 is shaped, dimensioned, and/or configured for mediating fluid introduction into the internal cavity 46 of the retention unit 26. In some embodiments, the inlet 48 is shaped, dimensioned, and/or configured for facilitating or

effectuating control of at least one of rate, pressure, and volume of fluid being introduced into the internal cavity 46 of the retention unit 26.

In several embodiments, the inlet 48 includes or carries a valve 56, the valve 56 facilitating or effectuating control of at least one of rate, pressure, and volume of fluid being introduced or flowing into the internal cavity 46 of the retention unit 26. Valves 56 used with particular devices 20 of embodiments of the present disclosure include valves known to a person of ordinary skill in the art. For instance, the valves 56 used with particular devices 20 of embodiments of the present disclosure include valves manufactured and/or retailed by Qosina, examples of which are listed in Qosina's online catalogue, accessible at www.qosina.com (accessed: 03 February 2010).

In most embodiments, the device 20 includes at least one inlet 48 (e.g., fluid inlet). The at least one inlet 48 can be carried by the retention unit 26 (e.g., one or both of the first and second retention units 26a, 26b) and/or the chute 24, more specifically the channel 34 of the chute 24, of the device 20.

In some embodiments, the device 20 includes an inlet 48 that is carried by the first retention unit 26a. In other embodiments, the device 20 includes two inlets 48, wherein one inlet 48a is carried by the first retention unit 26a and the other inlet 48b is carried by the channel 34 of the chute 24. In various embodiments wherein the anchor portion 22 includes multiple retention units 26 (e.g., two, three, four, or more retention units 26), one or each of the multiple retention units 26, and/or the channel 34 of the chute 24, can carry an inlet 48.

In embodiments where the device 20 include more than one inlet 48, each inlet 48 can be shaped, dimensioned, and/or configured for facilitating or effectuating control of at least one of rate, pressure, and volume of fluid being introduced into one of the internal cavity 46a of the first retention unit 26a, the internal cavity 46b of the second retention unit 26b, and/or the passage 36 of the channel 34.

Aspects of Representative Sheaths Corresponding to Retention Unit Embodiments

As above-mentioned, in many embodiments of the present disclosure, the anchor portion 22 includes multiple retention units 26 (e.g., the first and second retention units 26a, 26b). In various embodiments, the device 20 includes a sheath 50 (also known as an interconnecting sheath) that is disposed between the multiple retention units 26 (e.g., between the first and second retention units 26a, 26b).

FIG. 10A to 10E show anchor portions 22 that include sheaths or interconnecting sheaths 50 of various shapes, sizes, and configurations as provided by various embodiments of the present disclosure.

For purposes of brevity and clarity, representative anchor portions 22 described below includes two retention units 26 (i.e., the first and second retention units 26a, 26b). Accordingly, the sheath 50 is disposed between the first and second retention units 26a, 26b. However, a person of ordinary skill in the art will understand that it is possible to adapt embodiments described below to accommodate anchor portions 22 that include more than two retention units 26 and sheaths 50 disposed between the more than two retention units 26 in accordance with the scope of the present disclosure.

In many embodiments of the present disclosure, the sheath 50 facilitates or effectuates interconnection between the first and second retention units 26a, 26b. In numerous embodiments, the sheath 50 is physically connected to each of the first and second retention units 26a, 26b. In other embodiments, the sheath 50 is indirectly coupled to the first retention unit 26a and/or the second retention unit 26b, for instance via interconnecting or linking structures, mechanisms, and/or means (e.g., adhesives, clasps, hooks, or stitches) (not shown).

In many embodiments, the thickness of the sheath 50 is between approximately 0.01mm and 10mm. In some embodiments, the thickness of the sheath 50 is between approximately 0.05mm and 5mm. In several embodiments, the thickness of the sheath 50 is between approximately 0.1mm and 1mm. In specific embodiments, the thickness of the

sheath 50 is approximately 0.1mm, 0.2mm, 0.3mm, 0.4mm, 0.5mm, 0.6mm, 0.7mm, and 0.8mm.

In most embodiments, a length of the sheath 50 (which can be defined as a distance between the first retention unit 26a and second retention unit 26b) can be selected and varied, for example, depending upon the dimensions or size of the pylorus. For example, in many embodiments, the length of the sheath 50 is between approximately 10mm and 1cm. In some embodiments, the length of the sheath 50 is between approximately 20mm and 100mm. In specific embodiments, the length of the sheath 50 is approximately 40mm, 50mm, 60mm, 70mm, or 80mm.

Aspects of Support Structures Carried By Or Coupled To Sheaths

As shown in FIG. 10D to FIG. 10E, FIG. 11A to FIG. 11C, and FIG. 12, the anchor portion 22 of devices 20 of several embodiments of the present disclosure includes a number of support structures 52, for example a network of support struts 52 or support wires 52. In some embodiments, the support structures 52 are carried by the sheath 50. In several embodiments, the support structures 52 are disposed within the thickness of the sheath 50. In other embodiments, the support structures 52 are coupled to a surface of the sheath 50.

In many embodiments, the support structures 52 are shaped, dimensioned, and/or configured for providing structural support to the anchor portion 22. In numerous embodiments, the support structures 52 are shaped, dimensioned, and/or configured to enhance retention of the anchor portion 22 at the pylorus (e.g., trans-pyloric retention of the anchor portion 22). In addition, in particular embodiments, the support structures 52, for example the network of support struts 52 as shown in FIG. 11A to FIG. 11C, can provide at least some self-expandable functionality to portion(s) of the anchor portion 22 to thereby facilitate placement and/or retention of the anchor portion 22 at or across the pylorus.

FIG. 11A to FIG. 11C show an anchor portion 22 comprising a network of support structures or struts 52, such as generally C-shaped support structures or struts 52, in accordance with particular embodiments of the present disclosure. Such struts 52 extend between or interconnect the first retention unit 26a and the second retention unit 26b and are configured to provide structural integrity, resilience, and/or strength to the anchor portion 22.

As shown in FIG. 11A to FIG. 11C, each curved end or terminal portion of a C-shaped strut 52 (i.e., each loop present at an opposite end or terminal portion of the C-shaped strut 52) is coupled to one of the first retention unit 26a and the second retention unit 26b. The C-shaped struts 52 can have atrumatic end or terminal portions. Such atrumatic end or terminal portions help to minimize or reduce the risk and/or occurrence of erosion or ulceration of the gastrointestinal mucosa during placement and retention of the anchor portion 22 at or across the pylorus. In several embodiments, the curved end or terminal portions (i.e., the loops) of the C-shaped struts 52 help to provide additional anchorage against the annular valve of the pylorus and additional radial flexibility against the peristaltic movement of the gastrointestinal walls. It will be understood that other shapes and/or configurations of struts 52 that are able to provide the same or substantially similar effects as compared to the C-shaped struts 52 are also included in the present disclosure.

FIG. 12 shows an anchor portion 22 that includes a corrugated portion or region 53. The corrugated portion 53 is located or positioned between the first retention unit 26a and the second retention unit 26b.

The corrugated portion 53 can be configured and/or constructed for accommodating peristaltic action associated with the pylorus. More specifically, the corrugated portion 53 is configured to facilitate or enable expansion and compression functionality (i.e., increase and decrease in distance) between the first retention unit 26a and the second retention unit 26b. In various embodiments, the flexibility afforded by corrugated portion 53 enables the anchor portion 22 to accommodate peristaltic action of the pylorus and hence enhance retention of the anchor portion 22 at or across the pylorus.

In some embodiments, the corrugated portion 53 is integrally formed with the network of support structures or struts 52 (e.g., the C-shaped struts 52). For example, the corrugated portion 53 can be integrated at a center or middle portion of the struts 52. In other embodiments, the corrugated portion 53 can be removably or reversibly coupled, inserted, or attached to the network of support structures or struts 52. As described above, the sheath 50 can carry or support the network of support structures or struts 52. Therefore, in several embodiments, the shape and/or configuration of the sheath 50 can conform to the shape and/or configuration (e.g., the corrugated configuration) of the corrugated portion 53.

In particular embodiments, the sheath 50 is configured and/or constructed to include the corrugated portion 53 between the first retention unit 26a and the second retention unit 26b. In other words, in particular embodiments, the corrugated portion 53 can be integrally formed with the sheath 50. Accordingly, in such embodiments, the network of support structures or struts 52 carried or supported by the sheath 50 can be shaped and/or configured to follow or substantially follow the shape (i.e., the corrugations) of the corrugated portion 53.

It will be understood that other forms of support structures 52 configured to provide the anchor portion 22 with a desired or target level of flexibility, resiliency, and/or strength are included within the scope of the present disclosure. In particular embodiments, the anchor portion 22 does not include, or does not require the use of, support structures 52 or can omit one or more types of support structures 52.

Fluid Communication Between Retention Units

As shown in FIG. 13, in various embodiments, the sheath 50 carries a linking or linkage passage 54 (also known as a linking or linkage channel, or a linking or linkage passageway) that is disposed between the first and second retention units 26a, 26b.

In several embodiments, the linking passage 54 fluidly interconnects the internal cavity 46a of the first retention unit 26a and the internal cavity 46b of the second retention unit 26a, 26b. This is to say, in several embodiments, the linking passage 54 enables fluid communication between the internal cavities 46a, 46b of the first and second retention units 26a, 26b.

In some embodiments, the internal cavity 46b of the second retention unit 26b is fluidly communicable with the passage 36 of the channel 34 that is carried by the chute 24. Accordingly, in some embodiments, fluid is communicable from the internal cavity 46b of the second retention 26b unit to the passage 36 of the channel 34 through the first opening 37 of the passage 36. In some embodiments, the internal cavity 46a of the first retention unit 26a is also fluidly communicable with the passage 36 of the channel 34 carried by the chute 24, for instance via the linking passage 54 and the internal cavity 46b of the second retention unit 26b.

In numerous embodiments, the device 20 includes a number of valves 56 positioned and/or configured for controlling fluid communication into, within, and/or between the internal cavity 46a of the first retention unit 26a, the internal cavity 46b of the second retention unit 26b, and/or the passage 36 of the channel 34.

For instance, as shown in FIG. 13, in some embodiments, the device 20 includes a first valve 56a coupled to the inlet 48 that is carried by the first retention unit 26a, the first valve 56a being configured for controlling fluid communication into the internal cavity 46a of the first retention unit 26a. In addition, the device 20 includes a second valve 56b positioned and/or configured to control fluid communication between the internal cavity 46a, 46b of the first and second retention units 26a, 26b.

As shown in FIG. 13, in certain embodiments, the device 20 further includes a third valve 56c positioned and/or configured to control fluid communication between the internal cavity 46b of the second retention unit 26b and the passage 36 of the channel 34. In some embodiments, the third valve 56c can be positioned at, or carried by, the channel 34.

In several embodiments, a valve 56 can be shaped, dimensioned, and/or configured for maintaining a selected pressure within at least one of the first retention unit 26a, the second retention unit 26b, and/or the passage 36. More specifically, in selected embodiments, a valve 56 is shaped and dimensioned to maintain or control pressure of fluid within the first retention unit 26a and/or the second retention unit 26b.

In many embodiments, each valve 56 is a one-way valve that is shaped, dimensioned, and/or configured to allow unidirectional flow of fluid in response to detection of a predetermined pressure and/or volume of fluid. For instance, the second valve 56b as shown in FIG. 13 can be a one-way valve that is shaped, dimensioned, and/or configured to allow unidirectional flow of fluid from the internal cavity 46a of the first retention unit 26a to the internal cavity 46b of the second retention unit 26b upon detection of a predetermined pressure and/or volume of fluid within the internal cavity 46a of the first retention unit 26a. Likewise, the third valve 56c as shown in FIG. 13 can be a one-way valve that is shaped, dimensioned, and/or configured to allow unidirectional flow of fluid from the internal cavity 46b of the second retention unit 26b to the passage 36 of the channel 34 upon detection of a predetermined pressure and/or volume of fluid within the internal cavity 46b of the second retention unit 26b.

As above-described, in many embodiments of the present disclosure, the introduction of fluid into the internal cavities 46a, 46b of the first and second retention units 26a, 26b by way of the fluid inlets 48 and corresponding valves 56 facilitates or effectuates inflation of the first and second retention units 26a, 26b from the compressed state to the inflated state. In many embodiments, the inflation of the first and second retention units 26a, 26b facilitates or effectuates the retention, more specifically trans-pyloric retention, of the anchor portion 22. In addition, the introduction and flow of fluid through passage 36 of the channel 34 effectuates longitudinal extension of the chute 24, and thereby inflation of the chute 24, as described in further detail hereinafter.

Extension, Expansion, or Inflation of Representative Chute Embodiments

The channel 34, more specifically the passage 36 of the channel 34, is shaped, dimensioned, and/or configured for facilitating the flow of fluid therethrough to thereby effectuate a longitudinal extension or expansion of the chute 24. In other words, in many embodiments, the channel 34, more specifically the passage 36 of the channel 34, is shaped, dimensioned, and/or configured for facilitating successful inflation of the chute 24.

FIG. 14A to 14E shows various representative configurations of the channel 34 as provided by various embodiments of the present disclosure.

In most embodiments, the size, diameter, length, configuration, shape, and/or number of channels 34 can be determined and varied, for instance in order to provide the chute 24 with particular characteristics and/or properties as provided by embodiments of the present disclosure. For example, in some embodiments, at least one of channel size, diameter, length, configuration, shape, and number is selected in order to achieve ease of inflation and/or a desired torque resistance of the chute 24. In addition, in various embodiments, at least one of the size, diameter, length, configuration, shape, and number of the channel 34 is selected in order to facilitate the longitudinal extension of the chute 24, and/or control of pressure of fluid flowing through the passage 36 of the channel 34.

As above-mentioned, in several embodiments, the channel 34 is carried or disposed along, or adjacent to, a wall 30, 32 of the chute 24. More specifically, in some embodiments, the channel 34 is disposed at least substantially between the inner and outer walls 30, 32 of the chute 24 (i.e., at least substantially within the thickness of the chute's walls).

In many embodiments, the diameter of the passage 36 of the channel 34 is between approximately 0.01mm and 5mm. In numerous embodiments, the diameter of the passage 36 of the channel 34 is between approximately 0.1mm and 2mm. In selected

embodiments, the diameter of the passage 36 of the channel 34 is approximately 0.5mm, 0.75mm, 1mm, 1.25mm, or 1.5mm.

In many embodiments, the diameter of the passage 36 of the channel 34 is uniform along the length thereof. Alternatively, the diameter of the passage 36 of the channel 34 is non-uniform along a length of the fluid channel 34. For example, the diameter of the passage 36 of the channel 34 can be smaller along a specified length (e.g., a first half) of the passage 36 of the channel 34 in order to promote a slower flow-rate of the fluid along said specified length of the passage 36 of the channel 34. By adjusting the diameter of the passage 36 of the channel 34, it can be possible to facilitate control of the rate of flow of fluid through the passage 36, pressure of fluid within the passage 36, torque/torsion resistance of the chute 34, and/or longitudinal extension of the chute 24.

In most embodiments, the length of the channel 34 is at least approximately 10cm. In many embodiments, the length of the channel 34 is at least approximately 20cm. In some embodiments, the length of the channel 34 is at least approximately 30cm. In selected embodiments, the length of the channel 34 is at least approximately 50cm, for instance approximately 60cm, 70cm, 80cm, or 100cm.

The length the channel 34 can be determined by the configuration of the channel 34. In addition, the length of the channel 34 can correspond to, or be correlated with, the length of the chute 24. Representative examples of configurations of the channel 34 are shown in FIG. 14A to 14E.

In some embodiments, the channel 34 is continuous (i.e., includes continuous channel portions). In other embodiments, the channel 34 includes multiple distinct or unconnected channel portions. For purposes of the present disclosure, each channel portion can be known, or referred to, as a channel 34. Therefore, chutes 24 of various embodiments of the present disclosure can be said to include one or more channels 34.

In some embodiments, for example as shown in FIG. 14A, the channel 34 has a spiral or zigzag configuration. In other embodiments, for example as shown in FIG. 14B, the channel 34 includes multiple (e.g., two) channels or channel portions 34, for instance a first channel 34a and a second channel 34b, which are generally parallel to each other.

In yet other embodiments, for example as shown in FIG. 14C, the channel 34 includes multiple (e.g., two) channels, for instance a first channel 34a and a second channel 34b, which are disposed in a generally criss-cross and/or overlapping configuration. Alternatively, as shown in FIG. 14D, the channel 34 can include multiple channels, for instance a first channel 34a, a second channel 34b, and a third channel 34c, which are disposed in a generally wave-like configuration.

In addition, FIG. 14E shows a channel 34 running in a parallel slanted direction or configuration along a length of the chute 24. In many embodiments, a wavelength or pitch of the channel 34 along the length of the chute 24 can be varied, for instance for providing particular characteristics or properties of the chute 24 (e.g., a particular torque resistance). For purposes of the present disclosure, the wavelength of the channel 34 can be regarded to be a distance between immediately adjacent sections or portions of, or points on, the channel 34 along a defined length of the chute 24.

In many embodiments, the wavelength or pitch of the channel 34 is between approximately 10mm and 750mm. In some embodiments, the wavelength or pitch of the channel 34 is between approximately 50mm and 500mm. In selected embodiments, the wavelength/pitch of the channel 34 is between approximately 100mm and 300mm, for example approximately 150mmm, 200mm, or 250mm.

Although specific configurations of the channel 34 are described above, a person skilled in the art, with the present disclosure, will understand that channels of alternative configurations are also included within scope of the present disclosure. For instance, channels including passages having a combination of zig-zag, wave-like, and parallel configurations are also included within the scope of the present disclosure.

Inflation via Fluid Communication in Representative Device Embodiments

Referring again to FIG. 13, FIG. 13 shows a representative device 20 as provided by an embodiment of the present disclosure.

The device 20 as shown in FIG. 13 includes the anchor portion 22 and the chute 24. The anchor portion 22 of the device 20 shown in FIG. 13 includes the first and second retention units 26a, 26b interconnected by the sheath 50. The chute 24 is coupled to the second retention unit 26b. The chute 24 includes the channel 34, which is disposed along, or adjacent to, the walls 30, 32 thereof. The first retention unit 26a can be positioned at the side of the pylorus that is proximal the stomach, and the second retention unit 26b can be positioned at the side of the pylorus that is proximal the duodenum, thereby facilitating or effectuating trans-pyloric retention of the anchor portion 22.

As shown in FIG. 13, the channel 34 is of a substantially spiral configuration. In addition, the device 20 of FIG. 13 includes the linking passage 54 disposed between the first and second retention units 26a, 26b for fluidly interconnecting the internal cavities 46a, 46b of the first and second retention units 26a, 26b. Furthermore, the passage 36 of the channel 34 is fluidly communicable with the internal cavity 46b of the second retention unit 26b, and correspondingly the internal cavity 46a of the first retention unit 26a via the linking passage 54.

The device 20 shown in FIG. 13 further includes an inlet 48 coupled to the first retention unit 26a, the inlet 48 being shaped, dimensioned, and/or configured for mediating fluid introduction into the first retention unit 26a. The device 20 further includes the first valve 56a carried by the first retention unit 26a and disposed at the inlet 48 for controlling at least one of rate, pressure, and/or volume of fluid being introduced into the internal cavity 46a of the first retention unit 26a.

The device 20 also includes the second valve 56b carried by the second retention unit 26b and disposed between the internal cavity 46b of the second retention unit 26b and the

passage 36 of the channel 34 for controlling fluid communication (e.g., rate, pressure, and/or volume of fluid) from the internal cavity 46b of the second retention unit 26b to the passage 36 of the channel 34.

In many embodiments, fluid introduced into the internal cavity 46a of the first retention unit 26a via the inlet 48 shown in FIG. 13 flows therefrom into the internal cavity 46b of the second retention unit 26b via the linking passage 54. In many embodiments, the fluid subsequently flows from the internal cavity 46b of the second retention unit 26b into the passage 36 of the channel 34. In numerous embodiments, the third valve 56c positioned between the internal cavity 46b of the second retention unit 26b and the passage 36 of the channel 34 is configured for allowing uni-directional flow of fluid from the internal cavity 46b of the second retention unit 26b to the passage 36 of the channel 34 in response to or upon detection of a pre-determined pressure and/or volume of fluid within the internal cavity 46b of the second retention unit 26b.

In most embodiments, flow of fluid (e.g., inflation medium or inflation fluid) through the passage 36 of the channel 34 (e.g., from the first opening to the second opening of the channel) effectuates longitudinal extension of the chute 24, and accordingly deployment of the chute 24 from a compressed state to an elongated or inflated state. The deployment or inflation of the chute 24 disposes the walls 30, 32 of the chute 24 along the walls of the duodenum and/or jejunum.

In most embodiments of the present disclosure, the walls 30, 32 of the chute 24 are shaped, dimensioned, configured, and/or designed for at least partially impeding movement of matter thereacross. For instance, in many embodiments, at least one of length, porosity, and/or thickness of the walls 30, 32 of the chute 24 is selected for at least partially impeding movement of ingested matter present within the lumen 28 of the chute 24 across the walls 30, 32 of the chute 24.

Accordingly, in many embodiments of the present disclosure, the deployment or inflation of the chute 24 within the duodenum facilitates or effectuates modification in the

absorption pattern of ingested matter (e.g., solid, semi-solid, and/or liquid food matter) by the walls of the duodenum. In numerous embodiments, the deployment of the chute 24 within the duodenum facilitates or effectuates a reduction in quantity of ingested matter (e.g., solid, semi-solid, and/or liquid food matter) being absorbed by the walls of the duodenum.

In many embodiments of the present disclosure, the modification in the absorption pattern of ingested matter (e.g., solid, semi-solid, and/or liquid food matter) by the intestinal walls (e.g., duodenal walls), more specifically the reduction in the quantity of ingested matter being absorbed by the intestinal walls, can help to prevent, combat, cure, and/or alleviate obesity. In several embodiments, the modification in the absorption pattern of ingested matter (e.g., solid, semi-solid, and/or liquid food matter) by the intestinal walls (e.g., duodenal walls), more specifically the reduction in the quantity of ingested matter being absorbed by the intestinal walls, can help to to prevent, combat, cure, and/or alleviate metabolic-type conditions or disorders, for instance Type II Diabetes. Accordingly, the use of the device 20 provided by many embodiments of the present disclosure facilitates or effectuates the combat, prevention, cure, and/or alleviation of obesity when the device 20 is implanted, positioned, retained, anchored, and/or secured within the gastrointestinal tract (e.g., at the pylorus) of the patient.

Devices 20 provided by embodiments of the present disclosure can be used in association with management and/or treatment of physiological conditions involving the body's digestive system (or gastrointestinal system) and/or metabolic systems. For instance, in selected embodiments, the device 20 can be used for managing or treating obesity and/or diabetes. In addition, in specific embodiments, the device 20 can be used together with other devices, methods, or techniques known in art for managing or treating physiological conditions involving the body's digestive system, for example obesity and diabetes.

In most embodiments of the present disclosure, function or use of the device 20 requires inflation of the retention units 26 (e.g., the first and second retention units 26a, 26b)

and/or the chute 24. In many embodiments, fluid (also known as inflation fluid or inflation medium) is used for inflating the retention units 26 and/or the chute 24.

In many embodiments of the present disclosure, fluid is introduced into the internal cavities 46a, 46b of first and second retention units 26a, 26b and/or the passage 36 of the channel 34 using a fluid delivery tube 60 (also known as an inflation tube or an inflation device). The fluid delivery tube 60 conveys the fluid or inflation medium from a source of fluid, which is typically disposed outside the body of the patient, to the device 20, more specifically the internal cavities 46a, 46b of first and second retention units 26a, 26b and/or the passage 36 of the channel 34, which is retained within the gastrointestinal tract (e.g., at the pylorus).

In many embodiments, the fluid delivery tube 60 is coupled or attached to the inlet 48 before mediating introduction of the fluid into the internal cavities 46a, 46b of first and second retention units 26a, 26b and/or the passage 36 of the channel 34.

In most embodiments, the inlet 48 is designed and/or configured to support docking or coupling with the fluid delivery tube 60. For instance, in some embodiments, the inlet 48 is shaped and/or configured for fit coupling to the fluid delivery tube 60, more specifically an end of the fluid delivery tube 60.

In some embodiments, the inlet 48 is designed and/or configured to support a luer-type, or generally luer-like, docking, connection, or coupling with the fluid delivery tube 60. In selected embodiments, the inlet 48 is designed and/or configured for supporting magnetic luer-type docking, connection, or coupling with the fluid delivery tube 60.

Brief Overview of Luer-Type Connection

Luer-type connection, commonly known as luer locking or luer lock fitting, provides leak-proof connections or coupling. Luer locks typically include two components or parts, namely a first or male component and a second or female component, which can be coupled or connected together in a luer-type connection.

One component, for instance the male component, has a relatively fixed position, and the other component, for instance the female component, is rotatable to be fitted, connected, or coupled to the male component. Typically the male component includes a docking station, for instance a passage, opening, or hole, said docking station including a threaded portion to which at least a portion of the rotatable female component can be coupled, attached, or fitted to (the threaded portion also referable to as a receiving portion or receiver). The rotatable female component includes an inner tube or channel through which fluid flows. This tube includes an attachment structure or tab, which can be fitted into the docking station of the male component.

When the female component is rotated relative the male component, the attachment structure of the female component enters, and hence couples with, the docking station of the make component. A portion of the attachment structure also interlocks with the threaded portion of the male component to thereby provide a substantially liquid-tight seal between the male and female components.

A magnetic luer lock (or magnetic luer-type connection) operates or functions by applying the basic principle of the luer-type connection. However the magnetic luer lock includes an embedded magnet in each of the male and female components, the embedded magnets facilitating or effectuating the coupling or attachment between the male and female components. The use of magnetic fields helps in the fitting of the attachment structure the rotatable female component within the receiver formed on the male component.

Aspects of Representative Docking Embodiments

FIG. 15A and FIG. 15B show representative diagrams of docking or coupling structures (e.g., magnetic docking or coupling) between a fluid delivery tube 60, more specifically an end of the fluid delivery tube 60, and an inlet 48 of the device 20 in accordance with various embodiments of the present disclosure.

As shown in FIG.15A and FIG. 15B, in many embodiments, the inlet 48 includes a docking station, slot, or groove 64 for receiving a docking or attachment tab 66 carried by the fluid delivery tube 60. In numerous embodiments, the docking tab 66 refers to a tab or structure that protrudes from a surface of the fluid delivery tube 60.

In several embodiments, the docking station 64 includes a receiving cavity or channel 68, in which the docking tab 66 can be accommodated. This is to say, the receiving cavity 68 of the inlet 48 is shaped and dimensioned for facilitating or enabling fit-coupling with the docking tab 66 of the fluid delivery tube 60.

In various embodiments, the docking station 64 and the docking tab 66 each include a magnet 70 for facilitating and/or enhancing the docking or coupling of the fluid delivery tube 60 to the inlet 48, more specifically to the docking station 64 of the inlet 48. More specifically, the magnet 70a of the docking station 64 attracts the magnet 70b of the docking tab 66 for enhancing the docking or coupling of the fluid delivery tube 60 to the inlet 48.

FIG. 16 shows a representative diagram of electromagnetic docking or coupling between a fluid delivery tube 60 and an inlet 48 of the device 20 in accordance with various embodiments of the present disclosure.

As shown in FIG. 16, in some embodiments, the inlet 48 includes a ring 72 that includes a metal or metal composition, for instance at least one of nickel, iron, and cobalt. In several embodiments, the ring 72 is embedded within a polymer tubing (not shown) of the inlet. In some embodiments, the ring 72 is carried along a wall of the inlet 48.

In several embodiments, the inlet 48 further includes an outer collar or retaining structure 73 that is shaped and dimensioned for receiving and/or accommodating at least a portion of the fluid delivery tube 60. In some embodiments, fitting of at least a portion of the fluid delivery tube 60 within the retaining structure 73 facilitates accurate positioning and/or docking of the fluid delivery tube 60 with the inlet 48.

In addition, as shown in FIG. 16, the fluid delivery tube 60, more specifically an end of the fluid delivery tube 60, includes an electromagnet 74. Typically, an electromagnet includes a coil of wire, which acts as a magnet when an electric current passes through it, but stops acting as a magnet in the absence of electric current flow through it. An electromagnet is commonly wrapped or coiled around a core of ferromagnetic material, for example steel, which enhances the magnetic field produced by the coil.

The electromagnet 74 of various embodiments of the present disclosure includes an iron ring 76 and a coil of wire 78 (e.g., copper wire) disposed around the iron ring 76. In several embodiments, the electromagnet 74, or at least a portion thereof, is embedded within, or carried by, a portion of a wall 76 of the fluid delivery tube 60. In various embodiments, the electromagnet 74, or at least a portion thereof, is embedded within a polymer tubing (not shown) carried by the fluid delivery tube 60.

The wire 78 can be connected to an electrical source (not shown). When an electric current is passed through the wire 78 (i.e., when the electromagnet 74 is at an "on" state), an electromagnetic force of attraction is created between the fluid delivery tube 60, more specifically the electromagnet 74 carried by an end of the fluid delivery tube 60, and the inlet 48, more specifically the ring 72 of the inlet 48. The electromagnetic force of attraction between the fluid delivery tube 60 and the inlet 48 facilitates docking or coupling of the fluid delivery tube 60 to the inlet 48. When there is no electric current passing through the wire 78 (i.e., when the electromagnet 74 is in an "off" state), there exist no electromagnetic field, and hence no electromagnetic force of attraction between the fluid delivery tube 60, more specifically the electromagnet 74 carried by an end of the fluid delivery tube 60, and the inlet 48, more specifically the ring 72 of the inlet 48.

Fluid Delivery Using Representative Fluid Delivery Tubes

FIG. 17A to FIG. 17D show the coupling of representative fluid delivery tubes 60 of various designs to several devices 20 for facilitating or effectuating the inflating the

retention unit(s) 26 and/or the chute 24 in accordance with various embodiments of the present disclosure.

Fluid delivery tubes 60 of various designs and/or configurations can be used for introducing fluid into the internal cavities 46a, 46b of the first and second retention units 26a, 26b, and/or the passage 36 of the channel 34, of devices 20. For instance, the design and/or configuration of the fluid delivery tube 60 can be dependent upon the number and/or position of the inlet(s) 48 of the particular device 20. The introduction of fluid into the internal cavities 46a, 46b of the first and second retention units 26a, 26b facilitates or effectuates inflation of the first and second retention units 26a, 26b, and the introduction of fluid into the passage 36 of the channel 34 facilitates or effectuates inflation of the chute 24.

In some embodiments where the device 20 includes multiple inlets 48, for instance, one inlet 48 carried by the first retention unit 26a and another inlet 48 carried by the channel 34 of the chute 24, one fluid delivery tube 60 can be consecutively coupled to each of the multiple inlets 48 for consecutively introducing fluid into the device 20, for instance, the internal cavity 46a of the first retention unit 26a and the passage 36 of the channel 34 respectively. Alternatively, where the device 20 includes multiple inlets 48, either multiple fluid delivery tubes 60 or a single fluid delivery tube 60 with multiple fluid outlets 62 can be used for simultaneously introducing fluid at different locations of the device 20.

In many embodiments, the position of the inlet 48 on the device 20, for example on the first retention unit 26a, the second retention unit 26b, and/or the channel 34 of the chute 24, can be determined for facilitating access thereof to the fluid delivery tube 60. This is to say, the position of the inlet 48 on the device 20 can be determined for facilitating coupling or attachment to the fluid delivery tube 60.

In several embodiments of the present disclosure, for instance as shown in FIG. 17A, the fluid delivery tube 60 is a substantially straight tube that is couplable to the inlet 48

carried by the first retention unit 26a. In the embodiment as shown in FIG. 17A, the fluid delivery tube 60 mediates introduction of fluid into the internal cavity 46a of the first retention unit 26a. Fluid introduced into the internal cavity 46a of the first retention unit 26a flows to the internal cavity 46b of the second retention unit 26b via the linking passage 54, before subsequently flowing into the passage 36 of the channel 34.

In addition, as shown in FIG. 17A, a valve 56 is positioned at the inlet 48 carried by the first retention unit 26a for facilitating or effectuating control of fluid introduction (e.g., rate and/or volume of fluid introduction) into the internal cavity 46a of the first retention unit 26a. In some embodiments, another valve 56 can be positioned between the internal cavity 46b of the second retention unit 26b and the passage 36 of the channel 34 to thereby control fluid communication therebetween.

In some embodiments of the present disclosure, for instance as shown in FIG. 17B, the fluid delivery tube 60 has a forked or branched configuration at an end portion thereof. More specifically, the fluid delivery tube 60 as shown in FIG. 17B branches at the end portion thereof to provide two fluid outlets (or outlet channels) 62. The two fluid outlets 62 can be coupled to two inlets 48 carried by the device 20. More specifically, a first fluid outlet 62a can be coupled to one inlet 48 that is carried by the first retention unit 26a for introducing fluid into the internal cavity 46a of the first retention unit 26a, and a second fluid outlet 62b can be coupled to the another inlet 48 that is carried by the channel 36 of the chute 34 for introducing fluid into the passage 36 of the channel 34.

In addition, valves 56 can be positioned at each of the two inlets 48 to thereby facilitate or effectuate control of fluid introduction (e.g., rate and/or volume of fluid introduction) into the internal cavity 46a of the first retention unit 26a as well as the passage 36 of the channel 34.

In various embodiments of the present disclosure, for instance as shown in FIG. 17C, multiple (e.g. two) fluid delivery tubes 60 can be used for introducing fluid into the internal cavities 46a, 46b of first and second retention units 26a, 26b and/or passage 36 of

the channel 34. More specifically, a first fluid delivery tube 60a can be coupled to one inlet 48 carried by the first retention unit 26a for introducing fluid into the internal cavity 46a of the first retention unit 26a and a second fluid delivery tube 60b can be simultaneously, or consecutively, coupled to another inlet 48 carried by the channel 34 for introducing fluid into the passage 36 of the channel 34.

In addition, valves 56 can be positioned at, or carried by, the two inlets 48 to thereby facilitate or effectuate control of fluid introduction (e.g., rate and/or volume of fluid introduction) into the internal cavity 46a of the first retention unit 26a as well as the passage 36 of the channel 34.

In some embodiments of the present disclosure, for example as shown in FIG. 17D, the device 20 can further include a fluid tube 57 (also known as a fluid passage, channel, and/or link) that is specifically designed and/or configured to fluidly inter-connect the passage 36 directly with an inlet 48 that is positioned at the first retention unit 26a. In several embodiments, the fluid tube 57 is configured to bypass the internal cavities 46 of the retention units 26. Accordingly, a fluid delivery tube 60 can be coupled to the inlet 48 positioned at the first retention unit 26a for delivering or introducing fluid directly into the passage 36 of the channel 34. A valve 56 can be coupled to the inlet 48 for controlling the introduction of fluid (e.g., rate and/or volume of fluid) into the fluid tube 57, and subsequently into the passage 36 of the channel 34.

In the embodiment as shown in FIG. 17D, a same or different fluid delivery tube 60 can be used to introduce fluid into the internal cavity 46a of the first retention unit 26a through another inlet 48 that is also carried by the first retention unit 26a. Fluid introduced into the internal cavity 46a of the first retention unit 26a flows to the internal cavity 46b of the second retention unit 26b via the linking passage 54. In addition, a valve 56 can be positioned between the internal cavity 46b of the second retention unit 26b and the passage 36 of the channel 34 for controlling fluid communication therebetween.

Representative System Embodiments and Aspect(s) of System Embodiments

In many embodiments of the present disclosure, each of the device 20 and the fluid delivery tube(s) 60 form a part of a system for placing, positioning, retaining, anchoring, and/or securing the device 20 within the gastrointestinal tract (e.g., at the pylorus) as provided by the present disclosure.

FIG. 18A shows a schematic of a representative system 100 for placing, positioning, retaining, anchoring, and/or securing the device 20 within the gastrointestinal tract (e.g., at the pylorus) in accordance with several embodiments of the present disclosure.

In many embodiments, the system 100 includes the device 20, the fluid delivery apparatus or tube(s) 60, a delivery sheath 110, and a stabilizer or plunger 120. The delivery sheath 110 can be configured to carry or enclose portions of the device 20, the fluid delivery tube(s) 60, and the stabilizer 120. Additionally or alternatively, the system 100 can further include a guidance or guiding mechanism for guiding at least part of the system 100, for example the device 20, into or through portions of the gastrointestinal tract, as further detailed below.

The system 100 is typically introduced into the body, more specifically the gastrointestinal tract, of a patient via an oral-esophageal insertion (e.g., in association with a gastroesophageal endoscopy procedure). The delivery sheath 110 can be shaped and dimensioned in accordance with an expected size or diameter of a patient's esophagus, such that the delivery sheath 110 and the elements or structures carried therewithin can be inserted in a manner that avoids significant esophageal distortion. That is, the delivery sheath 110 can have a diameter or cross sectional area that is at least somewhat smaller than an expected cross sectional area of the patient's esophagus.

In some embodiments, the delivery sheath 110 has a diameter between approximately 5mm and 30mm. In various embodiments, the delivery sheath 110 has a diameter between approximately 10mm and 20mm, for instance approximately 12mm, 14mm, 16mm, or 18mm. In some embodiments, the delivery sheath 110 has a length between

approximately 0.8m and 2.0m. In various embodiments, the delivery sheath has a length between approximately 1.0m and 1.8m, for instance 1.2m, 1.3m, 1.4m, 1.5m, 1.6m, or 1.75m.

The delivery sheath 110 can be shaped, dimensioned, and/or configured for facilitating the maintenance of the device 20 carried therewithin in the compressed state. In many embodiments, the delivery sheath 110 is transparent or at least somewhat transluscent. In addition, in many embodiments, the delivery sheath 110 is made of a biocompatible, and/or waterproof material. Furthermore, in numerous embodiments, the delivery sheath 110 at least substantially flexible and/or soft.

In most embodiments, the device 20, more specifically at least the anchor portion 22 (e.g., the first and second retention units 26a, 26b) and the chute 24 of the device 20, are in a compressed, collapsed, folded, and/or bundled state during the introduction or insertion of the device 20 into the gastrointestinal tract of the patient. For instance, the device 20 can be compressed such that it is at least substantially encased, or carried, within the delivery sheath 110 during displacement of the device 20 through the gastrointestinal tract towards the pylorus. More specifically at least the anchor portion 22 and/or the chute 24 of the device 20, are longitudinally and/or radially compacted during displacement thereof through the gastrointestinal tract towards a target site or target anatomical location (e.g., a target site for retaining the anchor portion 22). In other words, in several embodiments, the device 20, more specifically at least the anchor portion 22 and/or the chute 24 of the device 20, exist in a compressed state during introduction into the body and/or displacement thereof through portions of the gastrointestinal tract towards a target site or target anatomical location (e.g., a target anatomical site for retaining the anchor portion 22).

In several embodiments, the stabilizer 120 is couplable to the delivery sheath 110. In numerous embodiments, the stabilizer 120 is shaped, dimensioned, and/or configured to facilitate displacement of the device 20 through the gastrointestinal tract. This is to say, in numerous embodiments, the stabilizer 120 facilitates placement of the device 20 within

the gastrointestinal tract (e.g., at the pylorus). In various embodiments, the stabilizer 120 is shaped, dimensioned, and/or configured to help to maintain a position of the device 20 within the gastrointestinal tract (e.g., at the pylorus), for instance during inflation of the retention unit(s) 26 and/or the chute 24, and/or during a removal of the device 20 from the delivery sheath 110.

In many embodiments, the fluid delivery tube 60 is coupled to the inlet 48 for introducing fluid into the internal cavity 46 of the retention unit 26 and/or the passage 36 of the channel 34. As previously mentioned, the introduction of fluid into the internal cavity 46 of the retention unit 26 facilitates or effectuates inflation of the retention unit 26 from the compressed state to the inflated state, and the introduction of fluid into the passage 36 of the channel 34 facilitates or effectuates longitudinal extension of the chute 24 to thereby inflate the chute 24.

For purposes of the present disclosure, the inflation of the retention units 26 (e.g., the first and second retention units 26a, 26b) and the chute 24 can be collectively referred to as an inflation of the device 20.

In most embodiments, the inflation of one or more portions of the device 20 occurs after the device 20, more specifically the anchor portion 22 of the device 20, is positioned or placed at the target anatomical site (or target site). For instance, in many embodiments, the inflation of the device 20 occurs after one or more elements of the anchor portion 22 are positioned at the pylorus. In numerous embodiments, the inflation of the chute 24 occurs after the anchor portion 22 is retained in the trans-pyloric configuration.

In several embodiments, the system 100 includes a set of visual indicators or markers (or position markers) (not shown) for facilitating determination of the position of the device 20 (e.g., the anchor portion 22 of the device 20) within the gastrointestinal tract. In various embodiments, the set of markers is colored, or otherwise shaped or constructed, for enhancing ease of locating the set of markers within the gastrointestinal tract. In numerous embodiments, the set of markers includes a first marker, which is carried by

the first retention unit 26a, and a second marker, which is carried by the second retention unit 26b. In other embodiments, the set of markers can include at least one marker that is carried by the chute 24.

The ability to determine or verify the position of the device 20 within the gastrointestinal tract facilitates accurate positioning of the device 20 within the gastrointestinal tract (e.g., at the pylorus). For instance, the ability to determine the position of the anchor portion 22 facilitates accurate trans-pyloric retention of the anchor portion 22, thereby enabling enhanced (e.g., securer) retention of the device 20 within the gastrointestinal tract.

For purpose of the present disclosure, the target site for retaining one or more elements of the anchor portion 22 can be at the pylorus. However, a person of ordinary skill in the art, with the present disclosure, will understand that the target site can include other anatomical sites along the gastrointestinal tract.

In a number of embodiments involving a delivery sheath 110, the device 20 can be significantly compressed, compacted, folded, and/or bundled both a) longitudinally or lengthwise, as well as b) transversely or radially such that the device 20 occupies a generally small, small, or very small volume within the delivery sheath 110 in order to aid the introduction or insertion of the device 20 into the body. As described in detail hereafter, in certain embodiments, such as embodiments involving particular types of guidance mechanisms or elements, a device 20 can be compressed or compacted primarily with respect to its radial or transverse extent, and possibly compacted at least somewhat with respect to its longitudinal or lengthwise extent, to facilitate the introduction of the device 20 into the patient's body.

FIG. 18B and FIG. 18C show an aspect of a representative system 100 that includes a wire 130, for example a guide wire, in accordance with various embodiments of the disclosure. In some embodiments, the wire 130 facilitates insertion of the device 20 into the body and/or displacement of the device 20 through at least a portion of the gastrointestinal tract. More particularly, the wire 130 carries portions of the device 20

during insertion or deployment of the device 20 into the body and/or displacement of the device 20 through at least a portion of the gastrointestinal tract.

In several embodiments, the device 20 is encased, or substantially disposed, between an inner sheath (also known as an inner tube or inner tubing) 112 and an outer sheath 114 (also known as an outer tube or outer tubing). A separation between the inner sheath 112 and the outer sheath 114 define or determine an extent to which the device 20 is radially compressed. In a representative implementation, the separation between the inner and outer sheaths 112, 114 can be between approximately 5mm and 20mm. In selected embodiments, the separation between the inner and outer sheaths 112, 114 can be between approximately 9mm and 19mm, for instance approximately 10mm, 12mm, 14mm, 16mm, or 18mm. In some embodiments, this can facilitate a radial compression of the device 20 of between approximately 15% and 95%. In various embodiments, this can facilitate a radial compression of the device 20 of between approximately 20% and 80%, for instance approximately 30%, 40%, 50%, 60%, and 70%.

The device 20 can be longitudinally wrapped or coiled around the inner sheath 112 in a curvilinear, serpentine, or spiral manner, such that the length of the device's chute 24 progressively coils along and around a length of inner sheath 112. In such a serpentine configuration, portions of the chute 24 can overlap to a certain degree, depending upon embodiment details.

An extent to which the chute 24 is longitudinally compacted as a result of its progressive coiling around and along a length of the inner sheath 112 can be approximately 0% or more. In many embodiments, an extent to which the chute 24 is longitudinally compacted as a result of its progressive coiling around and along a length of the inner sheath 112 can be between approximately 5% and 95%, for instance approximately 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, or 90%.

As previously indicated, the device's chute 24 can be encased between the inner and outer sheaths 112, 114. Additionally, in several embodiments, portions of the device's

anchor portion 26 can be carried between the inner and outer sheaths 112, 114. In certain embodiments, the diameter or cross sectional area of the inner and outer sheaths 112, 114 can be constant, or longitudinally vary depending upon which portion of the device 20 (e.g., the chute 24 or the anchor portion 26) is encased.

As further detailed below, the wire 130 can be inserted into a patient's body, such that an end 132 of the wire resides at or approximately at a target or expected distal anatomical location. The target distal anatomical location can be a given distance into the small intestine, for instance, a distance at, near, or generally near which a terminal portion of the chute 24, such as the terminal end of the chute 24 distal to the anchor portion 22 or the end 38 of the chute's channel 34, is intended to reside following deployment of the device 20 (e.g., at a given or expected distance away from the pylorus in the duodenum or jejunum).

When disposed between the inner and outer sheaths 112, 114, the encased device 20 can be slidably inserted along the wire 130 into the patient's body, toward and to the end 132 of the wire 130 and the target anatomical site. The inner sheath 112 has a diameter or cross sectional area that is at least slightly larger than that of the wire 130. Additionally, the inner sheath 112 generally be composed of a smooth or low friction material (e.g., Silicone) to facilitate smooth movement of the inner sheath 112 along a length of the wire 130.

In many embodiments, maintenance of the device 20 in a radially and/or longitudinally compressed state can facilitate or aid the displacement of the device 20 through the gastrointestinal tract towards the target site, more specifically the pylorus.

<u>Representative Process, and Aspects Thereof, for Positioning and Retaining Device Embodiments Within the Gastrointestinal Tract</u>

FIG. 19A and FIG. 19B show a flowchart of a representative process 200 for positioning, retaining, anchoring, and/or securing the device 20 within the gastrointestinal tract as provided by several embodiments of the present disclosure. In addition, a representative

set of figures illustrating various process portions, or aspects, of the process 200 is also provided by FIG. 20A to FIG. 20C. Furthermore, FIG. 21A to FIG. 21C show the device 20 at various durations, or at various process portions, of the process 200.

In a first process portion 205, the device 20 is introduced into the gastrointestinal tract of the patient. In most embodiments, the device 20 is introduced into the gastrointestinal tract of the patient via the oral-esophageal route. In many embodiments, the device 20 is at least substantially encased within the delivery sheath 110 during the introduction of the device 20 into the gastrointestinal tract.

In a second process portion 210, the device 20 is maneuvered or displaced through the gastrointestinal tract towards the target site or target anatomical site. In most embodiments, the target site is at the pylorus. In many embodiments, the target site is trans-pyloric. In many embodiments, the device 20 is maneuvered through the gastrointestinal tract and placed at the pylorus using endoscopic guidance (e.g., in association with a gastroesophageal endoscopy procedure). In several embodiments, the stabilizer 120 is used for facilitating the maneuvering of the device 20 through the gastrointestinal tract.

In most embodiments, the device 20 is at least one of longitudinally and radially compacted during its introduction into the gastrointestinal tract and its displacement through the gastrointestinal tract to the pylorus. In some embodiments, device 20 is in the compressed or collapsed state during its introduction into the gastrointestinal tract and its displacement through the gastrointestinal tract to the pylorus.

The maintenance of the device 20 at the compressed state facilitates the introduction of the device 20 into the gastrointestinal tract. In addition, maintaining the device 20 at the compressed state facilitates the maneuvering of the device 20 through the gastrointestinal tract. The device 20 when at the compressed state has a shorter length and/or smaller width (or diameter).

In numerous embodiments, at least the external surfaces of the delivery sheath 110 include a lubricious material or composition to reduce friction between the delivery sheath 110 and the gastrointestinal walls. A representative lubricious material or composition is polyvinvylpurrolidone (PVP). However, a person of ordinary skill in the art will appreciate that other lubricious material known in the art can alternatively be included, applied, or used to reduce friction between the delivery sheath 110 and other surfaces (e.g., gastrointestinal walls) within the scope of the present disclosure.

In a third process portion 215, the anchor portion 22, more specifically the first and second retention units 26a, 26b, are placed or positioned in the trans-pyloric configuration. This is to say, in many embodiments, the first retention unit 26a is placed at the first side of the pylorus that is proximal (e.g., facing) the stomach and the second retention unit 26b is placed at the second side of the pylorus that is proximal (e.g., facing) the duodenum.

A fourth process portion 220 involves a determination and/or verification of position of the device 20, more specifically the anchor portion 22 of the device 20, at, or across, the pylorus. In most embodiments, the fourth process portion 220 involves determination of trans-pyloric positioning or placement of the anchor portion 22.

As previously described, the system 100 includes the set of markers for facilitating the determination of the position of the anchor portion 22. In many embodiments, the markers are endoscopically visible markers. For instance, as described above, the set of markers provided by many embodiments of the present disclosure includes colored markers carried by the first and second retention units 26a, 26b to aid or enable visual determination of the position of the anchor portion 22. Alternatively, or additionally, in various embodiments, the set of markers are radio-opaque markers. The position of such radio-opaque markers can be determined with the use of X-ray.

The ability to determine or verify the position of the anchor portion 22 (e.g., trans-pyloric configuration of the anchor portion 22), ensures that any inflation of the device 20 occurs

subsequent an accurate placement of the anchor portion 22 (e.g., trans-pyloric placement of the anchor portion 22).

If it is determined that the anchor portion 22 is not positioned in a desired position (e.g., trans-pyloric position), a readjustment of the position or placement of the anchor portion 22, and hence the device 20, can be performed in a fifth process portion 225.

Upon verification that the anchor portion 22 has been accurately positioned or placed, for instance in the trans-pyloric configuration, the delivery sheath 110 is then removed from gastrointestinal tract in a sixth process portion 230. The device 20, which is encased within the delivery sheath 110 during the process portions 205 to 225, is removed from the delivery sheath 110 in the sixth process portion 230.

In several embodiments, the stabilizer 120 is used for maintaining the position of the device 20 during the removal of the delivery sheath 110 from the gastrointestinal tract. In some embodiments, the stabilizer 120 is used for maintaining the anchor portion 22 in the trans-pyloric configuration during the removal of the delivery sheath 110 from the gastrointestinal tract.

In most embodiments, the device 20 is removed from within the delivery sheath 110 prior to inflation of the device 20. This is to say, in most embodiments, the delivery sheath 110 is removed from the gastrointestinal tract before fluid is introduced into the internal cavity 46 of the retention unit 26 and/or the passage 36 of the channel 34 of the device 20.

In most embodiments, the stabilizer 120 is removed from the gastrointestinal tract in a seventh process portion 235 subsequent the removal of the delivery sheath 110 from the gastrointestinal tract.

In most embodiments, fluid is introduced into the internal cavity 46 of the retention unit 26 and/or the passage 36 of the channel 34 by way of the fluid delivery tube 60. In

several embodiments, the fluid delivery tube 60 is coupled to the inlet 48 prior to the introduction of the device 20 into the gastrointestinal tract in the process portion 205, and remains coupled to the inlet 48 during each of process portions 210 to 235. However in some embodiments, the fluid delivery tube 60 is coupled or attached to the inlet 48 after introduction of the device 20 into the gastrointestinal tract, for instance during, or after, one of process portions 210 to 235. In several embodiments, the fluid delivery tube 60 is coupled to the inlet 48 after determination or verification of the trans-pyloric placement of the anchor portion 22.

An eighth process portion 240 involves docking, coupling, or attachment of the fluid delivery tube 60 to the inlet 48. As previously described, fluid delivery tubes 60 of several designs and/or configurations can be coupled to one or more inlets 48, either simultaneously or consecutively, within the scope of the present disclosure.

For instance, in embodiments wherein the device 20 includes an inlet 48 carried by the first retention unit 26a, the eighth process portion 240 can involve the docking or coupling of one fluid delivery tube 60 to said inlet 48 carried by the first retention unit 26a. Alternatively, in embodiments wherein the device 20 includes additional inlets 48, the eighth process portion 240 can involve docking or coupling of at least one fluid delivery tube 60 (which can include multiple fluid outlets 62) to said multiple inlets 48, either simultaneously or consecutively. For example, in some embodiments, the eighth process portion 240 involves the docking or coupling of one fluid delivery tube 60, the fluid delivery tube 60 including two fluid outlets 62, to two inlets 48 simultaneously, wherein one inlet 48 is carried by the first retention unit 26a and the other inlet 48 is carried by the channel 34 of the chute 24.

In many embodiments, the docking or coupling of the fluid delivery tube 60 to the inlet 48 can be via a luer-type connection. In several embodiments, the attachment of the fluid delivery tube 60 to the inlet 48 can be via a magnetic luer-type connection. In numerous embodiments, the use of the luer-type connection (e.g., magnetic luer-type connection)

facilitates enhanced docking or coupling (e.g., faster and/or easier coupling, and/or a securer or tighter coupling) of the fluid delivery tube 60 to the inlet 48.

In a ninth process portion 245, fluid (e.g., inflation medium or inflation fluid) is introduced into the internal cavities 46 of the retention units 26 and/or the passage 36 of the channel 34 by way of the fluid delivery tube 60. The introduction of fluid into the internal cavities 46 of the retention units 26 and/or passage 36 of the channel 34 facilitates or effectuates inflation of the retention units 26 and/or chute 24 respectively in a tenth process portion 250. This is to say, fluid flow within the internal cavities 46 of the retention units 26 and/or passage 36 of the channel 34 facilitates or effectuates inflation of the retention units 26 and/or chute 24 respectively in a tenth process portion 250.

In several embodiments, fluid is introduced via only one inlet 48, for example the inlet 48 carried by the first retention unit 26a. In most embodiments wherein the fluid is introduced through only one inlet 48, the inflation of the device 20 can be described as progressive. More specifically, the fluid first effects the inflation of the first retention unit 26a, followed by the second retention unit 26b as the fluid flows into the internal cavity 46b of the second retention unit 26b, and finally the chute 24 when the fluid flows into, and within, the passage 36 of the channel 34.

In some embodiments, fluid is simultaneously introduced into multiple inlets 48, for example an inlet 48 carried by the first retention unit 26a and an inlet carried 48 by the channel 34 of the chute 24. In many embodiments wherein fluid is simultaneously introduced into multiple inlets 48, the inflation of the first retention unit 26a occurs in tandem, or simultaneously, with the inflation of the chute 24. The inflation of the first retention unit 26a is followed by inflation of the second retention unit 26b caused by fluid flowing through the internal cavity 46b of the second retention unit 26b.

In alternative embodiments, for instance in embodiments wherein the second internal cavity 46b is not fluidly communicable with the passage 34 of the channel 34, the fluid delivery tube 60 can be first attached to an inlet 48 carried by the first retention unit 26a,

and subsequently to an inlet 48 carried by the channel 34 of the chute 24. Alternatively, the fluid delivery tube 60 can be attached to an inlet 48 carried by the first retention unit 26a that is coupled to the fluid tube 57, wherein the fluid tube 57 is specifically configured to fluidly interconnect directly with the passage 36 of the channel 34. In said embodiments, fluid is first introduced into the internal cavity 46a of the first retention unit 26a for inflating the first retention unit 26a, and subsequently introduced into the passage 36 of the channel 34 for inflating the chute 24. The inflation of the first retention unit 26a can be followed by inflation of the second retention unit 26b upon flow of fluid from the internal cavity 46a of the first retention unit 26a to the internal cavity 46b of the second retention unit 46b via the linking passage 54.

In many embodiments, the inflation of the first and second retention units 26a, 26b facilitates or effectuates retention (e.g., trans-pyloric retention) of the anchor portion 22 of the device 20 in an eleventh process portion 255. In addition, in many embodiments, the inflation of the chute 24 effectuates longitudinal extension of the chute 24, or inflation of the chute 24, into the duodenum and/or jejunum in a twelfth process portion 260. The inflation of the chute 24 into the duodenum and/or jejunum positions the walls 30, 32 of the chute 24 along the duodenal and/or jejunal walls.

As previously mentioned, in most embodiments, the walls 30, 32 of the chute 24 are designed and/or configured for controlling, inhibiting, and/or preventing movement of matter (e.g., ingested matter such as food matter, bile, and intestinal secretions) thereacross. In several embodiments, the walls 30, 32 of the chute 24 inhibits or prevents outflow of ingested material from within the lumen 28 of the chute 24 to the chute's exterior while allowing inflow of bile and/or intestinal secretions present in the duodenum into the lumen 28 of the chute 24. In many embodiments, the inflation of the chute 24 within the duodenum and/or jejunum reduces the amount of ingested matter, more specifically food matter, being absorbed by the duodenal and/or jejunal walls.

A thirteenth process portion 265 involves detaching the fluid delivery tube 60 from the inlet(s) 48 and removing the fluid delivery tube 60 from the gastrointestinal tract. The

device 20 is retained within the gastrointestinal tract subsequent completion of the process 200. More specifically, the anchor portion 22 of the device 20 is retained or anchored within the gastrointestinal tract (e.g., in the trans-pyloric configuration) upon completion of the process 200.

FIG. 19C shows a flowchart of a representative process 200A for facilitating positioning of the device 20 within the gastrointestinal tract as provided by several embodiments of the present disclosure. The process 200A involves the use of the wire 130 as shown in FIG. 20B and FIG. 20C for facilitating the maneuvering of the device 20 into and through portions of the gastrointestinal tract.

In several embodiments, the process 200A involves introduction of the wire 130 into the gastrointestinal tract in a first process portion 280. In numerous embodiments, in a second process portion 282, the wire 130 is displaced along the gastrointestinal tract for placing the end 132 of the wire 130 at or approximately at a target or expected distal anatomical location. As previously mentioned, the target distal anatomical location can be a given distance into the small intestine, for instance, a distance at, near, or generally near which a terminal portion of the chute 24, such as the terminal end of the chute 24 distal to the anchor portion 22 or the end 38 of the chute's channel 34, is intended to reside following deployment of the device 20 (e.g., at a given or expected distance away from the pylorus in the duodenum or jejunum).

In a third process portion 284, the device 20 is inserted into the gastrointestinal tract along the wire 130 for placement of one or more portions of the device 20 at a set of target anatomical sites (e.g., placement of the anchor portion 22 at or across the pylorus, and placement of a portion of the chute 24 at a given distance in the small intestine). In many embodiments, the device 20 is encased, or substantially disposed, between the inner and outer sheath 112, 114 during displacement along the wire 130 as the encased device 20 travels into and through portions of the gastrointestinal tract. Each of the device 20, the inner sheath 112, and the outer sheath 114 can be slidably inserted along the wire 130 toward the end 132 of the wire 130 and the target distal anatomical location.

In some embodiments, the device is at a coiled or twisted configuration between the inner and outer sheath 112, 114. The coiled or twisted configuration of the device 20, more specifically the chute 24 of the device 20, enables radial compression and possibly at least some longitudinal compression of the device 20, and more specifically a radial or transverse compaction of the chute 24 of the device 20.

In several embodiments, a fourth process portion 286 involves a determination of at least one position of at least one portion of the device 20. A position of the device 20 can be readjusted, where desired, in a fifth process portion 288. In many embodiments, the determination and readjustment of the device's 20 position in the fourth and fifth process portions 286, 288 can occur in a manner analogous or generally analogous to that described above with respect to FIGs. 19A and 19B.

In several embodiments, the process 200A involves placement of the anchor portion 22 at the pylorus and placement of the chute 24 distal to the pylorus (e.g., at a given or expected distance away from the pylorus in the duodenum and/or jejunum).

In a sixth process portion 290, the outer sheath 114, the inner sheath 112, and/or the wire 130 are removed from the gastrointestinal tract. In some embodiments, removal of the outer sheath 114 facilitates or enables at least some radial decompression of the chute 24, and typically at least some unwinding or uncoiling of the chute 24 from the inner sheath 112. Following the removal of the outer sheath 114, portions of the device 20 can be inflated or expanded, after which the inner sheath 112 and the wire 130 can be withdrawn from the patient's body. The removal of the outer sheath 114, the inner sheath 112, and/or the wire 130 can be done using methods known in the art (e.g., via an endoscope gripping or pulling mechanism).

In a seventh process portion 292, fluid is introduced into the internal cavity 46 of the retention unit 26 and/or the passage 36 of the channel 34 of the device 20 for inflating the retention unit 26 and/or the chute 24 of the device 20. The introduction of fluid into the

internal cavity 46 of the retention unit 26 and/or the passage 36 of the channel 34 of the device 20 can occur in a manner analogous to the introduction of fluid in the process 200 as described above, for instance, via the use of one or more fluid delivery tubes 60. The introduction of the fluid into the internal cavity 46 of the retention unit 26 causes inflation of the retention unit 26, and hence facilitates retention of the anchor portion 22 of the device 20 at or across the pylorus. In addition, in numerous embodiments, the introduction of fluid into the passage 36 of the channel 34 facilitates or effectuates radial expansion, and possibly at least some longitudinal extension, of the chute 24.

The order or sequence of the sixth and seventh process portions 192, 194 can be combined or reversed, for instance, depending upon required functions or implementations of the device 20 and a manner in which the device 20 is introduced, positioned, and/or deployed within or along portions of the gastrointestinal tract.

In several embodiments that include a wire 130, the placement and/or extension of at least a portion of the chute 24 of the device 20 within the duodenum and/or jejunum can be facilitated or effectuated by the wire 130. For instance, the wire 130 can be used for displacing at least a portion of the chute 24 to a desired position along the gastrointestinal tract (e.g., duodenum). In various embodiments, the wire 130 facilitates or aids at least partial longitudinal positioning of the chute 24 before or after the introduction of fluid into the internal cavities 46 of the retention units 26 and/or the passage 36 of the channel 34. In addition, in some embodiments, the wire 130 can be used for facilitating or aiding at least partial longitudinal extension of the chute 24.

As previously mentioned, the walls 30, 32 of chute 24 can inhibit or prevent transfer of ingested matter from within the lumen 28 of the chute 20 to the chute's exterior, thereby reducing, inhibiting, or preventing contact between the ingested matter and the gastrointestinal walls (e.g., duodenal and/or jejunal walls). Accordingly, the device 20 of many embodiments of the present disclosure can be used for reducing, limiting, inhibiting, and/or preventing absorption of ingested matter (e.g., food matter) by the gastrointestinal walls (e.g., duodenal and/or jejunal walls).

The device 20 provided by many embodiments of the present disclosure can be used for managing, treating, and/or preventing various physiological conditions, more specifically gastrointestinal conditions or digestive system conditions. For instance, in many embodiments of the present disclosure, a use or function of the device includes managing, treating, preventing, and/or alleviating obesity.

Representative Process(s), and Aspects Thereof, for Re-inflating Retention Unit Embodiments

An advantage provided by several embodiments of the present disclosure is the possibility of re-inflating the retention unit 26 and/or the chute 24 subsequent a first inflation thereof. This is to say, in several embodiments of the present disclosure, the fluid delivery tube 60 can be coupled, more specifically re-coupled, to the retention unit 26 and/or the channel 34 of the chute 24 for introducing fluid into the retention unit 26 and/or the channel 34 of the chute 24 in a repeated manner.

For purposes of brevity and clarity, the following description will be specifically related to the re-inflation of the chute 24. However, a person of ordinary skill in the art, with the present disclosure, will understand that the re-inflation of the retention unit 26 is correspondingly taught and disclosed by the present disclosure by applying the principles, techniques, process, and/or process portions as described below.

FIG. 22 shows a flowchart of a representative process 300 for re-inflating the chute 24 is provided in accordance with several embodiments of the present disclosure. In addition, a representative set of figures illustrating various process portions, or aspects, of the process 300 is also provided by FIG. 23A to 23C.

A first process portion 310 involves determining if the re-inflation of the chute 24 is required. For instance, in many embodiments, the re-inflation of the chute 24 can be required when the chute 24 is a twisted, contorted, or misaligned configuration within the duodenum. In some embodiments, re-inflation of the chute 24 can occur upon twisting or

contortion of the chute 24 such that ingested matter within the lumen 28 of the chute 24 can no longer flow through the lumen 28 of the chute 24 without encountering significant obstruction.

In some embodiments, the chute 24 can be radio-opaque (or include radio-opaque components) for facilitating X-ray determination of the configuration (e.g., twisted, contorted, or misaligned configuration) of the chute 24 within the gastrointestinal tract.

In a second process portion 320, the fluid delivery tube 60 is inserted, more specifically re-inserted, into the gastrointestinal tract and displaced towards the target site. In many embodiments, the fluid delivery tube 60 is displaced along the gastrointestinal tract to the pylorus. In many embodiments, the insertion of the fluid delivery tube 60 is endoscopically facilitated.

In a third process portion 330, the fluid delivery tube 60 is coupled or attached to the inlet 48. As above described, the fluid delivery tube 60 can be of various designs and/or configurations for attaching to one or more inlets 48 either simultaneously or consecutively. In some embodiments, the fluid delivery tube 60 is coupled to the inlet 48 coupled to the first retention unit 26a. In several embodiments, the fluid delivery tube 60 is coupled to the inlet 48 that is carried by the channel 34 of the chute 24.

In many embodiments, the coupling or attachment of the fluid delivery tube 60 to the inlet 48 is by way of a luer-type connection. In numerous embodiments, the coupling or attachment of the fluid delivery tube 60 to the inlet 48 is by way of a magnetic luer-type connection. In several embodiments, the use of the luer-type connection, for example the magnetic luer-type connection enhances, for example increases ease, tightness, and/or efficiency of, the coupling or attachment of the fluid delivery tube 60 to the inlet 48.

In a fourth process portion 340, fluid is introduced from the fluid delivery device 60 into the passage 36 of the channel 34 disposed along the walls 30,32 of the chute 34. In several embodiments, the fluid is introduced into the passage 36 of the channel 34 via the

inlet 48 carried by the first retention unit 26a. Fluid introduced into the internal cavity 46a of the first retention unit 26a flows into the passage 36 of the channel 34 via the linking passage 54 and the internal cavity 46b of the second retention unit 26b. In other embodiments, the fluid is introduced into the passage 36 of the channel 34 through the inlet 48 that is carried by the channel 34 of the chute 24.

The introduction of fluid into the passage 36 of the channel 34 thereby effectuates re-inflation of the chute 24 in a fifth process portion 350. More specifically, flow of fluid within or through the passage 36 of the channel 34 from the first opening 37 to the second opening 38 thereof effectuates re-inflation of the chute 24 in a fifth process portion 350.

In several embodiments, the flow of fluid through the passage 36 of the channel 34 facilitates longitudinal straightening and/or extension of the chute 24. In numerous embodiments, the flow of fluid through or within the passage 36 of the channel 34 facilitates re-deployment or re-inflation of the chute 24 to the extended state. In various embodiments, the re-inflation of the chute 24 facilitates or effectuates maintenance of the structural integrity of the chute 24.

In a sixth process portion 360, the fluid delivery tube 60 is detached or decoupled from the inlet 48 of the device 20 and removed from the gastrointestinal tract.

The ability to re-inflate the chute 24, for instance to remove an unwanted twisting or contortion of the chute 24, which can cause obstruction to flow of ingested matter through the lumen 28 of the chute 24, can be useful for maintaining optimal operation or function of the device 20. In addition, the ability to re-inflate the chute 24 while the device 20 is retained within the gastrointestinal tract (e.g., at or across the pylorus) can help to lengthen the time period of functional or operational usefulness of the device 20 within the body. In several embodiments, the ability to re-inflate the chute 24 while the device 20 is retained within the gastrointestinal tract (e.g., at or across the pylorus)

removes an existing need to remove and dispose of mal-functioning gastrointestinal implants, and replace such mal-functioning implants with new gastrointestinal implants.

Representative Process, and Aspects Thereof, for Retrieving the Device from the Gastrointestinal Tract

In many embodiments, the device 20 can be retrieved or removed from the gastrointestinal tract, for instance when the gastrointestinal condition (e.g., obesity) has been deemed to be successfully treated or cured or upon reaching a predetermined length of time.

FIG. 24 shows a flowchart of a representative process 400 for retrieving or removing the device 20 from the gastrointestinal tract as provided by an embodiment of the present disclosure. In addition, a set of representative set of figures illustrating various process portions, or aspects, of the process 400 is also provided by FIG. 25A to FIG. 25C.

In a first process portion 410, the retention units 26 (e.g., the first and second retention units 26a, 26b) are deflated. Deflation of the retention units 26 can be performed using various methods or techniques known in the art. For instance, the deflation of the retention units 26 can be effected by releasing the fluid within the internal cavities 46 of the retention units 26.

A second process portion 420 involves positioning a retrieval sheath 150 proximal the anchor portion 22 of the device 20. In several embodiments, the retrieval sheath 150 is endoscopically introduced into the gastrointestinal tract and maneuvered towards the anchor portion 22.

In a third process portion 430, the device 20 is pulled or displaced into the retrieval sheath 150. In many embodiments, the deflation of the retention units 26 reduces the diameter the retention units 26, thereby facilitating the pulling or displacement of the device 20 into the retrieval sheath 150. In addition, in numerous embodiments, the anchor portion 22 and/or chute 24 of the device 20 are made of an at least substantially flexible

and soft material, thereby increasing the ease of displacement of the device 20 into the retrieval sheath 150.

In a fourth process portion 440, the device 20 and the retrieval sheath 150 are removed from gastrointestinal tract, and hence from the body. In most embodiments, the removal of the device 20 and the retrieval sheath 150 from the body is via the oral-esophageal route.

Although a representative process 400 for retrieving or removing the device 20 from the body is described above, a person of ordinary skill in the art, with the present disclosure, will understand that other processes, methods, and techniques for retrieving or removing the device 20 from the body are also included within the scope of the present disclosure.

As described above, most embodiments of the present disclosure relate to devices that can be positioned, placed, retained, anchored, and/or secured within the gastrointestinal tract, for example at the pylorus. More specifically, many embodiments of the present disclosure relate to devices including an anchor portion that is shaped, dimensioned and/or configured for retention in a trans-pyloric configuration. The anchor portion of devices as provided by many embodiments of the present disclosure is at least substantially atraumatic. In many embodiments, the atraumatic anchor portion at least substantially reduces damage to the gastrointestinal walls (e.g., pyloric wall), thereby providing an advantage over many existing gastrointestinal implants that include traumatic anchoring structures, for example tissue-penetrating barbs and spikes, that can often cause significant damage to the gastrointestinal walls.

In addition, processes for positioning, retaining, anchoring, and/or securing the devices within the gastrointestinal tract, for example at the pylorus or in the trans-pyloric configuration, are provided by several embodiments of the present disclosure. Furthermore, processes for re-inflating the retention unit(s) and/or the chute of the device are provided by various embodiments the present disclosure. In many embodiments, said processes for re-inflating the retention unit(s) and/or the chute of the device can help to

ensure continued, extended, or prolonged usefulness or functionality of the device within the gastrointestinal tract, thereby extending the operational or functional lifespan of the device.

Aspects of particular embodiments of the present disclosure address at least one aspect, problem, limitation, and/or disadvantage associated with exiting gastrointestinal implants. While features, aspects, and/or advantages associated with certain embodiments have been described in the disclosure, other embodiments may also exhibit such features, aspects, and/or advantages, and not all embodiments need necessarily exhibit such features, aspects, and/or advantages to fall within the scope of the disclosure. It will be appreciated by a person of ordinary skill in the art that several of the above-disclosed systems, components, processes, or alternatives thereof, may be desirably combined into other different systems, components, processes, and/or applications. In addition, various modifications, alterations, and/or improvements may be made to various embodiments that are disclosed by a person of ordinary skill in the art within the scope and spirit of the present disclosure.

Claims

1. A device comprising:

an anchor portion that is shaped and configured for placement at a pyloric valve;

a chute coupled to the anchor portion, the chute comprising a first passage formed therethrough; and

a channel carried by chute, the channel being disposed along a wall of chute and comprising a second passage formed therewithin, the second passage being shaped and configured to allow flow of fluid therewithin to thereby effectuate a longitudinal extension of the chute.

2. The device as in claim 1, the second passage comprising a first end proximal the anchor portion and a second end distal the anchor portion, wherein the flow of fluid from the first end towards the second end effectuates longitudinal extension of the chute.

3. The device as in claim 1, wherein the first passage has a diameter that is substantially larger than a diameter of the second passage.

4. The device as in claim 1, wherein the longitudinal extension of the chute deploys the chute from a compressed state to an extended state.

5. The device as in claim 1, the chute comprising an inner wall and an outer wall formed around the inner wall such that a circumference of the outer wall is larger than a circumference of the inner wall, wherein the channel is carried proximate at least one of the inner and outer walls.

6. The device as in claim 5, wherein the channel is disposed substantially between the inner and outer walls of the chute.

7. The device as in claim 5, wherein at least a portion of the channel is disposed substantially along the circumference of a wall of the chute.

8. The device as in claim 2, wherein the first and second ends of the second passage include first and second openings respectively, wherein fluid flows into and out of the second passage via the first opening and second opening respectively, the outflow of fluid from the second opening corresponds to an outflow of fluid from the device.

9. The device as in claim 1, the anchor portion comprising a first retention unit shaped and dimensioned for placement at a first side of the pyloric valve.

10. The device as in claim 9, the anchor portion comprising a second retention unit disposed between the first retention unit and the chute.

11. The device as in claim 10, the second retention unit being shaped and dimensioned for placement at a second side of the pyloric valve, the first side of the pyloric valve facing a stomach and the second side of the pyloric valve facing a duodenum.

12. The device as in claim 11, wherein the chute is attached to the second retention unit, the longitudinal extension of the chute thereby one of facilitates and effectuates longitudinal extension of the chute along a length of the duodenum.

13. The device as in claim 11, wherein at least one of the first and second retention units comprises an internal cavity formed therewithin, the internal cavity shaped and dimensioned for allowing fluid communication therewithin.

14. The device as in claim 13, wherein fluid communication within the internal cavity of the at least one of the first and second retention units one of facilitates and

effectuates inflation of the at least one of the first and second retention units from a compressed state to an inflated state.

15. The device as in claim 14, wherein the inflation of the at least one of the first and second retention units to the inflated state one of facilitates and effectuates trans-pyloric retention of the anchor portion.

16. The device as in claim 13, wherein the second passage of the channel is fluidly communicable with the internal cavity of the first retention unit.

17. The device as in claim 16, wherein the second passage of the channel is fluidly communicable with the internal cavity the second retention unit.

18. The device as in claim 11, wherein each of the first and second retention units comprises an internal cavity formed therewithin, the internal cavity of each the first and second retention units being fluidly inter-communicable via a linking passage.

19. The device as in claim 18, further comprising at least one valve that is positioned and configured for controlling the flow of fluid into at least one of the internal cavity of the first retention unit, the internal cavity of the second retention unit, and the second passage of the channel.

20. The device as in claim 19, wherein the at least one valve is positioned and configured for controlling flow of fluid between one of (a) the internal cavities of the first retention unit and the second retention unit; (b) the internal cavity of the first retention unit and the second passage of the channel; and (c) the internal cavity of the second retention unit and the second passage of the channel.

21. The device as in claim 11, further comprising at least one inlet coupled to at least one of the first retention unit, the second retention unit, and the chute, the at least

one inlet being shaped and dimensioned to mediate fluid introduction into at least one of the internal cavity of the first retention unit, the internal cavity of the second retention unit, and second passage of the channel, respectively.

22. The device as in claim 21, wherein the at least one inlet is shaped and configured to control at least one of rate, pressure, and volume of fluid being introduced into the at least one of the internal cavity of the first retention unit, the internal cavity of the second retention unit, and second passage of the channel, respectively.

23. The device as in claim 22, wherein the at least one inlet is shaped and configured for docking with a fluid delivery tube.

24. The device as in claim 23, wherein the at least one inlet is shaped and dimensioned for supporting luer-type docking with the fluid delivery tube.

25. The device as in claim 23, wherein the at least one inlet is shaped and dimensioned for supporting one of magnetic and electromagnetic docking with the fluid delivery tube.

26. The device as in claim 11, wherein at least one of the first and second retention units comprises a set of structural features carried by a surface thereof, the set of structural features shaped and dimensioned for reducing a surface area of contact between the at least one of the first and second retention units and the first and second sides of the pyloric valve respectively.

27. The device as in claim 26, wherein the first retention unit comprises a first set of structural features, and the second retention unit comprises a second set of structural features, each of the first and second set of structural features being shaped and dimensioned to reduce surface area of contact between the first and second retention units and the first and second sides of the pyloric valve, respectively.

28. The device as in claim 27, the first and second sets of structural features including a number of protruding structures that are shaped and configured to extend from the first and second retention units at least substantially toward each other.

29. The device as in claim 28, wherein a height of the protruding structures is between approximately 0.1mm and 10mm, and a distance between adjacent protruding structures is between approximately 1mm and 100mm.

30. The device as in claim 29, wherein the height of the protruding structures is between approximately 1mm and 5mm spacing between adjacent protruding structures is between approximately 10mm and 50mm.

31. The device as in claim 28, wherein the shape and configuration of the first and second sets of structural features one of facilitate and effectuate enhanced trans-pyloric retention of the anchor portion.

32. The device as in claim 31, wherein the shape and configuration of the first and second set of structural features allows for at least some fluid communication between the first and second set of protrusions.

33. The device as in claim 11, the first retention unit comprising an extension extending therefrom for enhancing retention of the first retention unit at the first side of the pylorus.

34. The device as in claim 33, wherein the extension is of a substantially petal-shape.

35. The device as in claim 11, the anchor portion further comprising a sheath disposed between the first and second retention units.

36. The device as in claim 35, wherein the sheath interconnects the first and second retention units.

37. The device as in claim 35, wherein the sheath is shaped and contoured for shape-fitting with at least a portion of the pyloric valve during trans-pyloric retention of the anchor portion.

38. The device as in claim 35, the anchor portion further comprising at least one support structure that is carried by the sheath, the at least one support structure for at least one of providing structural support for the anchor portion and enhancing trans-pyloric retention of the anchor portion.

39. The device as in claim 38, wherein the at least one support structure comprises a network of struts that interconnects the first and second retention units, each strut of the network of struts comprising atrumatic terminals to one of prevent and minimize damage to the pyloric valve.

40. The device as in claim 39, wherein the each strut of the network of struts has a C-shape configuration, and wherein each looped end of each C-shaped strut is coupled to one of the first retention unit and the second retention unit.

41. The device as in claim 38, wherein the at least one support structure comprises a corrugated portion configured to enable expansion and compression of the anchor portion.

42. The device as in claim 35, wherein the thickness of the sheath is between approximately 0.05mm and 1mm.

43. The device as in claim 42, wherein the thickness of the sheath is between approximately 0.1mm and 0.5mm.

44. The device as in claim 42, wherein a length of the sheath interconnecting the first and second retention units is between approximately 10mm and 100mm.

45. The device as in claim 44, wherein the length of the sheath is between approximately 25mm and 75mm.

46. The device as in claim 15, wherein the first retention unit defines a lumen, the lumen of the first retention unit having a diameter of between approximately 25mm and 150mm when the first retention unit is at the inflated state.

47. The device as in claim 46, wherein the diameter of the lumen of the first retention unit is between approximately 50mm and 75mm when the first retention unit is at the inflated state.

48. The device as in claim 47, wherein the second retention unit defines a lumen, the lumen of the second retention unit having a diameter of between approximately 10mm and 100mm when the second retention unit is at the inflated state.

49. The device as in claim 48, wherein the diameter of the lumen of the second retention unit is between approximately 20mm and 50mm when the second retention unit is at the inflated state.

50. The device as in claim 15, wherein the internal cavity of the at least one of the first and second retention unit has a diameter of between approximately 1mm and 30mm.

51. The device as in claim 50, wherein the diameter of the internal cavity of the at least one of the first and second retention units is between approximately 5mm and 15mm.

52. The device as in claim 1, wherein the anchor portion has smooth and atraumatic surfaces.

53. The device as in claim 1, wherein at least one of the anchor portion and the chute is made of a biocompatible and at least substantially flexible polymer.

54. The device as in claim 53, wherein at least one of the anchor portion and the chute is made of least one of a polyurethane, silicone, polytetrafluoroethylene, polyvinyl chloride, silicone polyether urethane, and silicone polycarbonate urethane.

55. The device as in claim 4, wherein the chute has a length of between approximately 20cm and 100cm when at the extended state.

56. The device as claim 55, wherein the first passage of the chute has a diameter of between approximately 10mm and 100mm.

57. The device as claim 56, wherein the first passage of the chute has a diameter of between approximately 15mm and 50mm.

58. The device as in claim 55, wherein the second passage of the channel has a diameter of substantially less than approximately 10mm.

59. The device as in claim 58, wherein the second passage of the channel has a diameter of between approximately 1mm and 5mm.

60. The device as in claim 5, wherein a distance between the inner and outer walls of the chute is between approximately 0.05mm and 0.5mm.

61. The device as in claim 60, wherein the distance between the inner and outer walls of the chute is between approximately 0.1mm.

62. The device as in claim 5, wherein the chute carries a plurality of pores formed within the walls thereof.

63. The device as in claim 62, wherein a density of the plurality of pores formed within the walls of the chute is between approximately 1% and 50%.

64. The device as in claim 63, wherein the density of the plurality of pores formed within the walls of the chute is between approximately 10% and 25%.

65. The device as in claim 62, wherein the plurality of pores are shaped and dimensioned to one of facilitate and effectuate uni-directional flow of material across the walls of the chute.

66. The device as in claim 65, wherein the plurality of pores are shaped and dimensioned to substantially impede outflow of material from within the first passage of the chute to an exterior of the chute.

67. The device as in claim 62, wherein the pore size of the plurality of pores is between approximately 10microns and 500microns.

68. The device as in claim 67, wherein the pore size of the plurality of pores is between approximately 50microns and 200microns.

69. The device as in claim 62, wherein the plurality of pores is disposed along only approximately half of the chute's length.

70. The device as in claim 69, wherein the plurality of pores is disposed along only approximately one-third of the chute's length.

71. The device as in claim 12, wherein the longitudinal extension of the chute facilitates alignment of the walls of the chute substantially parallel to the walls of the duodenum.

72. The device as in claim 71, wherein the longitudinal extension of the chute one of facilitates or effectuates a modification of an absorption pattern by the walls of the duodenum.

73. A method for extending a device, the method comprising:

providing the device, the device comprising an anchor portion and a chute coupled to the anchor portion, the chute comprising a first passage formed therethrough and a channel carried by a wall of the chute, the channel comprising a second passage with a diameter that is substantially smaller than a diameter of the first passage, the channel comprising a first end proximal the anchor portion and a second end distal the anchor portion;

introducing fluid into the channel at the first end, the introduced fluid flowing from the first end towards the second end; and

longitudinally extending the chute, wherein the longitudinal extension of the chute is effectuated by the flow of fluid from the first end towards the second end of the channel.

74. The method as in claim 73, wherein the longitudinal extension of the chute deploys the chute from a compressed state to an extended state.

75. The method as in claim 73, wherein the chute comprises an inner wall and an outer wall formed around the inner wall such that a circumference of the outer wall is larger than a circumference of the inner wall, the channel being carried proximate to at least one of the inner and outer walls.

76. The method as in claim 75, wherein the channel is disposed substantially between the inner and outer walls of the chute.

77. The method as in claim 75, further comprising disposing at least a portion of the channel substantially along a circumference of a wall of the chute.

78. The method as in claim 73, further comprising shaping and configuring the anchor portion for one of facilitating and effectuating shape fitting with a pyloric valve.

79. The method as in claim 73, further comprising shaping and configuring the anchor portion for one of facilitating and effectuating trans-pyloric retention of the anchor portion.

80. The method as in claim 79, wherein shaping and configuring the anchor portion comprises coupling a support structure to the anchor portion, the support structure configured to provide structural support for the anchor portion and enhance trans-pyloric retention of the anchor portion.

81. The method as in claim 80, wherein the support structure comprises a corrugated portion configured to enable longitudinal expansion and compression of the anchor portion.

82. The method as in claim 79, wherein the anchor portion comprises a first retention unit shaped and dimensioned for placement at a first side of the pyloric valve and a second retention unit shaped and dimensioned for placement at a second side of the pyloric valve, the first side of the pyloric valve facing a stomach and the second side of the pyloric valve facing a duodenum.

83. The method as in claim 73, wherein the anchor portion comprises a first retention unit and a second retention unit, at least one of the first and second retention units comprising an internal cavity formed therewithin, the internal cavity shaped and dimensioned for allowing fluid communication therethrough.

84. The method as in claim 83, further comprising introducing fluid into the internal cavity of at least one of the first and second retention units for inflating the at least one of the first and second retention units from a compressed state to an inflated state.

85. The method as in claim 84, wherein the inflation of the at least one of the first and second retention units to the inflated state one of facilitates and effectuates trans-pyloric retention of the anchor portion.

86. The method as in claim 84, wherein the second passage of the channel is fluidly communicable with the internal cavity of at least one of the first and second retention units.

87. The method as in claim 86, further comprising communicating fluid from the internal cavity of at least one of the first and second retention units to the second passage of the channel.

88. The method as in claim 87, further comprising coupling at least one inlet to at least one of the first retention unit, the second retention unit, and the channel, the at least one inlet being shaped and dimensioned to mediate fluid introduction into at least one of the internal cavity of the first retention unit, the internal cavity of the second retention unit, and the second passage of the channel respectively.

89. The method as in claim 88, further comprising providing at least one valve positioned and configured for controlling the flow of fluid into at least one of the internal cavity of the first retention unit, the internal cavity of the second retention unit, and the second passage of the channel.

90. The method as in claim 89, the at least one valve being shaped and dimensioned for controlling at least one of rate, pressure, and volume of fluid being introduced

into the at least one of the internal cavity of the first retention unit, the internal cavity of the second retention unit, and second passage of the channel.

91. The method as in claim 88, wherein the at least one inlet is shaped and configured for facilitating coupling to a fluid delivery tube.

92. The method as in claim 91, wherein the at least one inlet is shaped and dimensioned for supporting luer-type coupling to the fluid delivery tube.

93. The method as in claim 91, wherein the at least one inlet is shaped and dimensioned for supporting one of magnetic and electromagnetic coupling to the fluid delivery tube.

94. The method as in claim 91, further comprising coupling the fluid delivery tube to the at least one inlet.

95. The method as in claim 94, further comprising detaching the fluid delivery tube from the at least one inlet.

96. The method as in claim 91, further comprising introducing fluid into the at least one of the internal cavity of the first retention unit, the internal cavity of the second retention unit, and second passage of the channel via the fluid delivery tube to thereby one of facilitate and effectuate at least one of inflation the first and second retention unit and longitudinal extension of the chute.

97. The method as in claim 83, further comprising:

encasing the chute of the device between an inner sheath and an outer sheath;

displacing a wire through the gastrointestinal tract and positioning an end of the wire at a target location within the gastrointestinal tract; and

displacing the chute of the device encased between inner and outer sheaths along the wire toward the end of the wire positioned at the target location within the gastrointestinal tract.

98. The method as in claim 97, wherein the target location is at a length along one of a group of the duodenum and the jejunum, the displacement of the chute of the device encased between the inner and outer sheaths along the wire toward the end of the wire positioned at the target location thereby facilitating positioning of the chute of the device along a length of one of the group of the duodenum and the jejunum.

99. A system for facilitating placement of a device relative to a pyloric valve, the system comprising:

a device comprising an anchor portion and a chute coupled to the anchor portion, the chute comprising a first passage formed therethrough and a channel disposed along a wall thereof, the channel comprising a second passage with a diameter that is substantially smaller than a diameter of the first passage, the first and second passages being shaped and dimensioned to communicate fluid therewithin;

a delivery sheath shaped and dimensioned for at least substantially carrying the device during displacement of the device towards the pyloric valve; and

a fluid delivery tube, the fluid delivery tube being reversibly couplable to the device for introducing fluid into the second passage of the channel.

100. The system as in claim 99, wherein flow of fluid through the second passage of the channel effectuates a longitudinal extension of the chute.

101. The system as in claim 100, wherein the longitudinal extension of the chute deploys the chute from a compressed state to an extended state.

102. The system as in claim 101, the chute comprising an inner wall and an outer wall formed around the inner wall such that a circumference of the outer wall is larger than a circumference of the inner wall, wherein the channel is carried proximate to at least one of the inner and outer walls.

103. The system as in claim 102, wherein the channel is disposed substantially between the inner and outer walls of the chute.

104. The system as in claim 103, the anchor portion comprising a first retention unit that is shaped and dimensioned for placement at a first side of the pyloric valve and a second retention unit that is shaped and dimensioned for placement at a second side of the pyloric valve, wherein the first side of the pyloric valve faces a stomach and the second side of the pyloric valve faces a duodenum, the retention unit thereby being shaped and dimensioned for trans-pyloric retention.

105. The system as in claim 104, further comprising a set of markers for facilitating accurate trans-pyloric placement of the anchor portion.

106. The system as in claim 105, wherein the set of markers comprises a first marker carried by the first retention unit and a second marker carried by the second retention unit.

107. The system as in claim 104, wherein the first retention unit comprises a first internal cavity formed therewithin and the second retention unit comprises a second internal cavity formed therewithin.

108. The system as in claim 107, the anchor portion of the device further comprising a connecting sheath disposed between the first retention unit and the second retention unit.

109. The system as in claim 107, the anchor portion of the device further comprising at least one support structure carried by the connecting sheath for at least one of providing structural support to the anchor portion and facilitating trans-pyloric retention of the anchor portion.

110. The system as in claim 109, wherein the at least one support structure comprises a network of struts that interconnects the first and second retention units, each strut of the network of struts comprising atrumatic terminals to one of prevent and minimize damage to the pyloric valve.

111. The system as in claim 110, wherein the each strut of the network of struts has a C-shape configuration, and wherein each looped end of each C-shaped strut is coupled to one of the first retention unit and the second retention unit.

112. The system as in claim 110, wherein the at least one support structure comprises a corrugated portion configured to enable expansion and compression of the anchor portion.

113. The system as in claim 107, further comprising a number of structural features carried by the first and second retention units for at least one of reducing surface area of contact between the first and second retention units and a wall of the pylorus, and enhancing trans-pyloric retention of the anchor portion.

114. The system as in claim 108, the anchor portion comprising an extension extending from the first retention unit for facilitating trans-pyloric retention of the anchor portion.

115. The system as in claim 108, the anchor portion of the device further comprising a linking passage carried by the connecting sheath for fluidly interconnecting the first and second internal cavities.

116. The system as in claim 115, wherein the fluid delivery tube is couplable to at least one of the first and second retention units to thereby one of facilitate and effectuate introduction of fluid into at least one of the first and second internal cavities.

117. The system as in claim 116, wherein the introduction of fluid into at least one of the first and second internal cavities thereby one of facilitates and effectuates inflates the first and second retention units.

118. The system as in claim 116, wherein the device includes at least one inlet, the fluid delivery tube couplable to the at least one inlet for introducing fluid into at least one of the first and second internal cavities.

119. The system as in claim 118, wherein the at least one inlet is shaped and dimensioned to enable luer-type coupling with the fluid delivery tube.

120. The system as in claim 118, wherein the at least one inlet is shaped and dimensioned to enable one of magnetic and electromagnetic coupling with the fluid delivery tube.

121. The system as in claim 118, wherein the at least one inlet comprises a valve that is shaped and configured for controlling at least one of rate, volume, and pressure of fluid introduced into the at least one of the first and second internal cavities.

122. The system as in claim 99, further comprising a stabilizer that is shaped and dimensioned for maintaining trans-pyloric placement of the anchor portion during removal of device from the delivery sheath.

123. The system as in claim 99, further comprising a wire that is shaped and dimensioned for displacement through a portion of the gastrointestinal tract to

thereby position an end of the wire at a target location within the gastrointestinal tract.

124. The system as in claim 123, further comprising an inner sheath and an outer sheath shaped and dimensioned for encasing at least a portion of the device, wherein the inner sheath is slidably displaceable along the wire towards the end of the wire.

125. The system as in claim 124, wherein the chute of the device is one of coiled and twisted when encased within the inner and outer sheaths to thereby facilitate at least one of radial and longitudinal compression of the chute.

126. The system as in claim 125, wherein displacement of the inner sheath along the wire towards the end of the wire correspondingly causes displacement of the chute of the device towards the end of the wire.

127. The system as in claim 99, wherein at least a portion of the chute of the device is radiopaque.

128. A device comprising:

an anchor portion shaped and dimensioned for trans-pyloric placement, the anchor portion comprising a first retention unit shaped and dimensioned for placement at a first side of a pyloric valve, the first side proximal a stomach, and a second retention unit shaped and dimensioned for placement at a second side of the pyloric valve, the second side proximal a duodenum; and

a chute coupled to the anchor portion and comprising a first passage formed therethrough, the chute comprising a channel carried by a wall of the chute, the channel comprising a second passage with a first end proximal the anchor portion and a second end distal the anchor portion,

wherein fluid communication from the first end towards the second end of the second passage of the channel effectuates longitudinal extension of the chute.

129. The device as in claim 128, the chute comprising an inner wall and an outer wall, the outer wall having a circumference larger than a circumference of the inner wall, wherein the channel is proximate to at least one of the inner and outer walls.

130. The device as in claim 129, wherein the channel is disposed substantially between the inner and outer walls of the channel.

131. The device as in claim 129, wherein the first and second ends of the channel are first and second openings respectively, fluid introduced into the second passage via the first opening and expelled from the second passage via the second opening.

132. The device as in claim 128, wherein the longitudinal extension of the chute deploys the chute from a compressed state to an extended state.

133. The device as in claim 132, wherein the first passage has a diameter that is substantially larger than a diameter of the second passage.

134. The device as in claim 133, wherein the first retention unit comprises a first internal cavity formed therewithin and the second retention unit comprises a second internal cavity formed therewithin, each of the first and second internal cavities shaped and dimensioned to enable fluid communication therewithin.

135. The device as in claim 134, wherein introduction of fluid into the first and second internal cavities causes inflation of the first and second retention units from a compressed state to an inflated state, the inflation of the first and second retention units to the inflated state one of facilitates and effectuates trans-pyloric retention of the anchor portion.

136. The device as in claim 135, the anchor portion of the device further comprising a connecting sheath disposed between the first retention unit and the second retention unit.

137. The device as in claim 136, the anchor portion of the device further comprising at least one support structure carried by the connecting sheath for at least one of providing structural support to the anchor portion and facilitating trans-pyloric retention of the anchor portion.

138. The device as in claim 137, wherein the at least one support structure comprises a network of struts that interconnects the first and second retention units, each strut of the network of struts comprising atrumatic terminals to one of prevent and minimize damage to the pyloric valve.

139. The device as in claim 138, wherein the each strut of the network of struts has a C-shape configuration, and wherein each looped end of each C-shaped strut is coupled to one of the first retention unit and the second retention unit.

140. The device as in claim 137, wherein the at least one support structure comprises a corrugated portion configured to enable expansion and compression of the anchor portion.

141. The device as in claim 136, the anchor portion comprising a number of structural features shaped and configured for at least one of reducing surface area of contact between the first and second retention units and a wall of the pylorus, and enhancing the trans-pyloric retention of the device.

142. The device as in claim 136, the anchor portion comprising an extension extending from the first retention unit, the extension shaped and dimensioned for facilitating trans-pyloric retention of the anchor portion.

143. A method for modifying matter absorption by an intestinal wall comprising:

placing a device at a pylorus, the device comprising an anchor portion and a chute coupled to the anchor portion, the chute comprising a first passage formed therethrough and a channel carried by a wall of the chute, the channel comprising a second passage with a diameter that is substantially smaller than a diameter of the first passage, the second passage further comprising a first end that is proximal the anchor portion and a second end that is distal the anchor portion; and

introducing fluid into the second passage via the first end, the fluid flowing from the first end towards the second end to thereby effectuate longitudinal extension of the chute.

144. The method as in claim 143, wherein the longitudinal extension of the chute deploys the chute from a compressed state to an extended state.

145. The method as in claim 143, wherein the chute comprises an inner wall and an outer wall formed around the inner wall such that a circumference of the outer wall is larger than a circumference of the inner wall, and wherein the channel is proximate to by at least one of the inner and outer walls.

146. The method as in claim 145, wherein the channel is disposed substantially between the inner and outer walls of the chute.

147. The method as in claim 145, wherein at least a portion of the channel is substantially along the circumferences of the walls of the chute.

148. The method as in claim 145, wherein the anchor portion is placed in a trans-pyloric configuration, the longitudinal extension of the chute to the extended state aligning the inner and outer walls of the chute along an intestinal wall.

149. The method as in claim 148, comprising communicating ingested matter through the first passage of the chute.

150. The method as in claim 149, wherein the walls of the chute comprises a plurality of pores that are shaped and dimensioned for controlling movement of matter across the walls of the chute.

151. The method as in claim 150, wherein the inner and outer walls of the chute inhibits movement of ingested matter from within the first passage of the chute to an exterior of the chute.

152. The method as in claim 151, wherein the ingested matter is food matter, the device facilitating reduction in absorption of food matter by the intestinal wall.

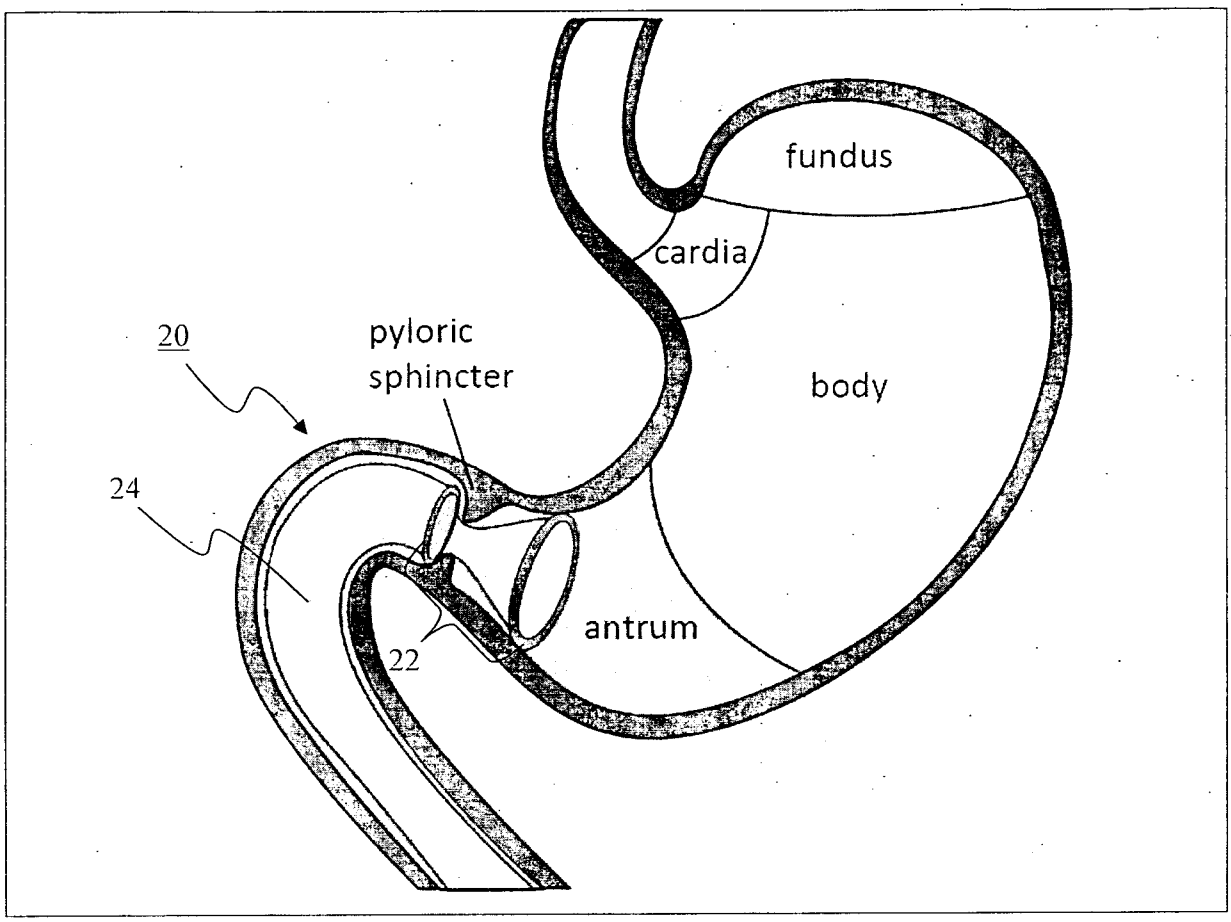


FIG. 1

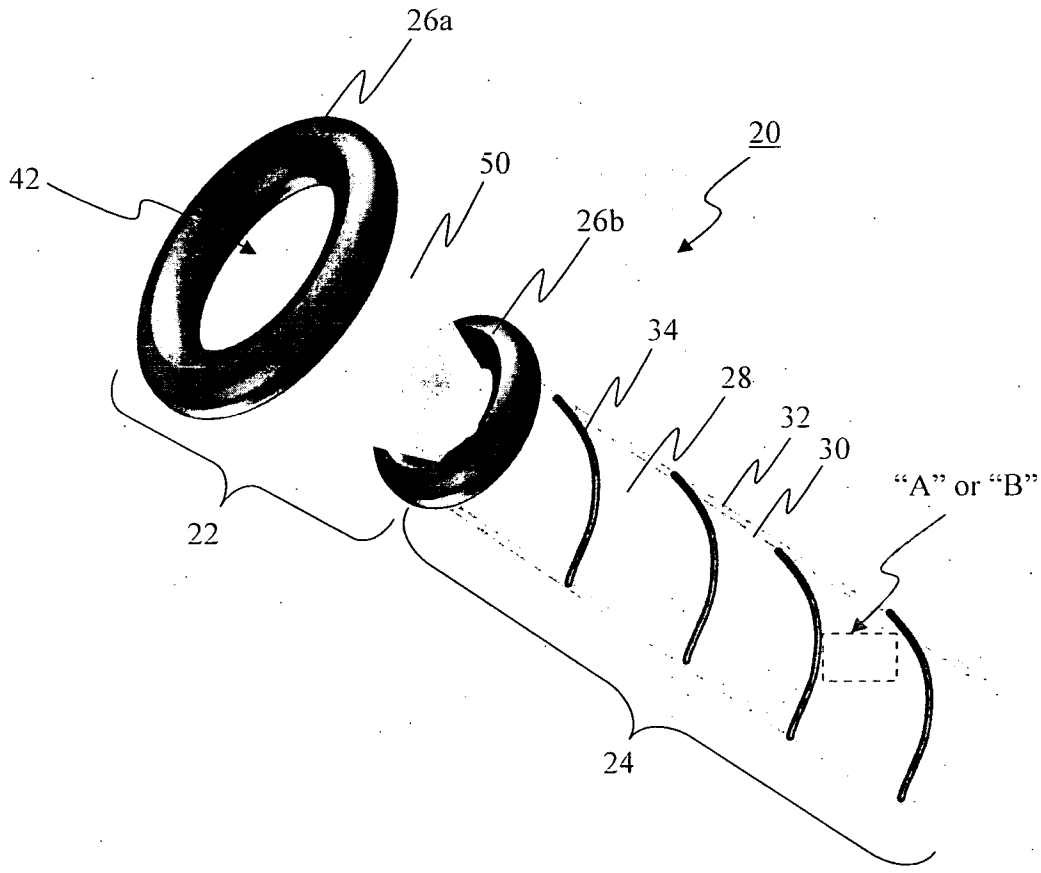


FIG. 2

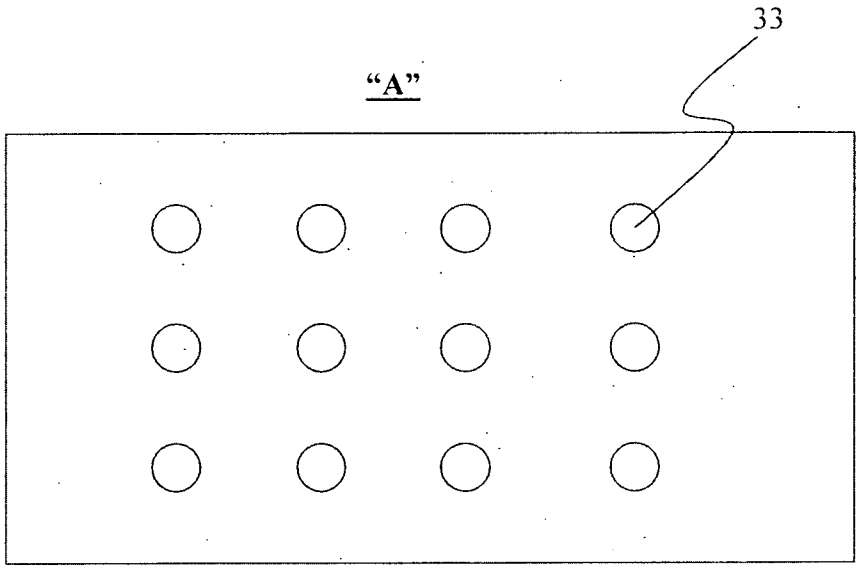


FIG. 3A

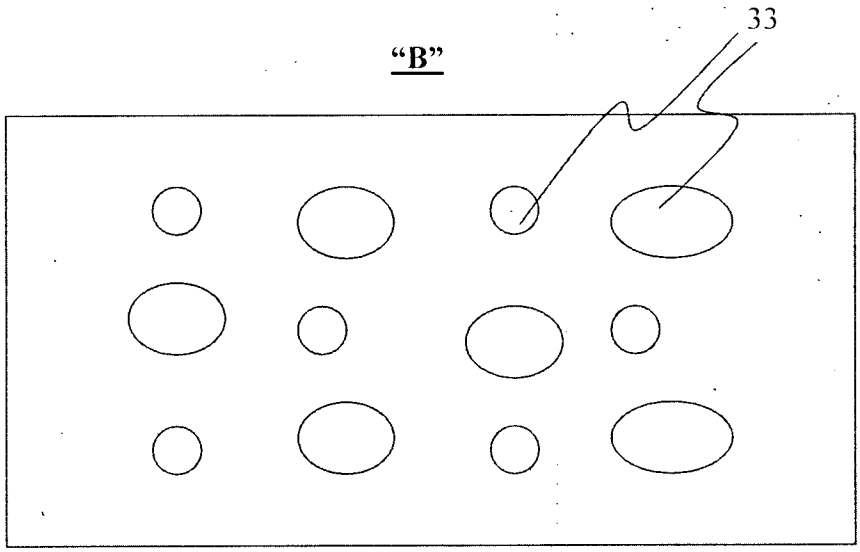


FIG. 3B

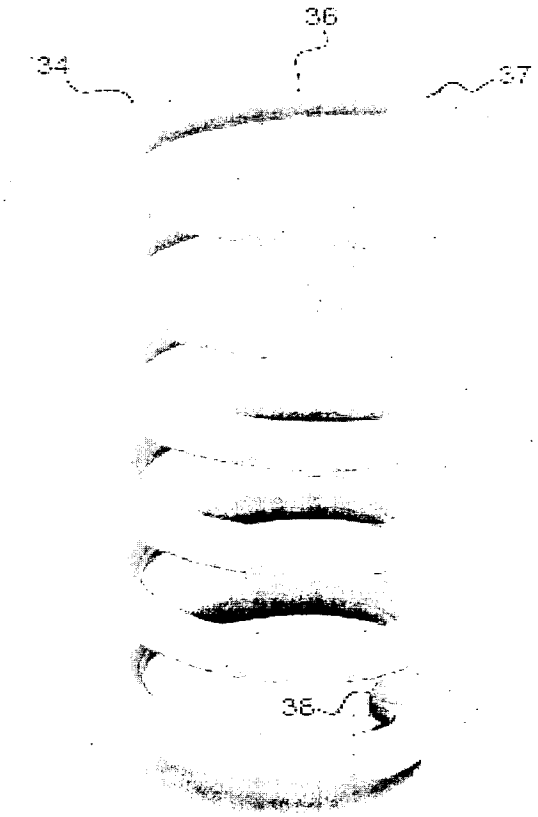


FIG. 4A

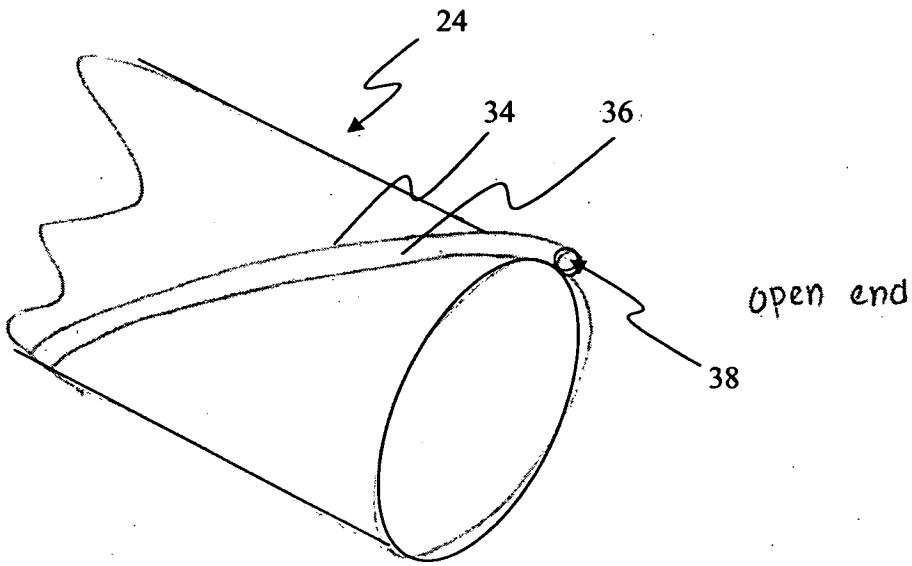


FIG. 4B

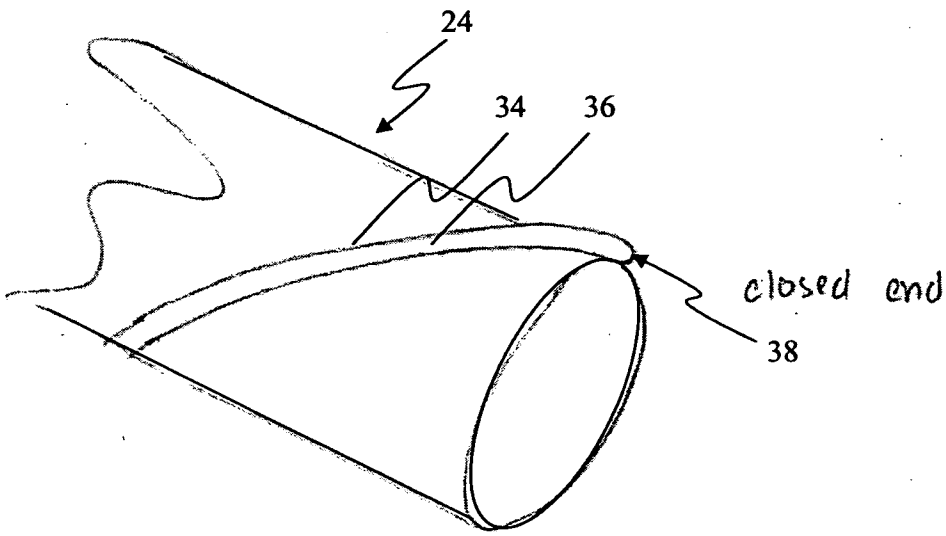


FIG. 4C

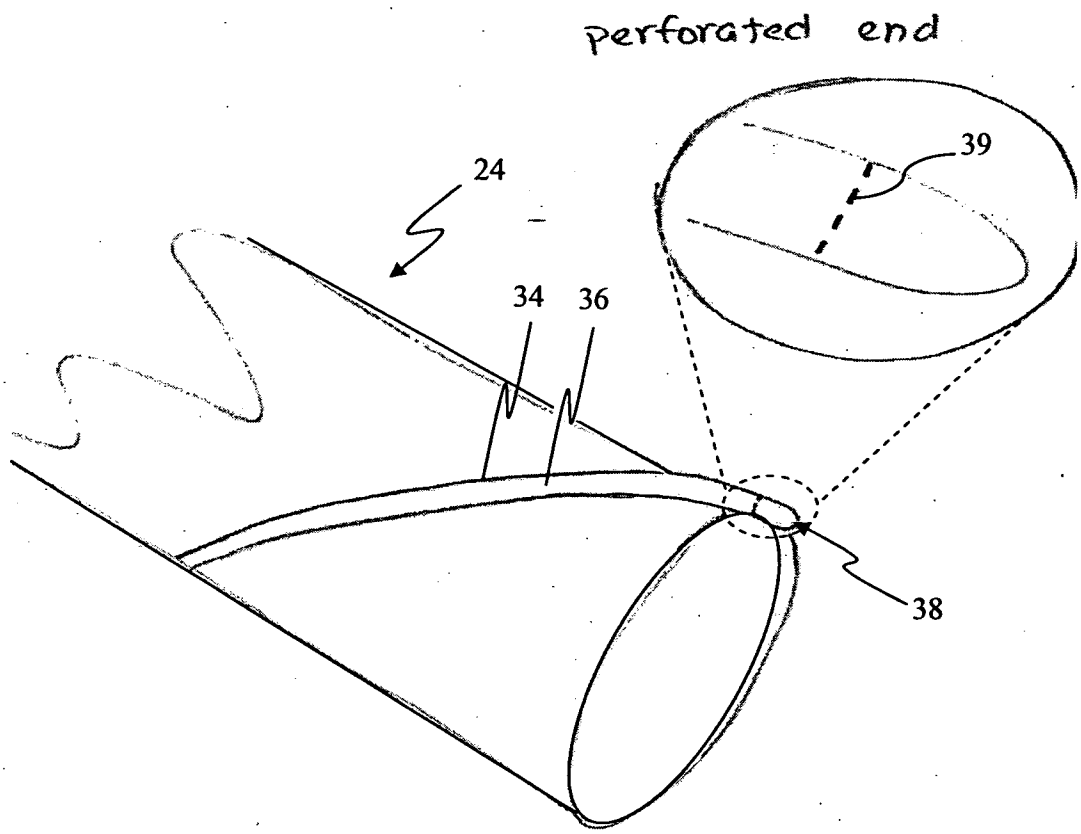


FIG. 4D

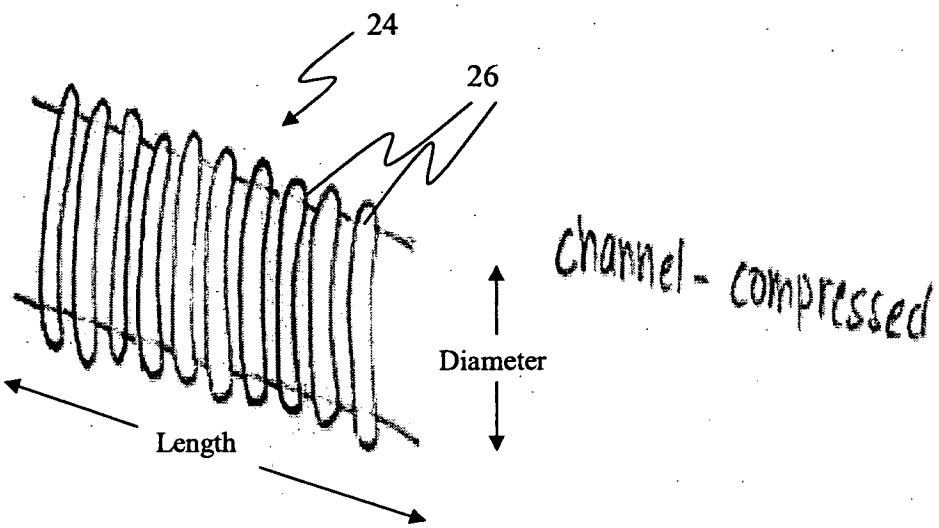

24
26
channel - compressed
Diameter
Length

FIG. 5A

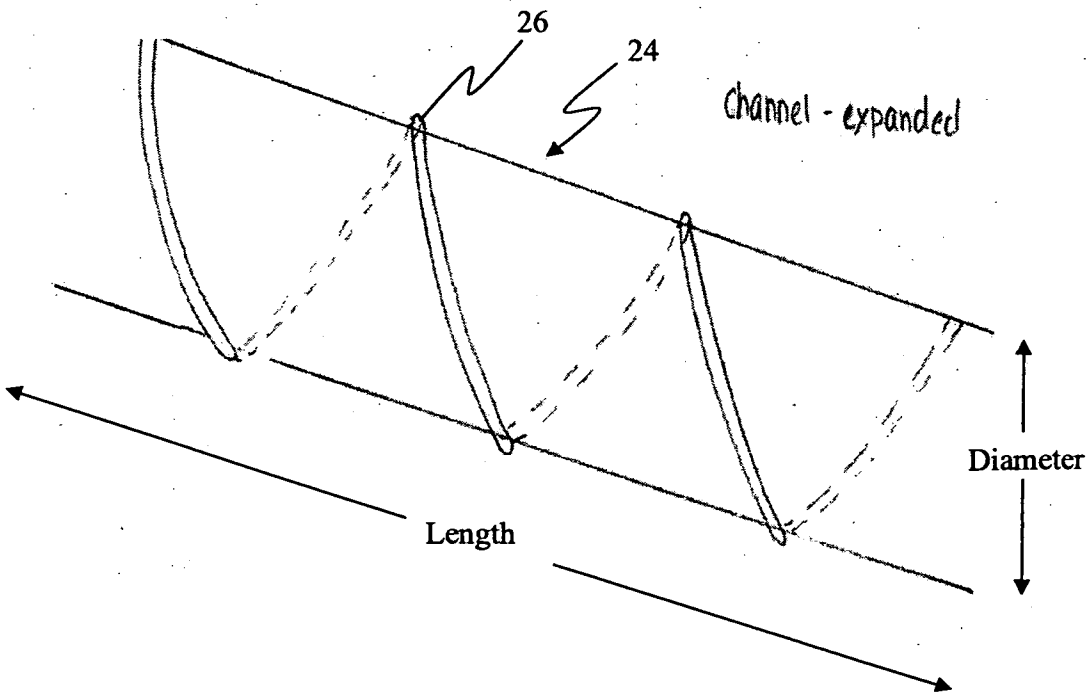

26
24
channel - expanded
Diameter
Length

FIG. 5B

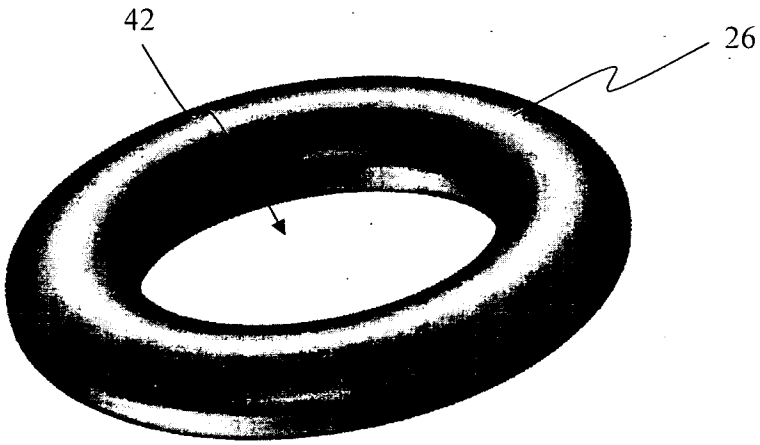


FIG. 6A

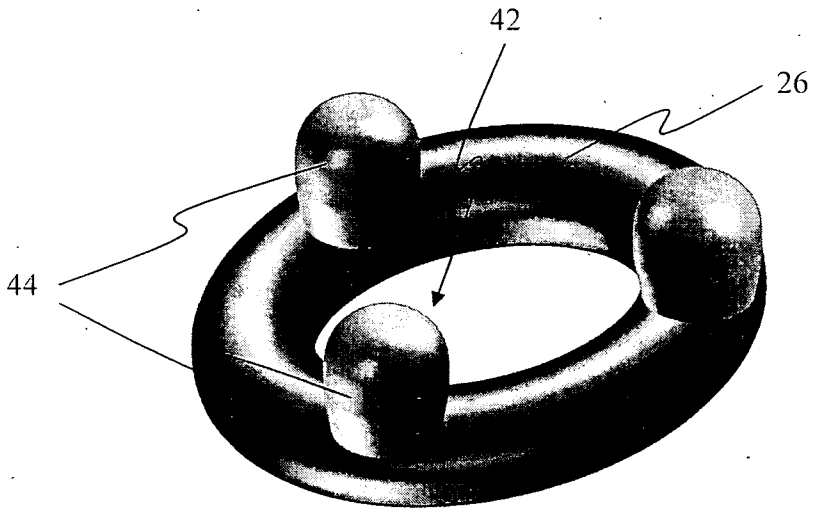


FIG. 6B

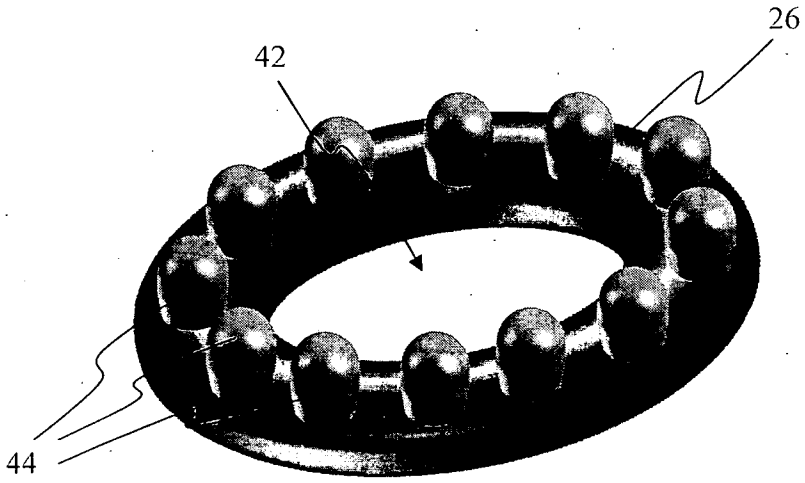


FIG. 6C

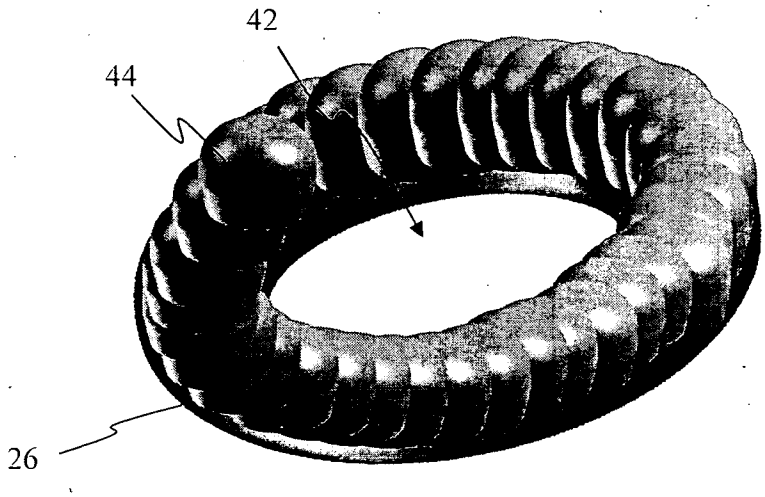


FIG. 6D

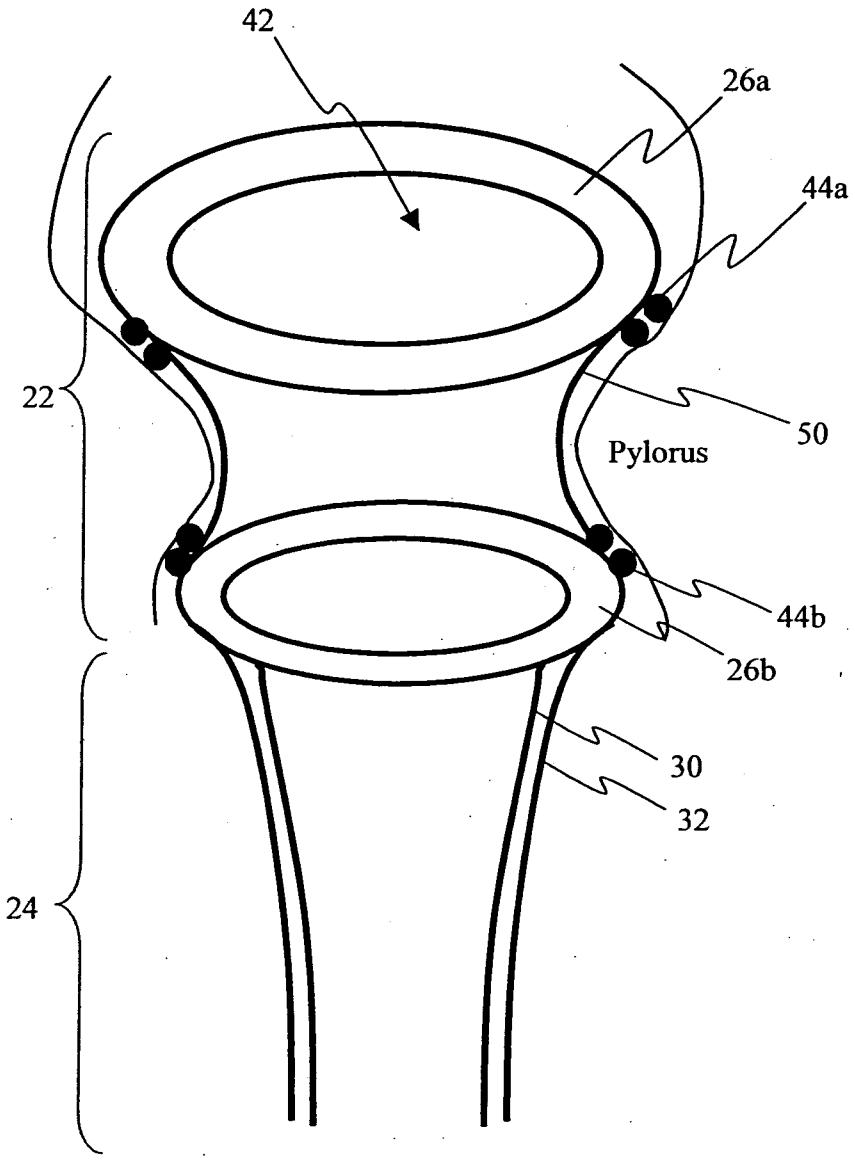


FIG. 7

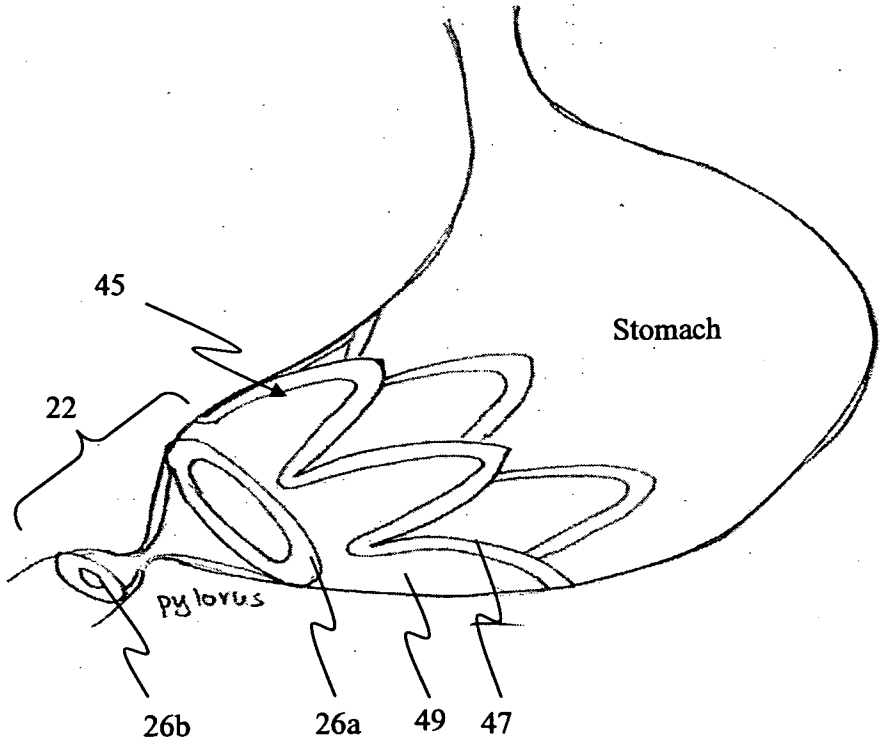


FIG. 8A

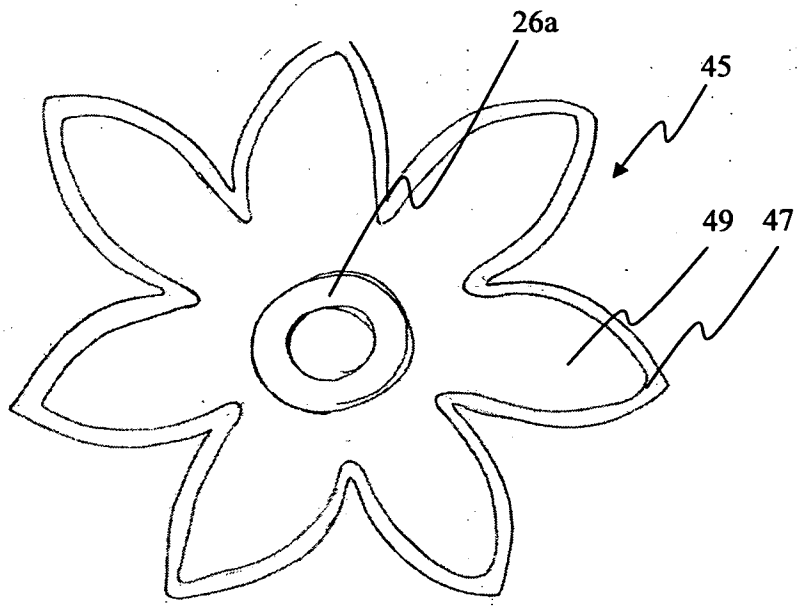


FIG. 8B

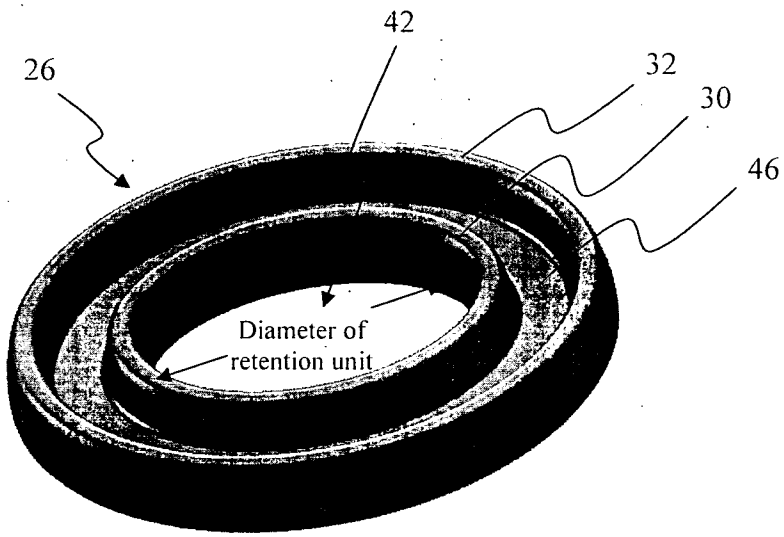


FIG. 9A

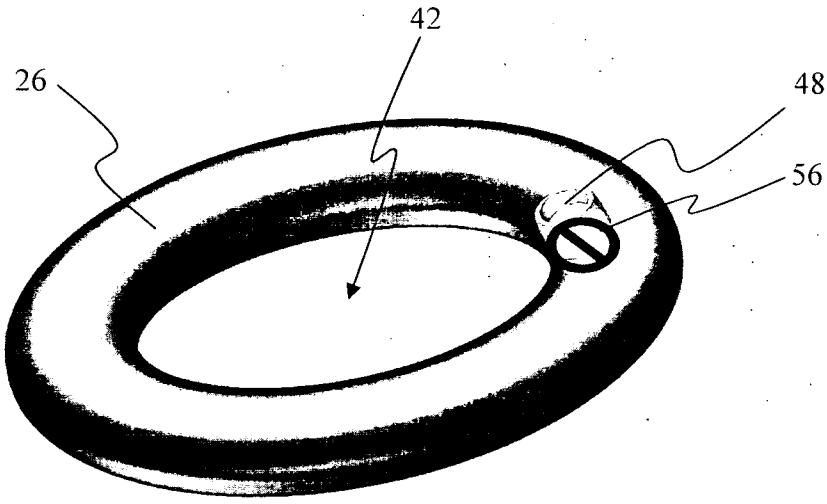


FIG. 9B

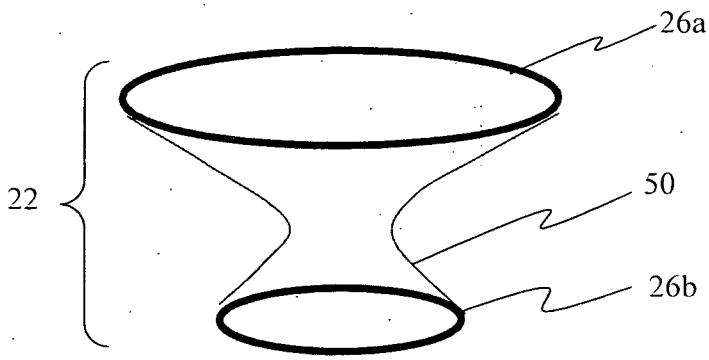


FIG. 10A

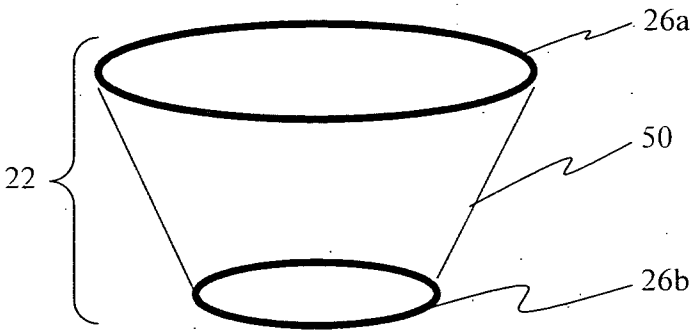


FIG. 10B

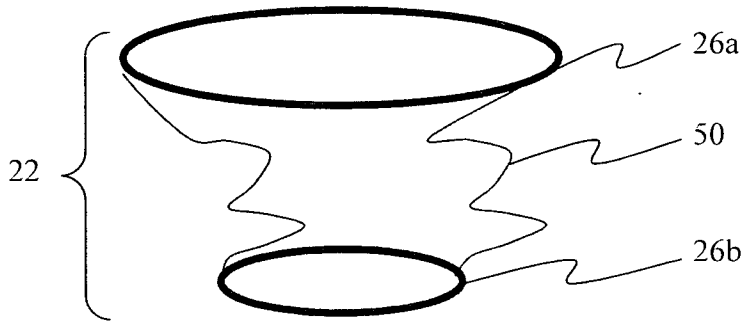


FIG. 10C

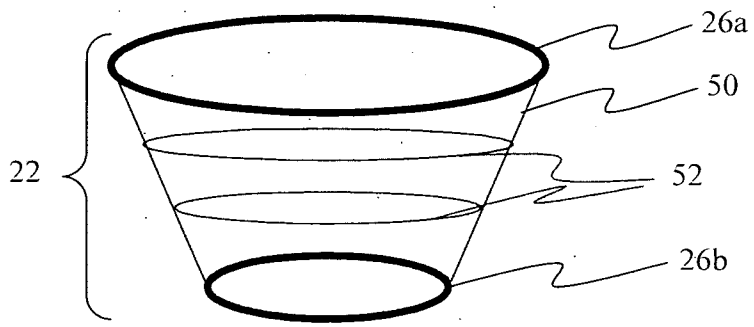


FIG. 10D

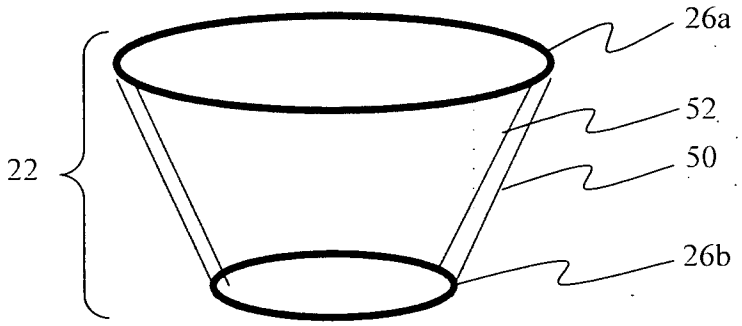


FIG. 10E

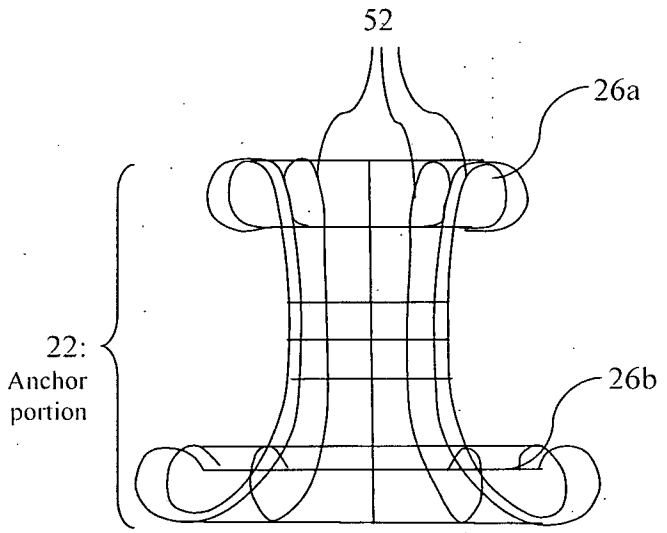


FIG. 11A

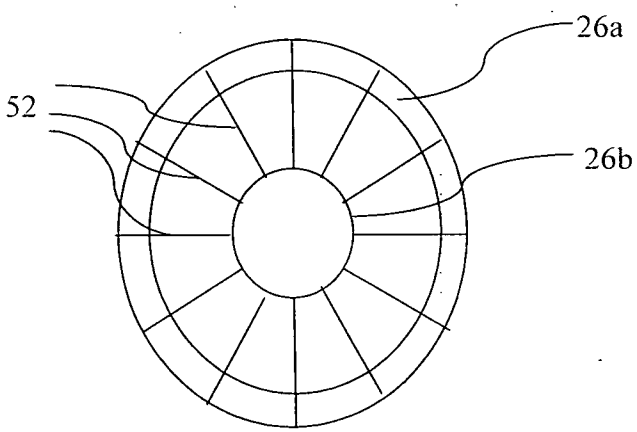


FIG. 11B

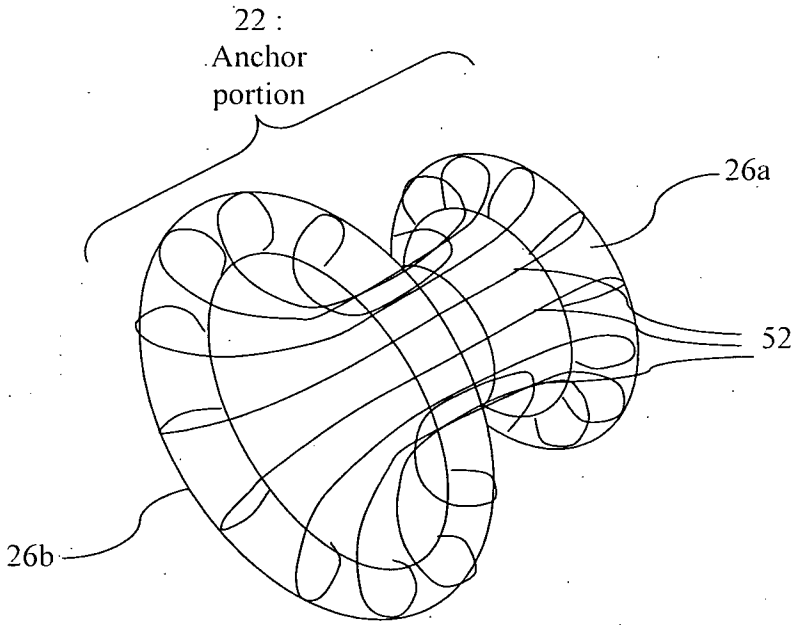


FIG. 11C

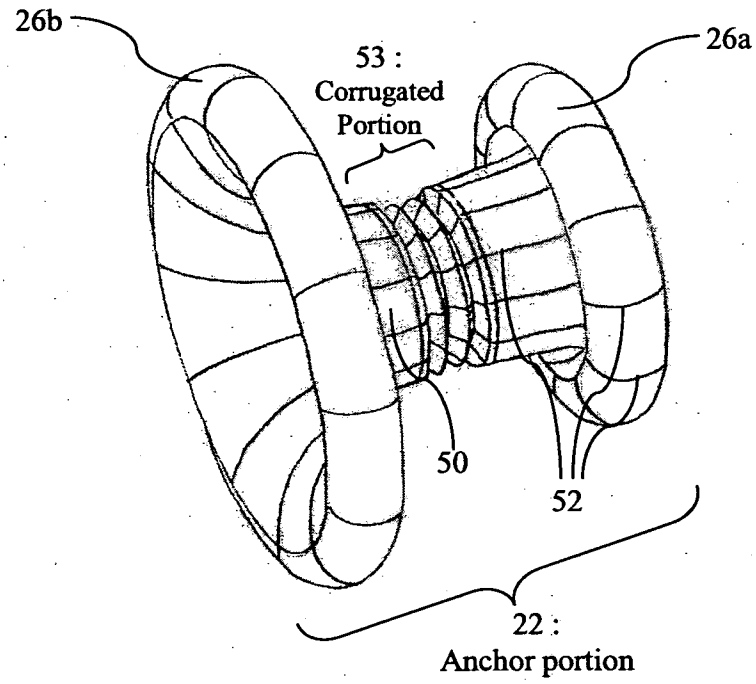


FIG. 12

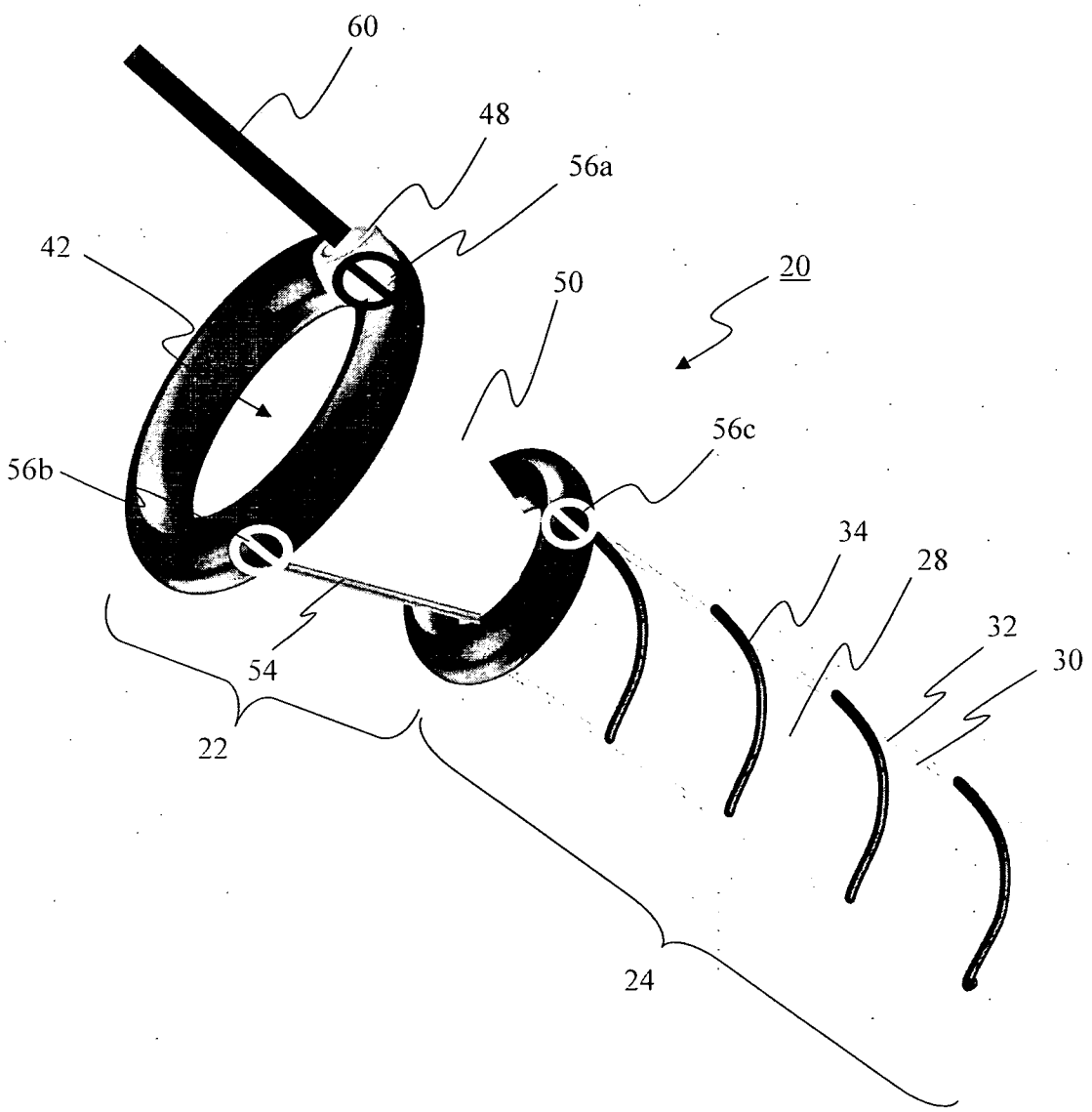


FIG. 13

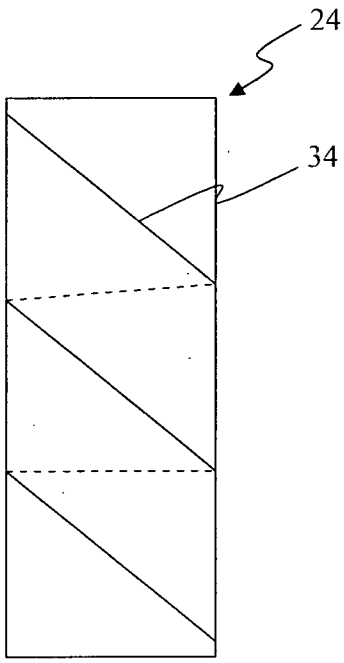


FIG. 14A

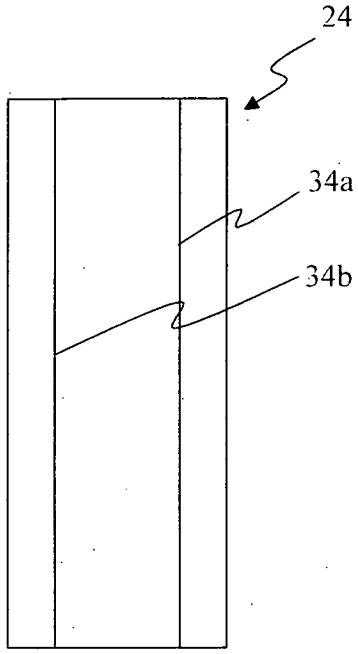


FIG. 14B

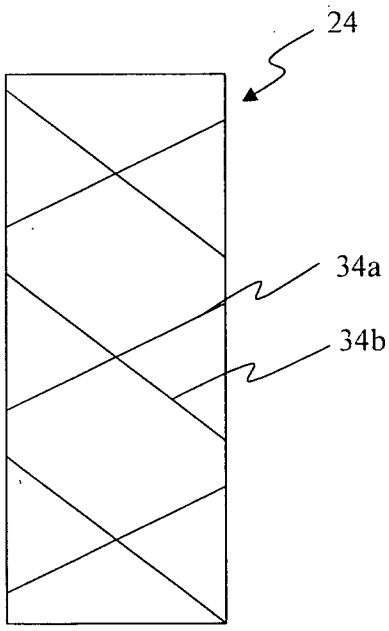


FIG. 14C

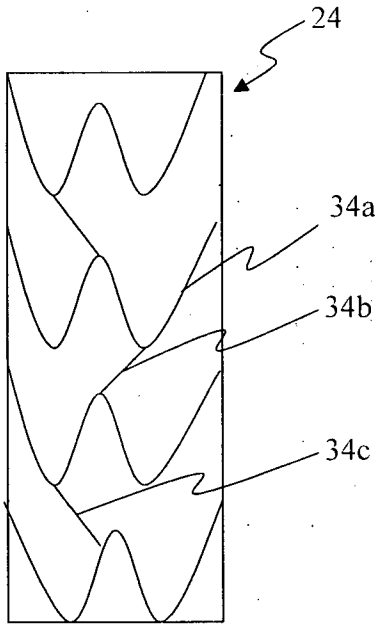


FIG. 14D

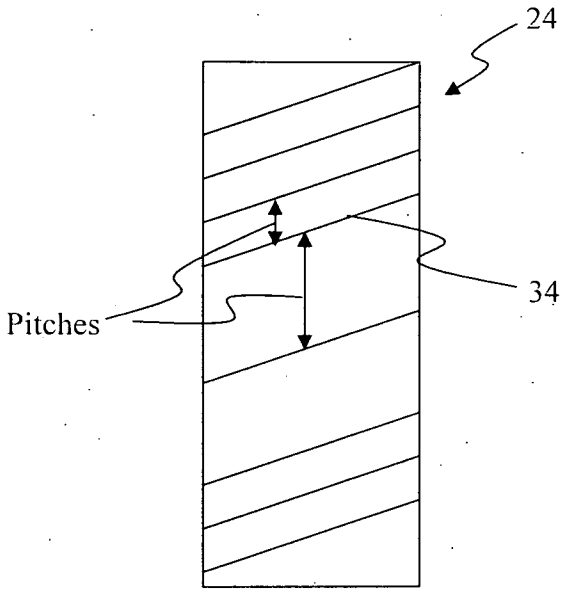


FIG. 14E

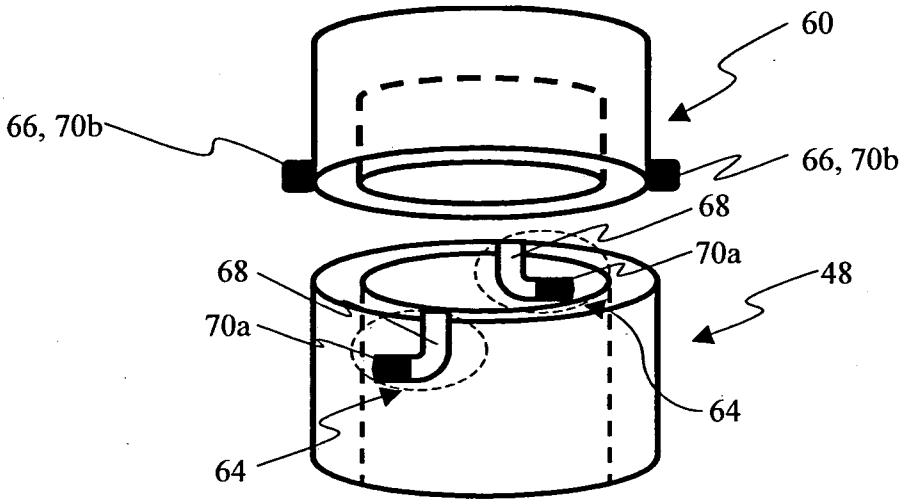


FIG. 15A

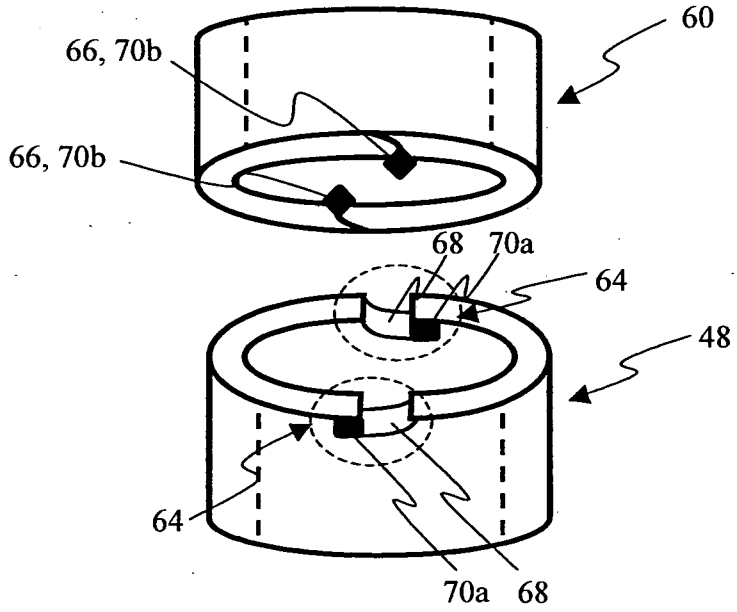


FIG. 15B

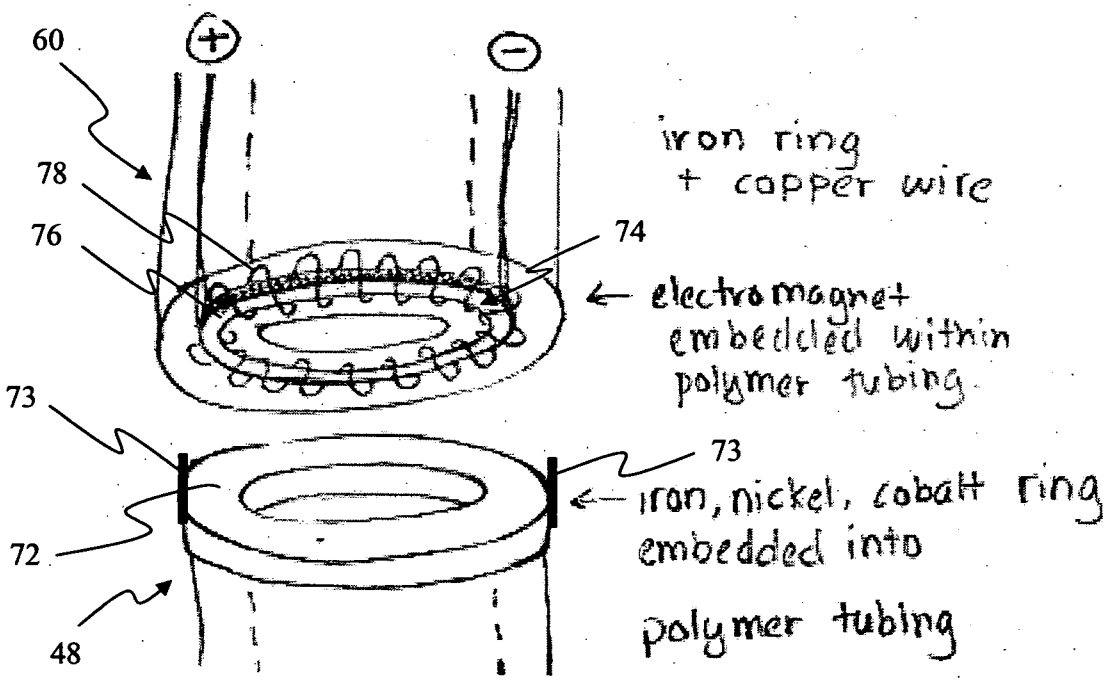

60
78
76
74
73
72
48
73
+
−
iron ring
+ copper wire
electromagnet
embedded within
polymer tubing
iron, nickel, cobalt ring
embedded into
polymer tubing

FIG. 16

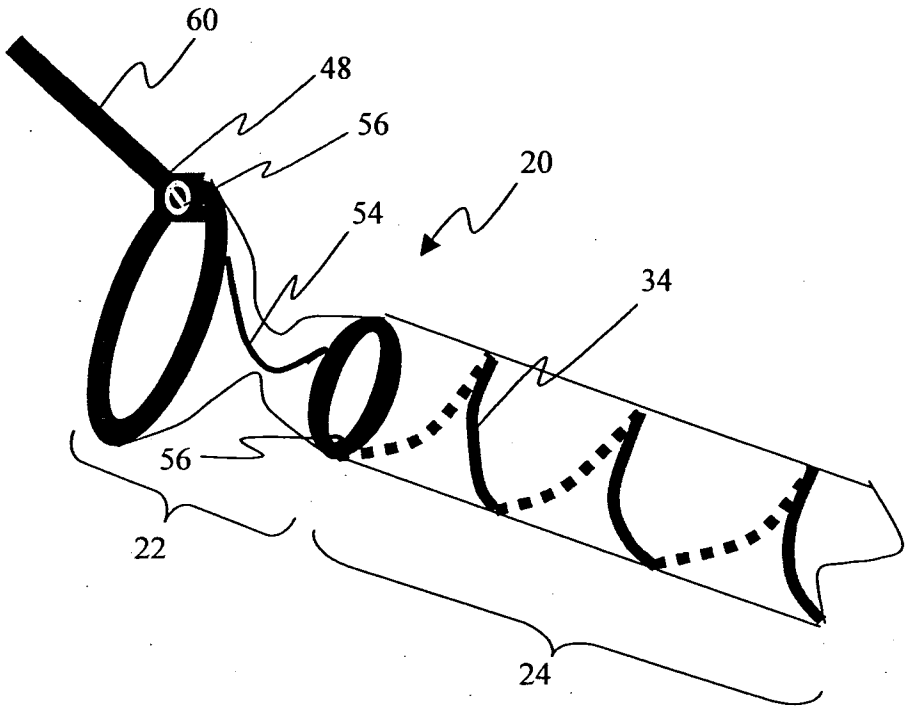


FIG. 17A

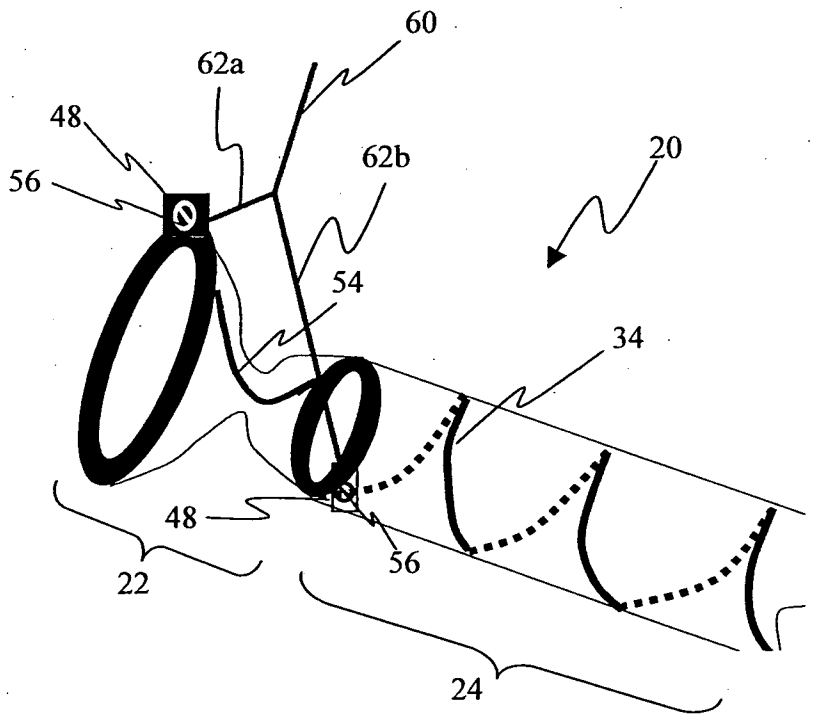


FIG. 17B

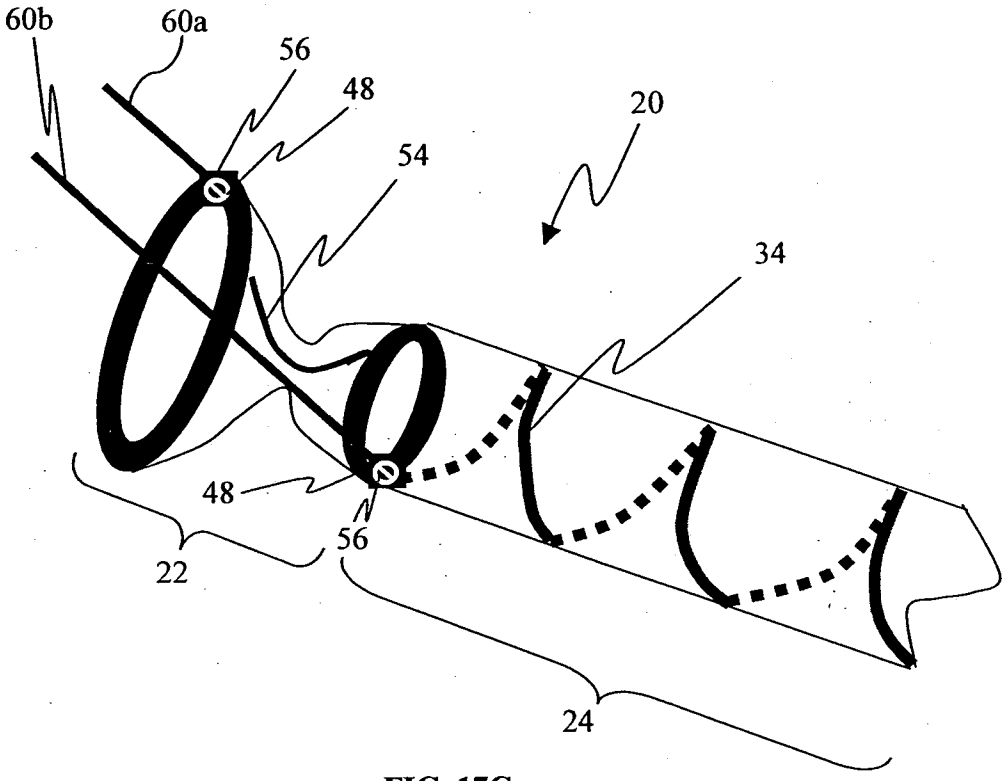


FIG. 17C

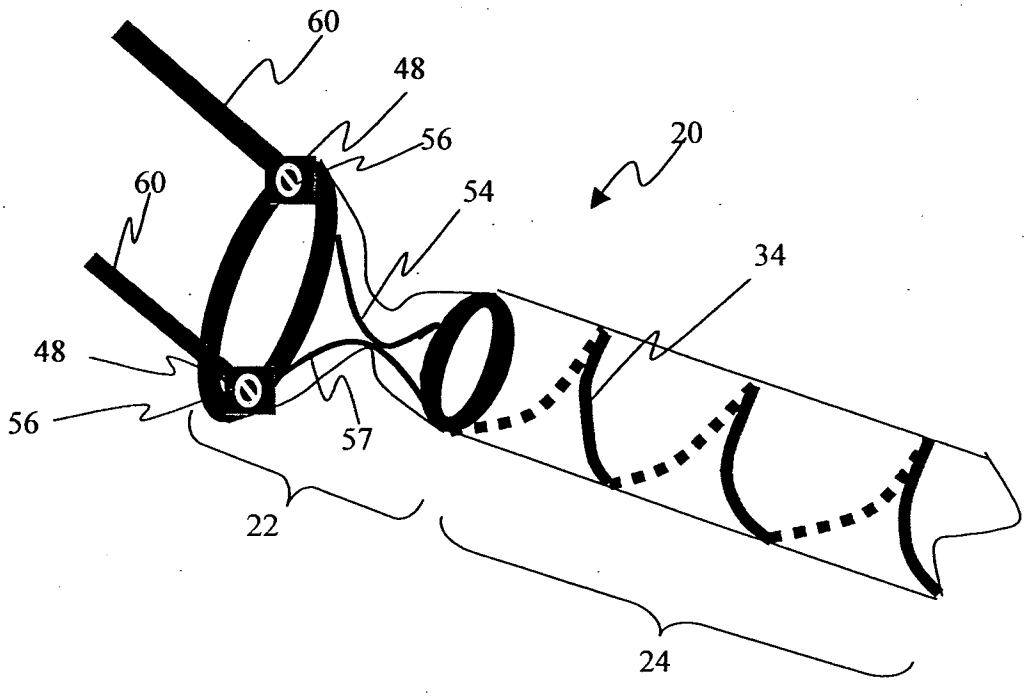


FIG. 17D

FIG. 17D

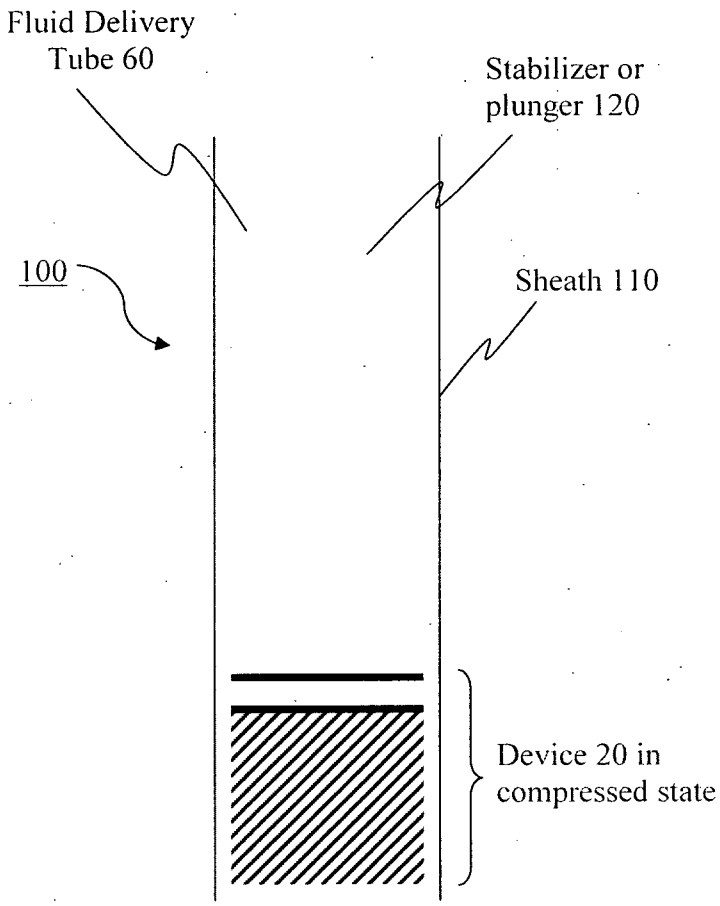


FIG. 18A

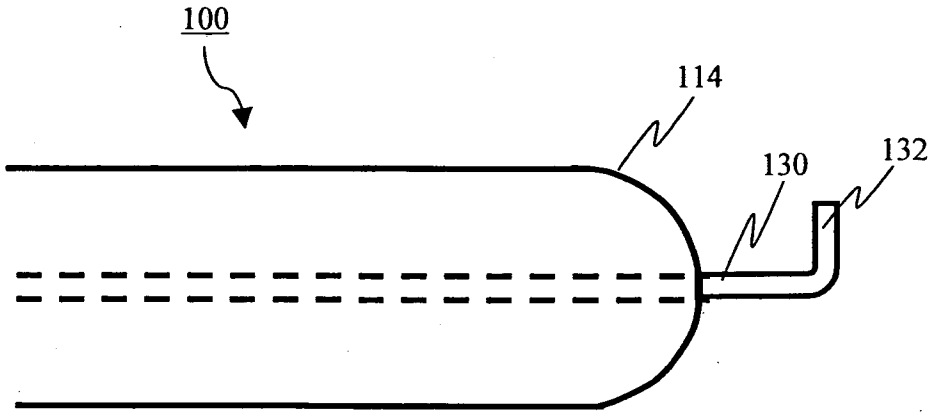


FIG. 18B

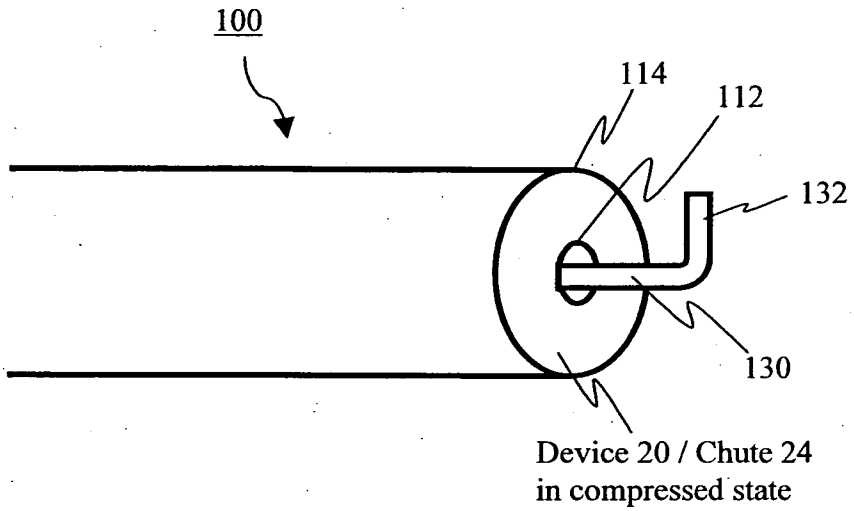


FIG. 18C

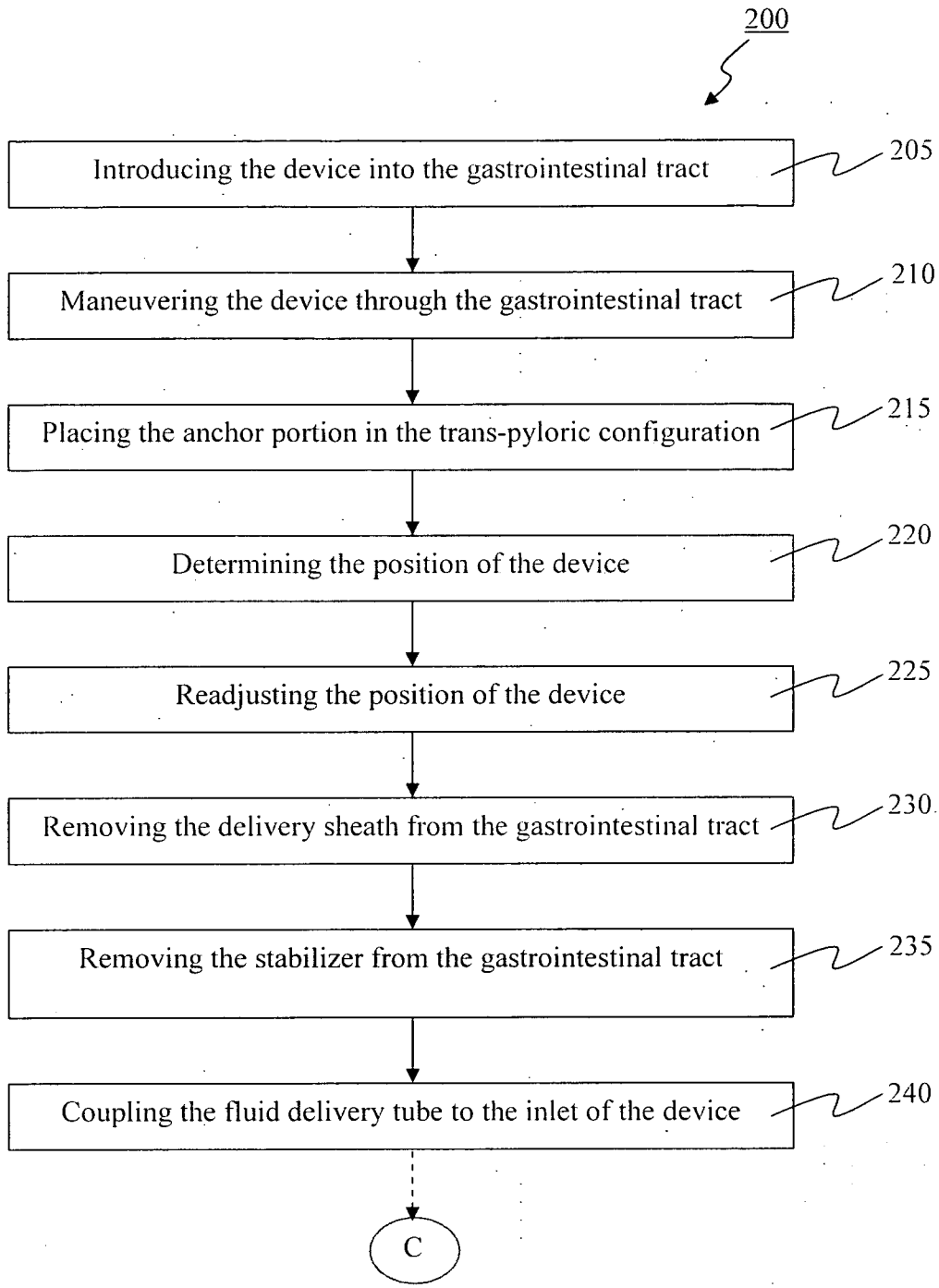

200
Introducing the device into the gastrointestinal tract
205
Maneuvering the device through the gastrointestinal tract
210
Placing the anchor portion in the trans-pyloric configuration
215
Determining the position of the device
220
Readjusting the position of the device
225
Removing the delivery sheath from the gastrointestinal tract
230
Removing the stabilizer from the gastrointestinal tract
235
Coupling the fluid delivery tube to the inlet of the device
240
C

FIG. 19A

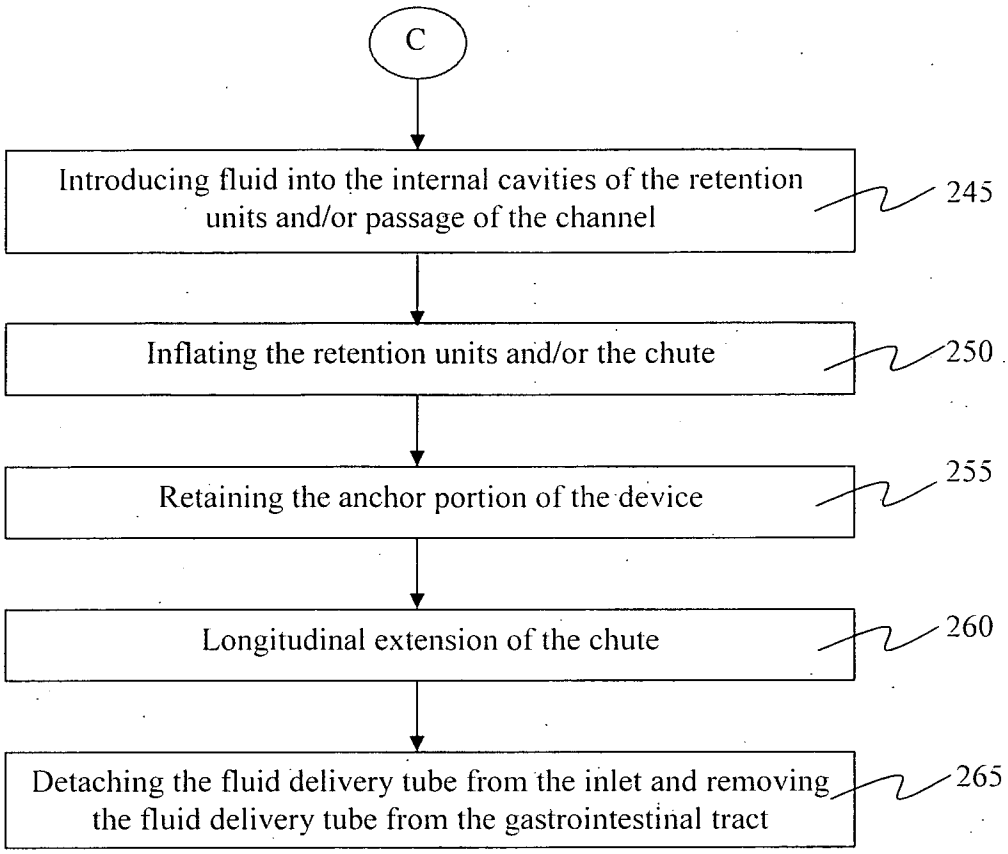

C
Introducing fluid into the internal cavities of the retention units and/or passage of the channel
245
Inflating the retention units and/or the chute
250
Retaining the anchor portion of the device
255
Longitudinal extension of the chute
260
Detaching the fluid delivery tube from the inlet and removing the fluid delivery tube from the gastrointestinal tract
265

FIG. 19B

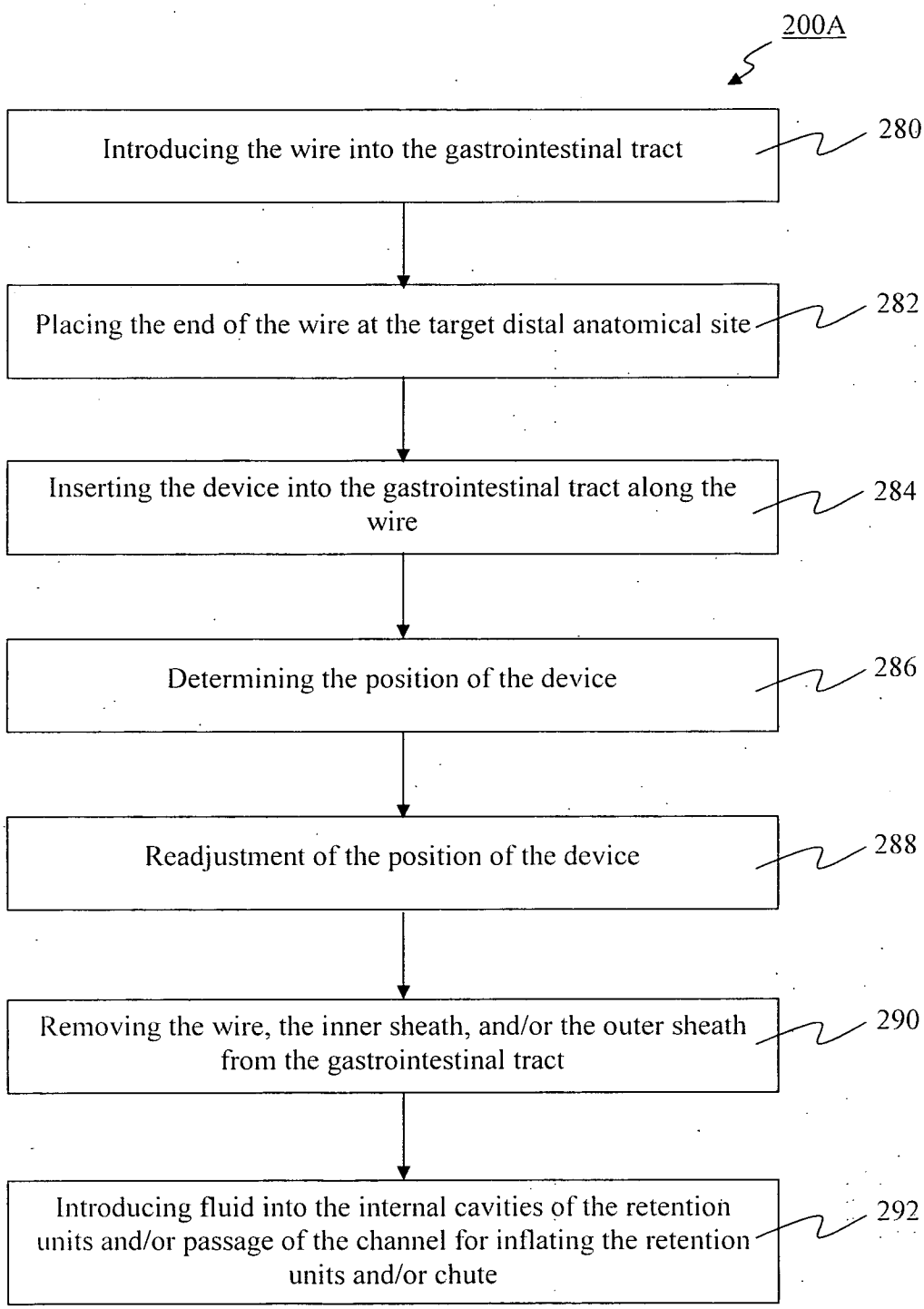
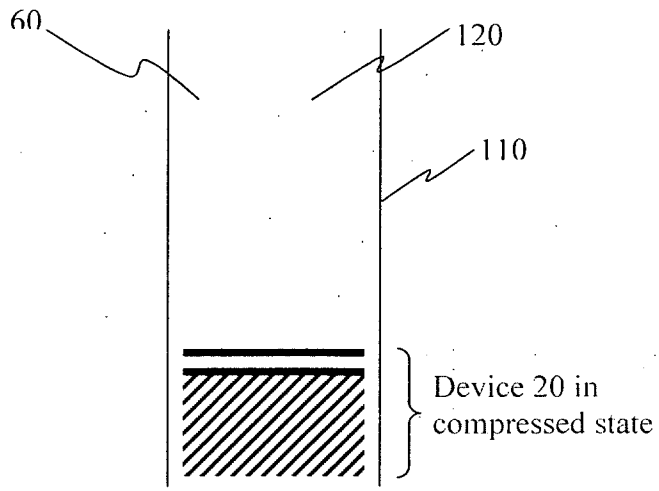
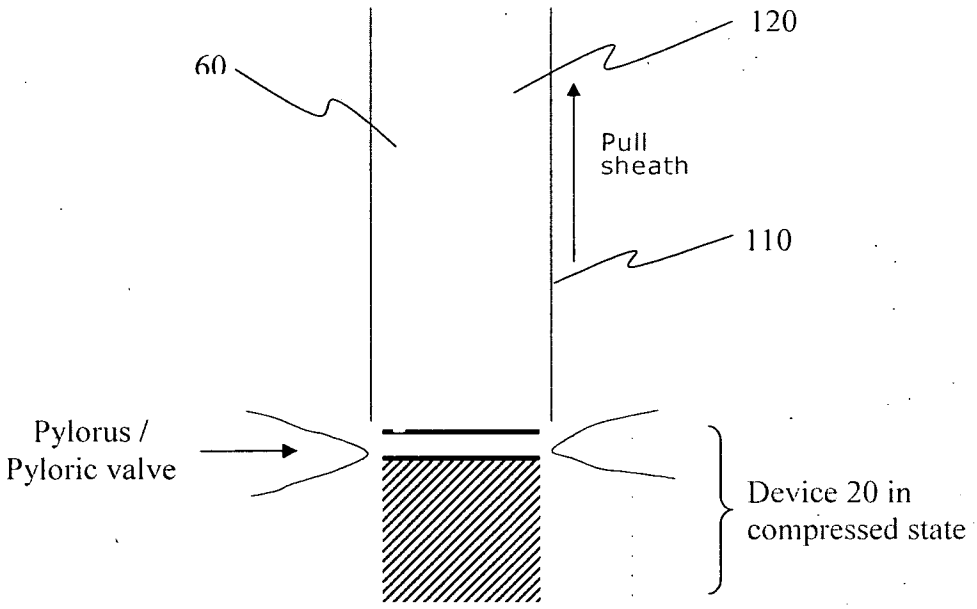

200A
Introducing the wire into the gastrointestinal tract
280
Placing the end of the wire at the target distal anatomical site
282
Inserting the device into the gastrointestinal tract along the wire
284
Determining the position of the device
286
Readjustment of the position of the device
288
Removing the wire, the inner sheath, and/or the outer sheath from the gastrointestinal tract
290
Introducing fluid into the internal cavities of the retention units and/or passage of the channel for inflating the retention units and/or chute
292

FIG. 19C



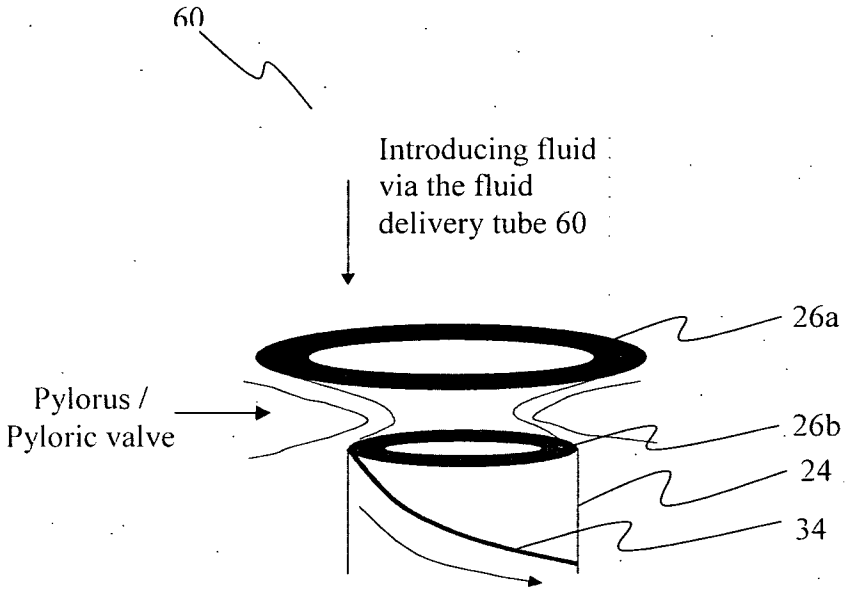
Delivery of device (in compressed state) through the gastrointestinal tract

FIG. 20A



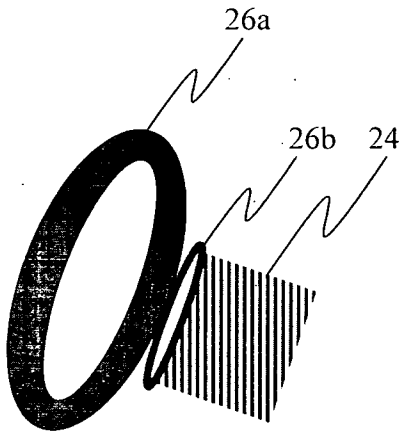
Removing the sheath with device is positioned in a trans-pyloric configuration

FIG. 20B



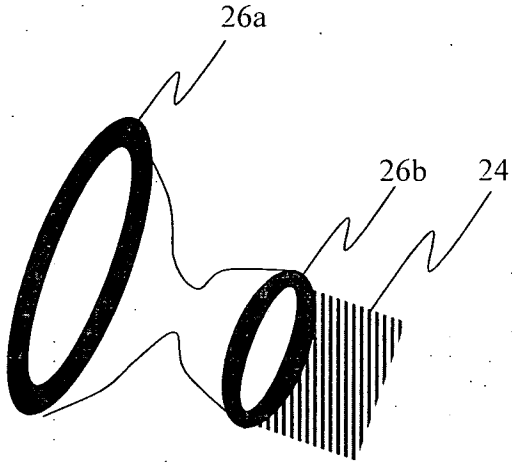
Inflating the retention units and the chute

FIG. 20C



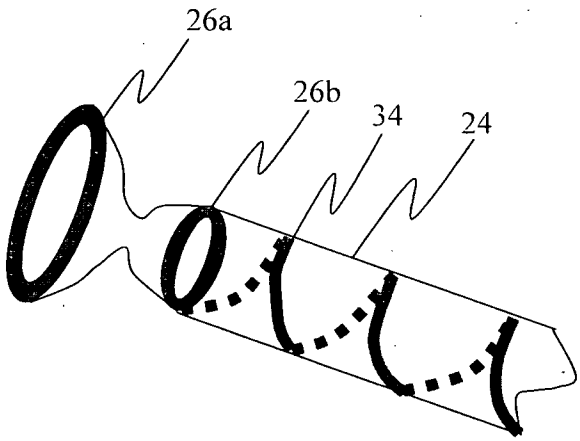
Step A: Inflating the first retention unit

FIG. 21A



Step B: Inflating the second retention unit

FIG. 21B



Step C: Longitudinal extension and inflation of the chute

FIG. 21C

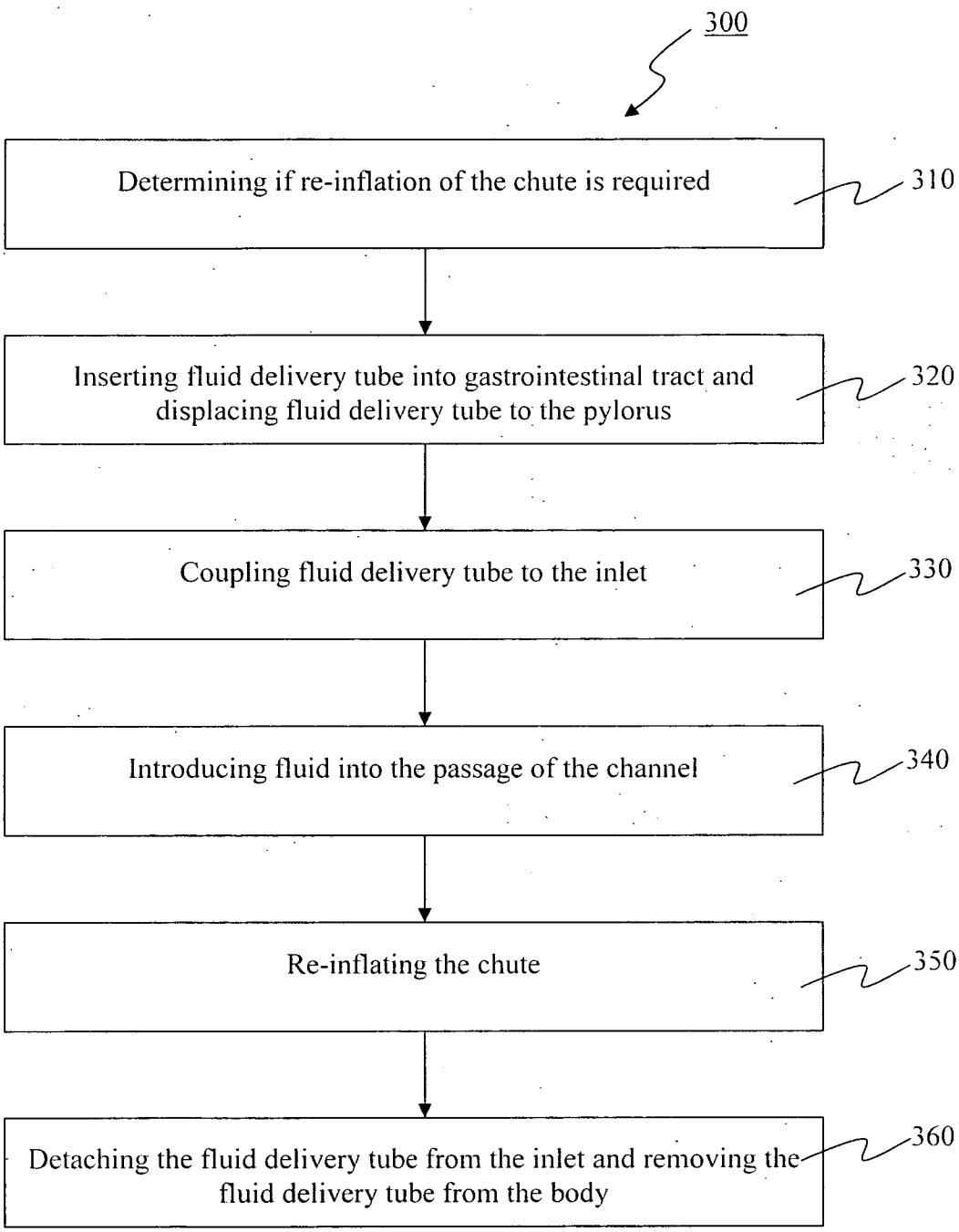
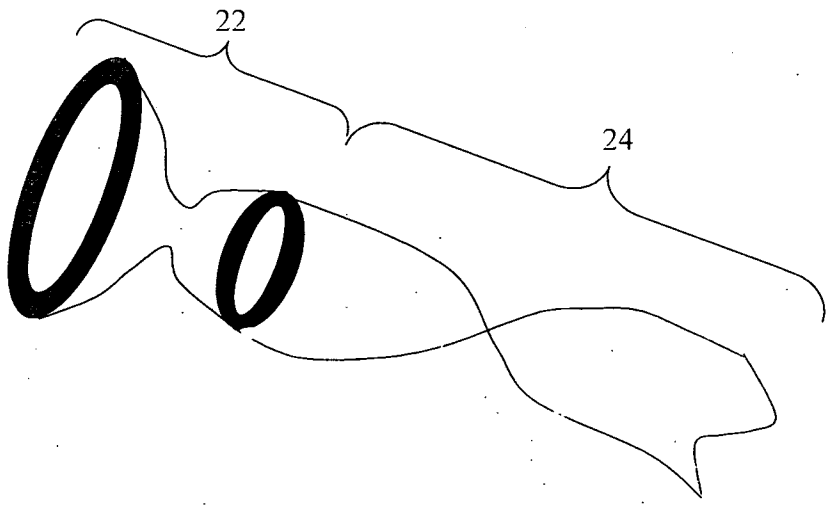
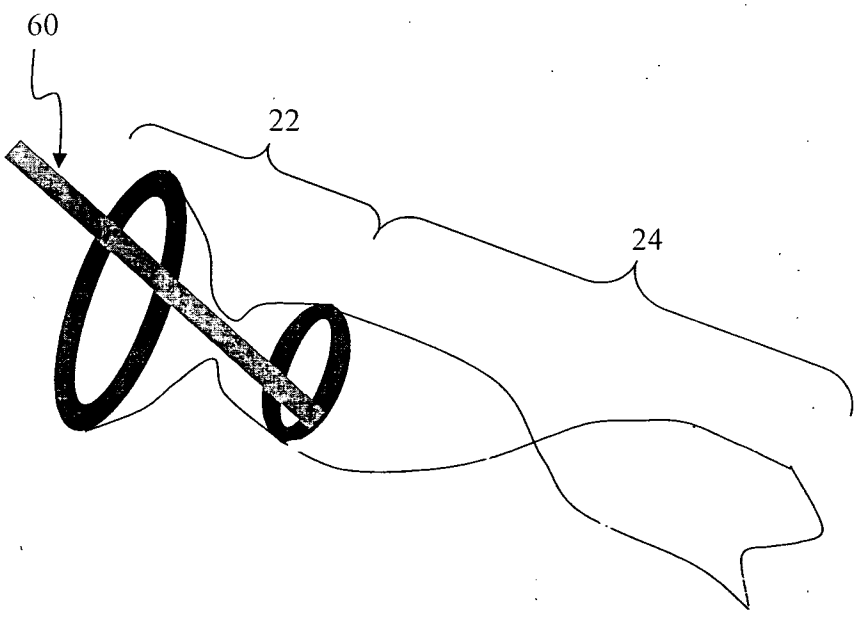

300
Determining if re-inflation of the chute is required
310
Inserting fluid delivery tube into gastrointestinal tract and displacing fluid delivery tube to the pylorus
320
Coupling fluid delivery tube to the inlet
330
Introducing fluid into the passage of the channel
340
Re-inflating the chute
350
Detaching the fluid delivery tube from the inlet and removing the fluid delivery tube from the body
360

FIG. 22



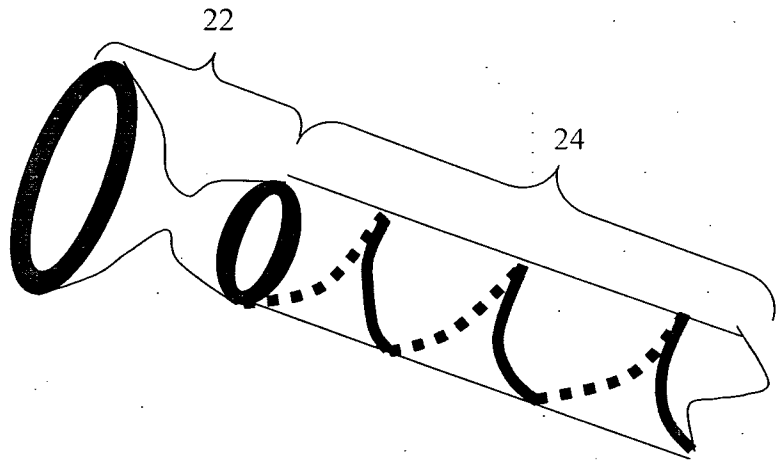
Step A: Determining that chute is in a twisted or misaligned configuration

FIG. 23A



Step B: Coupling the fluid delivery tube to the inlet of the channel

FIG. 23B



Step C: Re-inflating the chute

FIG. 23C

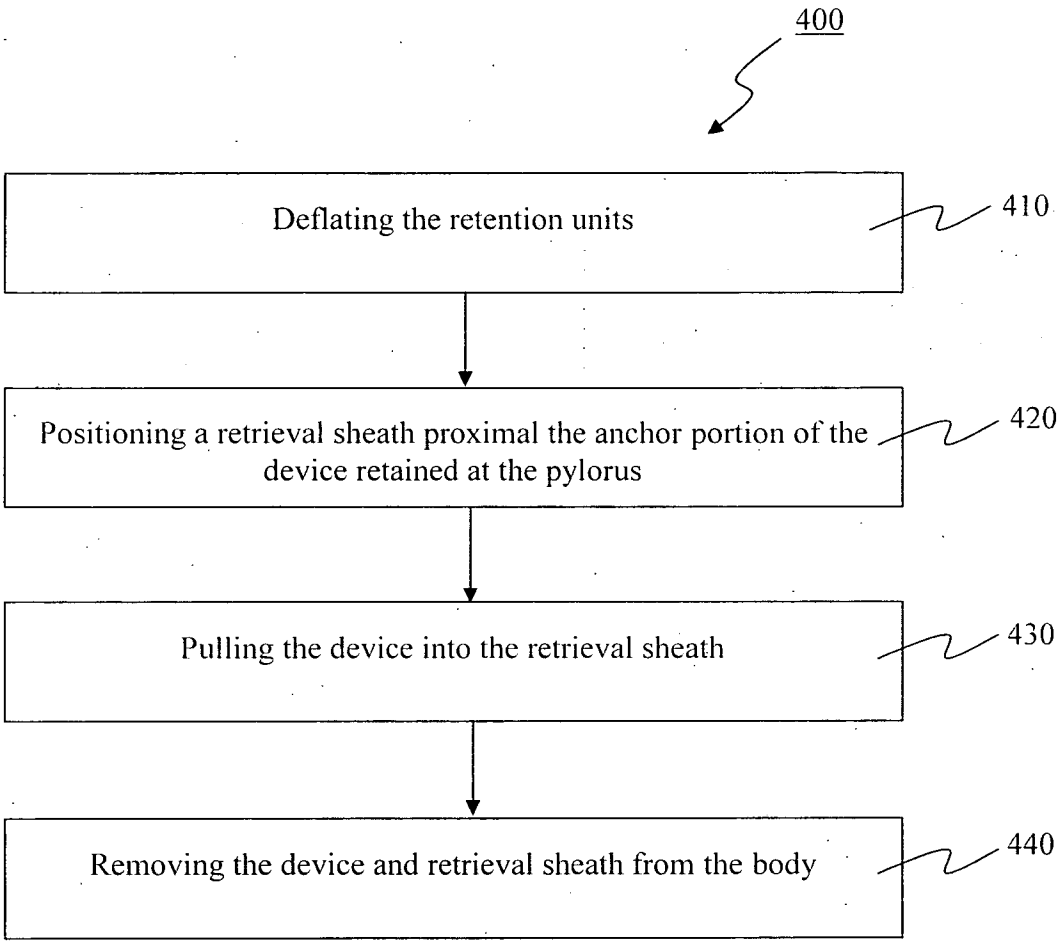
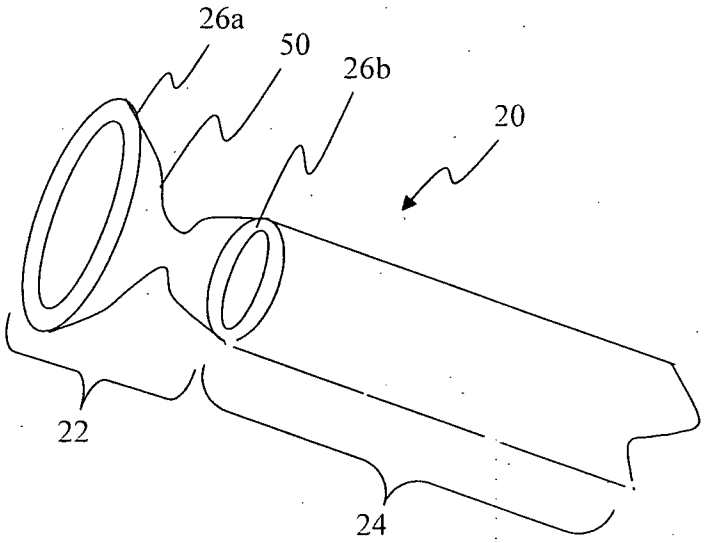
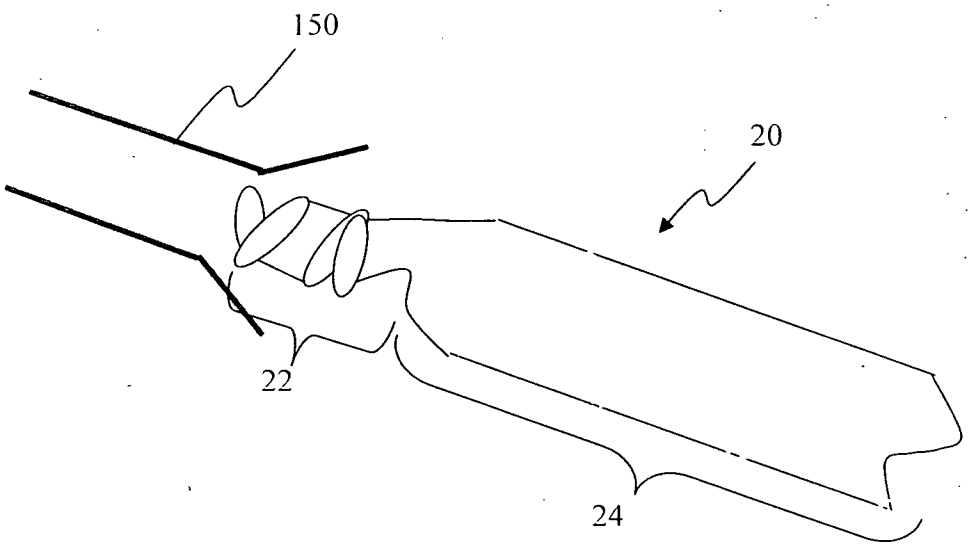

400
Deflating the retention units
410
Positioning a retrieval sheath proximal the anchor portion of the device retained at the pylorus
420
Pulling the device into the retrieval sheath
430
Removing the device and retrieval sheath from the body
440

FIG. 24



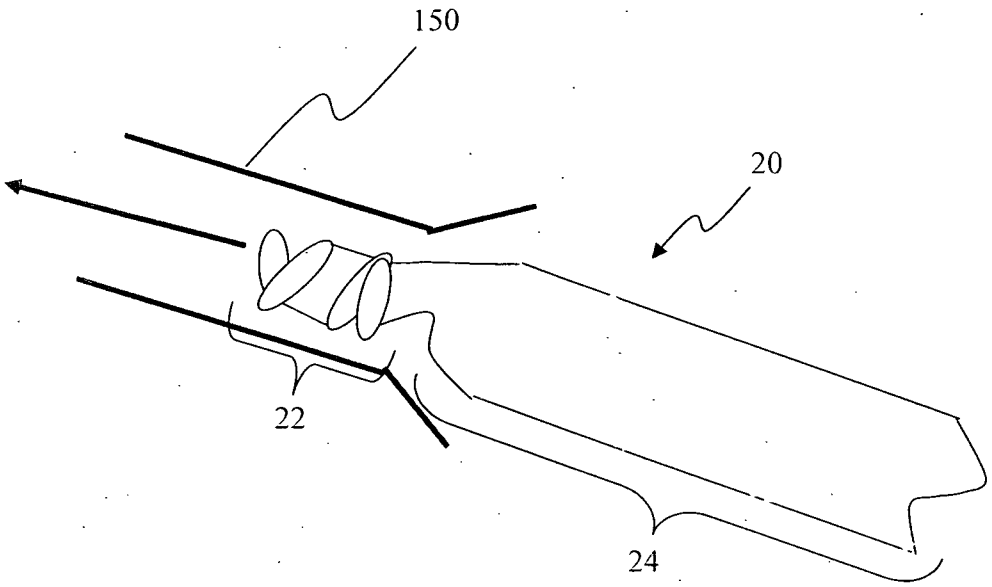
Step A: Deflating the retention units

FIG. 25A



Step B: Positioning the retrieval sheath proximal the deflated retention units

FIG. 25B



Step C: Pulling the device into the retrieval sheath

FIG. 25C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SG2011/000060

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. ***A61F 2/04*** (2006.01) ***A61B 17/00*** (2006.01) ***A61M 29/00*** (2006.01)

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)

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)
WPI, EPODOC: IPC A61B 17/-, A61F 2/-, A61M 29/- and Keywords (pylor+, gastr+, valve, exten+, passag+ , fluid) and like terms

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2008/0195226 A1 (WILLIAMS et al.) 14 August 2008 See figures 1A, 1B, 2A, 2B, 10A and 24A-24C; paragraphs [0048]-[0050], [0053]-[0054], [0063] and [0073]-[0075].	1-9, 52-70, 73-77, 99-103, 123-127 and 143-147
P, X	US 2011/0004228 A1 (PRIPLATA et al.) 6 January 2011 See abstract; figures 2, 3, 10A, 14 and 16; paragraphs [0100], [0102], [0105], [0109] to [0111], [0122], [0125]-[0131] and [0155].	1-7, 9-23, 52-57, 62, 71-80, 82-91, 94-96, 99-107, 109, 123, 128-130, 132-135, 143-146 and 148-152
A	US 2009/0259238 A1 (GRAU et al.) 15 October 2009 See abstract; figures 2, 4, 6, 11 and 15 to 17; paragraphs [0083], [0110]-[0120] and [0122]-[0135].	
A	US 5820584 A (CRABB) 13 October 1998 See figures 2 and 3.	

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

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"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

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Date of the actual completion of the international search	Date of mailing of the international search report
12 April 2011	13 APR 2011
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. +61 2 6283 7999	Authorized officer **OSCAR VIOLANTE** AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No : +61 2 6283 7959

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/SG2011/000060

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report	Patent Family Member					
US 2008195226	EP	2061397	WO	2008030403		
US 2011004228	US	2011000496	US	2011004146	US	2011004229
	US	2011004234	US	2011004236	US	2011004320
	US	2011046537				
US 2009259238	US	2009259237	US	2009259239	US	2009259240
	WO	2009126268	WO	2009126331		
US 5820584	NONE					

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX