Title: IMPROVED AND ENHANCED EXPLANT PROCESSES AND MECHANISMS FOR INTRAGASTRIC DEVICES

Abstract: A sealing device attached to an intragastric balloon device having a head flexibly attached to a body by a pivot portion, where the pivot portion provides the head with a closed state and an open state relative to the body and the intragastric device. The sealing device having one or more plugs configured to seal an aspiration port of a lumen when the head is in a closed state and further configured to release the aspiration port of the lumen when the head is in an open state.
CROSS-REFERENCE TO RELATED APPLICATION(S)

[0001] This application claims the benefit of U.S. Provisional Application No. 61/308,210 filed February 25, 2010, the subject matter of which is incorporated by reference in its entirety.

RELATED REFERENCES


BACKGROUND

[0003] This disclosure relates to implantable, expandable gastric devices. In particular, this disclosure relates to mechanisms and procedures for controlled deflation and explant of such devices.

[0004] Many conventional implantable gastric devices have a balloon filled with a biocompatible fluid. Such gastric devices are generally inserted into the stomach when the balloon is deflated and then inflated in vivo. The gastric devices are often left in the stomach for an extended period of time to treat severe obesity or other conditions. The gastric devices are eventually removed after completing the treatment or for other reasons by deflating the balloon, grasping the gastric device with an extraction tool, and extracting the gastric device via the
esophagus and mouth. Conventional gastric devices are deflated by attempting to puncture the balloon and aspirate the biocompatible fluid through a needle.

[0005] One challenge of deflating conventional devices is that the balloon may rupture when it is punctured by the needle. For example, the balloon typically degrades over time because stomach acids, fungi, and bacteria may degrade the integrity of the balloon wall, and the needle puncture may cause a degraded balloon wall to fail. Also, it is difficult to control the angle between the needle and the balloon, and the needle will tend to rip the balloon as opposed to puncturing the balloon at certain angles. When the balloon ruptures, the biocompatible fluid is quickly expelled into the stomach, which complicates the extraction procedure and may be uncomfortable to the patient. Furthermore, it is believed that uncontrolled rupture of the balloon may permit portions of the balloon to detach, expose interior portions of the device normally contained within the balloon, permit the needle to undesirably engage structures normally contained within the balloon, require additional steps to recover separated components of the balloon or device, or cause discomfort or injury to the patient.

[0006] Another challenge of implantable gastric devices is grasping the device for extraction. Several existing devices are grasped by a claw or snare. These procedures can be challenging because projections and/or other features that are easy to grasp may agitate the stomach wall. Thus, there is a need to improve the deflation and extraction of implantable gastric devices.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] Several embodiments of the present technology are described and shown with reference to the following description taken in conjunction with the accompanying drawings wherein like reference numerals denote like elements.

[0008] Figure 1 shows a perspective view of an intragastric device.

[0009] Figure 2 shows a top view of an intragastric device.

[0010] Figure 3 shows a sectional view of the intragastric device of Figure 2.

[0011] Figure 3A shows the perspective view of Figure 1 with a cut-out showing internal features of the intragastric device of Figure 1.

[0012] Figure 4 shows a sectional view of the intragastric device of Figure 2.
Figure 5 shows a perspective view of a sealing device in a closed state.

Figure 6 shows a perspective view of a sealing device in a closed state.

Figure 7 shows a side view of a sealing device in a closed state.

Figure 8 shows a front view of a sealing device in a closed state.

Figure 9 shows a top view of a sealing device in a closed state.

Figure 10 shows a bottom view of a sealing device in a closed state.

Figure 11 shows a sectional view of the sealing device of Figure 9.

Figure 12 shows a sectional view of the sealing device of Figure 9.

Figure 13 shows a perspective view of a sealing device in an open state.

Figure 14 shows a perspective view of a sealing device in an open state.

Figure 15 shows a side view of a sealing device in an open state.

Figure 16 shows a front view of a sealing device in an open state.

Figure 17 shows a top view of a sealing device in an open state.

Figure 18 shows a bottom view of a sealing device in an open state.

Figure 19 shows a sectional view of the sealing device of Figure 17.

Figure 20 shows a sectional view of the sealing device of Figure 17.

Figure 21 shows a perspective view of a sealing device in a closed state.

Figure 22 shows a perspective view of a sealing device in a closed state.

Figure 23 shows a side view of a sealing device in a closed state.

Figure 24 shows a front view of a sealing device in a closed state.

Figure 25 shows a top view of a sealing device in a closed state.

Figure 26 shows a bottom view of a sealing device in a closed state.

Figure 27 shows a sectional view of the sealing device of Figure 25.

Figure 28 shows a sectional view of the sealing device of Figure 25.

Figure 29 shows a perspective view of a sealing device in an open state.
[0038] Figure 30 shows a perspective view of a sealing device in an open state.

[0039] Figure 31 shows a side view of a sealing device in an open state.

[0040] Figure 32 shows a front view of a sealing device in an open state.

[0041] Figure 33 shows a top view of a sealing device in an open state.

[0042] Figure 34 shows a bottom view of a sealing device in an open state.

[0043] Figure 35 shows a sectional view of the sealing device of Figure 33.

[0044] Figure 36 shows a sectional view of the sealing device of Figure 33.

[0045] Figure 37 shows a perspective view of a sealing device in a closed state.

[0046] Figure 38 shows a perspective view of a sealing device in a closed state.

[0047] Figure 39 shows a side view of a sealing device in a closed state.

[0048] Figure 40 shows a front view of a sealing device in a closed state.

[0049] Figure 41 shows a top view of a sealing device in a closed state.

[0050] Figure 42 shows a bottom view of a sealing device in a closed state.

[0051] Figure 43 shows a sectional view of the sealing device of Figure 41.

[0052] Figure 44 shows a sectional view of the sealing device of Figure 41.

[0053] Figure 45 shows a partial perspective view of an intragastric device.

[0054] Figure 46 shows a perspective view of an intragastric device with a magnified view of a sealing device and a snare device.

[0055] Figure 47 shows a perspective view of an intragastric device with a magnified view of a sealing device.

[0056] Figure 48 shows a partial perspective view of an endoscope with suction device.

[0057] Figure 49 shows a partial side view of an endoscope with suction device.

[0058] Figure 50 shows a partial side view of an endoscope with suction device.

[0059] Figure 51 shows an end view of an endoscope with suction device.

[0060] Figure 52 shows a partial sectional view of an endoscope with suction device.
[0061] Figure 53 shows a partial sectional view of an endoscope with an alternative configuration.

DETAILED DESCRIPTION

[0062] Specific details of several embodiments of the present technology are described below with reference to an intragastric device with a sealing device and methods for implanting and explanting such devices. Although many of the embodiments are described below with respect to a dual balloon intragastric device, other types of devices with only one balloon or more than two balloons may be within the scope of the technology. Moreover, several other embodiments of the technology can have different configurations, components, or procedures than those described in this section. A person of ordinary skill in the art, therefore, will accordingly understand that the technology may have other embodiments with additional elements, or the technology may have other embodiments without several of the features shown and described below with reference to Figures 1-53.

[0063] Several embodiment of the present technology are directed to a sealing device for use with an intragastric device comprising a body fixedly attached to an intragastric balloon device and a head attached to the body. The sealing device can have at least one plug aligned with and configured to seal an aspiration port of a lumen when the plug is in a closed state. The sealing device can be further configured to provide access to the lumen when the plug is in an open state (e.g., when the plug is move so as to no longer fully obstruct the lumen).

[0064] Additional embodiments of the technology are directed to an intragastric balloon device comprising a shaft having a plurality of lumens and a plurality of balloons carried by the shaft. Each balloon can be fluidically coupled to a corresponding lumen of the shaft such that an interior portion of each balloon is in fluid communication with its corresponding lumen. The intragastric balloon device can further include a sealing device having a body fixedly attached to the shaft and/or one of the balloons. The sealing device can also have a head attached to the body and at least one plug configured to seal an aspiration port of one of the lumens when the plug is in a closed state and to provide fluidic access to the lumen when the plug is in an open state.

[0065] Still additional embodiments of the present technology are directed to a method of aspirating an intragastric balloon device comprising providing an endoscope device to the
intragastric balloon device within a gastric cavity. The intragastric balloon device includes at least one fluid-filled balloon and a sealing device with a body fixedly attached to the intragastric balloon device. The sealing device further includes a head attached to the body and at least one plug configured to seal an aspiration port of a lumen of the intragastric device when the plug is in a closed state and to provide fluidic access to the lumen when the plug is in an open state. The method can further comprise securing the endoscope device to at least a portion of the sealing device, moving the sealing device to an open state by removing the plug from the lumen, whereby access to fluid in the corresponding lumen is achieved, and aspirating the fluid from the at least one balloon via the lumen.

[0066] In one embodiment, an intragastric device 10 may include at least one collapsible, space-filling component, such as a balloon. As shown in Figure 1, a plurality of balloons (e.g., a first balloon 30a and a second balloon 30b) may be fixed to a shaft 20 of the intragastric device 10.

[0067] In the particular embodiments of the technology shown in Figures 1-3, the intragastric device 10 may include or be configured to interface with a sealing device 100 at an end of the intragastric device 10 and a plug 45 at another end of the intragastric device 10. As used herein, the terms "first" and "second" can refer to "proximal" and "distal" locations, relative locations, and orientations of structures, devices, and components. For example, the terms "first", "second", "proximal" and "distal" may be understood to refer to relative identifiers, rather than absolute identifiers except where expressly stated as such. As those having skill in the relevant art will recognize, variation and modification of the disclosure on the same basis is considered within the present disclosure.

[0068] Referring to Figure 3, the shaft 20 of the intragastric device 10 may include a plurality of lumens; each lumen can correspond to an individual balloon of the intragastric device 10. For example, a first lumen 40a may provide fluid communication from a first inflation port 47a to an interior portion of the first balloon 30a via a first inflation opening 32a. Likewise, a second lumen 40b may provide fluid communication from a second inflation port 47b to an interior portion of the second balloon 30b via a second inflation opening 32b.

[0069] According to embodiments, and as shown in Figure 3, each lumen may have a corresponding inflation port at an end of the lumens. Inflation ports may be configured to allow infusion of fluids into corresponding lumens and inhibit or prevent exit of fluids from the same.
Inflation ports may include check valves, clack valves, non-return valves, one-way valves, duckbill valves, reed valves, etc. For example, a plug 45 may be positioned at the end of the first balloon 30a to dispose the first inflation port 47a at an end of the first lumen 40a and to dispose the second inflation port 47b at an end of the second lumen 40b.

[0070] According to embodiments, and as shown in Figure 3, each lumen of the shaft 20 may be divided into inflation and aspiration chambers. For example, the first lumen 40a may be divided into a first inflation chamber 42a and a first aspiration chamber 44a by a first barrier 46a. Likewise, the second lumen 40b may be divided into a second inflation chamber 42b and a second aspiration chamber 44b by a second barrier 46b. Such barriers may partition a lumen into at least two separate chambers that may be fluidly connected via the interior portion of a corresponding balloon.

[0071] According to embodiments, each balloon may have an opening that fluidly connects the interior portion thereof with at least a portion of its corresponding lumen. According to embodiments, and as shown in Figure 3, each balloon may have a plurality of openings that connect the interior portion thereof with disparate chambers of its corresponding lumen. For example, a first inflation opening 32a may provide a fluid connection between the interior of the first balloon 30a and the first inflation chamber 42a, and a first aspiration opening 34a may provide a fluid connection between the interior of the first balloon 30a and the first aspiration chamber 44a.

[0072] According to embodiments, and as shown in Figures 3 and 3A, sleeves may be provided, each within the interior of a balloon and covering an inflation opening. Such sleeves may provide inflation of the balloon from the corresponding lumen while inhibiting or preventing deflation through the same opening. The sleeves may wrap radially around the portion of the shaft 20 near the corresponding opening. For example, a first sleeve 50a may be provided within the interior portion of the first balloon 30a and covering at least the first inflation opening 32a. Likewise, a second sleeve 50b may be provided within the interior portion of the second balloon 30b and covering at least the second inflation opening 32b. The sleeves may inhibit or prevent undesirable fluid pressure on inflation ports and thereby reduce leakage and associated issues. For example, when pressure within the balloon exceeds pressure in the corresponding lumen, a sleeve may be pressed against the corresponding opening to inhibit or prevent leakage into the lumen. When pressure within the lumen exceeds pressure
within the corresponding balloon, a sleeve may separate from the corresponding opening and permit infusion into the balloon via a space formed between the sleeve and shaft housing the lumen. Fluid flowing from the first inflation chamber 42a, through the first inflation opening 32a, through a space formed between the first sleeve 50a and the exterior surface of the shaft 20, and into the interior of the first balloon 30a is shown schematically by flow arrows 31a in Figure 3. Fluid flowing from the interior of the first balloon 30a, through the first aspiration opening 34a, and into the first aspiration chamber 44a is shown schematically by flow arrows 33a in Figure 3. Likewise, the second inflation opening 32b may provide a fluid connection between the interior of the second balloon 30b and the second inflation chamber 42b, and the second aspiration opening 34b may provide a fluid connection between the interior of the second balloon 30b and the second aspiration chamber 44b. Fluid flowing from the second inflation chamber 42b, through the second inflation opening 32b, through a space formed between the second sleeve 50b and the exterior surface of the shaft 20, and into the interior of the second balloon 30b is shown schematically by flow arrows 31b in Figures 3 and 3A. Fluid flowing from the interior of the second balloon 30b, through the second aspiration opening 34b, and into the second aspiration chamber 44b is shown schematically by flow arrows 33b in Figures 3 and 3A.

[0073] According to embodiments, and as shown in Figure 3, each lumen may have a corresponding aspiration port at an end of the lumen. Aspiration ports may be selectively covered by the sealing device 100, as further disclosed herein. For example, a first aspiration port 48a may be provided at a second end of the first lumen 40a. Likewise, a second aspiration port 48b may be provided at a second end of the second lumen 40b.

[0074] According to embodiments, and as shown in Figure 4, a guidewire channel 112 may extend through the sealing device 100, the plug 45, and the shaft 20 of the intragastric device 10. The guidewire channel 112 may be configured to accommodate a guidewire for assisted delivery and management of the intragastric device 10 during implant, explant, or maintenance thereof.

[0075] According to embodiments, and as shown in Figures 5-8, the sealing device 100 may be provided to selectably seal an end of the intragastric device 10. The sealing device 100 may include a body 102 and a head 104. The body 102 and head 104 may be flexibly coupled together by a joint 130, such as a pivot portion, which may enable the head 104 to move relative to the body 102 while maintaining a connection between the head 104 and the body 102. For
example, the sealing device 100 may have at least a closed state (see Figures 5-8) and an open state (see Figure 47) defined by the location or orientation of the head 104 and associated components relative to the body 102. In several embodiments, the joint 130 may comprise a rigid, semi-rigid, or flexible material that facilitates such a connection.

[0076] According to embodiments, and as shown in Figures 7 and 12, inter alia, at least the head 104 and the body 102 may define a recess 120 therebetween and adjacent to the joint 130, inter alia. The recess 120 may expose interior portions of the sealing device 100 and provide a securement location for devices to act upon the sealing device 100. For example, the recess 120 may facilitate operation of a snare or other device on the sealing device 100, as disclosed further herein.

[0077] According to embodiments, and as shown in Figures 5-8, inter alia, a flange 106 may extend radially outward from portions of the head 104 that do not otherwise exceed the circumferential limit of other components, such as the body 102 and the pivot portion 130, inter alia. The flange 106 may provide increased surface area and distribute forces applied at the head 104 across a greater surface area. The flange 106 may have a variety of geometries. For example, as shown in Figures 7 and 8, head 104 and the flange 106 separately or together may form a substantially smooth, convex surface which may be viewed as an arc in cross-section. For example, the top surface of the head 104 may be configured in an arc such that imaginary extensions of such an arc at least generally extend tangentially with a corresponding arc extending along the surface of nearby balloons (as shown in Figures 3 and 4), so as to provide a smooth transition between the outer surfaces of the head 104 and the balloon 30b. Likewise, the plug 45 can have a flat surface (or a convex surface similar to the surface of the head 104 and flange 106) that substantially aligns with the nearby surface of a balloon, so as to provide a smooth transition between the outermost surfaces of the plug 45 and balloon 30a. As also shown in Figure 4, the shape of walls of the balloons 30a and 30b may have a constant or near constant curvature as the surface of the balloon approaches the location of the sealing device 100 or plug 45. As shown in Figure 4, the walls of the balloons 30a and 30b can be further curved proximate to the sealing device 100 or plug 45 so as to curve sharply towards the inside of the balloon to join to the shaft 20 at a position disposed about the body 102 of the sealing device or about the base of the plug.
The balloons may be formed to present a fully-deflated state and a fully-inflated state, or a series of partially-inflated or over-inflated states suitable for the use of the intragastric device. A fully deflated state disposes the balloon so that it is pressed against or disposed loosely about the surface of the shaft so as to present a low profile for delivery. In a fully-inflated state, the balloon presents a profile in which the curvature of the surface of the balloon aligns with the curvature of the sealing device so as to minimize inflection points. In an over-inflated state, that balloon extends beyond the position observed with the fully-inflated state so as to present a balloon surface that curves inwardly towards an inwardly disposed sealing device. The balloon may also be formed of a material, or reinforced with a material, that limits the inflation of the balloon to a predetermined fully-inflated state, or that prevents further expansion of the balloon once the balloon achieves a fully-inflated state. The balloon may also be constructed of a flexible non-expandable material that is in a folded state when deflated and in a fully unfolded state when fully inflated.

According to embodiments, and as shown in Figures 9 and 10, inter alia, the flange 106 may include interruptions 108 or tabs around at least a portion of a perimeter of the head 104. The interruptions 108 may be configured to further distribute forces applied at the head 104. The interruptions 108 may further be configured to facilitate securement and interfacing with a securement device such as a snare, such that a portion of the snare is disposed within an interruption. For example, a snare configured to secure by radial constriction may better secure to the sealing device 100 by way of at least one of the interruptions 108.

According to embodiments, and as shown in Figures 8, 10, and 11, inter alia, the sealing device 100 may include at least one plug configured to interface with and selectively seal a corresponding lumen of the intragastric device 10. For example, a first plug 110a may be configured to selectively seal the first lumen 40a. Likewise, a second plug 110b may be configured to selectively seal the second lumen 40b. At least a portion of each plug may be configured to seal at least a portion of a corresponding lumen when the sealing device 100 is in a closed state. Plugs may be configured to leave open at least a portion of corresponding lumens when the sealing device 100 is in an open state. Accordingly, plugs may be of a rigid, semi-rigid, or flexible material to facilitate such selective sealing. The geometry of the plugs may correspond to that of the lumens. For example, the plugs may have similar cross-sectional geometry as that of the lumens, to provide proper sealing. The size, diameter, etc. of the plugs may exceed that of the lumens by a margin sufficient to facilitate sealing against pressure from
within the lumens. For example, radial pressure provided outwardly from a plug against the walls of a lumen into which it is inserted may provide frictional forces, electrostatic forces, Van der Waals forces, or hydrogen bonding forces, inter alia, to resist pressure from within the lumen tending to push the plug out of the lumen.

[0081] According to embodiments, and as shown in Figures 13-28, the sealing device 100 may be provided to selectably seal an end of the intragastric device 10. The body 102 and head 104 may be flexibly coupled together by one or more joints 140, such as flexible struts or connectors that extend between the body 102 and head 104. The joints 140 can moveably couple the head 104 to the body 102 while maintaining a connection between the body 102 and the head 104. For example, the sealing device 100 may have at least an open state (see Figures 13-20) and a closed state (see Figures 21-28) defined by the location or orientation of head 104 and associated components relative to body 102. Accordingly, at least the joints 140 may be of a rigid, semi-rigid, or flexible material to facilitate such a connection. The joints 140 may be compressible, bendable, articulated, spring-loaded, segmented, or otherwise capable of causing head to move from an open state to a closed state.

[0082] According to embodiments, and as shown in Figures 29-44, the sealing device 100 may be provided to selectably seal an end of the intragastric device 10. The body 102 and head 104 may be moveably coupled by a sliding mechanism in which the first plug 110a and the second plug 110b are configured such that the head 104 moves axially with respect to the body 102 while maintaining a connection between the body 102 and the head 104. For example, the sealing device 100 may have at least an open state (see Figures 29-36) and a closed state (see Figures 37-44) defined by the location or orientation of the head 104 and associated components relative to the body 102. Accordingly, the first plug 110a or the second plug 110b may be of a rigid, semi-rigid, or flexible material to facilitate such a connection. The first plug 110a or the second plug 110b may be configured to slide longitudinally within the corresponding lumen. Each of the first plug 110a and the second plug 110b may include a first channel 150a and a second channel 150b, respectively. The first channel 150a and the second channel 150b may fluidly connect an interior portion of each corresponding lumen with a space outside the intragastric balloon device 10 when the sealing device 100 is in the open state. The first channel 150a and the second channel 150b may prevent fluid connection between an interior portion of each corresponding lumen with the space outside the intragastric balloon device 10 when the sealing device 100 is in the open state. The first plug 110a and second plug 110b may each
include a stop 111 at one end, such as a limiter or shoulder, to prevent complete removal thereof from the corresponding lumen (as shown in Figures 35 and 36) because the stop 111 has a larger diameter that abuts a portion of the body 102 to prevent the disengagement of the first and second plugs 110a and 110b from the body 102. The first plug 110a and second plug 110b may each include a collar 113 to secure the head 104 in the closed state by resisting passage thereof through a portion of the body 102 (as shown in Figures 43 and 44) with an interference fit that secures the collar 113 within holes passing through the body 102.

[0083] According to embodiments, methods of inflating and the aspirating balloon device 10 are disclosed. According to embodiments, the intragastric device 10 may be provided with the balloons (e.g., first balloon 30a and second balloon 30b) in a deflated state. The sealing device 100 may be provided installed onto the intragastric device 10 and in a closed state.

[0084] According to embodiments, the intragastric device 10 may be provided to a gastric cavity of a patient and inflated. An insufflation fluid may be provided to the balloons via inflation ports, lumens, and openings. Where sleeves (e.g., first sleeve 50a and second sleeve 50b) and barriers (e.g., first barrier 46a and second barrier 46b) are provided, fluid may travel from inflation chambers (e.g., first inflation chamber 42a and second inflation chamber 42b) through inflation openings (e.g., first inflation opening 32a and second inflation opening 32b) and past sleeves (e.g., first sleeve 50a and second sleeve 50b) to inflate the balloons. Where aspiration openings (e.g., first aspiration opening 34a and second aspiration opening 34b) and aspiration chambers (e.g., first aspiration chamber 44a and second aspiration chamber 44b) are provided, fluid may flow there through during inflation or be restricted from the same until an aspiration process.

[0085] According to embodiments, a method for aspirating and explanting intragastric device 10 after emplacement and inflation thereof is disclosed. According to embodiments, and as shown in Figure 45, an endoscope 200 may be provided to observe and interact with the sealing device 100 of the intragastric device 10. Where the sealing device 100 is at an end of the intragastric device 10 that is distally located from an entrance point into the gastric cavity, a standard endoscope in a retroflexed position (e.g., "U-turn" shaped endoscope) may be used, as shown in Figure 45. The endoscope 200 may provide a variety of structures and functions, including visualization, working channels, and devices as disclosed further herein.
According to embodiments, and as shown in Figure 46, a snare 210 may be deployed from the endoscope 200 and secured to at least a portion of the sealing device 100. For example, the snare 210 may be secured onto at least one of the head 104, the flange 106, an interruption 108, and the pivot portion 130, including combinations thereof. Where initial securement is not satisfactory, partial securement may be used to reposition the intragastric device 10 or the sealing device 100 prior to re-securement. Those having skill in the art will recognize that a variety of devices, tools, and structures may be used to operate on the sealing device 100 from the endoscope 200. For example, the snare 210 may be any snare, grasper, forceps, needle, or other securing device for interfacing with at least a portion of the sealing device 100.

According to embodiments, and as shown in Figure 46, the snare 210 may cause the head 104 to move relative to the body 102 such that at least one plug is released from a sealed position within a lumen. For example, retraction of the head 104 by the snare 210 may cause the head 104 to pivot about the pivot portion 130. Such action may cause the first plug 110a to be removed from within the first lumen 40a and the second plug 110b to be removed from within the second lumen 40b.

According to embodiments, opening at least one lumen of the intragastric device 10 may cause fluid from within a corresponding balloon thereof to be capable of deflation. For example, a lumen that has been opened may be in fluid communication with an interior portion of a balloon via an opening. According to embodiments, opening at least one lumen of the intragastric device 10 may allow self deflation of a balloon based on a tendency of the balloon to contract or constrict or based on a pressure differential between the interior and exterior of the balloon.

According to embodiments, a suction device 220 may be provided with the endoscope 200 for operation on the intragastric device 10, as shown in Figures 48-52. The suction device 220 may be compatible with, attachable to, a component of, or an integral part of the endoscope 200. For example, the suction device 220 and endoscope 200 may provide a workspace 250 when brought to a portion of the intragastric device 10, such as the sealing device 100, before, during, or after opening at least one lumen of the intragastric device 10. The suction device 220 may cause fluid released from the intragastric device 10 to actively or passively be directed to a desired location (e.g., through an endoscope vacuum channel 222 or a working
lumen 202 to a reservoir). Accordingly, pressure at a distal end of the suction device 220 may be managed by any variety of devices, such as at a proximal end of suction device 220. The suction device 220 may cover all or part of the exposed portions of the sealing device 100. The suction device 220 may mate onto or within at least one lumen to controllably aspirate fluid from the intragastric device 10. As shown in Figure 52, the workspace 250 may be configured to have an internal shape or internal diameter that corresponds to the outer shape or outer diameter of the body 102, so as to facilitate the alignment of the workspace 250 with the sealing device 100 and alignment of the working lumen 202 with the first or second lumens 40a and 40b. In an alternative embodiment shown in Figure 53, the workspace 251 may be configured to provide an extended recess 251a configured to accept the shape of a portion of the sealing device 100 and to provide a chamber 251b within which a negative pressure can be maintained after the sealing device 100 sealably engages an edge 252c. The workspace 251 and recess 251a also facilitate the alignment of the workspace 251 with the sealing device 100, and facilitate the engagement between the endoscope 200 and first and second lumens 40a and 40b.

[0090] According to embodiments, partial or full deflation of the intragastric device 10 may facilitate subsequent explant, removal, or adjustment thereof. According to embodiments, the intragastric device 10 may be removed along with the endoscope 200 after deflation.

[0091] According to embodiments, a kit of parts is disclosed, including components disclosed herein, for use by a user. Included in the kit may be instructions for use.

[0092] While the method and agent have been described in terms of what are presently considered to be the most practical and preferred embodiments, it is to be understood that the disclosure need not be limited to the disclosed embodiments. It is intended to cover various modifications and similar arrangements included within the spirit and scope of the claims, the scope of which should be accorded the broadest interpretation so as to encompass all such modifications and similar structures. The present disclosure includes any and all embodiments of the following claims.

[0093] It should also be understood that a variety of changes may be made without departing from the essence of the invention. Such changes are also implicitly included in the description. They still fall within the scope of this invention. It should be understood that this disclosure is intended to yield a patent covering numerous aspects of the invention both independently and as an overall system and in both method and apparatus modes.
Further, each of the various elements of the invention and claims may also be achieved in a variety of manners. This disclosure should be understood to encompass each such variation, be it a variation of an embodiment of any apparatus embodiment, a method or process embodiment, or even merely a variation of any element of these.

Particularly, it should be understood that as the disclosure relates to elements of the invention, the words for each element may be expressed by equivalent apparatus terms or method terms—even if only the function or result is the same.

Such equivalent, broader, or even more generic terms should be considered to be encompassed in the description of each element or action. Such terms can be substituted where desired to make explicit the implicitly broad coverage to which this invention is entitled.

It should be understood that all actions may be expressed as a means for taking that action or as an element which causes that action.

Similarly, each physical element disclosed should be understood to encompass a disclosure of the action which that physical element facilitates.

Any patents, publications, or other references mentioned in this application for patent are hereby incorporated by reference. In addition, as to each term used it should be understood that unless its utilization in this application is inconsistent with such interpretation, common dictionary definitions should be understood as incorporated for each term and all definitions, alternative terms, and synonyms such as contained in at least one of a standard technical dictionary recognized by artisans and the Random House Webster’s Unabridged Dictionary, latest edition are hereby incorporated by reference.

Finally, all referenced listed in the Information Disclosure Statement or other information statement filed with the application are hereby appended and hereby incorporated by reference; however, as to each of the above, to the extent that such information or statements incorporated by reference might be considered inconsistent with the patenting of this/these invention(s), such statements are expressly not to be considered as made by the applicant(s).

In this regard it should be understood that for practical reasons and so as to avoid adding potentially hundreds of claims, the applicant has presented claims with initial dependencies only.
[00102] Support should be understood to exist to the degree required under new matter laws ~ including but not limited to United States Patent Law 35 U.S.C 132 or other such laws ~ to permit the addition of any of the various dependencies or other elements presented under one independent claim or concept as dependencies or elements under any other independent claim or concept.

[00103] To the extent that insubstantial substitutes are made, to the extent that the applicant did not in fact draft any claim so as to literally encompass any particular embodiment, and to the extent otherwise applicable, the applicant should not be understood to have in any way intended to or actually relinquished such coverage as the applicant simply may not have been able to anticipate all eventualities; one skilled in the art, should not be reasonably expected to have drafted a claim that would have literally encompassed such alternative embodiments.

[00104] Further, the use of the transitional phrase "comprising" is used to maintain the "open-end" claims herein, according to traditional claim interpretation. Thus, unless the context requires otherwise, it should be understood that the term "compromise" or variations such as "comprises" or "comprising", are intended to imply the inclusion of a stated element or step or group of elements or steps but not the exclusion of any other element or step or group of elements or steps.

[00105] Such terms should be interpreted in their most expansive forms so as to afford the applicant the broadest coverage legally permissible.
CLAIMS

I/We claim:

1. A sealing device, comprising:
   a body configured to engage an intragastric balloon device having a lumen;
   a head extending from the body and moveably coupled to the body to move between a
   closed state and an open state of the sealing device, wherein the head remains
   coupled to the body as the head moves between the closed state and the open
   state; and
   a plug extending from the head and configured to seal an aspiration port of the lumen of
   the intragastric balloon device when the sealing device is in the closed state and
   further configured to unseal at least a portion of the aspiration port when the
   sealing device is in the open state.

2. The sealing device of claim 1, wherein the head further comprises a flange
   portion extending radially outward from the head and having a plurality of interruptions.

3. The sealing device of claim 1, wherein the head and the body define a recess there
   between.

4. The sealing device of claim 1, wherein the head is moveably coupled to the body
   by a flexible joint.

5. The sealing device of claim 1, wherein the joint is one of a pivot portion
   extending between the head and the body or a plurality of struts extending between the head and
   the body.

6. The sealing device of claim 1, wherein the head is moveably attached to the body
   by a plurality of joints.
7. The sealing device of claim 1, wherein the head is slideably attached to the body by the plug.

8. The sealing device of claim 1, wherein at least a portion of the plug is configured to slide longitudinally within the lumen.

9. The sealing device of claim 1, wherein the plug further comprises a hole configured to fluidly connect an interior portion of the lumen with a space outside the intragastric balloon device when the sealing device is in the open state.

10. The sealing device of claim 1, wherein the plug has a limiter at one end to prevent the plug from exiting the lumen.

11. The sealing device of claim 1, wherein the plug contains a collar to secure the head in the closed state.

12. An intragastric balloon device, comprising:
   a shaft having a plurality of lumens including at least a first lumen with a first aspiration port and a second lumen with a second aspiration port;
   a plurality of balloons including at least a first balloon in fluid communication with the first lumen and a second balloon in fluid communication with the second lumen;
   and
   a sealing device having a body attached to the shaft, a head moveably coupled to the body to move between a closed state and an open state, and at least a first plug projecting from the head, wherein the head remains coupled to the body between the closed state and the open state, and wherein the first plug is configured to seal the first aspiration port of the first lumen when the head is in the closed state and further configured to open the first aspiration port of the first lumen when the head is in the open state.

13. The intragastric balloon device of claim 12, wherein the first and second lumens have a first inflation port and a second inflation port, respectively.
14. The intragastric balloon device of claim 12, wherein each balloon is in fluid communication with its corresponding lumen via an inflation opening.

15. The intragastric balloon device of claim 12, wherein each lumen is divided into an inflation chamber and an aspiration chamber by a barrier disposed between the inflation chamber and the aspiration chamber.

16. The intragastric balloon device of claim 15, wherein each balloon is in fluid communication with its corresponding inflation chamber via an inflation opening.

17. The intragastric balloon device of claim 15, wherein each balloon is in fluid communication with its corresponding aspiration chamber via an aspiration opening.

18. The intragastric balloon device of claim 17, further comprising a sleeve within each balloon selectably covering the corresponding aspiration opening thereof.

19. The intragastric balloon device of claim 12, further comprising a guidewire channel extending through the shaft and the sealing device.

20. The intragastric balloon device of claim 12, further comprising: a second plug attached to the shaft and opposite the sealing device; and a guidewire channel extending through the plug and the sealing device.

21. A method of aspirating an intragastric balloon device, comprising: securing an endoscope device to a head of a sealing device of the intragastric balloon device; moving the head of the sealing device from a closed state to an open state, wherein the closed state disposes a plug to obstruct a lumen of the intragastric balloon device, and wherein the open state disposes the plug to permit fluid communication through the lumen; and aspirating the fluid from the intragastric balloon device via the lumen.
22. The method of claim 21, wherein moving the head of the sealing device from a closed state to an open state relative to a body of the sealing device comprises pivoting the head via a pivot portion attaching the head to the body.

23. The method of claim 21, wherein moving the head of the sealing device from a closed state to an open state relative to a body of the sealing device comprises extending a joint connecting the head to the body.

24. The method of claim 21, wherein moving the head of the sealing device from a closed state to an open state relative to a body of the sealing device comprises sliding the head relative to the body via the plug along an axis of the lumen.

25. The method of claim 21, further comprising: disposing a suction device to controllably aspirate fluid from the lumen.

26. The method of claim 21, further comprising: deflating a balloon of the intragastric balloon device.

27. The method of claim 21, further comprising: removing the intragastric balloon device from the gastric cavity.
Fig. 4
INTERNATIONAL SEARCH REPORT

INTERNATIONAL APPLICATION No.
PCT/US2011/026233

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61M 25/10 (2011.01)

USPC - 600/1 16

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)

IPC(8) - A61F 2/12.52; A61M 25/10; 12; A61M 29/00; 02; A61M 31/00 (2011.01)

USPC - 251; 600/1; 16; 604/907, 909, 912, 913, 914, 915; 606/192; 623/7, 8

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 database and, where practicable, search terms used)

MicroPat, Google Advanced Patent, Google Images, Google

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y</td>
<td>US 4,356,824 A (VAZQUEZ) 02 November 1982 (02.11.1982) entire document</td>
<td>12-20, 25</td>
</tr>
</tbody>
</table>

Further documents are listed in the continuation of Box C.

a Special categories of cited documents:
"A" Document defining the general state of the art which is not considered to be of particular relevance
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"&" Document member of the same patent family

Date of the actual completion of the international search
03 April 2011

Date of mailing of the international search report
26 APR 2011

Authorized officer: Blaine R. Copenheaver

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