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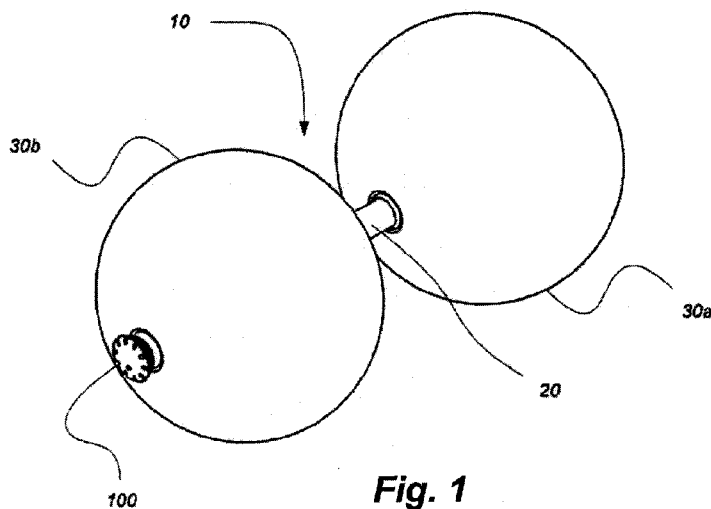
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(54) Title: IMPROVED AND ENHANCED ASPIRATION PROCESSES AND MECHANISMS FOR INTRAGASTRIC DEVICES



(57) Abstract: A sealing device attached to an intragastric balloon device having a at least one flexible membrane aligned with and configured to seal an aspiration port of a lumen when the membrane is in a closed state and further configured to provide access to the lumen when the membrane is in an open state.



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IMPROVED AND ENHANCED ASPIRATION PROCESSES AND
MECHANISMS FOR INTRAGASTRIC DEVICES

CROSS-REFERENCE TO RELATED APPLICATION(S)

[0001] This application claims the benefit of U.S. Provisional Application No. 61/302,459 filed February 8, 2010, the subject matter of which is incorporated by reference in its entirety.

RELATED REFERENCES

[0002] This application incorporates by reference: U.S. Pat. Pub. No. 2007/0100367, published May 3, 2007; U.S. Pat. Pub. No. 2007/0100368, published May 3, 2007; U.S. Pat. Pub. No. 2007/0100369, published May 3, 2007; U.S. Pat. Pub. No. 2007/0149994, published June 28, 2007; U.S. Pat. Pub. No. 2008/0243071, published October 2, 2008; U.S. Pat. Pub. No. 2008/0319471, published December 25, 2008; U.S. Pat. Pub. No. 2005/0159769, published July 21, 2005; U.S. Pat. Pub. No. 2009/0048624, published February 19, 2009; WIPO Pub. No. WO 2007/053556, published October 5, 2007; WIPO Pub. No. WO 2007/053707, published October 5, 2007; WIPO Pub. No. WO 2007/053706, published October 5, 2007; and WIPO Pub. No. WO 2007/075810, published May 7, 2007; each as if fully set forth herein in its entirety.

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.

[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 an end 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.

[0013] Figure 5 shows a perspective view of a sealing device.

[0014] Figure 6 shows a side view of a sealing device.

- [0015] Figure 7 shows a top view of a sealing device.
- [0016] Figure 8 shows a bottom view of a sealing device.
- [0017] Figure 9 shows a sectional view of the sealing device of Figure 7.
- [0018] Figure 9A shows an alternative sectional view of the sealing device of Figure 7.
- [0019] Figure 10 shows a sectional view of the sealing device of Figure 7.
- [0020] Figure 11 shows a partial perspective view of an intragastric device.
- [0021] Figure 12 shows a perspective view of an intragastric device with a magnified view of a sealing device and a snare device.
- [0022] Figure 13 shows a perspective view of an intragastric device with a magnified view of a sealing device and an aspiration device.
- [0023] Figure 14 shows a partial perspective view of an endoscope with suction device.
- [0024] Figure 15 shows a partial side view of an endoscope with suction device.
- [0025] Figure 16 shows a partial side view of an endoscope with suction device.
- [0026] Figure 17 shows an end view of an endoscope with suction device.
- [0027] Figure 18 shows a partial sectional view of an endoscope with suction device.
- [0028] Figure 19 shows a partial sectional view of an endoscope with an alternative configuration.

DETAILED DESCRIPTION

[0029] 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, but 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 1-19.

[0030] 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 flexible membrane aligned with and configured to seal an aspiration port of a lumen when the membrane is in a closed state. The sealing device can be further configured to provide access to the lumen when the membrane is in a open state (e.g., when a needle is passed through the membrane).

[0031] 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 balloon. The sealing device can also have a head attached to the body and at least one flexible membrane configured to seal an aspiration port of one of the lumens when the membrane is in a closed state and to provide fluidic access to the lumen when the membrane is in a open state.

[0032] 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 flexible membrane configured to seal an aspiration port of a lumen of the intragastric device when the membrane is in a closed state and to provide fluidic access to the lumen when the membrane is in a open state. The method can further comprise securing the endoscope device to at least a portion of the sealing device, penetrating the membrane of the sealing device with an aspiration device, whereby access to fluid in the corresponding lumen is achieved, and aspirating the fluid from the at least one balloon via the lumen.

[0033] 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., first balloon 30a and second balloon 30b) may be fixed to shaft 20 of intragastric device 10.

[0034] In the particular embodiments of the technology shown in Figures 1-3, the intragastric device 10 may include or be configured to interface with 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 “proximal”, “distal”, “first”, and “second” refer to relative locations and orientations of structures, devices, and components. For example, the terms “proximal”, “distal”, “first”, and “second” 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.

[0035] Referring to Figure 3, the shaft 20 of the intragastric device 10 may include a plurality of lumens in which each lumen corresponds to a balloon of intragastric device 10. For example, first lumen 40a may provide fluid communication from first inflation port 47a to an interior portion of first balloon 30a via first inflation opening 32a. Likewise, second lumen 40b may provide fluid communication from second inflation port 47b to an interior portion of second balloon 30b via second inflation opening 32b.

[0036] According to embodiments, and as shown in Figure 3, each lumen may have a corresponding inflation port at an end of the lumen. 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 valve, non-return valve, one-way valve, 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 first lumen 40a and to dispose the second inflation port 47b at an end of second lumen 40b.

[0037] According to embodiments, and as shown in Figure 3, each lumen of shaft 20 may be divided into inflation and aspiration chambers. For example, first lumen 40a may be divided into first inflation chamber 42a and first aspiration chamber 44a by first barrier 46a. Likewise, second lumen 40b may be divided into second inflation chamber 42b and second aspiration chamber 44b by 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.

[0038] According to embodiments, each balloon may have an opening that fluidly connects the interior portion of the balloon with at least a portion of a corresponding lumen. According to embodiments, and as shown in Figure 3, each balloon may have a plurality of openings that connect the interior portion of the balloon with disparate chambers of a corresponding lumen. For example, first inflation opening 32a may provide a fluid connection between the interior of first balloon 30a and first inflation chamber 42a, and first aspiration opening 34a may provide a fluid connection between the interior of first balloon 30a and first aspiration chamber 44a.

[0039] 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 shaft 20 near the corresponding opening. For example, first sleeve 50a may be provided within the interior portion of first balloon 30a and covering at least first inflation opening 32a. Likewise, second sleeve 50b may be provided within the interior portion of second balloon 30b and covering at least second inflation opening 32a. 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 first inflation chamber 42a, through first inflation opening 32a, through a space formed between first sleeve 50a and the exterior surface of shaft 20, and into the interior of first balloon 30a is shown schematically by flow arrows 31a. Fluid flowing from the interior of first balloon 30a, through first aspiration opening 34a, and into first aspiration chamber 44a is shown schematically by flow arrows 33a. Likewise, second inflation opening 32b may provide a fluid connection between the interior of second balloon 30b and second inflation chamber 42b, and second aspiration opening 34b may provide a fluid connection between the interior of second balloon 30b and second aspiration chamber 44b. Fluid flowing from second inflation chamber 42b, through second inflation opening 32b, through a space formed between second sleeve 50b and the exterior surface of shaft 20, and into the interior of

second balloon 30b is shown schematically by flow arrows 31b. Fluid flowing from the interior of second balloon 30b, through second aspiration opening 34b, and into second aspiration chamber 44b is shown schematically by flow arrows 33b.

[0040] 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 sealing device 100, as further disclosed herein. For example, first aspiration port 48a may be provided at an end of first lumen 40a. Likewise, second aspiration port 48b may be provided at an end of second lumen 40b.

[0041] According to embodiments, and as shown in Figures 4 and 10, guidewire channel 112 may extend through sealing device 100 and shaft 20 of intragastric device 10. Guidewire channel 112 may be configured to accommodate a guidewire for assisted delivery and management of intragastric device 10 during implant, explant, or maintenance thereof.

[0042] According to embodiments, sealing device 100 may be provided to selectably seal an end of intragastric device 10. As shown in Figures 5-6 and 9-10, sealing device 100 may include body 102 and head 104. Body 102 and head 104 may be fixably connected to each other. Body 102 may be selectably or fixedly attached to at least a portion of shaft 20 or intragastric device 10.

[0043] According to embodiments, and as shown in Figures 5-10, flange 106 may extend radially outward from portions of head 104 that do not otherwise exceed the circumferential limit of other components, such as body 102. Flange 106 may provide increased surface area and distribute forces applied at head 104 across a greater surface area. Flange 106 may be provided in a variety of geometries. For example, as shown in Figures 5-6 and 9-10, head 104 and 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 at least generally extend tangentially with the nearby surface of a balloon (as shown in Figures 3 and 4) so as to provide a smooth transition between the outer surfaces of head 104 and 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 surface of plug 45 and the balloon 30a. It is believed that geometries that form a step or a sizable gap between the surfaces of

the head and balloon provide inflection points that result in trauma in a biological environment. 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.

[0044] 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 facilitating 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 an fully unfolded state when fully inflated.

[0045] According to embodiments, and as shown in Figures 7 and 8, flange 106 may include interruptions 108, such as tabs, around at least a portion of a perimeter of head 104. Interruptions 108 may be configured to further distribute forces applied at head 104. 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 sealing device 100 by way of at least one of interruptions 108.

[0046] According to embodiments, and as shown in Figures 5, 7, and 9, at least one membrane may be provided to cover a corresponding lumen and provide controlled access by an aspiration device. For example, first membrane 110a may be configured to cover first

lumen 40a at an end of the lumen (i.e., at first aspiration port 48a). Likewise, second membrane 110b may be configured to cover second lumen 40b at an end of the lumen (i.e., at second aspiration port 48b). Such a condition may define a "closed state" of the membrane. The membrane may be of thin walls to provide selective access to the corresponding lumen for aspiration of the lumen by controlled crossing, penetration, or breach of the membrane. Such a condition may define an "open state" of the membrane. The measure of thinness may be determined by the nature of materials used and known pressure conditions during inflation of intragastric device 10. Accordingly, membranes may be of a rigid, semi-rigid, or flexible material to facilitate aspiration procedures. According to embodiments, membranes and surrounding structure may facilitate controlled aspiration by providing a sufficiently thin or flexible membrane that permits crossing, penetration, or breach of the membrane by an aspiration device while resisting undesirable rupture of the membrane beyond the locality of the aspiration device under pressurized conditions.

[0047] According to embodiments, membranes may be of a variety of geometries, including flat, as shown in Figure 9, convex (not shown), or concave (not shown). For example, an inner surface may be configured to extend into a corresponding lumen. By further example, an outer surface may be shaped to naturally guide an aspiration device to a desired location for subsequent operations. As shown in Figure 9A, the first membrane 110a and second membrane 110b may be disposed within a recess 111 so that the walls 113 of the recess 111 guide an aspiration device into an engagement with the intragastric device before the membranes are engaged. According to embodiments, membranes may be configured to adequately seal each corresponding lumen to retain fluids therein and avoid inadvertent evacuation of fluids out of intragastric device 10 or into other lumens. According to embodiments, membranes may be self-sealing, such that a sufficiently small hole pierced therein may recover a sealed state when the piercing object is removed. Such self-sealing may be facilitated by the nature of at least a portion of the fluid present at the membrane.

[0048] According to embodiments, any number of membrane layers may be provided. Where a plurality of layers are present, each layer may have disparate characteristics, such as rigidity, flexibility, expansion, porosity, etc. For example, two or more layers may cover ends of an inner layer that may have enhanced self-sealing characteristics by expanding when exposed to fluids caused by breach of the surrounding layers.

[0049] According to embodiments, methods of inflating and aspirating balloon device 10 are disclosed. According to embodiments, intragastric device 10 may be provided with balloons (e.g., first balloon 30a and second balloon 30b) in a deflated state. Sealing device 100 may be provided installed onto intragastric device 10.

[0050] According to embodiments, intragastric device 10 may be provided to a gastric cavity of a patient and inflated. An insufflation fluid may be provided to 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 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.

[0051] 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 11, endoscope 200 may be provided to view and interact with sealing device 100 of intragastric device 10. Where sealing device 100 is at an end of intragastric device 10 that is distally located from an entrance point into the gastric cavity, a standard endoscope in a retroflexed position (e.g., a "U-turn" shaped endoscope) may be used, as shown in Figure 11. Endoscope 200 may provide a variety of structures and functions, including visualization, working channels, and devices as disclosed further herein.

[0052] According to embodiments, and as shown in Figure 12, a snare 210 may be deployed from endoscope 200 and secured to at least a portion of sealing device 100. For example, snare 210 may be secured onto at least one of head 104, at least one flange 106, and at least one interruption 108, including combinations thereof. Where initial securement is not satisfactory, partial securement may be used to reposition intragastric device 10 or 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 engage and operate on sealing device 100

from endoscope 200. For example, snare 210 may be any snare, grasper, forceps, needle, or other securing device for interfacing with at least a portion of sealing device 100.

[0053] According to embodiments, and as shown in Figure 13, aspiration device 230 may be provided to engage sealing device 100. Aspiration device 230 may perform controlled crossing, penetration, or breach of a membrane to access a corresponding lumen by aspiration device 230 or another device. Such action may facilitate localized evacuation of fluids, as opposed to uncontrolled rupture of the surface of an inflated balloon, where widespread rupture and uncontrollable release of fluids is common due to the pressure conditions thereof. The aspiration device 230 may be directed into position to breach the membrane by guiding walls of a recess surrounding the membranes. The walls of the recess may guide the aspiration device 230 into alignment with the membranes before breaching the membranes.

[0054] According to embodiments, suction device 220 may be provided with endoscope 200 for operation on intragastric device 10, as shown in Figures 14-18. Suction device 220 may be compatible with, attachable to, a component of, or an integral part of endoscope 200. For example, suction device 220 and endoscope 200 may provide workspace 250 when brought to a portion of intragastric device 10, such as sealing device 100, before, during, or after opening at least one lumen of intragastric device 10. Suction device 220 may cause fluid released from intragastric device 10 to actively or passively be directed to a desired location (e.g., through endoscope vacuum channel 222 or working lumen 202 to a reservoir). Accordingly, pressure at a distal end of suction device 220 may be managed by any variety of devices, such as at a proximal end of suction device 220. Suction device 220 may cover all or part of the exposed portions of sealing device 100. Suction device 220 may mate onto or within at least one lumen to controllably aspirate fluid from intragastric device 10. In an alternative embodiment shown in Figure 19, the workspace 251 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 insertion of a portion of the sealing device 100 (such as the sealing device shown in Figure 9) into the workspace 251 and to align the first membrane 110a with first aspiration interface 252a and align the second membrane 110b with second aspiration interface 252b.

[0055] According to embodiments, accessing at least one lumen of intragastric device 10 may cause fluid from within a corresponding balloon thereof to be capable of deflation. For example, a lumen that has been accessed may be in fluid communication with an interior portion of a balloon via an opening. According to embodiments, accessing at least one lumen of intragastric device 10 may cause automatic 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 over sealing device 100 before, during, or after accessing at least one lumen. The suction device may cause fluid released to actively or passively be directed to a desired location (e.g., through endoscope 200 to a reservoir). Accordingly, pressure at a distal end of the suction device may be managed by any variety of devices, such as at a proximal end thereof. The suction device may cover all or part of the exposed portions of sealing device 100. The suction device may mate onto or within at least one lumen or membrane to controllably aspirate fluid from intragastric device 10. For example, a lumen may be provided within aspiration device 230 as a conduit for fluid.

[0056] According to embodiments, where membranes are of a self-sealing configuration, retraction of aspiration device 230 may result in at least substantial recovery of a seal over a corresponding lumen.

[0057] According to embodiments, partial or full deflation of intragastric device 10 may facilitate subsequent explant, removal, or adjustment thereof. According to embodiments, intragastric device 10 may be removed along with endoscope 200 after deflation.

[0058] 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.

[0059] 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.

[0060] 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.

[0061] 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.

[0062] 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.

[0063] 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.

[0064] 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.

[0065] Similarly, each physical element disclosed should be understood to encompass a disclosure of the action which that physical element facilitates.

[0066] 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.

[0067] 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).

[0068] 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.

[0069] Support should be understood to exist to the degree required under new matter laws -including but not limited to United States Patent Law 35 USC 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.

[0070] 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.

[0071] 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 "comprise" 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.

[0072] 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 first lumen; and
a head extending from the body, the head supporting a first membrane so as to align the first membrane with the first lumen when the body engages the intragastric balloon, the first membrane having a first state that seals a first aspiration port of the first lumen and a second state that provides fluidic access to the first lumen.
2. The sealing device of claim 1, wherein the head defines an axis of the sealing device and further comprises a flange portion extending radially outward from the axis, the flange having a plurality of interruptions.
3. The sealing device of claim 1, wherein the head defines an axis of the sealing device, the head defining an arcuate surface of the head that intersects the axis
4. The sealing device of claim 3, wherein the arcuate surface defines an arc that substantially aligns with a curvature of a surface of a balloon of the intragastric balloon.
5. The sealing device of claim 1, wherein the first membrane is configured to resist rupture beyond a locality of a breach formed in the first membrane by an aspiration device.
6. The sealing device of claim 1, wherein the first membrane is self-sealing.
7. The sealing device of claim 1, the head further supporting a second membrane disposed adjacent to the first membrane so as to align the second membrane with a second lumen of the intragastric balloon when the body engages the intragastric balloon.

8. The sealing device of claim 7, the head having an exterior surface and a wall extending from the exterior surface towards the body, the wall disposed between the exterior surface and the first and second membranes to define a recess adjacent the first and second membranes.

9. The sealing device of claim 8, the wall defining a first portion of the recess and a second portion of the recess, the wall defining the first portion of the recess configured to guide a first aspiration device to the first membrane.

10. The sealing device of claim 9, the wall defining the second portion of the recess configured to guide a second aspiration device to the second membrane.

11. An intragastric balloon device, comprising:

a shaft having a plurality of lumens including at least a first lumen and a second lumen;

a plurality of balloons including at least a first balloon at one end of the shaft and a second balloon at another end of the shaft, wherein an interior portion of the first balloon is in fluid communication with the first lumen and an interior portion of the second balloon is in fluid communication with the second lumen; and

a sealing device comprising a body engaging at least one of the shaft, the first balloon, and the second balloon, a head extending from the body and supporting at least one membrane configured to seal an aspiration port of one of the first or second lumens when the at least one membrane is in a first state and further configured to provide fluidic access to at least one of the first and second lumens when the at least one membrane is in a second state.

12. The intragastric balloon device of claim 11, wherein the first lumen communicates with a first inflation port and the second lumen communicates with a second inflation port.

13. The intragastric balloon device of claim 11, wherein the first balloon is in fluid communication with the first lumen via a first inflation opening, and the second balloon is in fluid communication with the second lumen via a second inflation opening.

14. The intragastric balloon device of claim 11, wherein the first lumen is divided into a first inflation chamber and a first aspiration chamber by a barrier disposed in the first lumen, and the second lumen is divided into a second inflation chamber and a second aspiration chamber by a barrier disposed in the second lumen.

15. The intragastric balloon device of claim 14, wherein the first balloon is in fluid communication with the first inflation chamber via a first inflation opening, and the second balloon is in fluid communication with the second inflation chamber via a second inflation opening.

16. The intragastric balloon device of claim 14, wherein the first balloon is in fluid communication with the first aspiration chamber via a first aspiration opening, and the second balloon is in fluid communication with the second aspiration chamber via a second aspiration opening.

17. The intragastric balloon device of claim 11, further comprising a first sleeve disposed within the first balloon to cover at least a portion of the first aspiration opening.

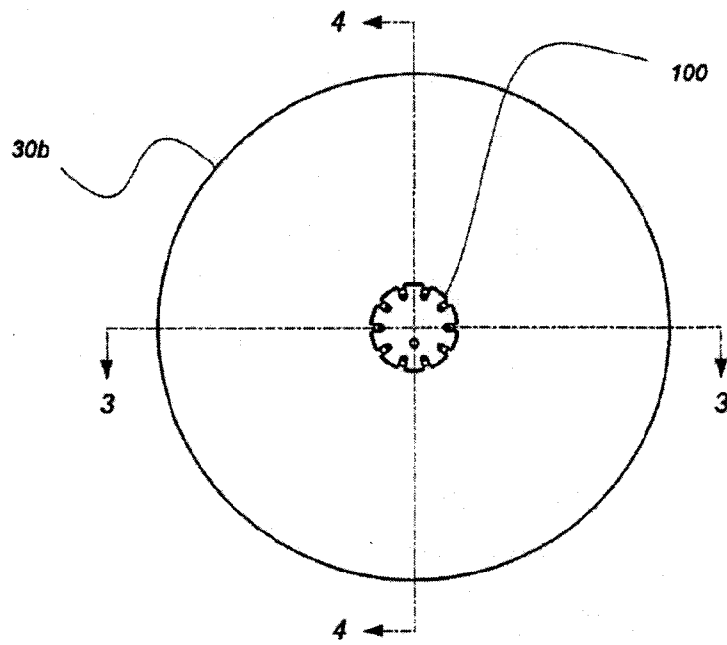
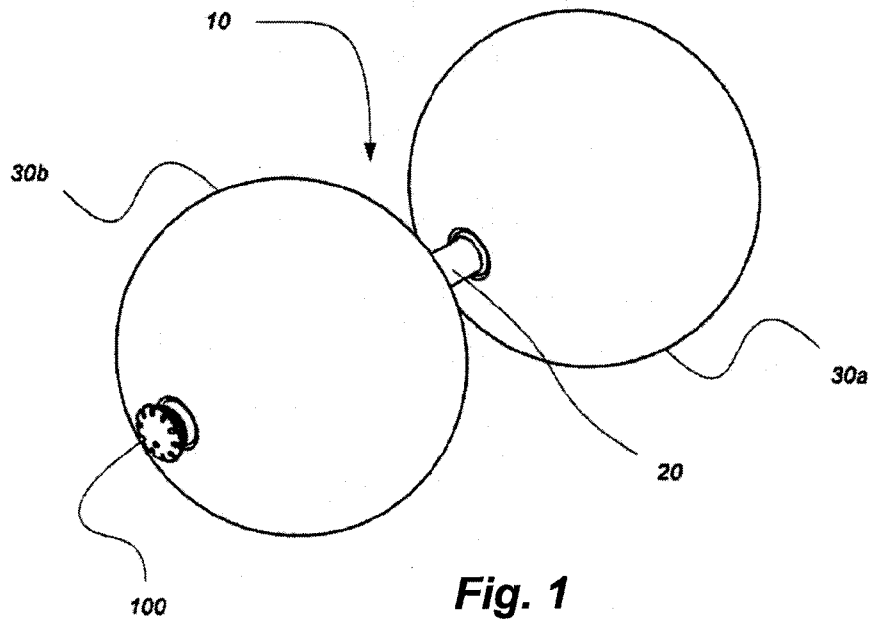
18. The intragastric balloon device of claim 11, further comprising a guidewire channel extending through the shaft and the sealing device.

19. The intragastric balloon device of claim 11, further comprising:
a plug engaging at least one of the shaft, the first balloon, and the second balloon, the plug being opposite the sealing device; and
a guidewire channel extending through the plug and the sealing device.

20. A method, comprising:
positioning an aspiration device proximate to a membrane of a sealing device of an intragastric device, wherein the membrane of the sealing device is separate from a balloon of the intragastric device;
inserting the aspiration device through the membrane to establish fluid communication between an interior channel of the aspiration device and a lumen communicating with the membrane; and
aspirating a fluid from the intragastric device to deflate a balloon.

21. The method of claim 20, the aspiration device communicating with a suction device to controllably aspirate fluid from the lumen.

22. The method of claim 20, further comprising:
removing the intragastric balloon device from the gastric cavity.



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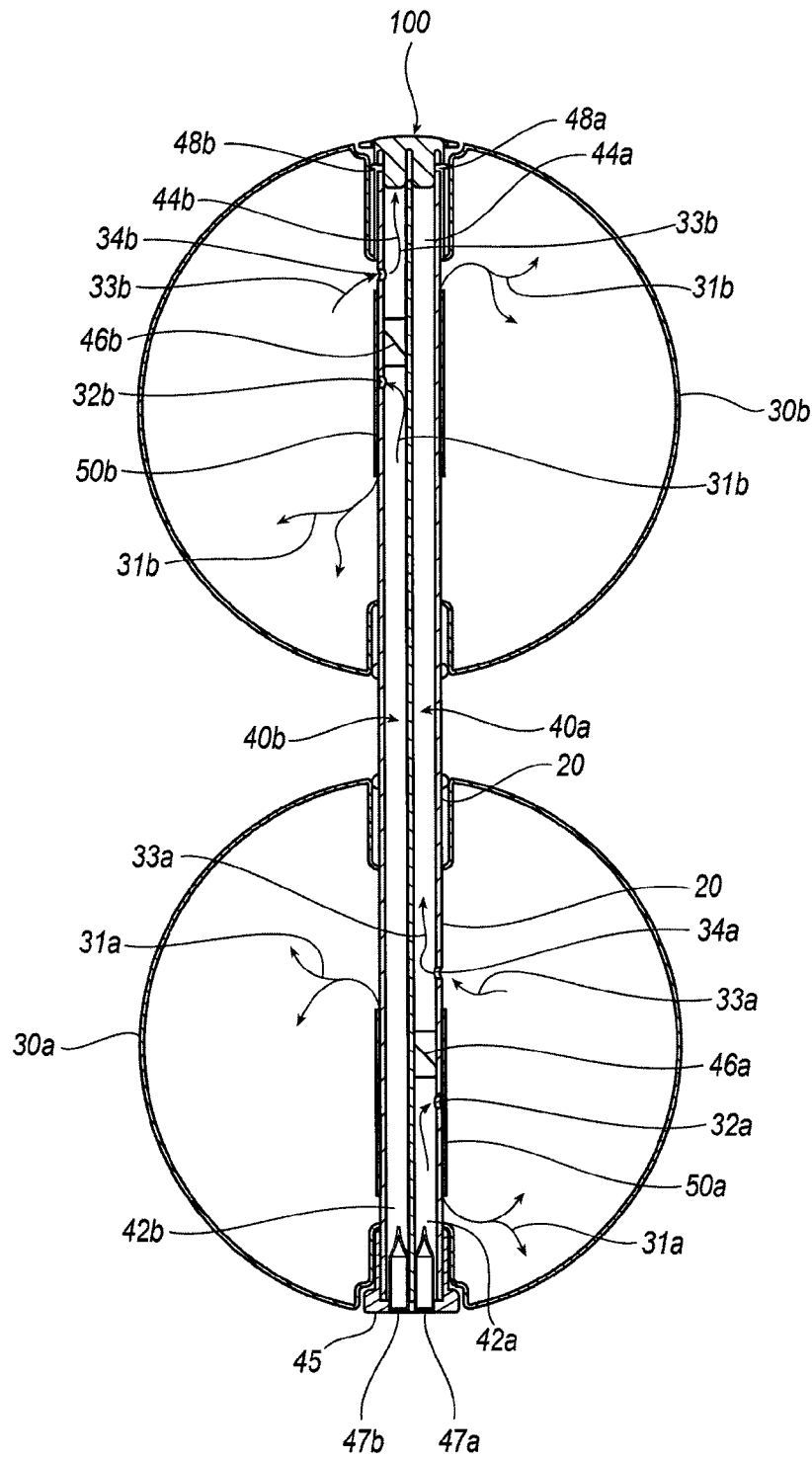


Fig. 3

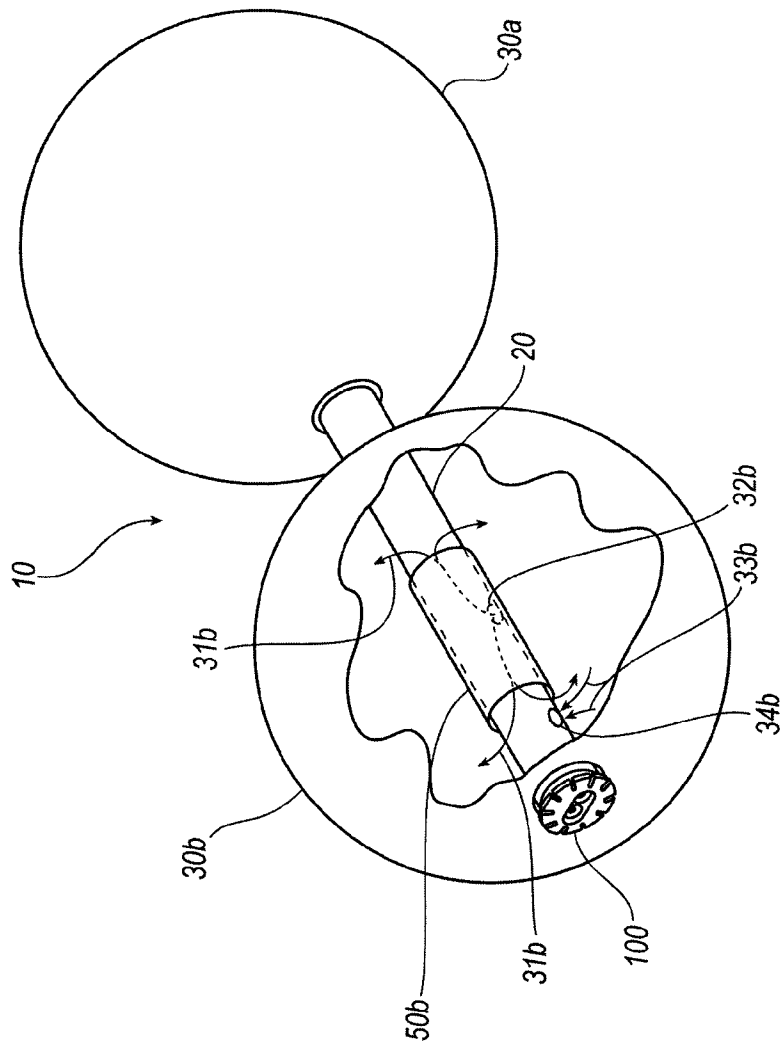


Fig. 3A

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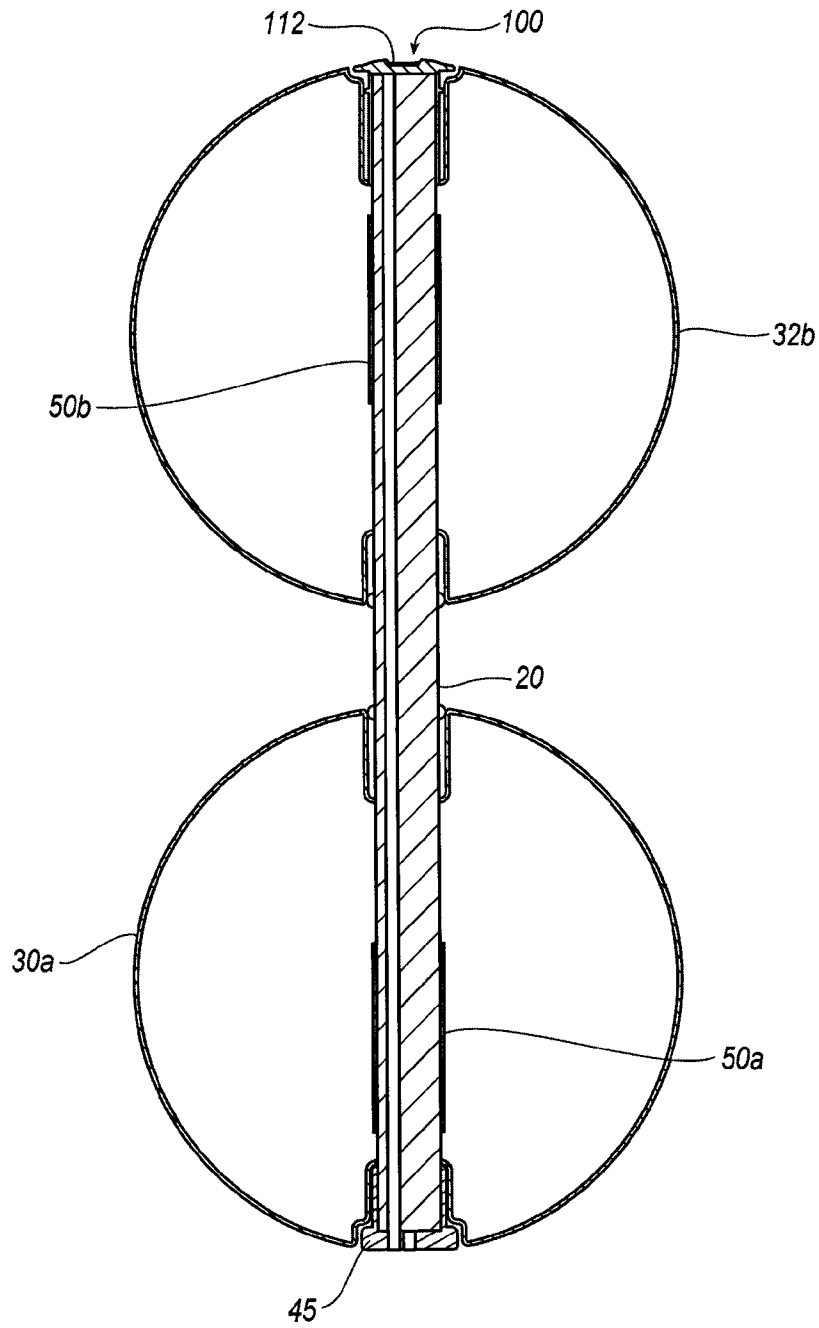


Fig. 4

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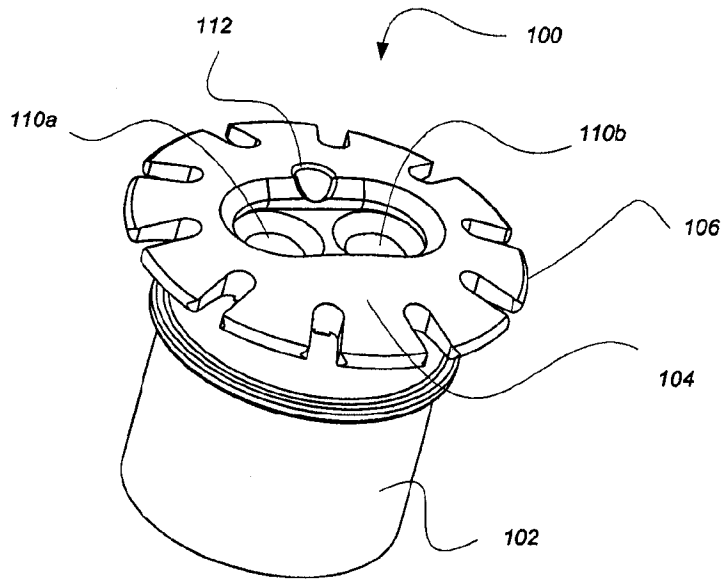


Fig. 5

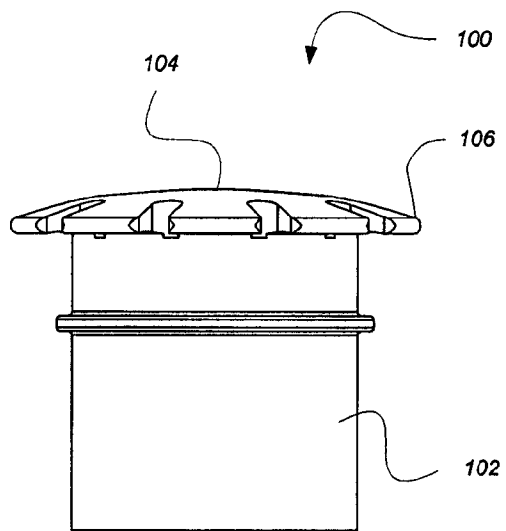


Fig. 6

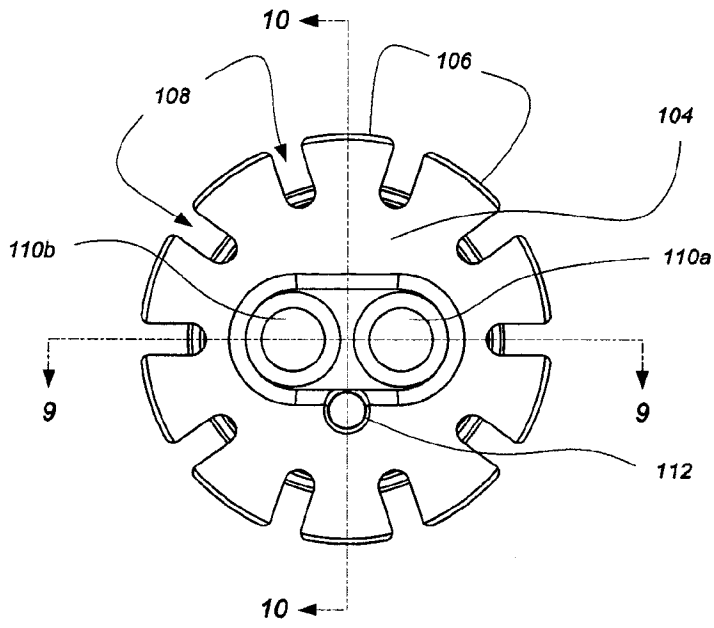


Fig. 7

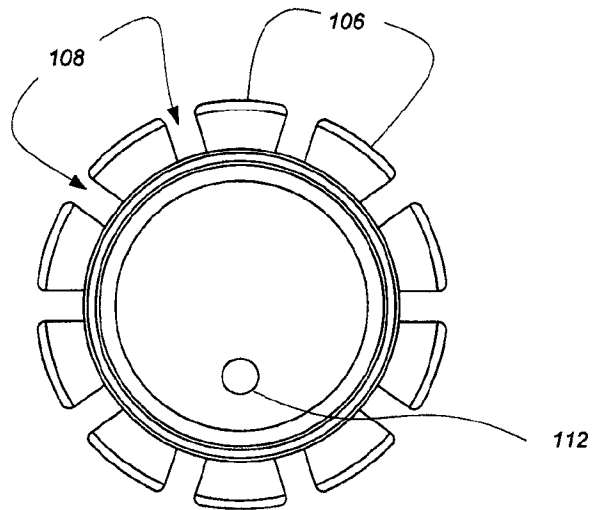


Fig. 8

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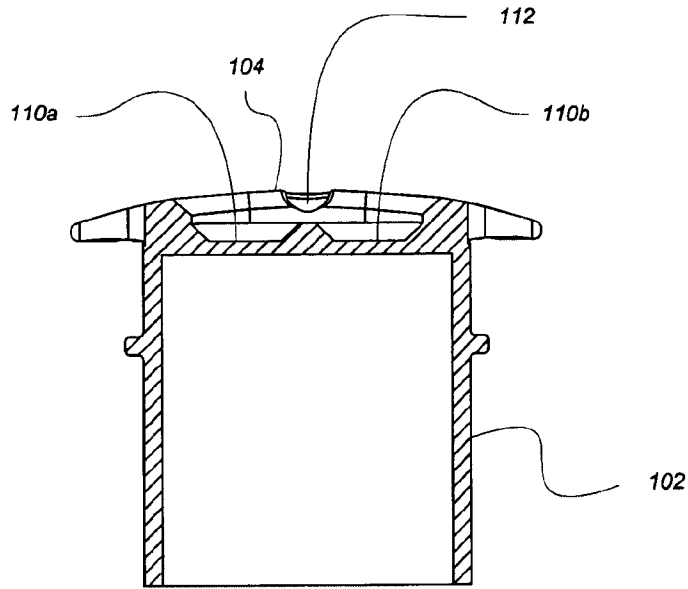


Fig. 9

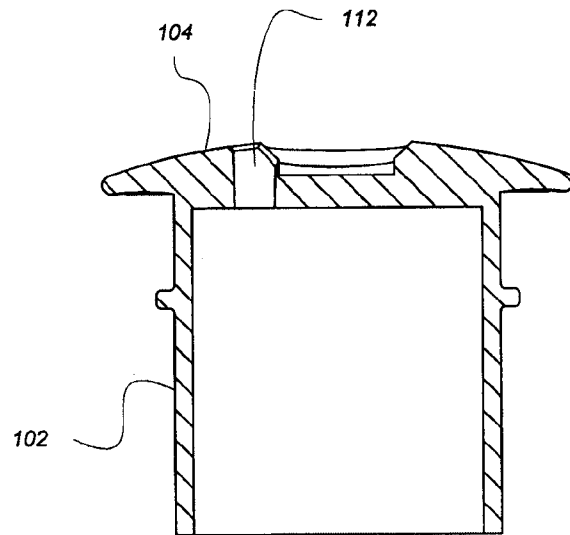


Fig. 10

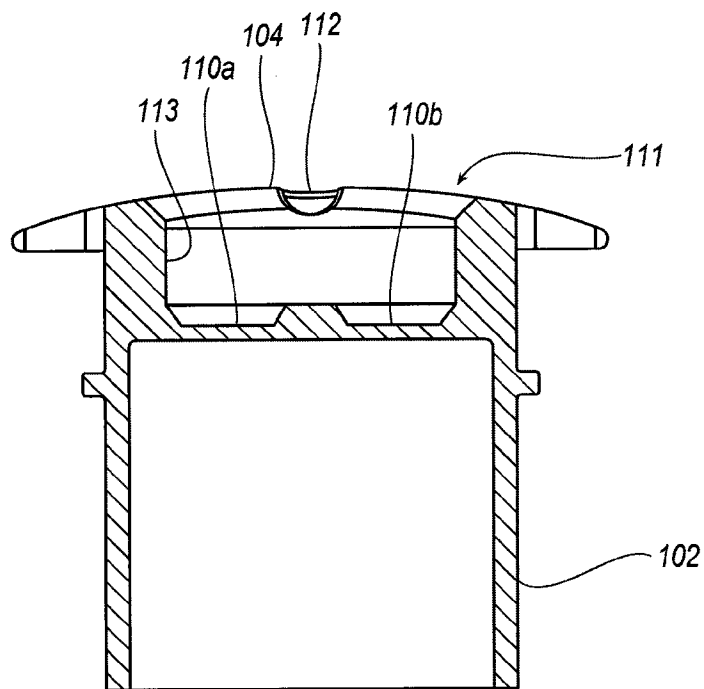


Fig. 9A

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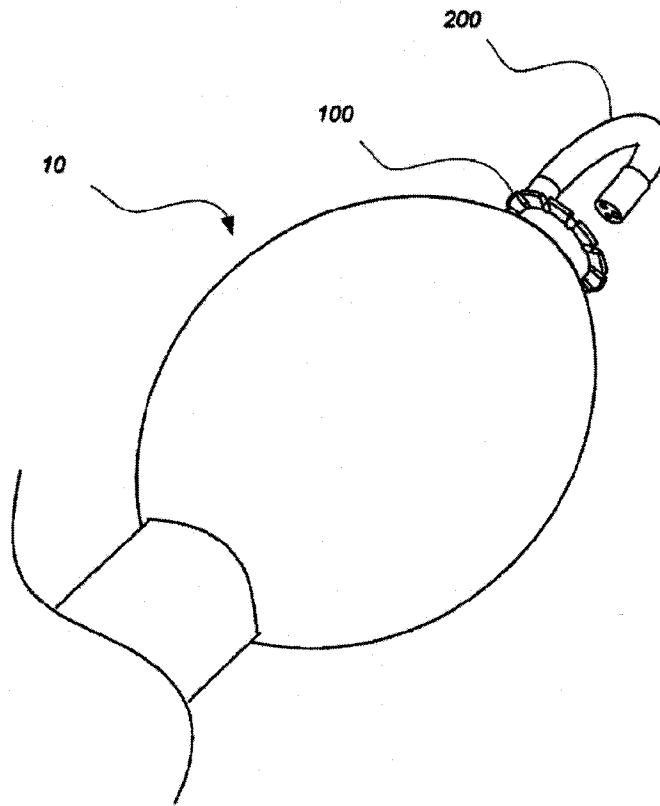


Fig. 11

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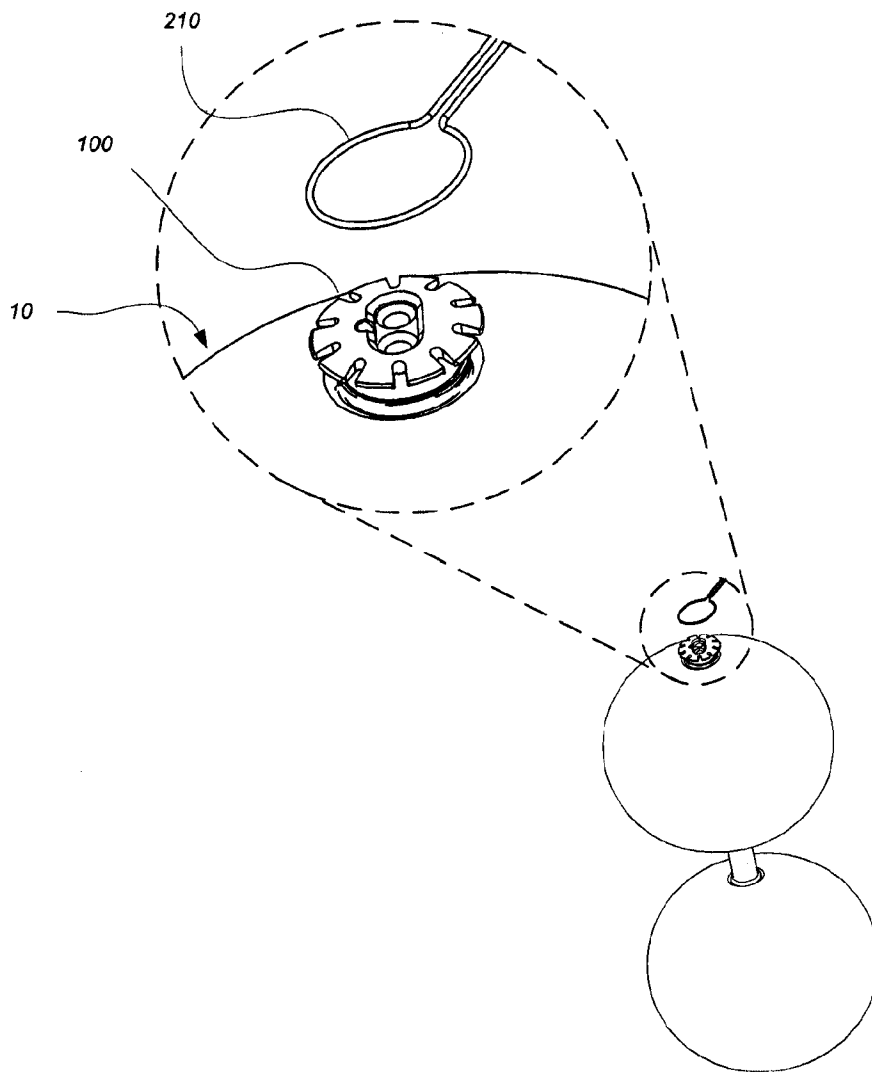


Fig. 12

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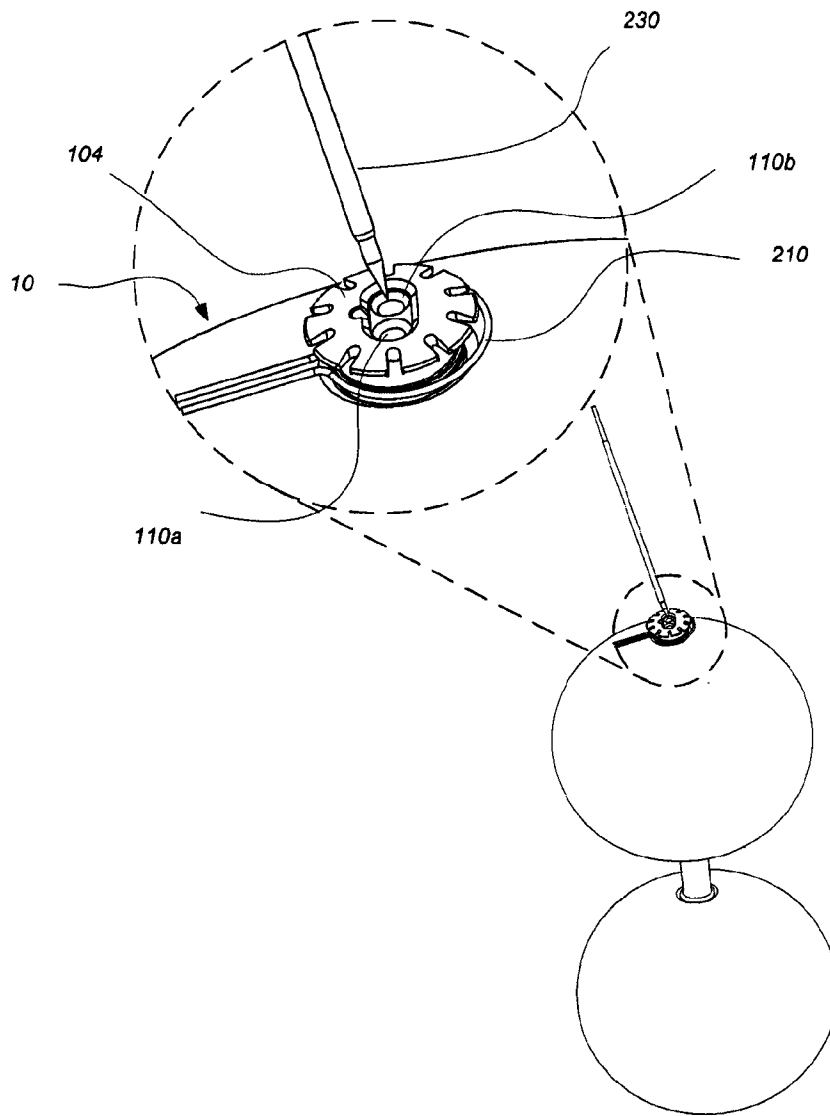


Fig. 13

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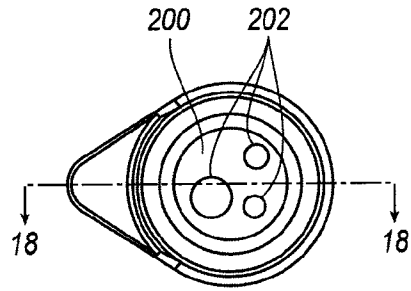


Fig. 17

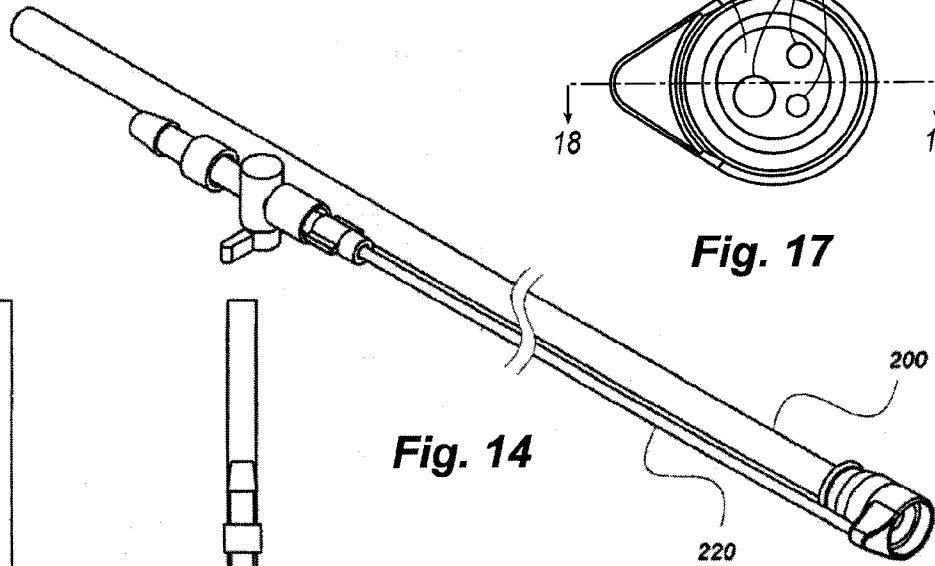


Fig. 14

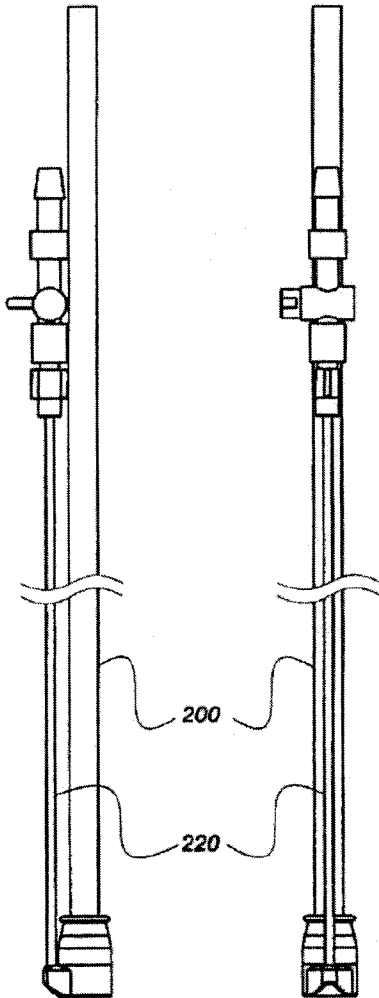


Fig. 15

Fig. 16

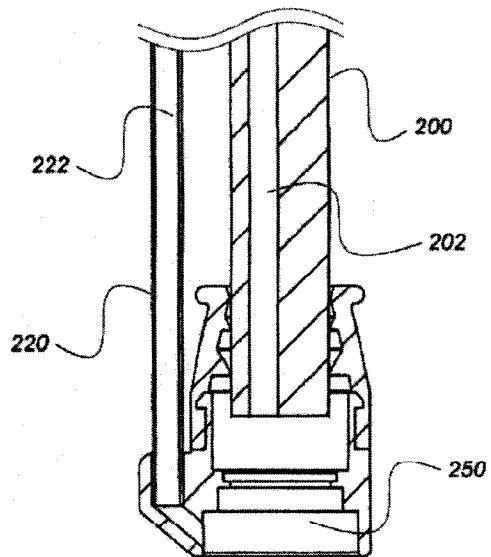


Fig. 18

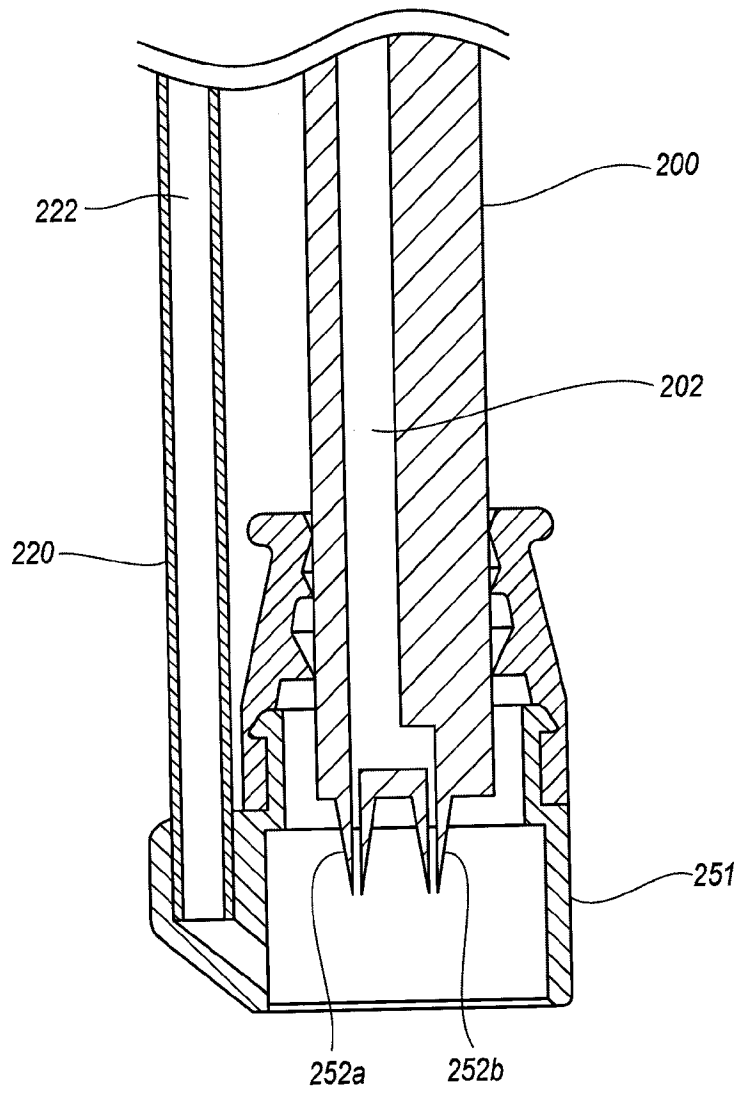


Fig. 19

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2011/024077

A. CLASSIFICATION OF SUBJECT MATTER IPC(8) - A61M 29/02 (2011.01) USPC - 606/192 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) - A61M 29/02, 31/00, 37/00 (2011.01) USPC - 606/192, 195 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) PatBase, Orbit, Google Patents		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2008/0319471 A1 (SOSNOWSKI et al) 25 December 2008 (25.12.2008) entire document	1-22
A	US 2008/0172079 A1 (BIRK) 17 July 2008 (17.07.2008) entire document	1-22
A	US 2006/0058829 A1 (SAMPSON et al) 16 March 2006 (16.03.2006) entire document	1-22
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/>		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 22 March 2011		Date of mailing of the international search report 06 APR 2011
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201		Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774