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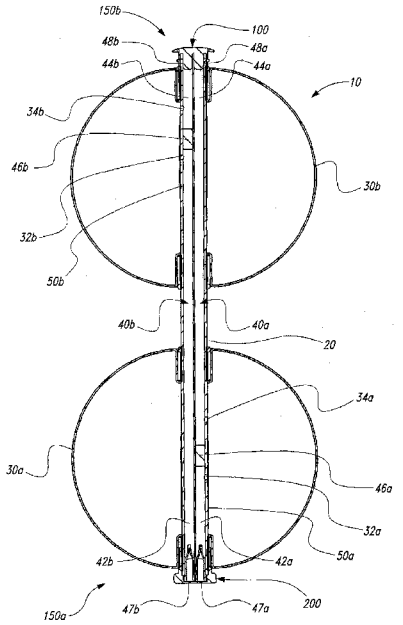


Fig. 3

(57) Abstract: Inflation devices for inflating intragastric devices and associated systems and methods are disclosed herein. In several embodiments, an inflation device can include a tube, an inner detent, and an outer detent. The tube can extend from a proximal portion of the inflation device to a distal portion of the inflation device, and can include a handle at the proximal portion and a barb at the distal portion. The barb can have a cross-sectional dimension greater than a cross-sectional dimension of a corresponding inflation port of an intragastric device. The inner detent can be positioned over the barb and can include a mating interface. The outer detent can be positioned over the inner detent, and can be configured to attach over a proximal cap of the intragastric device. The tube can be longitudinally advanceable relative to at least one of the inner and outer detents.

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INFLATION DEVICES FOR INTRAGASTRIC DEVICES WITH IMPROVED ATTACHMENT AND DETACHMENT AND ASSOCIATED SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATION(S)

[0001] This application claims the benefit of pending U.S. Provisional Patent Application No. 61/321,466, filed on April 6, 2010, entitled IMPROVED ATTACHMENT AND DETACHMENT DEVICES AND METHODS FOR INTRAGASTRIC BALLOONS, the disclosure of which is incorporated herein by reference in its entirety.

RELATED REFERENCES

[0002] This application incorporates by reference in their entirety each of the following applications and publications: U.S. Patent Application No. 11/768,152, filed June 25, 2007, entitled GASTRIC SPACE FILLER DEVICE, DELIVERY SYSTEM, AND RELATED METHODS; U.S. Patent Application No. 11/263,302, filed October 31, 2005, entitled INTRAGASTRIC SPACE FILLER; U.S. Pat. Pub. No. 2007/0100367, published May 3, 2007, entitled INTRAGASTRIC SPACE FILLER; U.S. Pat. Pub. No. 2007/0100368, published May 3, 2007, entitled INTRAGASTRIC SPACE FILLER; U.S. Pat. Pub. No. 2007/0100369, published May 3, 2007, entitled INTRAGASTRIC SPACE FILLER; U.S. Pat. Pub. No. 2007/0149994, published June 28, 2007, entitled INTRAGASTRIC SPACE FILLER AND METHODS OF MANUFACTURE; U.S. Pat. Pub. No. 2008/0243071, published October 2, 2008, entitled INTRAGASTRIC BALLOON SYSTEM AND THERAPEUTIC PROCESSES AND PRODUCTS; U.S. Pat. Pub. No. 2008/0319471, published December 25, 2008, entitled GASTRIC SPACE FILLER DEVICE, DELIVERY SYSTEM, AND RELATED METHODS; U.S. Pat. Pub. No. 2005/0159769, published July 21, 2005, entitled BALLOON SYSTEM AND METHODS FOR TREATING OBESITY; U.S. Pat. Pub. No. 2009/0048624, published February 19, 2009, entitled BALLOON SYSTEM AND METHODS FOR TREATING OBESITY; WIPO Pub. No. WO 2007/053556, published October 5, 2007, entitled INTRAGASTRIC SPACE FILLER; WIPO Pub. No. WO 2007/053707, published October 5, 2007, entitled INTRAGASTRIC SPACE FILLER; WIPO Pub. No. WO 2007/053706, published October 5, 2007, entitled

INTRAGASTRIC SPACE FILLER; and WIPO Pub. No. WO 2007/075810, published May 7, 2007, entitled INTRAGASTRIC SPACE FILLER.

TECHNICAL FIELD

[0003] The present technology relates generally to implantable gastric devices. In particular, the present technology relates to inflation devices for implanting and inflating an intragastric device in situ and associated systems and methods.

BACKGROUND

[0004] Implantable gastric devices can occupy a volume within a patient's stomach to decrease the available room for food. This creates a feeling of satiety that can control the patient's appetite and cause weight loss. Intragastric balloons, for example, can be filled with a biocompatible fluid (e.g., saline solution) and left within the stomach for an extended period of time to treat obesity and/or other weight related conditions. Implanting such an intragastric balloon generally includes inserting the deflated balloon through the patient's mouth or nose with a filler tube or catheter, and inflating the balloon in situ. The intragastric balloon can eventually be removed by deflating the balloon, grasping it with an extraction tool, and removing the intragastric balloon via the esophagus and mouth.

[0005] A challenge associated with the inflation of intragastric balloons is that conventional inflation tools can inadvertently disconnect from the intragastric balloons during insertion and/or inflation. However, if it is difficult to disconnect the intragastric balloon from the inflation tools, the extra force (e.g., tugging) necessary for disengagement can agitate or impose trauma on the stomach wall. Thus, there is a need to improve the inflation of intragastric devices.

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] Figure 1 is a schematic isometric view of an intragastric device in accordance with an embodiment of the present technology.

[0007] Figure 2 is a schematic top view of the intragastric device of Figure 1.

[0008] Figure 3 is a schematic cross-sectional view of the intragastric device taken substantially along the line 3-3 of Figure 2.

[0009] Figure 4 is a schematic cross-sectional view of the intragastric device taken along line 4-4 of Figure 2.

[0010] Figure 5 is a top view of a proximal portion of an inflation device in accordance with an embodiment of the present technology.

[0011] Figure 6 is a top view of a proximal portion of an intragastric device and a distal portion of the inflation device of Figure 5.

[0012] Figure 7 is a cut-away view of an inflation device engaged with an intragastric device in accordance with an embodiment of the present technology.

[0013] Figure 8 is a cut-away view of an inflation device and an intragastric device in accordance with another embodiment of the present technology.

[0014] Figures 9-12 are cut-away views of the inflation device of Figure 8 in various stages of engagement with the intragastric device in accordance with embodiments of the present technology.

[0015] Figure 13 is a side elevational view of an inflation assembly in accordance with an embodiment of the present technology.

DETAILED DESCRIPTION

[0016] Specific details of several embodiments of the present technology are described below with reference to an inflation device for an intragastric device and associated methods for inflating, implanting, and explanting such devices. Although many of the embodiments are described below with respect to a dual balloon intragastric device, other embodiments of intragastric devices can include only one balloon or more than two balloons. Moreover, several further 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 1-13.

[0017] The terms "distal" and "proximal" within this application reference a relative position of portions of an intragastric device and/or an inflation device with reference to an operator. Proximal refers to a position closer to the operator of the

device, and distal refers to a position that is more distant from the operator of the device.

[0018] Figure 1 is an isometric view of an intragastric device 10 in accordance with an embodiment of the present technology, and Figure 2 is a top view of the intragastric device 10 of Figure 1. The intragastric device 10 may include at least one expandable, space-filling component, such as a balloon 30. As shown in Figure 1, the intragastric device 10 can include a first balloon 30a and a second balloon 30b fixed to a shaft 20. In other embodiments, the intragastric device 10 can include additional balloons 30. As shown in Figures 1 and 2, the intragastric device 10 may also include or be configured to interface with a proximal cap 200 at a proximal portion 150a of the intragastric device 10.

[0019] Figure 3 is a cross-sectional view of the intragastric device 10 taken substantially along the line 3-3 of Figure 2. As shown in Figure 3, the shaft 20 of the intragastric device 10 may include a plurality of lumens 40 (identified individually as a first lumen 40a and a second lumen 40b), each corresponding to a balloon 30 of the intragastric device 10. For example, the 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, the 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.

[0020] Each lumen 40 may have a corresponding inflation port 47 at a proximal end thereof. The inflation ports 47 may be configured to allow infusion of fluids into corresponding lumens 40 and inhibit or prevent the exit of fluids from the same. The inflation ports 47 may include check valves, clack valves, non-return valves, one-way valves, duckbill valves, reed valves, flapper valves, etc. For example, the first inflation port 47a may be provided at a proximal end of the first lumen 40a. Likewise, the second inflation port 47b may be provided at a proximal end of the second lumen 40b.

[0021] As shown in Figure 3, each lumen 40 of the shaft 20 may be divided into inflation chambers 42 (identified individually as a first inflation chamber 42a and a second inflation chamber 42b) and aspiration chambers (identified individually as a first aspiration chamber 44a and a second aspiration chamber 44b). For example,

the first lumen 40a may be divided into the first inflation chamber 42a and the first aspiration chamber 44a by a first barrier 46a. Similarly, the second lumen 40b may be divided into the second inflation chamber 42b and the second aspiration chamber 44b by a second barrier 46b. Such barriers 46 may partition the lumens 40 into at least two separate chambers that may be fluidly connected via the interior portion of a corresponding balloon 30.

[0022] Each balloon 30 may have an opening that fluidly connects the interior portion of the balloon 30 with at least a portion of the corresponding lumen 40. As shown in Figure 3, each balloon 30 can have a plurality of openings that connect the interior portion of the balloon 30 with disparate chambers (e.g., the inflation chambers 42, the aspiration chambers 44) of the corresponding lumen 40. 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. Similarly, a second inflation opening 32b may provide a fluid connection between the interior of the second balloon 30b and the second inflation chamber 42b, and a second aspiration opening 34b may provide a fluid connection between the interior of the second balloon 30b and the second aspiration chamber 44b.

[0023] As further shown in Figure 3, the intragastric device 10 can include sleeves 50 (identified individually as a first sleeve 50a and a second sleeve 50b) within the interior of the balloons 30 that cover the inflation openings 32. Such sleeves 50 may allow inflation of the balloon from the corresponding inflation opening 32 while inhibiting or preventing deflation through the same opening 32. The sleeves 50 may wrap radially around the portion of the shaft 20 with compression force near the corresponding opening 32. For example, the first sleeve 50a may be provided within the interior portion of the first balloon 30a and cover at least the first inflation opening 32a. Similarly, the second sleeve 50b may be provided within the interior portion of the second balloon 30b and cover at least the second inflation opening 32b. The sleeve 50 may inhibit or prevent undesirable fluid passage through the inflation openings 32, and thereby reduce fluid leakage from inflated balloons 30 and associated issues. For example, when pressure within the balloon 30 exceeds pressure in the corresponding inflation chamber 42, the sleeve

50 may be pressed with radial compression against the corresponding inflation opening 32 to inhibit or prevent leakage into the lumen 40. When pressure within the inflation chamber 42 exceeds pressure within the corresponding balloon 30, the sleeve 50 may separate from the corresponding inflation opening 32 and permit fluid passage through the inflation opening 32 into the balloon 30.

[0024] Additionally, as shown in Figure 3, each lumen 40 may have a corresponding aspiration port 48 (identified individually as a first aspiration port 48a and a second aspiration port 48b) formed by the opening at the distal end thereof. The aspiration ports 48 may be selectively covered by a sealing device 100. For example, the first aspiration port 48a may be at a distal end of the first lumen 40a. Similarly, the second aspiration port 48b may be provided at a distal end of the second lumen 40b.

[0025] Figure 4 is a cross-sectional view of the intragastric device 10 taken substantially along the line 4-4 of Figure 2. In the illustrated embodiment, a guidewire channel 112 may extend through the sealing device 100, the proximal cap 200, 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.

[0026] Figure 5 is a top view of a proximal portion 350 of an inflation device 300 in accordance with an embodiment of the present technology. The inflation device 300 may be provided for delivery and inflation of the intragastric device 10 (Figures 1-4) in situ. As shown in Figure 5, at a proximal portion 350a, the inflation device 300 may include tubes 310 (identified individually as a first tube 310a and a second tube 310b) corresponding to each balloon 30 of the intragastric device 10. For example, the first tube 310a may mechanically and fluidly connect a first handle 330a to a first barb 320a (Figure 7), and the second tube 310b may mechanically and fluidly connect a second handle 330b to a second barb 320b (Figure 7). Longitudinal advancement and retraction of the first barb 320a and the second barb 320b may be actuated by a user operating the first handle 330a and the second handle 330b at the proximal portion 350a of the inflation device 300. As further shown in Figure 5, the tubes 310 can be enclosed, contained, and/or otherwise stored at least partially within a housing 312. In other embodiments, the inflation device 300 does not include the housing 312.

[0027] Figure 6 is a top view of the proximal portion 150 of the intragastric device 10 of Figures 1-4 and the distal portion 350b of the inflation device 300 of Figure 5. As shown in Figure 6, the distal portion 350b of the inflation device 300 may be configured to mate with the proximal cap 200 of the intragastric device 10. Advancement, retraction, and positioning of barbs 320 (Figure 7) may be sensed by a user holding a corresponding handle 330. Inflation of at least one of the first balloon 30a and the second balloon 30b can occur while the inflation device 300 is mated with the proximal cap 200 of the intragastric device 10.

[0028] Figure 7 is a cut-away view of the inflation device 300 of Figures 5 and 6 engaged with the intragastric device 10 of Figures 1-4 in accordance with an embodiment of the present technology. As shown in Figure 7, the inflation device 300 may include at least one of an outer detent 302 and an inner detent 304. The outer detent 302 and the inner detent 304 may be separate pieces or separate portions of the same integral piece. The outer detent 302 may mate around or over a distal portion (e.g., flared/flanged section) of the proximal cap 200. In selected embodiments, the outer detent 302 can be elastic such that the outer detent 302 can shrink when removed from the proximal cap 200 for a lower safety profile. In other embodiments, the outer detent 302 can be rigid or non-elastic (e.g., a fiber hoop) and configured to collapse. Whether elastic or non-elastic, the large outer detent 302 provides retention forces and stability that is generally higher than an internal fixed flange of a smaller diameter (e.g., as with a flanged attachment of the BIB device). Additionally, when collapsed, the outer detent 302 takes up less space in the esophagus to enable simultaneous retraction of both an associated catheter and scope, or serial retraction of both components.

[0029] The inner detent 304 may mate against a proximal portion of the proximal cap 200. Before, during, or after such mating, the first barb 320a may be inserted into the first inflation port 47a to provide fluid to the first lumen 40a, and the second barb 320b may be inserted into the second inflation port 47b to provide fluid to the second lumen 40b. In the embodiment illustrated in Figure 7, the mating interface 390 is a flat surface. In other embodiments, the mating interface 390 can include ridges, beveled edges, filleted edges, and/or other non-planar surfaces.

[0030] As shown in Figure 7, the first barb 320a and the second barb 320b may be longitudinally advanceable relative to at least one of the outer detent 302 and the

inner detent 304. At least a portion of the first barb 320a and/or the second barb 320b may have a diameter or cross-sectional area that exceeds the diameter or cross-sectional area of at least a portion of the corresponding inflation port 47 in an unengaged state. Accordingly, insertion of the first barb 320a into the first inflation port 47a or the second barb 320b into the second inflation port 47b may cause expansion of the proximal cap 200 in an engaged state. As indicated by the arrows in Figure 7, the expansion of the proximal cap 200 may be radially outward. The proximal cap 200 can also expand in other directions (e.g., toward the inner detent 304). Such expansion may reduce the ease with which the outer detent 302 may disengage from the proximal cap 200. For example, engaging the outer detent 302 around the proximal cap 200 may be made more secure by the expansion of the proximal cap 200 such that the force required to disengage the outer detent 302 from the proximal cap 200 is greater when one or both of the barbs 320 are engaged within the corresponding inflation port 47. Accordingly, the force required to disengage the outer detent 302 from the proximal cap 200 is lower when one or both of the barbs 320 are disengaged from the corresponding inflation ports 47.

[0031] Figure 8 is a cut-away view of an inflation device 800 and the intragastric device 10 in accordance with another embodiment of the present technology. The inflation device 800 includes features generally similar to the inflation device 300 described above with reference to Figures 5-7. For example, the inflation device 800 can include the tubes 301 connected to the barbs 320, the outer detent 302, and the inner detent 304. The inner detent 304 can also include the mating interface 390. As shown in Figure 8, the mating interface 390 can be configured to leave an open space 391 near the proximal cap 200 when the inflation device 800 and the proximal cap 200 are engaged. The open space 391 can be defined by the mating interface 390 and the proximal cap 200. For example, in the embodiment illustrated in Figure 8, the open space 391 is defined by a chamfered portion 393 of the mating interface 390 and the proximal cap 200. In other embodiments, the mating interface 390 can include scallops, ridges, and/or other cut-outs with different shapes and geometries that leave one or more open spaces 391 near the proximal cap 200.

[0032] The open space 391 may provide a channel into which the proximal cap 200 may expand. For example, insertion of at least one of the barbs 320 into the corresponding inflation ports 47 may cause expansion of the proximal cap 200. At

least some of the expansion of the proximal cap 200 may occur into the open space 391 rather than against the outer detent 302. The distribution of this expansion may increase the force required to disengage the outer detent 302 from the proximal cap 200, further allowing the proximal cap material to deflect when the barbs 320 are retracted. This allows a user to selectively reduce the engagement force of the outer 302 detent to the proximal cap 200.

[0033] Figures 9-12 show the inflation device 800 of Figure 8 in various stages of inserting the barbs 320 into the inflation ports 47 of the intragastric device 10. Referring to Figures 9-12 together, the intragastric device 10 may achieve an engaged state relative to inflation device 800. The outer detent 302 may be mated around a distal portion of the proximal cap 200, and the inner detent 304 may be mated against a proximal portion of the proximal cap 200. As shown in Figures 9 and 10, the first barb 320a and the second barb 320b may be mated within the corresponding first and second inflation ports 47a-b. In the engaged state, as shown in Figure 10, the proximal cap 200 may expand due at least to the insertion of the barbs 320 into the corresponding inflation ports 47. The expansion of the proximal cap 200 may be against the outer detent 302, the inner detent 304, or the open space 391 defined by at least mating interface 390 and proximal cap 200.

[0034] In selected embodiments, engaging the intragastric device 10 with the inflation device 800 may be performed in situ within a gastric cavity of a patient. For example, the inflation device 800 may be attached to an intragastric device 10 that was previously deployed within the gastric cavity.

[0035] In other embodiments, engaging the intragastric device 10 with the inflation device 800 may be performed before insertion into a patient. For example, the intragastric device 10 and the inflation device 800 may be provided together in an engaged state or as a part of a kit of parts. Directions for use may further be provided. In the engaged state, the outer detent 302 may be mated around to a distal portion of the proximal cap 200, the inner detent 304 may be mated against a proximal portion of the proximal cap 200, and the first barb 320a and the second barb 320b may be mated within the first inflation port 47a and the second inflation port 47b, respectively. In the engaged state, the proximal cap 200 may be expanded.

[0036] The engaged intragastric device 10 and the inflation device 800 may be delivered to a gastric cavity. A fluid may be flowed to intragastric device 10. For example, the fluid may flow through at least one of the first handle 330a, the first tube 310a, the first barb 320a, the first inflation port 47a, the first inflation chamber 42a, the first inflation opening 32a, and the first balloon 30a. Similarly, the fluid may flow through at least one of the second handle 330b, the second tube 310b, the second barb 320b, the second inflation port 47b, the second inflation chamber 42b, the second inflation opening 32b, and the second balloon 30b. As such, at least one of the first balloon 30a and the second balloon 30b may be inflated to a desired volume.

[0037] In selected embodiments, the first balloon 30a and the second balloon 30b may be inflated simultaneously. Similarly, any number of balloons 30 may be inflated simultaneously corresponding to the number of separate inflation structures (e.g., handles 330, tubes 310, barbs 340, inflation ports 47, inflation chambers 42, and inflation openings 32). A plurality of inflation structures may reduce the total amount of time required to inflate the balloons 30 of intragastric device 10 by a factor corresponding to the number of inflation structures. For example, where N number of inflation structures are provided, the amount of time required to inflate the balloons 30 of the intragastric device 10 may be reduced by a factor of N. Additionally, because each balloon 30 includes at least one corresponding inflation structure, there is no need to attach a barb 320 to one inflation port 47, inflate, detach, and repeat the process with another inflation port 47.

[0038] As shown in Figures 11 and 12, at least one of the first barb 320a and the second barb 320b may be retracted and removed from the corresponding inflation port 47. The open space 391 can facilitate withdrawal of the barbs 320 as it allows silicone material from the proximal cap 200 a place to go during barb withdrawal. In selected embodiments, a user may feel tactile feedback as each barb 320 moves out of the proximal cap 200. A user may also hear an audible feedback when the barb stops against the inner detent 304 if such a stop is provided, especially when the barb 320 stops against the inner detent 304. Accordingly, the proximal cap 200 may contract due to the removal of at least one of the first barb 320a and the second barb 320b. Such contraction may result in lower forces applied by the proximal cap 200 on the outer detent 302 or the inner detent 304. Therefore,

the force required to disengage the outer detent 302 and/or the inner detent 304 from the proximal cap 200 may be reduced once the proximal cap 200 has contracted.

[0039] To disengage and separate the inflation device 800 from the intragastric device, the outer detent 302 may be removed from around the proximal cap 200 and the inner detent 304 may be removed from against the proximal cap 200. In selected embodiments, such separation of the inflation device 800 from the intragastric device 10 can result from the application of lateral forces. For example, the inflation device 800 may be advanced against the inflated gastric device 10, causing it to distort or rotate. The distorted shape or rotation of intragastric device 10 may cause a lateral force to be applied at the engagement location of the intragastric device 10 and the inflation device 800, causing it to buckle at the engagement location. Such forces may exceed the forces maintaining engagement. As described above, the forces maintaining engagement can be reduced after removal of the first barb 320a and/or the second barb 320b or by the mating interface 390. The reduction of this force may likewise reduce the force placed on the gastric wall supporting such actions. The body of the inflation device 800 may provide an opposing force to retract the barbs 320 such that the inserted barbs 320 do not exceed engagement forces, but with the removed barbs 320 it does exceed engagement forces. This allows for secure placement as well as very little to no pull force on removal of the inflation device 800.

[0040] In other embodiments, the inflation device 800 may be separated from the intragastric device 10 by opposing forces. A tension force may be provided by retracting the inflation device 800 at a second end thereof. An opposing force against the intragastric device 10 may be provided by the gastroesophageal junction. The junction may provide such a force after the balloon(s) 30 of intragastric device 10 are inflated such that a diameter thereof exceeds the diameter of the gastroesophageal junction. When force is applied from the gastroesophageal junction, it is inherent that a substantially equal tensile force applies to the engagement location of the inflation device 800. Reduction of the force required to disengage inflation device 800 from intragastric device 10 may be beneficial in that the force applied to and from the gastroesophageal junction is reduced. Accordingly, trauma to the gastroesophageal junction is likewise reduced.

[0041] In further embodiments, a force may be applied to the intragastric device 10 from another device that holds the intragastric device 10 in place relative to the retraction of the inflation device 800. For example, a rigid or partially rigid structure may hold the intragastric device 10 in place while the inflation device 800 is retracted.

[0042] Figure 13 is a side elevational view of a proximal portion of an inflation assembly 1300 in accordance with an embodiment of the present technology. The inflation assembly 1300 can be coupled to the inflation devices 300 and 800 described above, and can be used to inject or otherwise introduce fluid into the intragastric device 10 (Figures 1-4). For example, Figure 13 shows one of the tubes 310 at the proximal portion 350a of the intragastric device 300 or 800 coupled to a connector 1302 of the inflation assembly 1300. The connector 1302 can place a syringe and/or other fluid injection device 1304 in fluid communication with the tube 310. In the illustrated embodiment, for example, the connector 1302 is a Y-connector. In other embodiments, inflation assembly 1300 can include other suitable connectors 1302 that join the fluid injection device 1304 with the tubes 310. In operation, the fluid injection device 1304 can receive fluids and introduce them to the intragastric device 10 through the tubes 310. In selected embodiments, the fluid injection device 1304 can be used to introduce specific fluids into the balloons 30, such as mineral oils, antimicrobial agents, and/or other desired fluids or materials. The fillant fluid can be introduced into the balloons 30 through the fluid injection device 1304 and/or from a different site in fluid communication with the tubes 310. For example, as shown in Figure 13, a fluid line 1308 (e.g., an IV line) can connect to one or more containers (e.g., a saline bag) that store the desired quantity of fluid for each balloon 30.

[0043] As further shown in Figure 13, the inflation assembly 1300 can include one or more valves 1306 (identified individually as a first valve 1306a and a second valve 1306b) that regulate the direction of the fluid. For example, the valves 1306 can be one-way check valves to prevent backflow of the fluid as it enters the inflation assembly 1300. In the embodiments illustrated in Figure 13, the first valve 1306a is positioned in line with the tubes 310 and the second valve 1306b is positioned in line with the fluid injection device 1304 to prevent backflow from each site of fluid entry.

In other embodiments, one or more other valves 1306 can be included in the inflation assembly 1300 to regulate fluid entry and/or exit.

[0044] Additionally, the inflation assembly 1300, the inflation devices 300 and 800, and/or the intragastric device 10 described above can include features that reduce or prevent the mitigation of bacteria into the intragastric device 10 during or after implantation, inflation, deflation, and/or removal procedures. For example, the inflation assembly 1300 and the intragastric device 10 can include features that prevent bacteria from entering the balloons 30, and/or prevent bacteria from growing inside the balloons 30 during and after implantation. These features can prevent detrimental expansion of the balloons 30 caused by bacterial growth and its by-products (e.g., gas), reduce the likelihood of infection, and/or otherwise decrease failure of the intragastric device 10.

[0045] In selected embodiments, for example, components of the intragastric device 10, the inflation devices 300 and 800, the inflation assembly 1300, and/or associated devices (e.g., the delivery catheter, secondary inflation lines, syringes, containers, etc.) can be sterilized. The individual components of the inflation assembly 1300, the intragastric device 10, and/or other related tools and devices may be stored within a sterile kit as individual sterilized components. A sterile area or field can be used for set-up, implantation, and/or removal of the intragastric device 10. For example, associated devices can be attached to the inflation devices 300 and 800 on a sterile device tray, card, and/or other sterile working space before implantation. This sterile field can be packaged with the inflation devices 300 and 800, intragastric device 10, and/or inflation assembly 1300. Additionally, a cover (e.g., a hood, a cap) can encase connection sites (e.g., lures), the handles 330, related injection lines, fluid insertion containers 1304, and/or other components before implantation of the intragastric device 10. These covers can maintain the sanitation of the inflation devices 300 and 800, intragastric device 10, the inflation assembly 1300, and/or associated devices during implantation and inflation procedures. For example, covers can be pre-attached to portions (e.g., connection sites) of the inflation devices 300 and 800, intragastric device 10, and/or the inflation assembly 1300, such that the covered portion remains sanitized.

[0046] In other embodiments, the intragastric device 10, the inflation devices 300 and 800, the inflation assembly 1300, and/or portions thereof can be pre-

attached before implantation such that the joined components can be sterilized together. For example, the inflation assembly 1300 can be pre-attached to the tubes 310. As another example, the inflation devices 300 and 800 can be pre-attached to the intragastric device 10.

[0047] In further embodiments, the inflation devices 300 and 800, the intragastric device 10, and/or associated devices can be comprised at least partially of materials with anti-microbial agents or other anti-bacterial features. The balloons 30, for example, can be made from a diphenyl loaded material. Additionally, the balloons 30 can be pressurized to reduce bacteria ingress.

[0048] The balloons 30 can also be filled with bacteriostatic fillants to prevent bacteria from growing within the balloons 30. For example, a sterile 0.9% sodium chloride solution bacteriostatic may be used as a fillant. Bacteriostatic agents can also be incorporated directly into the fillant. In selected embodiments, a bacteriostatic sealant, such as mineral oil with preservatives (e.g., tacophenol) can be used to kill expected bio-burden within the balloons 30.

[0049] In further embodiments, the inflation devices 300 and 800, the intragastric device 10, and/or other associated delivery and inflation devices can include other features to limit bacterial growth within the balloons 30. In selected embodiments, bacterial food sources can be reduced or eliminated. For example, powdered food sources (e.g. corn starch) on the intragastric device 10 and/or the inflation devices 300 and 800 may be replaced with sodium bicarbonate that is a less accessible carbon food source and creates a pH environment that is not favorable for some intragastric microbes. In other embodiments, a surface treatment (e.g., silicone dispersion) may be applied to interior portions of the balloons 30 to fill open pores in the balloon material. Lubricants (e.g., mineral oil) can also be injected inside the balloons 30 to fill porous portions. Inert and/or bacteriostatic dusting powder (e.g., zinc oxide, amoxicillin, barium sulfate, etc) can also be used within or over the balloons 30.

[0050] From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but that various modifications may be made without deviating from the spirit and scope of the technology. For example, the intragastric device 10 shown in Figures 1-4 includes

two balloons and the inflation devices 300 and 800 of Figures 5-12 include two corresponding inflation lines. However, other embodiments can include multiple inflation lines for individual balloons 30 to decrease inflation time. Certain aspects of the new technology described in the context of particular embodiments may be combined or eliminated in other embodiments. For example, the intragastric devices described above include balloons, but the intragastric devices can include other inflatable, elastic space-fillers. Additionally, the methods of engaging and separating the inflation device 800 from the intragastric device 300 described above with reference to Figures 8-12 can similarly apply to the inflation device 300 of Figure 7. Further, while advantages associated with certain embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. An inflation device, comprising:

an outer detent at a distal portion of the inflation device configured to connect over a proximal cap of an intragastric device;

an inner detent having a mating interface; and

at least one tube fluidly connecting a handle at a proximal portion of the inflation device to a barb at the distal portion of the inflation device, the barb having a cross-sectional dimension greater than a cross-sectional dimension of a corresponding inflation port of the intragastric device, wherein the barb is configured to expand the proximal cap when the barb is inserted into the inflation port.

2. The inflation device of claim 1 wherein the barb is configured to mate within an inflation port of the intragastric device.

3. The inflation device of claim 2 wherein the inflation port is fluidly connected to an inflatable balloon of the intragastric device.

4. The inflation device of claim 1 wherein the barb is longitudinally advanceable relative to at least one of the outer detent and the inner detent.

5. The inflation device of claim 1 wherein the mating interface is configured to leave an open space when the inner detent mates with the proximal cap.

6. The inflation device of claim 5 wherein the open space is defined by the mating interface and the proximal cap.

7. The inflation device of claim 5 wherein the mating interface is configured to allow at least a portion of the proximal cap to expand into the open space.

8. The inflation device of claim 1 wherein the mating interface includes a chamfered portion.

9. The inflation device of claim 1 wherein the barb is configured to cause the proximal cap to contract when not inserted within the inflation port.

10. The inflation device of claim 1 wherein the outer detent is configured to mate with a distal portion of the proximal cap.

11. The inflation device of claim 1 wherein the inner detent is at least partially within the outer detent.

12. An inflation device, comprising:

a tube extending from a proximal portion of the inflation device to a distal portion of the inflation device, the tube having a handle at the proximal portion and a barb at the distal portion, wherein the barb has a cross-sectional dimension greater than a cross-sectional dimension of a corresponding inflation port of an intragastric device;

an inner detent over the barb, the inner detent having a mating interface; and

an outer detent over the inner detent, the outer detent being configured to attach over a proximal cap of the intragastric device, wherein the tube is longitudinally advanceable relative to at least one of the inner and outer detents.

13. The inflation device of claim 12 wherein the mating interface includes a chamfered portion.

14. The inflation device of claim 12 wherein a portion of the mating interface defines an open space when the inner detent mates with the proximal cap.

15. The inflation device of claim 12 wherein the tube is a first tube, the handle is a first handle, the barb is a first barb, the inflation port is a first inflation port, and wherein the inflation device further comprises:

a second tube extending from the proximal portion of the inflation device to the distal portion of the inflation device, the second tube having a second handle at the proximal portion and a second barb at the distal portion, wherein the second barb has a cross-sectional dimension greater than a cross-sectional dimension of a corresponding second inflation port of an intragastric device, and wherein the first and second inflation ports are fluidly connected to a first balloon and a second balloon, respectively, of the intragastric device.

16. A method of inflating an intragastric device, the method comprising:

connecting an inflation device with a proximal cap of an intragastric device, wherein an outer detent of the inflation device is mated around the proximal cap, and wherein an inner detent of the inflation device is mated against a portion of the proximal cap;

inserting a barb of the inflation device into an inflation port of the intragastric device;

delivering the intragastric device to a gastric cavity;

flowing a fluid into the intragastric device via the barb and the inflation port, wherein a balloon of the intragastric device is inflated with the fluid;

retracting the barb from the inflation port; and

removing the outer detent from around the proximal cap and the inner detent from against the proximal cap to disconnect the inflation device from the proximal cap.

17. The method of claim 16 wherein connecting the inflation device comprises forming an open space between a mating interface of the inner detent and the proximal cap such that at least a portion of the proximal cap expands into the open space when the inflation device mates with the proximal cap.

18. The method of claim 16 wherein inserting the barb comprises inserting a barb having a greater cross-sectional dimension than a cross-sectional dimension of the inflation port such that the proximal cap expands when the barb is inserted.

19. The method of claim 16 wherein retracting the barb from the inflation port contracts the proximal cap.

20. The method of claim 16 wherein retracting the barb from the inflation port reduces the force required to remove the outer detent from around the proximal cap and the inner detent from against the proximal cap.

21. The method of claim 16 wherein retracting the barb comprises retracting a handle connected to the barb by a tube.

22. The method of claim 16 wherein removing the outer detent further comprises applying an axial force relative to the inflation device and the intragastric device.

23. The method of claim 16 wherein removing the outer detent further comprises applying a lateral force relative to the inflation device and the intragastric device.

24. A method of preventing bacterial growth within an intragastric device for trans-oral placement, the method comprising:

sterilizing the intragastric device, an inflation device for inflating the intragastric device, and an inflation assembly configured to be coupled to the inflation device,

wherein at least a portion of a packaging of the intragastric device, the inflation device, and/or the inflation assembly is configured as a sterile field for device set-up,

wherein a cover is provided for at least one connection site of the inflation device, the injection device, and the inflation assembly;

attaching the intragastric device and the inflation device together before sterilization or during device preparation in the sterile field; and

attaching the inflation assembly and the inflation device during device preparation in the sterile field or after trans-oral placement of the intragastric device.

25. A method of preventing bacterial growth within a balloon of an intragastric device, the method comprising:

delivering the intragastric device to a gastric cavity using an inflation device; and

filling at least a portion of the balloon with at least one of a sterile bacteriostatic fillant and a bacteriostatic sealant, wherein the bacteriostatic sealant is configured to kill a selected bio burden inside the balloon.

26. A method of preventing bacterial growth on and within a balloon of an intragastric device, the method comprising:

eliminating a food source from within the balloon;

performing a surface treatment on an interior portion of the balloon, wherein the surface treatment fills open pores of the balloon;

adding lubricants within the balloon, wherein the lubricant fills open pores of the balloon; and

adding at least one of an inert dusting powder and a bacteriostatic dusting powder within the balloon.

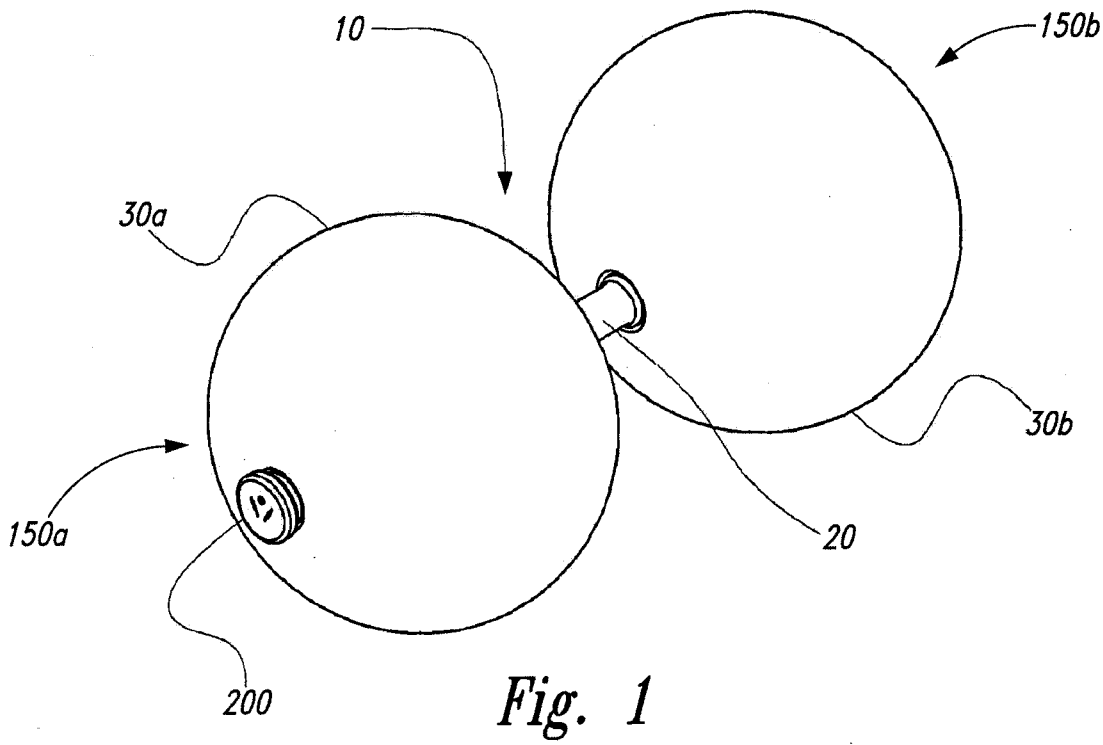


Fig. 1

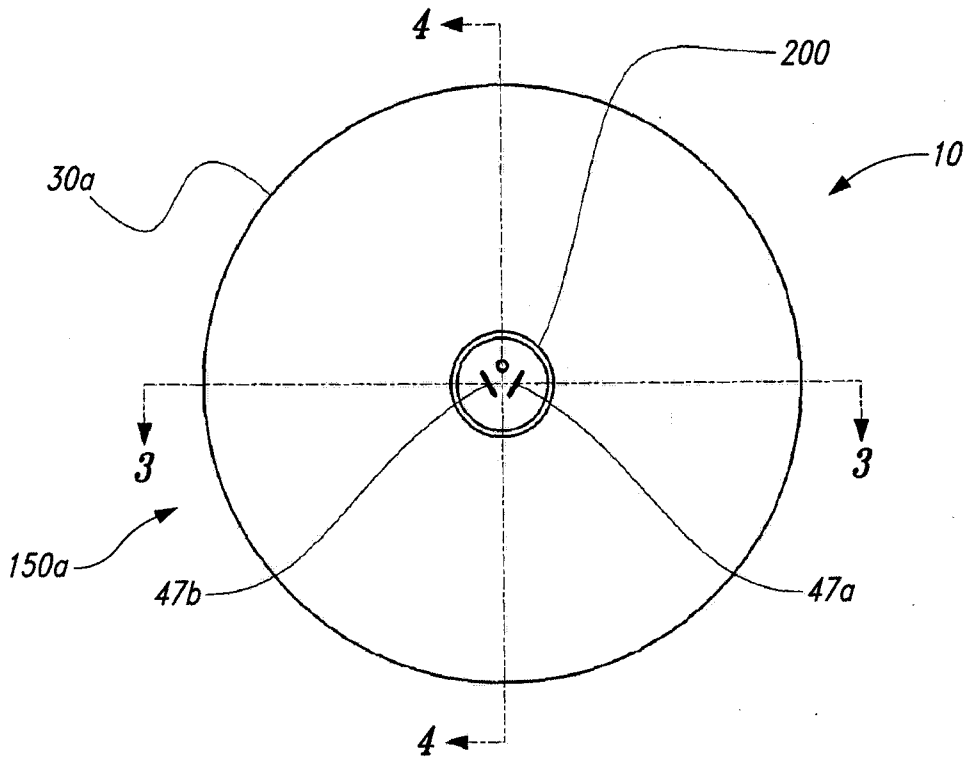


Fig. 2

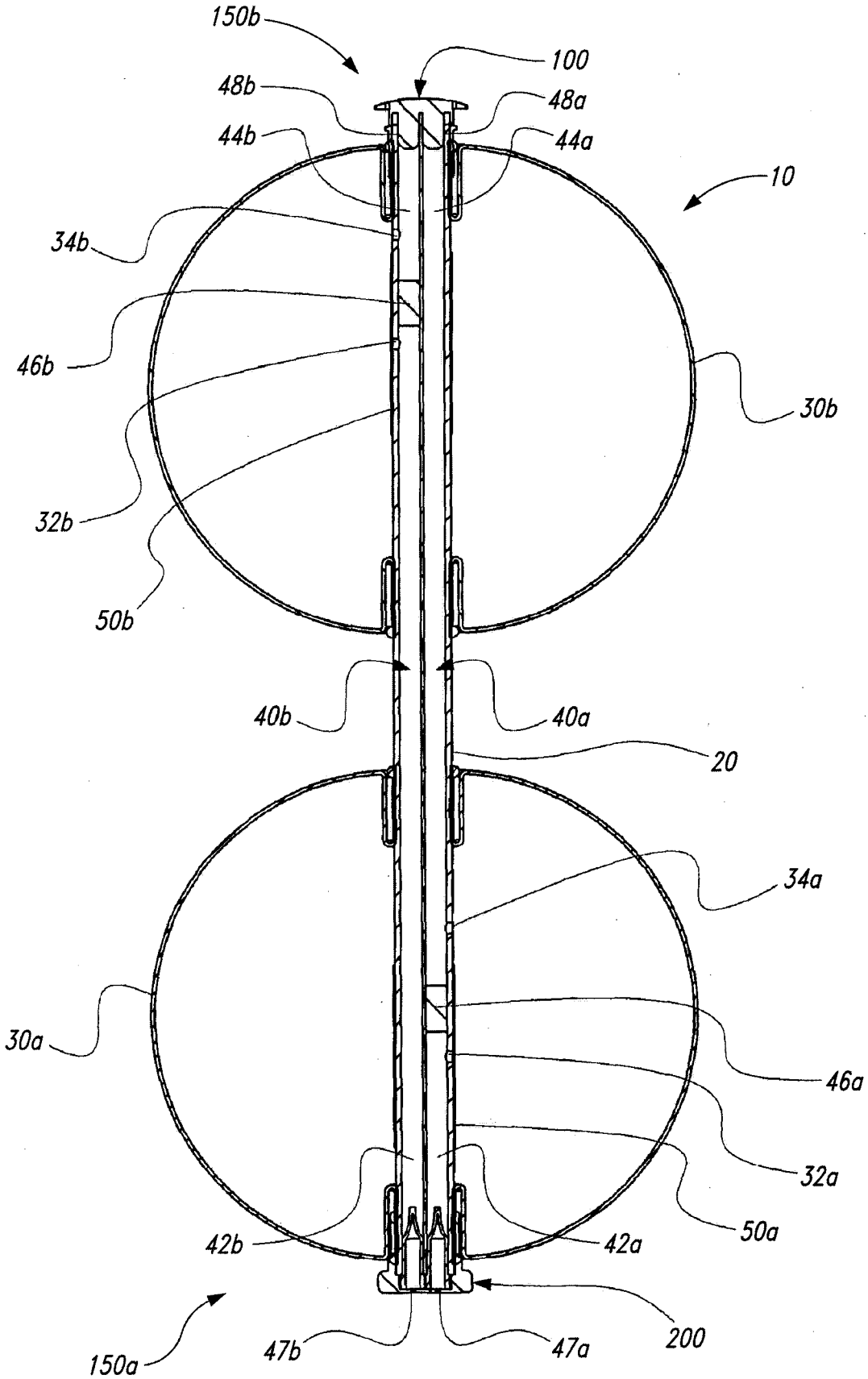

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Fig. 3

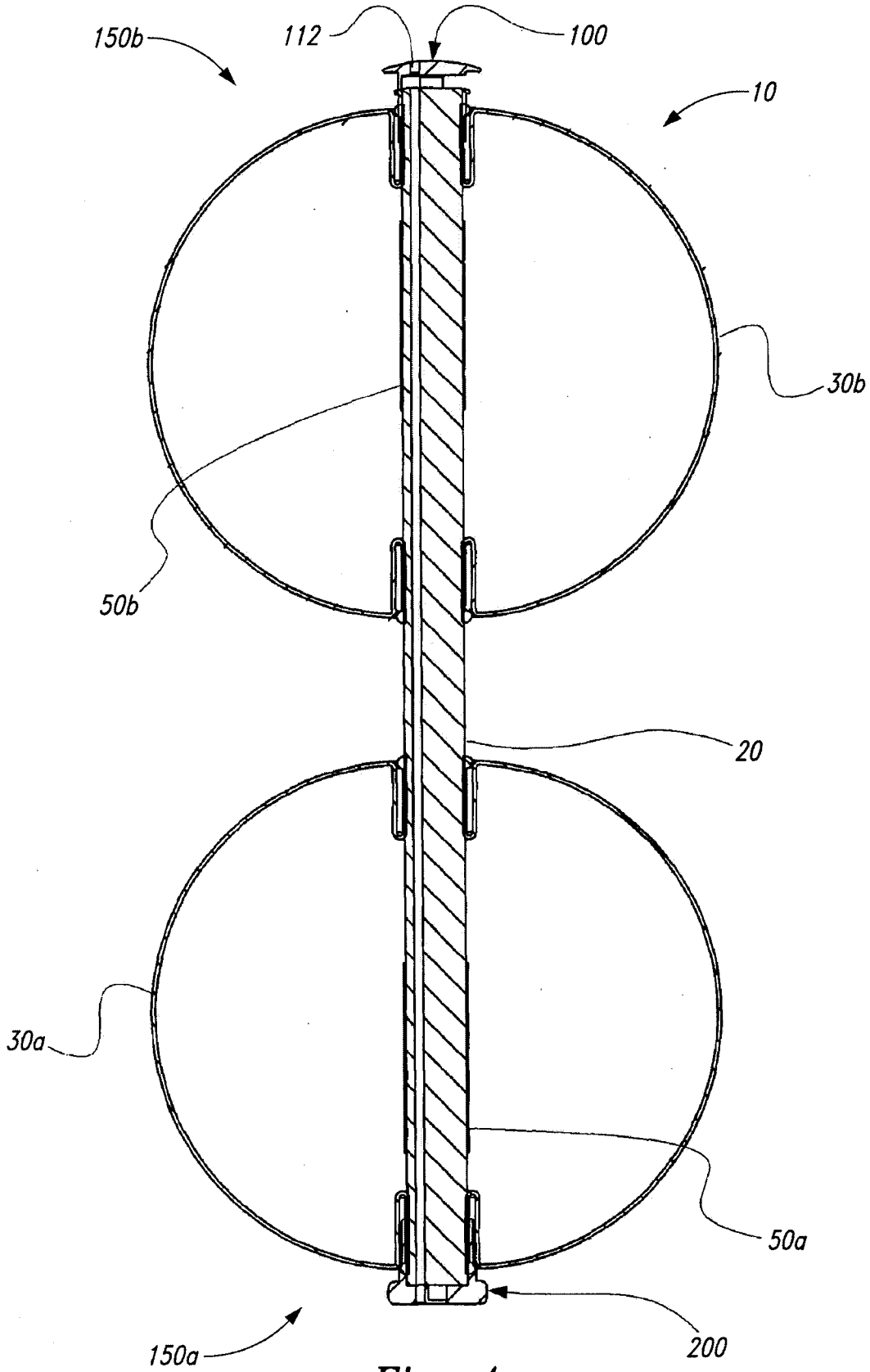


Fig. 4

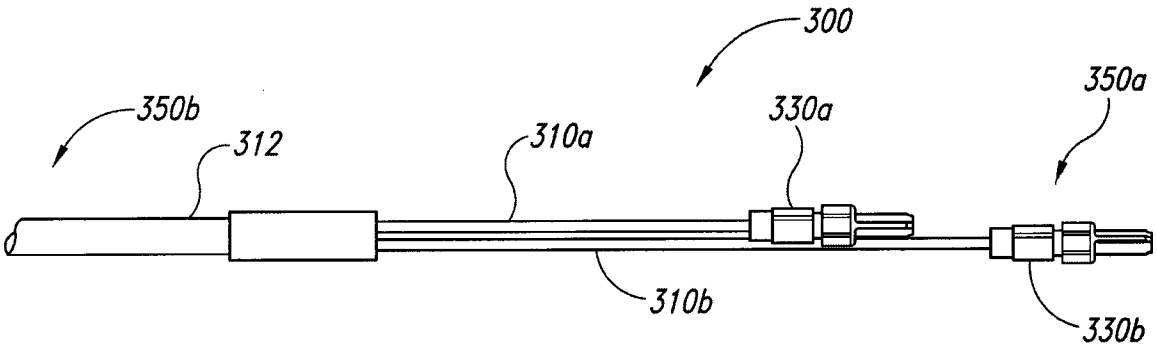

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Fig. 5

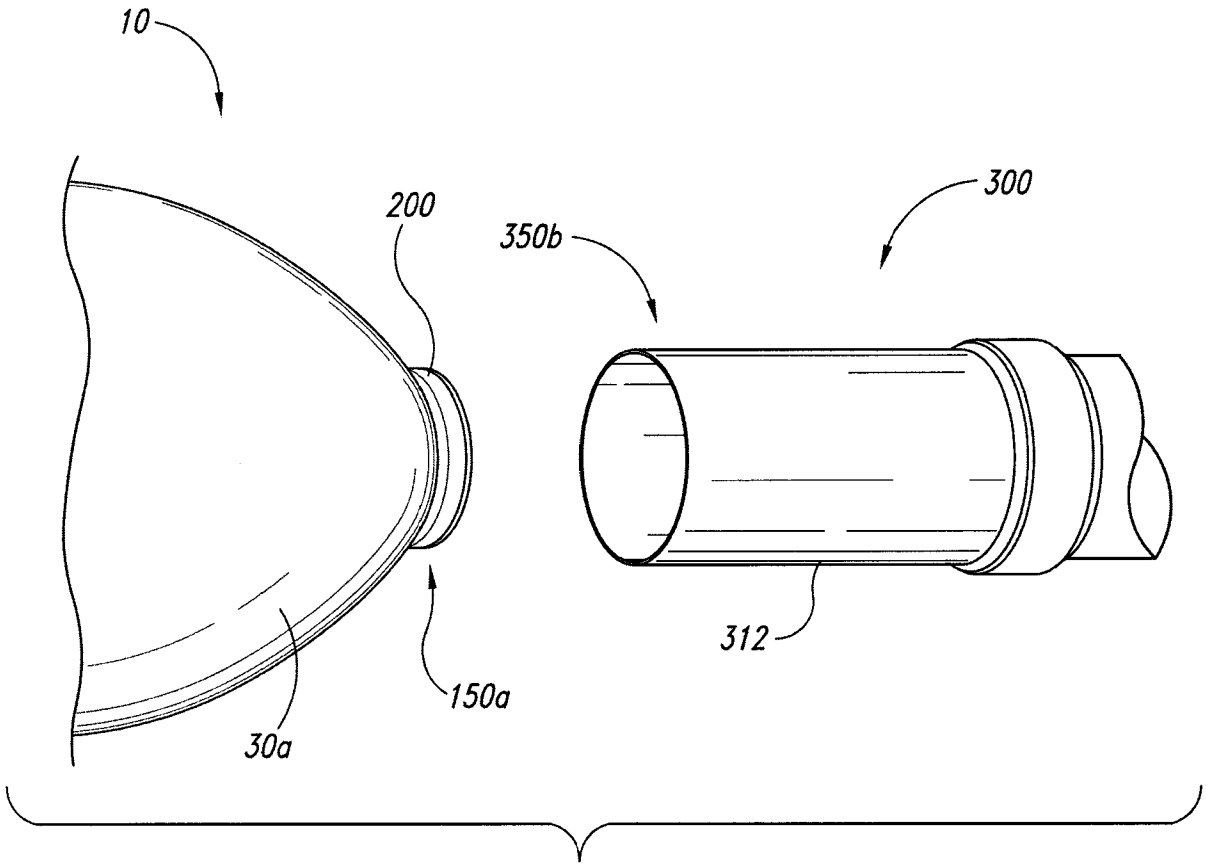

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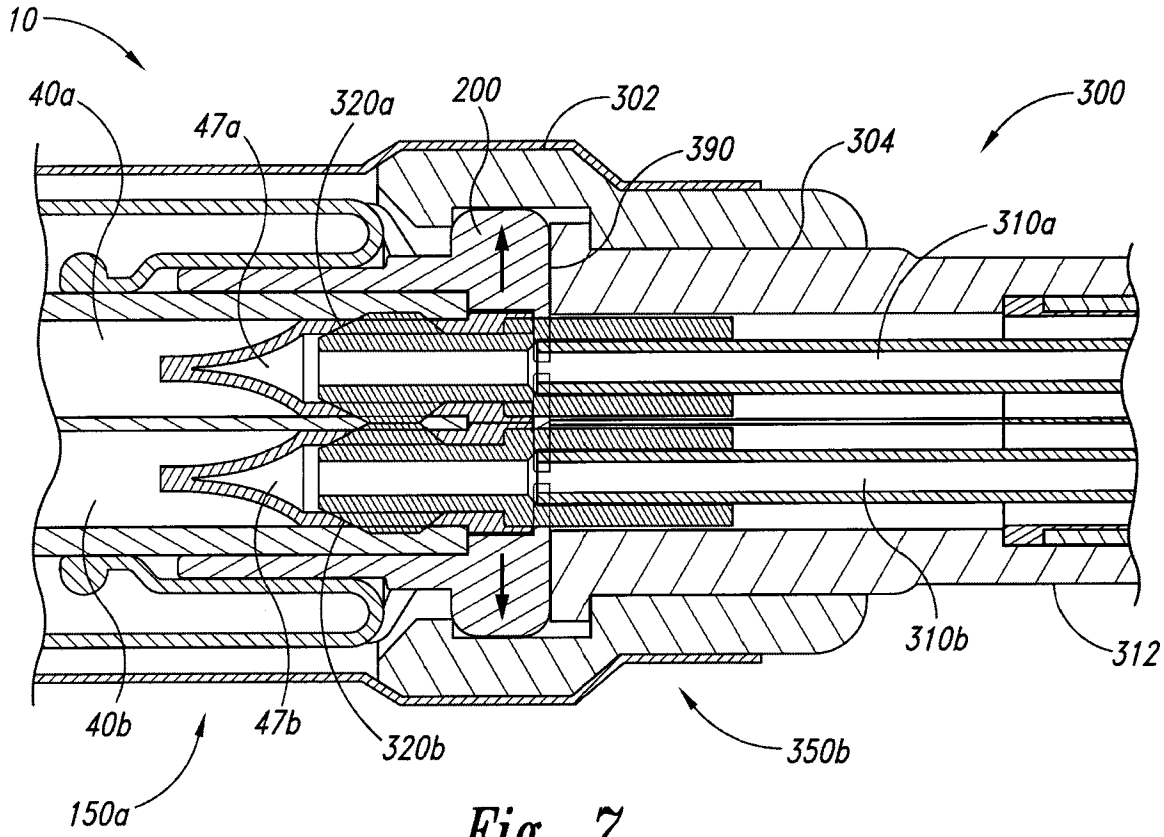

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Fig. 7

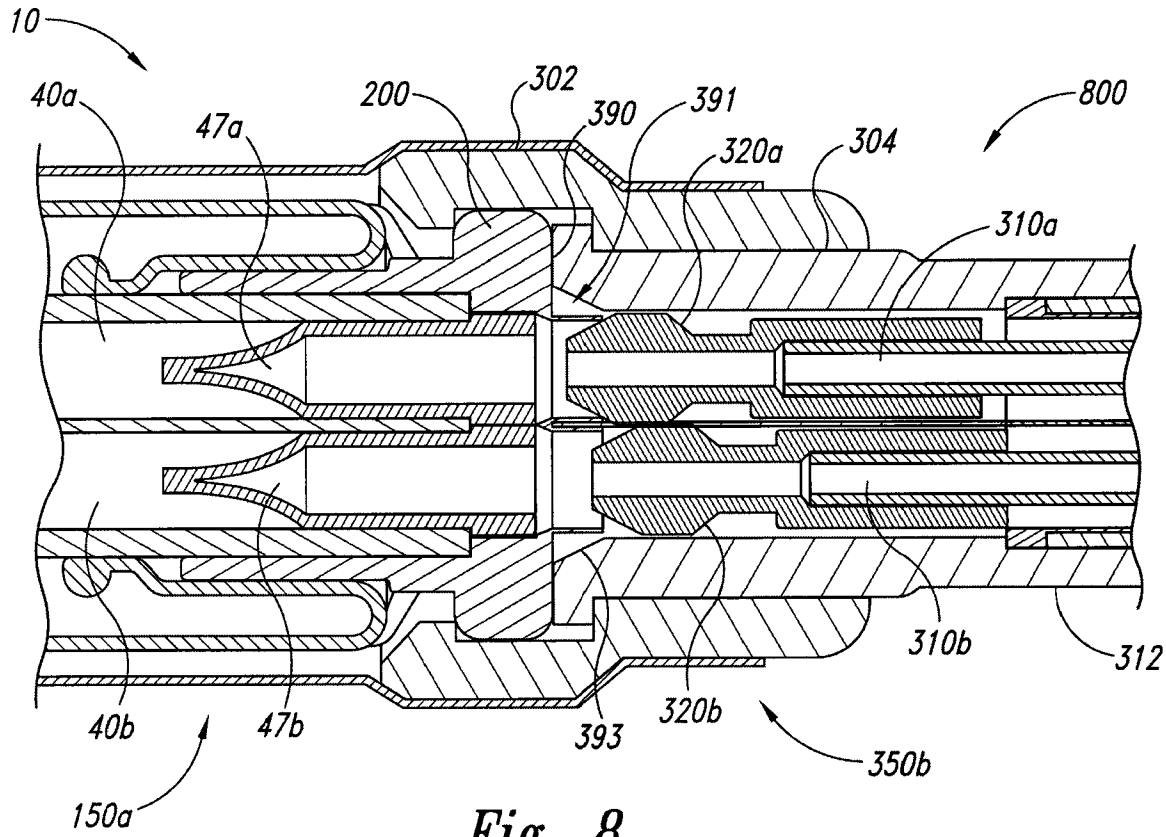

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Fig. 8

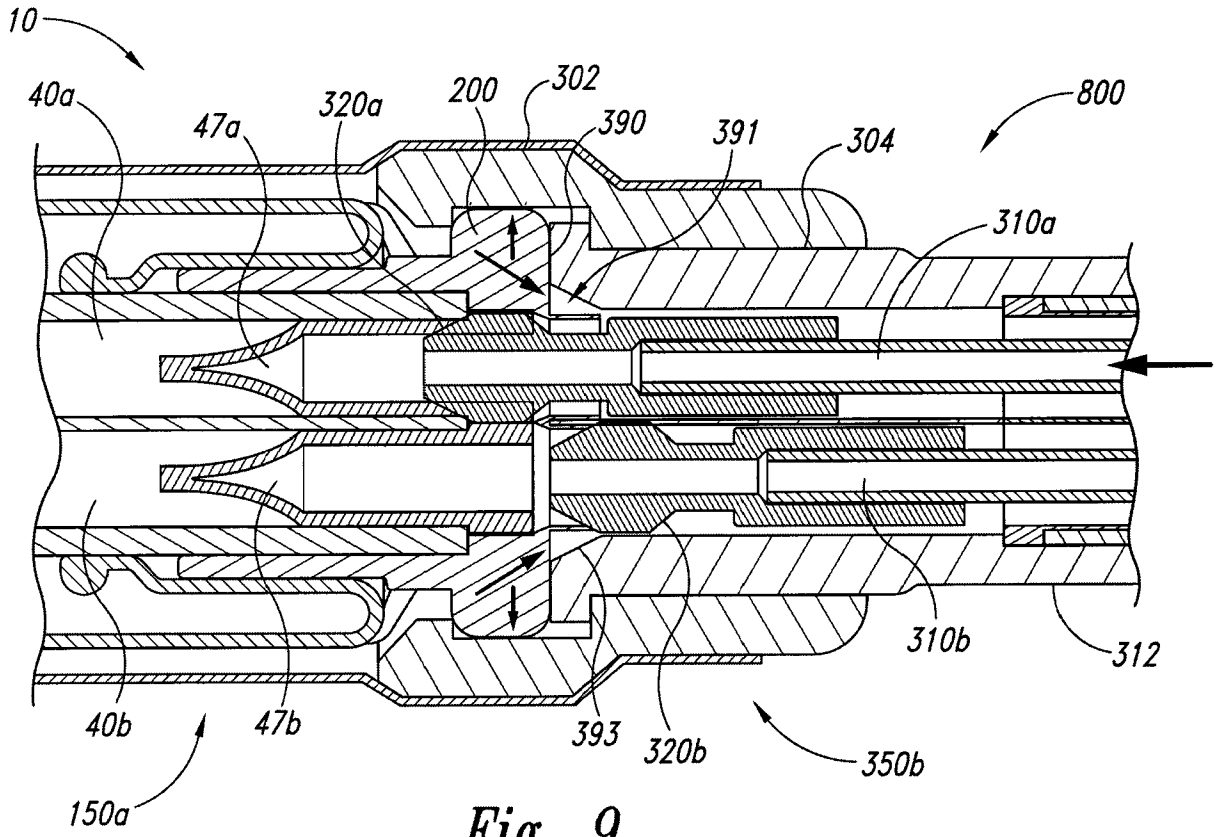

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Fig. 9

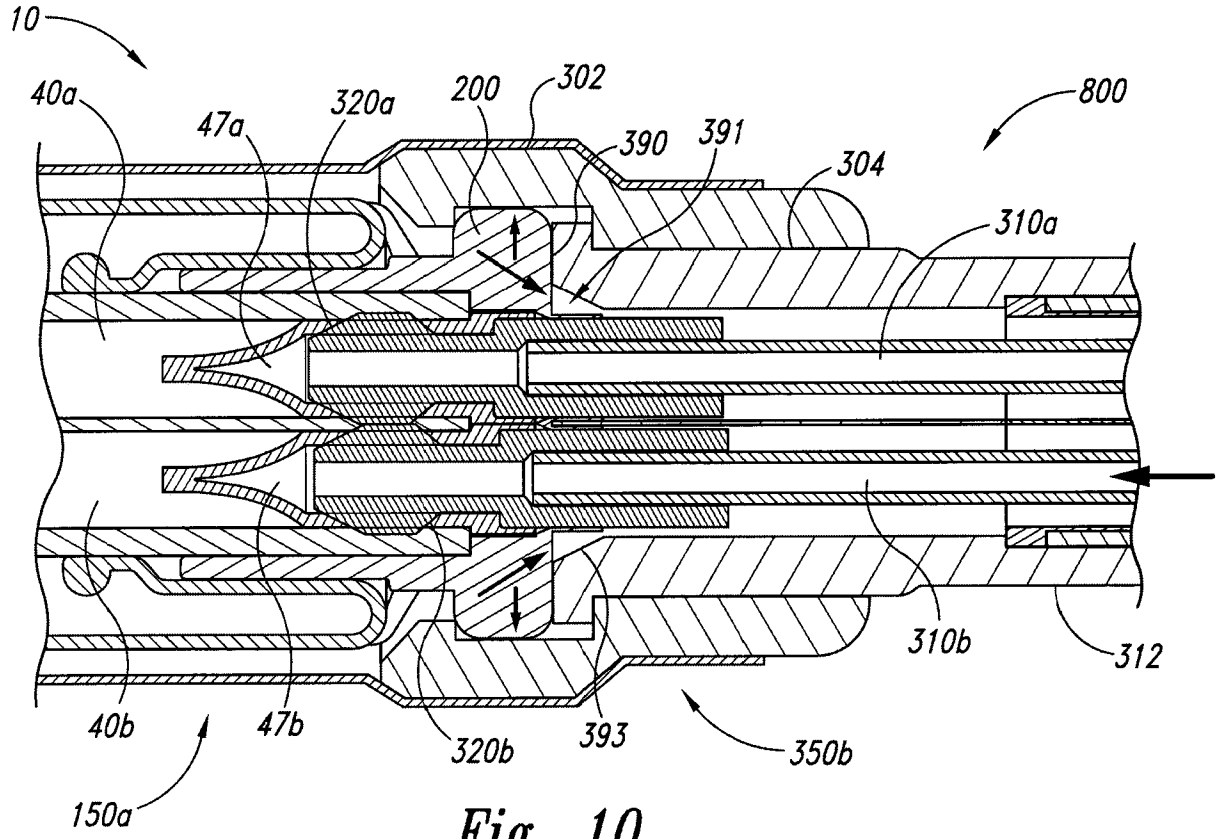

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Fig. 10

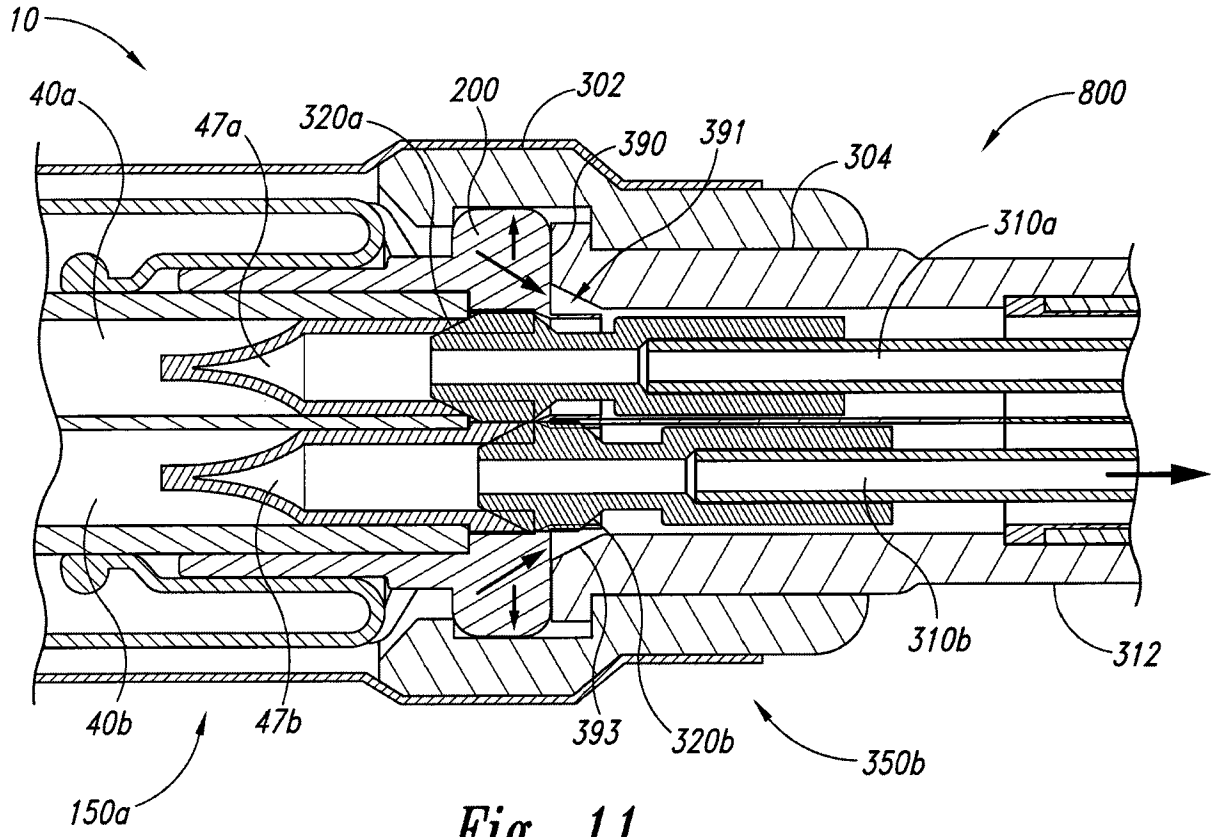

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Fig. 11

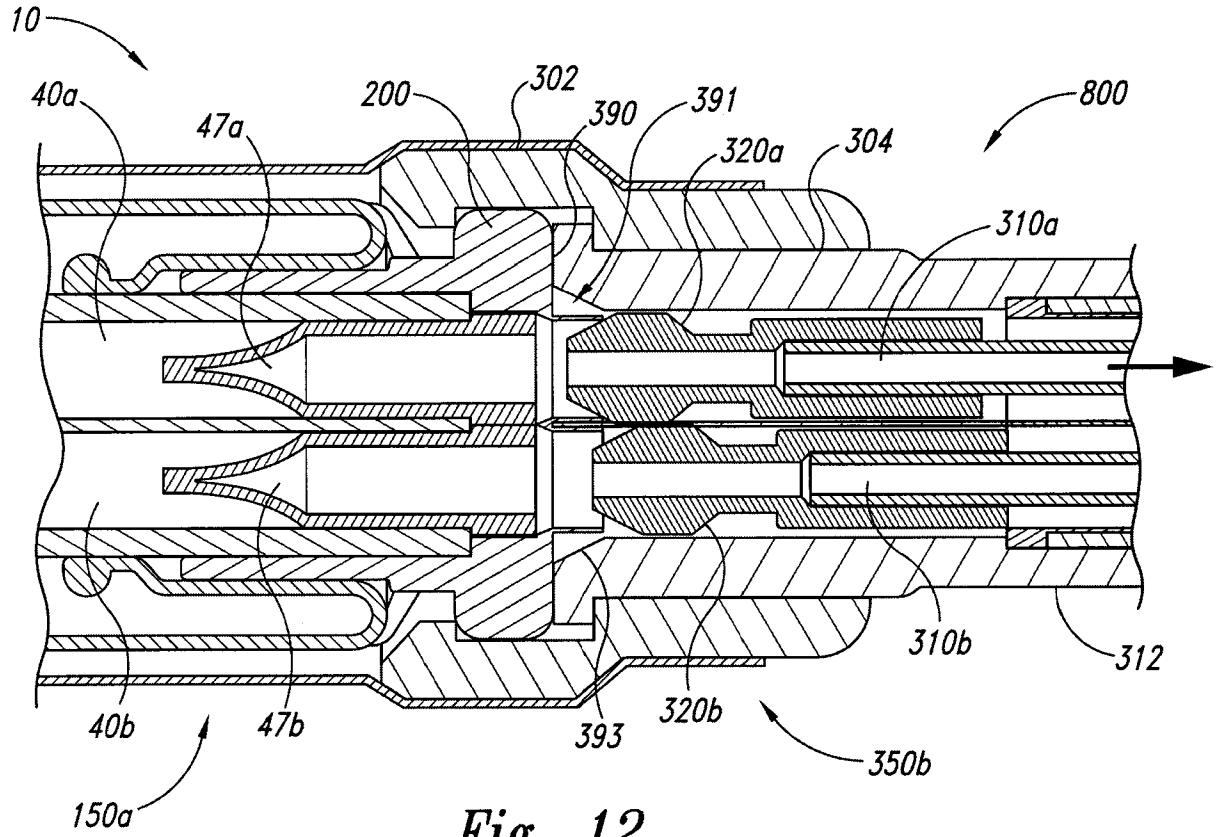

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Fig. 12

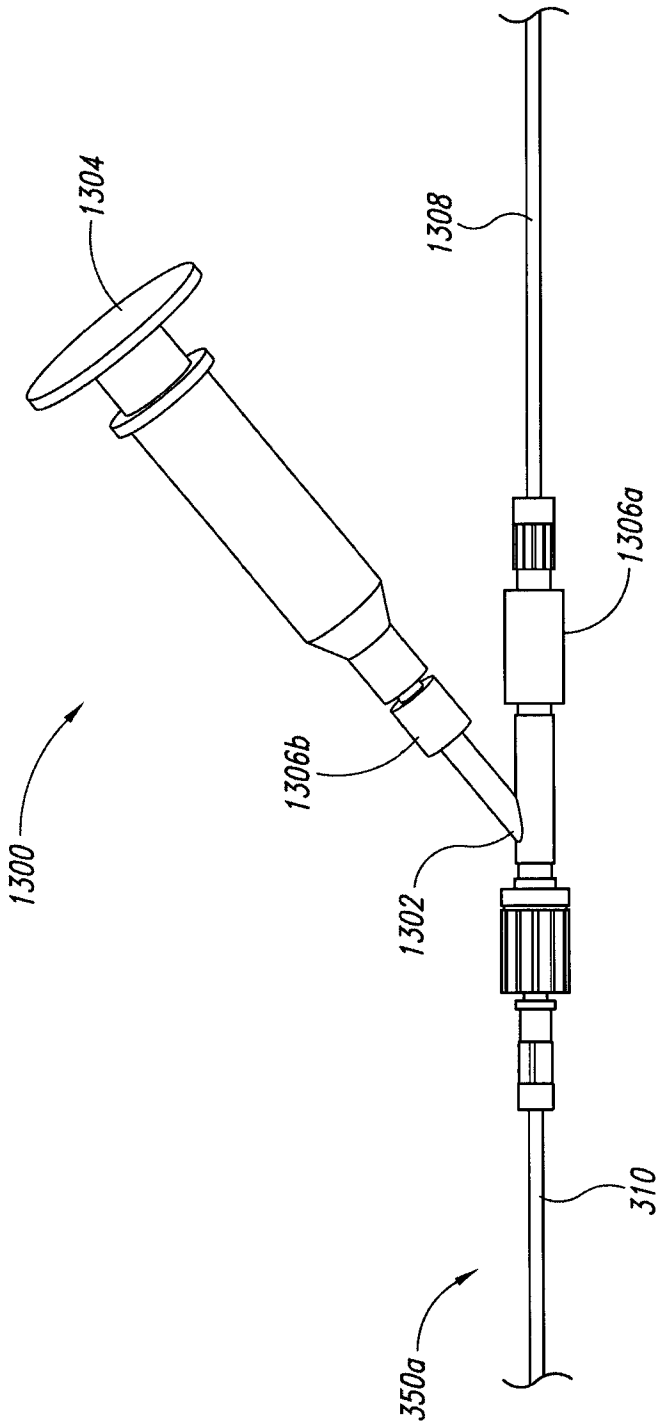


Fig. 13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/031463

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/04 (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) - A61F 2/04 (2011.01)
USPC - 606/192

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, Engineering Village, Google

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 2008/0319471 A1 (SOSNOWSKI et al) 25 December 2008 (25.12.2008) entire document	16, 20-21, 23 --- 1-15, 17-19, 22, 24-26
Y	US 2008/0190363 A1 (CHEN et al) 14 August 2008 (14.08.2008) entire document	1-15, 17-19
Y	US 2004/0127915 A1 (FLEENOR et al) 01 July 2004 (01.07.2004) entire document	22
Y	US 2008/0058887 A1 (GRIFFIN et al) 06 March 2008 (06.03.2008) entire document	24, 26
Y	US 2009/0275973 A1 (CHEN et al) 05 November 2009 (05.11.2009) entire document	25-26
Y	US 2006/0259020 A1 (SHARRATT) 16 November 2006 (16.11.2006) entire document	26

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* Special categories of cited documents:
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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
07 June 2011	27 JUN 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

Form PCT/ISA/210 (second sheet) (July 2009)