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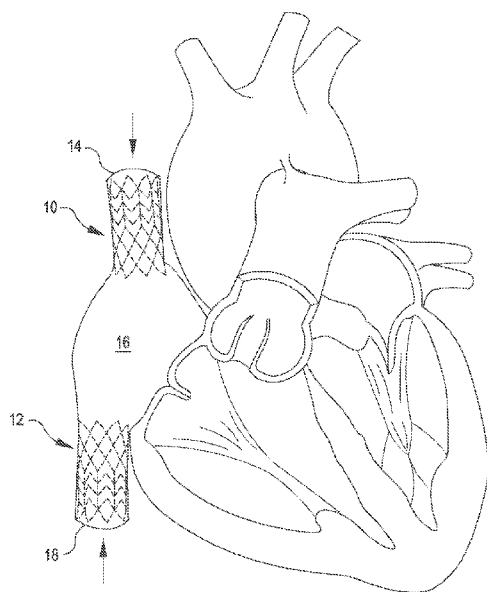
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- (54) **Title:** PERCUTANEOUS CAVAL VALVE IMPLANTATION FOR SEVERE TRICUSPID REGURGITATION

FIG. 1



(57) **Abstract:** Implantable prosthetic valves and related methods for treating tricuspid valve regurgitation block transmission of elevated pressure during ventricular systole upstream along the superior vena cava and the inferior vena cava. A method for treating tricuspid valve regurgitation includes implanting a first prosthetic valve into the superior vena cava adjacent to the junction of the superior vena cava and the right atrium and implanting a second prosthetic valve into the inferior vena cava adjacent to the junction of the inferior vena cava and the right atrium. The implanted first and second prosthetic valves accommodate blood flow to the right atrium and block back flow of blood from the right atrium, thereby decreasing pressure within the superior vena cava and within the inferior vena cava. In many embodiments, the first and second prosthetic valves are configured to accommodate blood flow from one or more adjacent veins covered by the respective implanted valve.



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PERCUTANEOUS CAVAL VALVE IMPLANTATION FOR SEVERE TRICUSPID REGURGITATION

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CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Application No. 62/102,131, filed January 12, 2015, which is incorporated by reference herein in its entirety.

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BACKGROUND

[0002] The tricuspid valve is a heart valve that controls flow of blood between the right atrium and the right ventricle. The tricuspid valve opens to accommodate transfer of blood from the right atrium into the right ventricle during ventricular diastole when the right ventricle refills with blood following ventricular systole (contraction). The tricuspid valve closes to prevent back flow of blood from the right ventricle into the right atrium during ventricular systole.

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[0003] Significant tricuspid valve regurgitation is a common malady that can be caused in numerous ways. For example, the tricuspid valve can be damaged via rheumatic fever.

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Certain carcinoid syndromes can affect the tricuspid valve by producing fibrosis due to serotonin production by tumors. Some people are born with congenital abnormalities of the tricuspid valve. For example, congenital apical displacement of the tricuspid valve typically causes significant tricuspid regurgitation. The tricuspid valve can also be damaged via infection introduced as a result of intravenous drug use.

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[0004] Significant tricuspid valve regurgitation may cause substantial complications such as fatigue, severe limb and abdominal swelling, liver cirrhosis, and generally poor outcomes (including death) if left untreated. There is at present no clinically available device to treat this condition other than through open heart surgery. The complex geometry of the tricuspid valve and lack of suitable adjacent anchoring zone makes direct implantation of a

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replacement tricuspid valve difficult. Moreover, many patients with severe tricuspid valve regurgitation have concomitant heart disease and co-morbidities that make conventional open

heart surgery very high risk. As a result, many of these patients are not operated on and suffer from severe problems of fluid overload (leg and abdominal swelling), fatigue, and even liver disease.

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BRIEF SUMMARY

[0005] The following presents a simplified summary of some embodiments of the invention in order to provide a basic understanding of the invention. This summary is not an extensive overview of the invention. It is not intended to identify key/critical elements of the invention or to delineate the scope of the invention. Its sole purpose is to present some
10 embodiments of the invention in a simplified form as a prelude to the more detailed description that is presented later.

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[0006] The methods and related devices disclosed herein are suitable for treatment of significant tricuspid regurgitation. Instead of replacing the tricuspid valve during open heart surgery, two prosthetic unidirectional valves can be implanted – one in the superior vena cava (SVC) adjacent to the junction between the SVC and the right atrium and one in the inferior vena cava (IVC) adjacent to the junction between the IVC and the right atrium. The
implanted unidirectional valves accommodate venous return back to the right atrium while preventing back transmission of high systolic pressures to the patient's organs. The
implanted unidirectional valves improve forward flow and cardiac output, thereby reducing
20 associated complications. The two prosthetic unidirectional valves can be delivered via catheter through any suitable vein(s) (e.g., one through the internal jugular vein and the other through the femoral vein, both through the femoral vein) using any suitable pain control approach (e.g., local anesthesia and/or general anesthesia) with little complexity. The
prosthetic unidirectional valves disclosed herein may inhibit migration of the valves, reduce
25 risk of embolization, and/or accommodate blood flow from veins that empty into the SVC and/or IVC adjacent to the junction with the right atrium. The prosthetic unidirectional valves can also be used in other suitable applications (e.g., treating pulmonary valve regurgitation, treating other venous diseases such as saphenous incompetency with a smaller version of the prosthetic unidirectional valve, and other venous locations other than adjacent
30 to the junctions between the SVC and the right atrium and the IVC and the right atrium).

[0007] Thus, in one aspect, a method of treating tricuspid valve regurgitation is provided. The method includes supporting a first expandable frame via contact between the first expandable frame and the superior vena cava (SVC) adjacent to the junction of the SVC and

the right atrium. A first unidirectional valve is supported via the first expandable frame. The first unidirectional valve reconfigures from an open configuration accommodating flow of blood from the SVC to the right atrium to a closed configuration substantially blocking back flow of blood from the right atrium to the SVC in response to blood pressure downstream of the first unidirectional valve increasing above blood pressure upstream of the first unidirectional valve. The first unidirectional valve reconfigures from the closed configuration to the open configuration in response to blood pressure downstream of the first unidirectional valve decreasing below blood pressure upstream of the first unidirectional valve. A second expandable frame is supported via contact between the second expandable frame and the inferior vena cava (IVC) adjacent to the junction of the IVC and the right atrium. A second unidirectional valve is supported via the second expandable frame. The second unidirectional valve reconfigures from an open configuration accommodating flow of blood from the IVC to the right atrium to a closed configuration substantially blocking back flow of blood from the right atrium to the IVC in response to blood pressure downstream of the second unidirectional valve increasing above blood pressure upstream of the second unidirectional valve. The second unidirectional valve reconfigures from the closed configuration to the open configuration in response to blood pressure downstream of the second unidirectional valve decreasing below blood pressure upstream of the second unidirectional valve.

[0008] In many embodiments of the method, migration of the first expandable frame and/or the second expandable frame is inhibited via one or more mitigation inhibiting features. For example, the method can include any combination of (a) inhibiting upstream migration of the first expandable frame via contact between a first downstream crown structure of the first expandable frame and the SVC and/or between the first downstream crown structure and the junction of the SVC and the right atrium; (b) inhibiting upstream migration of the second expandable frame via contact between a second downstream crown structure of the second expandable frame and the IVC and/or between the second downstream crown structure and the junction of the IVC and the right atrium; (c) inhibiting migration of the first expandable frame via contact between a first upstream crown structure of the first expandable frame and the SVC; (d) inhibiting migration of the second expandable frame via contact between a second upstream crown structure of the second expandable frame and the IVC; (e) inhibiting migration of the first expandable frame via contact between a plurality of first outwardly extending anchor segments of the first expandable frame and the SVC; and (f) inhibiting

migration of the second expandable frame via contact between a plurality of second outwardly extending anchor segments of the second expandable frame and the IVC.

[0009] In many embodiments of the method, a flow blocking covering is used to inhibit regurgitation around the respective unidirectional valve. For example, the method can

5 include one or both of (a) inhibiting regurgitation around the first unidirectional valve by blocking radial flow of blood through the first expandable frame via a first flow blocking covering over a portion of the first expandable frame supporting the first unidirectional valve; and (b) inhibiting regurgitation around the second unidirectional valve by blocking radial flow of blood through the second expandable frame via a second flow blocking covering over
10 a portion of the second expandable frame supporting the second unidirectional valve.

[0010] In many embodiments of the method, implanting one or both of the first and second expandable frames includes partially expanding a downstream portion of the respective expandable frame with the downstream crown structure downstream of the respective atrial junction, then retracting the respective partially expanded expandable frame to contact the

15 downstream crown structure with the respective junction, and then expanding the rest of the respective expandable frame. For example, the method can include at least one of: (a) advancing the first expandable frame downstream through the SVC in a non-expanded configuration to position the first downstream crown structure downstream of the junction between the SVC and the right atrium; partially expanding the first expandable frame by
20 expanding a downstream portion of the first expandable frame that includes the first downstream crown structure; retracting the partially expanded first expandable frame upstream through the SVC to interface the first downstream crown structure with the junction between the SVC and the right atrium; and completing expansion of the first expandable member subsequent to the first downstream crown structure being interfaced with the
25 junction between the SVC and the right atrium; or (b) advancing the second expandable frame downstream through the IVC in a non-expanded configuration to position the second downstream crown structure downstream of the junction between the IVC and the right atrium; partially expanding the second expandable frame by expanding a downstream portion of the second expandable frame that includes the second downstream crown structure;

30 retracting the partially expanded second expandable frame upstream through the IVC to interface the second downstream crown structure with the junction between the IVC and the right atrium; and completing expansion of the second expandable member subsequent to the

second downstream crown structure being interfaced with the junction between the IVC and the right atrium.

[0011] Many embodiments of the method include accommodating blood flow from adjacently terminating veins to the right atrium. For example the method can include one or both of (a) supporting a first flow blocking covering by the first expandable member; reconfiguring the first flow blocking covering to accommodate flow of blood from one or more SVC-terminating blood vessels to the right atrium in response to a blood pressure differential applied to the first flow blocking covering; and reconfiguring the first flow blocking covering to inhibit back flow of blood from the right atrium to the one or more SVC-terminating blood vessels in response to a blood pressure differential applied to the first flow blocking covering; or (b) supporting a second flow blocking covering by the second expandable member; reconfiguring the second flow blocking covering to accommodate flow of blood from one or more IVC-terminating blood vessels to the right atrium in response to a blood pressure differential applied to the second flow blocking covering; and reconfiguring the second flow blocking covering to inhibit back flow of blood from the right atrium to the one or more IVC-terminating blood vessels in response to a blood pressure differential applied to the second flow blocking covering. The method can include one or both of (a) supporting a first flow blocking covering via a plurality of first separated struts extending downstream from an upstream base portion of the first expandable frame; deforming each of the plurality of first separated struts radially inward to position the first flow blocking covering to accommodate flow of blood from one or more SVC-terminating blood vessels to the right atrium in response to a blood pressure differential applied to the first flow blocking covering; and deforming each of the plurality of first separated struts radially outward to position the first flow blocking covering to inhibit back flow of blood from the right atrium to the one or more SVC-terminating blood vessels in response to a blood pressure differential applied to the first flow blocking covering; or (b) supporting a second flow blocking covering via a plurality of second separated struts extending downstream from an upstream base portion of the second expandable frame; deforming each of the plurality of second separated struts radially inward to position the second flow blocking covering to accommodate flow of blood from one or more IVC-terminating blood vessels to the right atrium in response to a blood pressure differential applied to the second flow blocking covering; and deforming each of the plurality of second separated struts radially outward to position the second flow blocking covering to inhibit back flow of blood from the right atrium to the one or more IVC-

terminating blood vessels in response to a blood pressure differential applied to the second flow blocking covering. The method can include one or both of (a) accommodating flow of blood from one or more SVC-terminating blood vessels to the right atrium via apertures in the first expandable frame; or (b) accommodating flow of blood from one or more IVC-terminating blood vessels to the right atrium via apertures in the second expandable frame.

[0012] Any suitable approach can be used to expand the first and second expandable frames in the method of treating tricuspid valve regurgitation. For example, one or both of the first expandable frame and the second expandable frame can be self-expanding. One or both of the first expandable frame and the second expandable frame can be expanded via inflation of one or more catheter mounted inflatable members on which the respective frame is mounted in a non-expanded configuration.

[0013] In another aspect, an implantable prosthetic valve for treating tricuspid valve regurgitation is provided. The implantable prosthetic valve includes an expandable frame and a unidirectional valve supported by the expandable frame. The expandable frame is configured for implantation into at least one of: (a) the superior vena cava (SVC) adjacent to the junction of the SVC and the right atrium, or (b) the inferior vena cava adjacent to the junction of the IVC and the right atrium. The unidirectional valve is configured to (a) reconfigure from an open configuration accommodating flow of blood to the right atrium to a closed configuration substantially blocking back flow of blood from the right atrium in response to blood pressure downstream of the unidirectional valve increasing above blood pressure upstream of the unidirectional valve, and (b) reconfigure from the closed configuration to the open configuration in response to blood pressure downstream of the unidirectional valve decreasing below blood pressure upstream of the unidirectional valve.

[0014] In many embodiments of the implantable prosthetic valve, the expandable frame includes one or more migration inhibiting features. For example, the expandable frame can include any combination of (a) an outwardly extending downstream crown structure that is shaped to be interfaced with the junction of the SVC and the right atrium or the junction of the IVC and the right atrium to inhibit upstream migration of the expandable frame; (b) an outwardly extending upstream crown structure that is shaped to be interfaced with the SVC or the IVC to inhibit migration of the expandable frame; and (c) a plurality of outwardly extending anchor segments configured to inhibit migration of the expandable frame via contact with the SVC or the IVC.

[0015] In many embodiments of the implantable prosthetic valve, the expandable frame is reconfigurable from a non-deployed configuration to a partially-deployed configuration and from the partially-deployed configuration to a fully-deployed configuration. The non-deployed configuration of the expandable frame is sized for intraluminal delivery. A

5 downstream portion of the expandable frame that includes the downstream crown structure is at least partially expanded in the partially-deployed configuration so that the downstream crown structure has a diameter sized to engage at least one of the junction of the SVC and the right atrium or the junction of the IVC and the right atrium during an upstream movement of the expandable frame in the partially-deployed configuration to provide a tactile feedback
10 indicating the expandable frame is positioned for reconfiguration from the partially-deployed configuration to the fully-deployed configuration. The implantable prosthetic valve can be self-expanding and can include one or more eyelets for retaining an upstream portion of the expandable frame within a delivery sheath during the upstream movement of the expandable frame in the partially-deployed configuration.

15 **[0016]** The implantable prosthetic valve can be configured in any suitable manner to be implanted via an intraluminal catheter. For example, the expandable frame can be self-expanding and constrained via the intraluminal catheter in a non-expanded configuration during positioning prior to deployment. As another example, the expandable frame can be expandable via inflation of one or more catheter mounted inflatable members.

20 **[0017]** In many embodiments, the implantable prosthetic valve is configured to inhibit regurgitation around the unidirectional valve. For example, the implantable prosthetic valve can include a flow blocking covering over a portion of the expandable frame supporting the unidirectional valve to inhibit regurgitation around the unidirectional valve by blocking radial flow of blood through the first expandable frame.

25 **[0018]** In many embodiments, the implantable prosthetic valve is configured to accommodate blood flow from adjacently terminating veins to the right atrium. For example the implantable prosthetic valve can include a flow blocking covering over the expandable frame that is configured to (a) reconfigure to accommodate flow of blood from one or more SVC-terminating blood vessels to the right atrium or one or more IVC-terminating blood
30 vessels to the right atrium in response to a blood pressure differential applied to the flow blocking covering; and (b) reconfigure to inhibit back flow of blood from the right atrium to one or more SVC-terminating blood vessels or the right atrium to one or more IVC-

terminating blood vessels in response to a blood pressure differential applied to the flow blocking covering. The implantable prosthetic valve can include a flow blocking covering and the expandable frame can include a plurality of separated struts extending downstream from an upstream base portion of the expandable frame, the plurality of separated struts supporting the flow blocking covering, each of the plurality of separated struts being configured to (a) deform radially inward to position the flow blocking covering to accommodate flow of blood from one or more SVC-terminating blood vessels to the right atrium or one or more IVC terminating blood vessels to the right atrium in response to a blood pressure differential applied to the flow blocking covering; and (b) deform radially outward to position the flow blocking covering to inhibit back flow of blood from the right atrium to one or more SVC-terminating blood vessels or the right atrium to one or more IVC-terminating blood vessels in response to a blood pressure differential applied to the flow blocking covering. The expandable frame can include apertures adapted to accommodate flow of blood from one or more SVC-terminating blood vessels to the right atrium or one or more IVC-terminating blood vessels to the right atrium.

[0019] In another aspect, an implantable prosthetic valve is provided. The implantable prosthetic valve includes a unidirectional valve and an expandable frame supporting the unidirectional valve. The unidirectional valve is configured to (a) reconfigure from an open configuration accommodating flow of blood to a closed configuration substantially blocking back flow of blood in response to blood pressure downstream of the unidirectional valve increasing above blood pressure upstream of the unidirectional valve, and (b) reconfigure from the closed configuration to the open configuration in response to blood pressure downstream of the unidirectional valve decreasing below blood pressure upstream of the unidirectional valve. The expandable frame includes at least one of (a) an outwardly extending downstream crown structure that is shaped to inhibit migration of the expandable frame, (b) an outwardly extending upstream crown structure that is shaped to inhibit migration of the expandable frame, and (c) a plurality of outwardly extending anchor segments configured to inhibit migration of the expandable frame.

[0020] In many embodiments, the implantable prosthetic valve includes a flow blocking covering supported by the expandable frame. The flow blocking covering is configured to at least one of (a) inhibit regurgitation around the unidirectional valve by blocking radial flow of blood through the first expandable frame, and (b) reconfigure to accommodate downstream flow of blood in response to a blood pressure differential applied to the flow

blocking covering, and reconfigure to inhibit back flow of blood in response to a blood pressure differential applied to the flow blocking covering.

[0021] For a fuller understanding of the nature and advantages of the present invention, reference should be made to the ensuing detailed description and accompanying drawings.

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BRIEF DESCRIPTION OF THE DRAWINGS

[0022] **FIG. 1** illustrates implanted prosthetic unidirectional valves adjacent to the junction between the superior vena cava (SVC) and the right atrium and adjacent to the junction between the inferior vena cava (IVC) and the right atrium to treat tricuspid valve regurgitation, in accordance with many embodiments.

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[0023] **FIG. 2** is a simplified cross-sectional schematic diagram of prosthetic unidirectional valves implanted adjacent to the junction between the superior vena cava (SVC) and the right atrium and adjacent to the junction between the inferior vena cava (IVC) and the right atrium to treat tricuspid valve regurgitation, in accordance with many embodiments.

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[0024] **FIGS. 3A and 3B** illustrate an embodiment of an expandable frame of an implantable prosthetic unidirectional valve.

[0025] **FIGS. 4A and 4B** illustrate another embodiment of an expandable frame of an implantable prosthetic unidirectional valve.

[0026] **FIGS. 5A and 5B** illustrate another embodiment of an expandable frame of an implantable prosthetic unidirectional valve.

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[0027] **FIG. 6** illustrates another embodiment of an expandable frame of an implantable prosthetic unidirectional valve.

[0028] **FIG. 7** is a simplified cross-sectional schematic diagram illustrating accommodation of blood flow from a vein covered by a prosthetic valve through a sidewall of an expandable frame of the prosthetic valve, in accordance with many embodiments.

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[0029] **FIGS. 8A and 8B** are simplified cross-sectional schematic diagrams illustrating configurations of a flow blocking covering for accommodating downstream blood flow from a vein covered by a prosthetic valve and inhibiting upstream backflow of blood to the covered vein, in accordance with many embodiments.

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[0030] FIGS. 9A and 9B are simplified cross-sectional schematic diagrams illustrating configurations of an expandable frame of a prosthetic valve and a flow blocking covering supported by the expandable frame for accommodating downstream blood flow from vein covered by a prosthetic valve and inhibiting upstream backflow of blood to the covered vein, in accordance with many embodiments.

[0031] FIGS. 10A through 10D are simplified cross-sectional schematic diagrams illustrating intraluminal implantation of a self-expanding embodiment of a prosthetic unidirectional valve at the junction between the superior vena cava (SVC) and the right atrium or adjacent to the junction between the inferior vena cava (IVC) and the right atrium, in accordance with many embodiments.

[0032] FIGS. 11A through 11E are simplified cross-sectional schematic diagrams illustrating intraluminal implantation of an inflatable member expanded embodiment of a prosthetic unidirectional valve at the junction between the superior vena cava (SVC) and the right atrium or adjacent to the junction between the inferior vena cava (IVC) and the right atrium, in accordance with many embodiments.

[0033] FIGS. 12A and 12B show example SVC pressure waveforms before and after prosthetic valve implantation.

[0034] FIGS. 13A and 13B show example right atrial pressure and central venous pressure after prosthetic valve implantation.

DETAILED DESCRIPTION

[0035] In the following description, various embodiments of the present invention will be described. For purposes of explanation, specific configurations and details are set forth in order to provide a thorough understanding of the embodiments. However, it will also be apparent to one skilled in the art that the present invention may be practiced without the specific details. Furthermore, well-known features may be omitted or simplified in order not to obscure the embodiment being described.

[0036] The implantable prosthetic unidirectional valves and related methods described herein can be used in the field of interventional cardiology or cardiothoracic surgery. The implantable prosthetic unidirectional valves and related methods described herein are particularly well suited for treating patients with severe tricuspid valve regurgitation. By implanting a first prosthetic unidirectional valve adjacent to the junction between the superior

vena cava (SVC) and the right atrium and a second prosthetic unidirectional valve adjacent to the junction between the inferior vena cava (IVC) and the right atrium, forward flow and thus cardiac output can be improved, thereby reducing patient complications induced by the tricuspid regurgitation. The first prosthetic unidirectional valve can be delivered

5 percutaneously through the internal jugular vein or the femoral vein via a delivery catheter.

The second prosthetic unidirectional valve can be delivered percutaneously through the femoral vein via a delivery catheter. The first and the second prosthetic unidirectional valves can be implanted using any suitable pain control approach (e.g., local anesthesia and/or general anesthesia) with little complexity.

10 **[0037]** The implantable prosthetic unidirectional valves described herein are configured to address unique challenges associated with implantation of prosthetic valves in veins. First, venous devices are prone to migration and/or embolization, which may be catastrophic. In many embodiments, the implantable prosthetic unidirectional valves described herein include one or more outwardly extending retention features that inhibit proximal or distal migration

15 of the implanted prosthetic valve. For example, in many embodiments the implantable prosthetic unidirectional valves described herein include a plurality of outwardly extending anchoring segments configured to inhibit migration of the implanted prosthetic valve.

Second, in many embodiments the implantable prosthetic unidirectional valves described herein are configured to accommodate blood flow from adjacent veins covered by the

20 implanted valve. The ability to accommodate blood flow from covered veins allows the prosthetic valve to be longer thereby enabling more secure anchorage to the vein. In many embodiments, the implantable prosthetic unidirectional valves described herein include a flared downstream crown structure, which aids in positioning and stability during

implantation. In many embodiments, the implantable prosthetic unidirectional valves

25 described herein are configured so that very little of the implanted valve is exposed in the atrium thereby reducing risks associated with disposing a device within the atrium (e.g., thromboembolism).

[0038] In many embodiments, the implantable prosthetic unidirectional valves described herein include an expandable frame constructed from a suitable material (e.g., a nitinol based material) supporting a unidirectional valve of suitable configuration (e.g., including valve leaflets). In many embodiments, expandable frame includes an outwardly extending downstream crown structure that is radially wider than the main body of the expandable frame by a suitable length (e.g., about 5 mm). In many embodiments, the downstream crown

structure is configured to prevent upstream migration of the valve during systole when right atrial pressures are elevated.

[0039] Turning now to the drawing figures in which like reference numbers refer to like elements in the various figures, **FIG. 1** illustrates implanted prosthetic unidirectional valves used to treat tricuspid valve regurgitation, in accordance with many embodiments. The implanted valves include a first prosthetic unidirectional valve 10 implanted in the superior vena cava (SVC) 14 adjacent to the junction between the SVC 14 and the right atrium 16 and a second prosthetic unidirectional valve 12 implanted in the inferior vena cava (IVC) 18 adjacent to the junction between the IVC 18 and the right atrium 16. The first prosthetic unidirectional valve 10 accommodates blood flow from the SVC 14 to the right atrium 16 and blocks back flow of blood from the right atrium 16 to the SVC 14. The second prosthetic unidirectional valve 12 accommodates blood flow from the IVC 18 to the right atrium 16 and blocks back flow of blood from the right atrium 16 to the IVC 18. As a result, the illustrated implanted unidirectional valves 10, 12 function to inhibit back transmission of high atrial pressures (which may occur during ventricular systole as a result of tricuspid valve regurgitation) along the SVC 14 and the IVC 18.

[0040] **FIG. 2** is a simplified cross-sectional schematic diagram illustrating the first prosthetic valve 10 implanted adjacent to the junction 20 between the SVC 14 and the right atrium 16 and the second prosthetic valve 12 implanted adjacent to the junction 22 between the IVC 18 and the right atrium 16 to treat tricuspid valve regurgitation, in accordance with many embodiments. In the illustrated embodiments, each of the first and second prosthetic valves 10, 12 includes an expandable frame 24, a unidirectional valve 26, and a flow blocking covering 28. In many embodiments, the expandable frame 24 is a stent frame that is expandable (e.g., balloon expanded, self-expanding) from a non-expanded configuration in which the prosthetic valve 10, 12 is delivered via a catheter to an expanded configuration in which the expandable frame 24 is interfaced with the SVC 14 or the IVC 18. The expandable frame 24 can be made from any suitable material, for example, from a shape memory alloy such as nitinol based alloy.

[0041] In many embodiments, the expandable frame 24 supports the unidirectional valve 26 and includes an outwardly extending downstream crown structure 30, an outwardly extending upstream crown structure 32, and a plurality of outwardly extending anchor segments 34. In many embodiments, the expandable frame 24 includes interconnected struts

that form a substantially cylindrical main body from which the downstream crown structure 30, the upstream crown structure 32, and each of the plurality of anchor segments 34 outwardly extend. As described herein, the downstream crown structure 30 can be interfaced with the junction 20, 22 during implantation of the prosthetic valve 10, 12 to generate a tactile feedback during implantation that indicates correct relative positioning of the expandable frame 24 relative to the junction 20, 22 for completion of expansion of the expandable frame 24 during implantation of the prosthetic valve 10, 12. In many embodiments, the expandable frame 24 includes struts that are interconnected to form apertures between adjacent struts, the downstream crown structure 30, the upstream crown structure 32, and the plurality of anchor segments 34. In many embodiments, the downstream crown structure 30 extends radially outward from a main cylindrical body of the expandable frame 24 by a suitable distance (e.g., about 5 mm) to engage the junction 20, 22 to sufficiently inhibit upstream migration of the expandable frame during systole when pressure in the right atrium 16 is elevated while not extending into the right atrium 16 to an extent that would result in increased risk associated with a large device in the right atrium 16 (e.g., thromboembolism). In many embodiments, the upstream crown structure 32 and the anchor segments extend outwardly by a suitable distance (e.g., about 1 to 2 mm) to engage the SVC 14 or the IVC 18 sufficiently to inhibit migration of the prosthetic valve 10, 12 without extending by a distance that would risk penetration through the SVC 14 or the IVC 18.

[0042] In many embodiments, the expandable frame 24 is configured to accommodate blood flow from adjacent venous channels that empty into the SVC 14 or the IVC 18. For example, in many embodiments, the expandable frame 24 has apertures designed so that important drainage vessels emptying into the SVC 14 or the IVC 18 (in particular the hepatic portal vein) are not occluded by the implanted prosthetic valve 10, 12.

[0043] In many embodiments, the unidirectional valve 26 is mounted to and supported by the expandable frame 24. In many embodiments, the unidirectional valve 26 includes valve leaflets supported by the expandable frame 24 and reconfigures, in response to blood pressure applied to the valve leaflets, between an open configuration accommodating blood flow through the unidirectional valve 26 to the right atrium 16 to a closed configuration blocking back flow of blood from the right atrium 16. In the illustrated embodiment, the flow blocking covering 28 blocks radial flow of blood through the expandable frame 24 adjacent to the

unidirectional valve 26, thereby inhibiting regurgitation of blood around the unidirectional valve 26 when the unidirectional valve 26 is in the closed configuration.

[0044] FIG. 3A illustrates a first embodiment 24a of the expandable frame 24 of the implantable prosthetic unidirectional valve 10, 12. The expandable frame 24a includes a plurality of interconnected struts 36 and apertures 38, 40 between adjacent struts 36.

[0045] In a downstream (relative to the direction of blood flow) portion 42 of the expandable frame 24a, the interconnected struts 36 extend along and around the expandable frame 24 so that the downstream portion 42 has a cylindrical shape and the apertures 38 have a rhombus shape. At the downstream end of the downstream portion 42, segments 44 of the interconnected struts 36 flare outwardly to form the downstream crown structure 30. FIG. 3B shows an end view of the downstream crown structure 30 formed by the outwardly flaring segments 44. The downstream crown structure 30 has an outer diameter 46 that is wider than an outer diameter 48 of the cylindrical portion of the downstream portion 42 by a suitable distance (e.g., about 5 mm) to inhibit upstream migration of the expandable frame 24a without extending into the right atrium 16 to an extent that would result in increased risk associated with a large device in the right atrium 16 (e.g., thromboembolism). In many embodiments, the downstream portion 42 of the expandable frame 24a supports the unidirectional valve 26 and the flow blocking covering 28, which blocks flow of blood through the apertures 38 to inhibit regurgitation of blood around the unidirectional valve 26 when the unidirectional valve 26 is in the closed configuration.

[0046] In an upstream (relative to the direction of blood flow) portion 50 of the expandable frame 24a, the interconnected struts 36 include struts 51 that extend parallel to the direction of blood flow and outwardly extending anchor struts 52 connected to adjacent pairs of the struts 51. At the upstream end of the upstream portion 50, segments 54 of the interconnected struts 36 flare outwardly to form the upstream crown structure 32. In many embodiments of the expandable frame 24a, the flow blocking covering 28 does not cover the apertures 40 in the upstream portion 50 and the apertures 40 are configured to accommodate blood flow from adjacent venous channels that empty into the SVC 14 or the IVC 18. For example, in many embodiments, the apertures 40 are designed so that important drainage vessels emptying into the SVC 14 or the IVC 18 (in particular the hepatic portal vein) are not occluded by the implanted prosthetic valve 10, 12. Because the implanted prosthetic valve 10, 12 is configured to accommodate blood flow from veins covered by the implanted valve

10, 12, the expandable frame 24 can have an overall length 55 that is longer than if the expandable frame 24 was short enough to not cover adjacently terminating veins. As a result of the longer overall length 55, the expandable frame 24 has increased radial contact with the SVC 14 or the IVC 18, thereby better inhibiting migration of the prosthetic valve 10, 12 and
5 reducing risk of embolization. In many embodiments, the outwardly extending anchor struts 52 and the outwardly flaring segments 54 forming the upstream crown structure 32 extend outwardly by a suitable distance (e.g., about 1 to 2 mm) to engage the SVC 14 or the IVC 18 sufficiently to inhibit migration of the prosthetic valve 10, 12 without extending by a distance that would risk penetration through the SVC 14 or the IVC 18.

10 [0047] FIG. 4A and FIG. 4B illustrate a second embodiment 24b of the expandable frame 24 of the implantable prosthetic unidirectional valve 10, 12. The expandable frame 24b has an upstream portion 50 configured the same as the upstream portion 50 of the expandable frame 24a and a downstream crown structure 30 configured similar to the downstream crown structure 30 of the expandable frame 24a. The expandable frame 24b has a downstream
15 portion 56 that differs from the downstream portion 42 of the expandable frame 24a. In the illustrated embodiment, the downstream portion 56 includes three struts 58 that extend parallel to the direction of blood flow and connect the upstream portion 50 with the downstream crown structure 30. The downstream portion 56 has three apertures 60, each of which is bounded by a respective two of the struts 58, the downstream crown structure 30,
20 and the upstream portion 50. At the downstream end of the downstream portion 56, segments 44 flare outwardly to form the downstream crown structure 30. The downstream crown structure 30 has an outer diameter 46 that is wider than an outer diameter 48 of the cylindrical portion of the expandable frame 24b by a suitable distance (e.g., about 5 mm) to inhibit upstream migration of the expandable frame 24b without extending into the right atrium 16 to an extent that would result in increased risk associated with a large device in the right atrium
25 16 (e.g., thromboembolism).

[0048] In many embodiments of the expandable frame 24b, the upstream portion 50 supports the unidirectional valve 26 and the flow blocking covering 28 is supported by both the upstream portion 50 and the downstream portion 56. As described herein with reference
30 to FIG. 8A and FIG. 8B, the configuration of the downstream portion 56 enables reconfiguration of the flow blocking covering 28 from a flow accommodating configuration that accommodates flow of blood from one or more veins outlets covered by the implanted prosthetic valve 10, 12 to the right atrium 16 to a flow blocking configuration that blocks

back flow of blood from the right atrium 16 to the one or more covered veins outlets and blocks flow of blood through the apertures 40 to inhibit regurgitation of blood around the unidirectional valve 26 when the unidirectional valve 26 is in the closed configuration.

[0049] FIG. 5A and FIG. 5B illustrate a third embodiment 24c of the expandable frame 24 of the implantable prosthetic unidirectional valve 10, 12. The expandable frame 24c is configured similar to the expandable frame 24a, but further includes upstream eyelets 62 for constraining the prosthetic valve 10, 12 relative to a delivery catheter during implantation of the valve 10, 12.

[0050] FIG. 6 illustrates a fourth embodiment 24d of the expandable frame 24 of the implantable prosthetic unidirectional valve 10, 12. The expandable frame 24d has an upstream portion 50 configured the same as the upstream portion 50 of the expandable frames 24a, 24b, 24c. The expandable frame 24d has a downstream portion 64 that includes a plurality of separated struts 66 that extend downstream from the upstream portion 50 parallel to the direction of blood flow. At the downstream end of the downstream portion 64, segments 68 flare outwardly to form a downstream crown structure 70, which is similar to the downstream crown structure 30 but lacks interconnection between the segments 68.

[0051] In many embodiments of the expandable frame 24d, the upstream portion 50 supports the unidirectional valve 26 and the flow blocking covering 28 is supported by both the upstream portion 50 and the downstream portion 64. As described herein with reference to FIG. 9A and FIG. 9B, the separated struts 66 are configured to deflect radially inward to accommodate flow of blood from one or more veins outlets covered by the implanted prosthetic valve 10, 12 to the right atrium 16. When the unidirectional valve 26 is in the closed configuration, the separated struts 66 extend straight downstream and support the flow blocking covering 28 in a configuration that blocks back flow of blood from the right atrium 16 to the one or more covered veins outlets and blocks flow of blood through the apertures 40 to inhibit regurgitation of blood around the unidirectional valve 26 when the unidirectional valve 26 is in the closed configuration.

[0052] FIG. 7 is a simplified cross-sectional schematic diagram illustrating accommodation of blood flow from a vein 74 covered by an implanted prosthetic valve 10, 12 through a sidewall of an expandable frame (e.g., expandable frame 24a) of the prosthetic valve 10, 12, in accordance with many embodiments. In the illustrated embodiment, the flow blocking covering 28 does not extend over the upstream portion 50 of the expandable frame

24a thereby accommodating a flow of blood 72 from the vein 74 covered by the implanted valve 10, 12 to the right atrium 16 when the unidirectional valve 26 is in the open configuration. When in the closed configuration, the unidirectional valve 26 blocks back flow of blood from the right atrium 16 as well as substantially blocking upstream transmission of elevated pressure from the right atrium 16. The flow blocking covering 28 blocks back flow of blood around the unidirectional valve 26 when the unidirectional valve 26 is in the closed configuration.

[0053] FIGS. 8A and 8B are simplified cross-sectional schematic diagrams illustrating configurations of an implanted prosthetic valve 10, 12 (which includes the expandable frame 24b) that accommodate a flow of blood 72 from a vein 74 covered by the prosthetic valve 10, 12 to the right atrium 16 when the unidirectional valve 26 is in the open configuration as illustrated in FIG. 8A and inhibiting upstream backflow of blood from the right atrium 16 to the covered vein 74 when the unidirectional valve 26 is in the closed configuration as illustrated in FIG. 8B. In the blood flow accommodating configuration illustrated in FIG. 8A, the flow blocking covering 28 is in a configuration in which downstream portions of the flow blocking covering 28 extend through the apertures 60 in the downstream portion 56 of the expandable frame 24b, thereby providing a route for blood from the covered vein 74 to the right atrium 16. In the blood flow inhibiting configuration illustrated in FIG. 8B, the flow blocking covering is in a configuration in which the downstream portions of the flow blocking covering do not extend through the apertures 60 in the downstream portion 56 of the expandable frame 24b, thereby blocking back flow of blood from the right atrium 16 to the covered vein 74.

[0054] FIGS. 9A and 9B are simplified cross-sectional schematic diagrams illustrating configurations of an implanted prosthetic valve 10, 12 (which includes the expandable frame 24d) that accommodate a flow of blood 72 from a vein 74 covered by the prosthetic valve 10, 12 to the right atrium 16 when the unidirectional valve 26 is in the open configuration as illustrated in FIG. 9A and inhibiting upstream backflow of blood from the right atrium 16 to the covered vein 74 when the unidirectional valve 26 is in the closed configuration as illustrated in FIG. 9B. In the blood flow accommodating configuration illustrated in FIG. 9A, the separated struts 66 and the downstream portion of the flow blocking covering 28 supported by the separated struts 66 are deflected inwardly, thereby providing a route for blood from the covered vein 74 to the right atrium 16. In the blood flow inhibiting configuration illustrated in FIG. 9B, the separated struts 66 and the downstream

portion of the flow blocking covering 28 supported by the separate struts are not deflected inwardly and extend along the interior surface of the SVC 14 or the IVC 18, thereby blocking back flow of blood from the right atrium 16 to the covered vein 74.

[0055] FIGS. 10A through 10D are simplified cross-sectional schematic diagrams

5 illustrating intraluminal implantation of a self-expanding embodiment of a prosthetic unidirectional valve 10, 12 at the junction 20 between the SVC 14 and the right atrium 16 or adjacent to the junction 22 between the IVC 18 and the right atrium 16, in accordance with many embodiments. As illustrated in FIG. 10A, a catheter assembly 100 used to implant the valve 10, 12 is shown after being advanced along a guide wire 102 to a position partially
10 extending into the right atrium 16. The catheter assembly 100 includes an outer sheath 104 configured to radially constrain the valve 10, 12 in an unexpanded configuration during delivery. Any suitable route can be used for the guide wire 102 and to advance the catheter assembly 100 along the guide wire 102. For example, when implanting the valve 10 in the SVC 14 adjacent to the junction 20 between the SVC 14 and the right atrium 16, the guide
15 wire 102 and the catheter assembly 100 can be routed to the implantation location percutaneously via the jugular vein or the femoral vein. When implanting the valve 12 in the IVC 18 adjacent to the junction 22 between the IVC 18 and the right atrium 16, the guide wire 102 and the catheter assembly 100 can be routed to the implantation location percutaneously via the femoral vein.

20 **[0056]** From the configuration shown in FIG. 10A, the valve 10, 12 can be partially deployed via relative movement between the outer sheath 104 and the valve 10, 12 to produce the partially-expanded configuration shown in FIG. 10B. For example, the catheter assembly 100 can be configured so that the outer sheath 104 can be retracted proximally (upstream) relative to the valve 10, 12 to release a suitable downstream portion of the valve 10, 12 to
25 expand the downstream crown structure 30 to a diameter sufficient to be interfaced with the junction 20, 22 (as illustrated in FIG. 10C) via subsequent proximal retraction of the catheter assembly 100. As an alternative, the catheter assembly 100 can include a pusher 108 that can be advanced distally relative to the outer sheath 104 to eject a suitable downstream portion of the valve 10, 12 to expand the downstream crown structure 30 to a diameter sufficient to be
30 interfaced with the junction 20, 22 via subsequent proximal retraction of the catheter assembly 100. Interfacing the downstream crown structure 30 with the junction 20, 22 can be used to generate a tactile response transmitted via the catheter assembly 100 to the surgeon operating the catheter assembly 100, thereby confirming positioning of the catheter assembly

100 for finishing deployment of the valve 10, 12 to the resulting implanted configuration illustrated in **FIG. 10D**.

[0057] **FIGS. 11A** through **11E** are simplified cross-sectional schematic diagrams illustrating intraluminal implantation of an inflatable member expanded embodiment of a prosthetic unidirectional valve 10, 12 at the junction 20 between the SVC 14 and the right atrium 16 or adjacent to the junction 22 between the IVC 18 and the right atrium 16, in accordance with many embodiments. As illustrated in **FIG. 11A**, a catheter assembly 200 used to implant the valve 10, 12 is shown after being advanced along a guide wire 102 to a position partially extending into the right atrium 16. The catheter assembly 200 includes a distal inflatable member 202 and a proximal inflatable member 204. The inflatable member expanded valve 10, 12 is crimped onto the distal and proximal inflatable members 202, 204 to produce an unexpanded configuration for intraluminal delivery of the valve 10, 12 to the implantation site. Any suitable route can be used for the guide wire 102 and to advance the catheter assembly 100 along the guide wire 102. For example, when implanting the valve 10 in the SVC 14 adjacent to the junction 20 between the SVC 14 and the right atrium 16, the guide wire 102 and the catheter assembly 100 can be routed to the implantation location percutaneously via the jugular vein or the femoral vein. When implanting the valve 12 in the IVC 18 adjacent to the junction 22 between the IVC 18 and the right atrium 16, the guide wire 102 and the catheter assembly 100 can be routed to the implantation location percutaneously via the femoral vein.

[0058] From the configuration shown in **FIG. 11A**, the valve 10, 12 can be partially deployed via partial inflation of the distal inflatable member 202. The distal inflatable member 202 is partially inflated so as to expand the downstream crown structure 30 to a diameter sufficient to be interfaced with the junction 20, 22 (as illustrated in **FIG. 11C**) via subsequent proximal retraction of the catheter assembly 200. Interfacing the downstream crown structure 30 with the junction 20, 22 can be used to generate a tactile response transmitted via the catheter assembly 200 to the surgeon operating the catheter assembly 200, thereby confirming positioning of the catheter assembly 200 for finishing deployment of the valve 10, 12 via expansion of the distal and proximal inflatable members 202, 204 as illustrated in **FIG. 11D**. The distal and proximal inflatable members 202, 204 can then be deflated to produce the resulting implanted configuration illustrated in **FIG. 11E**.

[0059] FIGS. 12A and 12B show example SVC pressure waveforms before and after prosthetic valve implantation that reflect reduction in transmitted atrial back pressure. In the example, implantation of the prosthetic valves 10, 12 reduced the pressure in the SVC from a maximum of about 14.5 mmHg to a maximum of about 6.0 mm Hg.

5 [0060] FIGS. 13A and 13B show example right atrial pressure and central venous pressure after prosthetic valve implantation that reflect reduction in transmitted atrial back pressure. In the example, the implanted prosthetic valves 10, 12 function to limit the central venous pressure to a maximum of about 6.5 mmHg in spite of the maximum right atrial pressure being about 14.5 mmHg.

10 [0061] Other variations are within the spirit of the present invention. Thus, while the invention is susceptible to various modifications and alternative constructions, certain illustrated embodiments thereof are shown in the drawings and have been described above in detail. It should be understood, however, that there is no intention to limit the invention to the specific form or forms disclosed, but on the contrary, the intention is to cover all
15 modifications, alternative constructions, and equivalents falling within the spirit and scope of the invention, as defined in the appended claims.

[0062] The use of the terms “a” and “an” and “the” and similar referents in the context of describing the invention (especially in the context of the following claims) are to be construed to cover both the singular and the plural, unless otherwise indicated herein or
20 clearly contradicted by context. The terms “comprising,” “having,” “including,” and “containing” are to be construed as open-ended terms (i.e., meaning “including, but not limited to,”) unless otherwise noted. The term “connected” is to be construed as partly or wholly contained within, attached to, or joined together, even if there is something intervening. Recitation of ranges of values herein are merely intended to serve as a shorthand
25 method of referring individually to each separate value falling within the range, unless otherwise indicated herein, and each separate value is incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (*e.g.*, “such as”) provided herein, is
30 intended merely to better illuminate embodiments of the invention and does not pose a limitation on the scope of the invention unless otherwise claimed. No language in the

specification should be construed as indicating any non-claimed element as essential to the practice of the invention.

[0063] Preferred embodiments of this invention are described herein, including the best mode known to the inventors for carrying out the invention. Variations of those preferred

5 embodiments may become apparent to those of ordinary skill in the art upon reading the foregoing description. The inventors expect skilled artisans to employ such variations as appropriate, and the inventors intend for the invention to be practiced otherwise than as specifically described herein. Accordingly, this invention includes all modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by
10 applicable law. Moreover, any combination of the above-described elements in all possible variations thereof is encompassed by the invention unless otherwise indicated herein or otherwise clearly contradicted by context.

[0064] All references, including publications, patent applications, and patents, cited herein are hereby incorporated by reference to the same extent as if each reference were individually
15 and specifically indicated to be incorporated by reference and were set forth in its entirety herein.

WHAT IS CLAIMED IS:

1 1. An implantable prosthetic valve for treating tricuspid valve
2 regurgitation, the implantable prosthetic valve comprising:
3 an expandable frame configured for implantation into at least one of: (a) the
4 superior vena cava (SVC) adjacent to the junction of the SVC and the right atrium, or (b) the
5 inferior vena cava adjacent to the junction of the IVC and the right atrium; and
6 a unidirectional valve supported by the expandable frame, the unidirectional
7 valve being configured to:
8 reconfigure from an open configuration accommodating flow of blood to the
9 right atrium to a closed configuration substantially blocking back flow of blood from the right
10 atrium in response to blood pressure downstream of the unidirectional valve increasing above
11 blood pressure upstream of the unidirectional valve, and
12 reconfigure from the closed configuration to the open configuration in
13 response to blood pressure downstream of the unidirectional valve decreasing below blood
14 pressure upstream of the unidirectional valve.

1 2. The implantable prosthetic valve of claim 1, wherein the expandable
2 frame includes an outwardly extending downstream crown structure that is shaped to be
3 interfaced with the junction of the SVC and the right atrium or the junction of the IVC and
4 the right atrium to inhibit upstream migration of the expandable frame.

1 3. The implantable prosthetic valve of claim 2, wherein:
2 the expandable frame is reconfigurable from a non-deployed configuration to a
3 partially-deployed configuration and from the partially-deployed configuration to a fully-
4 deployed configuration;
5 the non-deployed configuration of the expandable frame is sized for
6 intraluminal delivery; and
7 a downstream portion of the expandable frame that includes the downstream
8 crown structure is at least partially expanded in the partially-deployed configuration so that
9 the downstream crown structure has a diameter sized to engage at least one of the junction of
10 the SVC and the right atrium or the junction of the IVC and the right atrium during an
11 upstream movement of the expandable frame in the partially-deployed configuration to
12 provide a tactile feedback indicating the expandable frame is positioned for reconfiguration
13 from the partially-deployed configuration to the fully-deployed configuration.

1 4. The implantable prosthetic valve of claim 3, wherein the expandable
2 frame is self-expanding.

1 5. The implantable prosthetic valve of claim 4, wherein the expandable
2 frame includes one or more eyelets for retaining an upstream portion of the expandable frame
3 within a delivery sheath during the upstream movement of the expandable frame in the
4 partially-deployed configuration.

1 6. The implantable prosthetic valve of any one of claims 1 through 3,
2 wherein the expandable frame is expandable via inflation of one or more catheter mounted
3 inflatable members.

1 7. The implantable prosthetic valve of any one of claims 1 through 6,
2 wherein the expandable frame includes an outwardly extending upstream crown structure that
3 is shaped to be interfaced with the SVC or the IVC to inhibit migration of the expandable
4 frame.

1 8. The implantable prosthetic valve of any one of claims 1 through 7,
2 wherein the expandable frame includes a plurality of outwardly extending anchor segments
3 configured to inhibit migration of the expandable frame via contact with the SVC or the IVC.

1 9. The implantable prosthetic valve of any one of claims 1 through 8,
2 further comprising a flow blocking covering over a portion of the expandable frame
3 supporting the unidirectional valve to inhibit regurgitation around the unidirectional valve by
4 blocking radial flow of blood through the first expandable frame.

1 10. The implantable prosthetic valve of any one of claims 1 through 8,
2 further comprising a flow blocking covering over the expandable frame that is configured to:
3 reconfigure to accommodate flow of blood from one or more SVC-terminating
4 blood vessels to the right atrium or one or more IVC-terminating blood vessels to the right
5 atrium in response to a blood pressure differential applied to the flow blocking covering; and
6 reconfigure to inhibit back flow of blood from the right atrium to one or more
7 SVC-terminating blood vessels or the right atrium to one or more IVC-terminating blood
8 vessels in response to a blood pressure differential applied to the flow blocking covering.

1 11. The implantable prosthetic valve of any one of claims 1 through 8,
2 further comprising a flow blocking covering, and wherein the expandable frame comprises a
3 plurality of separated struts extending downstream from an upstream base portion of the
4 expandable frame, the plurality of separated struts supporting the flow blocking covering,
5 each of the plurality of separated struts being configured to:

6 deform radially inward to position the flow blocking covering to accommodate
7 flow of blood from one or more SVC-terminating blood vessels to the right atrium or one or
8 more IVC terminating blood vessels to the right atrium in response to a blood pressure
9 differential applied to the flow blocking covering; and

10 deform radially outward to position the flow blocking covering to inhibit back
11 flow of blood from the right atrium to one or more SVC-terminating blood vessels or the
12 right atrium to one or more IVC-terminating blood vessels in response to a blood pressure
13 differential applied to the flow blocking covering.

1 12. The implantable prosthetic valve of any one of claims 1 through 9,
2 wherein the expandable frame comprises apertures adapted to accommodate flow of blood
3 from one or more SVC-terminating blood vessels to the right atrium or one or more IVC-
4 terminating blood vessels to the right atrium.

1 13. The implantable prosthetic valve of any one of claims 1 through 12,
2 wherein radial force is used to inhibit migration of the expandable frame.

1 14. An implantable prosthetic valve comprising:
2 a unidirectional valve configured to:

3 reconfigure from an open configuration accommodating flow of blood
4 to a closed configuration substantially blocking back flow of blood in response to blood
5 pressure downstream of the unidirectional valve increasing above blood pressure upstream of
6 the unidirectional valve; and

7 reconfigure from the closed configuration to the open configuration in
8 response to blood pressure downstream of the unidirectional valve decreasing below blood
9 pressure upstream of the unidirectional valve; and

10 an expandable frame supporting the unidirectional valve and including at least
11 one of:

an outwardly extending downstream crown structure that is shaped to inhibit migration of the expandable frame;

an outwardly extending upstream crown structure that is shaped to inhibit migration of the expandable frame; and

a plurality of outwardly extending anchor segments configured to inhibit migration of the expandable frame.

15. The implantable prosthetic valve of claim 14, further comprising a flow blocking covering supported by the expandable frame, the flow blocking covering being configured to at least one of:

(a) inhibit regurgitation around the unidirectional valve by blocking radial flow of blood through the first expandable frame; or

(b) reconfigure to accommodate downstream flow of blood in response to a blood pressure differential applied to the flow blocking covering, and reconfigure to inhibit back flow of blood in response to a blood pressure differential applied to the flow blocking covering.

16. A method of treating tricuspid valve regurgitation, the method comprising:

supporting a first expandable frame via contact between the first expandable frame and the superior vena cava (SVC) adjacent to the junction of the SVC and the right atrium;

supporting a first unidirectional valve via the first expandable frame;

reconfiguring the first unidirectional valve from an open configuration accommodating flow of blood from the SVC to the right atrium to a closed configuration substantially blocking back flow of blood from the right atrium to the SVC in response to blood pressure downstream of the first unidirectional valve increasing above blood pressure upstream of the first unidirectional valve;

reconfiguring the first unidirectional valve from the closed configuration to the open configuration in response to blood pressure downstream of the first unidirectional valve decreasing below blood pressure upstream of the first unidirectional valve;

supporting a second expandable frame via contact between the second expandable frame and the inferior vena cava (IVC) adjacent to the junction of the IVC and the right atrium;

18 supporting a second unidirectional valve via the second expandable frame; and
19 reconfiguring the second unidirectional valve from an open configuration
20 accommodating flow of blood from the IVC to the right atrium to a closed configuration
21 substantially blocking back flow of blood from the right atrium to the IVC in response to
22 blood pressure downstream of the second unidirectional valve increasing above blood
23 pressure upstream of the second unidirectional valve; and
24 reconfiguring the second unidirectional valve from the closed configuration to
25 the open configuration in response to blood pressure downstream of the second unidirectional
26 valve decreasing below blood pressure upstream of the second unidirectional valve.

1 17. The method of claim 16, further comprising at least one of:
2 inhibiting upstream migration of the first expandable frame via contact
3 between a first downstream crown structure of the first expandable frame and the SVC and/or
4 between the first downstream crown structure and the junction of the SVC and the right
5 atrium; or
6 inhibiting upstream migration of the second expandable frame via contact
7 between a second downstream crown structure of the second expandable frame and the IVC
8 and/or between the second downstream crown structure and the junction of the IVC and the
9 right atrium.

1 18. The method of claim 17, further comprising at least one of:
2 (a) advancing the first expandable frame downstream through the SVC or the
3 IVC in a non-expanded configuration to position the first downstream crown structure
4 downstream of the junction between the SVC and the right atrium;
5 partially expanding the first expandable frame by expanding a downstream
6 portion of the first expandable frame that includes the first downstream crown structure;
7 retracting the partially expanded first expandable frame upstream through the
8 SVC to interface the first downstream crown structure with the junction between the SVC
9 and the right atrium; and
10 completing expansion of the first expandable member subsequent to the first
11 downstream crown structure being interfaced with the junction between the SVC and the
12 right atrium; or

(b) advancing the second expandable frame downstream through the IVC in a non-expanded configuration to position the second downstream crown structure downstream of the junction between the IVC and the right atrium;

partially expanding the second expandable frame by expanding a downstream portion of the second expandable frame that includes the second downstream crown structure;

retracting the partially expanded second expandable frame upstream through the IVC to interface the second downstream crown structure with the junction between the IVC and the right atrium; and

completing expansion of the second expandable member subsequent to the second downstream crown structure being interfaced with the junction between the IVC and the right atrium.

19. The method of any one of claims 16 through 18, further comprising at least one of:

inhibiting migration of the first expandable frame via contact between a first upstream crown structure of the first expandable frame and the SVC; or

inhibiting migration of the second expandable frame via contact between a second upstream crown structure of the second expandable frame and the IVC.

20. The method of any one of claims 16 through 19, further comprising at least one of:

inhibiting migration of the first expandable frame via contact between a plurality of first outwardly extending anchor segments of the first expandable frame and the SVC; or

inhibiting migration of the second expandable frame via contact between a plurality of second outwardly extending anchor segments of the second expandable frame and the IVC.

21. The method of any one of claims 16 through 20, further comprising at least one of:

inhibiting regurgitation around the first unidirectional valve by blocking radial flow of blood through the first expandable frame via a first flow blocking covering over a portion of the first expandable frame supporting the first unidirectional valve; or

inhibiting regurgitation around the second unidirectional valve by blocking radial flow of blood through the second expandable frame via a second flow blocking

8 covering over a portion of the second expandable frame supporting the second unidirectional
9 valve.

1 22. The method of any one of claims 16 through 21, further comprising at
2 least one of acts (a) or acts (b):

3 (a) supporting a first flow blocking covering by the first expandable member;
4 reconfiguring the first flow blocking covering to accommodate flow of blood
5 from one or more SVC-terminating blood vessels to the right atrium in response to a blood
6 pressure differential applied to the first flow blocking covering; and

7 reconfiguring the first flow blocking covering to inhibit back flow of blood
8 from the right atrium to the one or more SVC-terminating blood vessels in response to a
9 blood pressure differential applied to the first flow blocking covering; or

10 (b) supporting a second flow blocking covering by the second expandable
11 member,

12 reconfiguring the second flow blocking covering to accommodate flow of
13 blood from one or more IVC-terminating blood vessels to the right atrium in response to a
14 blood pressure differential applied to the second flow blocking covering; and

15 reconfiguring the second flow blocking covering to inhibit back flow of blood
16 from the right atrium to the one or more IVC-terminating blood vessels in response to a blood
17 pressure differential applied to the second flow blocking covering.

1 23. The method of any one of claims 16 through 22, further comprising at
2 least one of acts (a) or acts (b):

3 (a) supporting a first flow blocking covering via a plurality of first separated
4 struts extending downstream from an upstream base portion of the first expandable frame;

5 deforming each of the plurality of first separated struts radially inward to
6 position the first flow blocking covering to accommodate flow of blood from one or more
7 SVC-terminating blood vessels to the right atrium in response to a blood pressure differential
8 applied to the first flow blocking covering; and

9 deforming each of the plurality of first separated struts radially outward to
10 position the first flow blocking covering to inhibit back flow of blood from the right atrium to
11 the one or more SVC-terminating blood vessels in response to a blood pressure differential
12 applied to the first flow blocking covering; or

(b) supporting a second flow blocking covering via a plurality of second separated struts extending downstream from an upstream base portion of the second expandable frame,

deforming each of the plurality of second separated struts radially inward to position the second flow blocking covering to accommodate flow of blood from one or more IVC-terminating blood vessels to the right atrium in response to a blood pressure differential applied to the second flow blocking covering; and

deforming each of the plurality of second separated struts radially outward to position the second flow blocking covering to inhibit back flow of blood from the right atrium to the one or more IVC-terminating blood vessels in response to a blood pressure differential applied to the second flow blocking covering.

24. The method of any one of claims 16 through 23, further comprising at least one of:

accommodating flow of blood from one or more SVC-terminating blood vessels to the right atrium via apertures in the first expandable frame; or

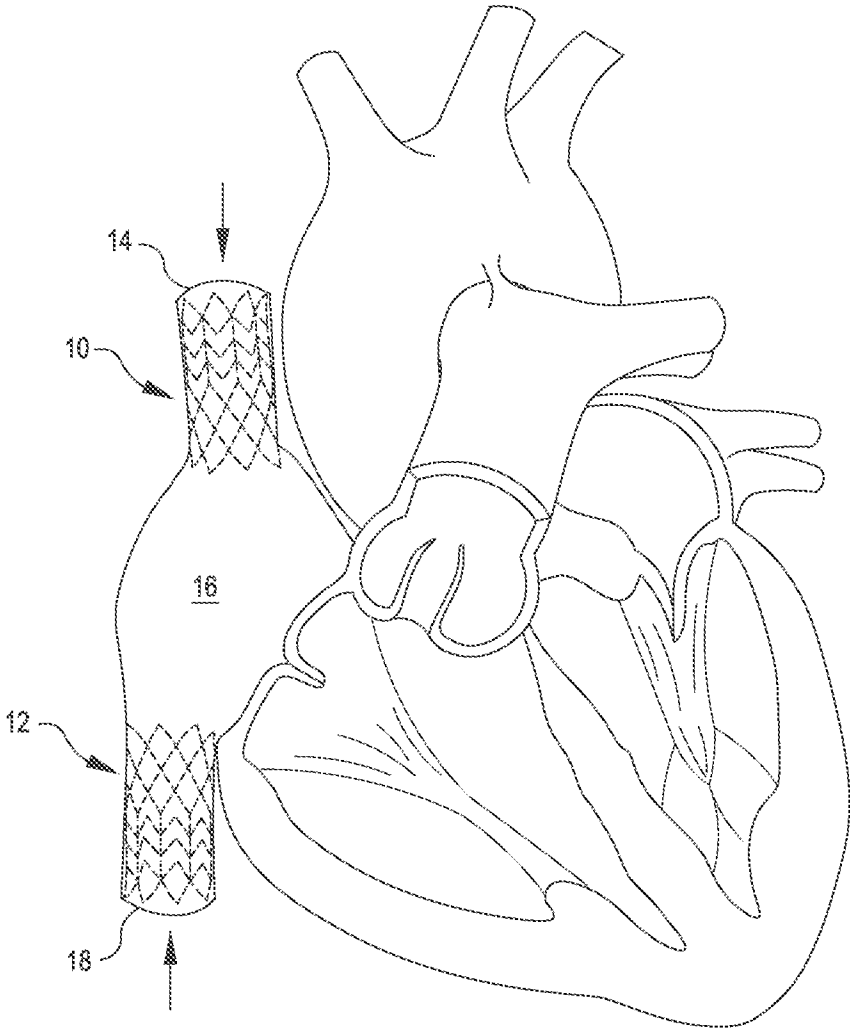
accommodating flow of blood from one or more IVC-terminating blood vessels to the right atrium via apertures in the second expandable frame.

25. The method of any of claims 16 through 24, wherein at least one of the first expandable frame or the second expandable frame is self-expanding.

26. The method of any of claims 16 through 25, wherein at least one of the first expandable frame or the second expandable frame is expanded via inflation of one or more catheter mounted inflatable members.

27. The method of any of claims 16 through 26, wherein radial force is used to inhibit migration of at least one of the first expandable frame or the second expandable frame.

FIG. 1



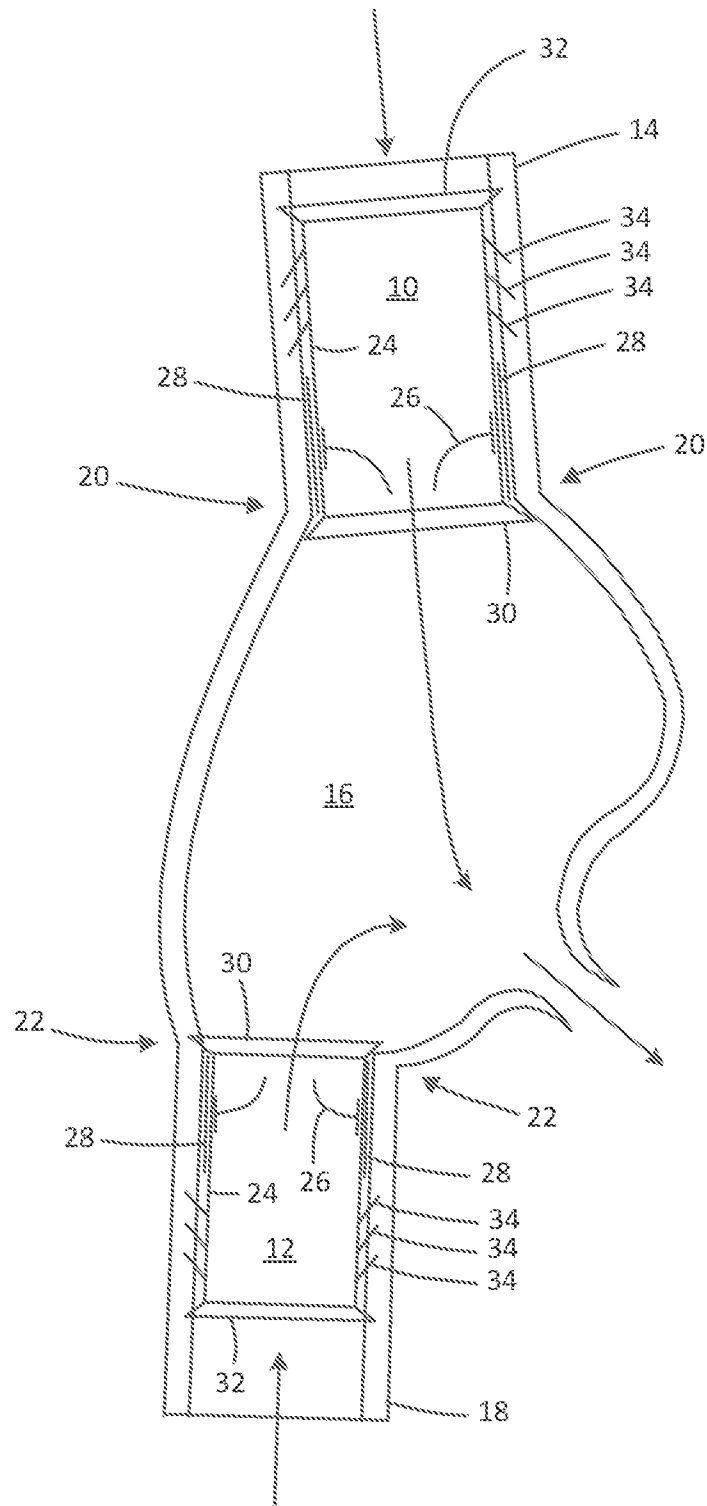


FIG. 2

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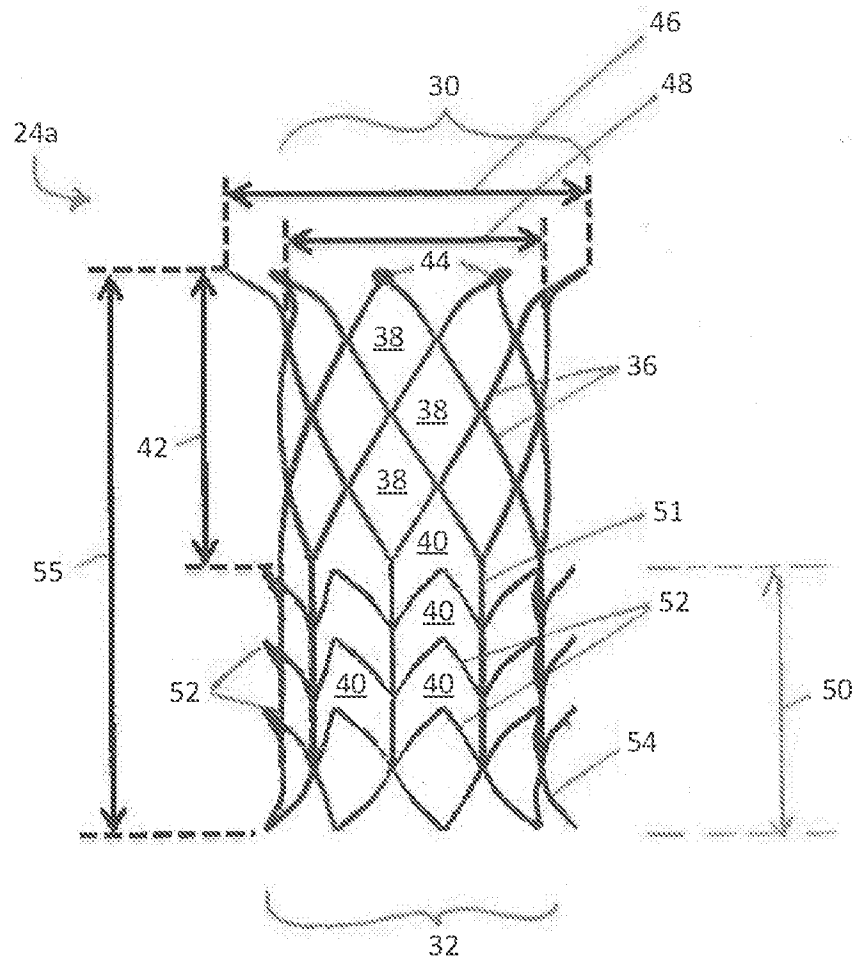


FIG. 3A

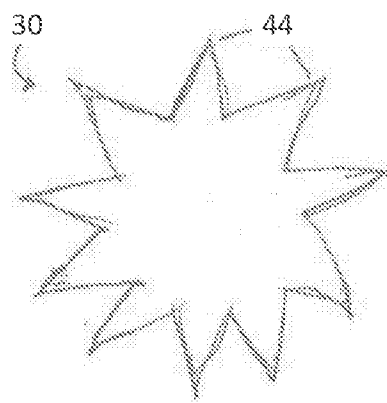


FIG. 3B

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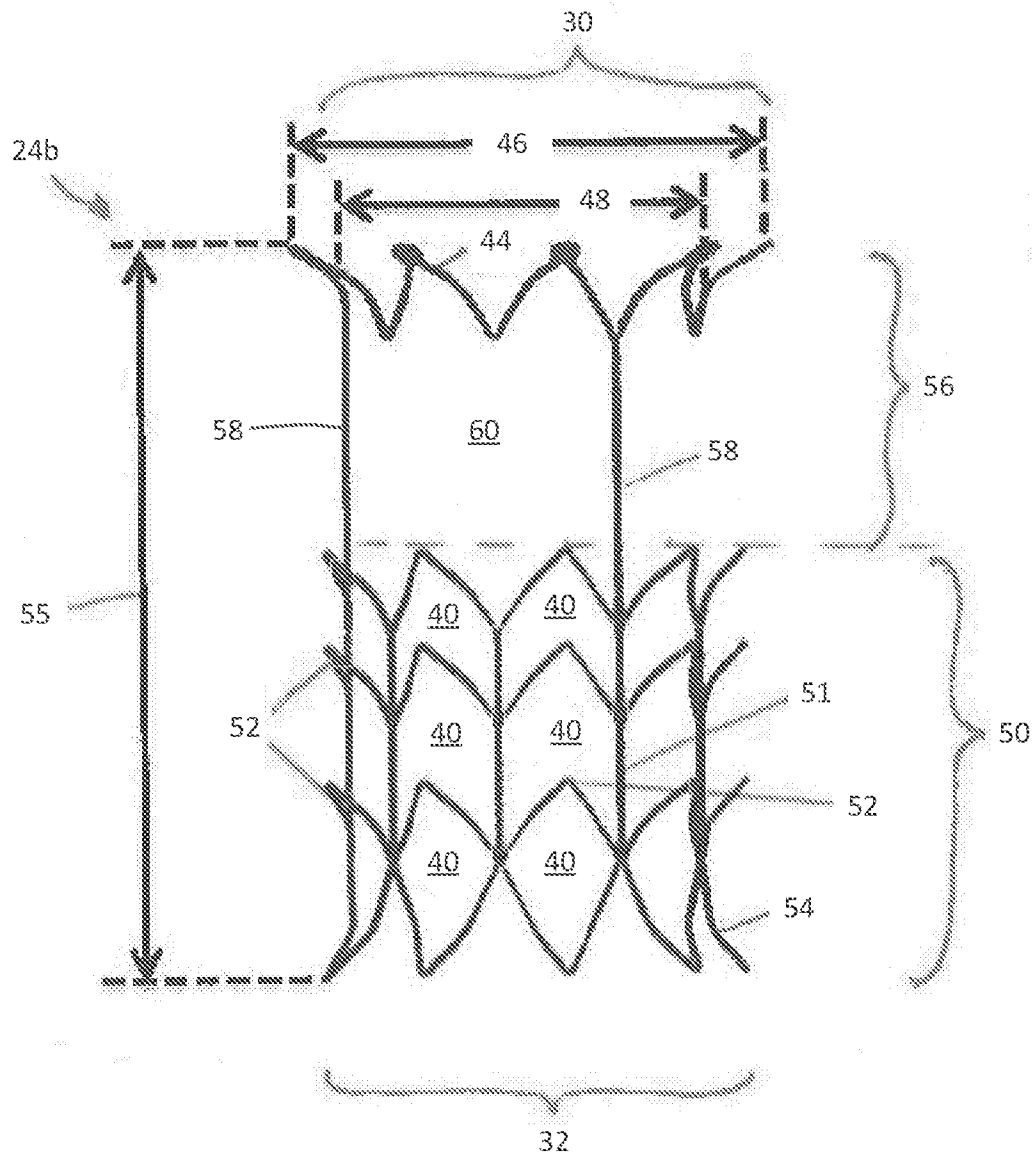


FIG. 4A

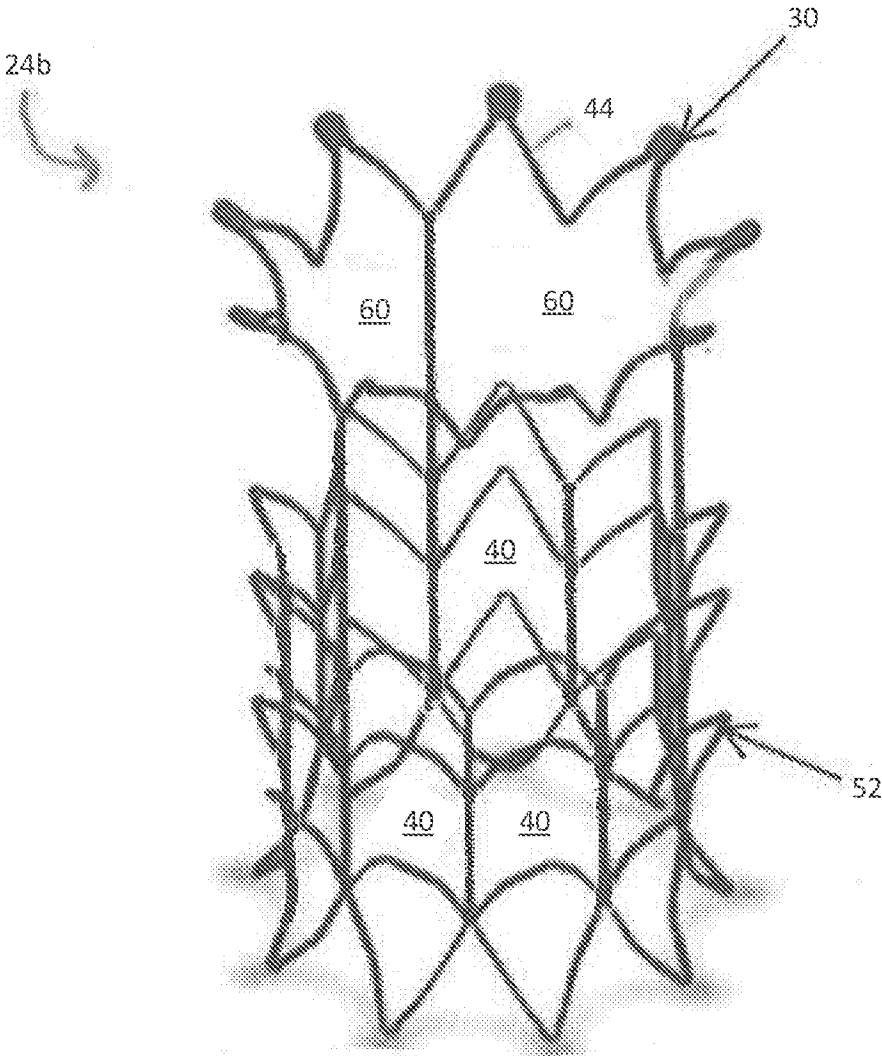


FIG. 4B

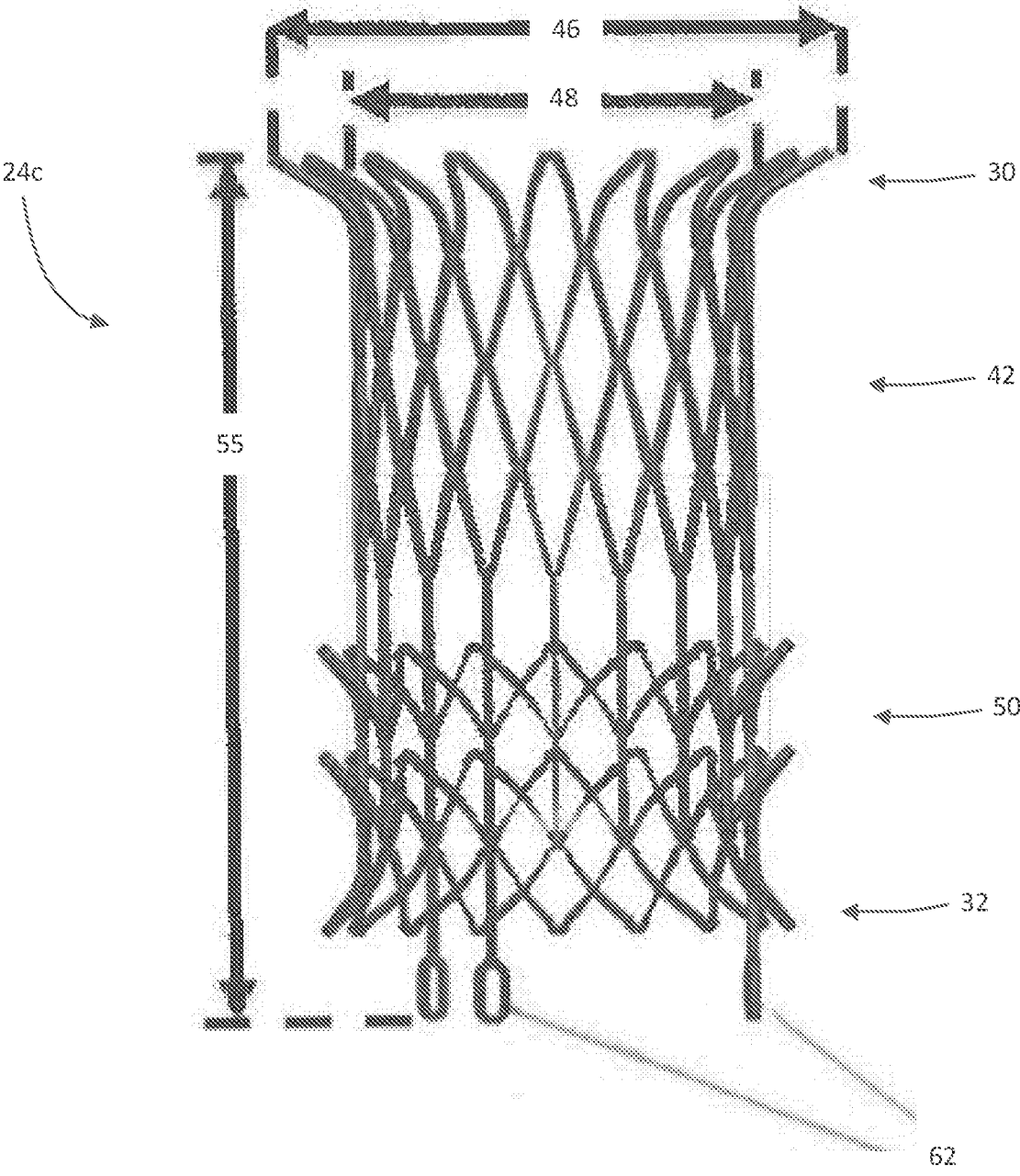


FIG. 5A

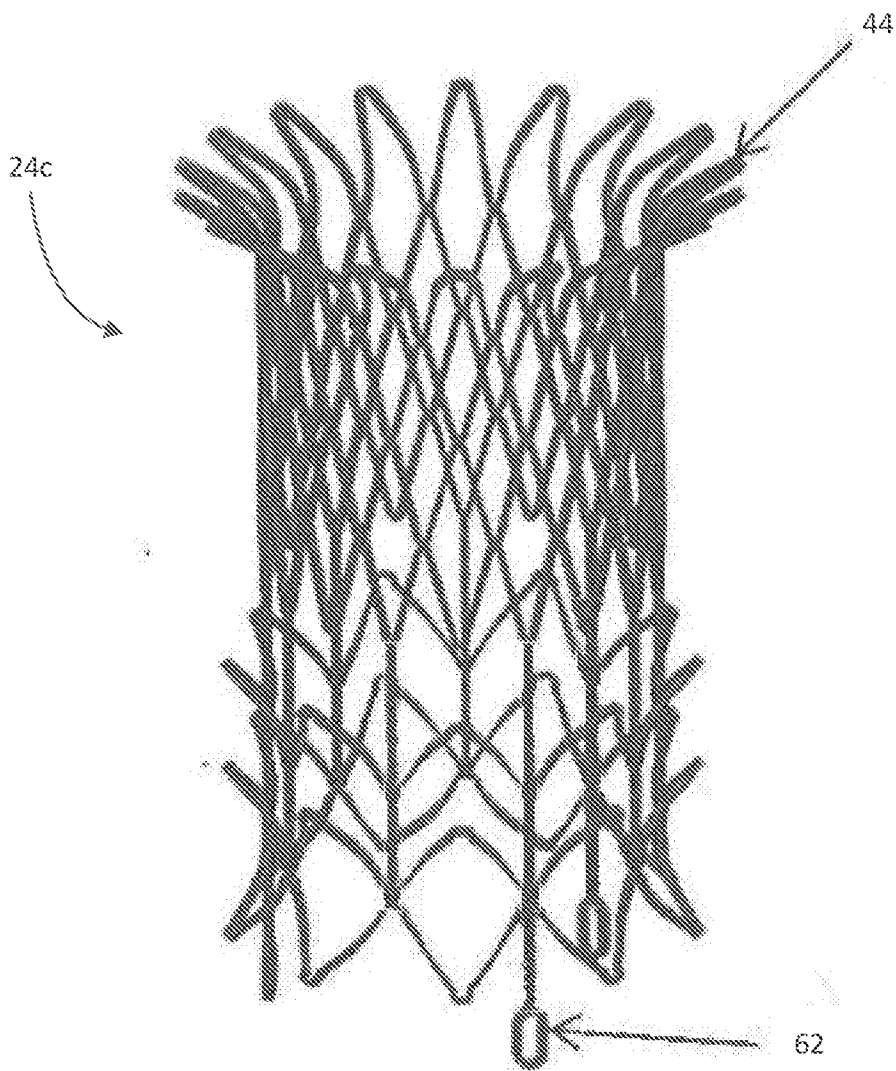


FIG. 5B

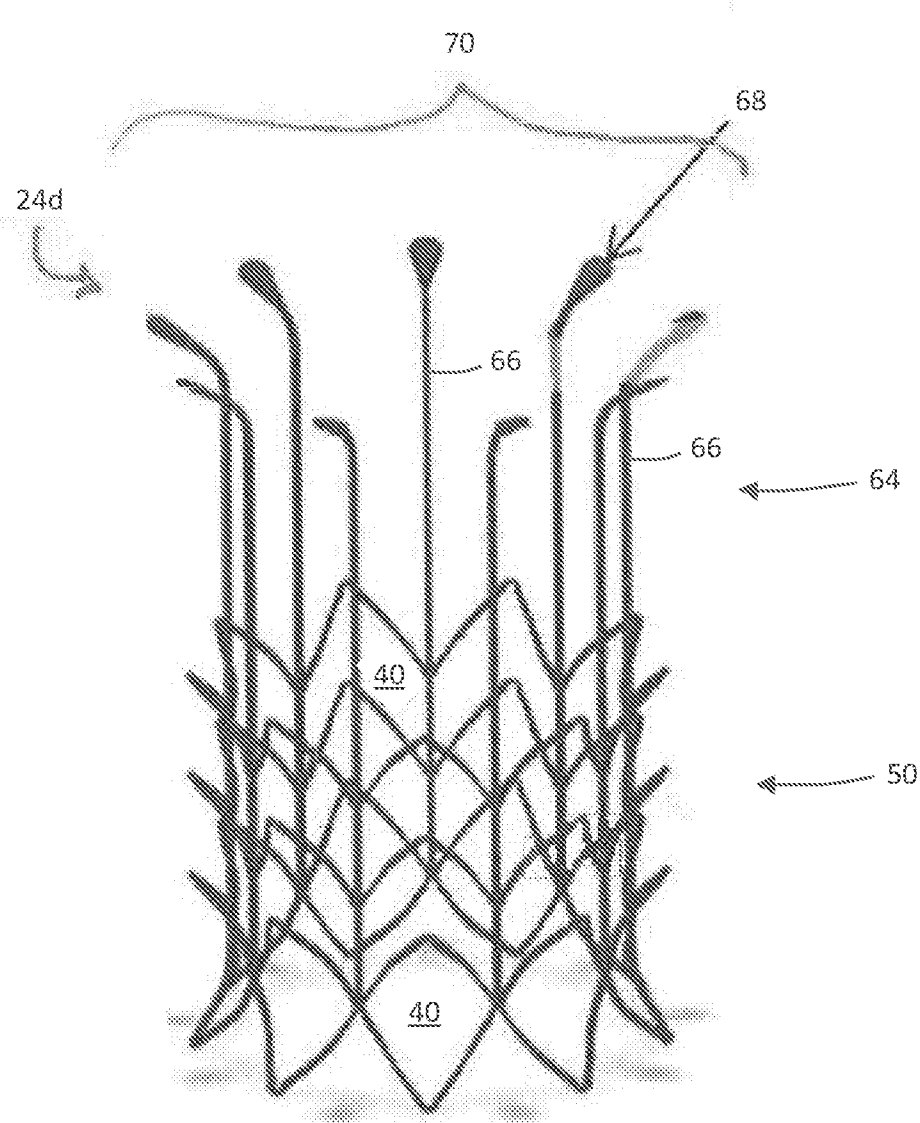


FIG. 6

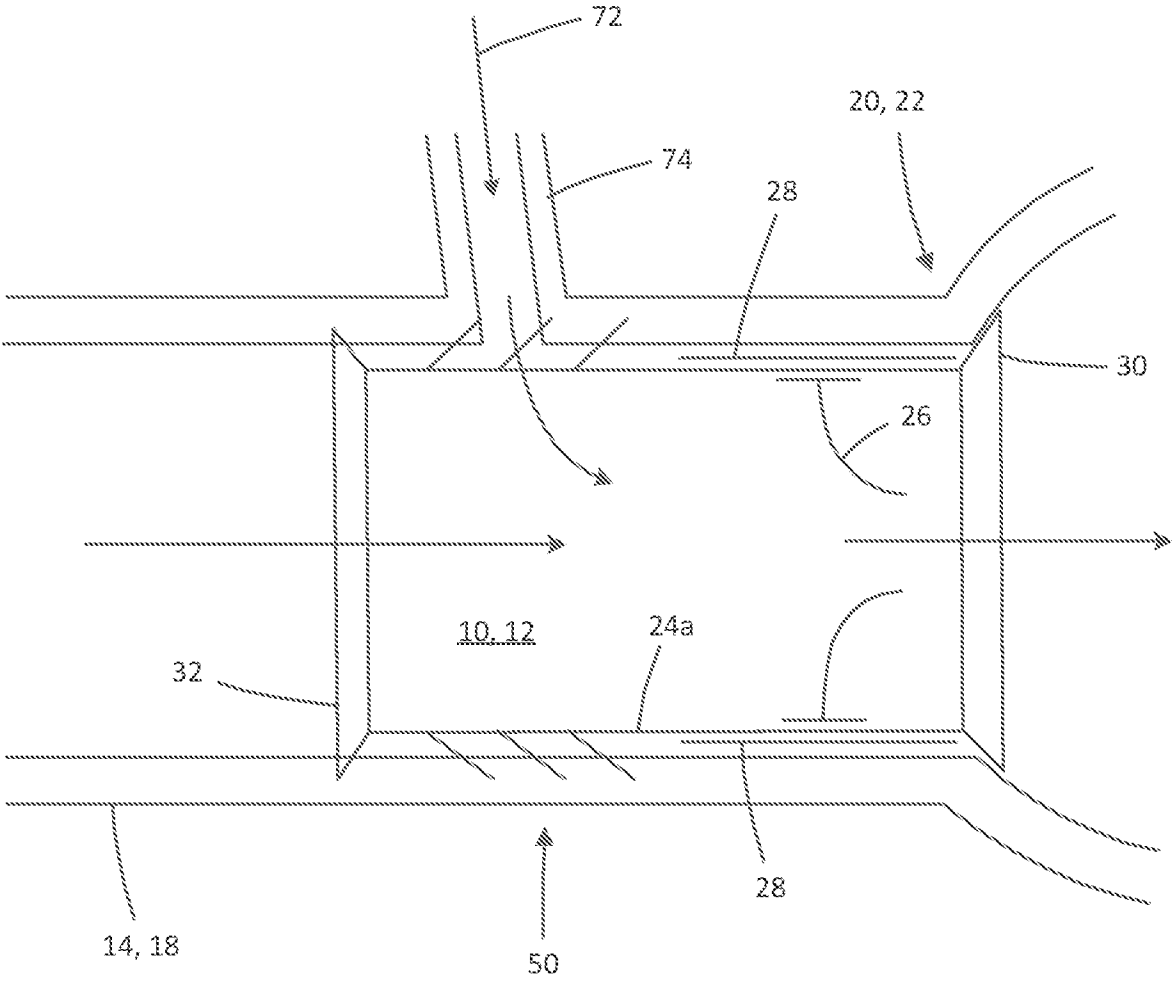


FIG. 7

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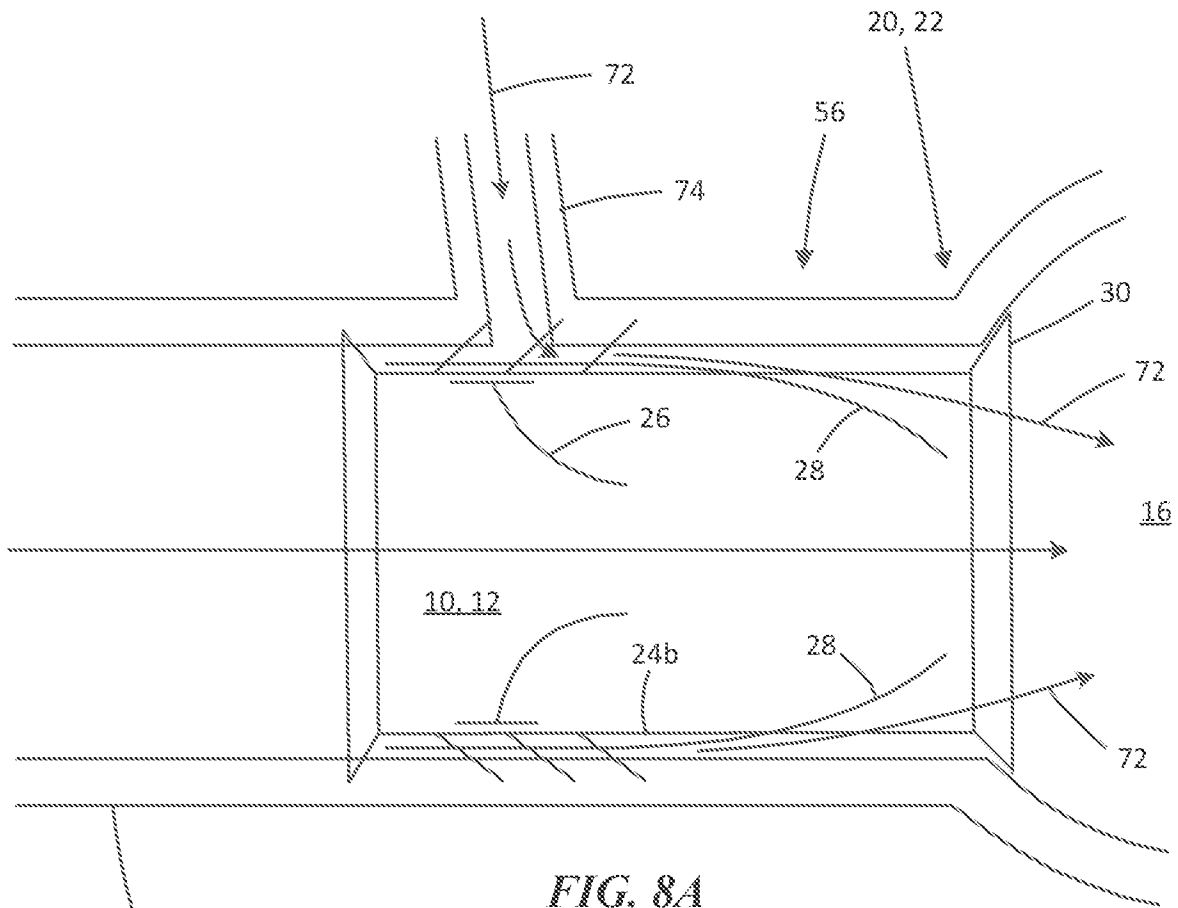


FIG. 8A

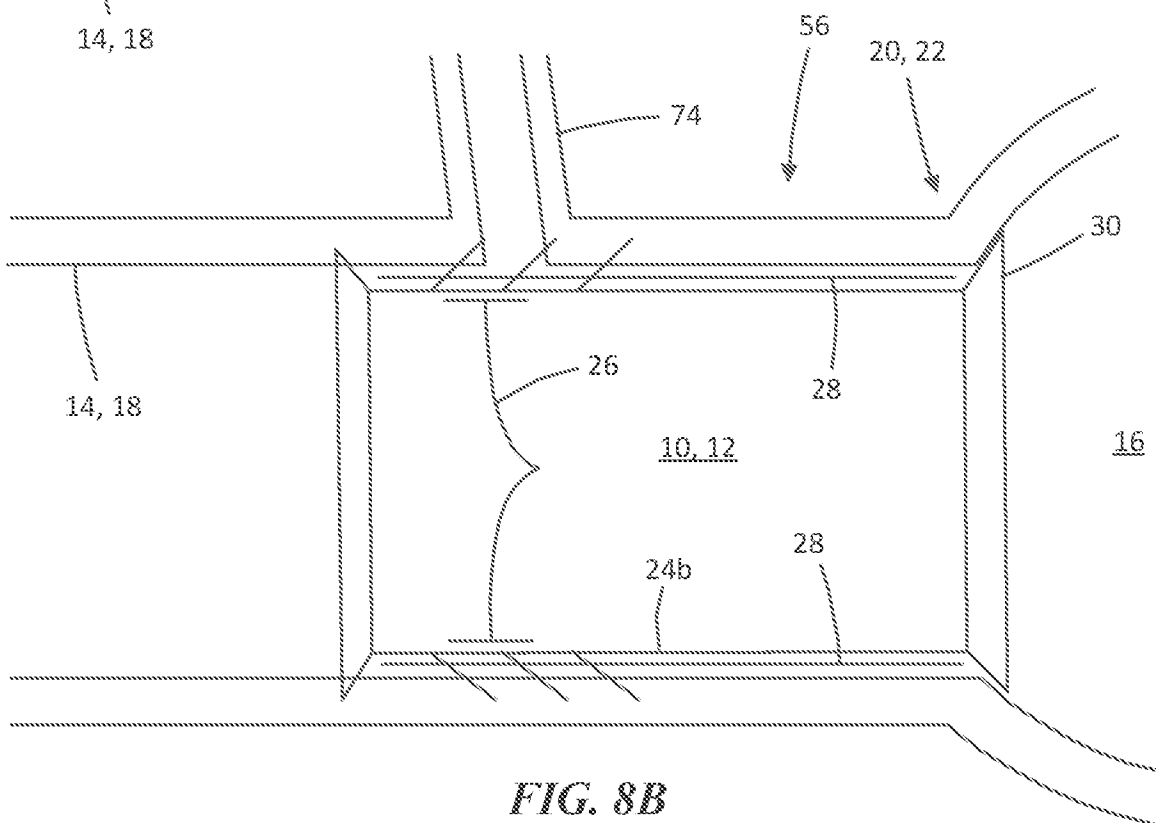
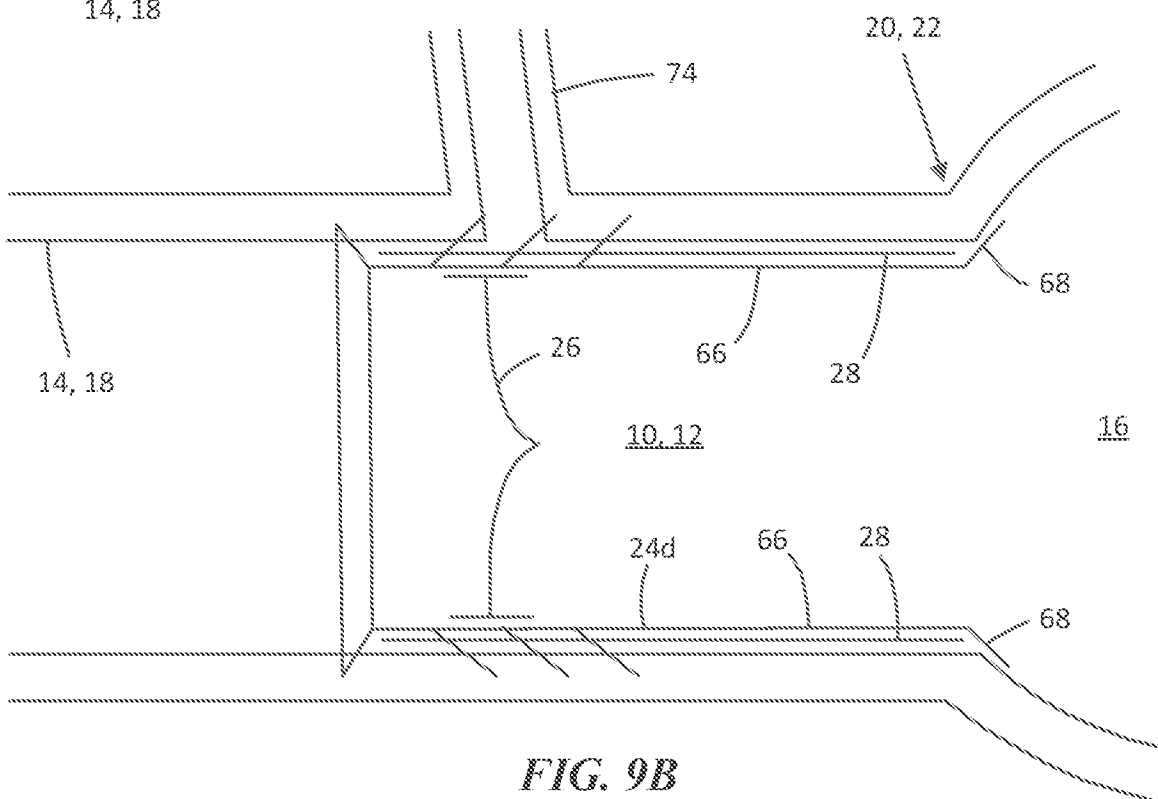
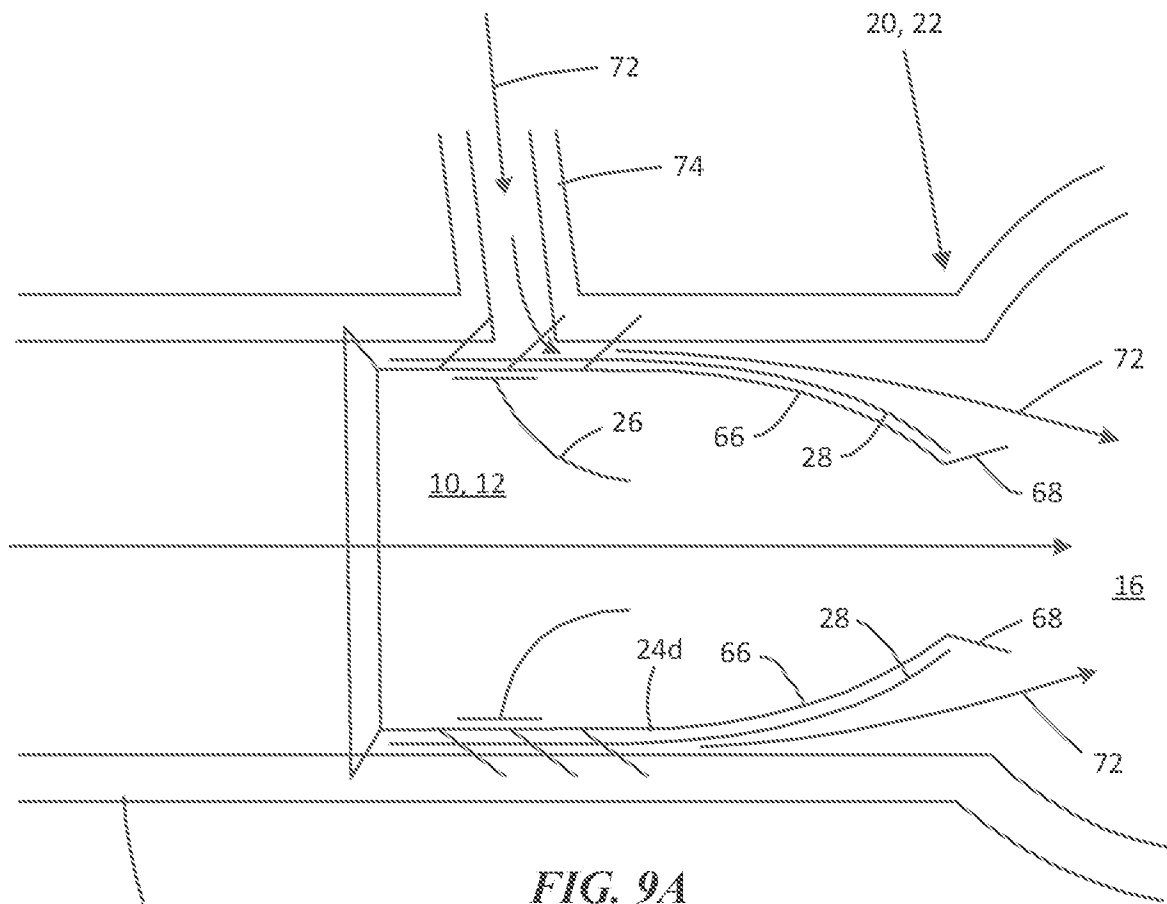
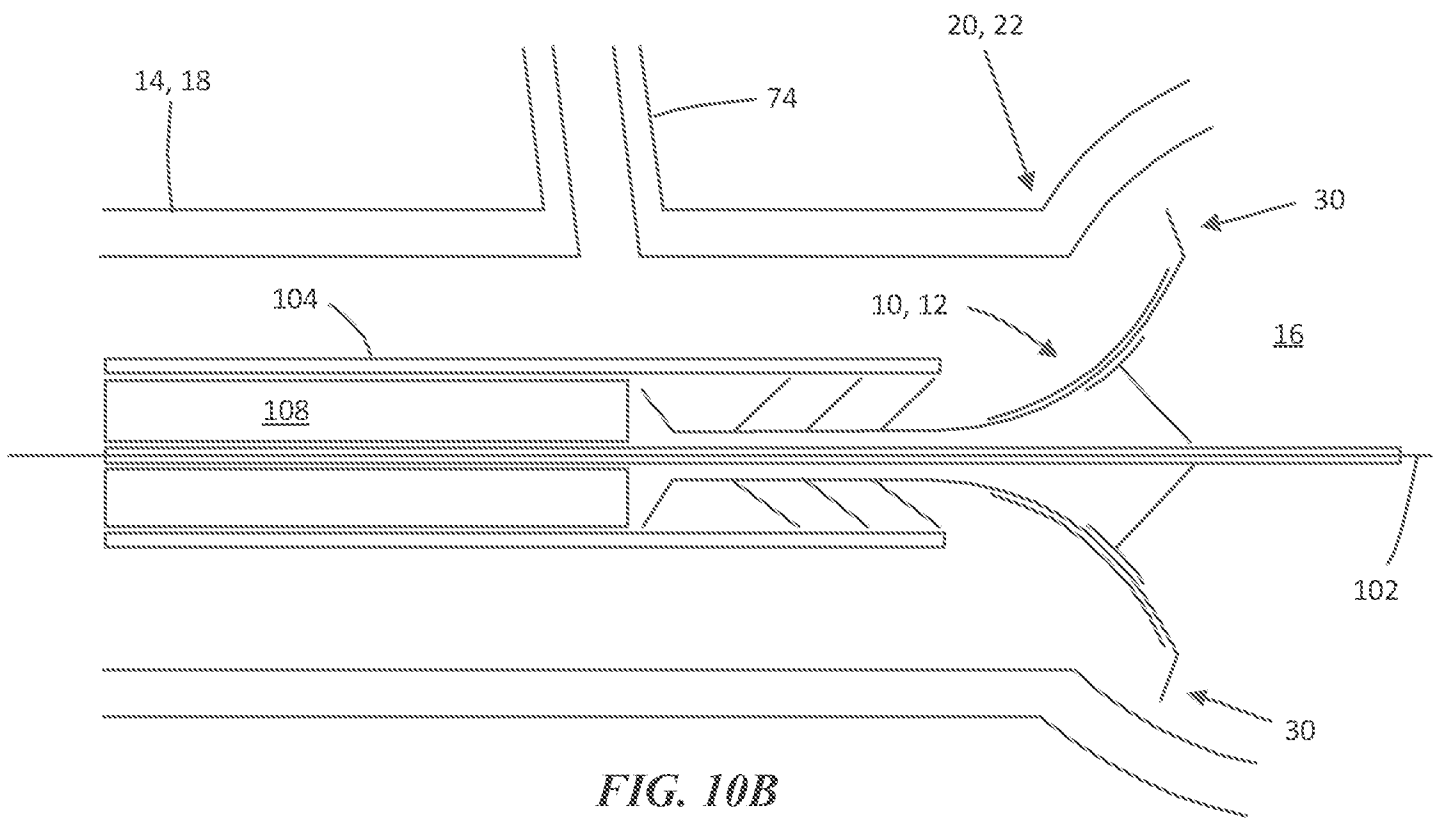
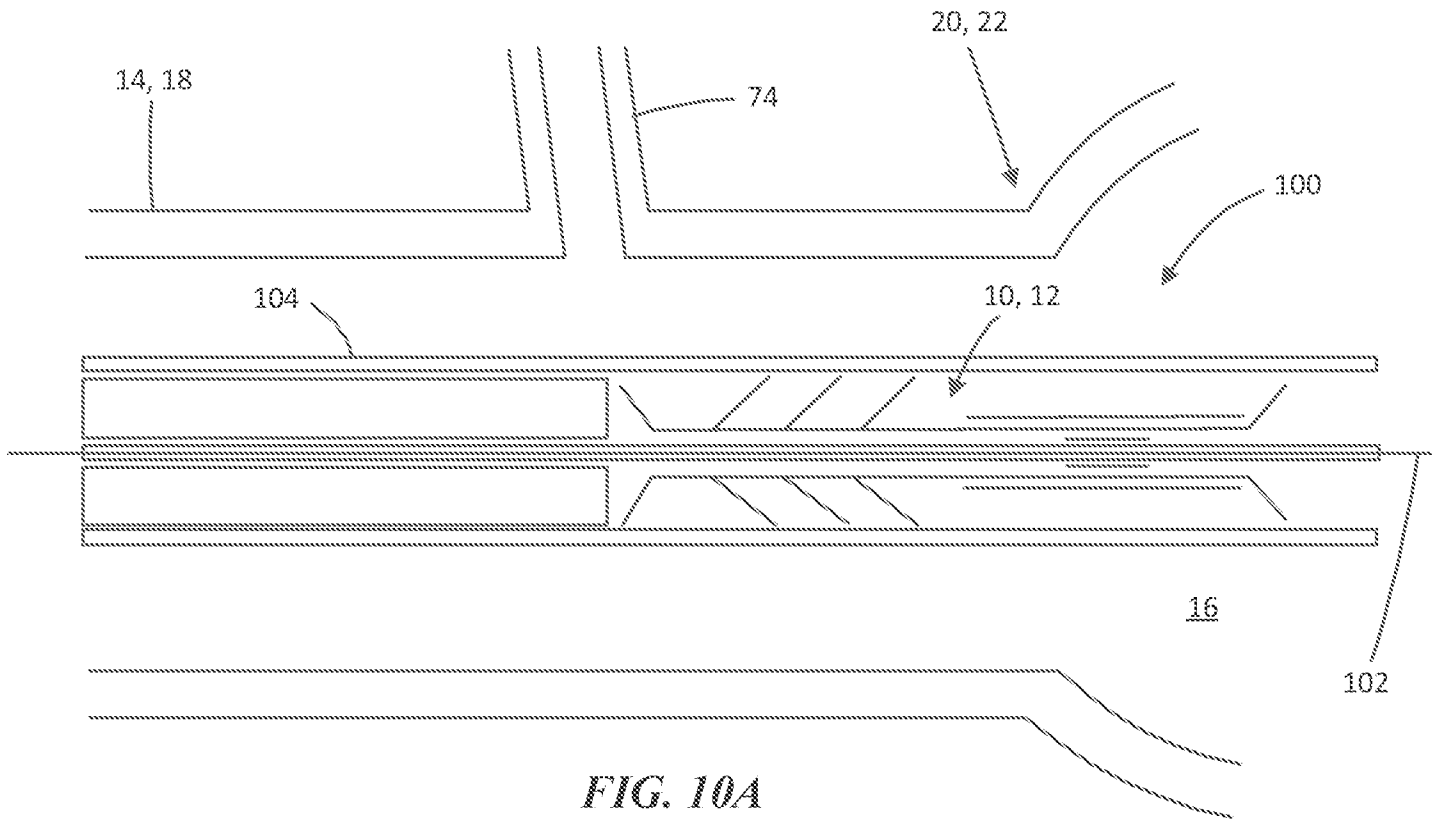


FIG. 8B

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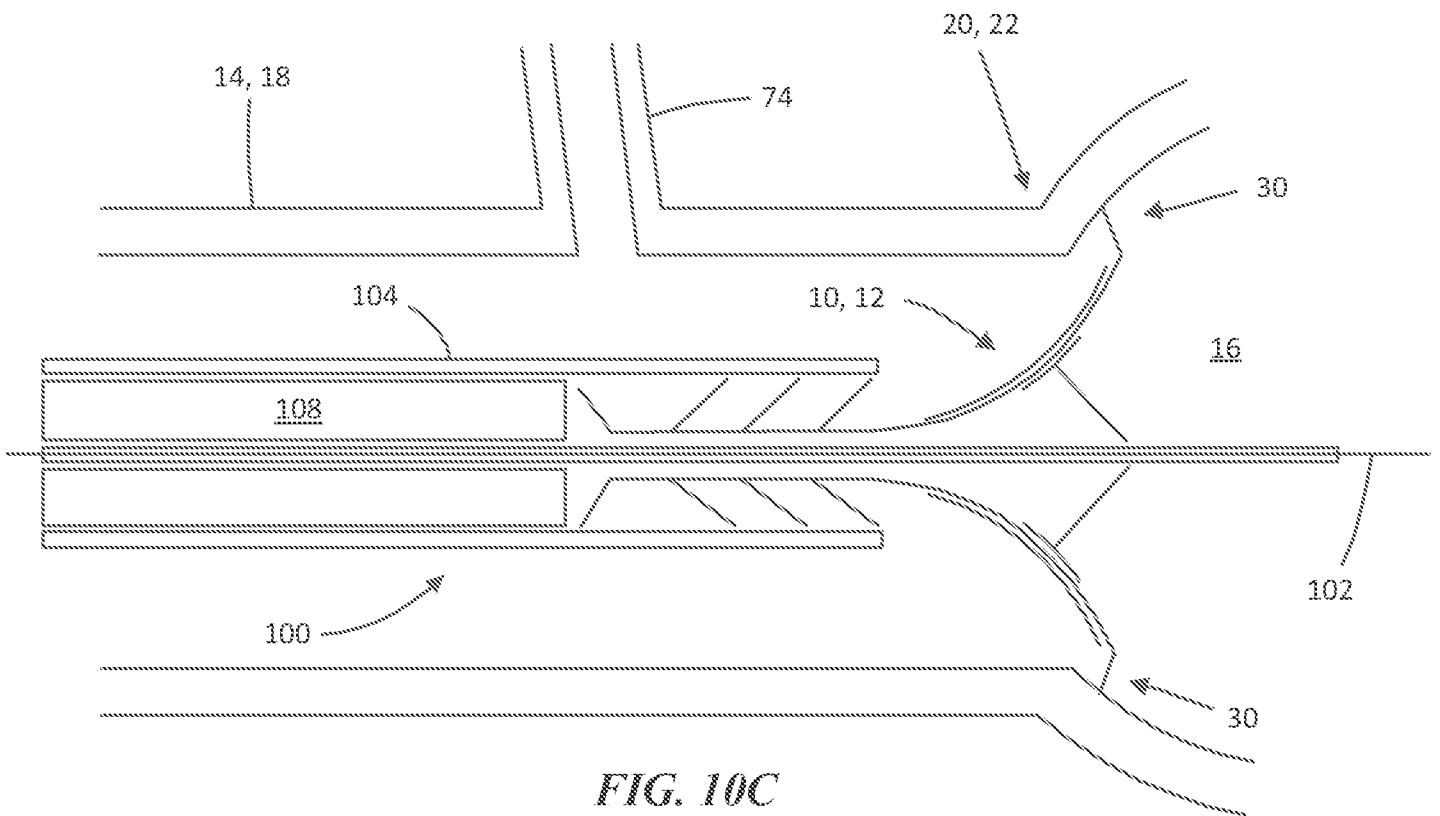


FIG. 10C

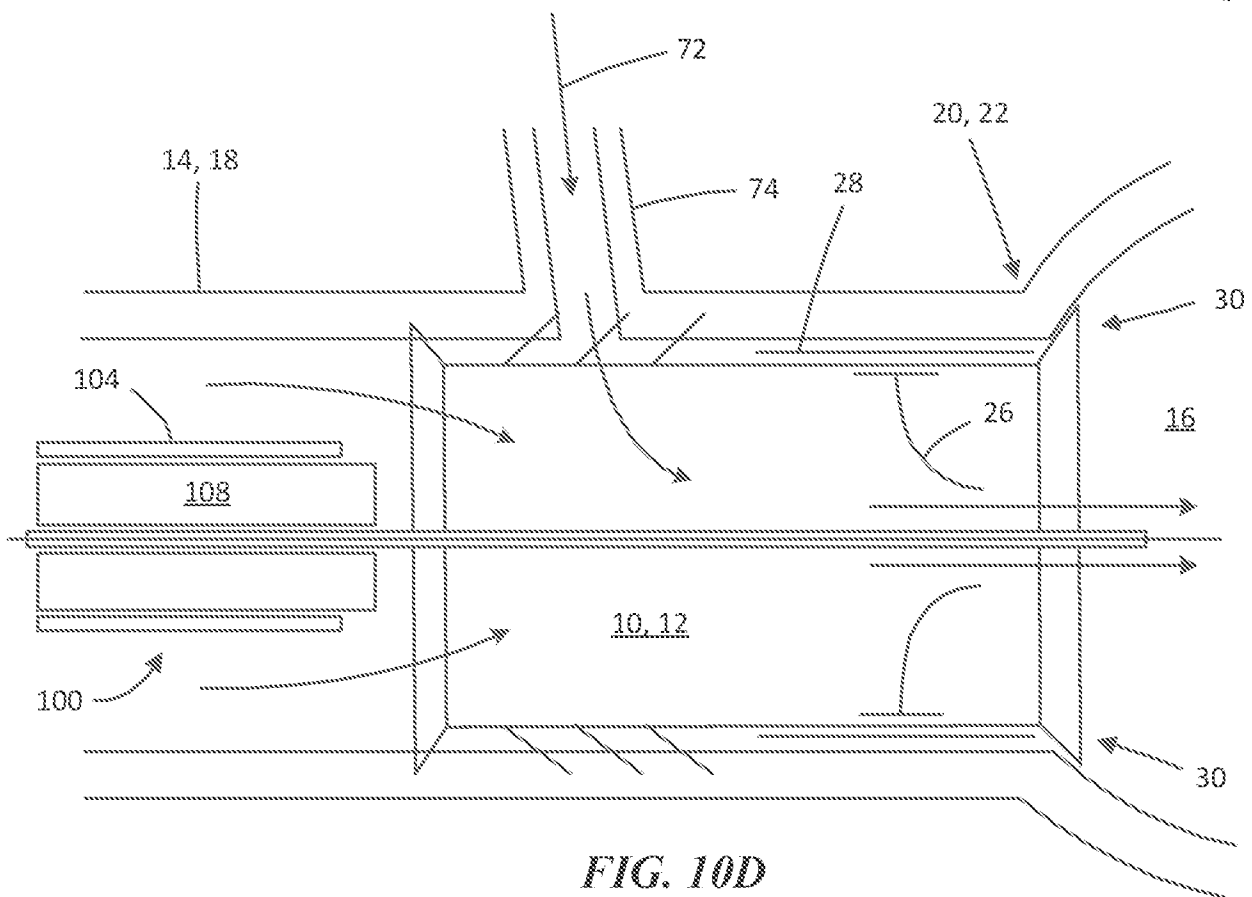
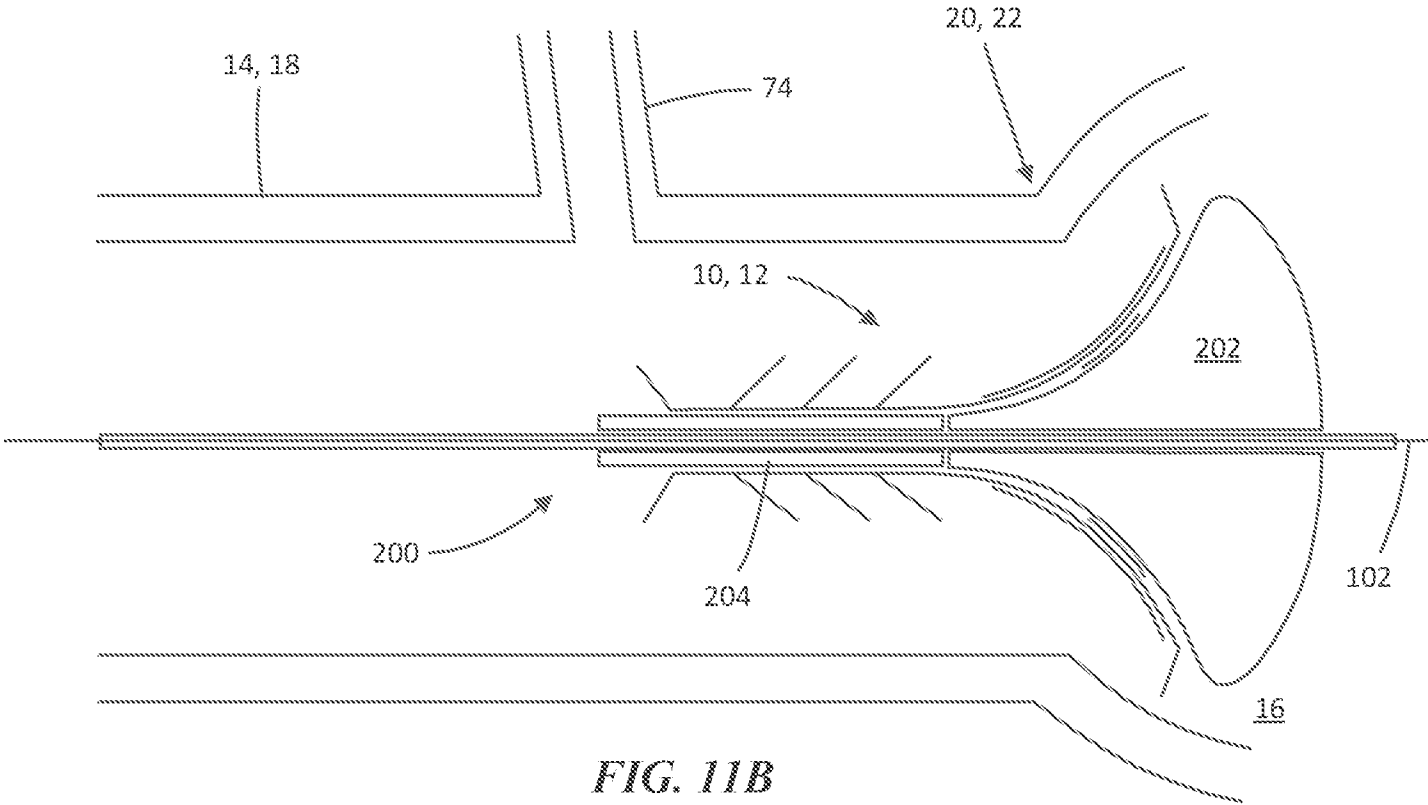
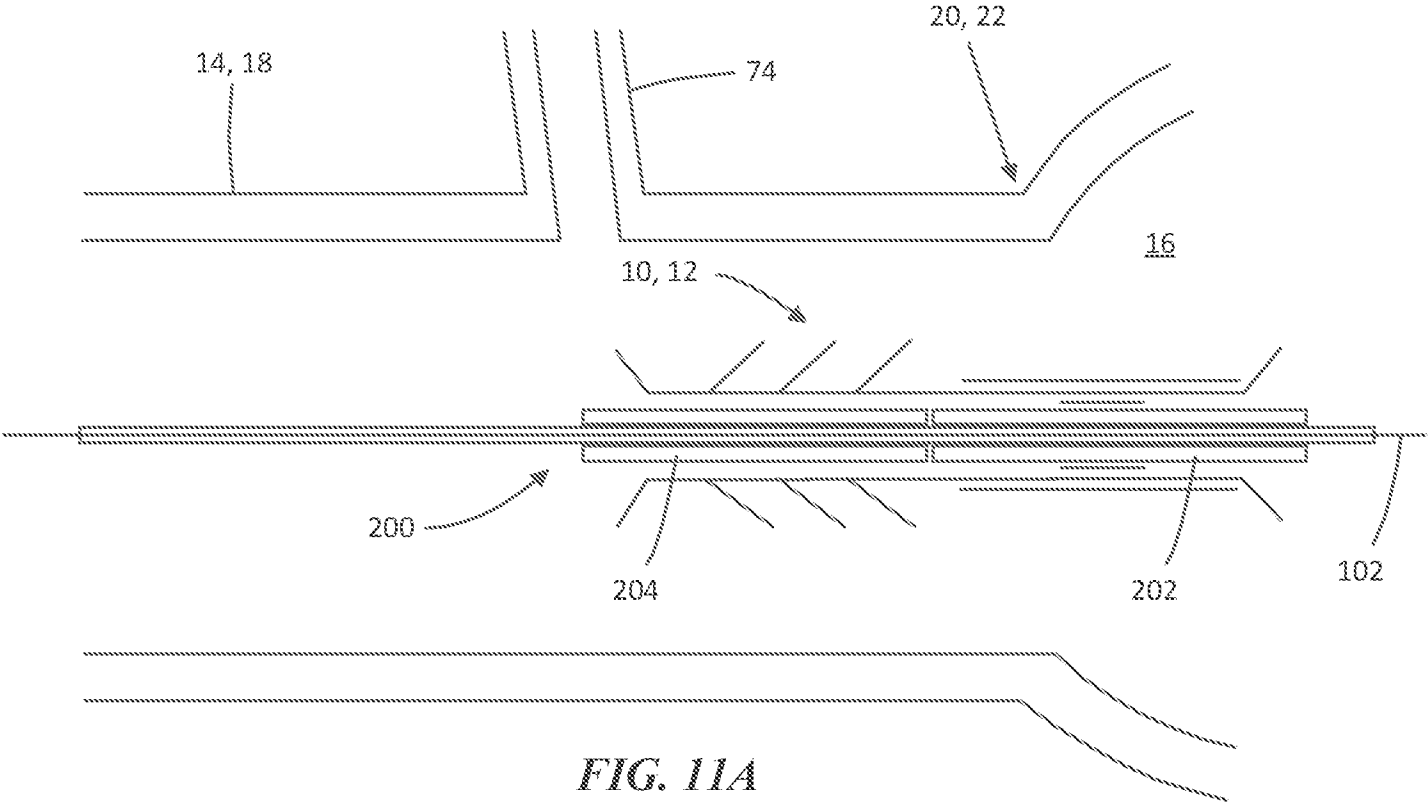
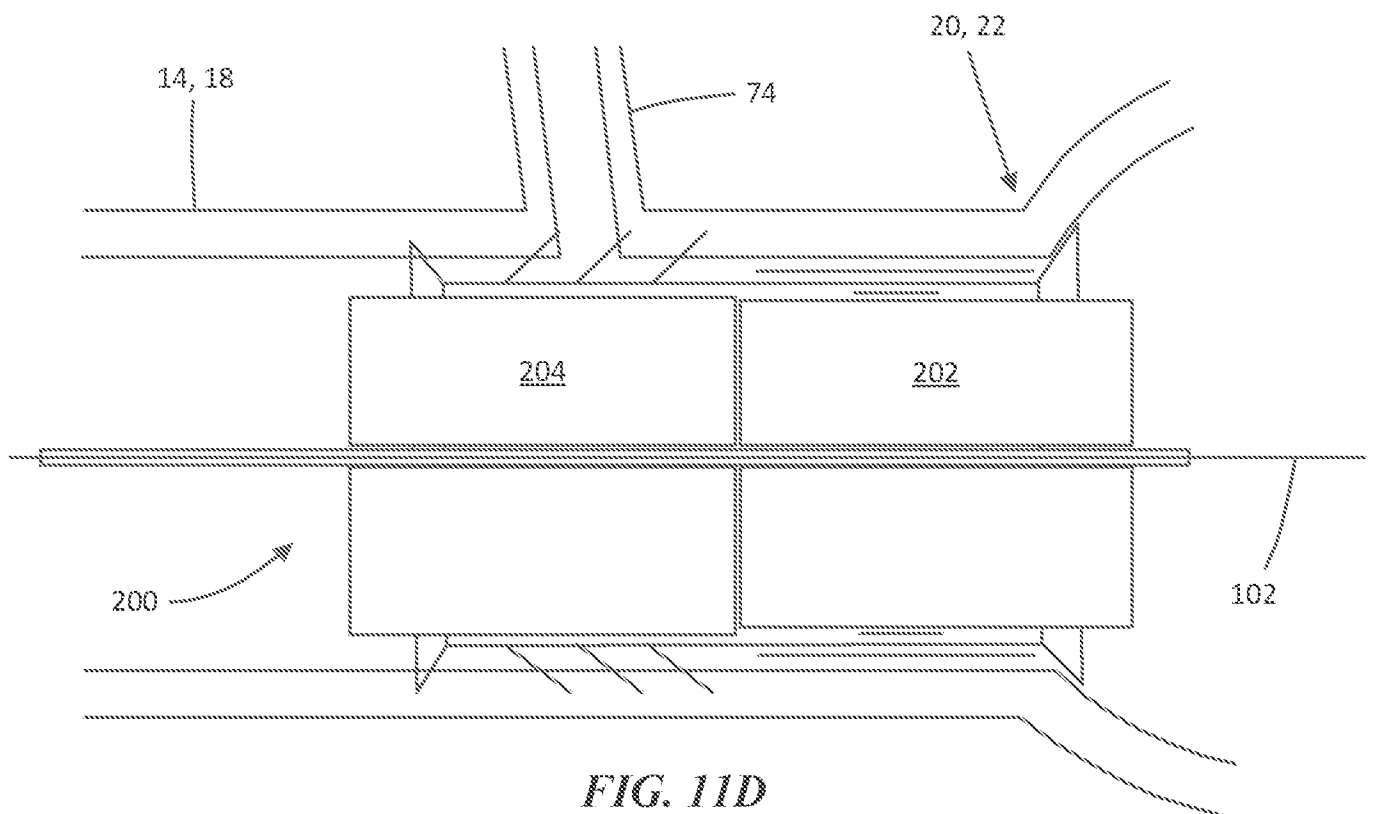
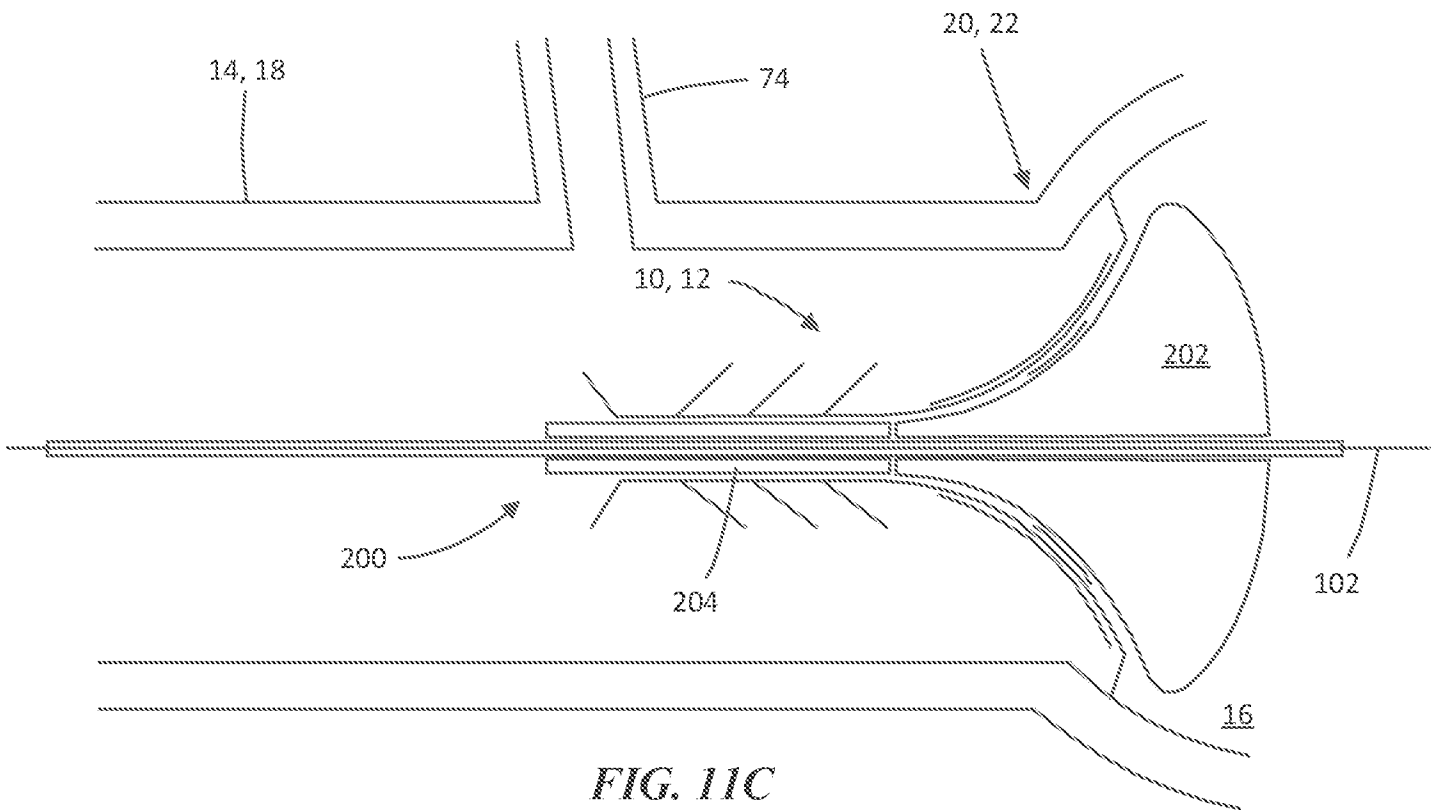


FIG. 10D

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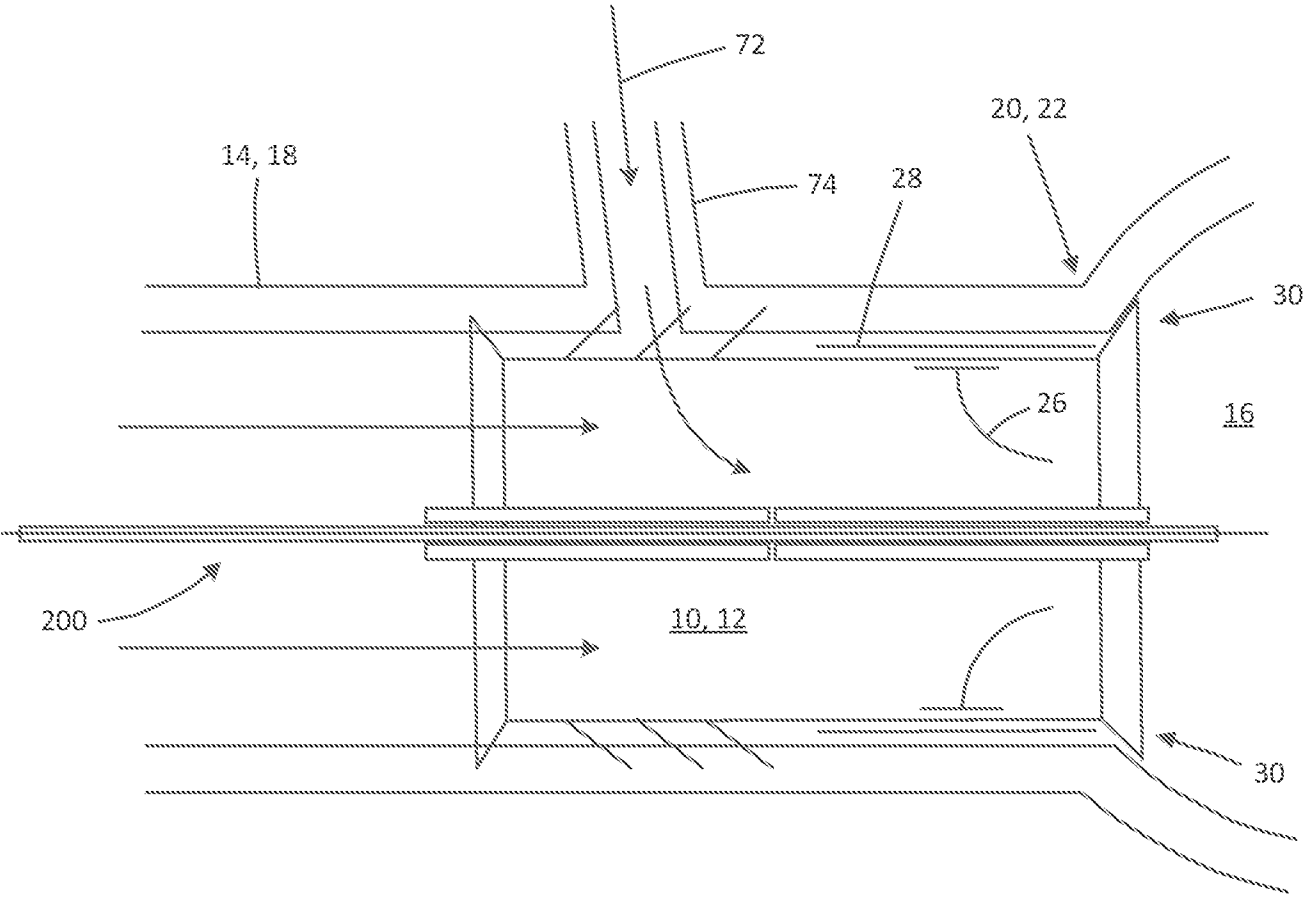
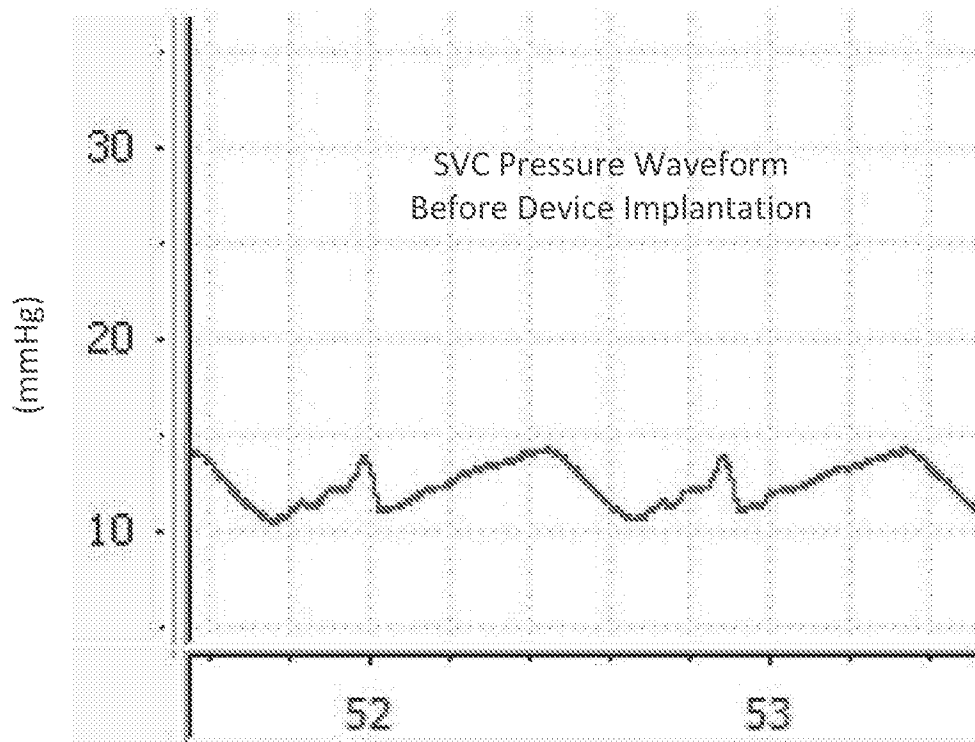
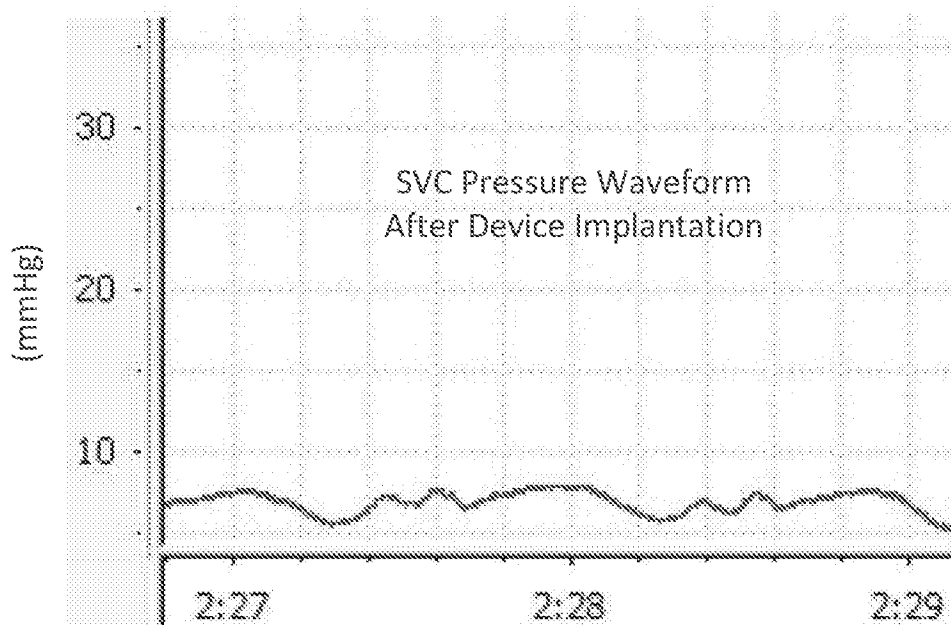
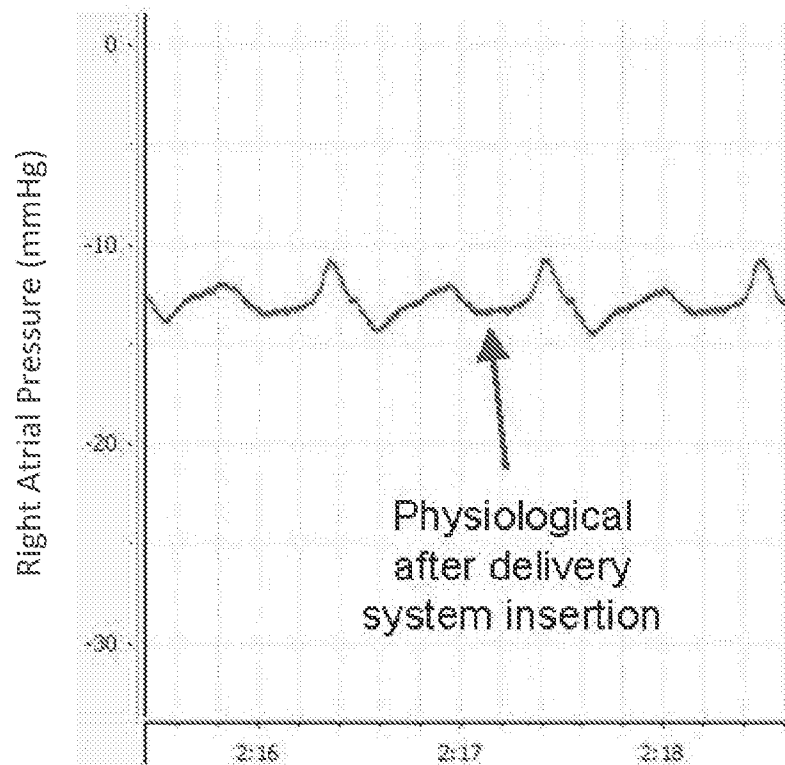
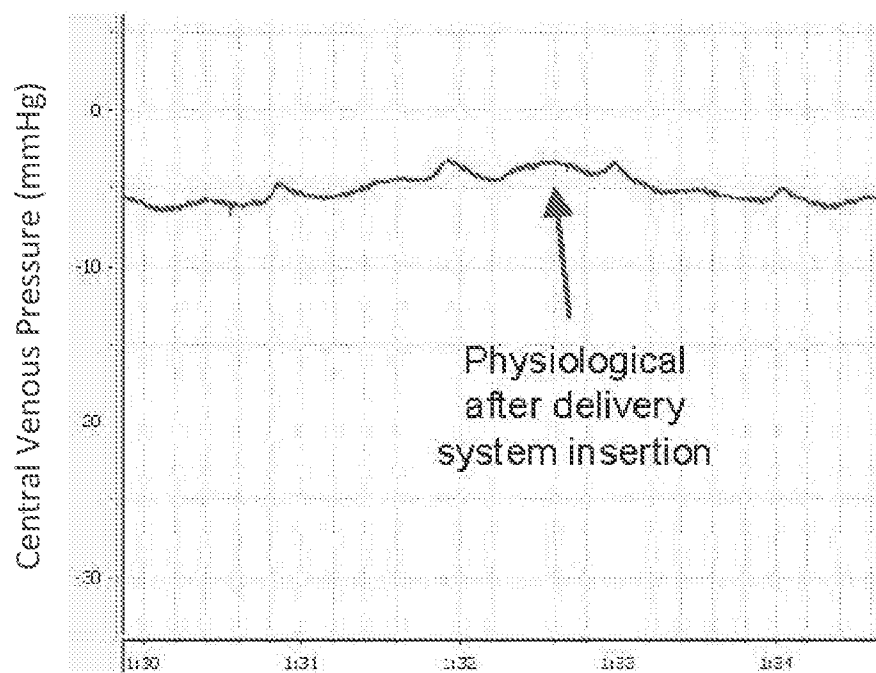


FIG. 11E

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*FIG. 12A**FIG. 12B*

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*FIG. 13A**FIG. 13B*

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SG2016/050012

A. CLASSIFICATION OF SUBJECT MATTER

Int.Cl. A61F2/07 (2013.01) i, A61F2/24 (2006.01) i

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)

Int.Cl. A61F2/07, A61F2/24

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

Published examined utility model applications of Japan 1922-1996
 Published unexamined utility model applications of Japan 1971-2016
 Registered utility model specifications of Japan 1996-2016
 Published registered utility model applications of Japan 1994-2016

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 2011/0106244 A1 (FERRARI, Markus) 2011.05.05, paragraphs [0024], [0041]-[0042], [0060]-[0073], Fig.1 & US 2014/0200663 A1 & WO 2009/092782 A1 & EP 2244668 A	1-9, 12-21, 24-27 10-11, 22-23
X A	US 2004/0206363 A1 (MCCARTHY, Patrick M., QUIJANO, Rodolfo C.) 2004.10.21, all documents, all figures & WO 2004/093638 A2 & EP 1620040 A	1-9, 12-21, 24-27 10-11, 22-23
X A	US 2004/0210306 A1 (QUIJANO, Rodolfo C., MCCARTHY, Patrick M.) 2004.10.21, all documents, all figures & WO 2004/093935 A2 & EP 1620042 A	1-9, 12-21, 24-27 10-11, 22-23



Further documents are listed in the continuation of Box C.



See patent family annex.

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Date of the actual completion of the international search

23.02.2016

Date of mailing of the international search report

08.03.2016

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Japan Patent Office

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3I 3835

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SG2016/050012

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 2010/0298927 A1 (THE CLEVELAND CLINIC FOUNDATION) 2010.11.25, abstract, paragraphs [0069]-[0072], Fig.8 & US 2006/0276813 A1 & WO 2006/127412 A1 & EP 1895941 A	1-9, 12-21, 24-27 10-11, 22-23
X A	WO 2012/018599 A1 (COOK MEDICAL TECHNOLOGIES LLC) 2012.02.09, all documents, all figures & US 2012/0136430 A1 & EP 2600798 A	1-9, 12-21, 24-27 10-11, 22-23
A	US 2004/0260390 A1 (THE CLEVELAND CLINIC FOUNDATION) 2004.12.23, paragraphs [0168]-[0170], Figs.27-28 & WO 2006/012322 A1	1-27
A	US 2008/0154356 A1 (OBERMILLER, Joseph F., OSSE, Francisco Jose, THORPE, Patricia E.) 2008.06.26, paragraph [0041], Fig.16 & WO 2001/054625 A1 & JP 2004-500189 A & EP 1900343 A2	1-27
A	WO 2011/072084 A2 (AVALON MEDICAL LTD., COLORADO STATE UNIVERSITY RESEARCH FOUNDATION) 2011.06.16, paragraph [00105] & US 2011/0319988 A1 & JP 2013-512765 A & EP 2509538 A	1-27
A	WO 2013/028387 A2 (TENDYNE HOLDINGS, INC.) 2013.02.28, paragraph [00361] & US 2014/0214159 A1 & JP 2014-528761 A & EP 2741711 A	1-27
A	US 2009/0138078 A1 (COOK INCORPORATED, COOK BIOTECH INCORPORATED) 2009.05.28, paragraphs [0075], [0078] (Family: none)	1-27
A	US 2003/0208261 A1 (THORPE, Patricia E., OSSE, Franciso J.) 2003.11.06, paragraph [0053] & WO 2001/066043 A1 & JP 2003-525695 A & EP 1259194	1-27

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SG2016/050012

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	A US 2011/0190874 A1 (DC DEVICES, INC.) 2011.08.04, all documents, all figures & WO 2011/094521 A2	1-27