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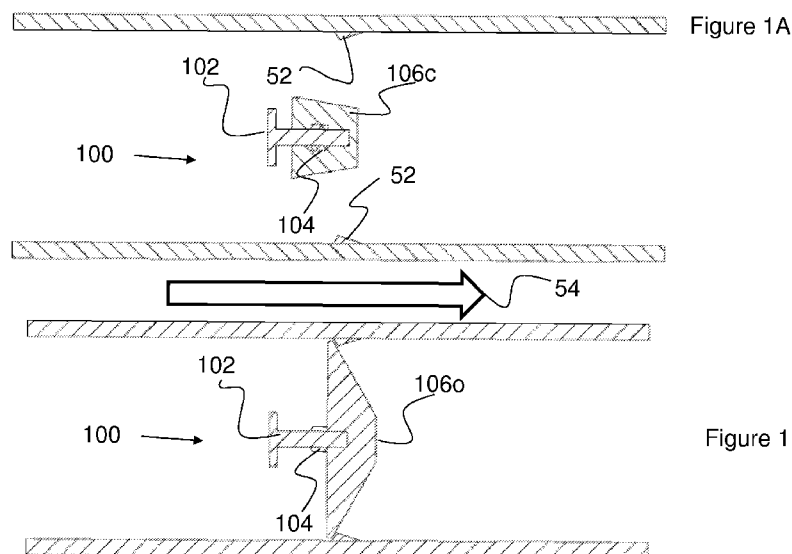
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(54) Title: AN IMPLATABLE PROSTHETIC VALVE CONTROLLABLE WITH A PIEZOELECTRIC MEMS ACTUATOR



(57) Abstract: The present invention relates to prosthetic valve that is controllable with a piezoelectric actuator and in particular to a prosthetic valve that may be implanted within a support structure at an implantation site therein providing a controllable passageway about the implantation site.

AN IMPLATABLE PROSTHETIC VALVE CONTROLLABLE WITH A PIEZOELECTRIC MEMS ACTUATOR

FIELD OF THE INVENTION

The present invention relates to prosthetic valve that is controllable with a piezoelectric actuator and in particular to a prosthetic valve that may be implanted within a support structure at an implantation site therein providing a controllable passageway about the implantation site.

BACKGROUND OF THE INVENTION

Systems in general require adequate control and in particular flow control be it in the form of fluid flow control such as a hydraulic system or electric flow control in an electrical system. Similarly organic and biological systems require flow control about its various systems. For example a biological system such as the human body consists of many areas that require flow control and gaiting of flowing fluids such as the circulatory system, respiratory system, nervous system, endocrine system, digestive system, gastro-intestinal system and the renal-urinary system. Such flow control may be realized at a great variety levels within individual systems and between each such system that are in fluid communication with one another. Similarly, such flow control may be realized at the macro, organ level such as with the heart and the circulatory system or at the micro, cellular level, for example a synapse.

For example the heart and circulatory system requires flow control where valves are extensively used in various locations to control and direct blood flow throughout the circulatory system. Circularity valves include both venous valves that are disposed within the veins to control the blood flow and prevent retrograde blood flow through the veins. The other major form of circulatory valves includes heart valves that located within the heart to control blood flow through the heart.

The mitral valve and tricuspid valve are unidirectional heart valves that separate the atria left and right respectively, from the corresponding heart ventricles. These valves have a distinct anatomical and physiological structure,

having two (mitral, bicuspid) or three (tricuspid) sail-like leaflets connected to a subvalvular mechanism of strings (chordae tendinae) and papillary muscles forming a part of the heart's ventricular shape, function and size.

The heart has four chambers: the right and left atria, and the right and left ventricles. The atria receive blood and then pump it into the ventricles, which then pump it out into the body through the aorta.

The synchronous pumping actions of the left and right sides of the heart constitute the cardiac cycle. The cycle begins with a period of ventricular relaxation, called ventricular diastole. The cycle ends with a period of ventricular contraction, called ventricular systole.

The heart has four valves that ensure that blood does not flow in the wrong direction during the cardiac cycle; that is, to ensure that the blood does not back flow from the ventricles into the corresponding atria, or back flow from the arteries into the corresponding ventricles. The valve between the left atrium and the left ventricle is the mitral valve. The valve between the right atrium and the right ventricle is the tricuspid valve. The pulmonary valve is at the opening of the pulmonary artery. The aortic valve is at the opening of the aorta.

The opening and closing of heart valves occur primarily as a result of pressure differences. For example, the opening and closing of the mitral valve occurs as a result of the pressure differences between the left atrium and the left ventricle. During ventricular diastole, when ventricles are relaxed, the venous return of blood from the pulmonary veins into the left atrium causes the pressure in the atrium to exceed that in the ventricle. As a result, the mitral valve opens, allowing blood to enter the ventricle. As the ventricle contracts during ventricular systole, the intraventricular pressure rises above the pressure in the atrium and pushes the mitral valve shut.

As noted above, these valves feature a plurality of leaflets connected to chordae tendinae and papillary muscles, which allow the leaflets to resist the high pressure developed during contractions (pumping) of the left and right ventricles. In a healthy heart, the chords become taut, preventing the leaflets from being forced into the left or right atria.

Prolapse is a term used to describe the condition wherein the coaptation edges of each leaflet initially may coapt and close, but then the leaflets rise higher and the edges separate and the valve leaks. This is normally prevented by contraction of the papillary muscles and the normal length of the chords. Contraction of the papillary muscles is simultaneous with the contraction of the ventricle and serves to keep healthy valve leaflets tightly shut at peak contraction pressures exerted by the ventricle.

Valve malfunction can result from the chords becoming stretched, and in some cases tearing. When a chord tears, the result is a flailed leaflet. Also, a normally structured valve may not function properly because of an enlargement of the valve annulus pulling the leaflets apart. This condition is referred to as a dilation of the annulus and generally results from heart muscle failure. In addition, the valve may be defective at birth or because of an acquired disease, usually infectious or inflammatory.

Diseases of the valves can cause either narrowing (stenosis) or dilatation (regurgitation, insufficiency) or a combination of those, of the valve. Surgical treatment for repair or replacement of the valves includes an open-heart procedure, extracorporeal circulation and, if replaced, a complete resection of the diseased valve.

Currently all available surgical options for valve replacement involve open heart surgery; although minimally invasive methods for valve replacement are more desirable, such methods are still in the early stages of development.

The gastrointestinal system ('GI') also utilized a variety of native valves in the form of sphincters to control movement of fluids within the GI system, for example the cardiac sphincter gating flow between the esophagus and stomach while the pyloric sphincter control flow from the stomach onto the duodenum. Other examples of such GI valve control sphincters include the anus. The GI system further includes ducts to control and direct flow thereabout, for example the hepatic duct, pancreatic duct, common bile duct.

The urinary system also utilized a variety of native valves in the form of ducts such as the ureters, urinary bladder, urinary sphincter, urethral sphincter.

Each of the above described native valves requires continuous and meticulous control of the native valves to ensure quality of life. Unfortunately, with time native valves fail and require replacement often due to disease states such as with valve prolapsed or atherosclerosis in the cardiovascular system. Other disease states such as cancer for example within the GI system require removal of a great portion of the GI therein losing the native valves. Currently solutions for such situations include colostomy bags and ports.

A common problem relating to flow control within the urinary system includes incontinence where control over the urinary bladder and native sphincter is lost due to loss of muscle tone, with no solutions offered.

SUMMARY OF THE INVENTION

The present invention overcomes the drawbacks of the background art by providing, in at least some embodiments, an implantable prosthetic valve that is controllable with a MEMS motor to compensate for a damaged valve or replace a damaged valve and one that is small in size facilitating minimally invasive insertion of the prosthetic valve.

A preferred embodiment of the present invention provides an implantable prosthetic valve controllable with a piezoelectric MEMS actuator that most preferably may be implanted and/or placed and/or disposed about any anatomy or portion of anatomy requiring flow control. Optionally and preferably an implantable prosthetic valve according to the present invention may for example be placed to replace and/or compensate for and/or complement and/or concertedly work with, in and/or about any native anatomy for example including but not limited to a passageway, lumen, lumen within an organ, alveoli, valve, vessel, blood vessel, artery, vein, ventricle, atria, tube, ureter, urethra, synapse, bladder, sphincter, body cavity, trachea, bronchi, bodily lumen, duct, gastrointestinal lumen and/or body to provide gaiting control through the passageway.

An optional embodiment of the present invention provides for placing and/or implanting a prosthetic valve may be placed within the circulatory system

to replace native heart valves and/or venous valves throughout the circulatory system.

Within the context of this application the term skirt refers to a thin film and/or tissue forming the valve closure provided for replacing the native leaflet valve anatomy.

Within the context of this application the term vascular valve refers to any venous valves or heart valves for example including but not limited to, the mitral, bicuspid, tricuspid valves, pulmonary, valve, aortic valve.

Within the context of this application the term MEMS interchangeably utilized to refer to a micro-electromechanical system and therein identifying a small scale actuator and/or motor, similarly the terms MEMS may also refer to a nano-motor or the like nano-scale actuator.

Within the context of this application the term passageway may be used to refer to any passageway and or lumen through which flow control is required and that may be controlled with a prosthetic valve according to optional embodiments of the present invention. A passageway and/or lumen may for example include but is not limited to at least one or more of a lumen, lumen within an organ, alveoli, valve, vessel, blood vessel, artery, vein, ventricle, atria, tube, ureter, urethra, synapse, bladder, sphincter, body cavity, trachea, bronchi, bodily lumen, duct, gastrointestinal lumen and/or body to provide gating control through the passageway.

An optional embodiment of the present invention provides for a prosthetic valve for complementing and/or replacing a native valve comprising a piezoelectric actuator fit with and/or associated with a valve skirt.

Optionally the prosthetic valve may further comprise a valve regulator for mitigating the valve skirt and the piezoelectric actuator for controlling the position of the valve skirt about the shaft of the piezoelectric actuator.

Optionally the prosthetic valve wherein the valve skirt comprises a supportive frame structure provided from memory shape polymers, plastics and/or

alloys chosen from the group consisting of nitinol, stainless steel 316, polymers, BrCu alloy, CoCr alloy, and any combination thereof.

Optionally the prosthetic valve wherein the valve skirt may be provided from biocompatible materials selected from the group consisting of flexible film, biological tissue, pericardia tissue, synthetic materials.

Optionally the prosthetic valve may be configured to associate with the valve annulus or valve anatomy.

Optionally the prosthetic valve may be configured to associate with a stent or supportive mesh structure.

Optionally the prosthetic valve may be configured to associate with a stent or supportive mesh structure at the valve annulus or valve anatomy.

Optionally the valve skirt of the prosthetic valve may be shaped according to the native valve anatomy.

Optionally the valve skirt of the prosthetic valve may be configured to have a static shape.

Optionally the valve skirt of the prosthetic valve may be configured to have an open configuration and a closed configuration.

Optionally the valve skirt the prosthetic valve may be configured to toggle between the open and closed configuration with a valve regulator disposed about the shaft of the piezoelectric actuator.

Optionally the prosthetic valve may be disposed relative to the direction of blood flow.

Optionally the prosthetic valve may be configured to provide an open valve position and a closed valve position by selectively activating the piezoelectric actuator about the actuator base.

Optionally the prosthetic valve placed to replace a native venous valve or heart valve.

Optionally the prosthetic valve may be placed adjacent to a native venous valve.

Optionally the prosthetic valve may be placed at a native venous valve to complement the native venous valve and/or flow.

Optionally the prosthetic valve may be utilized to introduce a venous valve in a vein devoid of a native venous valve.

Optionally the prosthetic valve may be introduced within an organ and/or tissue.

Optionally the prosthetic valve introduced within at least one or more organ selected from the group consisting of brain, liver, heart, lung, kidney, pancreases, spleen, GI tract, or a combination thereof.

Optionally the prosthetic valve may be provided in a plurality of sizes, for example length and/or diameter to fit within the appropriate and/or intended anatomy as previously described. Optionally the prosthetic valve may be customized to fit a specific anatomy for example including but not limited to a passageway, lumen, lumen within an organ, alveoli, cardiac valve, vessel, blood vessel, artery, vein, ventricle, atria, tube, ureter, urethra, synapse, bladder, sphincter, body cavity, trachea, bronchi, bodily lumen, duct, or the like.

Optionally and preferably the prosthetic valve may be provided with a length from about 10 mm (millimeters) to about 16 mm (millimeters). Optionally the prosthetic valve may be provided with a length from about 5 mm (millimeters) to about 20 mm (millimeters). Optionally the prosthetic valve may be provided with a length from about up to about 30 mm (millimeters).

Optionally and preferably the prosthetic valve may be provided with a diameter from about 3mm to about 6mm. Optionally the prosthetic valve may be provided with a diameter of about 3mm or about 4mm or about 5mm or about 6mm. Optionally the prosthetic valve may be provided with a diameter from about 1mm up to about 10mm.

Optionally and preferably the prosthetic valve may further comprise a sensor module. Optionally and preferably the sensor module may comprise at least one and more preferably a plurality of sensors. Most preferably sensor module and/or individual sensors disposed therein may be in communication with actuator and/or actuator control module and/or valve prosthesis control module.

More preferably sensor module comprises at least two or more sensors disposed about the prosthetic valve assembly, most preferably about the valve seat,

therefore most preferably providing to a first sensor disposed before and/or anterior and/or proximal to the valve seat and a second sensor disposed about after and/or posterior and/or distal to the valve seat.

Optionally sensor module may comprise a plurality of optional sensors for example including but not limited to temperature sensor, pressure sensor, flow sensor, pH sensor, on/off sensor, any combination thereof or the like. Optionally sensor module may comprise at least two of the same sensor about the valve seat.

Optionally the sensor module may be disposed within a supportive mesh and/or valve house, or the like.

Optionally and preferably the sensor module provides for flow control through the prosthetic valve assembly. Most preferably sensor data provide for determining the flow pressure. Optionally and preferably sensor data may provides for determining and/or facilitating the function of the valve control module to depict valve positioning for example including but not limited to fully open, partially open, closed or any optional valve position therebetween,

An optional embodiment of the present invention provides for prevention of retrograde blood flow within the circulatory system.

An optional embodiment of the present invention provides for the treatment of related brain disease for example including but not limited to Parkinson's and/or Alzheimer's by introducing venous valves to veins disposed within the brain.

An optional embodiment of the present invention may provide for urinary and/or fecal incontinence control, wherein an implantable valve is disposed about the required anatomy within the GI tract and/or urinary tract. For example, a prosthetic valve assembly according to the present invention may be utilized to complement the anal sphincter in order to provide for controllable gating for fecal incontinence. Optionally, an optional prosthetic valve assembly according to the present invention may be placed within the urinary system for example to complete urinary sphincter and urinary bladder to gain control over urinary incontinence.

An optional embodiment of the present invention may provide for flow control about the GI system, for example about the upper GI tract such as the esophagus, cardiac sphincter and/or stomach in order to gate and/or control food intake.

An optional embodiment of the present invention may provide for flow control about the GI system, for example about the lower GI tract for example the large intestine to replace and/or compensate for native valves lost to removal of portions of the large intestine during colonectomy.

An optional and preferred piezoelectric linear actuator and/or motor utilized within the valve assembly of the present invention most preferably comprises a piezoelectric or electrostrictive substrate, with an electrode provided on each of both surfaces of the piezoelectric or electrostrictive substrate; an elastic body, attached and/or coupled or otherwise associated with one surface or each of both surfaces of the piezoelectric or electrostrictive substrate; a movable shaft coupled at an end thereof, to the elastic body or the piezoelectric or electrostrictive substrate attached to the elastic body, the movable shaft being operated in conjunction with the piezoelectric or electrostrictive substrate such that the moveable shaft displaces and/or moves a load and/or a movable body (regulator) along the movable shaft;

Although the present application provides description and embodiments that are specific to a piezoelectric MEMS actuator and/or motor, however the scope of the present invention is not limited to a piezoelectric MEMS actuator or the specific piezoelectric actuator described. Embodiments of the present invention may be adapted to function with and/or utilize other forms of MEMS motor and/or nano motor or the like sufficiently small motors with the embodiments of the present invention.

Although the present application provides description and embodiments describe a specific application relating to the cardiovascular system and use of an implantable prosthetic valve. However, the present invention is not limited to such cardiovascular applications as the implantable prosthetic valve may be disposed

within any organ, organ system, passageway in the human or animal body providing for prosthetic flow control about an implantation site. Optionally and preferably the valve assembly according to the present invention may be utilized with various biological passageway applications for example including but not limited to organ, vessel, blood vessels, arteries, veins, tube, bladder, sphincter, passageway and/or body to provide gaiting control through the passageway.

Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. The materials, methods, and examples provided herein are illustrative only and not intended to be limiting.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of the preferred embodiments of the present invention only, and are presented in order to provide what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the invention. In this regard, no attempt is made to show structural details of the invention in more detail than is necessary for a fundamental understanding of the invention, the description taken with the drawings making apparent to those skilled in the art how the several forms of the invention may be embodied in practice.

In the drawings:

Figures 1A-D show a schematic illustrative diagram of an optional valve according to an optional embodiment of the present invention, Figure 1A showing a cross-section of the open valve configuration, Figure 1B showing a cross-section of the closed valve configuration, Figure 1C showing a perspective see through view of the open valve configuration, Figure 1D showing a perspective see through view of the closed valve configuration,

Figure 2 provides an exploded view of the valve of Figures 1A-D according to an optional embodiment of the present invention.

Figures 3A-B show a schematic illustration of MEMS piezoelectric actuator controlling the opening and closure of the valve according to the present invention;

Figures 4A-B show a schematic non-limiting illustration of an optional valve skirt according to optional non-limiting embodiments of the present invention; Figure 4A shows the valve skirt in a closed configuration when the valve is open and Figure 4B shows the valve skirt in its open configuration when the valve is closed.

Figures 5A-C show variable views of a schematic non-limiting illustration of a valve regulator according to an optional embodiment of the present invention mediating between valve skirt and piezoelectric actuator.

Figures 6A-D show a schematic illustrative diagram of an optional valve according to an optional embodiment of the present invention, Figure 6A showing a cross-section of the open valve configuration, Figure 6B showing a cross-section of the closed valve configuration, Figure 6C showing a perspective see through view of the open valve configuration, Figure 6D showing a perspective see through view of the closed valve configuration,

Figure 7 provides an exploded view of the valve of Figures 6A-D according to an optional embodiment of the present invention;

Figures 8A-B show a schematic illustrative diagram showing a perspective view of an optional prosthetic valve assembly according to an optional embodiment of the present invention, Figure 8A showing a cross-section of the open valve configuration and Figure 8B showing a cross-section of the closed valve configuration;

Figures 9A-B show a schematic illustrative diagram of an optional prosthetic valve assembly according to an optional embodiment of the present invention, Figure 9A showing a cross-section of the open valve configuration and Figure 9B showing a cross-section of the closed valve configuration;

Figure 10 provides an exploded view of the prosthetic valve assembly shown in Figures 8-9, according to an optional embodiment of the present invention;

Figures 11A provides a close up cross section view of an optional supportive mesh structure according to an optional embodiment of the present invention; and

Figures 11B provides a close up perspective view of an optional valve regulator according to an optional embodiment of the present invention; and

Figure 12 shows a flowchart of an optional method according to the present invention depicting an optional method for delivering the prosthetic valve according to the present invention; and

Figure 13 shows a schematic bloc diagram of a system according to the present invention.

DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

The present invention provides, in at least some embodiments, a valve prosthesis and method of insertion thereof which supports and functionally complements the mitral and/or tricuspid valve without replacing it.

The principles and operation of the present invention may be better understood with reference to the drawings and the accompanying description. The following figure reference labels are used throughout the description to refer to similarly functioning components are used throughout the specification hereinbelow.

- 50 tissue section
- 52 native valve annulus;
- 54 flow arrow;
- 100 valve assembly;
- 101 valve assembly;
- 102 piezoelectric actuator;
- 102b actuator base;
- 102c actuator coupler;
- 102p actuator control module (power supply and electronics);

- 102s actuator shaft;
- 104 valve regulator;
- 104c valve regulator coupler;
- 106 valve prosthesis skirt;
- 106c valve prosthesis skirt closed configuration;
- 106f valve prosthesis skirt frame;
- 106o valve prosthesis skirt open configuration;
- 108 valve prosthesis skirt;
- 108d valve prosthesis distal configuration;
- 108f skirt frame
- 108h valve prosthesis head portion;
- 108p valve prosthesis proximal configuration;
- 108t valve prosthesis tail portion;
- 110 valve assembly;
- 110s valve assembly seat;
- 112 valve assembly housing;
- 112a radial support structure;
- 112b radial support structure;
- 112d distal end of housing structure;
- 112p proximal end of housing structure;
- 112r housing recess;
- 114 valve assembly plunger;
- 116 intra-valve sensor module;
- 116s pressure sensors;
- 116w wiring
- 118 actuator cover;
- 120 Auxiliary device;
- 140 Valve actuating assembly;
- 150 Valve System.

Referring now to the drawings, Figures 1A-D are schematic illustrative diagrams of an optional valve assembly 100 within a tissue 50, according to an optional embodiment of the present invention.

Figures 1A, 1C show an open state of valve assembly 100 while Figures 1B, 1D depict a closed state of valve assembly 100. Optionally and preferably valve 100 may be placed within any passageway and/or anatomy for example a portion of the circulatory system most preferably the veins and/or heart. Optionally valve 100 may be placed within the vasculature of any organ, organ system or tissue of the body for example including but not limited to the brain, heart, liver, lungs, kidney, spleen or the like in any combination thereof.

Optionally valve assembly 100 may be placed within the cardiovascular system to replace a native heart valve or venous valve.

Optionally valve assembly 100 may be placed within any passageway and/or anatomy to introduce a prosthetic valve in a location devoid of a native valve.

Optionally valve assembly 100 may be placed within any passageway and/or anatomy adjacent to a native valve, therein complementing the native valve.

Optionally valve assembly 100 may be placed within the cardiovascular system adjacent to a native venous valve to complement a native venous valve.

Figure 1A, 1B show prosthetic valve assembly 100 that is optionally and preferably deployed within anatomy and/or tissue 50 preferably about the valve anatomy optionally and preferably the valve annulus 52 and /or valve seat for example when valve assembly is disposed within supportive mesh stent-like structure (Figures 8-11). Optionally valve assembly 100 may be deployed within tissue 50 and coupled and/or otherwise associated with a stent or a stent-like supportive mesh structure (not shown, Figures 8-11) disposed about the valve anatomy, optionally and preferably the valve annulus.

Optionally and preferably prosthetic valve according to the present invention may be realized in the form of a heart valve, accordingly assembly 100

may be oriented within tissue 50 relative to the blood flow, for example as depicted by directional arrow 54.

Optionally and most preferably prosthetic valve assembly 100 comprises a MEMS piezoelectric actuator 102, valve regulator 104 and valve prosthesis skirt 106. Most preferably MEMS piezoelectric actuator 102 and valve regulator 104 concertedly provide for opening and closing valve assembly 100 about and/or within anatomy 50 and most preferably about annulus 52. Most preferably valve 100 may be toggled from an open formation, Figure 1A to a closed formation Figure 1B by activating piezoelectric actuator 102 about its base 102b to displace valve regulator 104 distally along actuator shaft 102s therein causing prosthesis skirt 106 to expand from a closed profile 106c to an open profile 106o. Most preferably control actuator 102 is provided with power and electronics control module 102p, most preferably associated about base 102b. Most preferably actuator 102 may be controlled with actuator control module 102p most preferably comprising power supply and electronics required to energize assembly 100, within an implanted passageway.

Optionally actuator 102 may be provided in a plurality of sizes to fit within the appropriate and/or intended anatomy for example a venous valve within the cardiovascular system. Optionally actuator 102 may be constructed to have a shaft 102s length of up to about 16 mm (millimeters) more preferably having a shaft 102s length from about 6 mm (millimeters) to about 16 mm (millimeters). Optionally and most preferably shaft 102s may be configured to have a length from about 10 mm (millimeters) to about 16 mm (millimeters).

Optionally valve assembly 100 and/or actuator 102 may be constructed to have a diameter of up to about 30 mm (millimeters) and more preferably from about 4mm (millimeters) to about 30 mm (millimeters).

Optionally skirt 106 may be provided from biocompatible material optionally and preferably features a flexible film optionally and preferably made of biocompatible biological tissue such as pericardia tissue but may also optionally feature one or a combination of synthetic materials. Optionally, skirt 106 may be provided with a frame structure 106f defining its shape both in the closed

formation 106c and open formation 106o. For example, skirt 106 may assume a conic section shape having a trapezoid cross section having a narrow base as depicted in the closed formation 106c, Figure 4A; while skirt 106 may assume an open umbrella like shape having a conic section shape having a trapezoid cross section having a wide base as depicted in the open formation 106o, Figure 4B.

Optionally skirt frame 106f may be provided from a plurality of biocompatible materials for example memory shape polymers, plastics and/or alloys including but not limited to nitinol, stainless steel 316, polymers, BrCu alloy, CoCr alloy, any combination thereof, or the like.

Optionally skirt 106 may be constructed to have a diameter to correspond to fit within the implanted location. Optionally skirt 106 may be constructed to have a diameter of up to about 40 mm (millimeters), optionally and preferably up to about 30 mm (millimeters) and more preferably from about 4mm (millimeters) to about 30 mm (millimeters).

Most preferably skirt 106 may be provided from durable biocompatible materials that may be implanted and kept in place for an extended period of time.

Optionally and preferably as piezoelectric actuator 102 is activated about its base portion 102b with control module 102p causes valve regulator 104 to displace about shaft portion 102s to open and/or close skirt 106, for example in a manner similar to opening and closing an umbrella therein providing for a valve 100 that may be provided in the open (Figure 1A, 1C) and closed (Figure 1B, 1D) formation.

Most preferably actuator 102 is controllable with appropriate electronic providing an electric current to base portion 102b to activate actuator 102, with control module 102p. Optionally piezoelectric actuator 102 may be activated by pressure differentials across the natural valve anatomy 54.

Figure 1C provides a perspective see through view of Figure 1A, showing the open valve configuration of valve 100 wherein skirt 106 assumes the closed formation 106c. Figure 1D shows a perspective see through view of Figure 1B, showing the closed valve configuration.

Figure 2 provides an exploded view of valve assembly 100 of Figures 1A-B according to an optional embodiment of the present invention, showing actuator 102, valve regulator and skirt 106 that may be disposed within a portion of an anatomy 50 or a supportive mesh or stent-like structure and/or housing. Optionally and preferably assembly 100 is placed relative to a flow 54 most preferably provided to control flow 54 through a passageway.

Figures 3A-B show a schematic illustration of MEMS piezoelectric actuator 102 providing for controlling the opening and closure of an optional valve assembly 100 about anatomy 50 or supportive mesh or stent-like structure/housing most preferably about a valve seat or valve annulus 54. Most preferably actuator 102 comprises a piezoelectric base 102b connected to shaft 102s, for example as described in US Patent No. 7,498,719 to Piotr et al, incorporated herein by reference as if fully set forth. Most preferably shaft 102s is moveable therein providing for displacing valve regulator 104 along the shaft. Most preferably shaft 102s is moved when an input pulse is applied to base 102b, via control module 102p, causing base 102b to vibrate in a direction controllable by the input pulse applied thereto via control module 102p. Preferably when base 102b vibrates such vibration is transmitted to shaft 102s and thereafter to regulator 104 therein providing for linear motion of the regulator 104 about shaft 102s.

Optionally and preferably base 102b includes at least one piezoelectric or electrostrictive substrates that is coupled with an elastic body. Most preferably base 102b includes an elastic body sandwiched between two piezoelectric or electrostrictive substrates. Optionally and preferably individual piezoelectric substrates may be individually activated to control the direction of movement of regulator 104 about shaft 102s.

Figure 4A-B show a schematic non-limiting illustration of an optional valve skirt 106, as previously described. Figure 4A shows the valve skirt 106 in a closed configuration 106c when valve 100 is open and Figure 4B shows the valve skirt 106 in its open configuration 106o when the valve 100 is closed.

Optionally skirt 106 may be provided from biocompatible material optionally and preferably features a flexible film optionally and preferably made of biocompatible biological tissue such as pericardia tissue but may also optionally feature one or combination of synthetic materials. Optionally, skirt 106 may be provided with a frame structure 106f defining its shape both in the closed formation 106c and open formation 106o. For example, skirt 106 may assume a conic section shape having a trapezoid cross section having a narrow base as depicted in the closed formation 106c, Figure 4A; while skirt 106 may assume an open umbrella like shape having a conic section shape having a trapezoid cross section having a wide base as depicted in the open formation 106o, Figure 4B.

Optionally skirt frame 106f may be provided from a plurality of biocompatible materials for example memory shape polymers, plastics and/or alloys including but not limited to nitinol, stainless steel 316, polymers, BrCu alloy, CoCr alloy, any combination thereof, or the like.

Most preferably skirt 106 may be provided from durable biocompatible materials that may be implanted and kept in place for an extended period of time.

Figures 5A-C show variable views of a schematic non-limiting illustration of a valve regulator 104 according to an optional embodiment of the present invention mediating between valve skirt 106 and piezoelectric actuator 102. Further optional valve regulator 104 is shown and described with respect to figure 11B.

Figures 6A-D show a schematic illustrative diagram of an optional valve assembly 101 comprising an optional valve skirt 108 and piezoelectric actuator 102. Most preferably valve assembly 101 functions similarly to valve assembly 100 as described with respect to Figures 1-5. Valve skirt 108 may be provided in the form of an arrow like shape having a head portion 108h and a tail portion 108t. Valve skirt 108 may optionally and preferably provided with static dimensions and/or shape within an anatomy 50 or housing or mesh stent-like support structure. Therefore most preferably skirt 108 does not open and/or close as described and

shown with valve skirt 106, Figure 1-5. Optionally head portion 108h may be customized to a particular valve anatomy 50 and or valve annulus 54 or valve seat within a valve housing or mesh stent-like support structure so as to provide for appropriate closure.

Optionally skirt 108 may be provided from biocompatible material optionally and preferably features a flexible film optionally and preferably made of biocompatible biological tissue such as pericardia tissue but may also optionally feature one or combination of synthetic materials. Optionally, skirt 108 may be provided with a frame structure 108f that optionally and preferably may be provided with a static shape configured to mitigate with annulus 52.

Optionally skirt frame 108f may be provided from a plurality of biocompatible materials for example memory shape polymers, plastics and/or alloys including but not limited to nitinol, stainless steel 316, polymers, BrCu alloy, CoCr alloy, any combination thereof, or the like.

Most preferably skirt 108 may be provided from durable biocompatible materials that may be implanted and kept in place for an extended period of time.

Most preferably valve skirt 108 may be configured to close valve annulus 52 by displacing skirt 108 distally about shaft 102s toward annulus 52 therefore providing the closed configuration of valve assembly 101, as shown in Figure 6B, 6D. As previously described skirt 108 may be displaced about actuator 102 in particular about shaft 102s by activating at least one or more piezoelectric substrate of base 102b, as previously described. Optionally and preferably the closed valve 101 position may be provided by displacing skirt 108 distally about shaft 102s toward annulus 52 and/or stent or mesh-like supportive structure, for example as shown in Figure 6B and 6D. An open valve 101 configuration may preferably be achieved by displacing skirt 108 proximally about shaft 102s toward base 102b and away from annulus 52 and/or stent or mesh-like supportive structure, for example as shown in Figure 6A and 6C.

Figure 7 provides an exploded view of valve assembly 101 as shown in Figures 6A-D. Most preferably skirt 108 associates with valve actuator 102

wherein shaft 102s may be associated with and/or fits into the lumen of tail portion 108t.

Now referring to Figures 8-1 that show varying views of an optional valve assembly 110 according to an optional and preferred embodiment of the present invention. Valve assembly 110 comprising valve actuating assembly 140 disposed within housing 112. Most preferably valve actuating assembly 140 comprises actuator 102, valve regulator 104, valve plunger 114 and valve skirt cover 118. Optionally valve assembly 110 may further comprise sensor module 116, most preferably disposed within and/or about and/or associated with housing 112.

Figure 8A shows a perspective see-through view of valve assembly 110 in the open configuration. Most preferably valve assembly 110 provides for flow control and/or gating through a valve assembly housing 112. Most preferably valve assembly is disposed within a housing 112 that may optionally and preferably be realized in the form of a stent and/or stent like mesh support structure that may be implanted or otherwise associated and/or disposed within an organ, vessel, tube, bladder, sphincter, passageway and/or body to provide gating control through the passageway.

Most preferably valve assembly 110 comprises, housing 112, piezoelectric actuator 102, valve regulator 104, valve plunger 114 and valve skirt cover 118. Optionally and preferably assembly 110 may further comprise a sensor module 116.

Most preferably piezoelectric actuator 102 and valve regulator 104 work concertedly, as previously described, to open or close valve assembly 110 about housing 112, within an implanted passageway. Most preferably actuator 102 may be controlled with actuator control module 102p most preferably comprising power supply and electronics required to energize assembly 110, about an implanted passageway.

Most preferably MEMS piezoelectric actuator 102 and valve regulator 104 concertedly provide for opening and closing valve assembly 110 about housing 112 within an implanted passageway. Most preferably valve assembly 110 may be toggled from an open formation, Figure 8A and 9A, to a closed formation Figure

8B and 9B by activating piezoelectric actuator 102 with control module 102p, about base 102b to displace valve regulator 104 distally along actuator shaft 102s. Most preferably activating actuator 102 and displacing regulator 104 causes valve plunger 114 to contract from an open and/or narrow profile and/or stretched conformation 114o (Figures 8A, 9A) to a closed and/or short and/or expanded wide profile 114c, (Figures 8B, 9B).

Valve plunger 114 is optionally and preferably provided in the form of a spring, stent-like mesh, mesh or the like, most preferably to allow for it to be deformed into both an open conformation as shown in Figure 8A, 9A and a closed conformation as shown in Figure 8B, 9B. Optionally valve skirt may be provided from pliable, elastic, super-elastic materials, alloys, nitinol, or the like. Most preferably plunger 114 may be stretched to form the open configuration 114o and contracted to form the closed configuration 114c.

Most preferably control of plunger 114 is provided with valve regulator 104 that may be coupled and/or otherwise associated with plunger 114. Optionally and preferably regulator 104 may be associated with plunger 114 via a regulator connector and/or coupler 104c, Figure 11B. Most preferably movement of regulator 104 provides for the movement of plunger 114 about the length of shaft 102s.

Optionally, in its open configuration plunger 114o is configured to have a cylindrical and/or elongated tube profile, at least partially fitting over shaft 102s. Optionally, in its closed configuration plunger 114c is configured to have an elliptical and/or ovoid and/or prolate spheroid type shape, having a central portion with a large diameter and two end portions with smaller diameter, therein configured to have a football, and/or egg type shape.

Most preferably actuator cover 118 provides for covering actuator 102, valve regulator 104, valve assembly plunger 114, providing a continuous stretchable surface optionally and preferably providing for and acting as a protective layer over the length of actuator 102 and plunger 114. Optionally cover 118 may be provided from pliable, semi-pliable, flexible, semi-flexible, stretchable

biocompatible materials for example including but not limited to film, silicone, polymers or the like.

Optionally and preferably assembly 110 may further comprise a sensor module 116. Optionally and preferably sensor module 116 comprise at least one and more preferably a plurality of sensors 116s in communication with actuator 102. More preferably sensor module comprises at least two or more sensors about valve assembly 110. Optionally and most preferably sensor module 116 comprises at least two pressure sensors 116s disposed about valve assembly 110 about valve seat 110s. Most preferably at least two pressure sensors 116s provide for measuring two pressure levels about valve seat 110s most preferably before and after valve seat 110s. Optionally sensor module 116 may comprise a plurality of optional sensors for example including but not limited to temperature sensor, pressure sensor, flow sensor, pH sensor, on/off sensor, or the like.

Most preferably sensor module 116 is functionally coupled with actuator 102 for example by wired 116w and/or wireless means. Optionally and preferably sensor module 116 are rendered functional and/or energized and/or powered with the electronics and control utilized by actuator 102. Optionally sensor module 116 may be provided with independent power supply. Most preferably sensor module 116 contributes data provided to control of valve assembly 110 by providing necessary data for gating control. Optionally sensor module 116 may be functionally coupled with actuator 102, through coupler 102c, for example provided in the form of an electrode or the like conducting material.

For example, valve assembly 110 may be provided with at least two pressure sensors 116s that are coupled by wire 116w to actuator control module 102p. Most preferably pressure sensor allows for determining pressure differentials between the at least two pressure sensors to determine when and/or how much to open or close valve 110 about valve seat 110s. Most preferably a control module 102p reads both pressure sensor and accordingly decides how to gate the sensor.

Figure 8B shows a perspective see-through view of valve assembly 110 in the closed configuration. Most preferably assembly 110 is closed based on a control signal from actuator control module 102p. Most preferably such a control signal activates actuator shaft 102 to displace valve regulator 104 distally in order to maneuver plunger 114 from the open configuration 114o to the closed configuration 114c. Most preferably in the closed configuration plunger 114c does provide for any flow through valve body and/or housing 112. Most preferably plunger 114 in the closed configuration is provides a radius with housing 112 about which flow is blocked. Optionally in the closed configuration plunger 114c is configured to minimize any retrograde flow through the valve housing 112.

Housing 112, shown in greater detail in Figure 11A, is most preferably provided in the form of a stent and/or a stent-like supportive mesh structure. Housing 112 may optionally be configured to have a low profile configuration so as to allow for delivery, for example in the way a stent is delivery.

Optionally housing 112 is configured to have a low profile and/or delivery configuration that surrounds and/or encases and/or envelopes actuator assembly 102. Optionally housing 112 may be collapsed about actuator 102, therein assuming a low profile and/or delivery configuration, and expanded, for example with a semi-compliant balloon to assume a final and/or functional configuration.

Optionally cover 118 may be utilized during the delivery of assembly 110 to expand housing 112 from a delivery profile and/or configuration to a functional configuration. Optionally cover 118 may be provided from pliable polymer for example in the form of a semi-compliant balloon configuration about actuator 102, therein most preferably providing for delivery of assembly 110 by radially expanding cover 118, for example with compressed air, for example in the form of a semi-compliant balloon during stent delivery, to expand housing 112 within a passageway and/or anatomy.

Optionally housing 112 comprises a first radial support member 112a and a second radial support member 112b. Optionally first support member 112a provides for coupling with actuator 112. Optionally housing 112 may comprise a recess and/or cavity 112r for receiving and/or associating with a sensor module

116, for example as shown in Figure 11A. Optionally first member 112a provides a recess for securely receiving and/or fitting with actuator 102 and control module 102p. Optionally second support member 112b may be provided for balancing and maintaining an open lumen across supporting housing 112 near the distal end 112d.

Figure 9A shows a cross-sectional view of the open valve configuration, as described with respect to Figure 8A, while showing the direction of flow with arrow 54.

Figure 9B showing a cross-section of the closed valve configuration, as described with respect to Figure 8B, while showing the direction of flow with arrow 54.

Figure 10 provides an exploded view of the prosthetic valve assembly 110 as shown and described in Figures 8-9.

Figures 11A shows a close up cross section view of housing 112 showing recess 112r optionally and preferably provided for storing and receiving sensor module 116 comprising at least one and more preferably, at least two and most preferably a plurality of sensors. Optionally, housing 112 provides an optional supportive mesh structure according to an optional embodiment of the present invention; and

Figures 11B shows a close up perspective view of an optional valve regulator 104 according to an optional embodiment of the present invention. Most preferably regulator 104 comprises a coupler 104c for coupling to valve plunger 114.

Figures 11C provides a close up perspective view of a valve plunger 114 according to an optional embodiment of the present invention, as previously described.

Figure 12 shows a flowchart of an optional method for delivering an optional prosthetic valve (100, 101, 110) to an implantation site. First in stage 1200, an implantation site is prepared prior to initiating the procedure. Optionally stage 1200 may involve configuring valve assembly 110 and housing 112 to a low profile and/or delivery configuration, for example through a catheter and/or a

guidewire as is known in the art during stent deployment, for example. Optionally the low profile and/or delivery profile of valve assembly (110, 100, 101) may be configured such that housing 112 is collapsed about and/or centered over actuator 102 most preferably about cover 118. Optionally cover 118 may be provided from pliable polymers for example in the form of a semi-compliant balloon configuration utilized to expand housing 112 radially from a delivery profile and/or configuration to a functional implanted configuration. Optionally cover 118 may be provided from pliable polymers for example in the form of a semi-compliant balloon configuration centered about actuator 102, therein most preferably providing for delivery of assembly 110 by radially expanding cover 118, for example with compressed air, for example in the form of a semi-compliant balloon utilized during stent delivery, to expand housing 112 within a passageway and/or anatomy.

Next in state 1202, valve assembly 110 is deployed onto a delivery site, wherein housing assembly 112, optionally provided in the form of a stent-like mesh, is deployed within a passageway. Optionally housing 112 may be radially expanding utilizing cover 118, as a semi-compliant balloon as previously described.

Optionally housing 112 may be delivered independent of actuator 102 assembly such that actuator assembly 102 may be coupled with housing 112 following its deployment within an anatomy, as depicted in optional stage 1204.

Optionally in stage 1204, an actuator assembly is delivered to housing 112 and coupled with actuator 102 assembly, for example about actuator support structure 112a most preferably about proximal end 112p.

Next in stage 1206 actuator assembly and optional sensors module 116 are activated about the passageway. Optionally actuator assembly 102 is configured relative to an auxiliary device providing for external and/or telemetric control of valve assembly 100/101/110.

Figure 13 shows as schematic block diagram of an optional system 150 comprising an optional valve 100,101,110 according to the present invention and

an optional auxiliary device 120 most preferably in communication with valve control module 102p. Optionally auxiliary device 120 may for example include but is not limited to smart-phone, PDA, robot, watch, mobile communication device, computer, mobile computer, or the like device comprising a display, data processing and communication modules. Optionally auxiliary device 120 may for example provide for receiving and/or displaying data relating to the functioning of valve assembly 110/100/101 or portions thereof, for example sensor module 116.

Optionally and preferably system 150 provides for remote control and/or communication and/or data exchange and/or data analysis and/or display between valve assembly 110 and an optional auxiliary device 120. Optionally system 150 may optionally be used by a user implanted with valve assembly 110 or optionally by a third party for example including but not limited to a nurse, physician, caregiver, trained technician, or the like.

Optionally auxiliary device 120 may capable of remotely activating and/or controlling and/or communicating with control module 102p to control valve actuator 102.

Optionally system 150 may provided for optionally communication between auxiliary device 120 and valve assembly 100/101/110 for example including but not limited to wired, wireless, near field, contactless, RF, optical, acoustic, ultrasound, any combination thereof or the like communication protocols or means.

While the invention has been described with respect to a limited number of embodiment, it is to be realized that the optimum dimensional relationships for the parts of the invention, to include variations in size, materials, shape, form, function and manner of operation, assembly and use, are deemed readily apparent and obvious to one skilled in the art, and all equivalent relationships to those illustrated in the drawings and described in the specification are intended to be encompassed by the present invention.

Therefore, the foregoing is considered as illustrative only of the principles of the invention. Further, since numerous modifications and changes will readily

occur to those skilled in the art, it is not described to limit the invention to the exact construction and operation shown and described and accordingly, all suitable modifications and equivalents may be resorted to, falling within the scope of the invention.

Having described a specific preferred embodiment of the invention with reference to the accompanying drawings, it will be appreciated that the present invention is not limited to that precise embodiment and that various changes and modifications can be effected therein by one of ordinary skill in the art without departing from the scope or spirit of the invention defined by the appended claims.

Further modifications of the invention will also occur to persons skilled in the art and all such are deemed to fall within the spirit and scope of the invention as defined by the appended claims.

While the invention has been described with respect to a limited number of embodiments, it will be appreciated that many variations, modifications and other applications of the invention may be made.

What is claimed is:

1. An implantable prosthetic valve assembly (100,101,110) provided for flow control through a passageway the valve assembly comprising:
 - a. a piezoelectric actuator (102) fit with a valve regulator (104) controllable with a actuator power and control module (102p) wherein said valve regulator (104) may be displaced about an actuator shaft (102s) to regulate flow through said passageway; and
 - b. wherein said valve regulator (104) provides for flow control through said passageway by manipulating a valve plunger (114) or skirt (106,108), associated therewith.
2. The prosthetic valve of claim 1 wherein said valve regulator (104) provides for controlling the position of said valve skirt (106, 108) or plunger (114) about the shaft (102s) of said piezoelectric actuator.
3. The prosthetic valve assembly of claim 1 wherein said valve plunger (114) is provided in the form of a spring, stent-like mesh, mesh having a plurality of configuration including an open configuration (114o) and a closed configuration (114c).
4. The valve assembly of claim 1 further comprising a sensor module comprising at least two or more sensors selected from the group consisting of temperature sensor, pressure sensor, flow sensor, pH sensor, on/off sensor, in any combination thereof.
5. The prosthetic valve of claim 1 wherein said valve skirt (108, 106) comprises a supportive frame structure (106f, 108f) provided from memory

shape polymers, plastics and/or alloys chosen from the group consisting of nitinol, stainless steel 316, polymers, BrCu alloy, CoCr alloy, and any combination thereof.

6. The prosthetic valve of claim 1 wherein said valve skirt (106, 108) or a valve cover (118) is provided from biocompatible materials selected from the group consisting of flexible film, biological tissue, pericardia tissue, synthetic materials.
7. The prosthetic valve of claim 1 wherein said valve is configured to associate with the valve annulus or valve anatomy (50).
8. The prosthetic valve of claim 1 wherein said valve assembly is configured to be associate with or housed within a housing (112).
9. The prosthetic valve of claim 8 wherein said housing (112) is provided in the form of a stent or supportive mesh structure.
10. The prosthetic valve of claim 8 wherein said housing is configured to have a low profile or delivery configuration.
11. The prosthetic valve of claim 7 wherein said valve assembly is configured to associate with a stent or supportive mesh structure disposed at a native valve annulus (52) or valve anatomy (50).
12. The prosthetic valve of claim 7 wherein said valve skirt (106, 108) is shaped according to the valve anatomy or valve annulus (52).
13. The prosthetic valve of claim 2 wherein said valve skirt (108) is configured to have a static shape.

14. The prosthetic valve of claim 1 wherein said valve skirt (106) is configured to have an open configuration (106o) and a closed configuration (106c), or a plurality of intermittent position therebetween.
15. The prosthetic valve of claim 1 wherein said valve is disposed relative to the direction of blood flow.
16. The prosthetic valve of claim 1 disposed within an anatomy and providing flow control within at least one system or organ selected from the group consisting of: brain, liver, heart, lung, kidney, pancreases, spleen, stomach, small intestine, large intestine, circulatory system, respiratory system, nervous system, endocrine system, digestive system, gastro-intestinal system and the renal-urinary system.
17. The prosthetic valve assembly of claim 1 wherein said valve may be disposed about a passageway selected from the group consisting of lumen, lumen within an organ, alveoli, cardiac valve, venous valve, vessel, blood vessel, artery, vein, ventricle, atria, tube, ureter, urethra, synapse, bladder, sphincter, body cavity, trachea, bronchi, bodily lumen, gastrointestinal lumen and duct.
18. The prosthetic valve of claim 1 implanted within an anatomy for complementing or compensating or replacing a native flow control anatomy.
19. The prosthetic valve of claim 15 wherein said flow control anatomy is a native valve or sphincter.
20. The prosthetic valve of claim 1 implanted within an anatomy for introducing flow control through said anatomy.

21. An implantable prosthetic valve assembly (110) provided for flow control through a passageway the valve assembly comprising:
- a. a valve assembly housing (112) provided in the form of a mesh or stent like support structure for housing a valve actuating assembly (140);
 - b. Said valve actuating assembly (140) comprising a piezoelectric actuator (102) fit with a valve regulator (104) controllable with a actuator power and control module (102p) wherein said valve regulator (104) may be displaced about an actuator shaft (102s) to regulate flow through said passageway; and wherein said valve regulator (104) manipulates a valve plunger (114) associated therewith, to assume a closed configuration (114c) or an open configuration (114o) therein providing for flow control through said passageway;
 - c. wherein said actuating assembly (140) is covered with a flexible valve cover (118) assuming an open and or closed configuration within the lumen of said housing (112).
22. The valve assembly of claim 21 wherein said assembly may be configured to have a low profile delivery configuration wherein said housing 112 is collapsed centered about said flexible valve cover (108) comprising said actuating assembly (140).
23. The valve assembly of claim 21 wherein said valve cover (118) is provided in the form of an expandable semi-compliant balloon provided for radially expanding said housing (112) from a low profile delivery configuration to a deployed functional configuration.
24. The valve assembly of claim 21 further comprising a sensor module comprising at least one or more sensors.

25. The valve assembly of claim 21 further comprising a sensor module comprising at least two sensors.
26. The valve assembly of claim 24 or 25 wherein said housing (112) comprises a recess for housing said sensor module.
27. The valve assembly of claim 24 or 25 wherein said sensor module is functionally coupled with said control module (102p).
28. The valve assembly of claim 25 wherein said sensor module comprises a sensor selected from the group consisting of temperature sensor, pressure sensor, flow sensor, pH sensor, on/off sensor, in any combination thereof.
29. The valve assembly of claim 28 wherein said at least two sensor are disposed about the valve seat wherein a first sensor is disposed anterior to said valve seat and a second sensor disposed posterior to said valve seat.
30. A system (150) providing flow control about a passageway and/or anatomy comprising: valve assembly (110, 100, 101) according to any of claims 1-29, in communication with an auxiliary device 120 about a valve control module (102p).
31. The system of claim 30 wherein said auxiliary device (120) comprises a display, process and communication modules.
32. The system of claim 31 wherein said auxiliary device 120 is selected from the group consisting of a smart-phone, PDA, robot, watch, mobile communication device, computer, mobile computer.

33. The system of claim 30 wherein said auxiliary device (120) may for example provide for receiving and/or displaying data relating to the state of said valve assembly (110/100/101).
34. The system of claim 33 wherein said auxiliary device (120) interrogates and/or displays data from at least one or more sensor disposed about a sensor module (116).
35. The system of claim 30 provides for remote control, communication and/or data exchange and/or data analysis and/or display, between valve assembly (110) and auxiliary device (120).
36. The system of claim 35 wherein said communication and remote control, may be controlled by a user comprising said valve assembly or third party.
37. The system of claim 30 wherein communication between auxiliary device (120) and valve assembly (100/101/110) with communication protocols selected from wired, wireless, near field, contactless, RF, optical, acoustic, ultrasound, or any combination thereof.
38. A method for deploying the valve assembly (100, 101) of claim 1 within an anatomy or passageway (50) the method comprising deploying a stent like support structure about the annulus (52) of said anatomy or passageway and associating said valve assembly (101,100) with said housing.
39. A method for deploying the valve assembly (110) of claim 21 within an anatomy or passageway, the method comprising:
- a. providing said valve assembly (110) in a low profile or delivery configuration wherein housing (112) is collapsed over valve actuating cover (118) wherein said actuating cover is provided in the

form of a flexible semi-compliant balloon covering the actuating assembly (140);

- b. associating said valve assembly (110) with a guidewire or delivery tool and advancing said valve assembly (110) to said anatomy or passageway;
- c. expanding said semi-compliant balloon cover (118) therein radially expanding housing (112) to securely associate within the lumen of said anatomy; and
- d. activating said actuating assembly (140) to control the flow through said anatomy via said housing (112).

40. A method for deploying the valve assembly (110) of claim 21 within an anatomy or passageway the method comprising:

- a. deploying housing (112) within the lumen of said anatomy or passageway by expanding a semi-compliant balloon; and
- b. Delivering said valve actuating assembly (140) within the lumen of housing (112) and associating said valve actuating assembly (140) with said housing (112) over the proximal end (112p) and by associating or otherwise coupling with a support structure (112a).

Figure 1A

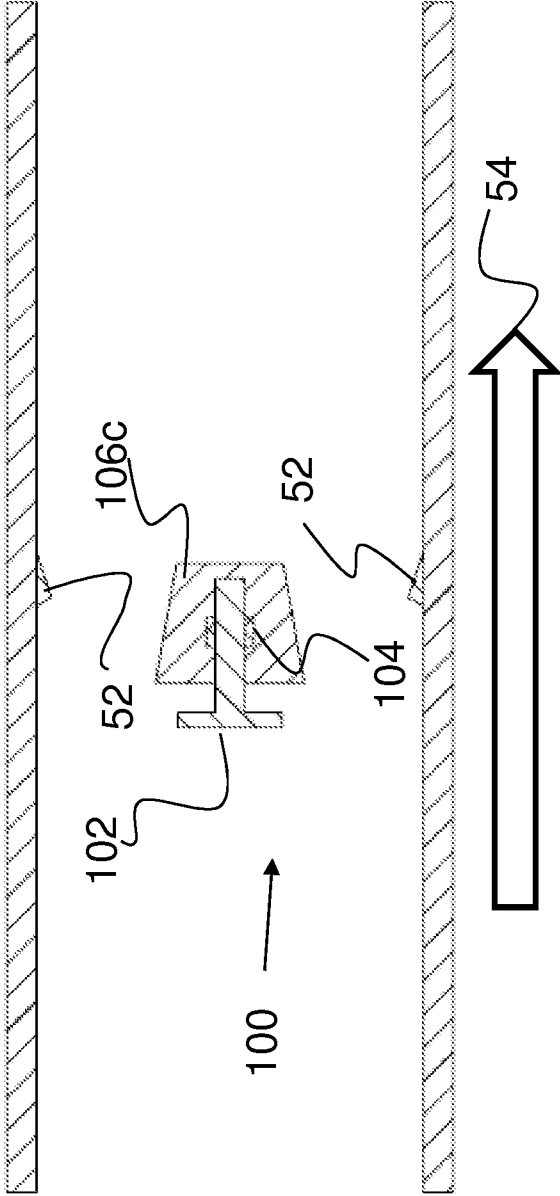


Figure 1B

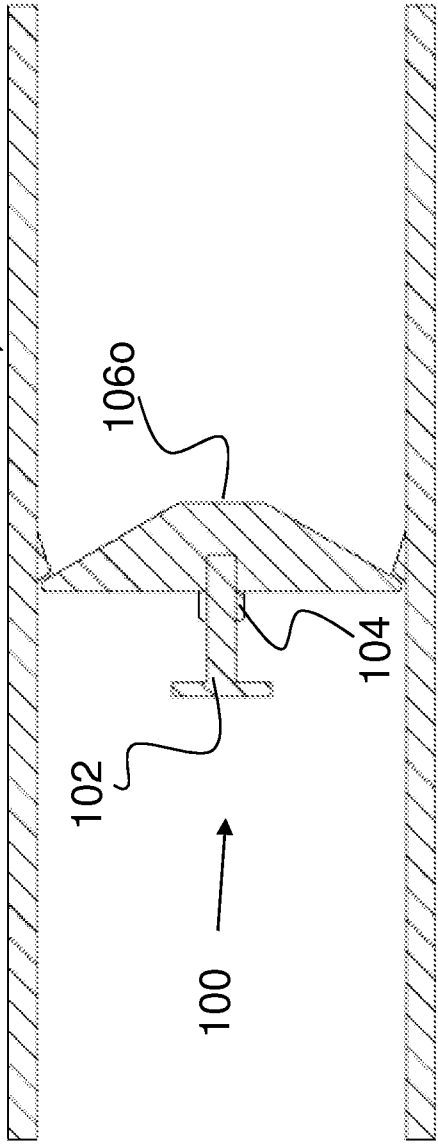


Figure
1C

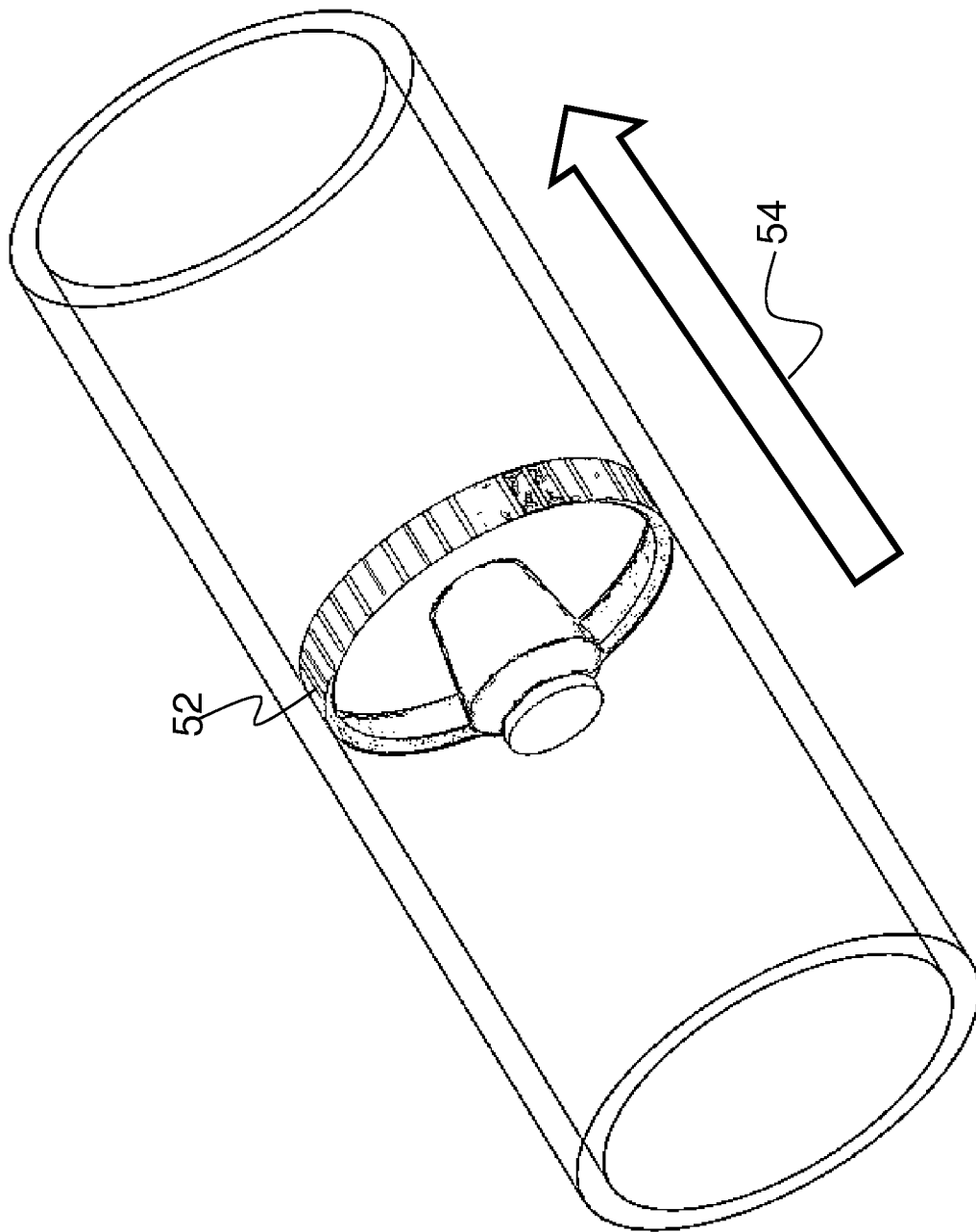
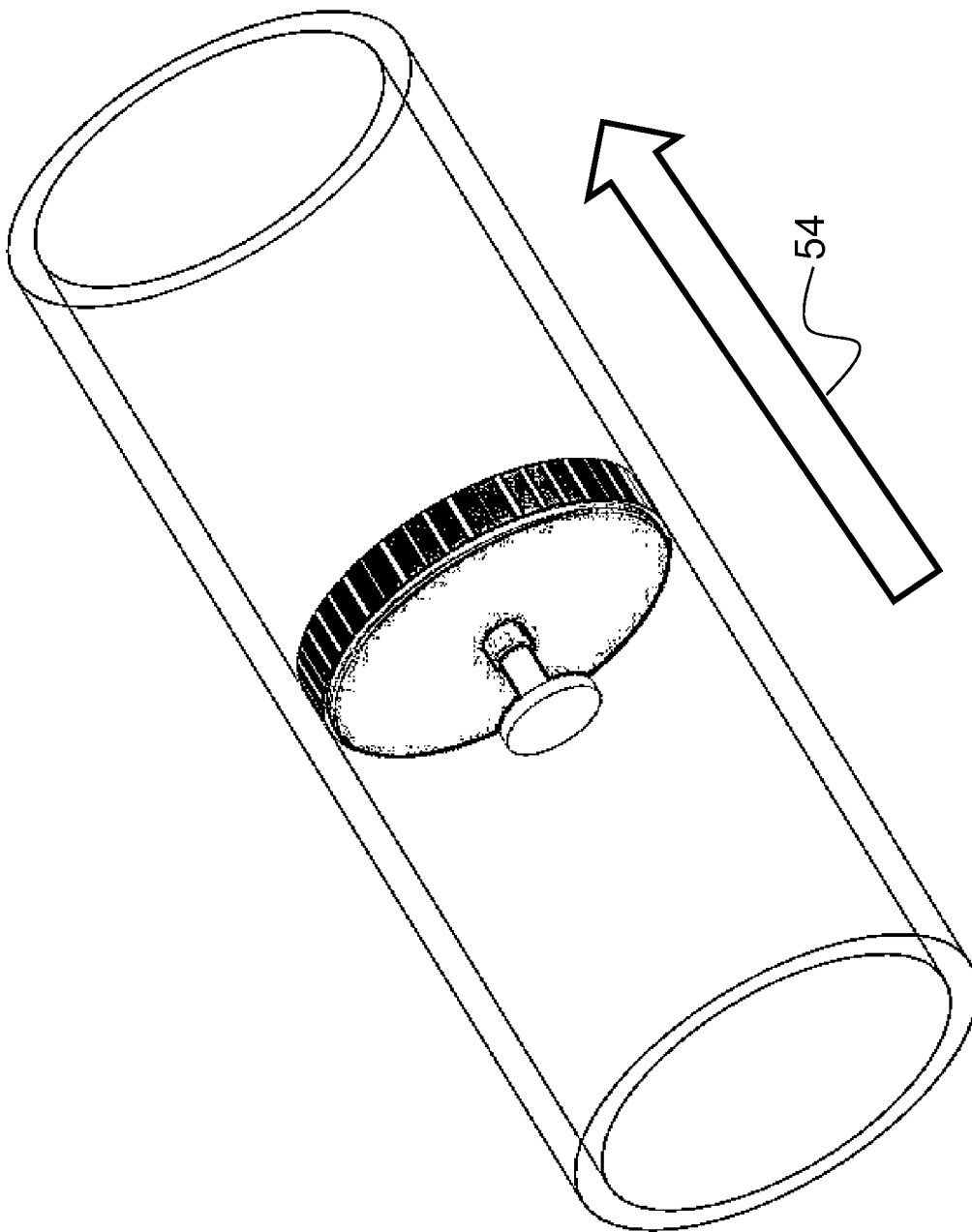


Figure
1D



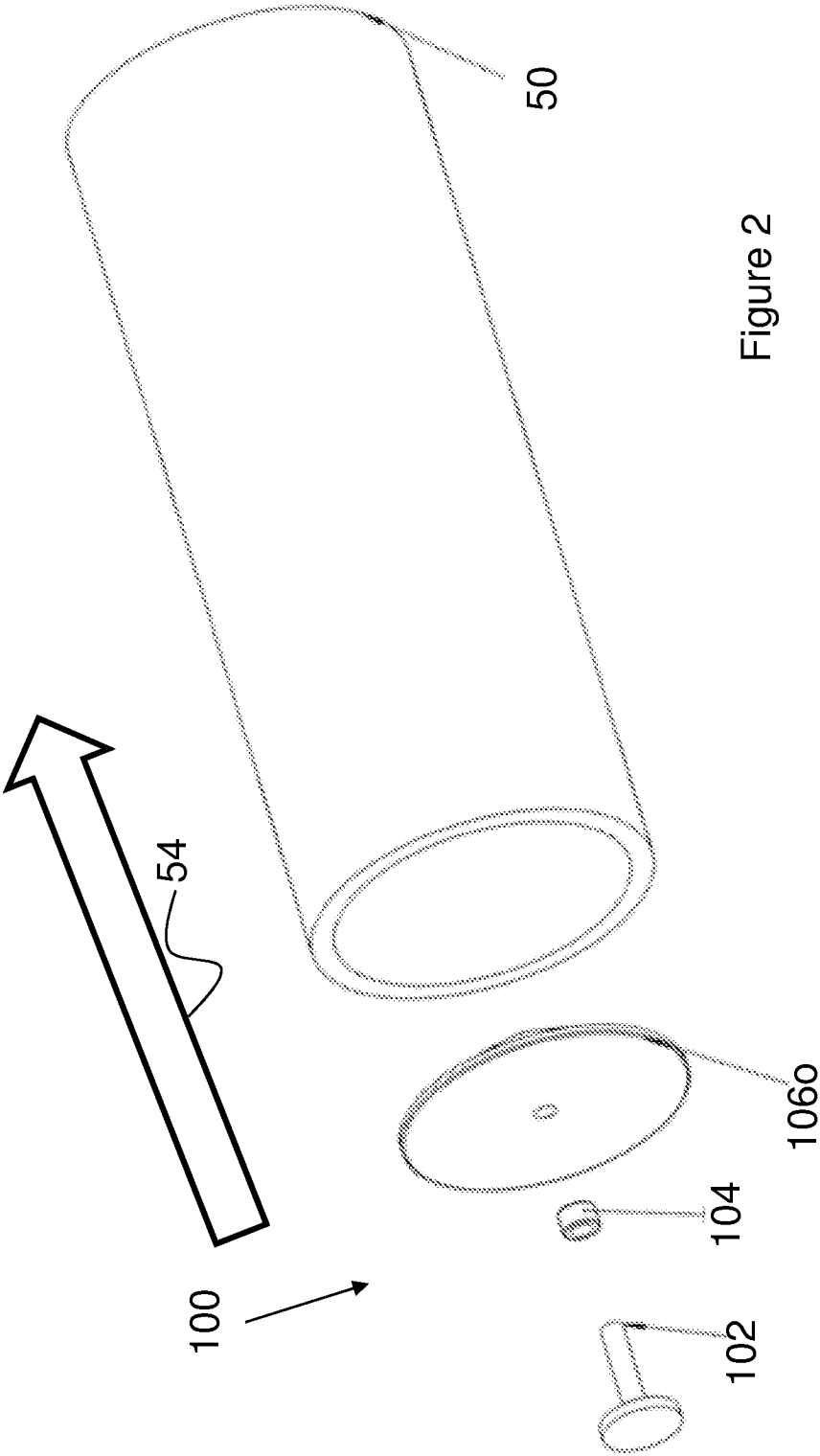


Figure 2

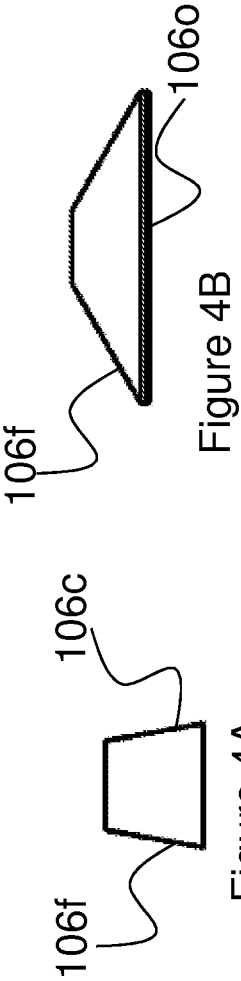


Figure 4A

Figure 4B

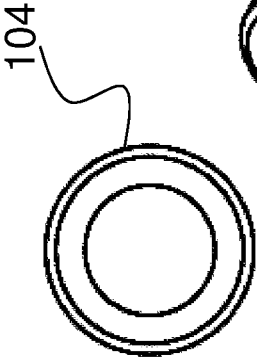


Figure 5A

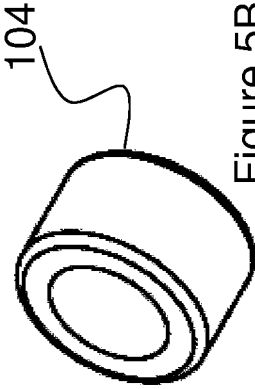


Figure 5B

Figure 5C

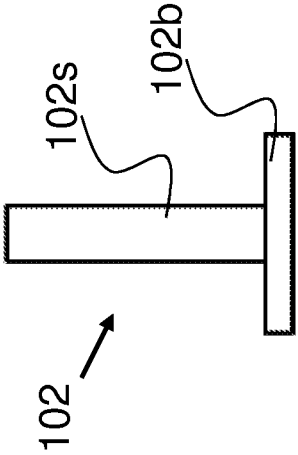
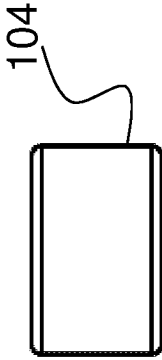


Figure 3A

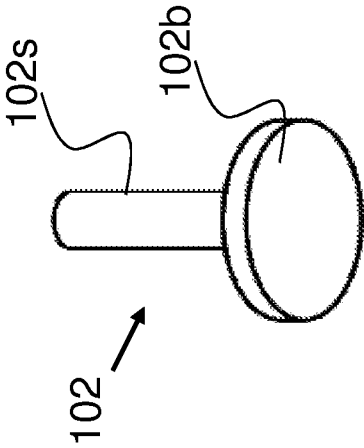


Figure 3B

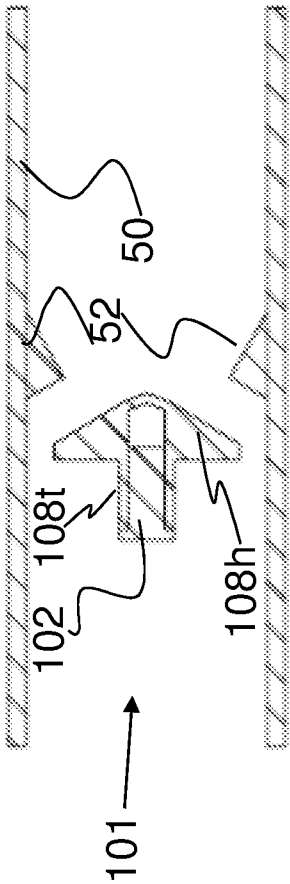


Figure 6A

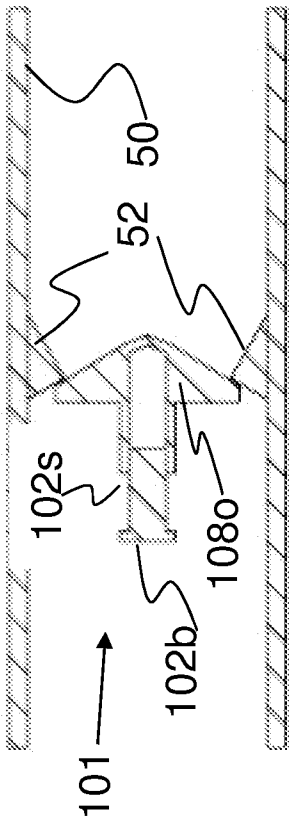


Figure 6B

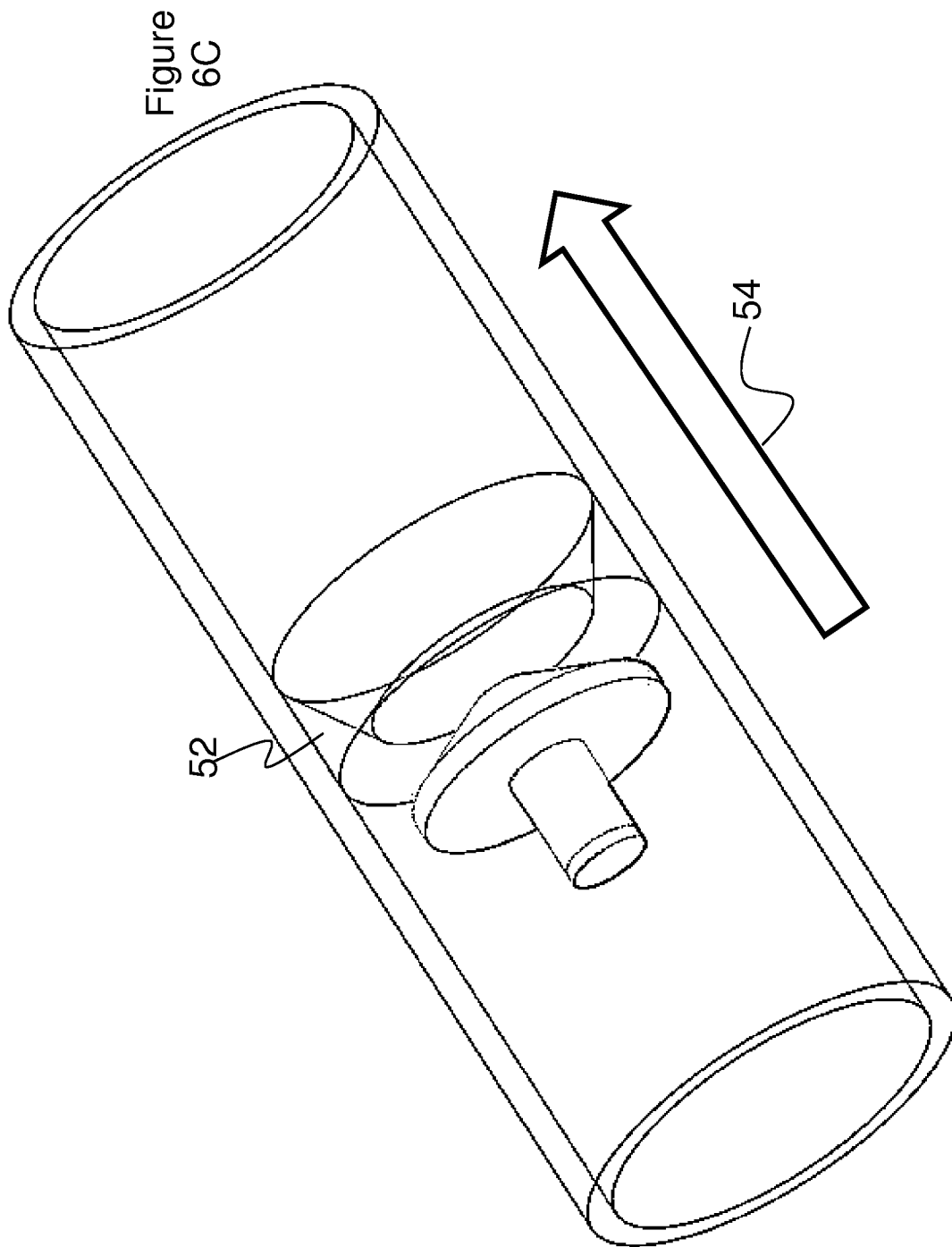
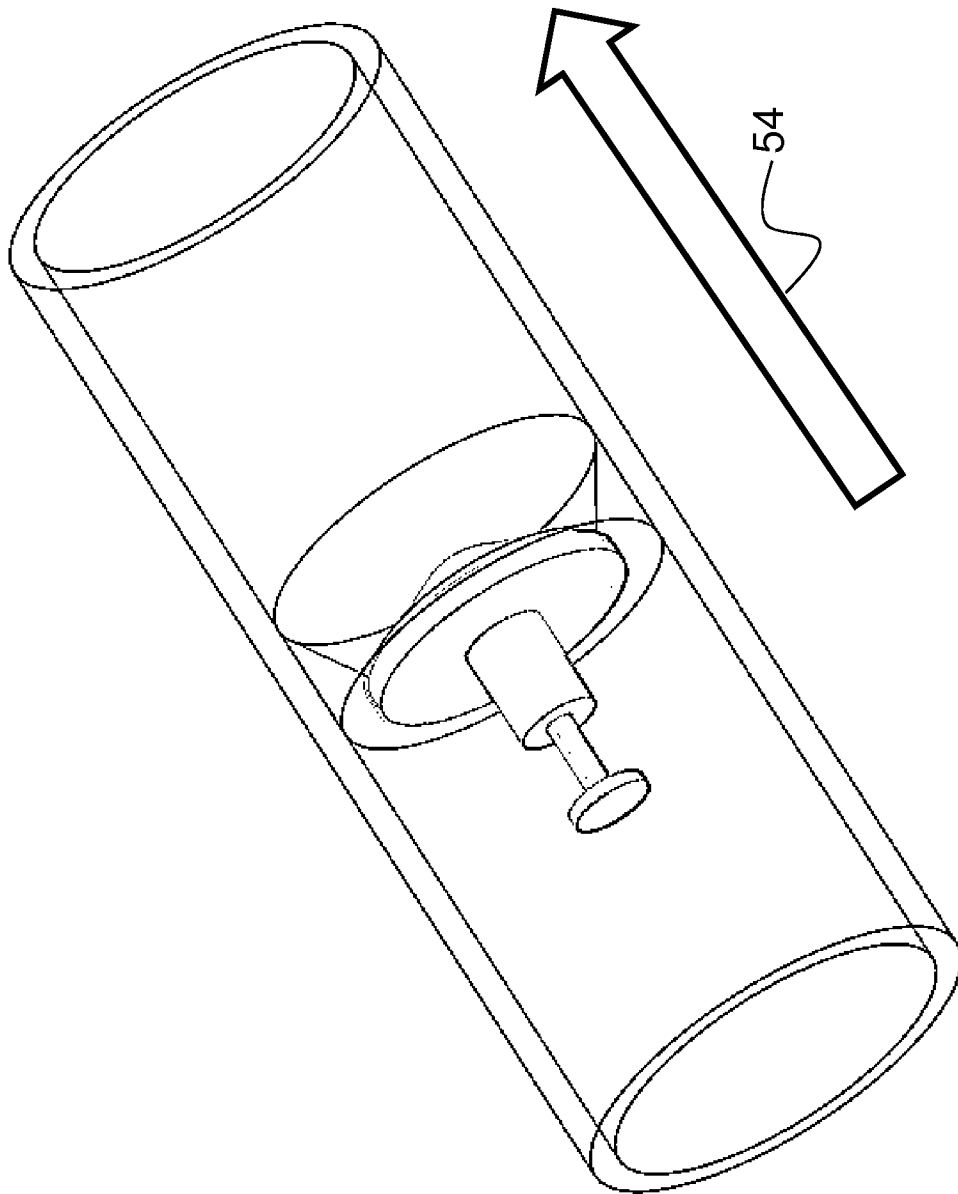
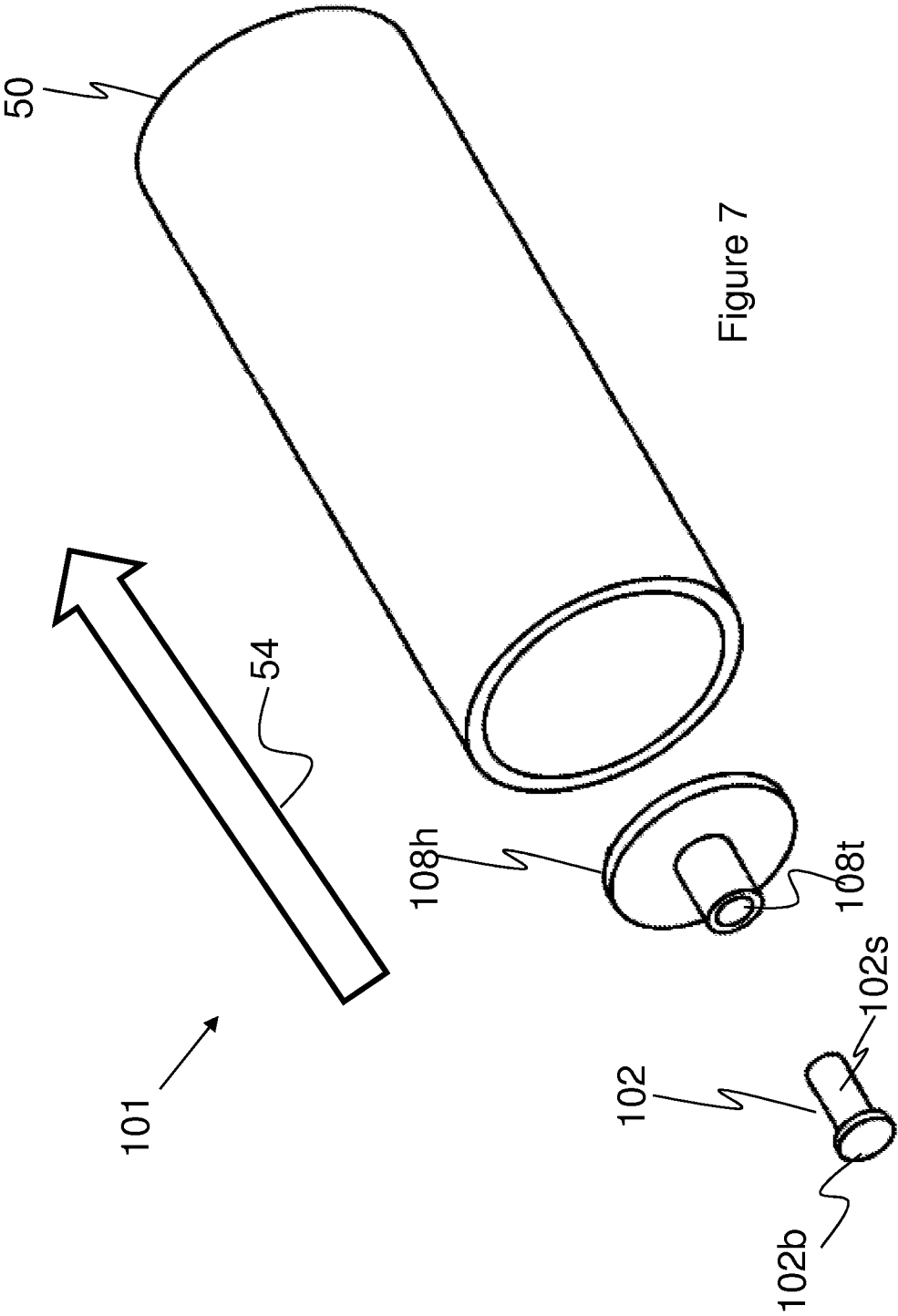


Figure
6D





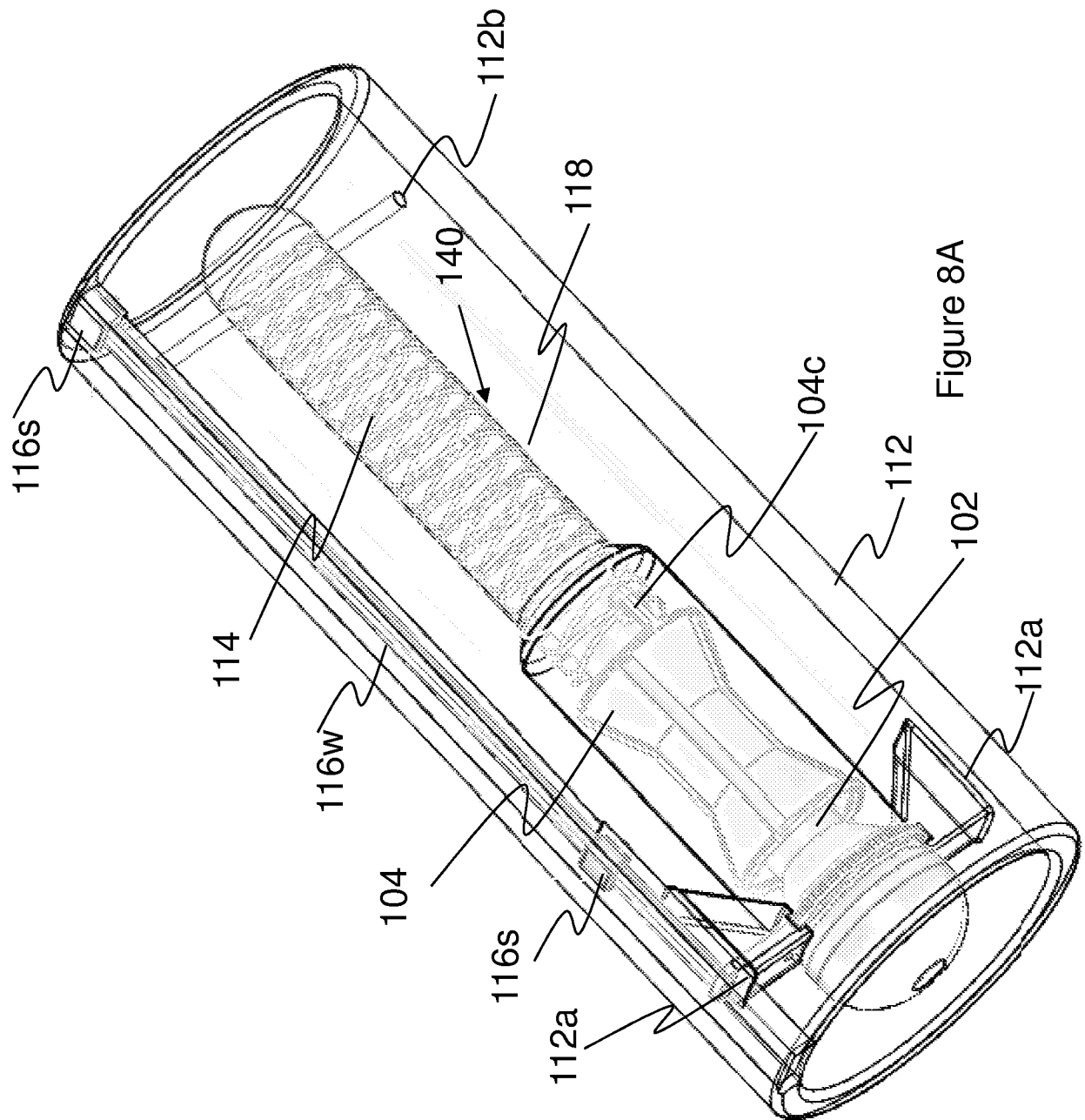


Figure 8A

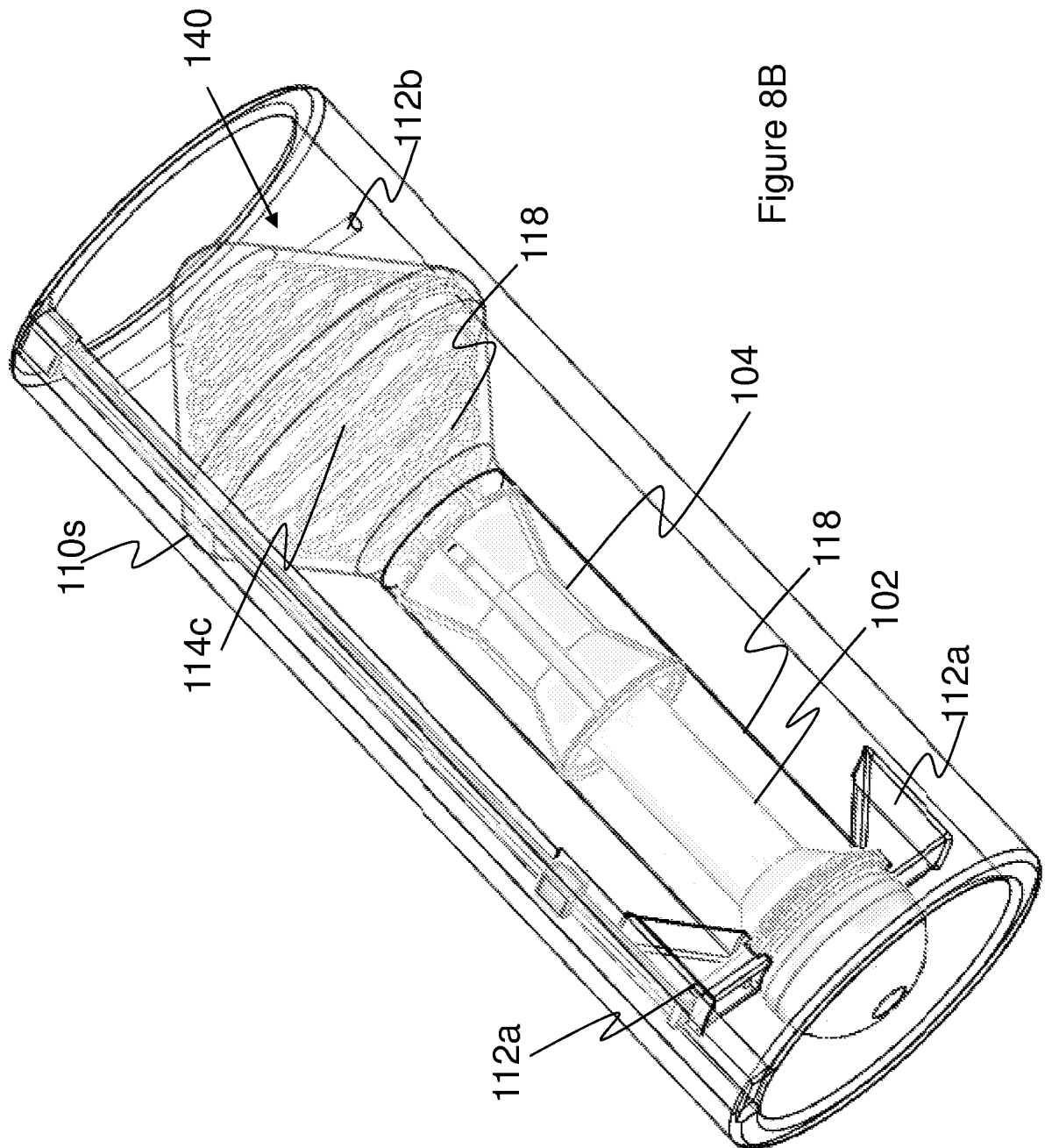


Figure 8B

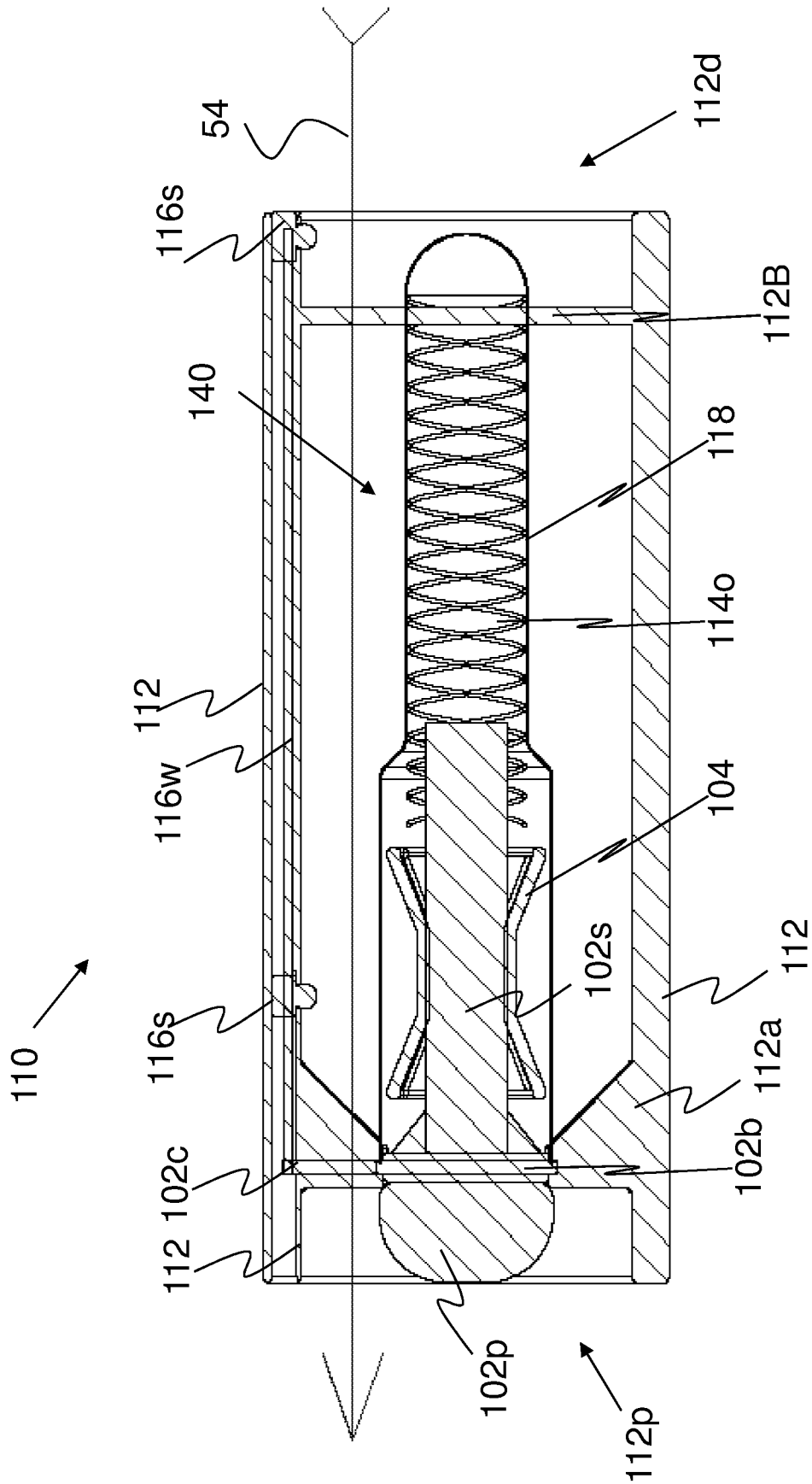


Figure 9A

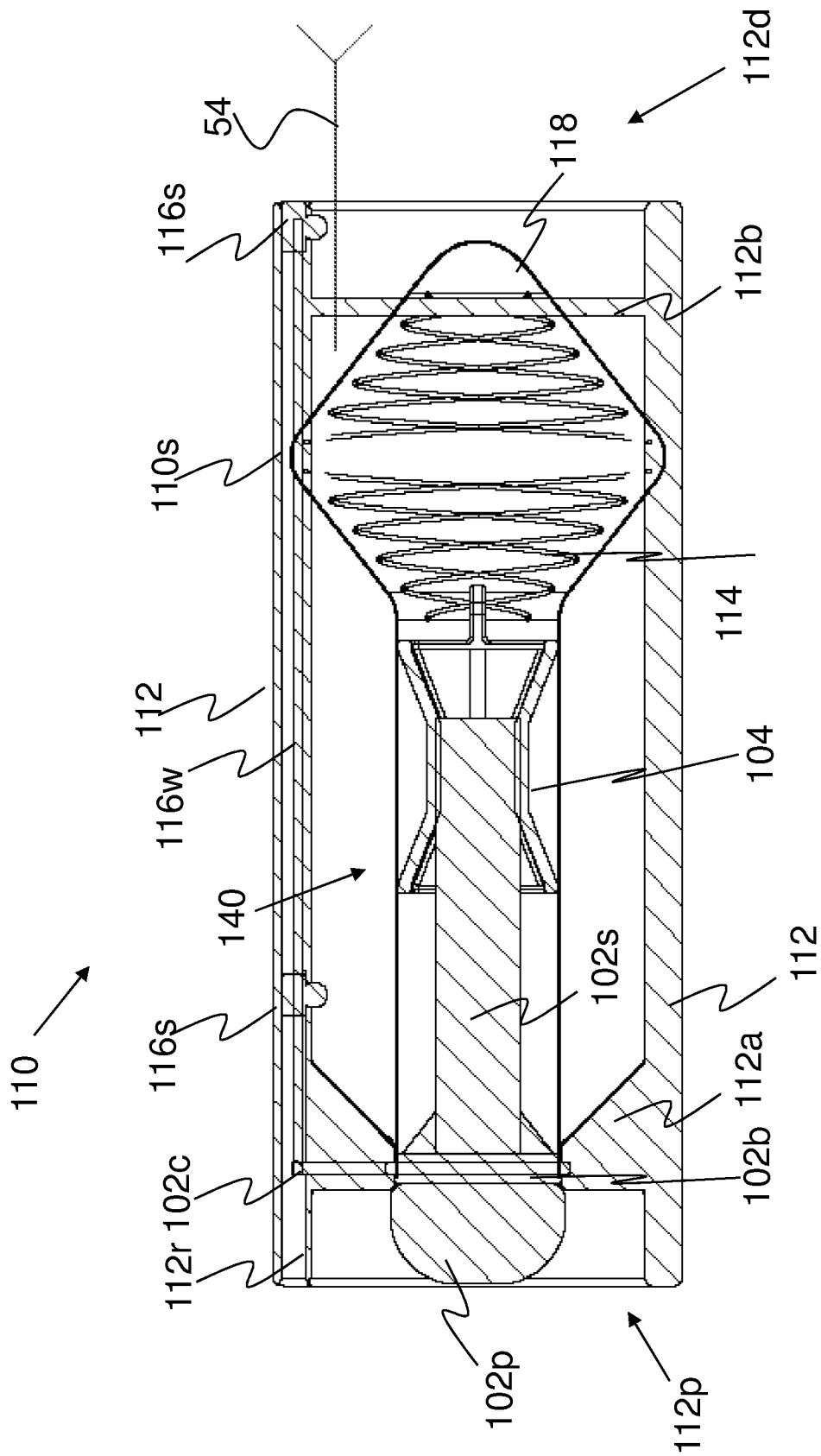


Figure 9B

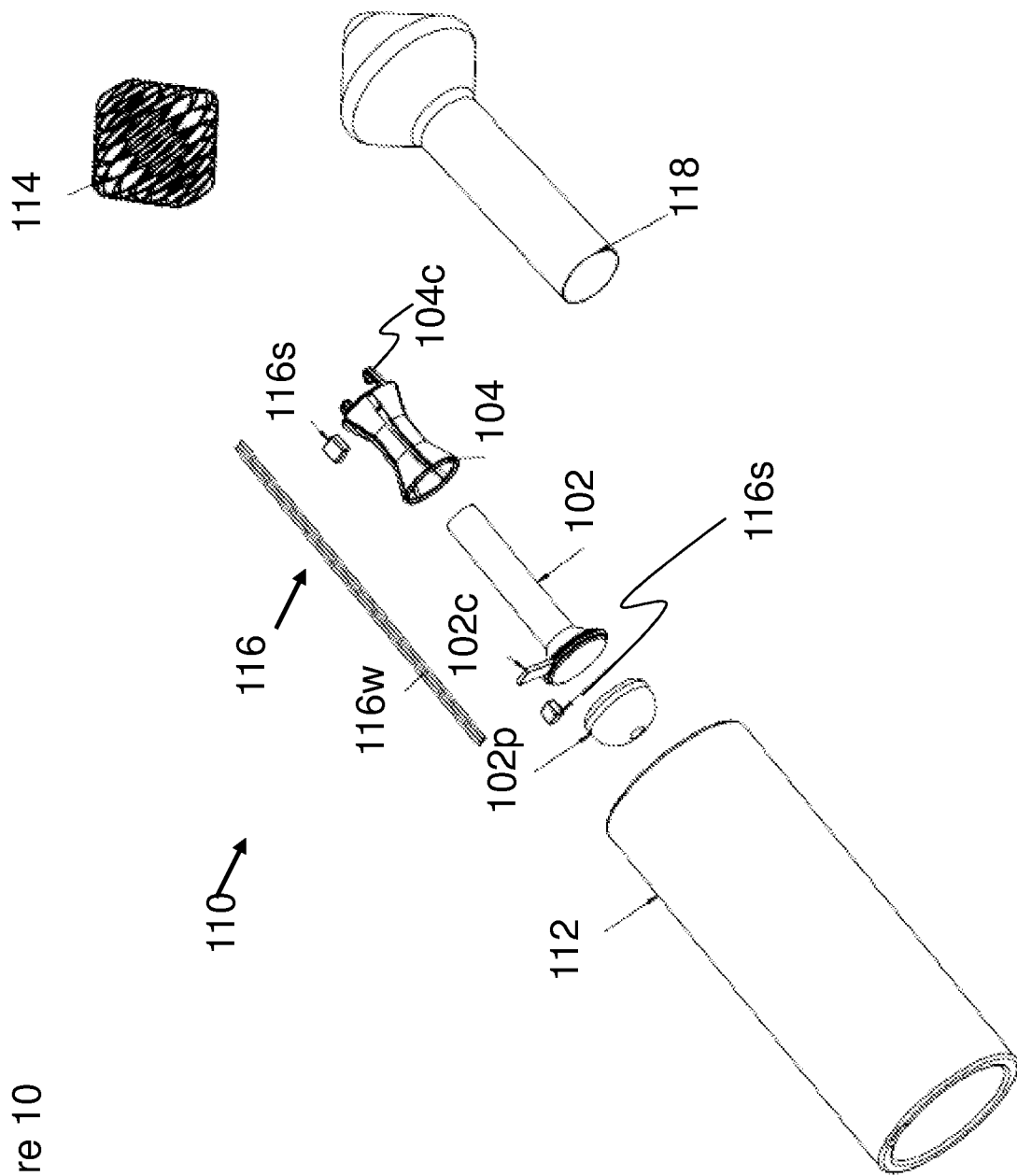


Figure 10

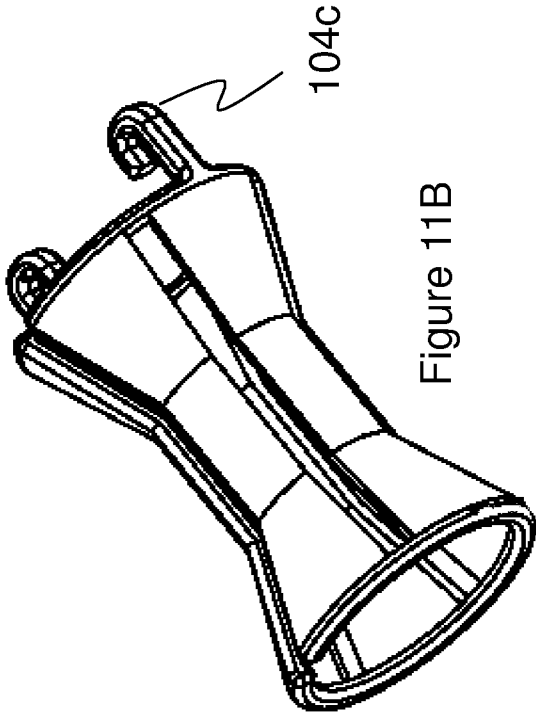


Figure 11B

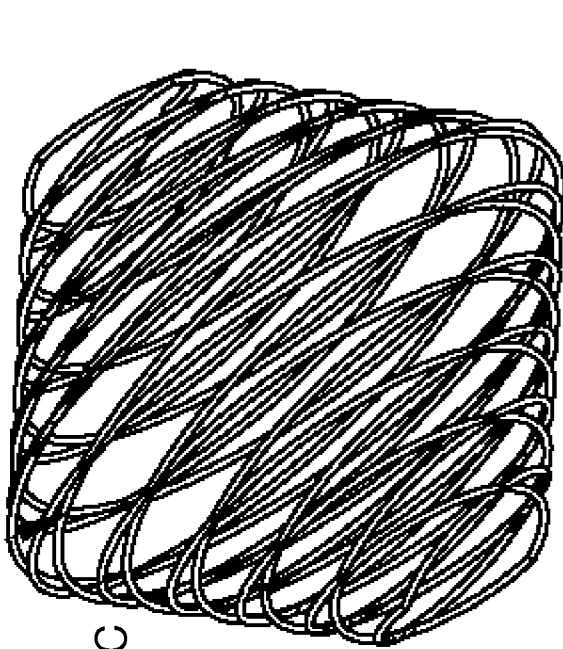


Figure 11C

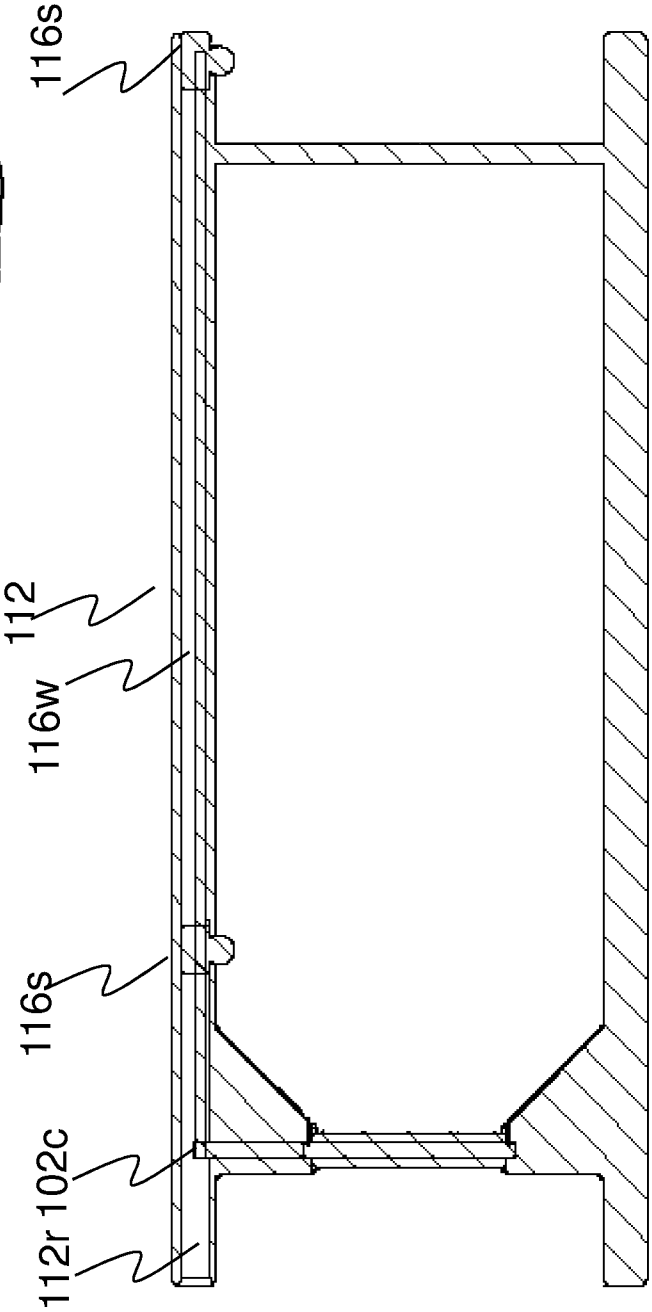


Figure 11A

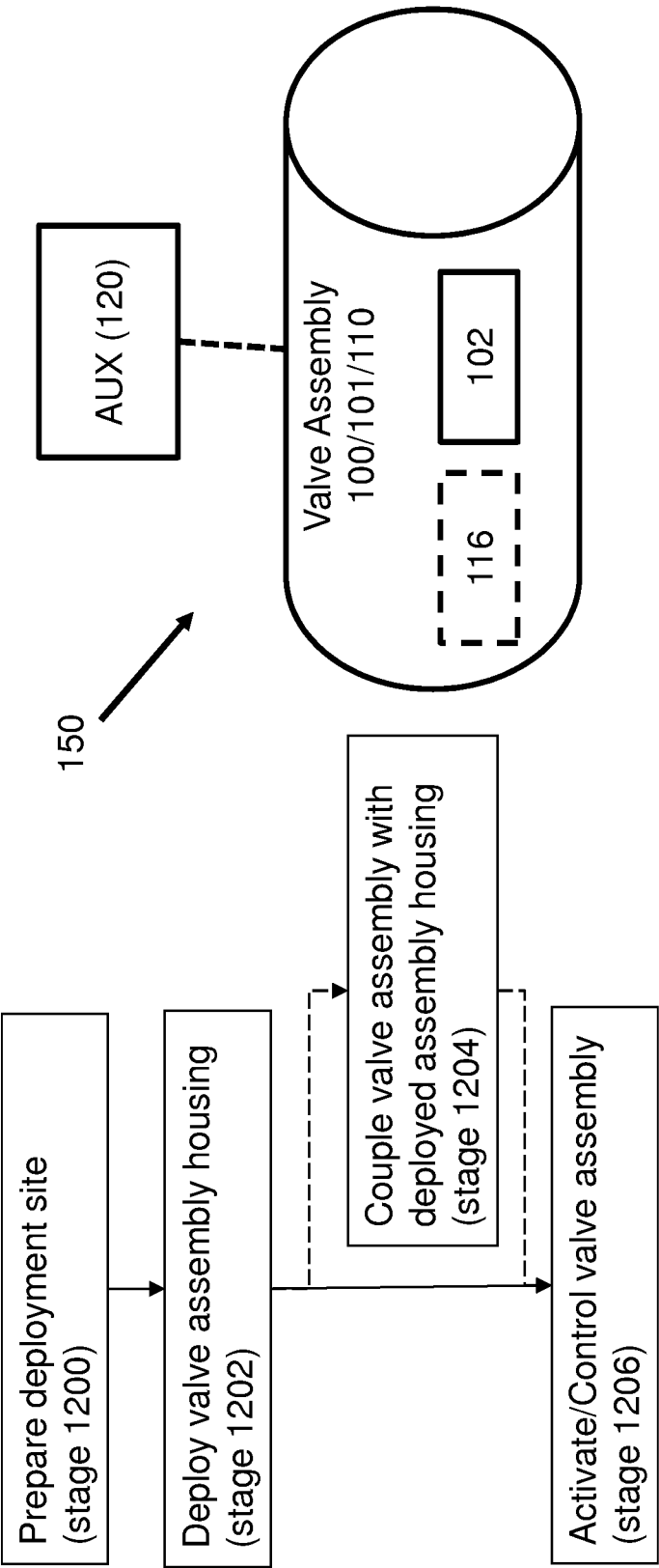


Figure 12

Figure 13