(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
25 June 2020 (25.06.2020)

WIPO | PCT

(10) International Publication Number
WO 2020/132485 A1

(51) International Patent Classification:
A61F 5/00 (2006.01) *A61M 25/00* (2006.01)
A61M 39/24 (2006.01) *A61B 17/12* (2006.01)
A61M 39/04 (2006.01)

(21) International Application Number:
PCT/US2019/067921

(22) International Filing Date:
20 December 2019 (20.12.2019)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/784,106 21 December 2018 (21.12.2018) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report (Art. 21(3))*

(54) **Title:** VALVE WITH DOCKING STATION FOR GASTROINTESTINAL BALLOON

(57) **Abstract:** A gastrointestinal balloon system includes a gastrointestinal balloon and a valve located within the gastrointestinal balloon. The valve is configured to allow fluid flow into and out of the gastrointestinal balloon. The valve includes a string coupled to the valve, the string having a loop on a proximal end and a catheter having a lumen. The lumen is configured to receive a grasping tool. The grasping tool extends out a distal end of the catheter for grabbing the loop to align the catheter with the valve. The valve may be a series of self-sealing two-way valves, a check valve, or two-way valve. A method of using a valve in a gastrointestinal balloon is also described.

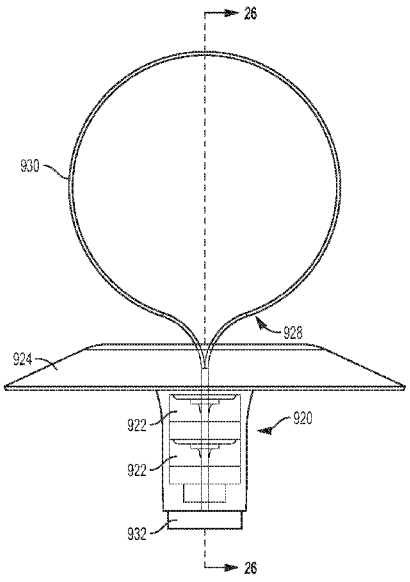

FIG. 25

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Valve with Docking Station for Gastrointestinal Balloon

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Application No. 62/784,106 filed December 21, 2018, the disclosure of which is incorporated herein by reference in its entirety.

TECHNICAL FIELD OF THE INVENTION

[0002] The present invention relates generally to implantable medical devices and systems that include a check valve, and methods of using implantable medical devices and systems with a check valve. Specifically, the present invention relates to devices, systems, and methods for a check valve and a gastrointestinal balloon including a check valve. The present invention also relates generally to a check valve with docking station. The check valve with docking station may be in a remote location or a difficult to access locations. The present invention relates to valves for access to a remote location, such as, a gastrointestinal balloon located in a patient. The present invention relates to a series of valves with a docking station.

BACKGROUND OF THE INVENTION

[0003] Morbid obesity remains an ever-growing problem in the U.S. Varying forms of gastric bypass surgery have developed and have improved over the last few decades. Recently, laparoscopic gastric bypass has emerged as a less invasive surgical option. However, bariatric surgery is fraught with morbidity of up to 20%, with a re-operation rate approaching 25% at 3-5 years post-operation. Bariatric surgery carries an operative mortality of 0.5%. Diet and pharmaceutical alternatives have not been very effective, with a high recidivism rate. Intragastric balloons in use may achieve weight loss and a drop in body mass

index (BMI). However, it is desirable to be able to change the volume of the balloon while in the stomach of a patient, either to increase the balloon volume or decrease the balloon volume, as balloon effect wears off after several months and enlarging the balloon can rejuvenate the balloon effect, and some balloons may cause intolerance and require balloon volume decrease.

[0004] There is a need to be able to change the volume of a gastrointestinal balloon while the balloon is in the stomach of a patient. In order to access the balloon valve to adjust balloon volume while the balloon is still in the stomach, there are two options. One option is to bring the valve out of the stomach to the mouth of a patient, where balloon volume may be manually adjusted. For example, some existing gastrointestinal balloon systems use a stretchable inflation tube that may stretch from a stomach to the mouth of the patient, or about 2.5-10 times its length, to facilitate inflation or adjustment of volume of the balloon. The inflation tube is partly inside and partly outside of the balloon. U.S. Patent Application Publication No. 2006/0142731 and U.S. Patent No. 8,403,952, which are incorporated herein by reference, describe a floating anchor that may be used, for example, with the gastrointestinal balloon. However, further improvements may be made to limit side effects from implantable devices including, but not limited to, tissue trauma, difficulty finding the tube, and difficulty grasping the tube, some of which may result of components of the devices that are located on the outside of the gastrointestinal balloon.

[0005] Another option is to keep the valve stationary in the balloon and access the valve itself while the valve resides in the stomach, without removing any of the components from the stomach. However, direct access to the balloon valve while the valve is within the stomach via an endoscope is extremely difficult and may not be feasible because the positioning of the endoscope relative to the balloon valve requires pinpoint precision with

head-on engagement. This is a technically difficult maneuver for an endoscope engaging a spherical balloon in the wet environment of the stomach. For example, the balloon may easily move within the stomach while, or as a result of, attempting to engage the valve.

[0006] Thus, there exists a need for improved gastrointestinal balloon devices, systems, and methods for accessing a balloon valve while it is in the stomach in a way that provides a high success rate for engaging with the valve to adjust the balloon volume.

BRIEF SUMMARY OF THE INVENTION

[0007] According to embodiments of the invention, a gastrointestinal balloon is immobilized within the stomach to improve the ease of engaging the valve. In particular, the balloon may be immobilized while at the same time allowing access to the valve at the correct angle by the inflation tool. A check valve is a type of valve that may be used for changing the volume of a gastrointestinal balloon. However, a standard check valve cannot be simultaneously immobilized and accessed with current check valve configurations and technology.

[0008] Thus, novel devices, systems, and methods are provided herein for a check valve used in inflatable medical devices, including but not limited to gastrointestinal balloons that may be simultaneously immobilized and accessed while in a body cavity. After immobilization of the balloon and aligning of the inflation tool to the balloon valve, the balloon may be inflated or deflated.

[0009] Additional features, advantages, and embodiments of the invention are set forth or apparent from consideration of the following detailed description and drawings. Moreover, it is to be understood that both the foregoing summary of the invention and the

following detailed description are exemplary and intended to provide further explanation without limiting the scope of the invention as claimed.

[0010] According to an embodiment of the present disclosure, a check valve for use in a gastrointestinal balloon may include a housing having an entry, the entry configured to allow fluid flow into and out of the gastrointestinal balloon; a plunger configured to open and close the entry; and an attachment extending from a proximal end of the housing. The attachment is configured to be grasped by a tool to permit aligning of a catheter with a proximal end of the housing.

[0011] The check valve includes an open position and a closed position, wherein the check valve is configured to be moved to the open position in a stomach. The check valve is configured to be mobile in a stomach. The catheter is configured to impact the proximal end of the housing. The plunger further comprising a plunger head, a plunger arm, and a plunger tail. The plunger head includes an opening for the attachment to extend through and a seal for sealing the opening. The plunger arm is formed from a cylindrical body with two semi-circular arms extending between the cylindrical body and a distal end of the plunger head. The plunger tail is coupled to a distal end of the plunger arm. The plunger head, plunger arm, and plunger tail are integrally formed as a single unit. An o-ring seal is located between the plunger arm and the plunger tail. A block is coupled to the housing and coupled to the attachment. A spring is coupled between the block and a proximal end of the housing. An opening in the proximal end of the housing is configured to removably receive a distal end of the catheter.

[0012] According to an embodiment of the present disclosure, a gastrointestinal balloon system, may include a gastrointestinal balloon; a valve located within the gastrointestinal balloon, the valve configured to allow fluid flow into and out of the

gastrointestinal balloon; an attachment coupled to the valve, the attachment having a connector on a proximal end; and a shaft having a lumen, the lumen configured to receive a grasping tool. The grasping tool extends out a distal end of the shaft for grabbing the connector to align the shaft with the valve.

[0013] The shaft is a catheter and the catheter has a tapered distal tip. The valve separates an interior of the gastrointestinal balloon with an exterior of the gastrointestinal balloon. The gastrointestinal balloon is configured to be inflated or deflated through the valve. The valve includes a proximal opening, a plunger, and an o-ring to seal an entry into the gastrointestinal balloon. The valve is a check valve. The attachment is a string.

[0014] According to an embodiment of the present disclosure, a method of accessing a gastrointestinal balloon may include inserting a catheter through a channel of a gastroscope and into a stomach of a patient; inserting a grasping tool through a lumen of the catheter and extending the grasping tool through a distal end of the catheter; grasping an attachment with the grasping tool, wherein the attachment is coupled to a check valve; moving the check valve into alignment with the catheter; moving a plunger in the check valve such that the check valve is moved from a closed position to an open position; and inflating or deflating the gastrointestinal balloon through the check valve.

[0015] The method includes removably impacting the catheter into the check valve. The method includes impacting the catheter into the check valve comprises impacting a distal end of the catheter with a proximal opening of a housing of the check valve. The method includes moving the plunger in the check valve comprises distally moving the plunger in the check valve. The method includes releasing the attachment from the grasping tool and removing the grasping tool from the catheter prior to inflating or deflating the gastrointestinal balloon. The distal end of the catheter is tapered.

[0016] According to an embodiment of the present disclosure, a check valve system may include a check valve having a housing, the housing having a distal opening and a proximal opening, the distal opening configured to be sealed; an elongated member coupled to the housing, the elongated member having a proximal end with a connector; a tool configured to grasp the connector; and an impacting member configured to engage a proximal end of the housing. The tool is inserted through the impacting member to grasp the connector to align and immobilize the check valve with the impacting member. The tool is subsequently pulled to engage the impacting member into the proximal end of the housing to open the distal opening of the check valve. The check valve is configured for installation in a stomach, in a pipeline, in a plumbing line, or in a body cavity. A spring is configured to bias the check valve to a closed position.

[0017] According to an embodiment of the present disclosure, a two-way valve may include a body configured to allow two-way flow. The body may have a docking end configured to receive a tool for positioning the body in a first position; anda port end configured to be disposed in a cavity. The valve has the first position and a second position. The docking end further includes an attachment to align the tool with the docking end.

[0018] The first position is an open configuration and the second position is a closed configuration, the valve biased to the second position. The two-way valve is a check valve. The attachment is a strap. The docking end comprises an opening in a proximal end of the body. The opening is configured to receive the tool for releasably impacting the plunger.

[0019] According to an embodiment, a valve for a gastrointestinal balloon, the valve comprising: a first valve formed of a self-sealing material; and an attachment extending from an interior of the gastrointestinal balloon through the first valve to an exterior of the gastrointestinal balloon.

[0020] According to an embodiment, the valve further comprising a second valve located in series with the first valve, the second valve formed of a self-sealing material, wherein the attachment extends through the second valve.

[0021] According to an embodiment, the valve further comprising a first spacer separating the first valve from the interior of the gastrointestinal balloon, the attachment extending through the first spacer.

[0022] According to an embodiment, the valve further comprising a second spacer located in series and between the first valve and the second valve.

[0023] According to an embodiment, wherein a first opening through the first valve and a second opening through the second valve are aligned.

[0024] According to an embodiment, wherein the first opening and the second opening each have a first state preventing fluid flow therethrough and a second state allowing passage of a tool.

[0025] According to an embodiment, wherein, in the first state, the first opening and the second opening are closed around the attachment.

[0026] According to an embodiment, wherein the self-sealing material is silicone.

[0027] According to an embodiment, wherein the first valve is formed as a cylindrical disc with an opening therethrough, the opening configured to receive the attachment.

[0028] According to an embodiment, further comprising an open position and a closed position, wherein the valve is configured to move to the open position in a stomach.

[0029] According to an embodiment, wherein the open position permits passage of a tool and the closed position prohibits flow of fluid.

[0030] According to an embodiment, further comprising a block configured to prevent removal of the attachment from the valve.

[0031] According to an embodiment, the attachment extends through a center of the first valve.

[0032] According to an embodiment, a gastrointestinal balloon system may include a self-sealing valve; an attachment extending through the self-sealing valve; and a tool configured to track over the attachment and pass through the self-sealing valve.

[0033] According to an embodiment, wherein the tool is configured to centrally track over the attachment such that a central axis of the tool and the attachment are substantially coaxial.

[0034] According to an embodiment, the self-sealing valve comprises a first self-sealing valve and a second self-sealing valve located in series.

[0035] According to an embodiment, the self-sealing valve has an open position and a closed position, wherein, in the open position, the tool and the attachment pass through an opening of the self-sealing valve, and wherein, in the closed position, only the attachment passes through the opening of the self-sealing valve.

[0036] According to an embodiment, a method of accessing a gastrointestinal balloon, the method comprising: grasping an attachment extending through a self-sealing valve; tracking a tool over the attachment and toward the self-sealing valve; pushing the tool through an opening in the self-sealing valve, still tracking over the attachment, thus opening the self-sealing valve; and inflating or deflating the gastrointestinal balloon through the tool.

[0037] According to an embodiment, wherein tracking the tool over the attachment comprises passing the attachment through a lumen of the tool.

[0038] According to an embodiment, wherein pushing the tool through an opening in the self-sealing valve comprises expanding the opening by entering a distal end of the tool into the opening.

[0039] According to an embodiment, wherein the self-sealing valve is a series of two self-sealing valves formed of silicone.

[0040] According to an embodiment, further comprising removing the tool from the self-sealing valve thus closing the self-sealing valve.

[0041] According to an embodiment, a system for accessing an interior of a gastrointestinal balloon may include a gastrointestinal balloon; two contiguous valves; and a string running through a center of each of the two contiguous valves and exiting the gastrointestinal balloon, wherein the string is configured to be grasped by a user to track a tool over the string and directly through the two contiguous valves and into the interior of the gastrointestinal balloon.

[0042] According to an embodiment, the two contiguous valves comprise a first valve located in series with a second valve, a first opening of the first valve and a second opening of the second valve being coaxially aligned.

[0043] According to an embodiment, the two contiguous valves abut and touch each other.

[0044] According to an embodiment, the system may include a spacer between the two contiguous valves.

[0045] According to an embodiment, the system may include a tool configured to centrally track over the string and pass through the two contiguous valves.

BRIEF DESCRIPTION OF DRAWINGS

[0046] The accompanying drawings, which are included to provide a further understanding of the invention and are incorporated in and constitute a part of this specification, illustrate preferred embodiments of the invention and together with the detailed description serve to explain the principles of the invention. In the drawings:

[0047] FIG. 1 shows a standard check valve attached to a balloon, with the valve in the closed position.

[0048] FIG. 2 shows the standard check valve of FIG. 1, with the valve in the open position.

[0049] FIG. 3 shows a check valve in a gastrointestinal balloon according to an embodiment of the present invention.

[0050] FIG. 4 shows a close-up view of the check valve of FIG. 3, with the valve in the closed position.

[0051] FIG. 5 shows a close-up view of the check valve of FIG. 3 from a perspective rotated 90° relative to the view shown in FIG. 4.

[0052] FIG. 6 shows a close-up of the check valve of FIG. 3 in an open position according to an embodiment of the present invention.

[0053] FIG. 7 shows a catheter to be used in conjunction with the balloon and check valve and a step in a method of operating the check valve of FIG. 3, according to an embodiment of the present invention.

[0054] FIG. 8 shows a portion of the catheter, according to an embodiment of the present invention.

[0055] FIG. 9 shows a check valve in operation with a catheter and a grasping tool, according to an embodiment of the present invention.

[0056] FIG. 10A shows an exemplary grasping tool in a closed position, according to an embodiment of the present invention.

[0057] FIG. 10B shows an exemplary grasping tool in an open position, according to an embodiment of the present invention.

[0058] FIG. 11 shows a biluminal connector, according to an embodiment of the present invention.

[0059] FIG. 12 shows the biluminal connector of FIG. 11 with a coupling sleeve, according to an embodiment of the present disclosure.

[0060] FIG. 13 shows the biluminal connector and coupling sleeve of FIG. 12 coupled to a gastroscope, according to an embodiment of the present disclosure.

[0061] FIGS. 14A-14E show cross-sectional views of the biluminal connector of FIG. 11 taken along various axes of FIG. 11, according to an embodiment of the present disclosure.

[0062] FIGS. 15 shows an alternative method for grasping the string, according to an embodiment of the present disclosure.

[0063] FIG. 16 shows a check valve in a gastrointestinal balloon according to another embodiment of the present invention.

[0064] FIG. 17 shows a close-up view of the check valve of FIG. 16, with the valve in the closed position.

[0065] FIG. 18 shows a close-up view of the check valve of FIG. 16 from a perspective rotated 90° relative to the view shown in FIG. 17.

[0066] FIG. 19 shows a close-up of the check valve of FIG. 16 in an open position according to an embodiment of the present invention.

[0067] FIG. 20 shows a catheter to be used in conjunction with the balloon and check valve of FIG. 16 and a step in a method of operating the check valve, according to an embodiment of the present invention.

[0068] FIG. 21 shows a check valve in operation with a catheter and a grasping tool, according to an embodiment of the present invention.

[0069] FIG. 22 shows a check valve in an open position with fluid flowing therethrough, according to an embodiment of the present invention.

[0070] FIG. 23 shows the check valve of FIG. 22 in the open position, rotated 90 degrees from the view of FIG. 22, according to an embodiment of the present invention.

[0071] FIG. 24 shows the check valve of FIG. 22 in the closed position, with fluid isolated on either side of the valve, according to an embodiment of the invention.

[0072] FIG. 25 shows a valve attached to a balloon, according to an embodiment of the present invention.

[0073] FIG. 26 shows a cross-sectional view of the valve of FIG. 25 taken along the section line 26-26.

[0074] FIG. 27 shows an exploded view of the valve of FIG. 25.

[0075] FIG. 28 shows an exploded view of the valve of FIG. 25.

[0076] FIG. 29 shows a valve attached to a balloon, according to an embodiment of the present invention.

[0077] FIG. 30 shows a cross-sectional view of the valve of FIG. 29 taken along the section line 29-29.

DETAILED DESCRIPTION OF THE INVENTION

[0078] Devices, systems and methods are described herein with reference to the figures and in the context of medical devices, in particular a gastric balloon. In one aspect, a check valve with docking station can be provided to improve the ability to control the check valve for purposes of adjusting a gastric balloon (such as inflating and deflating the balloon). The check valve with docking station can improve the user's ability to change the volume of a gastrointestinal balloon while the balloon is in the stomach of a patient. The check valve with docking station can be used in other environments in order to access and adjust the valve in hard to reach areas where the devices may or may not be stabilized. The check valve docking features can be implement in other medical devices as well as non-medical devices and used as described herein in accordance with the principles of the invention. The check valve may include a plunger, string, spring, and valve housing. The string may be coupled to the housing such that when grasped and pulled, it aligns an opening of the valve housing with an impacting member for operating the opening and closing of the valve. Thus, the valve may be controlled from a remote location to allow fluid to flow into or out of the valve, as will be appreciated from the disclosure to follow.

[0079] A standard check valve 10, as shown in FIGS. 1 and 2 (in the closed and opened positions, respectively), cannot be simultaneously immobilized and accessed with current check valve configurations and technology. FIGS. 1 and 2 depict a check valve 10 which separates the exterior 12 of the balloon from the interior or cavity 14 of the balloon.

The check valve 10 may include a housing 16, plunger head 18, plunger arm 20, and a plunger tail 22. In FIG. 1, a spring 24, at a full extension length L_E, keeps the check valve 10 in a closed position by pushing plunger head 18 away (to the left in the view shown in FIG. 1) from the mouth or entry 26 into the balloon cavity 14. The plunger head 18 in turn pulls the plunger arm 20 and the plunger tail 22 to the left and closes the entry 26 into the balloon cavity 14 by pulling an o-ring 28 to the left. In FIG. 2, The plunger head 18 is pushed toward (to the right in the view shown in FIG. 2) the entry 26 which contracts the spring 24 to a length L_C, thereby allowing the plunger head 18 to move to the right (FIG. 2) towards the balloon cavity entry 26. The plunger head 18 then pushes the plunger arm 20 and the plunger tail 22 to the right which pushes the o-ring 28 to the right and opens for the bi-directional flow of fluid (arrows F) into and out of the balloon cavity 14.

[0080] Engaging the check valve 10 in the balloon while the check valve 10 sits in the body cavity (*e.g.* the stomach) requires some method of immobilization and proper alignment of a tool on the check valve 10 of the balloon, followed by applying force to push the spring 24 towards the balloon cavity 14 (thereby opening flow F to the balloon cavity 14). Therefore, the present invention provides a novel modification to check valve technology that may accomplish these goals. The novel check valve has utility not only in the intragastric adjustable balloon, but also in other inflatable medical devices in any body cavity or check valves for industrial and non-medical use, such as in plumbing. Therefore, references to "gastrointestinal balloons" or "stomach" are for example only, and are not intended to limit the scope of the invention.

[0081] FIG. 3 shows a valve 100 according to an embodiment of the invention. The valve 100 may be a check valve, two-way valve, two directional flow valve, or other valve having an opening configured to be selectively opened and closed in accordance with the

principle of the invention. For ease of description, the valve 100 is referred to herein as a check valve 100. The check valve 100 may include a docking station to allow for alignment and engagement of an impacting member to open and close the check valve 100. The check valve 100 is shown within a balloon 300 or integral with a sidewall 302 of the balloon 300. The balloon 300 may be an adjustable balloon located in a patient's stomach. Alternatively, the check valve 100 may be located in a flow line of a plumbing or other hydraulic system. The balloon 300 may have an interior cavity 114 separated from an exterior space 112 (*e.g.* the stomach environment). The check valve 100 may separate the interior cavity 114 of the balloon 300 from the exterior space 112 of the balloon 300. The check valve 100 may be provided with an attachment 200, such as an elongated member 200, such as a string 200 that may be have a connector 202. The connector 202 may be an "easy grasp" loop 202 that exits into the exterior space 112 of the balloon 300. The string 200 with easy grasp loop 202 may be formed of nylon. The attachment 200 may be an elongated member, a bungee, a stretchy member, a string, a cable, a cord, other elongated device, or anything in accordance with the principles of invention capable of coupling to the check valve 100 and being grasped by a tool. For ease of description, the attachment 200 is described as a string 200 and the connector 202 is described as a loop 202. The string 200 may be a single string 200 having opposing distal ends, each coupled to a block 130 (FIG. 4) of the housing of the check valve 100 with the easy grasp loop 202 formed therebetween.

[0082] Moving (*e.g.* by pulling or pushing the impacting member and/or tool) the loop 202 into an impacting member 400 (FIG. 7), such as a catheter, may immobilize the balloon 300 and may guide the inflation/pushing catheter (not depicted) to the target (i.e., the check valve 100), as will be described to follow. The string 200 may have a proximal end having a loop (such as easy grasp loop 202) configured to be grasped be a tool. The easy

grasp loop 202 may be pulled into a catheter by a grasping tool dispatched through an endoscope, as will be described in more detail. As may be appreciated, the balloon 300 may be located in a patient's stomach. The balloon 300 (including check valve 100) may be floating or otherwise mobile within the stomach as the balloon is not secured to any wall therein. As previously mentioned, inflation and deflation of the balloon 300 may be difficult due to the mobile nature of the balloon 300. In conventional applications, the balloon 300 is removed from the stomach. With the present check valve 100, attachment 200, and docking station, the balloon 300 is capable of being inflated or deflated while the balloon 300 remains in the patient's stomach. That is, as will be described below, the check valve 100 may be immobilized and aligned with a tool, the tool configured to open the valve and allow flow into or out of the balloon 300 as necessary. The fluid allowed to flow through the check valve 100 may be liquid, air, inflation fluid, or other fluid in accordance with principles of the invention.

[0083] FIG. 4 depicts a close-up view of the check valve 100 with the balloon 300 omitted for clarity. The check valve 100 in FIG. 4 is depicted in a closed position. The check valve 100 may be biased in the closed position by a spring 124. In this manner, once inflated or deflated to the appropriate level, the check valve 100 may retain the balloon 300 (not depicted) in the desired state. The check valve 100 may include a housing 116, a plunger head 118, a plunger arm 120, a plunger tail 122, the spring 124, an o-ring 128, and a block 130. The housing 116 may be formed as a single piece or may be formed as a first housing portion 116a and a second housing portion 116b coupled together. The entry 126 may be formed integral with an interior surface of the housing 116 or may be a separate piece secured (*e.g.* with threads or fasteners) to an interior surface of the housing 116. The block 130 may be built into, integrally formed with, or otherwise secured to the housing 116. Thus, the block

130 may be a stationary, non-moving component against which the spring 124 may be compressed. Alternatively, the block 130 may be permitted to move a small distance until engagement with an interior surface of the housing 116. As may be appreciated, the spring 124 may be compressed between the surface 130a of the block 130 and a distal surface of the plunger head 118.

[0084] In the check valve 100, the plunger head 118, plunger arm 120, and plunger tail 122 may all be connected as one unit, similar to the check valve 10 of FIG. 1. Alternatively, the plunger head 118, plunger arm 120, and plunger tail 122 may be formed integrally. The plunger arm 120 may be formed as a solid piece as is the plunger arm 20 of FIG. 1. Alternatively, the plunger arm 120 may be split in the middle, leaving space for other parts, such as the string 200, to be connected to the block 130 within the housing 116 of the check valve 100, as will be described in relation to FIG. 5.

[0085] With continued reference to FIG. 4, in the closed position, the spring 124 may be extended to a length L_E pushing the plunger head 118 to the left in FIG. 4. In the closed position, the plunger tail 122 may hold the o-ring 128 in a sealing position with the entry 126 to the interior cavity (114 in FIG. 3) of the balloon 300 (FIG. 3). The closed position of FIG. 4 may be the normal position of the check valve 100. That is, the spring 124 may bias check valve 100 to a normally closed position. It may be appreciated that the plunger 118, 120, 122 may slide with respect to the block 130. That is, the block 130 may extend through an interior of the plunger arm 120 (FIG. 5) and the plunger may move with respect to the block 130 to compress the spring 124 against the block 130 and extend the o-ring 128 off of the entry 126 allowing flow therethrough.

[0086] Referring now to FIG. 5, a close-up view of the check valve 100 of FIG. 4 is shown, rotated 90° from the perspective of FIG. 4. The plunger head 118, plunger arm 120,

and plunger tail 122 of the check valve 100 may be formed as a single, integral piece or may be formed as separate parts coupled or secured together. The plunger head 118 may be generally cylindrical with a hole (not shown) through which the string 200 may pass. The plunger head 118 may be disc shaped. The hole may be located in the center of the plunger head 118 or may be located anywhere through plunger head 118 to facilitate connection of the string 200 to the block 130. The plunger head 118 may further include a silicone seal 134 for sealing the hole and the string 200 within. The silicone seal may prevent fluid from passing through the hole having the string 200. The plunger head 118 may include a cut out or groove 136 for coupling to the plunger arm 120. Alternatively, the plunger head 118 and the plunger arm 120 may formed as an integral piece.

[0087] With continued reference to FIG. 5, the plunger arm 120 may be cylindrical. The plunger arm 120 may be split in the middle such that a cavity 132 is located between opposing sides 120a and 120b of the plunger arm 120. At the proximal end, the plunger arm sides 120a, 120b may be coupled or integral with the plunger head 118. At the distal end, the plunger arm 120 main (cylindrical) body may be coupled to or integral with a neck (not shown) that is in turn coupled or integral with the plunger tail 122. The neck may have a reduced diameter from the plunger arm 120 and/or plunger tail 122 such that the o-ring 128 may be fitted around the neck. The string 200 may have two ends 200a, 200b which extend through the plunger head 118 and through the cavity 132 of the plunger arm 120. The two ends 200a and 200b may then be coupled, secured, or attached to the block 130. Alternatively, the string 200 may be one or multiple strings with knots, loops, or components that may allow for grasping by a tool. As previously described, the plunger, including plunger arm 120, may be allowed to move with respect to the block 130 and the housing 116.

[0088] Referring now to FIG. 6, the check valve 100 is depicted in an open position, with the balloon 300 (FIG. 3) removed for clarity. In the open position, the plunger head 118 may be pushed to the right in FIG. 6 within the housing 116. Pushing or moving the plunger head 118 may shorten the spring 124 to the contracted length L_C. As may be appreciated, the spring 124 may be secured between a proximal surface 118a of the plunger head 118 and a distal surface 130a of the block 130. In this manner, the block 130 may operate as a stopper beyond which the spring 124 cannot pass. As the plunger head 118 is moved or pushed to the right, plunger arms 120 are correspondingly moved or pushed to the right due to the integral or coupled nature of the components. The plunger arms 120 move the neck (not depicted) and plunger tail 122 into the interior cavity 114 (FIG. 3) of the balloon and out of the housing 116. As the plunger tail 122 is moved out of the housing 116, the o-ring 128 is moved away from the entry 126, thus unseating the o-ring 128 from the entry 126 and allowing flow into and out of the interior cavity 114 of the balloon 300.

[0089] Fig 7 shows an embodiment of an impacting member as a catheter 400, which may, for example, have a 2-3.5 mm outer diameter with a wall thickness of 0.1 to 0.6 mm. The catheter 400 may be made of a semi-flexible material that allows the catheter to assume curves up to 90 degrees, yet at the same time maintain rigidity. Materials such as Teflon, low friction synthetic polymers, polymers coated with materials that produce a non-friction surface such as parylene or Teflon, and other material types may be employed. The catheter 400 may have a lumen with a diameter of 0.8 to 3.3 mm. The catheter 400 may be used in conjunction with the check valve 100. The catheter 400 may be made of any suitable biocompatible material or material used for medical devices. The catheter 400 may have a tip 402, but is not limited to the shape shown in Fig. 7. The tip 402 may be tapered, a luer, cone shaped, straight, or rounded tip. The tip 402 may facilitate entry of the catheter 400 into an

opening 116c of the housing portion 116b. The opening 116c may be a proximal opening of the housing 116 and the entry 126 may be a distal opening of the housing 116. The catheter 400 may have a central lumen 404 through which a grasping tool 500 may extend. The grasping tool 500 may grab or secure the easy grasp loop 202 (FIG. 3) of the string 200, as will be described to follow. The tip 402 may encounter the plunger head 118 during operation of the check valve 100 to move the plunger head 118 and thus open the check valve 100. As may be appreciated, the proximal end of the housing portion 116b, opening 116c, the plunger head 118, and the string 200 may be considered a docking station for the check valve 100. That is, the catheter 400 is aligned with and impacted with these components such that alignment and operation of the check valve 100 are permitted. In this regard, the components act as a docking station for the catheter 400 and tool 500.

[0090] Referring to FIG. 8, a proximal part 406 of the catheter 400 may be Y-shaped with a homeostatic valve 408 at each arm that may be tightened or loosened to regulate flow and thereby prevent backflow outside of the catheter 400. The proximal part 406 may include an inflation and/or deflation site 410 for inflating and/or deflating the balloon 300. The proximal part 406 may have a handle with mechanical control that closes and opens the hook 502 (FIG. 10) of grasping tool 500, or a handle that closes and opens the grasper of any type of grasping device.

[0091] Referring to FIG. 9, during operation, an endoscope is extended into a patient's stomach. A catheter 400 with a grasping tool 500 are inserted therethrough. The grasping tool 500, such as grasping forceps used in endoscopic procedures may be inserted into the lumen 404 of the catheter 400 through the homeostatic valve 408 (FIG. 8). During the procedure, the balloon, check valve, catheter, and grasping tool may all be located within the patient's stomach. The forceps or similar grasping tool 500 may grasp the string 200 by

the easy grasp loop 202 and pull the check valve 100 toward the catheter 400. At the same time, the catheter 400 may be advanced toward the check valve 100. This may easily guide the grasping tool 500 to the target, the opening 116c, of the check valve 100. The catheter 400 then enters the opening 116c of the housing 116 of the check valve 100. Such alignment of the catheter 400 with the check valve 100 allows for immobilization of the check valve 100.

[0092] While fixating the catheter 400 and gastroscope with one hand, the grasping tool 500 (now grasping string 200) within the catheter 400 is pulled back with the other hand. This motion causes the tip 402 to releasably engage the plunger head 118 of the check valve 100. Continued pulling of the string 200 pushes the catheter tip 402 into releasably impacting the housing 116 and thereby causing the plunger head 118 to move to the right (as shown in the figures) or towards the interior cavity 114 of the balloon 300. This movement causes the plunger arm 120 and the plunger tail 122 to move to the right which thereby unseats the o-ring 128 and opens the check valve 100. At the same time, the tip 402 of the catheter 400 impacts into the housing 116. Alternatively, the catheter 400 may be straight, and the opening 116c of the housing may be cone shaped resulting in the same impaction effect. The catheter 400 may impact into the housing 116, which maintains the check valve 100 in an open position. The distal movement of the plunger head 118, the plunger arm 120, and the plunger tail 122, the check valve 100 opens to bi-directional flow by separating the o-ring 128 from contacting the entry 126. Once the catheter 400 is impacted and the check valve 100 is open, the string 200 may be released by the grasping tool 500 and the grasping tool 500 may be pulled out of the catheter 400. This may open more space in the lumen 404 and allow enhanced flow of fluid. Alternatively, the grasping tool 500 may be left in place and flow may continue at a slower pace.

[0093] After inflation or deflation is completed, the catheter 400 may be removed from the docking station or entry to the check valve 100. The tool 500, catheter 400, and endoscope may be removed from the patient's stomach and from the patient.

[0094] The force of the catheter 400 on the check valve 100 to impact and disengage the check valve 100 may be between 0.8 kg and 2 kg. The forces to contract and relax the spring 124 may be less than the forces that impact the valve by 25% to 40%. If the spring forces are greater than the impaction forces then the spring 124 may disengage the catheter 400 from the check valve. 100

[0095] With continued reference to FIGS. 3-9, and described in another manner, during operation, the grasping tool 500 exits the endoscope and grasps the easy grasp loop 202 of the string 200. The grasping tool 500 may be pulled while the tip 402 of the catheter 400 has entered into the check valve 100 of the balloon 300. The catheter 400 may enter with ease, until the tip 402 broadens and impacts the plunger head 118 inside the housing 116 of the check valve 100. The grasping tool 500 may be pulled hard to impact the catheter 400 into the check valve 100. If the catheter 400 is not impacted into the check valve 100, the check valve 100 may close prematurely. As the catheter 400 impacts inside the housing 116, the catheter 400 pushes the plunger head 118 toward the entry 126 (compressing the spring 124). This in turn pushes the plunger arm 120 and the plunger tail 122 forward, unseating the o-ring 128 from the entry 126, and opens the check valve 100 to bi-directional flow. At this point the grasping tool 500 may release the string 200 (since the cone-tipped catheter 400 is impacted inside the housing 116). The grasping tool 500 may then be pulled out of the catheter 400. At this time, fluid may be admitted from the inflation site 410 (or removed through the deflation site 410), though the lumen 404 of the catheter 400, through the entry 126 of the check valve 100 and into the interior cavity 114 of the balloon 300. With reference

to FIG. 6, the flow may enter the opening 116c of the housing 116, flow around the plunger head 118, around and through the plunger arms 120, through the entry 126, and past the o-ring 128 and plunger tail 122. It may be appreciated that during deflation, flow may follow the same path in the reverse direction. Once inflation/deflation is completed, the catheter 400 is pulled out of the check valve 100 and the spring 124 expands to its preferred position, which brings the plunger head 118, plunger arm 120, and plunger tail 122 back to the closed position (FIG. 5) with the o-ring 128 sealed in the entry 126 and flow of fluid prevented.

[0096] Although the catheter 400 is described as impacting the check valve 100, the catheter may be forced into the valve in other manners. For example, the catheter 400 may be secured to the check valve opening 116c with a turning motion. That is, the catheter 400 may have a tip 402 which may be screwed or threaded into the valve opening 116c. One may appreciate that the inner surface of opening 116c and the outer surface of the catheter tip 402 may have complementary threads or other surfaces to allow the rotational and longitudinal movement.

[0097] FIGS. 10A and 10B depict the grasping tool 500 in an open (FIG. 10A) and closed (FIG. 10B) position. In the open position, the grasping tool 500 may have a hinged arm or hook 502 (or other connection type) that may align with the easy grasp loop 202 (FIG. 3) of the string 200. Once properly aligned, the hinged arm or hook 502 may be actuated to close thus enclosing the easy grasp loop 202 and securing the grasping tool 500 to the check valve 100 via the string 200. Once grasped, the grasping tool 500 may be pulled to pull the string 200 and thus the check valve 100 and balloon 300 into alignment with the catheter 400. After proper alignment, the aforementioned impacting and opening of the check valve 100 may be performed. The grasping tool 500 may then be opened to release the check valve 100 (after impaction and/or opening). The grasping tool 500 may have a curved end that is hinged

and can be opened to a straight position. In the closed position (FIG. 10B), the length of the hinged arm or hook 502 is within 0.5 to 2 mm of the inner diameter of the catheter. The hinged arm or hook 502 may be moved into a position that can grasp (FIG. 10A) or to a position that does not grasp (FIG. 10B). The grasping tool 500 may alternatively be other types of grasping tools, such as a rat-tooth grasper or hook grasper.

[0098] Thus, as may be appreciated from the foregoing disclosure, during a procedure to inflate and/or deflate the balloon, a catheter may be inserted into the channel of a standard flexible gastroscope, as practiced routinely by those skilled in the art of gastrointestinal endoscopy. As previously mentioned, the check valve and method of aligning and opening the check valve may be utilized in other body cavities or for industrial, plumbing, pipelines, wellbores, or other non-medical uses. For example, a check valve may be located in a pipeline. The pipeline may be inaccessible from the outer surface (*e.g.* a buried pipeline). The check valve may be biased to a normally closed position (as previously described) or biased to a normally open position. When it is desired to open or close the check valve, a grasping tool, similar to the grasping tool 500 but sized and dimensioned to fit in a pipeline instead of a catheter, may be extended into the pipeline inside another device (*e.g.* inside a tubular snake). Once inside the pipeline, the grasping tool may grasp a loop on a string coupled to the pipeline and align an impacting device (similar to the impacting catheter 400) with an opening of the check valve. The grasping tool may pull the impacting device into alignment and impact the check valve in a manner similar to that previously described to effectuate opening and/or closing of the check valve.

[0099] In an alternative embodiment shown in FIGS. 11-14, the flow of inflation/deflation fluid may be separated from the lumen having the grasping tool 500. There may be a need to separate the grasping tool 500 from the flow of inflation fluid for fear of

gastric fluid contamination. This may be accomplished using a biluminal connector 600. In this embodiment, the catheter 400 may be replaced with the biluminal connector 600 having a proximal end 602 which sits in a distal end of a channel of a gastroscope 800 (FIG. 13). The biluminal connector 600 may have a distal end 604 which impacts the check valve 100 (not depicted). The distal end 604 may have a tip 606 for guiding the tool into alignment into the check valve 100. The tip 606 may be the same as or similar to the tip 402 of the catheter 400. The biluminal connector 600 may further have an opening 608 in the side wall of the biluminal connector 600. The opening 608 may allow entry and/or exiting of the inflation and/or deflation fluid.

[0100] The immobilization of the balloon with the grasping of the string can be performed with the grasping tool, as previously described. The grasping tool may be alone in the gastroscope channel and the inflation may be performed in a second channel, separated from the gastroscope channel. The biluminal connector 600 may have two lumens, as best depicted in FIGS. 14B and 14C. A first, central lumen 612 may extend from the proximal end 602 (see FIG. 14A) to the distal end 604 (see FIG. 14E). Once coupled to the gastroscope, the first lumen 612 may allow entry of the grasping tool 500 through the gastroscope channel and through the first lumen 612 to allow for grasping, alignment, and impaction of the check valve 100 as previously described. The first lumen 612 may be wholly separated from a second lumen 614 (FIGS 14B, 14C). The second lumen 614 may be an annular lumen extending circumferentially around the outer surface of the first lumen 612 such that the first lumen 612 and the second lumen 614 are concentric. The second lumen 614 may be located distally to the gastroscope 800. The second lumen 614 may be open distal to the gastroscope channel and allow entry from an outer side channel parallel to the gastroscope 800. The entry may be located through opening 608 such that a flexible tube may be coupled to opening 608

to allow for bi-directional flow (inflation and/or deflation) through the flexible tube, second lumen 614, and check valve 100 (not depicted). The external channel provided in the flexible tube may run parallel to the gastroscope 800 and then may turn in to the distal end of the gastroscope 800 and enter the second lumen of the biluminal connector 600.

[0101] Referring to FIG. 12, the biluminal connector 600 may have a silicone sleeve 700 to secure the biluminal connector 600 to the gastroscope 800. The sleeve 700 may have an opening 708 which aligns with the opening 608 of the biluminal connector 600. The biluminal connector 600 may be stabilized on the distal end of the gastroscope 800 (FIG. 13) with the sleeve 700. The biluminal connector 600 may further have a plug 610. The plug 610 may have a rounded or atraumatic distal tip that may be placed into the distal opening of the biluminal connector 600. The plug 610 may be pushed out by the grasping tool at any time. The plug 610 may be silicone or other flexible rubbery material or can be made of a material that melts at body temperature such as those used with medication capsules.

[0102] Referring to FIG. 13, the sleeve 700 may fit snugly around the distal end of the gastroscope 800. The inflation tube may be external to the gastroscope and enter through the opening 708. The biluminal connector 600 may have the proximal end 602 sitting within the distal channel of the gastroscope 800. The distal tip 606 may enter the check valve 100 (FIG. 3) and move the plunger head, the plunger arm, and the plunger tail distally. Near the distal end of the biluminal connector 600, the body widens with its tapering profile to impact within the check valve 100. As may be appreciated, the biluminal connector may prevent contamination of inflation fluid with gastric fluid and may allow the gastroscope channel to utilize its suctioning function during the procedure.

[0103] FIGS. 14A-14D depict cross-sectional views of the biluminal connector 600 taken along the lines A, B, C, and D of FIG. 1. FIG. 14E depicts a cross-sectional vie of the

biluminal connector 600 at the distal end. FIG. 14A shows the first lumen 612 which sits within the gastroscope channel and allows entry of the grasping tool. FIG. 14B shows the opening 608 through which the external inflation channel enters into the second lumen 614 which is an outer concentric lumen to the first lumen 612. FIG. 14C shows the concentric bilumena with supporting walls 616. FIG. 14B shows the first lumen 612 through which the tool travels and grasps the string 200 (FIG. 3).

[0104] The biluminal connector 600 may be made from silicone or a firmer material, such as Teflon or other synthetic material. The biluminal connector 600 may have a wall thickness of 0.2 to 5 mm with a central lumen of 0.8 to 2.20 mm that accommodates a grasping tool with an external diameter of 0.7 to 3.0 mm. The biluminal connector 600 may be 6-15 mm long and 3-12 mm wide.

[0105] Referring to FIG. 15, an alternative approach to accessing the balloon valve within the stomach is to separate the immobilization of the balloon from the accession of the valve. One method of immobilization is to place handles on the balloon (not depicted) that are grasped by the scope. Following this immobilization step, the valve (check valve, duck valve, or any type of valve) is accessed with a catheter that enters from the lumen of the endoscope into the valve and opens the valve, as previously described. Upon withdrawal of the catheter the valve closes. Following closure of the valve, the immobilization of the balloon is discontinued. As an example of the handles on the balloon one could place two loops of string (nylon for example) at the 3 o'clock and 9 o'clock positions of the valve housing. The two loops may be grasped by two grasping forceps 900 that exit at the 3 o'clock and 9 o'clock positions in a sleeve 902 that surrounds the endoscope 904. The two forceps 900 grasp the two loops (not depicted) and pull them toward the endoscope tip and

immobilize the balloon. The sleeve 902 may be a silicone sleeve with a lumen for one or more grasping forceps 900.

[0106] FIGS. 17-21 depict a check valve assembly similar to the check valve 100. As may be appreciated, the exact dimensions and relationships of the valve and plunger may be altered to achieve optimized alignment, immobilization, and actuation of the check valve. For example, as depicted in the embodiment of FIGS. 17-21, the spring may have more or fewer coils. The easy grasp loop of the string may be larger or smaller than depicted in FIG. 3. The string may be formed from multiple strings tied or fastened together. The balloon wall may have a longer stem or a differently contoured outer wall. Other modifications to the balloon, check valve, and catheter are within the scope of this disclosure.

[0107] Referring to FIGS. 22-24, operation of the check valve 100 or check valve of FIGS. 17-21 may be appreciated. For clarity, the catheter 400 is omitted from FIGS. 22-24, but one may appreciate that the catheter 400 would be aligned with the opening to impact the check valve to effectuate opening of the check valve. In the open position of FIG. 22, the plunger including plunger head 118, plunger arm 120, and plunger tail 122 may be seen extending out of the housing 116. In this position, the o-ring 128 is not seated in the opening of the housing 116. The force of the catheter (not depicted) has moved the plunger (including plunger head 118, plunger arm 120, and plunger head 122) toward the interior of the balloon, compressing the spring 124 between the plunger head 118 and the block 130, and moving the o-ring 128 off of the seat of the opening into housing 116. Thus, fluid is allowed to flow between the interior of the valve and the interior of the balloon. The fluid may be seen to flow around the string 200, around the plunger head 118, plunger arm 120, and plunger tail 122, and through the valve opening past the o-ring 128. It may be appreciated that during inflation, fluid may be introduced into the housing 116 through the endoscope and through

catheter (not depicted) to inflate the balloon. During deflation, fluid may be removed in the reverse direction to remove fluid from the interior of the balloon.

[0108] With reference to FIG. 23, the check valve 100 is still in the open position, but is depicted rotated 90 degrees from the position of FIG. 22. Fluid flow in FIG. 23 flows around the spring 124, plunger 118, 120, 122, and through the distal end opening of the check valve 100. Referring now to FIG. 24, the check valve 100 is depicted in the closed position. As may be appreciated, fluid may be located on the left side of the o-ring 128 (inside the balloon) and on the right side of the o-ring 128 (in the valve housing and in the stomach), however flow between these two areas is not permitted. The spring 124 is shown in the normally extended position, forcing the plunger head 118 toward the right and thus maintaining the o-ring 128 in the closed position.

[0109] Referring to FIGS. 25-30, another valve feature is shown and described. The valve may be similar as the valve previously described. The valve of FIGS. 25-30 may be provided in similar environments such as in a gastrointestinal balloon and/or other remote locations. As previously described, the valve may be in an unstable, remote location (*e.g.*, the gastrointestinal balloon within a patient's stomach). The valve may be include a docking station, as previously described, to allow for the immobilization, accessing, and opening and closing of the valve. The valve of FIGS. 25-30 may be accessed with a catheter, as previously described. The catheter may be deployed into the docking end or docking station of the valve to allow for access to the interior of the balloon to inflate and/or deflate the balloon. As in previous embodiments, the catheter may track centrally over an attachment (*e.g.*, a string) to allow for the catheter to access the docking end/docking station and subsequently open and/or close the valve.

[0110] FIGS. 25-28 show a valve according to another embodiment. The valve 920 may be a valve assembly. The valve 920 and the balloon 924 may have a centerline 26-26. The valve 920 may include one or more valves 922. The one or more valves 922 may be arranged in series. That is, a centerline that is coaxial along the axis 26-26 may run through a center of each of the one or more valves 922 such that the one or more valves 922 are coaxial. Although two valves 922a, 922b are shown, more or fewer valves may be provided. One valve 922 may be sufficient to allow for the access and docking of the tool within the valve. However, two or more valves 922 may be provided for redundancy, that is, to ensure proper operation of the docking station and back-up sealing between the interior and exterior of a balloon 924. The valves 922 may be formed as cylindrical discs with an opening therethrough. The opening may be a central opening extending from a top surface to a bottom surface of the valve 922. The opening may be tapered or conical to facilitate entry of a tool or may be a pinhole opening through the length of the valve that tightly seals around the attachment 928 or tool. The valve 920 may be considered a docking station. That is, the valve 920 may allow for the guiding, alignment, and entering of a tool into a remote area, such as, for example, a gastrointestinal balloon. As discussed previously, the remote location may be mobile, for example, the floating gastrointestinal balloon within the stomach of a patient. The mobility of the remote location may make the valve 920 difficult or impossible to access. Such mobility may require, in conventional valves, the removal of the valve form the remote location to provide a stable environment for accessing the valve. The valve 920 may provide a docking station that allows for the immobilization and subsequent inflation/deflation of the balloon while the balloon remains in the remote, mobile or floating location. That is, the valve 920 allows for the docking, immobilization, and opening and/or closing while the gastrointestinal balloon remains in the patient's stomach.

[0111] The valve 920 maybe coupled to the balloon 924, such as previously described. The balloon 924 may have an opening 926 for receiving the valve 920. As shown and described with respect to previous embodiments, the opening 926 may be located within the balloon 924. That is, the opening 926 may not extend past an exterior surface 924a of the balloon 924. The opening 926 may have an end 926a that extends downward from the exterior surface 924a and into the interior of the balloon. The balloon 924 is shown truncated for clarity in FIGS. 25 and 26. However, the balloon 924 may extend in a manner that creates a cavity that is accessible through the valve 920. The opening 926 may be substantially cylindrical such that the opening 926 is a cylindrical bore surrounded by a wall of the balloon 924. The opening 926 may house the one or more valves 922 and the one or more spacers.

[0112] The valve 920 may include an attachment 928, such as an elongated member, such as a string that may be have a connector 930. The connector 930 may be an "easy grasp" loop that exits into the exterior space (*e.g.,* the space surrounding the balloon) of the balloon 924. The attachment 928 with easy grasp loop or connector 930 may be formed of nylon. The attachment 928 may be an elongated member, a bungee, a stretchy member, a string, a cable, a cord, other elongated device, or anything in accordance with the principles of invention capable of coupling to the valve 920 and being grasped by a tool, such as described with respect to previous embodiments. For ease of description, the attachment 928 is described as a string and the connector 930 is described as a loop, however other modes are contemplated. The string or attachment 928 may be a single string having opposing distal ends 928a, 928b (FIG. 27), each coupled to a block 932. The block 932 may be a beam or bar to which the distal ends 928a, 928b are fixed or coupled. Alternatively, the block 932 may be the distal ends 928a, 928b fixed together such that they may not pass through an opening in the spacer 934. The block 932 may form a T-shape (for example, see FIG. 27) such that the string or

attachment 928 may be prohibited or preventing from detaching or uncoupling from the valve 920. Although the block 932 is shown in a left to right configuration in FIG. 25, the block 932 may be orientated along any axis of the valve 920 and/or balloon 924 so long as the block 932 prevents removal of the attachment 928 from the valve 920. The loop or connector 930 is shown in an enlarged circular shape in FIGS. 25-28, however the loop or connector 930 may take a smaller shape, such as described with respect to FIG. 3.

[0113] As mentioned, the valve 920 may include one or more valves 922. The valve 920 may include one or more spacers 934, 936, 938. A first spacer 934 may be located at a first end of the valve 920. A second spacer 936 may be located on the first spacer 934, as shown in FIG. 26. A first valve 922a may be located on the first spacer 934. A third spacer 938 may be located on the first valve 922a. A second valve 922b may be located on the third spacer 938. Although shown as separate components one or more of the one or more valves 922 and/or the spacers 934, 936, 938 may be formed integrally and/or coupled together. That is, for example, the first spacer 934 and the second spacer 936 may be formed as a single, integral component.

[0114] Each of the one or more valves 922 and the one or more spacers 934, 936, 938 may have an opening extending therethrough. For example, the first valve 922a and the second valve 922 may have openings 940a, 940b, respectively, extending through the valves. The one or more spacers 934, 936, 938 may have an opening 934a, 936a, 938a, respectively, extending through the spacers. The openings 940a, 940b, 934a, 936a, 938a may be coaxial and/or aligned. The attachment 928 may extend through the openings 940a, 940b, 934a, 936a, 938a and be coupled to or integral with the block 932. That is, the first distal end 928a and the second 928b may be coupled to, integral with, or otherwise attached to the block 932. The attachment 928 may be extended through the openings of the one or more valves and the one

or more spacers such that the loop or connector 930 extends out of the opening 926 and into the exterior space around the balloon 924.

[0115] The opening 934a may be sized such that the attachment 928 may extend therethrough and also such that the block 932 is prohibited from extending through the opening 934a. In this manner, the block 932 may anchor or hold the attachment 928 to the valve 920. The openings 936a and/or 938a may be formed of any size that is sufficient to allow passage of the attachment 928 and the tool, to be described later.

[0116] The openings 940a, 940b of the one or more valves 922 may be formed of a size just large enough to accommodate the attachment 928. That is, the attachment 928 may be bounded on all sides by walls of the valve 922 such that no air or other fluid may flow through the one or more valves 922. The one or more valves 922 may be formed of a flexible material such that, upon insertion of a tool, the openings 940a, 940b may be enlarged to allow passage of the tool. The one or more valves 922 may be formed of a solid silicone. The one or more valves 922 may be a self-sealing valve. The self-sealing valve may be formed of a self-sealing material, such as, for example, silicone. The one or more valves 922 may be formed of a flexible material, such as solid silicone, with a small hole or opening at or around the center of the valve. That is, the one or more valves 922 may be formed of a material that is allowed to be opened or expanded from a first state (closed) to a second state (open) and back to the first state (closed). The one or more valves 922 may be formed of a material that allows for repetitive opening and closing. The openings 940a, 940b may be in the normally closed position, the position where the attachment 928 extends therethrough but no fluid is permitted to pass through. The openings 940a, 940b may be transitioned from the normally closed position to the open position by advancing a tool through the opening 940a, 940b to expand, distort or otherwise flex the openings 940a, 940b to accommodate the tool.

[0117] As mentioned, the valves 922 may be formed of a flexible material with a tiny, pinhole sized hole extending therethrough. The pinhole may be the opening 940 and may be sized to accommodate the attachment 928 in the closed position but also prevent flow therethrough. In the open position, the pinhole may be able to accommodate both the attachment 928 and the tool. The opening 940 may tightly surround the attachment 928 in the closed position and may tightly surround the tool in the open position. The opening may be a pinhole opening that runs the length of the flexible (*e.g.*, silicone) valve 922. The valve 922 may be a loose duck-valve or duck-valve like valve.

[0118] Thus, in a first state, the openings 940a, 940b may have a first size sufficient to allow passage of the attachment 928 but not sufficient to allow passage of fluids and/or passage of a tool with a diameter larger than the attachment. In a second state, the openings 940a, 940b may have a second size sufficient to allow passage of the attachment 928 and sufficient to allow passage of the tool with a diameter larger than the attachment. In the second state, a fluid may be passed through tool and thus through the one or more valves 922. The fluid may exit through ports 942 in the first spacer 934 and allowed to flow into the interior of the balloon 924. Although 8 ports 942 are shown in FIG. 28, more or fewer may be provided. As many ports 942 as possible may be provided in the spacer 934 such that the flow through the spacer 934 from the catheter may be as great as possible without reducing the integrity of the valve 920 and/or without allowing the attachment 928 to disengage from the valve 920. Additionally, the ports 942 may take alternative shapes or sizes. For example, two c-shaped ports may be provided or a single, annular or donut shape port may be provided.

[0119] In an embodiment where a single valve 922 is present, the spacer 938 and/or the spacer 936 may be omitted. In an embodiment where three valves 922 are present, an

additional spacer may be located between the second valve 922b and a third valve (not depicted) about the second valve 922b. In the case where three or more valves 922 are present, the opening 926 and the associated walls of the balloon 924 may be extended further into the interior of the balloon 924 such that the entirety of the valve 920, including all valves 922 and all spacers, are located below the surface 924a of the balloon 924.

[0120] In an embodiment, the valve 920 may include a second block 946, as shown in FIGS. 29 and 30. The second block 946 may assist in preventing removal of the attachment 928 from the valve 920. The second block 946 may be substantially spherical. Alternatively, the second block 946 may be T-shaped like the block 932. The block 932 and the second block 946 may hold the attachment 928 in the opening 934a and prevent removal therefrom. The second block 946 may prevent the attachment 928 from being pushed into the valve 920 and or the interior of the balloon 924. The valve 920 and balloon 924 may have a centerline 29-29. The assembly may be aligned along the axis 29-29 similar to the assembly of FIGS. 25-28 being aligned on the axis 26-26.

[0121] The valve 920 of FIGS. 25-28 and/or FIGS. 29-30 may be overmolded such that the valve 920 takes the appearance or may be considered a single, integral part. The valve 920 may then be inserted into the balloon 924 as a single component. The second valve 922b may be redundant of the first valve 922a and may allow for confirmation and/or validation of closing and opening of the valve.

[0122] The valves may be separated by one or more spacers. One or more of the spacers may be optional. One or more spacers may be omitted. That is, the valves may be separated by one or more spacers, may not be separated by one or more spacers, or combinations thereof. The valves may be next to each other, together in sequence, next or near in line or sequence, adjacent, or contiguous. The valves may abut one another. That is,

the bottom surface of one valve may touch or rest on the top surface of a subsequent valve. Although described with two spacers, more or fewer may be provided. Although described with two valves, more or fewer may be provided.

[0123] The valve 920 may operate in a manner similar to the method described with respect to FIG. 9. During operation, an endoscope may be extended into a patient's stomach. A catheter 400 (FIG. 9) with a grasping tool 500 may be inserted therethrough. The grasping tool 500, such as grasping forceps used in endoscopic procedures may be inserted into the lumen 404 of the catheter 400 through the homeostatic valve 408 (FIG. 8). During the procedure, the balloon, valve, catheter, and grasping tool may all be located within the patient's stomach. The forceps or similar grasping tool 500 may grasp the string or attachment 928 by the easy grasp loop or connector 930 and pull the valve 920 toward the catheter 400. At the same time, the catheter 400 may be advanced toward the valve 920. This may easily guide the grasping tool 500 to the target or docking end, the opening 940b of the second valve 922b. The catheter 400 then enters the opening 940b, passes through the openings 938a, 940a, and 936a. The tip 402 (FIG. 9) of the catheter 400 may stop or be located in a space 944 of the spacer 934. The tip 402 may be offset from the inner surface of the spacer 934 such that fluid may easily flow from the lumen 404 of the catheter out of the ports 942 in the spacer 934. Such alignment of the catheter 400 with the check valve 100 allows for both immobilization of the valve 920 and thus the balloon 924 and entry into the valve 920 and balloon 924.

[0124] While fixating the catheter 400 and gastroscope with one hand, the grasping tool 500 (now grasping string or attachment 928) within the catheter 400 is pulled back with the other hand. This motion causes the tip 402 to extend through the opening 940b. Continued pulling of the string or attachment 928 pushes the catheter tip 402 into the

remaining openings and finally into the space 944. Alternatively, once the catheter 400 is aligned with the docking end, the catheter 400 and thus the catheter tip 402 may be pushed into the openings 940b and then continue to be pushed through opening 940a and into the space 944. The opening 940b and/or the opening 940a may be tapered to assist and ease guiding of the catheter 400 into the valve 920. So long as the catheter 400 extends through the valve 920, fluid may be allowed to flow into and/or out of (*e.g.* bi-directional flow) the balloon 924. To close the valve 920, the catheter 400 may be removed, thus returning the openings 940a, 940b back to the first state.

[0125] After inflation or deflation is completed, the catheter 400 may be removed from the docking station or entry to the valve 920. The tool 500, catheter 400, and endoscope may be removed from the patient's stomach and from the patient.

[0126] During the passage of the catheter 400 through the openings of the valves 922 and spacers, the catheter 400 may track over the attachment 928 which also extends through the openings of the valves 922 and spacers. That is, in the position where the valve is open and the catheter is in place for inflation and/or deflation of the balloon 924, both the catheter 400 and the attachment 928 may extend through the openings 904a, 940b, 938a, 936a, and 944. The openings 938a, 936a, and 944 may be sized to accommodate the catheter 400. The openings 940a, 940b may be formed in a self-sealing material such that the openings are permitted to expand to a size accommodating the catheter 400 and then seal or contract to a position prohibiting entry of the catheter 400. In the position where the valve is closed and the catheter is removed, the attachment 928 may extend through the openings 904a, 940b, 938a, 936a, and 944, but fluid flow through the valve 920 and specifically valves 922 may be prohibited.

[0127] Although the catheter 400 is described as impacting the valve 920, the catheter may be forced into the valve in other manners. For example, the catheter 400 may be secured to the opening 940a with a turning motion. That is, the catheter 400 may have a tip 402 which may be screwed or threaded into the valve opening 940a. One may appreciate that the inner surface of opening 940a and the outer surface of the catheter tip 402 may have complementary threads or other surfaces to allow the rotational and longitudinal movement.

[0128] Accordingly, any of the aforementioned valves and/or assemblies may allow for tracking of a tool, such as a catheter, over the attachment to provide guidance, alignment, and entry of the tool into the valve. That is, the attachment may be grasped by a first tool, and a second tool, such as a catheter, may be guided or tracked over the attachment to allow entry of the second tool into the opening of the balloon, thus actuating or opening the valve located in the opening of the balloon. In this manner, the attachment may operate as a guide or tracking member to allow for access and opening of the valve. The attachment may extend through the center of the valve or valves. The catheter may guide centrally over the attachment such that the catheter enters centrally into the opening of the balloon and/or the valve.

[0129] The valve of the present disclosure may be a valve having an attachment (*e.g.*, a string) extending centrally therethrough. That is, the valve may have the attachment running or extending through the venter of the valve. The valve may be two contiguous valves with an attachment or string that runs or extends through their center and exits the balloon. The attachment or string may enable a user to grasp the attachment or string and use the attachment or string as a tract to guide the catheter or other tool directly into the valve. The central string may facilitate entering the valve and changing (*e.g.*, inflating or deflating) the balloon volume.

[0130] As may be appreciated from the foregoing disclosure, the check valve of the disclosure may be used in a gastrointestinal balloon. The disclosure further includes a device, system, and method to immobilize the balloon within the body while at the same time providing access to the valve in such a way that the volume can be adjusted. The system can include the balloon and check valve, the catheter, and tool that is configured for grasping onto part of the valve to hold it in place. The disclosure may also include the method of performing this maneuver.

[0131] Additionally, the valve may be a check valve, although other valve types (*e.g.* ball valves, sleeve valves, etc.) may be provided. The check valve may include a spring inside that maintains the valve in a closed position and the spring is compressed to open the valve.

[0132] The check valve and balloon may be suitability immobilized while a force is applied to compress the spring. The balloon may be used in the stomach, but may be used for any inflatable, implanted device. The check valve may include a portion that may be grasped by a tool inserted to inflate/deflate the balloon. In some embodiments, this is a loop that extends out from the valve and is grasped by a grasping tool. The loop may be pulled (away from the balloon) by the catheter/device to immobilize the balloon. Grasping forceps, inserted through the catheter, may be used to pull the loop. After the catheter engages with the valve, the loop can optionally be released with the catheter remains engaged to inflate/deflate the balloon.

[0133] Additionally, as described, the check valve may be used in systems, methods, and environments other than a gastrointestinal balloon. The check valve in may have a string, or other extension, extending from the check valve. The string/extension may be grabbed by a tool inserted into the flow path to access the check valve.

[0134] Although the foregoing description is directed to the preferred embodiments of the invention, it is noted that other variations and modifications will be apparent to those skilled in the art, and may be made without departing from the spirit or scope of the invention. Moreover, features described in connection with one embodiment of the invention may be used in conjunction with other embodiments, even if not explicitly stated above.

CLAIMS

1. A valve for a gastrointestinal balloon, the valve comprising:

a first valve formed of a self-sealing material; and

an attachment extending from an interior of the gastrointestinal balloon through the first valve to an exterior of the gastrointestinal balloon.

2. The valve of claim 1, further comprising a second valve located in series with the first valve, the second valve formed of a self-sealing material, wherein the attachment extends through the second valve.

3. The valve of claim 2, further comprising a first spacer separating the first valve from the interior of the gastrointestinal balloon, the attachment extending through the first spacer.

4. The valve of claim 3, further comprising a second spacer located in series and between the first valve and the second valve.

5. The valve of claim 2, wherein a first opening through the first valve and a second opening through the second valve are aligned.

6. The valve of claim 5, wherein the first opening and the second opening each have a first state preventing fluid flow therethrough and a second state allowing passage of a tool.

7. The valve of claim 6, wherein, in the first state, the first opening and the second opening are closed around the attachment.

8. The valve of claim 1, wherein the self-sealing material is silicone.

9. The valve of claim 1, wherein the first valve is formed as a cylindrical disc with an opening therethrough, the opening configured to receive the attachment.

10. The valve of claim 1, further comprising an open position and a closed position, wherein the valve is configured to move to the open position in a stomach.

11. The valve of claim 10, wherein the open position permits passage of a tool and the closed position prohibits flow of fluid.

12. The valve of claim 1, further comprising a block configured to prevent removal of the attachment from the valve.

13. The valve of claim 1, wherein the attachment extends through a center of the first valve.

14. A gastrointestinal balloon system, the gastrointestinal balloon system comprising:

a self-sealing valve;

an attachment extending through the self-sealing valve; and

a tool configured to track over the attachment and pass through the self-sealing valve.

15. The gastrointestinal balloon system of claim 14, wherein the tool is configured to centrally track over the attachment such that a central axis of the tool and the attachment are substantially coaxial.

16. The gastrointestinal balloon system of claim 14, wherein the self-sealing valve comprises a first self-sealing valve and a second self-sealing valve located in series.

17. The gastrointestinal balloon system of claim 14, wherein the self-sealing valve has an open position and a closed position,

wherein, in the open position, the tool and the attachment pass through an opening of the self-sealing valve, and

wherein, in the closed position, only the attachment passes through the opening of the self-sealing valve.

18. A method of accessing a gastrointestinal balloon, the method comprising:

grasping an attachment extending through a self-sealing valve;

tracking a tool over the attachment and toward the self-sealing valve;

pushing the tool through an opening in the self-sealing valve, still tracking over the attachment, thus opening the self-sealing valve; and

inflating or deflating the gastrointestinal balloon through the tool.

19. The method of claim 18, wherein tracking the tool over the attachment comprises passing the attachment through a lumen of the tool.

20. The method of claim 18, wherein pushing the tool through an opening in the self-sealing valve comprises expanding the opening by entering a distal end of the tool into the opening.

21. The method of claim 18, wherein the self-sealing valve is a series of two self-sealing valves formed of silicone.

22. The method of claim 18, further comprising removing the tool from the self-sealing valve thus closing the self-sealing valve.

23. A system for accessing an interior of a gastrointestinal balloon, the system comprising:

a gastrointestinal balloon;

two contiguous valves; and

a string running through a center of each of the two contiguous valves and exiting the gastrointestinal balloon,

wherein the string is configured to be grasped by a user to track a tool over the string and directly through the two contiguous valves and into the interior of the gastrointestinal balloon.

24. The system of claim 23, wherein the two contiguous valves comprise a first valve located in series with a second valve, a first opening of the first valve and a second opening of the second valve being coaxially aligned.

25. The system of claim 23, wherein the two contiguous valves abut and touch each other.

26. The system of claim 23, further comprising a spacer between the two contiguous valves.

27. The system of claim 23, further comprising a tool configured to centrally track over the string and pass through the two contiguous valves.

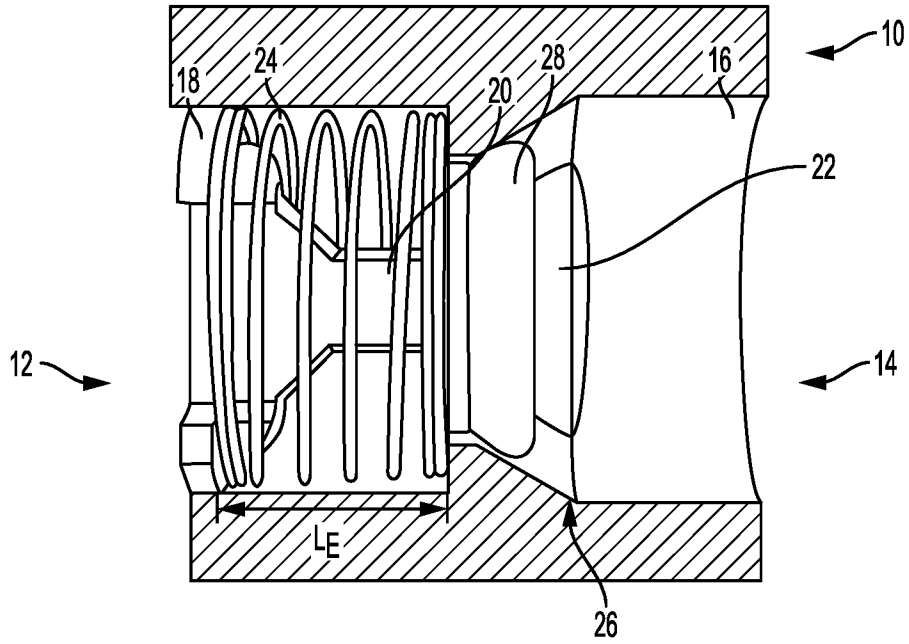


FIG. 1

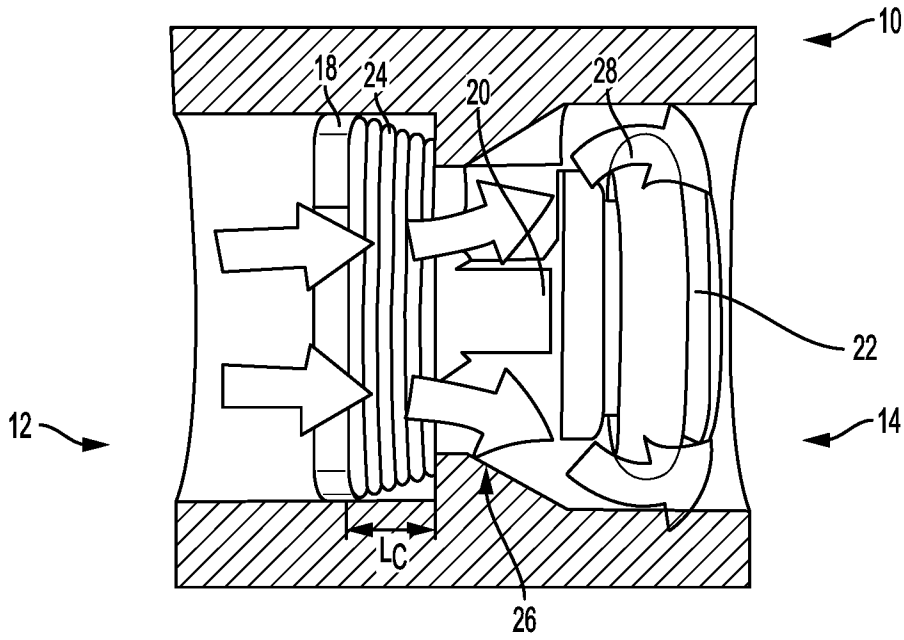


FIG. 2

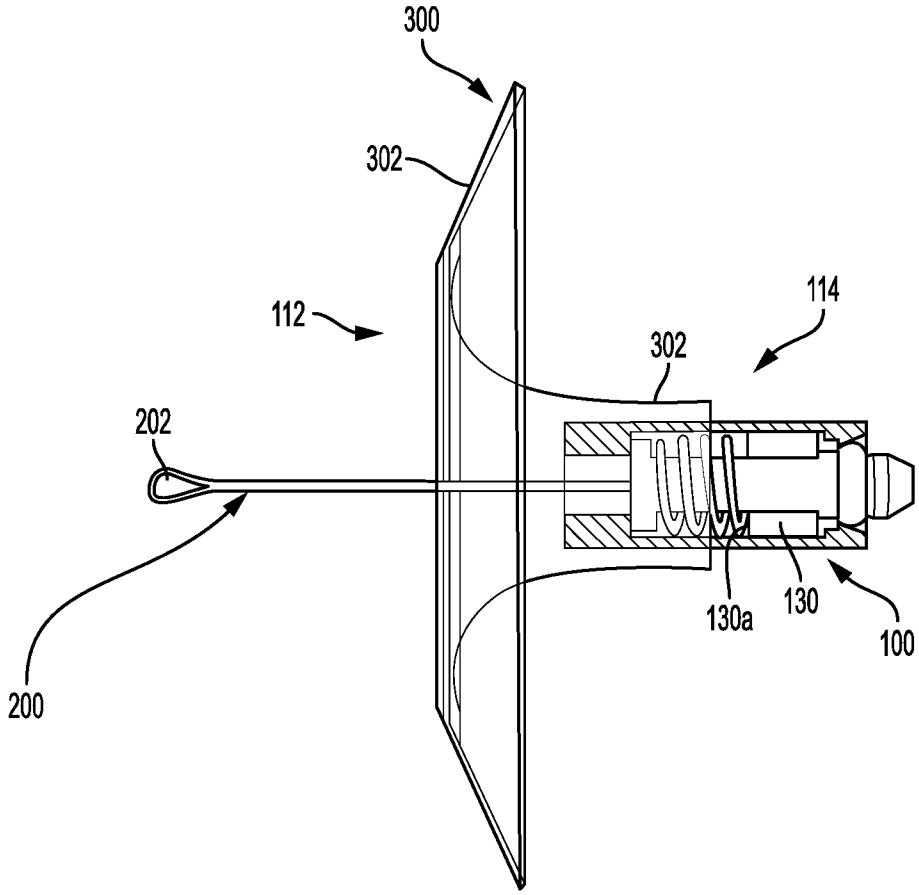


FIG. 3

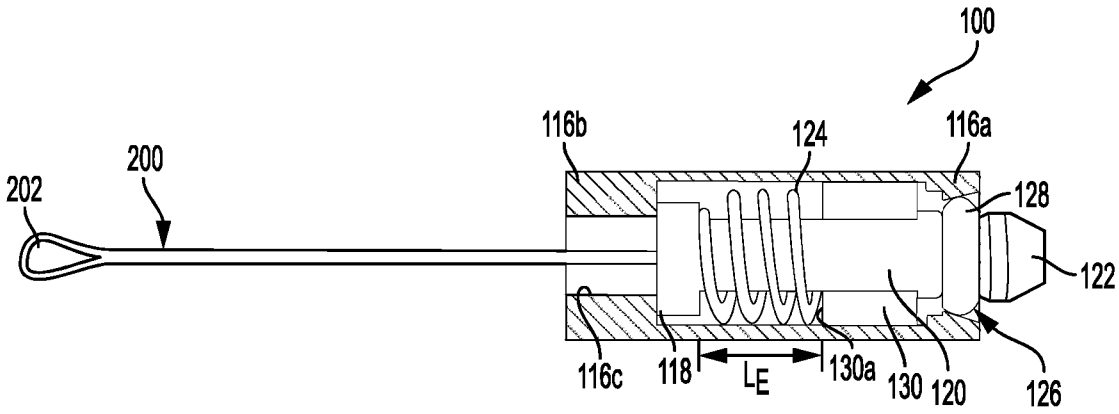


FIG. 4

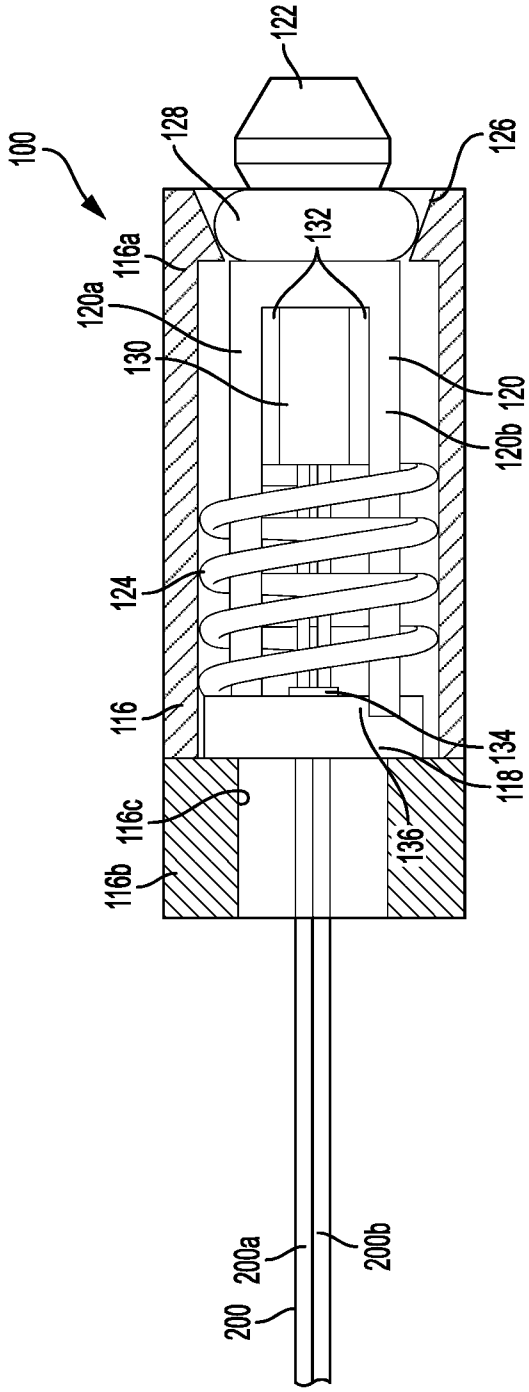

122
128
126
100
132
116a
120a
130
120
120b
124
116
134
118
116c
136
116b
200a
200b
200

FIG. 5

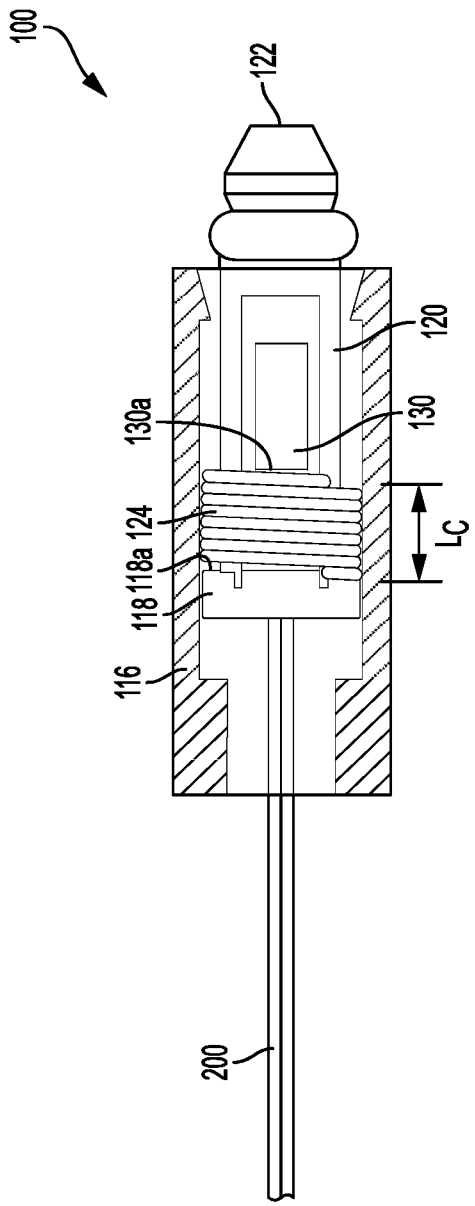


FIG. 6

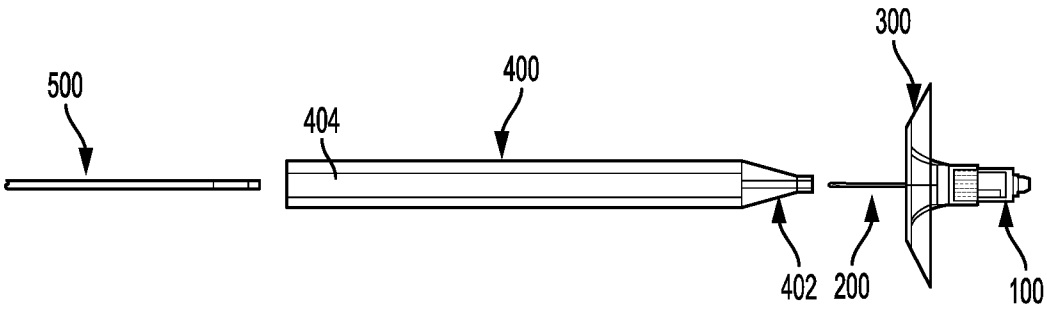


FIG. 7

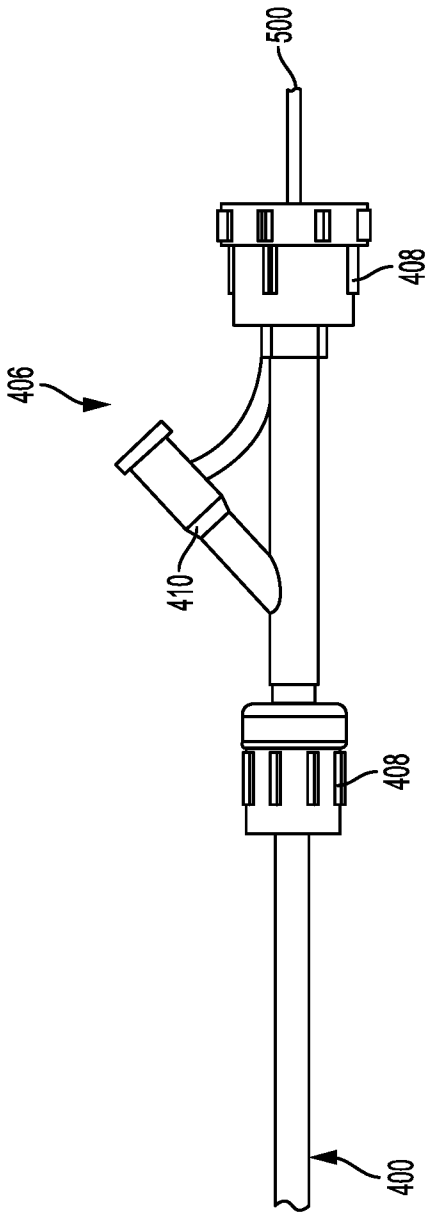


FIG. 8

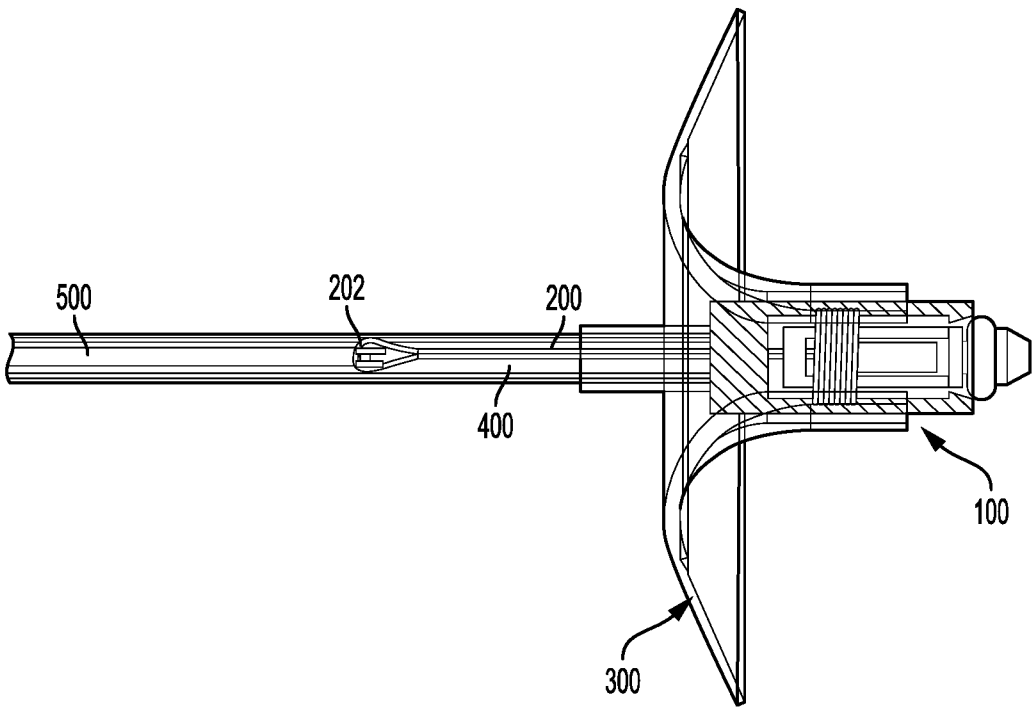


FIG. 9

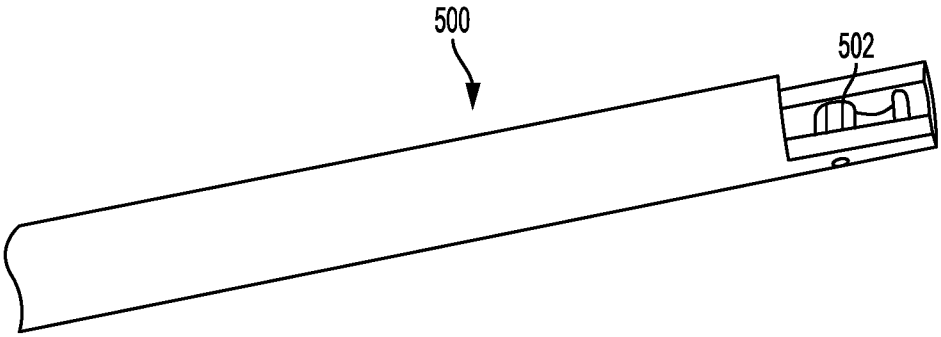


FIG. 10A

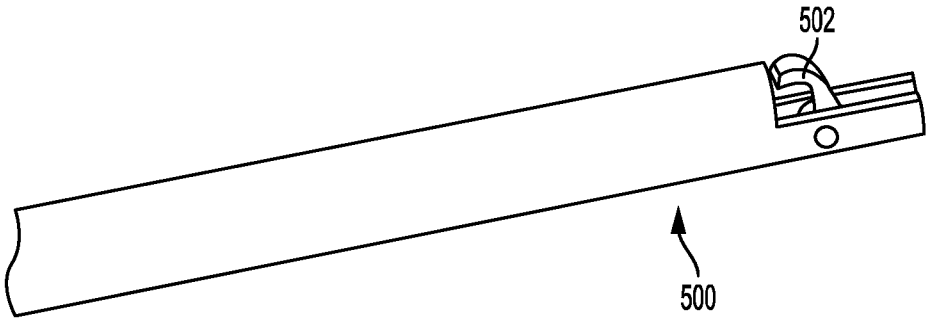


FIG. 10B

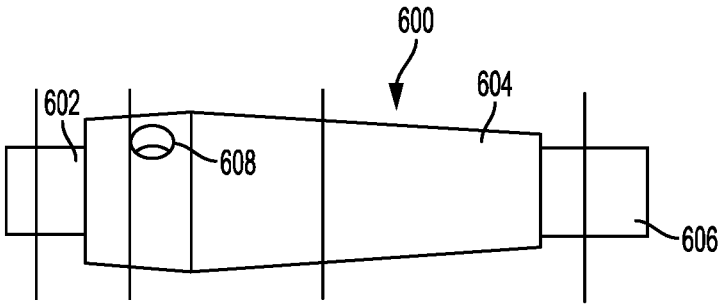


FIG. 11

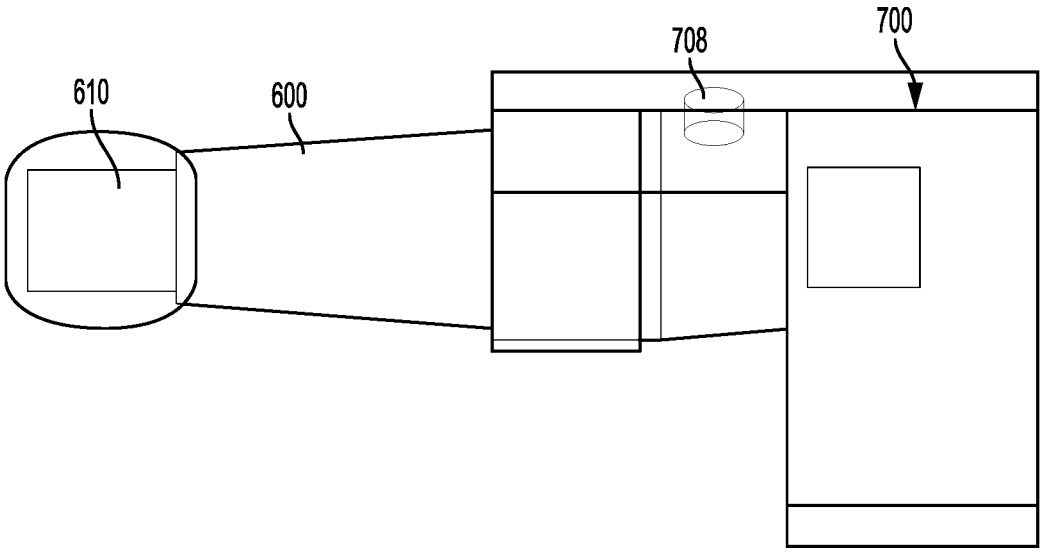


FIG. 12

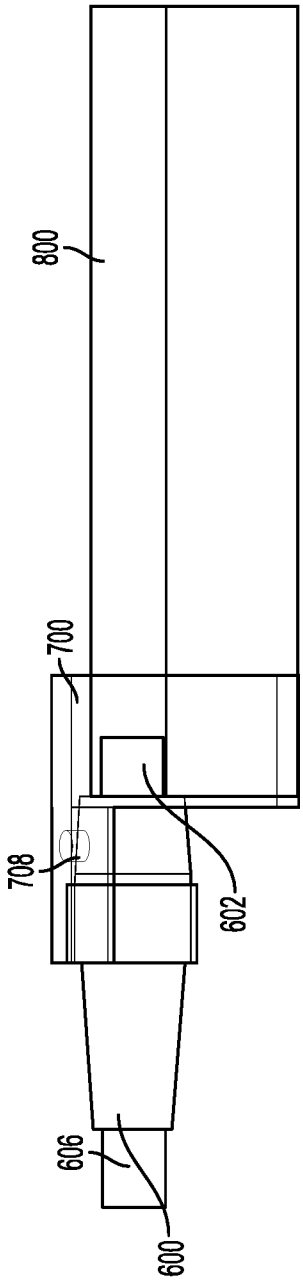


FIG. 13

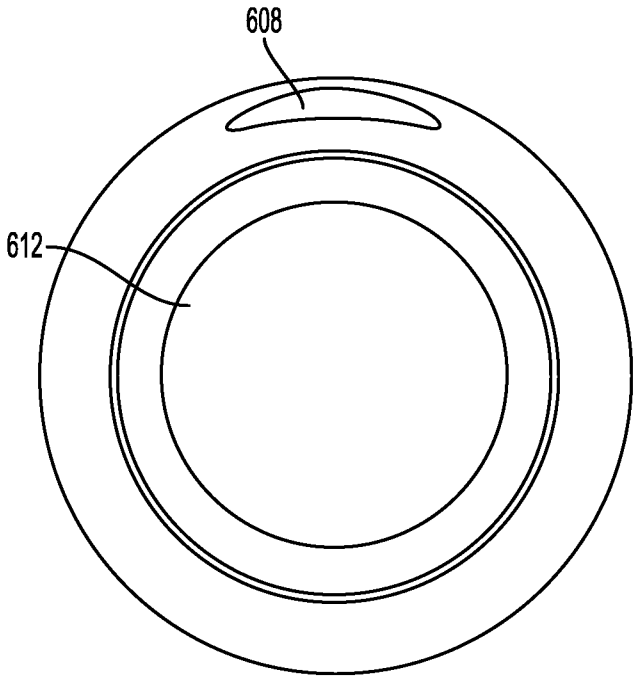


FIG. 14A

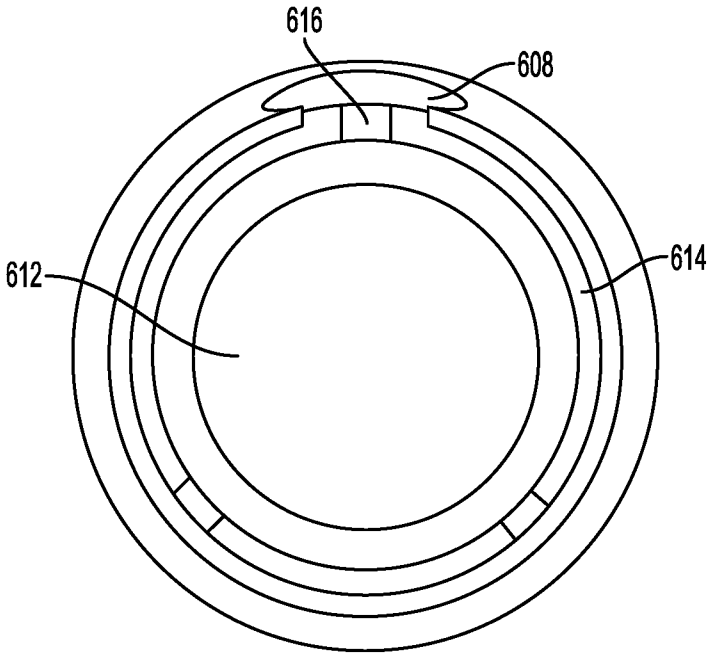


FIG. 14B

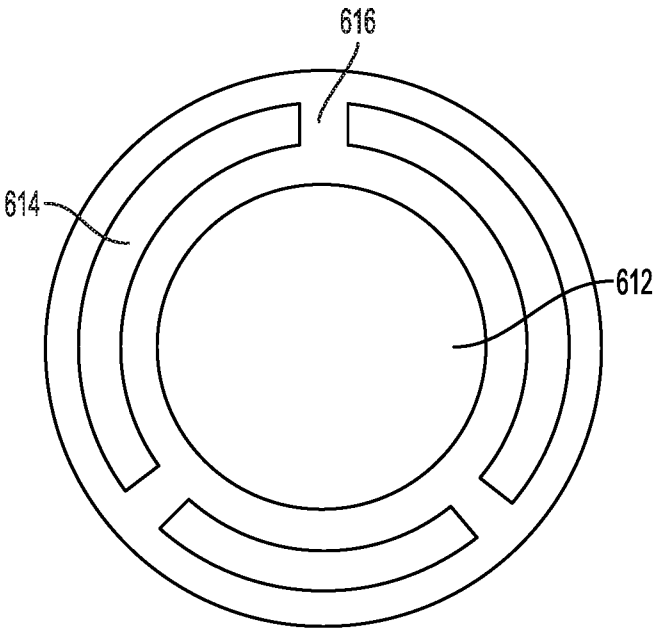


FIG. 14C

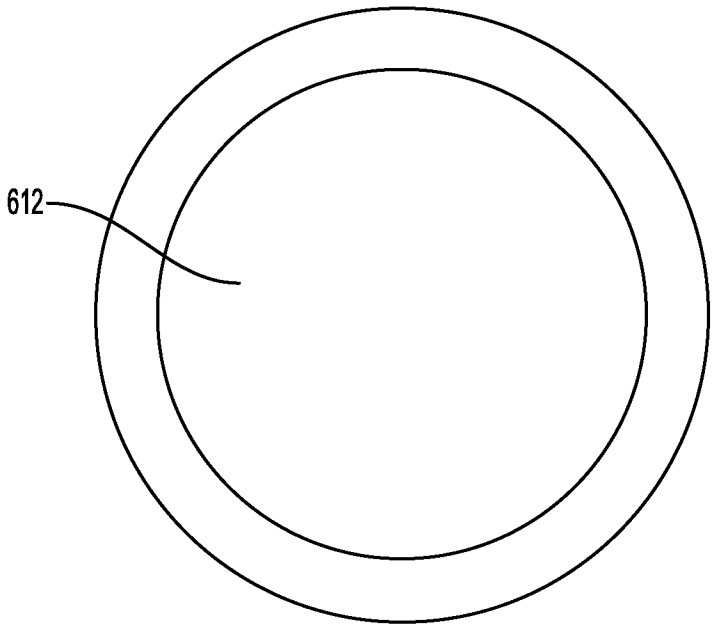


FIG. 14D

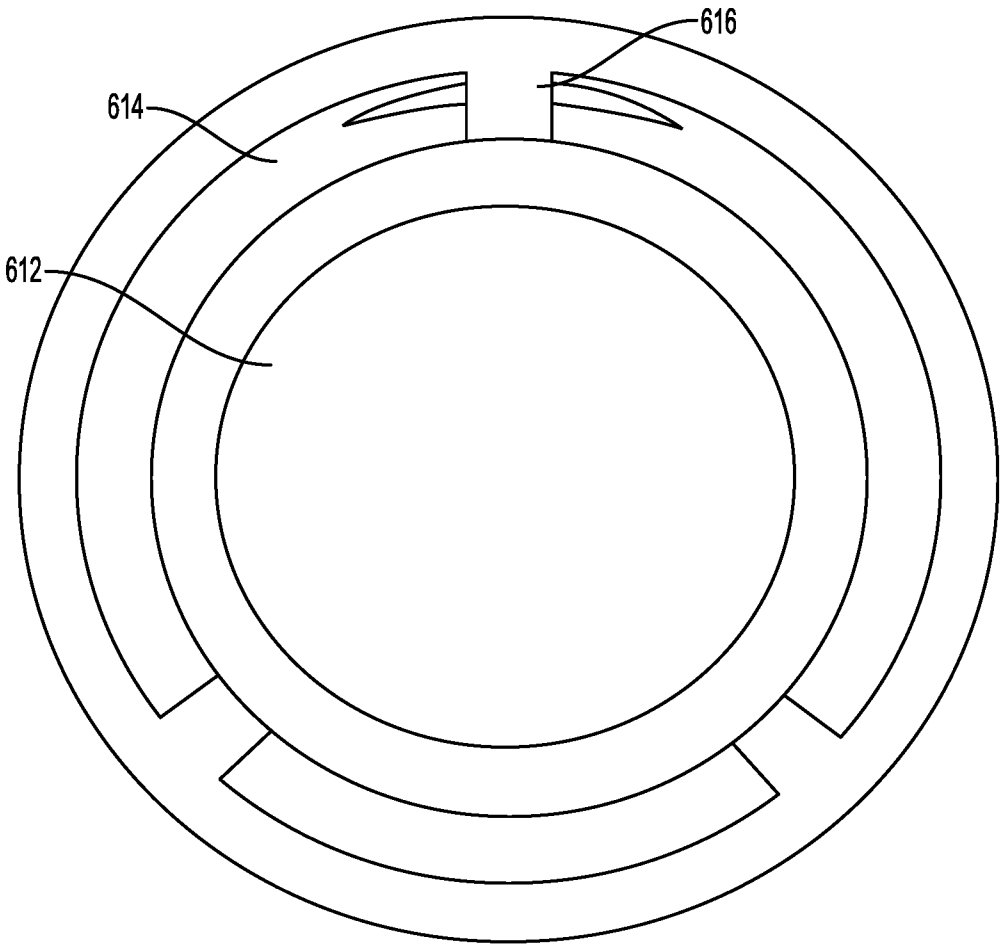


FIG. 14E

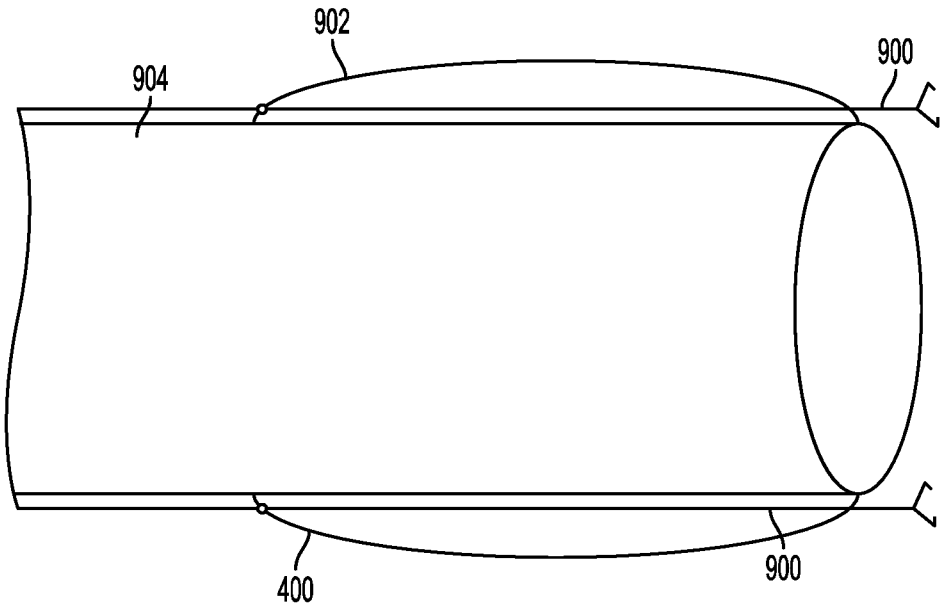


FIG. 15

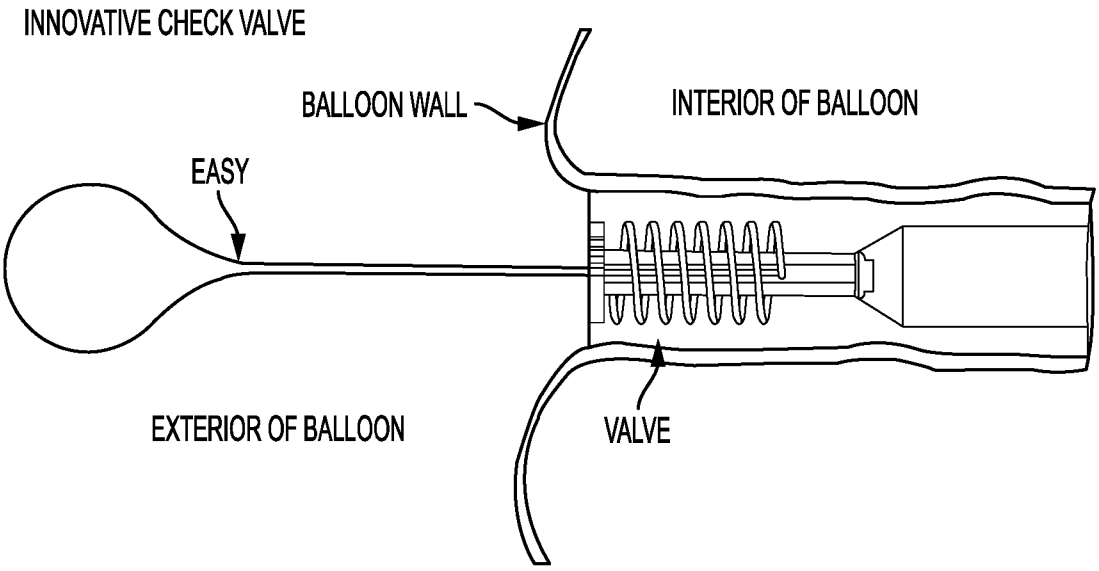

INNOVATIVE CHECK VALVE
BALLOON WALL
INTERIOR OF BALLOON
EASY
EXTERIOR OF BALLOON
VALVE

FIG. 16

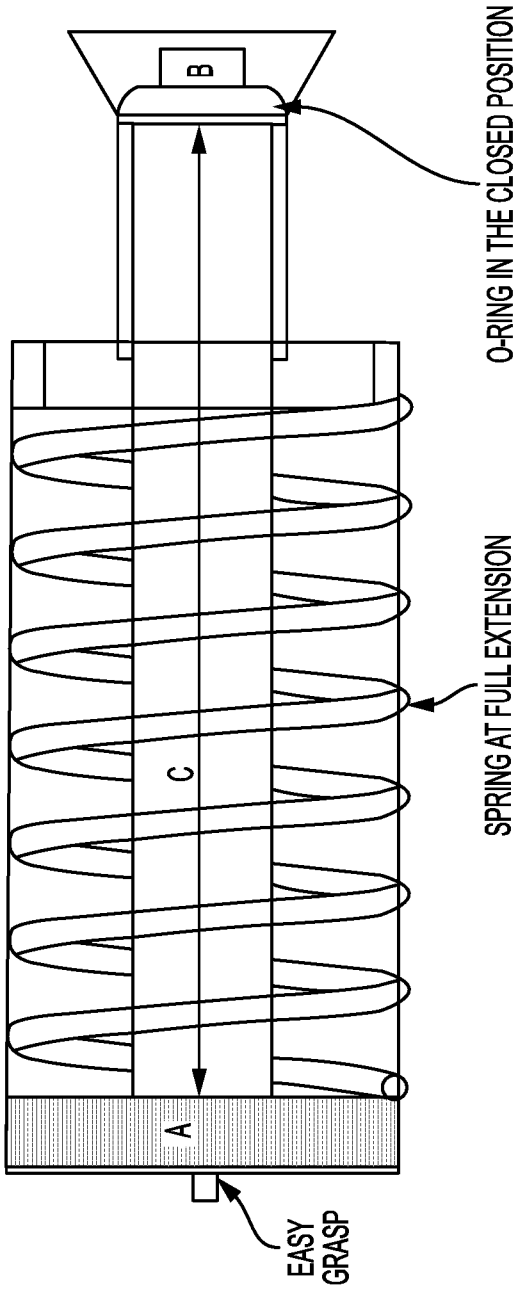

B
O-RING IN THE CLOSED POSITION
SPRING AT FULL EXTENSION
C
A
EASY GRASP

FIG. 17

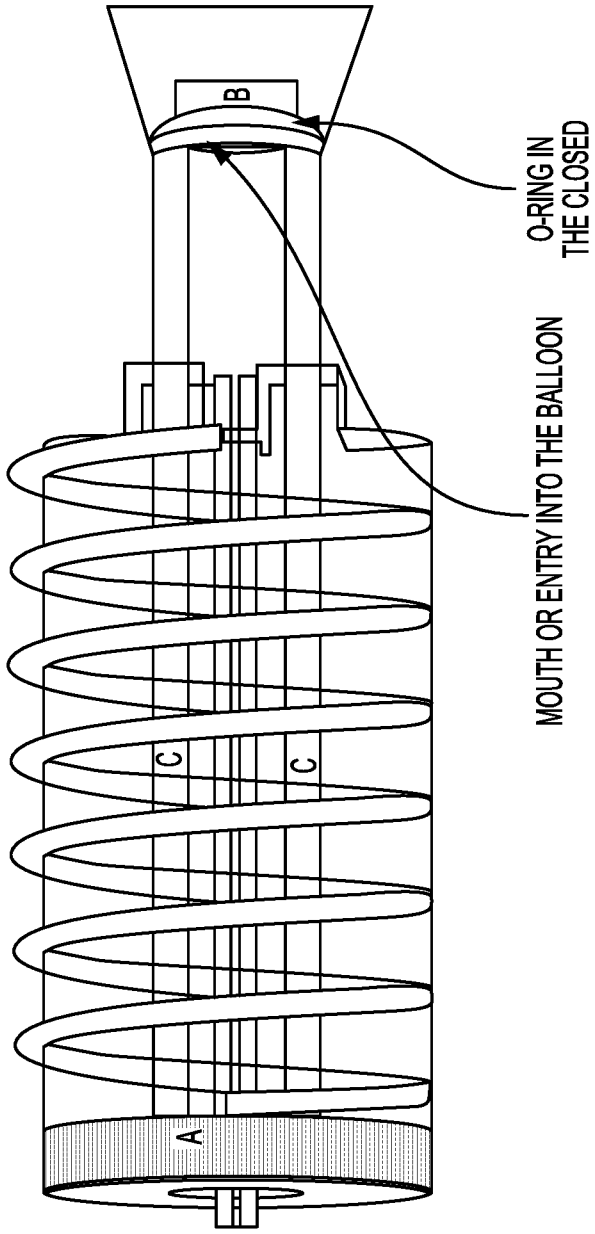


FIG. 18

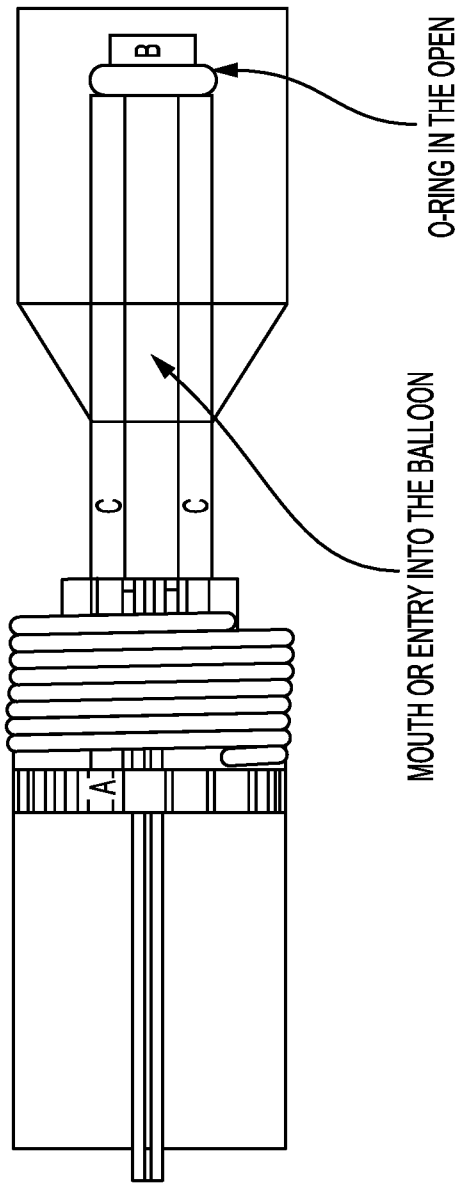


FIG. 19

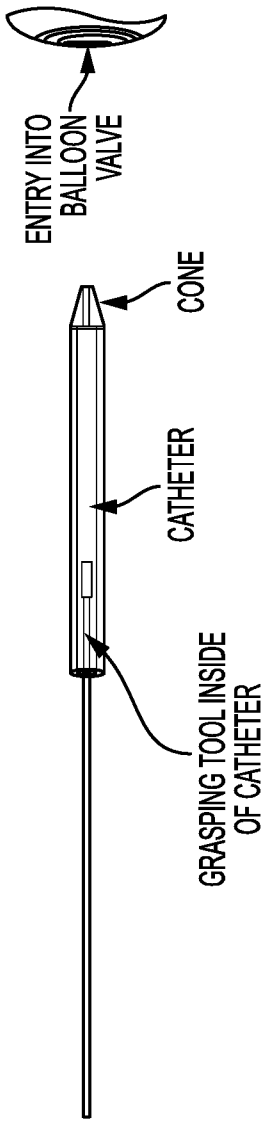

ENTRY INTO BALLOON VALVE
CONE
CATHETER
GRASPING TOOL INSIDE OF CATHETER

FIG. 20

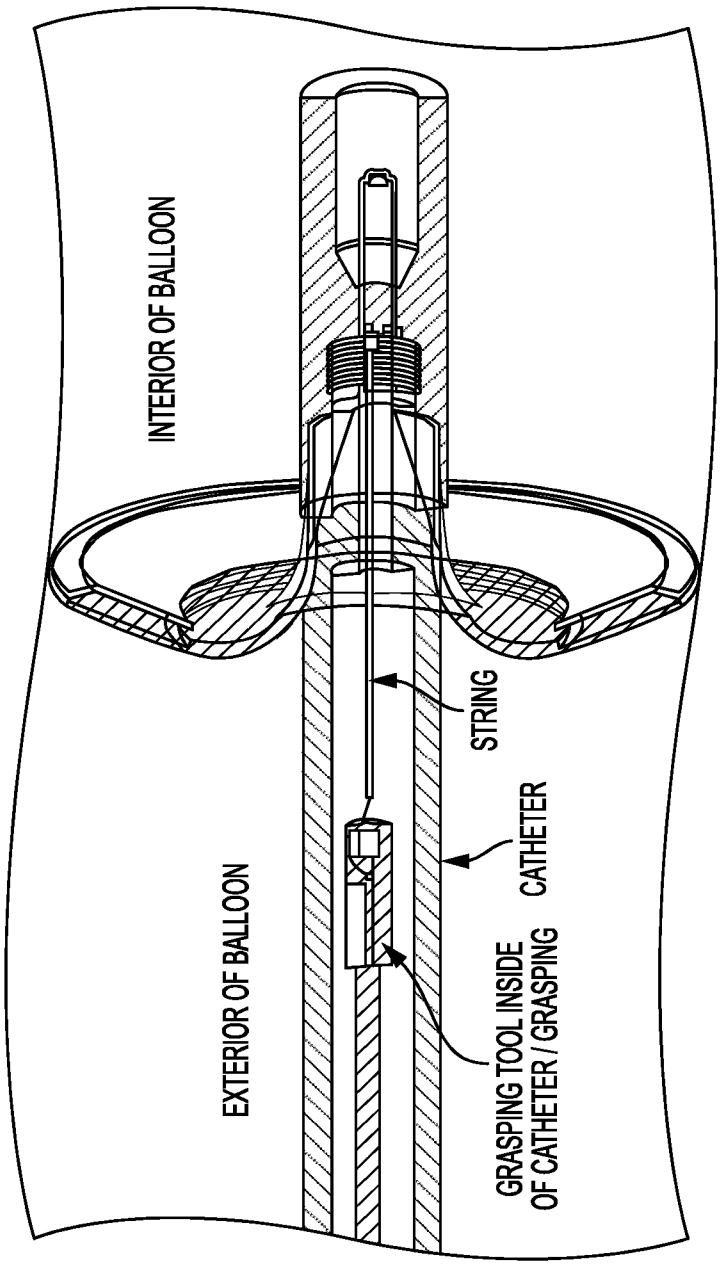

INTERIOR OF BALLOON
STRING
CATHETER
EXTERIOR OF BALLOON
GRASPING TOOL INSIDE OF CATHETER / GRASPING

FIG. 21

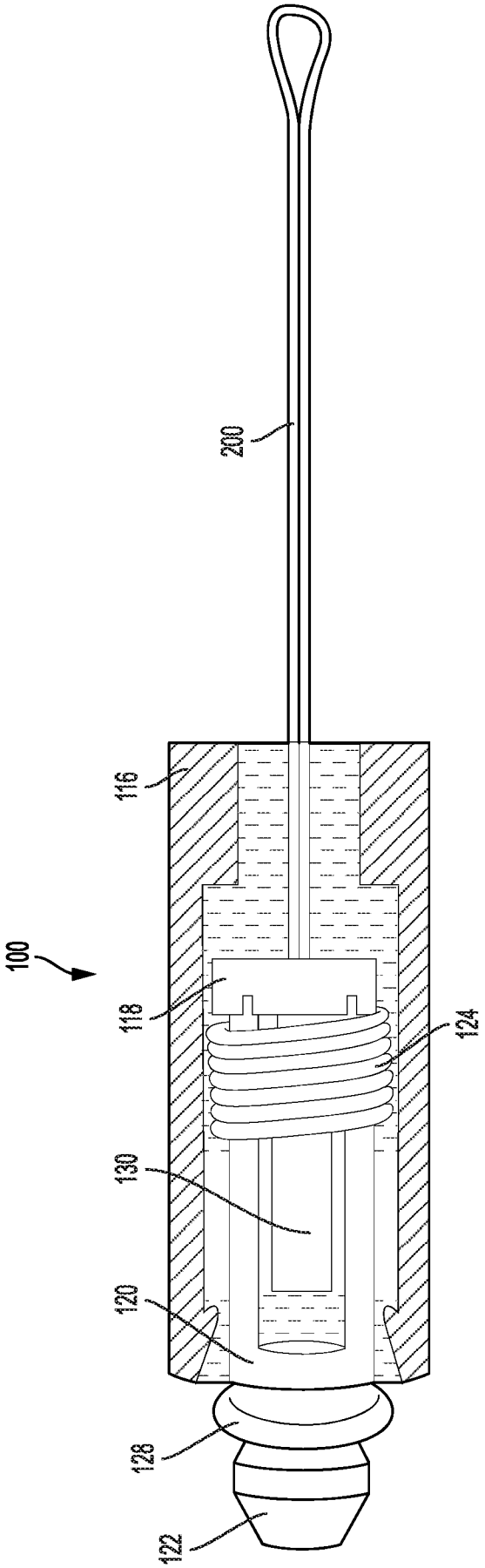


FIG. 22

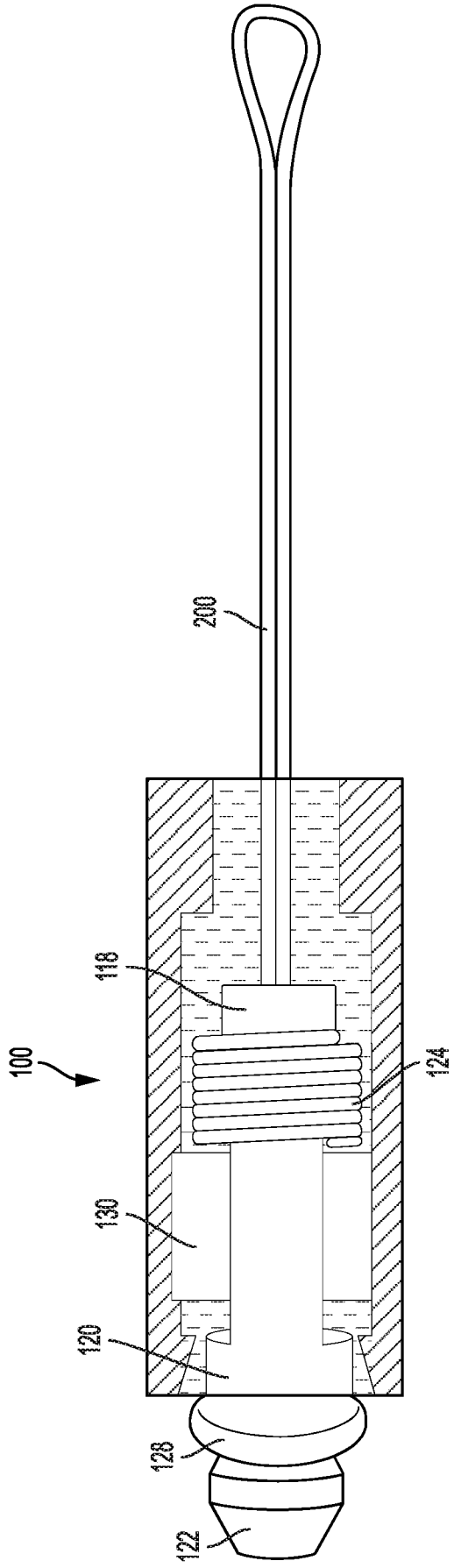


FIG. 23

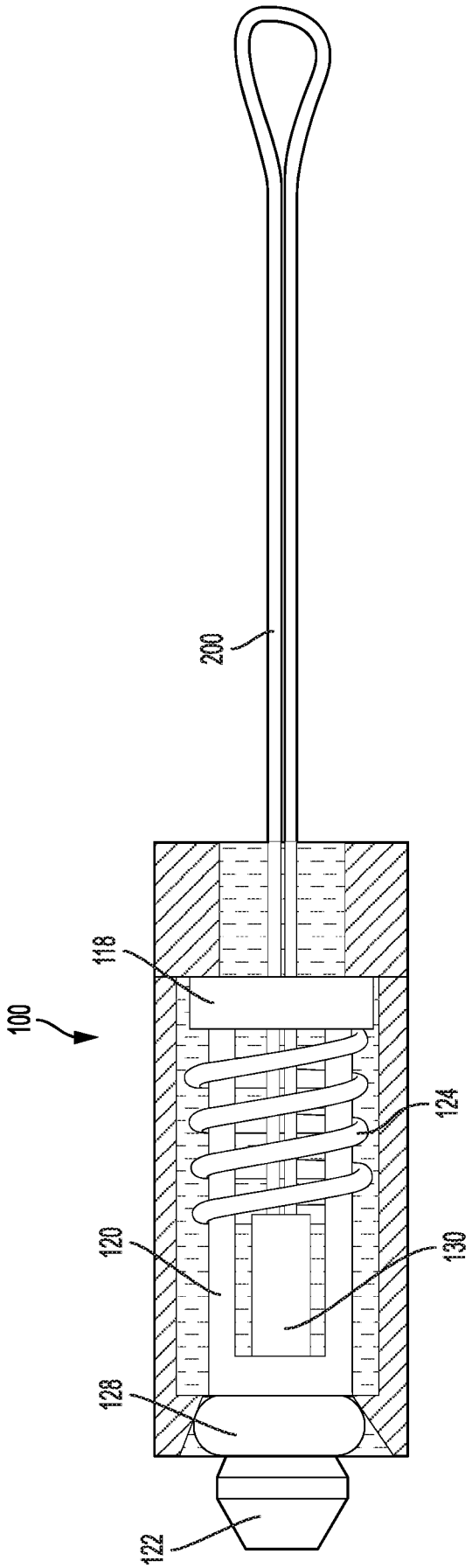


FIG. 24

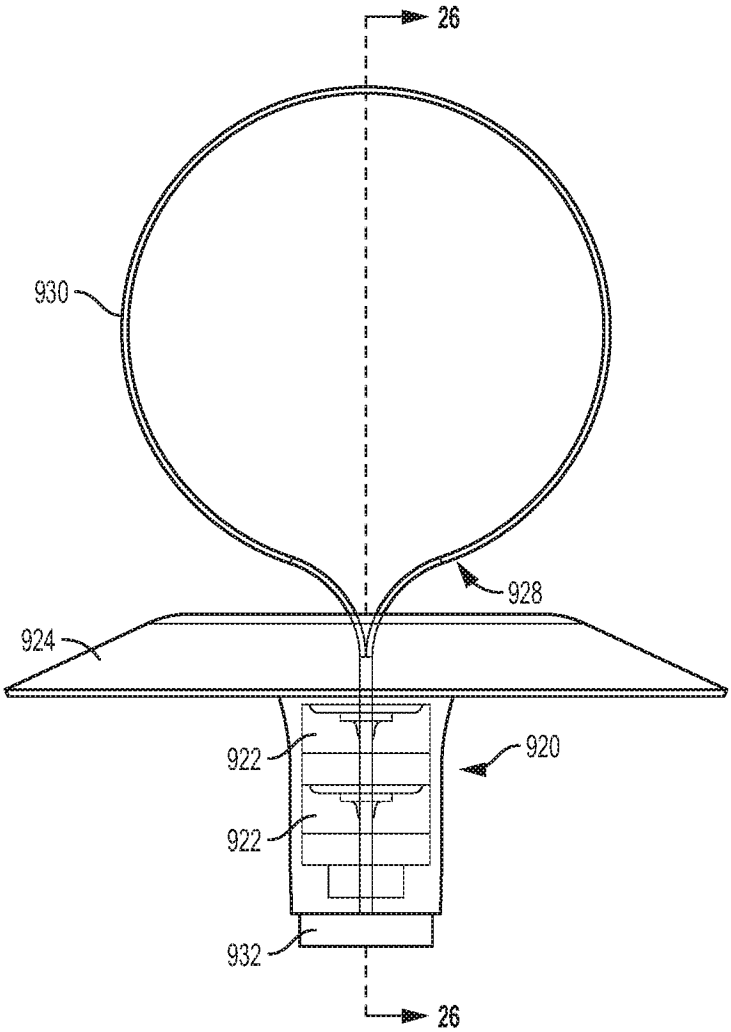

26
930
928
924
922
920
922
932
26

FIG. 25

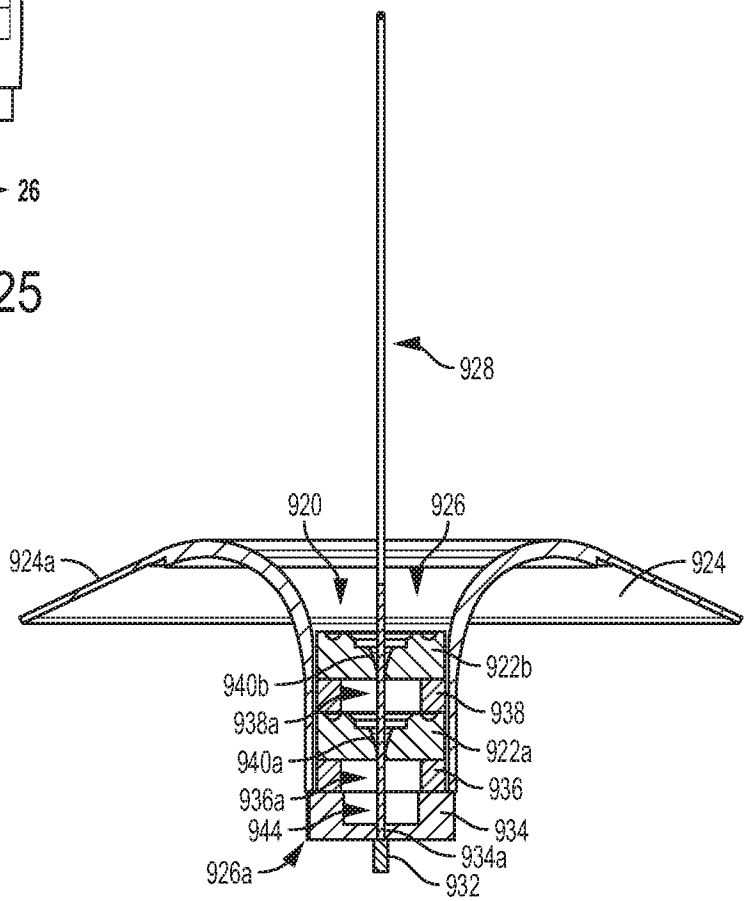

928
920
926
924a
924
922b
940b
938
938a
922a
940a
936
936a
934
944
934a
926a
932

FIG. 26

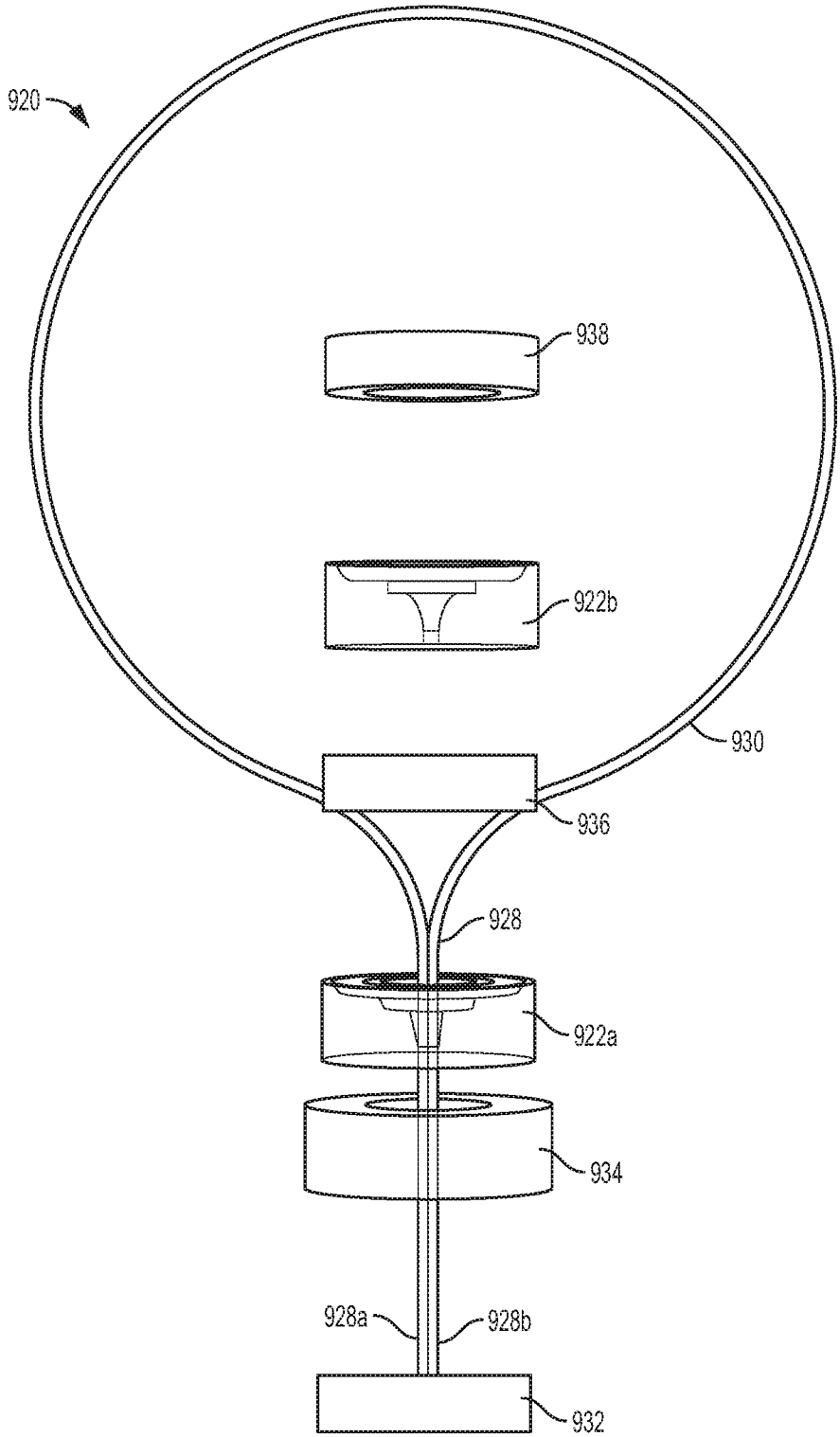
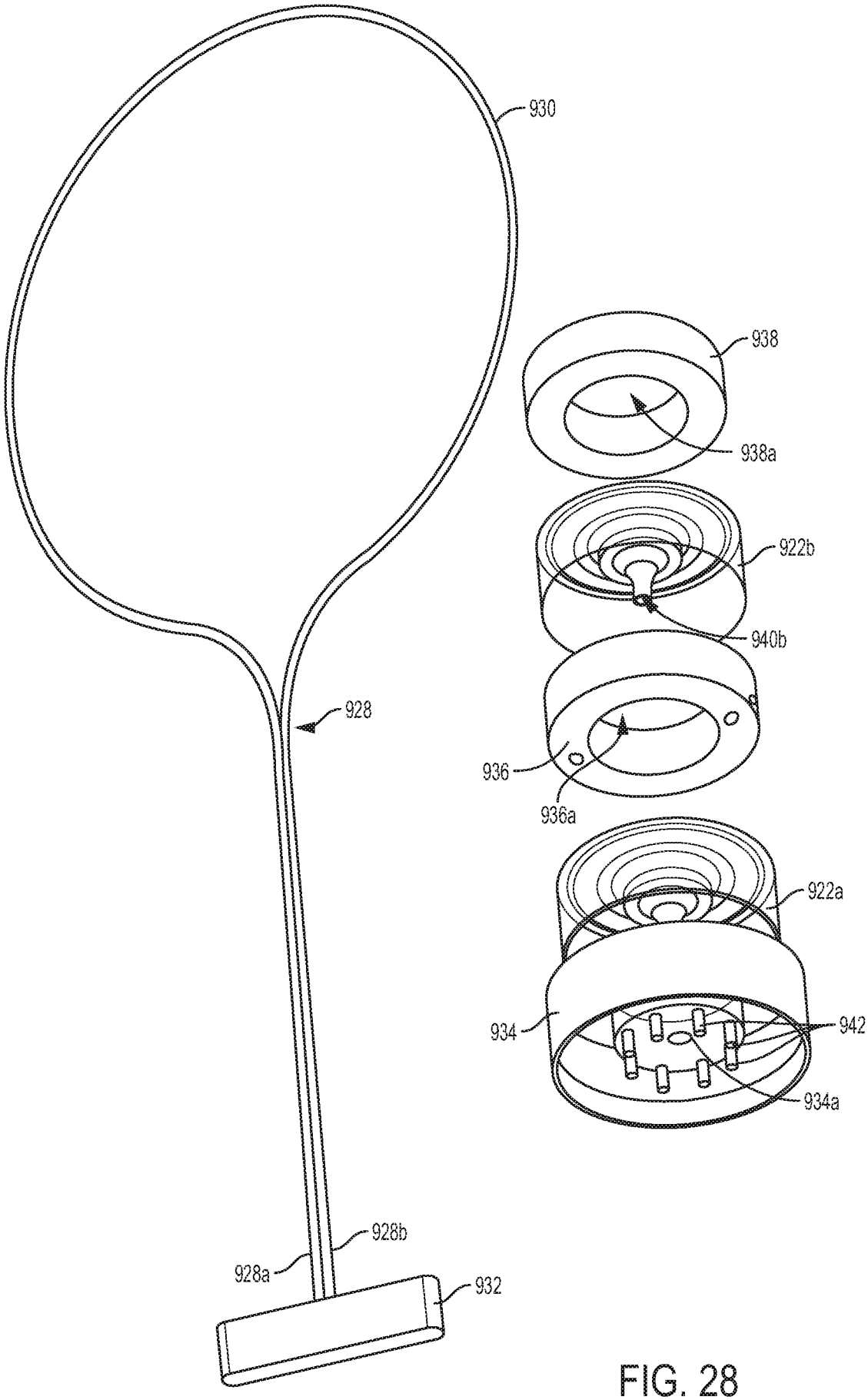


FIG. 27


930
928
928b
928a
932
938
938a
922b
940b
936
936a
922a
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942
934a

FIG. 28

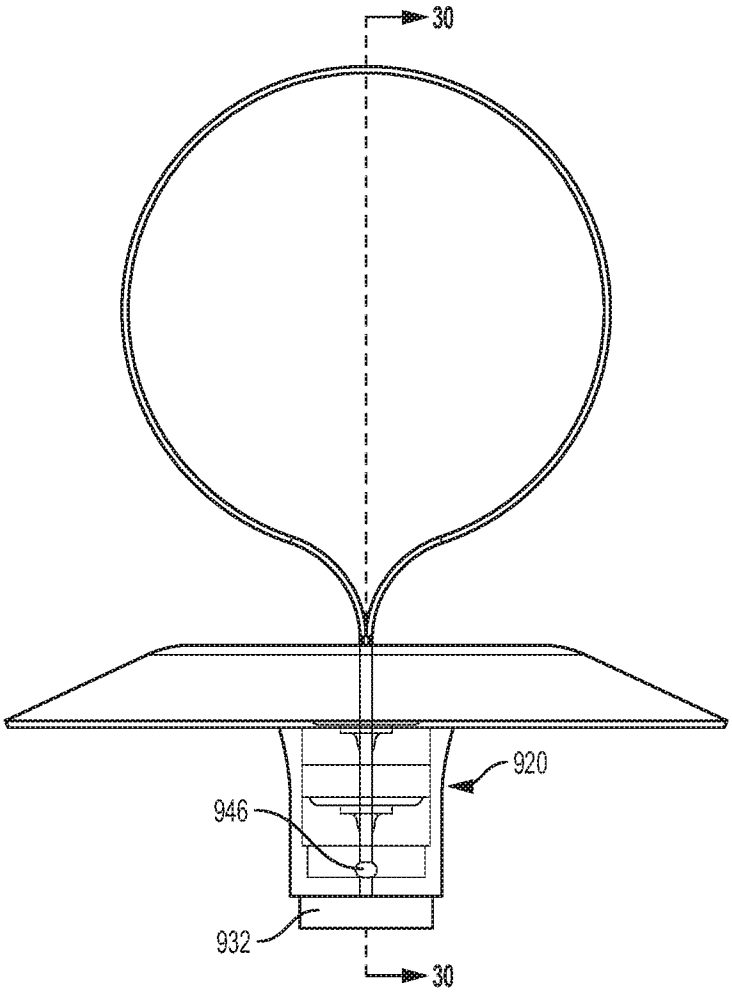

FIG. 29

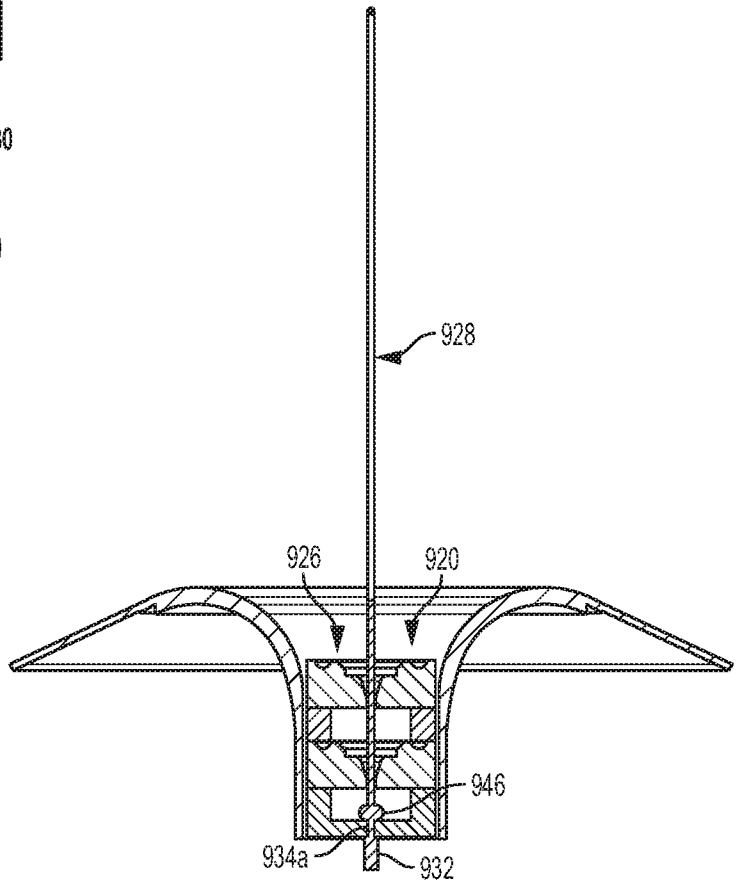

FIG. 30

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 19/67921

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61F 5/00; A61M 39/24; A61M 39/04; A61M 25/00; A61B 17/12 (2020.01)

CPC - A61F 5/0043; A61F 5/003; A61F 5/0089; A61F 5/0003; A61M 39/24; A61M 25/0082; A61M 39/04; A61B 17/12; A61B 1/018; A61B 1/273; A61B 17/12013; A61B 1/2736

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)
See Search History document

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

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 2007/0083224 A1 (HIVELY) 12 April 2007 (12.04.2007); entire document, especially para [0054]-[0058], and Fig. 1-3.	1-4 -- 5-7
X -- A	US 2018/0221184 A1 (SPATZ FGIA LTD) 9 August 2018 (09.08.2018); entire document, especially para [0011], [0048]-[0055], and Fig. 1-6.	1, 8-10, 12-13 -- 11, 23-27
Y -- A	US 2005/0256460 A1 (ROME et al.) 17 November 2005 (17.11.2005); entire document, especially para [0021], [0023], [0029]-[0032], and Fig. 2A-I.	5-7, 14-22 -- 23-27
Y -- A	US 2008/0172079 A1 (BIRK) 17 July 2008 (17.07.2008); entire document, especially para [0055]-[0059], and Fig. 1, 7, and 14-15.	14-22 -- 23-27
A	US 2017/0156909 A1 (OBALON THERAPEUTICS, INC.) 8 June 2017 (08.06.2017); entire document.	1-27
A	US 2012/0191123 A1 (BRISTER et al.) 26 July 2012 (26.07.2012); entire document.	1-27
A	US 2007/0118168 A1 (LOINTIER et al.) 24 May 2007 (24.05.2007); entire document.	1-27

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

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"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
12 February 2020	10 MAR 2020
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