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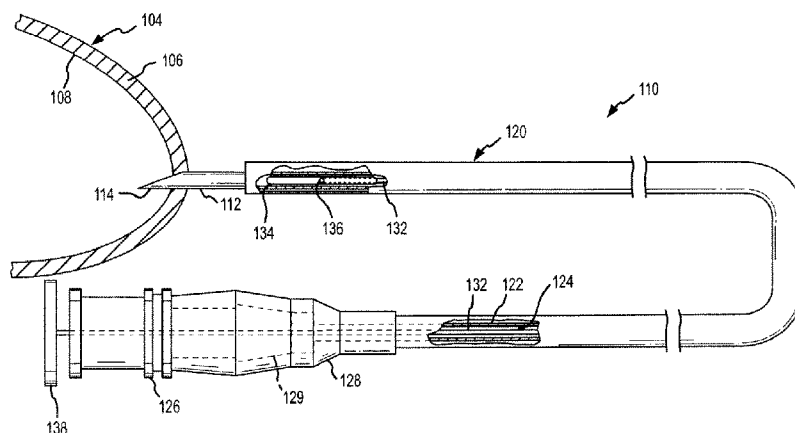
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(54) Title: INTRAGASTRIC BALLOON RETRIEVAL MECHANISMS



(57) Abstract: A mechanism (110) for removing a fluid-filled object (104) from a patient. The apparatus includes a deflation tube (120) with a puncture member (112) at one end of the tube for piercing a hole in the object wall (106). The apparatus includes a retrieval mechanism slidable within the deflation tube lumen. The retrieval mechanism includes an expansion element (134) that is expandable when positioned within the object from a first configuration with a dimension less than that of the deflation tube lumen to a second or deployed configuration with a dimension that is greater than an outer dimension of the puncture member. The expansion element contacts an inner surface of the inflatable object as the deflation tube and retrieval mechanism are withdrawn from the body cavity. The expansion element may be a T-bar, a foldable anchor, an inflatable member, or another expandable form.

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INTRAGASTRIC BALLOON RETRIEVAL MECHANISMS

BACKGROUND OF THE INVENTION

1. Field of the Invention.

[0001] The present invention relates, in general, to the use of an intragastric balloon and similar fluid-filled objects in treating obesity, and more particularly, to the devices and systems for endoscopical deflating and removing or retrieving such intragastric balloons and/or other fluid-filled objects from the stomachs of patients.

2. Relevant Background.

[0002] Intragastric balloons, such as that described in U.S. Pat. No. 5,084,061 or other balloons and objects commercially available, are designed for providing short-term therapy for moderately obese individuals who need to shed pounds in preparation for surgery or as part of a dietary and behavioral modification program. A challenge with such balloons or fluid-filled objects is their removal after completion of therapy.

[0003] A typical intragastric balloon is made of a silicone elastomer shell that is inserted into the stomach of a patient and then filled with fluid. For example, commercially available intragastric balloons are filled with saline solution or air but other fluids may be used in some situations. The intragastric balloon functions by partially filling the stomach, which enhances appetite control. Placement and filling of the intragastric balloon is completed non-surgically with a surgeon or doctor using an endoscope, gastroscope, or other device that is adapted for viewing internal cavities of a patient and with lumen or hollow channels for passing the retrieval instruments. Placement of intragastric balloons is temporary, and intragastric balloons are typically removed after six to twelve months.

[0004] Historically, endoscopic deflation and extraction of intragastric balloons has been an arduous task due to the difficulty associated with manipulating the balloon within the stomach. One method of removing the balloon involves several steps, each with its own tool. A sharp-ended puncture device, sometimes called a "killer," is inserted through the working channel of an endoscope to puncture the balloon. The puncture device is then removed, and

the saline solution is either allowed to enter the stomach cavity, or removed via an aspiration tube inserted through the working channel and into the balloon. Finally, a grasping device or "grasper" having prongs, teeth, or a wire loop is inserted through the working channel to snag or snare the outside surfaces of the balloon. Once the outside of the balloon is hooked or grasped, the grasping device is used to pull the balloon through the esophagus as the gastroscope is removed. Other tools have been developed that provide a single tool that can pierce the balloon's shell, evacuate the fluid to deflate the balloon, and grasp or hook the outer surfaces of the balloon.

[0005] Even with these efforts, the retrieval of untethered intragastric balloons or other fluid-filled objects from a patient's stomach continues to present problems and can be a difficult task. The outer surface of the balloons is coated with gastric fluids in the stomach and tends to be very slippery or slick, which makes it difficult for even a relatively sharp grasper tool to grasp the balloon. One technique for addressing this issue is described in U.S. Pat. No. 5,084,061 and includes providing a retrieval tab on the outer surface of the balloon. A tool with a hook, loop, or snare then has to be latched onto the tab to allow retrieval. This technique has not been widely adopted as it requires specially manufactured balloons or objects with the external tab and also requires that the balloon be manipulated within the patient's stomach to find and align the tab with the hook on the removal tool, and this is often difficult to perform endoscopically (e.g., with limited tool dexterity and in limited visibility and light provided by the endoscope).

[0006] Therefore, it is desirable to provide an endoscopic device for removing an intragastric balloon in which the above mentioned disadvantages are substantially overcome.

[0007] Hence, there remains a need for an improved tool for supporting deflation and retrieval of intragastric balloons and other fluid-filled objects from the stomach of patients. Preferably, such a tool would be useful with existing medical systems or tools such as endoscopes and would provide quicker and more effective grasping or capture of the balloon or object to better support out-patient procedures.

SUMMARY OF THE INVENTION

[0008] The present invention addresses the above problems by providing a system and method for removing fluid-filled objects, such as intragastric balloons, from a body cavity of a patient. In contrast to prior devices that grasp the outer surfaces of an object, the removal system of the present invention includes a retrieval mechanism that can be inserted within the object via a lumen of the device used to deflate or aspirate the object contents (e.g., an aspirator tube or the like). The retrieval mechanism includes an expansion element that can be compressed or provided in a first configuration that allows it to readily pass through the deflation tube lumen but that expands to a second or deployed configuration when it is positioned within the unrestricted space within the interior of deflated object to be removed. The second or deployed configuration of the expansion element is typically significantly larger than the outer dimensions of the deflation tube, and as a result, surfaces of the expansion element contact the inner surfaces of the object when the retrieval mechanism is withdrawn from the body cavity, thereby capturing and removing the object. The expansion element may take numerous forms, as discussed in detail herein, such as, but not limited to, a T-bar, a foldable anchor, an inflatable member, a spring retriever, an elongate body with tabbed ends, an expandable tubular body, and a rollable or collapsible cone.

[0009] More particularly, an apparatus is provided for removing an inflatable object from a body cavity of a patient. The apparatus includes an aspiration or deflation tube with a lumen and a puncture member, such as a hollow needle, at one end of the tube for piercing a hole in the wall of the inflatable object. The puncture member includes a lumen that is in fluid communication or is fluidly coupled with the deflation tube lumen. The apparatus further includes a retrieval mechanism that can be slid within the deflation tube lumen. Significantly, the retrieval mechanism includes an expansion element that is expandable when positioned within the inflatable object from a first configuration with a dimension less than that of the deflation tube lumen to a second or deployed configuration with a dimension measured transverse to the deflation tube lumen that is greater than an outer dimension of the puncture member. In this second or deployed configuration, the expansion element has at least one contact surface (e.g., a surface extending transverse to an axis of the puncture member lumen) that contacts an inner surface of the inflatable object proximate to the hole formed in the wall

of the inflatable object as the deflation tube and retrieval mechanism are withdrawn from the body cavity.

[0010] According to another aspect of the invention, a method is provided for evacuating and removing a fluid-filled object positioned in a body cavity. The method includes positioning an aspirator device in the body cavity and piercing a wall of the fluid-filled object with the aspirator device that includes a tube with a lumen, e.g., the piercing results in a portion of the tube passing through the shell wall and providing access to the interior of the object via the lumen. The method continues with advancing a retrieval mechanism into the lumen of the aspirator tube. The retrieval mechanism includes an expansion element that has a deployed configuration that is greater in size than the outer diameter of the aspirator tube, and the advancing includes extending the expansion element at least partially out of the lumen and into the pierced object. The expansion element then expands to its deployed configuration, and then the retrieval mechanism is withdrawn along with the aspirator device, which results in the expansion element contacting an inner surface of the object wall to cause the object to be removed from the body cavity along with the retrieval mechanism.

[0011] The retrieval mechanism typically also includes a flexible deployment member (such as a wire, wire rope, flexible tube, or the like) that is attached to the expansion element. The expansion element may take a number of forms, and for example, it may be selected from: a T-bar, an object inflated during the expanding of the expansion element, a folding anchor device that unfolds to the deployed configuration, a spring element that returns to an at-rest position during the expanding of the expansion element, an elongate body with tabs attached at opposite ends, a tubular body with slits cut in a spaced-apart manner, parallel to a longitudinal axis of the tubular body and with a tensioning wire attached to an end of tubular body, and a funnel collapsible into a cylinder and expandable into a frustaconical shape in the deployed configuration.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] Fig. 1 illustrates a partial cutaway view of an inflatable object retrieval system according to one embodiment that is useful for deflating and removing a fluid-filled object such as an intragastric balloon from the stomach or other cavity of a patient;

[0013] Figs. 2A-2C illustrate in more detail the “T-bar” retrieval mechanism shown in the system of Fig. 1 as it is being used to grasp and remove an object after deflation;

[0014] Figs. 3A-3C illustrate similarly to Figs. 2A-2C a retrieval mechanism according to the invention in which the expansion or grasper portion or element itself is inflatable and may be used in object retrieval systems such as that shown in Fig. 1;

[0015] Figs. 4A and 4B is another retrieval mechanism according to the invention that may be used with the system shown in Fig. 1 and that utilizes a “folding anchor” type of expansion or grasper element;

[0016] Figs. 5A and 5B is yet another retrieval mechanism that may be used with the system of Fig. 1 and that includes an expansion or grasper element that is made up of a spring member that uncoils to its at rest configuration within the retrieved object;

[0017] Figs. 6A and 6B illustrate a retrieval mechanism with an expansion or grasper element similar to that shown in Figures 2A-2C that utilizes a plurality of tabs to engage the inner surface of an object being retrieved;

[0018] Figs. 7A and 7B illustrates still another retrieval mechanism useful with the retrieval systems of the invention that includes yet another embodiment of an expansion or grasper element (e.g., an expandable tube tip) useful for grasping or engaging inner surfaces of a balloon or other inflatable/deflatable object; and

[0019] Figs. 8A-8D illustrates a retrieval mechanism with a funnel-based expansion or grasper element.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0020] The present invention is directed to methods and systems for retrieving fluid-filled objects from stomachs or other cavities of patients. The following description describes particularly systems and their operations for deflating, engaging or grasping, and retrieving or removing intrastomic balloons from the stomach of a patient, but the concepts are equally applicable to nearly any object or hollow shape that is inflatable with fluid. Intragastric balloon retrieval systems of the invention are described as being useful with standard

endoscopes, gastroscopes or the like that include a working channel through which the retrieval system can be passed to a stomach of a patient. Further, in a typical embodiment, the retrieval systems include a device for puncturing the shell of the intragastric balloon and for inserting an end of a tube, or an outlet of a lumen in such tube, within the intragastric balloon. The lumen can be used to deflate or aspirate the contents of the balloon. Then, during balloon retrieval procedures, a retrieval mechanism of the invention is inserted through the lumen (or is passed further through the lumen in embodiments in which the mechanism remains in the lumen during deflation).

[0021] Significantly, each embodiment of the retrieval mechanisms of the invention includes an expansion or grasping element at or proximal to its distal end that is inserted through the lumen of the deflation tube so as to extend beyond the tip or end of the deflation tube (or beyond a needle, prong, or other component used to pierce the balloon shell). These expansion elements each are adapted to contact and engage the inner surface of the intragastric balloon as the retrieval mechanism and the deflation or aspiration tube is withdrawn from the stomach of the patient. Typically, each expansion member is capable of taking on a first profile or dimensions (deployment configuration or profile) smaller than or equal to the inner diameter of the lumen such that it can pass through the deflation or aspiration tube. When in the open or unrestricted space within the intragastric balloon, the expansion element expands to a second profile or dimensions (deployed or retrieval configuration or profile) substantially greater than the outer diameter of the needle and/or tube.

[0022] This larger-sized profile or configuration and the contact surface(s) of the expansion element allow the expansion element to effectively contact or “grasp” the inner surface of the balloon adjacent to the hole that was previously formed in the balloon shell by the needle or puncture member of the retrieval mechanism. In some cases, the “grasping” includes trapping or pinching balloon material near the formed hole between the contact surfaces of the expansion element and the outer surfaces of the needle or puncture member or deflation tube. These and other features of the invention will become clear from the following description of the retrieval systems of the invention and the multiple embodiments of retrieval mechanisms useful in such systems to contact the inner surface of intragastric balloons so as to grasp or capture the balloons for efficient retrieval from a patient.

[0023] Figure 1 illustrates an inflatable/deflatable object removal system 110 of the invention that is particularly well suited for use when the object is an intragastric balloon. The object removal system 110 includes a single lumen tubing 120 that is configured with an outer wall 122 that has a diameter such that the tube 120 is small enough to pass through a working channel or lumen of an endoscope, gastroscope, or the like (not shown). The tube wall 122 defines a lumen 124 that extends from one to the other end of the tube 120. At the distal end, a needle or puncture member 112, such as a hollow cannulated needle with a relatively sharp tip 114, is provided, which may be an extension of the tube 120 or a separate component that is attached to the tube wall 122. The puncture member 112 optionally has its lumen or hollow center coupled to the lumen 124 or other channel through the tube 120 such that fluid (not shown) can be aspirated from an object or balloon 104 that has its shell or wall 106 pierced by the tip 114 of the member 112.

[0024] During deflation operations, the fluid contained by the inner surfaces 108 of the balloon wall 106 may be allowed to flow into the stomach or cavity of a patient, but often it is desirable to aspirate or evacuate the fluid via the tube 120. In this regard, the insertion of the needle member 112 results in the lumen 124 provided in the tube 120 being exposed to the interior space of the balloon 104 defined by the inner surface 108 of the balloon wall 106 (e.g., via the needle member 112 depending upon how deep the tube 120 is inserted into the balloon 104). To facilitate insertion and later deflation of the balloon 104, a connector 126 (e.g., a luer connector or the like) is provided with a tube connector that is also hollow or has an internal channel 129 at the proximal end of the removal system 110. After the tube 120 is positioned in a patient and the tip 114 has pierced a balloon 104, the connector 126 can be connected to a suction mechanism to apply suction and evacuate fluid from the balloon 104 via needle 112 and lumen 124 of tube 120. While the system 110 is shown with the single lumen tube 120 and a particular connector and puncture arrangement, these components can be varied significantly to practice the invention such as with a dual lumen tube, a different connector, and a differing needle or piercing device, with an important feature of the aspirator portion being the ability to pierce the wall 106 and position a lumen port, opening, or end within the balloon 104 to provide access to the inner surface 108 of the wall 106.

[0025] A significant feature of the system 110 is the improved ability of the system 110 for grasping and retrieving the deflated balloon 104. To this end, the system 110 includes a

retrieval mechanism (which is shown in more detail in Figures 2A-2C). The retrieval mechanism includes a deployment member 132 that may be a wire, a twisted wire rope, a flexible rod, a tube, or other component that is adapted for being pushed and pulled through the lumen 124 of the tube 120. As shown, the retrieval mechanism includes a handle 138 attached to the proximal end of the member 132 and an expansion element made up of a bar (or T-bar) 134 attached with connector 136 (such as a pin, solder or other connection). The handle 138 is used by an operator (such as doctor, surgeon, or other medical technician) to push the wire or member 132 until the distal end of the wire or member 132 and the bar 134 passes the tip 114 of the needle 112 and is positioned within the balloon 104. At this point (i.e., the deployed or fully deployed position), the expansion element is able to expand or convert from a first, smaller profile or configuration to a second, larger profile or configuration (e.g., a first profile with dimensions that allow the bar and wire 134 and 132 to fit within the lumen 124 and a second profile with dimensions that are larger than the tip 114 used to pierce the balloon wall 106). Because the expansion or conversion element is an important feature of the invention and system 110, the following figures and discussion emphasize a number of embodiments of retrieval mechanisms with varying expansion or conversion elements, with the tube 120 and other features of the system 110 being useful in combination with any of the retrieval mechanisms (and, as discussed earlier, the retrieval mechanisms being useful with removal systems other than that shown in Figure 1).

[0026] Figures 2A-2C illustrate one embodiment of a retrieval mechanism 230 that may be used in a removal system, such as system 110 of Figure 1. As shown, a deflation or aspiration tube 220 with a wall 222 defines a lumen 224 (such as a lumen with a circular or other shaped cross section). At the end of the tube 220 is a puncture or needle member 212 that is affixed to the tube wall 222 such as by threading and/or adhesive or the like. The tubing 220 and member 212 may be made of a number of materials to practice the invention such as flexible plastic or elastomer, e.g., PTFE, ETFE, or PDVF. With its outer dimensions being selected to be less than the inner diameter of an endoscope working channel, such as less than about 0.1 inches, this results in a lumen outer diameter less than this dimension, such as 0.08 inches, 0.05 inches, or less. The deploying or first profile or configuration of the retrieval mechanism 230 is selected to be less than the diameter of the lumen to allow its deployment into the

balloon interior. Clearly, the specific dimensions are not limiting with the more important aspect being the relative dimensions.

[0027] The puncture member 212 is shown after it has been used to pierce the balloon 104 by making a hole in the wall 106. As shown, the outlet or tip 216 of the member 212 is within the balloon 104 such that the lumen or channel 214 of the member 212 is within the balloon 104. In Figure 2A, the retrieval mechanism 230 is being deployed as shown at arrow 231 through the lumen 224 into the interior of the balloon 104. The retrieval mechanism 230 includes a deployment member 232 (e.g., a wire, wire rope, flexible rod, or the like made of metal or other materials), which is connected to a handle (not shown). An expansion element 225 is attached with connector 226 to the end of the deployment member 232. The expansion element 225 can be thought of as a T-bar and includes an elongate body of a width, W, with two opposing ends 228, 229 (shown curved in this embodiment but may take other shapes to practice the invention). The width, W, of the expansion element 225 is less than the lumen 224 and channel 214 in the puncture member 212. As shown, the expansion element 225 is collapsible onto the wire or deployment member 232 while it is being deployed through the lumen 224 of the tube 220. In other words, the bar or body of the expansion element 225 may be aligned with the wire 232 to fit into the tubing 220, and when emerging from the tubing 220 end 212 resumes a perpendicular orientation.

[0028] Figure 2B illustrates the expansion element 225 in its deployed profile or configuration in which its body is perpendicular to (or at least no longer aligned with) wire 232. The expansion element 225 swings down as shown with arrow 240 to the deployed or second larger profile. The larger or second profile results in the body or expansion element 225 having a length, L, that is larger than the outer diameter of the puncture element 212, and the length, L, is typically significantly larger than this diameter (e.g., 2 to 6 or more times larger than this diameter) with the upper limitation being that the length of the extension element 225 as measured along the elongate body from end 228 to end 229 is less than the inner diameter of the channel through which the tube 220 and balloon 104 be removed, e.g., less than a patient's esophagus inner diameter such as less than about 0.75 inches). With this profile, the element 225 is longer than the hole formed in the balloon wall 104.

[0029] As shown, the extension element 225 has a contact or grasping surface 227. When the retrieval mechanism 230 is withdrawn or pulled back toward the tube 220 as shown at arrow 242, the contact surface 227 of the expansion element 225 contacts (engages or grasps) the inner surface 108 of the balloon wall 106. This grasping or contact by the expansion element 225 is shown in Figure 2C. As shown, once the wire or deployment member 232 is pulled or withdrawn until the contact surface 227 abuts the tip or end 216 of the puncture member 212 (or pinches balloon wall 106), the tube 220 of the removal system is pulled or withdrawn as shown at arrows 246 to remove the balloon 104 along with the tube 220 and retrieval mechanism 230. The expansion element 225 is effective for grasping the balloon 104 by contacting the inner surface 108, and the balloon shell 106 can be pulled out of its environment (e.g., a stomach or other patient cavity) draped over the T-bar or elongate body of the expansion element 225.

[0030] Figures 3A to 3C illustrate another embodiment of a retrieval mechanism 330 being deployed into a balloon 104 that has been pierced by tube 220 and puncture member 212 (with similar components shown in Figures 2A to 2C not being described in detail). The mechanism 330 can be thought of as using a balloon grasper to grasp the inner surface 108 of the balloon wall 106. Specifically, the retrieval mechanism 330 includes a tube of smaller diameter than the tube 220, and this tube is advanced as shown in Figure 3A at arrow 331 through the lumen 224. At the end of the tube 332, a small balloon or inflatable expansion element 336 is provided in the lumen 334 of smaller tube 332. The expansion element 336 is attached at or near the end 338 of the tube 332.

[0031] As shown in Figure 3B, the expansion element 336 includes a wall or shell 337 and an inner surface 339. When the expansion element 336 (or end 338 of tube 332) is positioned within the balloon 104 (or past the hole in wall 106), air or other fluid 344 is forced through the lumen 334 of tube (or deployment member) 332 to force the element 336 out of the tube 332 and to apply pressure against inner surface 339 of wall 337 and inflate the expansion element 336 as shown with arrows 348. The inflation of element 336 may be controlled by achieving a predetermined pressure in the lumen 334 and element 336 or by inserting a predetermined volume of gas or fluid 344. At Figure 3C, the expansion element 336 is shown inflated to a second configuration or profile and an outer diameter, D, that is greater than the outer diameter of the puncture member 212 (and hole in wall 106), e.g., 10 times larger or the

like. The outer surfaces of the wall 337 (e.g., contact surfaces of the expansion element 336) abut or engage the inner surface 108 of the balloon wall 106 when the tube 332 is withdrawn into the deployment tube 220 until the expansion element 336 hits or is adjacent to the tip 216 of the puncture member 212. The tube 220 can then be withdrawn to remove the deflated intragastric balloon 104 with the balloon shell 106 draped over the expansion element 336. Again the diameter, D , is selected to be larger than the outer diameter of the member 212 and smaller than the channel through which the tube 220 is removed from a patient's body, such as less than about 0.75 inches when the channel is a patient's esophagus. The wall 337 of the expansion element 336 may be formed from many elastic materials such as rubber or the like, and in some cases, the contact surface or outer surface of wall 337 is rough (or roughened) to improve the "grasping" of inner surface 108 of balloon 104.

[0032] Figures 4A and 4B illustrate another embodiment of a retrieval mechanism 430 that includes an expansion element that can be thought of as a "folding anchor." Figure 4A illustrates the expansion element in the first or deploying profile or configuration in which it has dimensions that are less than or equal to the inner diameter of the lumen 224 of tube 220. The expansion element includes a connector 434 attached to the end of deploying member 433. The connector 434 may be a circular disk or plate that and the member 433 may be a wire, a wire rope, or other flexible component. The expansion element further includes a number of anchor legs 432 (such as 3 or more) that are elongate bodies with two ends 436, 439 and a contact surface 438.

[0033] Figure 4B illustrates how the legs 432 expand out or unfold/deploy when the expansion element is positioned beyond the tip 216 of puncture member 212 within the interior volume of the balloon 104 defined by shell 106. To this end, the legs are pivotally attached at ends 439 to the connector 434. In some embodiments, the legs and connector are formed such that the deployed or second profile shown in Figure 4B is an "at rest" configuration (such as by forming the anchor expansion element as a single piece) and the unfolding is the result of the legs returning to their at rest position. As shown, though, the legs "fall" or pivot from their first configuration shown in Figure 4A proximate to the deployment member 433 to the deployed or expanded, second configuration shown in Figure 4B. In the fully deployed position of Figure 4B, the expansion element of retrieval mechanism 430 has a "diameter" (or width), D , that is measured from the outer tip 436 of one

leg 432 to an outer tip of an opposing leg. This diameter, D, again is significantly larger than the outer diameter of the tube 220 and/or puncture member 212 (e.g., such as 2 to 10 times or more larger) and less than a predetermined maximum value to allow removal from a patient. Then, as shown at arrow 450, the deployment member 433 is pulled back into the tube lumen 224 until the contact surface 438 of the legs 432 contacts the inner surface 108 of the balloon wall 106 when the connector abuts or is proximate to the tip 216 of member 212. Then, the tube 220 and deployment member 433 are withdrawn or pulled from the patient to retrieve the deflated balloon 104.

[0034] Figures 5A and 5B illustrate yet another retrieval mechanism 530 useful in object removal systems of the invention. With this retrieval mechanism 530, the aspirator tube 220 is again placed within the hollow shape or shell 106 of the object or balloon 104. The retrieval mechanism 530 is then advanced down the lumen 224 into the balloon 104. The retrieval mechanism 530 includes a deployment member (e.g., a wire or the like) 534 that is connected at a first end 538 to an expansion element 536. The other distal end 539 of the expansion element 536 is fed into the balloon 104. This embodiment of the retrieval mechanism 530 can be thought of as a “spring” embodiment as the expansion element 536 may be made up of a length of spring, a spring coil, spring wire, or the like that can be “straightened” into a first profile or configuration for feeding through the tube lumen 224 and then, when in an unrestricted space such as the interior space of the balloon shell 106, the expansion element spring 536 returns to its at rest or second profile or configuration.

[0035] The unrestricted or at rest configuration of the expansion element 536 can be defined as having an outer dimension, D (even if not a true circle or sphere) that is larger than the outer diameter of the puncture member 212 and/or tube 220 as shown in Figure 5B (e.g., 2 to 10 or more times larger). As shown at arrow 550, the wire or deployment member 534 is withdrawn or pulled back up the lumen 224 of the tube 220 until the first or proximal end 538 of the expansion element 536 contacts or is pulled within the lumen 214 of the puncture member 212. At this point, the unrestricted spring, which has resumed its natural or at rest state of a coil, spiral, or other non-linear shape, may compress somewhat but is selected to have a stiffness (or resistance to leaving its at rest state) that allows it to contact the inner surface 108 of the balloon wall 106 and grasp the balloon 104. In other words, the expansion element 536 shown in Figure 5B is selected such that forces applied by the deflated balloon

inner surface 108 (“retraction forces”) do not compress the element 536 to a point where its dimension, D, is less than the outer diameter of the member 212. As a result, the expansion element 536 is able to “grasp” or engage the inner surfaces 108 when the tube 220 is withdrawn from the hole in the wall 104, and the balloon shell 106 can be pulled out of its environment draped over the spring element 536.

[0036] Figures 6A and 6B show another retrieval mechanism 630 with a “tab-based” expansion element. As shown by arrow 631, the tab expansion element is fed through the lumen 224 of the aspiration tube 220 with wire or deployment member 632. The member 632 is attached to the body 634 of the expansion element, and the body 634 can be aligned with the member 632 in a first, smaller profile or configuration of the expansion element. The elongated body 634 may be a relatively stiff or rigid tube or wire. On each opposite end of the body 634 is attached a tab or grasping member 638, 639. Each of these tabs 638, 639 may have a variety of shapes and be made of a variety of materials to practice the invention. As shown, the tabs 638, 639 are relatively planar and have a circular shape. In other cases, the tabs 638, 639 may be more spherical or hemispherical in shape or range toward planar but with a different shape such as square, rectangular, triangular, hyperbolic, or the like. The materials used for the body 634 and tabs 638, 639 may be the same (such as when these components are stamped out or formed as a unitary piece), may be selected for easy joining (such as soldering or the like), or may be different.

[0037] As shown in Figure 6B, body 634 of the expansion element “expands” by swinging out of alignment with the wire 632, such as to a perpendicular or transverse position relative to the wire 632. This expanded or second, larger profile or configuration of the expansion element results in the expansion element having a dimension or width, D, that is larger than the outer diameter of the puncture element 212 and tube wall 222 (e.g., 2 to 8 time or more larger with the ratio of 5:1 being used in some embodiments). When the wire 632 is withdrawn into the lumen 224, a surface of the body 632 proximate to the wire 632 contacts the tip or end 216 of the puncture member 212. In this illustrated position, the tabs 638, 639 extend outward from the puncture member 212. When, as shown by arrow 652, the tube 220 and retrieval mechanism 630 are withdrawn, contact surfaces of the tabs 638, 639 contact or “grasp” the inner surfaces of the balloon shell 106. The contact surfaces of each tab 638, 639 are typically about the size of or less than the inner diameter of the tube lumen 224 or lumen

214 of the puncture element 212, whichever is less, to allow the tabs 638, 639 to be passed through the tube 220 and member 212 into the balloon 104. The balloon shell 104 can then be pulled out of its environment draped over the shaped extensions 638, 639 of the expansion element of the retrieval mechanism 630.

[0038] Figures 7A and 7B illustrate still another retrieval mechanism 730 useful with object removal systems of the invention. As shown, the expansion element 733 of the retrieval mechanism 730 can be thought of as an expandable tube retriever or grasper. To this end, the retrieval mechanism 730 includes a hollow tube 732 of flexible plastic or elastomeric materials with an outer diameter less than the inner diameters of aspiration tube 220 and puncture member 212. The tube 732 can be passed or advanced as shown at arrow 731 in a deflated balloon 104. The tip or expansion element 733 includes a number of cut slits parallel to the axis of the tube 732, e.g., 4 slits spaced about 90 degrees apart about the circumference of the tip 733. The retrieval mechanism 730 further includes a wire 735 that is attached toward the distal end of the tip 733 such as to a plate 736 at or near the distal end of tip 733. When the expansion element or tip 733 is positioned within the shell 106 of the balloon 104, tension is applied as shown at arrow 750 to the wire or string 735 such that the attached end of the tip or plate 736 is pulled with the wire 735 toward the tube 220 or puncture member 212. This movement causes the expansion element 733 with the slits 734 to buckle and expand from the first small profile to a second profile (e.g., a cruciform shape or the like) with a width, W, that is larger than the outer diameter of the puncture member 212 and tube wall 222 (e.g., 2 to 5 or more times larger with a minimum ratio of 3.5:1 being used in some cases). The outer surfaces of the expansion element 733 then provide contact surfaces that contact the inner surface 108 of the balloon wall 106 when the retrieval mechanism 730 is pulled by wire 735 such that the expanded tip 733 abuts the puncture element 212 and the tube 220 is withdrawn as shown at 752.

[0039] Figures 8A to 8D illustrate a retrieval mechanism 830 that makes use of a funnel expansion element 834. The retrieval mechanism 830 includes a feed or deployment wire 832 that is used to deploy as shown at arrow 831 the expansion element 834, which is attached to the wire 832, through the lumen 224 of the aspiration tube 220. As shown by arrows 842 in Figure 8B, the funnel expansion element 834 expands outward from its first profile that is smaller than the inner diameter of the tube 220 and puncture member 212 to its second profile

with a width (or diameter), W, that is larger than the outer dimensions of the tube 220 and member 212. The expansion element 834 may include a circular plate 835 that is attached to the wire 832 and an expandable/retractable wall 836. The wall 836 may take a number of forms, and in one embodiment, is made of a plurality of vanes or ribs (such as elongate metal plates) that are wrapped about the wire 832. In this case, the wall 836 expands outward to width, W, and exposes interior surfaces 838 of the wall 836.

[0040] As shown by arrow 852 in Figure 8C, the tube 220 is withdrawn from the balloon such that the wire 832 of the retrieval mechanism 830 extends through the hole 856 in the balloon wall 106 and the expansion element 834 remains in the balloon 104 (e.g., the tube 220 is withdrawn initially without withdrawing or tensioning the wire 832). Then, as shown by arrow 862 in Figure 8D, tension is applied to the wire 832 of the retrieval mechanism 830 such that the funnel expansion element 834 moves toward the puncture member 212 and tube 220. The inner surface 108 of the balloon wall 106 is contacted by the upper edge of the wall 836 such that a portion of the balloon wall 106 is pinched or sandwiched between the inner surface 838 of the wall 836 of the expansion element 834 and the outer surfaces of the puncture member 212 and/or tube wall 222. Preferably, to support this grasping action, the shape of the wall 836 in the expanded or second configuration is selected to correspond to the conical shape of the exterior surfaces of the tip or puncture member 212 or end of tubing 220. When retracted, the balloon wall 106 is captured between the funnel expansion element 834 and the cone tip 212 with some force. The balloon shell 104 can then be pulled out of its environment by applying tension to the tube 220 and the wire 832 of the retrieval mechanism 830.

[0041] Although the invention has been described and illustrated with a certain degree of particularity, it is understood that the present disclosure has been made only by way of example, and that numerous changes in the combination and arrangement of parts can be resorted to by those skilled in the art without departing from the spirit and scope of the invention, as hereinafter claimed. For example, the body or bar 225 shown in Figures 2A to 2C may include a groove along one side for receiving the wire 232 when the expansion element is placed in the first profile for deploying through the aspiration tube. In other embodiments, the T-bar 225 can be attached by a loop at the end of the wire rather than being attached to the end of the wire 232. In the retrieval mechanism 430 of Figures 4A and 4B, the

anchor legs 432 may have a curved (or concave) shape to increase their strength and the outer ends or tips 436 may be textured or include small prongs or the like for enhanced grabbing of the inner surface 108 of the balloon wall 106. Further, the tube expansion element 733 of Figures 7A and 7B can be “locked” in the expanded position, such as, for example, by providing a slot or recessed latching surface in the inner lumen walls of the tube 732. A bead or ball or other shape may be attached to the wire 735 within the tip 733 (such as proximal to the plate 736). When the bead or ball is pulled to the slot or recessed latching surface within the tip 733, the expansion element 733 becomes latched or locked in the cruciform or expanded profile.

CLAIMS

1. An apparatus for removing an inflatable object from a body cavity of a patient, comprising:

a deflation tube having a puncture member at one end for forming a hole in a wall of the inflatable object and a lumen running there through; and

a retrieval mechanism slidably movable within the lumen, wherein the retrieval mechanism comprises an expansion element expandable from a first configuration in which the expansion element fits within the lumen to a second configuration in which the dimensions of the expansion element are greater than the lumen.

2. The apparatus of claim 1, wherein the expansion element in the second configuration comprises at least one contact surface transverse to a longitudinal axis of the lumen, whereby the contact surface contacts an inner surface of the inflatable object proximate to the hole when the deflation tube and retrieval mechanism are withdrawn from the body cavity.

3. The apparatus of claim 1, wherein the retrieval mechanism further comprises a flexible deployment member and wherein the expansion element comprises an elongate body attached to an end of the deployment member, wherein the body has a width less than an inner diameter of the deflation tube lumen and a length equal to the dimension of the second configuration of the expansion element.

4. The apparatus of claim 1, wherein the retrieval mechanism further comprises a tube with an outer diameter less than an inner diameter of the deflation tube lumen and with a lumen and wherein the expansion element is attached proximal to one end of the tube and in fluid communication with the lumen, the expansion element comprising an inflatable shell adapted for inflation to have an outer diameter of at least about the dimension of the second configuration of the expansion element, whereby outer surfaces of the inflatable shell contact inner surfaces of the inflatable object when the retrieval mechanism is removed from the body cavity.

5. The apparatus of claim 1, wherein the retrieval mechanism further comprises a deployment member and wherein the expansion element comprises a connector attached to the deployment member and one or more legs attached at a first end to the connector such

that each of the legs are foldable about the first end toward the deployment member in the first configuration and unfold away from the deployment member about the first end to position a second end spaced apart from the deployment member in the second configuration, the dimension of the second configuration being measured between two of the second ends of the legs.

6. The apparatus of claim 1, wherein the expansion element comprises a spring having the second configuration when unrestricted by external compressive force.

7. The apparatus of claim 1, wherein the retrieval mechanism comprises a flexible deployment member and wherein the expansion element comprises a substantially rigid, elongate body fixed to one end of the deployment member and two tabs fixed to opposite ends of the elongate body, the elongate body having a length greater than the outer dimension of the puncture member and the tabs having a maximum outer dimension less than an inner diameter of the lumens of the deflation tube and the puncture member.

8. The apparatus of claim 1, wherein the retrieval mechanism further comprises a tube with an outer dimension less than an inner diameter of the deflation tube lumen, the expansion element being provided at an end of the retrieval mechanism tube and comprising an elongate, tubular body with a plurality of slits cut parallel to a longitudinal axis of the tubular body and extending about the circumference of the tubular body and further comprising a wire within the retrieval mechanism tube and attached to the tubular body at a point distal to the retrieval mechanism tube, whereby tension applied to the wire causes the tubular body to expand from the first configuration to the second configuration by drawing the attachment point of the tubular body toward the retrieval mechanism tube.

9. The apparatus of claim 1, wherein the retrieval mechanism further comprises a flexible deployment member and the expansion element comprises a connector attached to the deployment member and a wall having a first end attached to the connector and a second end proximate to the deployment member, wherein the connector has a maximum dimension less than the inner diameter of the puncture member lumen and wherein the wall is formed to be rolled about the deployment member into the first configuration, the first configuration being substantially cylindrical, and to expand outward into the second configuration when

unrestricted, the second configuration being frustaconical and the dimension of the second configuration being measured as the width of the wall at the second end.

10. A method for evacuating and removing a fluid-filled object positioned in a body cavity of a patient, comprising:

positioning an aspirator device in the body cavity;

piercing a wall of the fluid-filled object with the aspirator device, wherein the aspirator device comprises a tube with a lumen;

sliding a retrieval mechanism in the lumen of the aspirator tube, wherein the retrieval mechanism comprises an expansion element having a deployed configuration greater in size than an outer diameter of the aspirator tube and wherein the sliding comprises extending the expansion element at least partially out of the lumen and into the pierced object;

expanding the expansion element to the deployed configuration; and

withdrawing the retrieval mechanism and the aspirator device from the body cavity, wherein during the withdrawing the expansion element contacts an inner surface of the object wall forcing the object to be removed from the body cavity with the retrieval mechanism.

11. The method of claim 10, wherein the retrieval mechanism comprises a flexible deployment member attached to the expansion element, and the method further comprises prior to the withdrawing, applying tension on the deployment member to force the expansion member to abut a tip fixed on the aspirator tube.

12. The method of claim 11, wherein the applying of the tension results in the expanding of the expansion element to the deployed configuration.

13. The method of claim 11, wherein the applying of the tension causes the expansion element to contact the inner surface of the object wall and to sandwich a portion of the wall between the expansion element and the tip of the aspirator tube.

14. The method of claim 10, wherein the expansion element is selected from the group consisting of a T-bar, an object inflated in the expanding of the expansion element, a folding anchor device that unfolds to the deployed configuration, a spring element that returns to an at-rest position during the expanding of the expansion element, an elongate body with tabs attached at opposite ends, a tubular body with slits cut in a spaced-apart

manner, parallel to a longitudinal axis of the tubular body and with a tensioning wire attached to an end of tubular body, and a funnel collapsible into a cylinder and expandable into a frustaconical shape in the deployed configuration.

15. An intragastric balloon removal system, comprising:

means for deflating a fluid-filled object positioned in a body cavity of a patient to pierce a wall of an intragastric balloon, wherein the deflating means comprises a tube with a lumen extending through the balloon wall; and

a retrieval mechanism comprising a flexible deployment member and an expansion element attached to an end of the deployment member, wherein the retrieval mechanism is slidably movable in the lumen of the deflating means and the expansion element is adapted to be in a first configuration facilitating movement of the retrieval mechanism in the lumen and in a second configuration larger than the lumen when the expansion element is within a cavity defined by the balloon wall, whereby the expansion element contacts an inner surface of the object wall when the deflating means and retrieval mechanism are withdrawn from the body cavity.

16. The system of claim 15, wherein the expansion element comprises an elongate body attached to an end of the deployment member, wherein the body has a width less than an inner diameter of the lumen and a length larger than an outer diameter of the deflating means tube.

17. The system of claim 15, wherein the retrieval mechanism further comprises a tube with an outer diameter less than an inner diameter of the deflating means tube lumen and with a lumen and wherein the expansion element is attached proximal to one end of the retrieval mechanism tube and in fluid communication with the lumen, the expansion element comprising an elastic shell adapted for inflation to an outer diameter greater than an outer diameter of the deflating means tube, whereby outer surfaces of the inflatable shell contact inner surfaces of the balloon wall when the retrieval mechanism is removed from the body cavity.

18. The system of claim 15, wherein the expansion element comprises a connector attached to the deployment member and one or more legs attached at a first end to the connector such that each of the legs are foldable about the first end toward the deployment

member for positioning within the deflation means tube lumen and pivotable away from the deployment member about the first end to position a second end of each of the legs spaced apart from the deployment member in the deployed configuration.

19. The system of claim 15, wherein the expansion element comprises a spring having the deployed configuration when unrestricted by external compressive force.

20. The system of claim 15, wherein the expansion element comprises a substantially rigid, elongate body fixed to one end of the deployment member and two tabs fixed to opposite ends of the elongate body, the elongate body having a length greater than an outer dimension of the deflating means tube and the tabs having a maximum outer dimension less than an inner diameter of the lumen of the deflating means tube.

21. The system of claim 15, wherein deployment member comprises a tube with an outer dimension less than an inner diameter of the deflating means tube lumen, the expansion element being provided at an end of the retrieval mechanism tube and comprising an elongate, tubular body with a plurality of slits cut parallel to a longitudinal axis of the tubular body and extending about the circumference of the tubular body and further comprising a wire within the retrieval mechanism tube and attached to the tubular body at a point distal to the retrieval mechanism tube, whereby tension applied to the wire causes the tubular body to expand from the first configuration to the second configuration by drawing the attachment point of the tubular body toward the retrieval mechanism tube.

22. The system of claim 15, wherein the expansion element comprises a connector attached to the deployment member and a wall having a first end attached to the connector and a second end proximate to the deployment member, wherein the connector has a maximum dimension less than the inner diameter of the deflating means tube lumen and wherein the wall is collapsible about the deployment member to be received within the deflating means tube lumen and expandable outward into the deployed configuration when unrestricted, the second configuration being frustaconical with a base at the second end of the wall.

23. The system of claim 15, wherein the expansion element comprises outer surfaces for contacting the inner surface of the object wall, the outer surfaces being modified to increase friction between the outer surfaces and the inner surface.

24. The system of claim 23, wherein the modification is performed by blasting, etching, or adding coatings.

25. The system of claim 23, wherein the inner surface of the object wall is modified to increase the friction between the outer surfaces of the expansion element and the inner surface.

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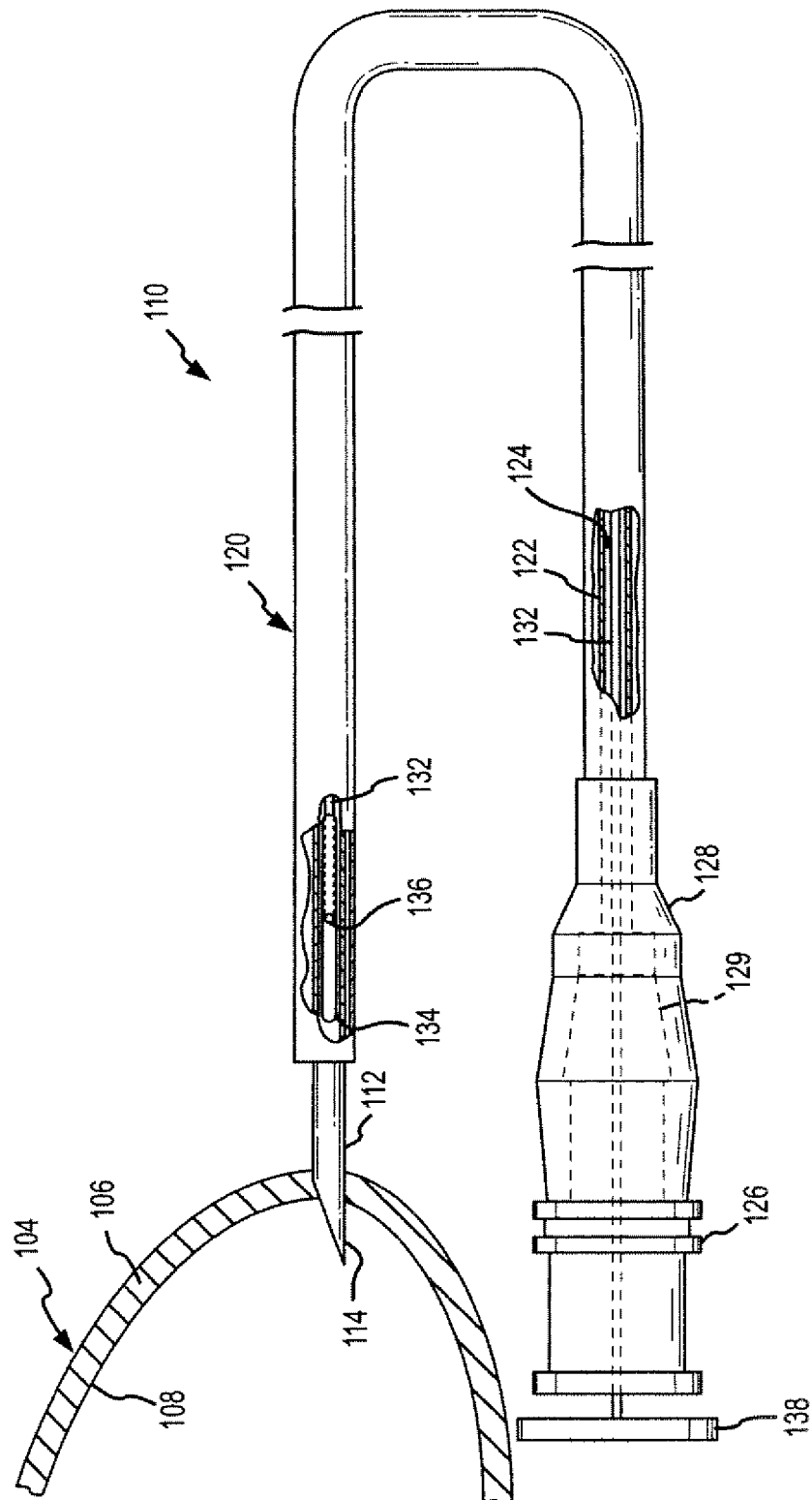


FIG. 1

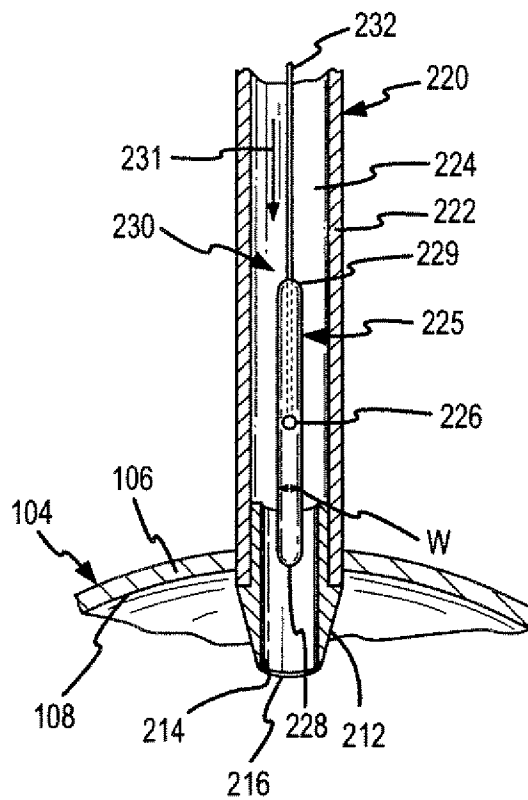


FIG. 2A

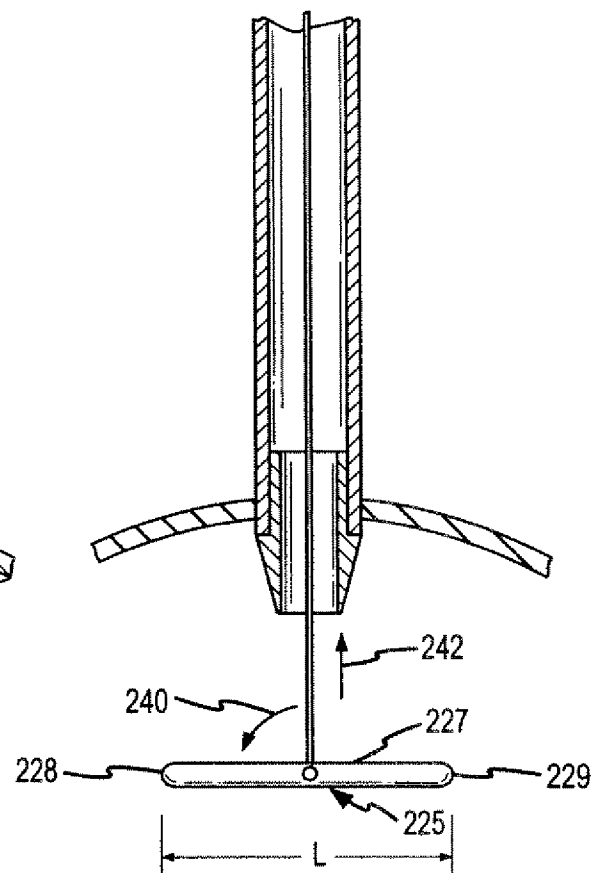


FIG. 2B

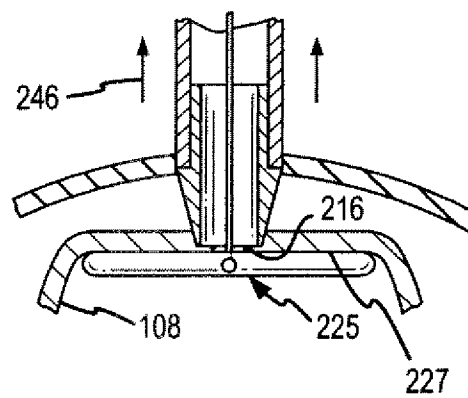


FIG. 2C

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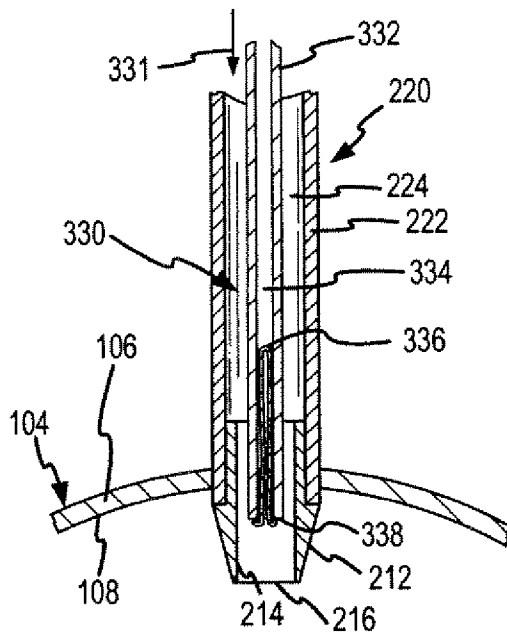


FIG. 3A

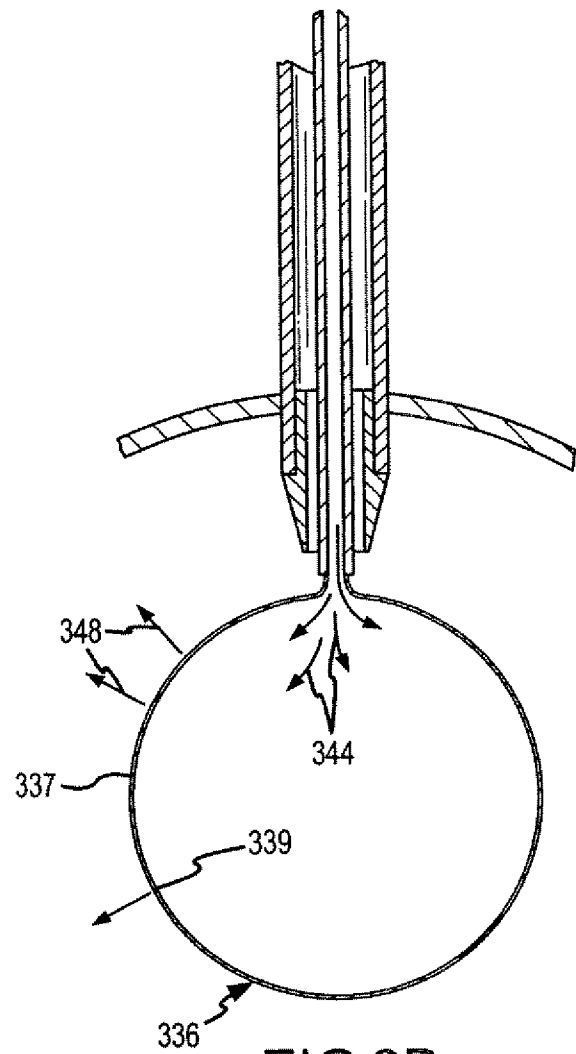


FIG. 3B

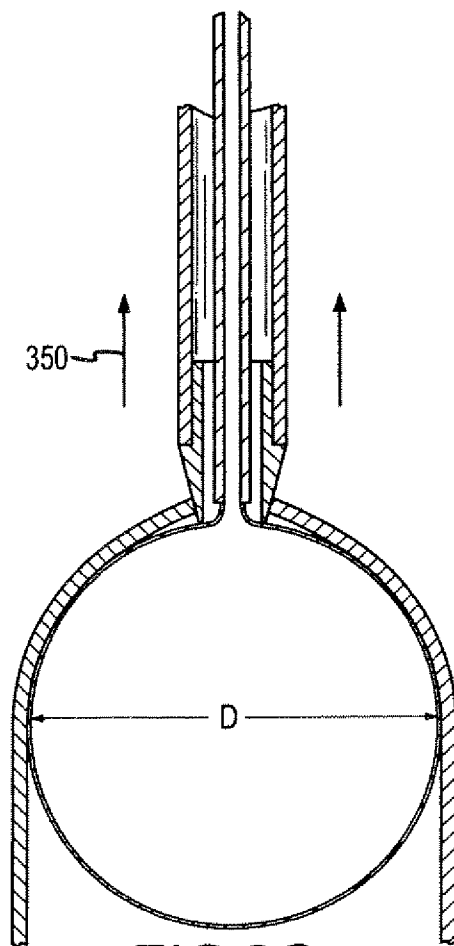


FIG. 3C

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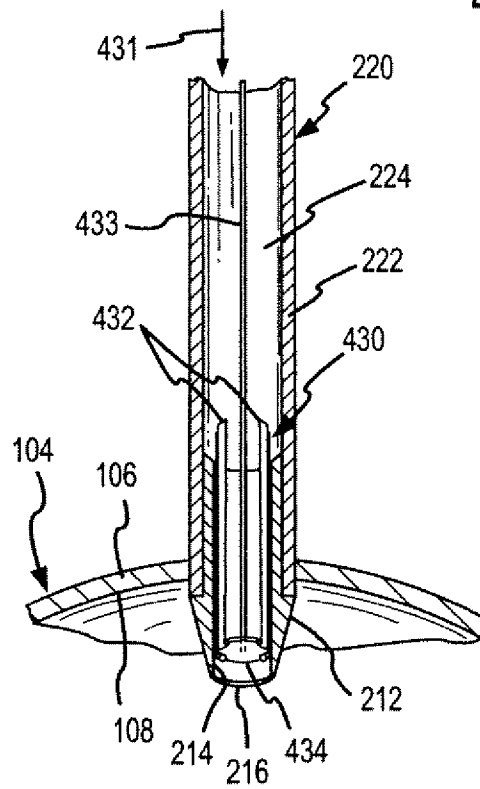


FIG.4A

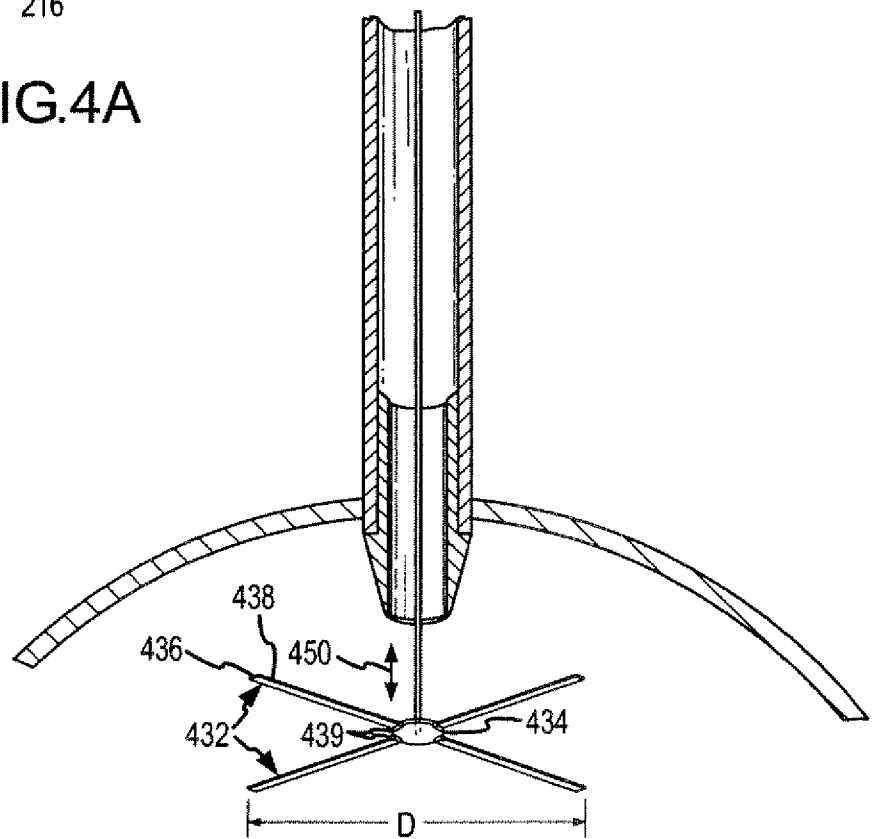


FIG.4B

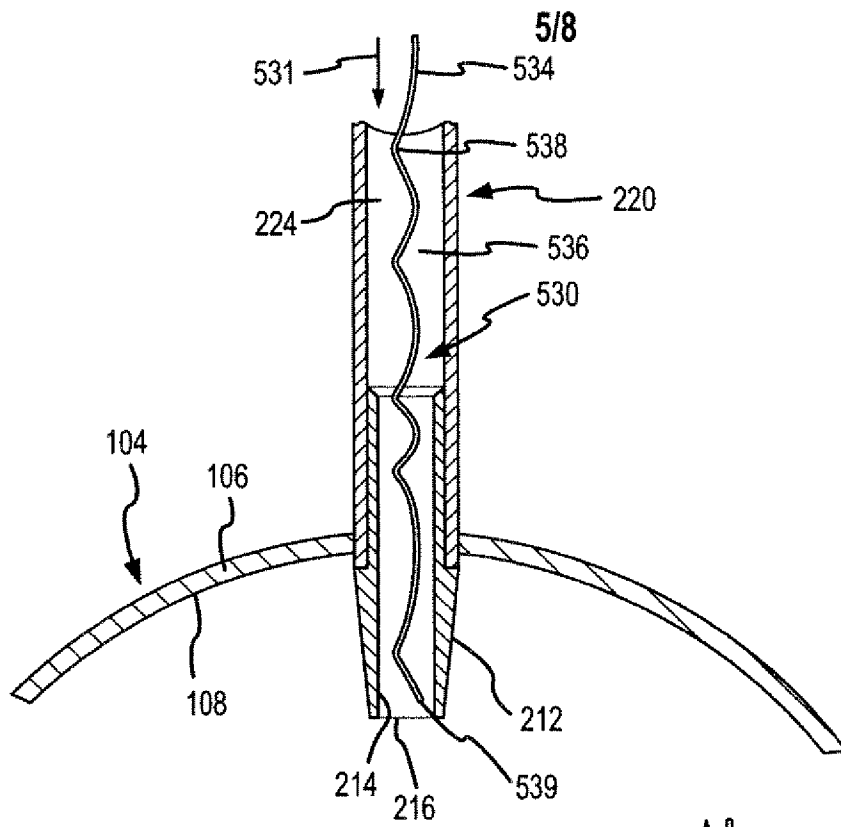


FIG. 5A

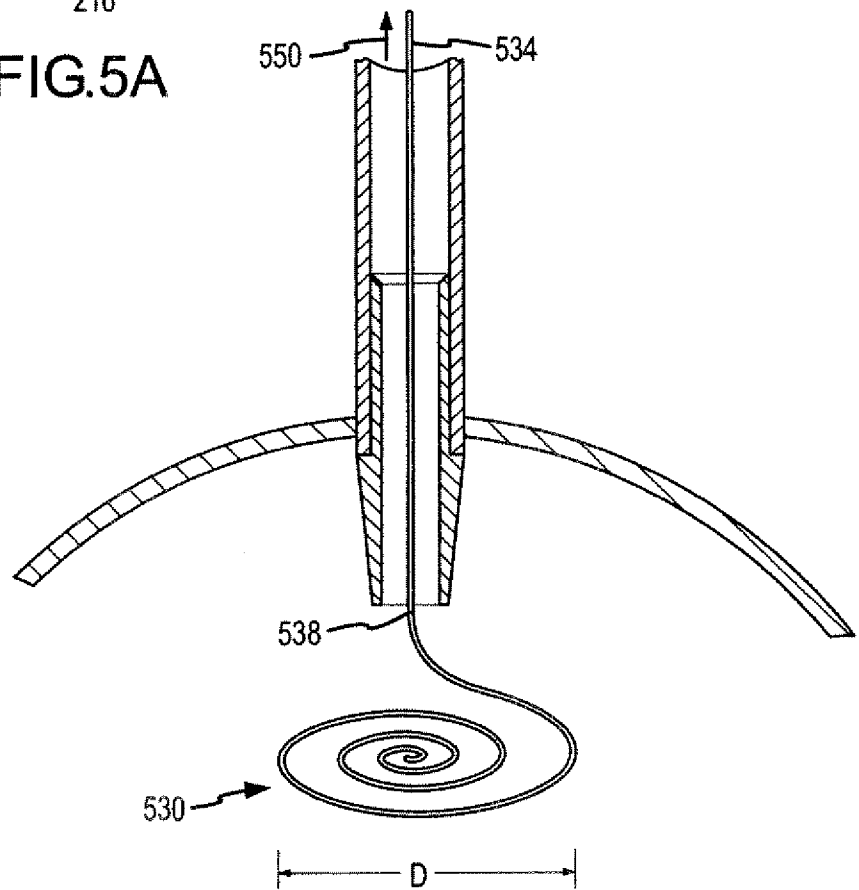


FIG. 5B

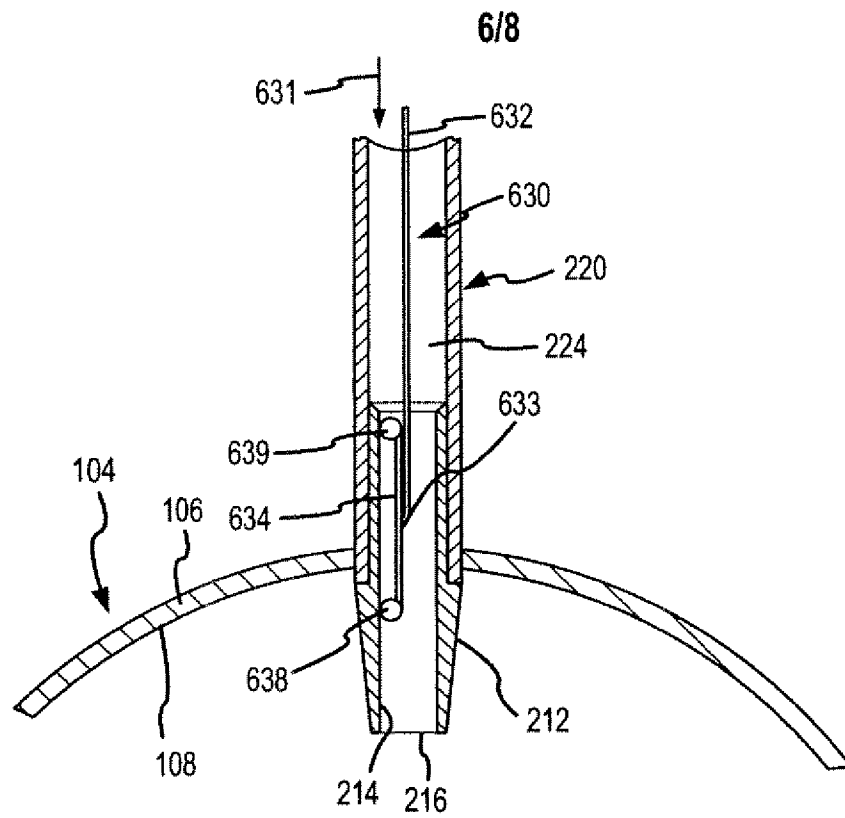


FIG.6A

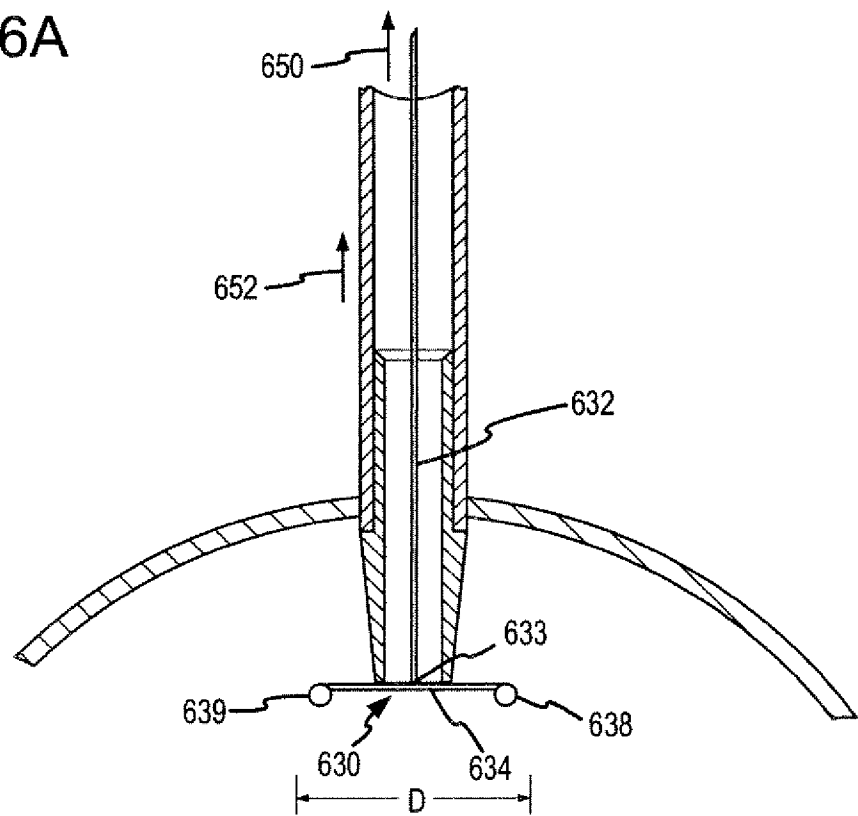


FIG.6B

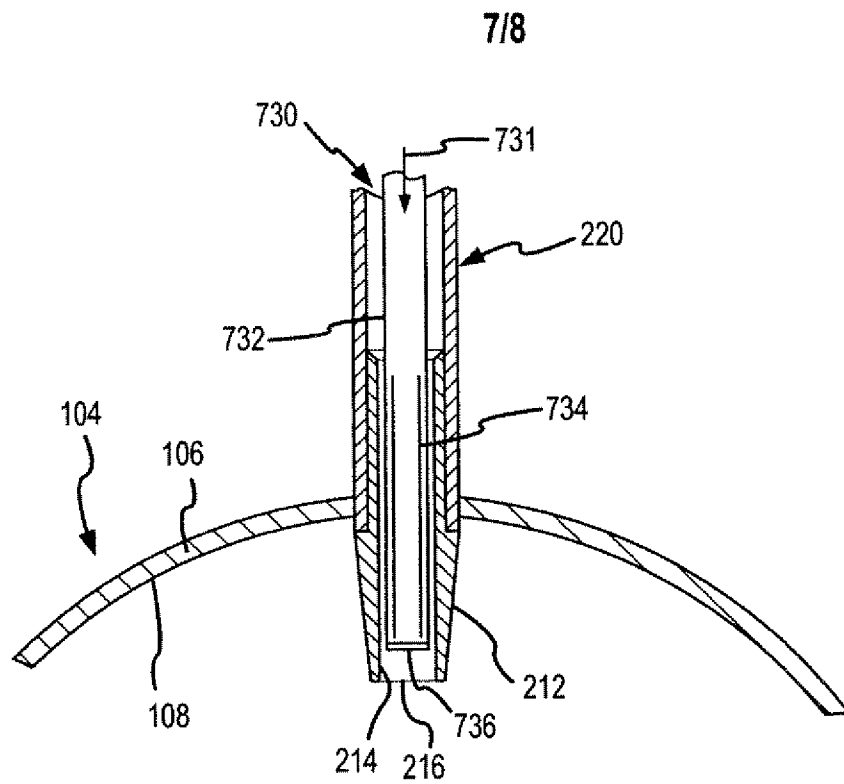


FIG. 7A

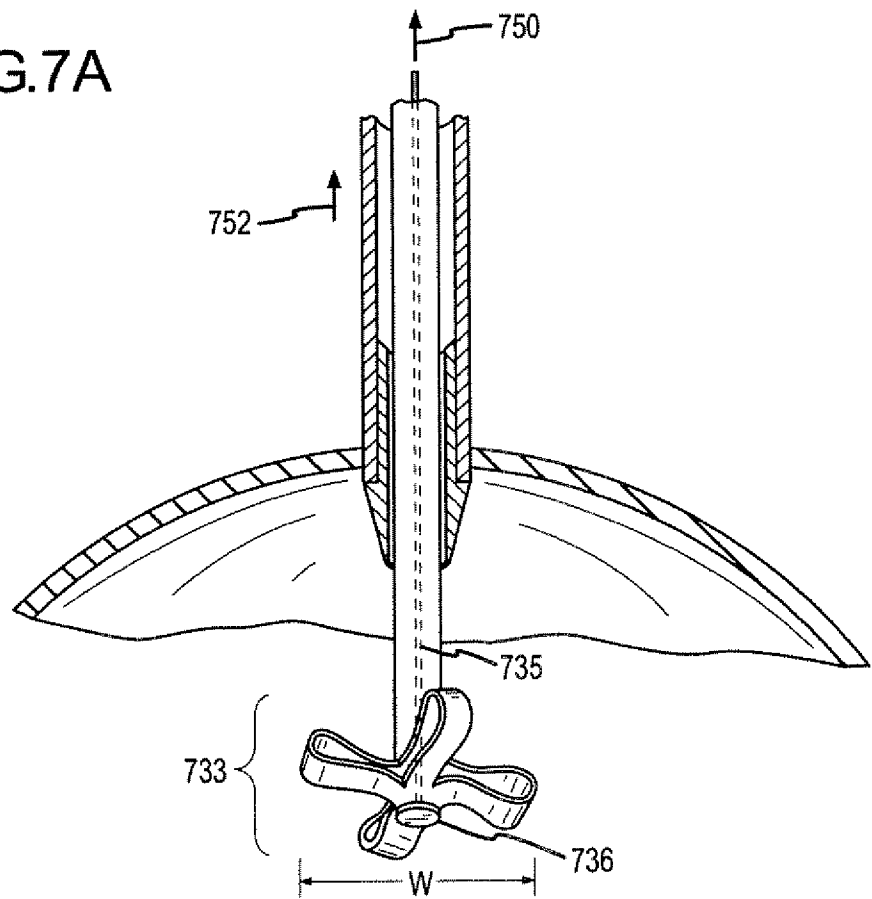


FIG. 7B

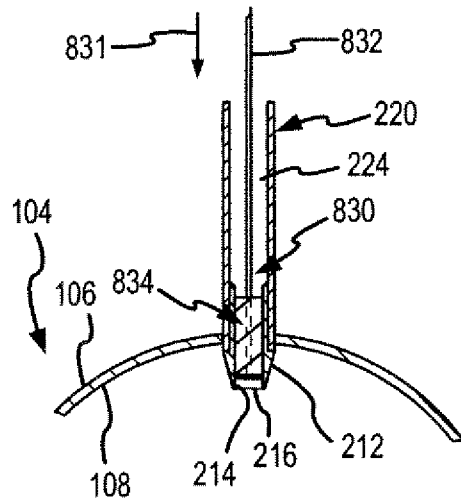


FIG. 8A

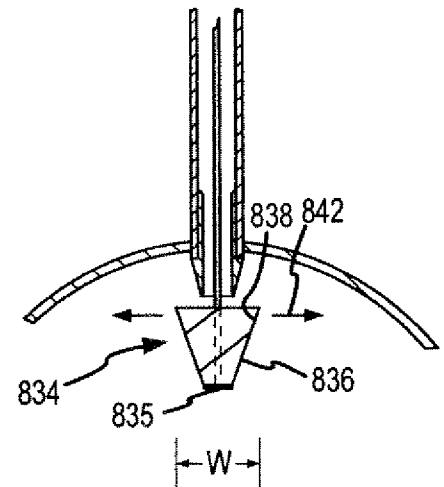


FIG. 8B

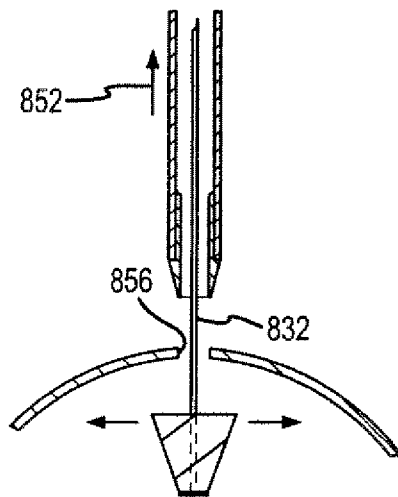


FIG. 8C

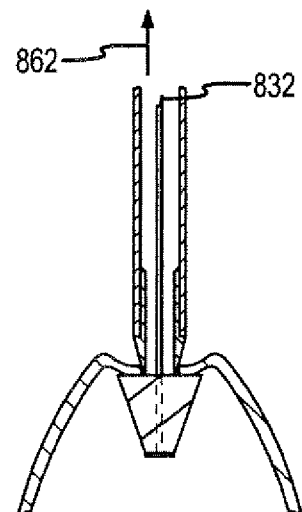


FIG. 8D

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2007/070785

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61F5/00

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)

A61F A61B

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	WO 03/055419 A (CIE EUROP D ETUDE ET DE RECH D [FR]; PAGANON PASCAL [FR]) 10 July 2003 (2003-07-10) the whole document	1-3,5,8, 15,16, 18,21 4,6,7, 17,19, 20,23,24
P,X	WO 2006/090018 A (CIE EUROP D ETUDE ET DE RECH D [FR]; PAGANON PASCAL [FR]; RICOL JEAN-P) 31 August 2006 (2006-08-31) the whole document	1,2,5, 15,18, 23-25
X A	US 4 598 699 A (GARREN LLOYD R [US] ET AL) 8 July 1986 (1986-07-08) the whole document	1,5,6 15,18
	----- -/-- -----	



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

& document member of the same patent family

Date of the actual completion of the international search

5 November 2007

Date of mailing of the international search report

14/11/2007

Name and mailing address of the ISA/

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Fax: (+31-70) 340-3016

Authorized officer

Jameson, Patricia

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2007/070785

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	JP 63 279854 A (OLYMPUS OPTICAL CO) 16 November 1988 (1988-11-16) abstract -----	1,15
Y	figures 1-7 -----	4,6,17, 19
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Y	figures 1-11 -----	7,20
A	WO 02/35980 A (SATIETY INC [US]; TORRE ROGER DE [US]; SCOTT J STEPHEN [US]; HOWELL TH) 10 May 2002 (2002-05-10) page 12, line 4 - page 14, line 2; figures 7-14,19 page 24, line 1 - page 25, line 20; figures 21-24 -----	1,3,6, 15,17,19
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2007/070785

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 10-14
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2007/070785

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