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(54) Title: AORTIC SHUNT

(57) Abstract: Methods and devices of treating or preventing hypertension. A shunt is created between the aorta and another location, such as the left atrium of the heart to help reduce pressure.

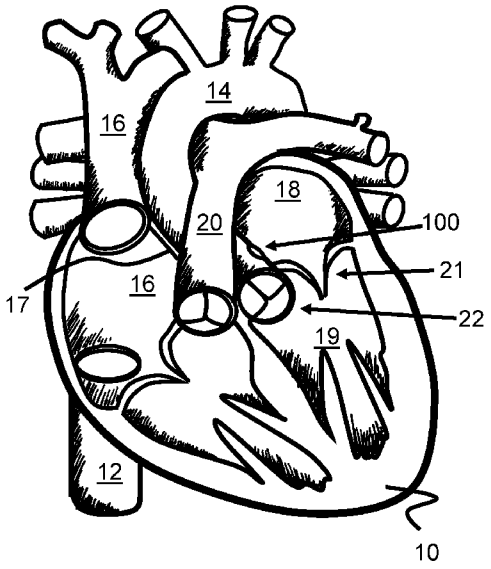

Figure 1

[Continued on next page]

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AORTIC SHUNT

RELATED APPLICATIONS

[0001] This application claims benefit of and priority to U.S. Provisional Application Serial No. 62/848,495 filed May 15, 2019 entitled *Aortic Shunt*, U.S. Provisional Application Serial No. 62/862,550 filed June 17, 2019 entitled *Congenital Defect Shunt, TriCuspid Atresia*, and U.S. Provisional Application Serial No. 62/942,631 filed December 2, 2019 entitled *Resizable Rivet Shunt*, all of which are hereby incorporated herein by reference in their entireties.

BACKGROUND OF THE INVENTION

[0002] Hypertension is a condition in which the force of the blood against the artery walls is too high. Usually hypertension is defined as blood pressure above 140/90, and is considered severe if the pressure is above 180/120. Over time, if untreated, it can cause health conditions, such as heart disease and stroke.

[0003] Maintenance of a normal blood pressure is dependent on the balance between the cardiac output and peripheral vascular resistance. Most patients with essential hypertension have a normal cardiac output but a raised peripheral resistance. Peripheral resistance is determined not by large arteries or the capillaries but by small arterioles, the walls of which contain smooth muscle cells. Contraction of smooth muscle cells is thought to be related to a rise in intracellular calcium concentration, which may explain the vasodilatory effect of drugs that block the calcium channels. Prolonged smooth muscle constriction is thought to induce structural changes with thickening of the arteriolar vessel walls possibly mediated by angiotensin, leading to an irreversible rise in peripheral resistance.

[0004] Hypertensive heart disease is a major cause of heart failure (HF) and mortality. Hypertension precedes HF occurrence in 75% of cases, and carries a six-fold increase in HF risk as compared to non-hypertensive individuals. Most importantly, a minority of patients survive 5 years after the onset of hypertensive HF. In hypertensive patients, the heart may present different patterns of adaptive remodeling: concentric remodeling, concentric hypertrophy, and eccentric hypertrophy. Although most hypertensive patients

are at high risk of developing concentric hypertrophy, a growing proportion of subjects display a concentric-to-eccentric progression eventually leading to left ventricular dilation and systolic dysfunction. Several factors including myocardial ischemia, ethnicity, genetic background, history of diabetes, and blood pressure pattern may significantly influence the pathway from hypertension to left ventricular dilation. Patients with a concentric hypertrophy usually develop HF with preserved ejection fraction (HFpEF), whereas those with an eccentric (dilated) phenotype develop HF with reduced ejection fraction (HFrEF). Lowering blood pressure has a striking effect in reducing the risk of HF.

[0005] One of the subcategories of heart failure with preserved ejection fraction that is more directly impacted by hypertension is hypertensive left ventricular hypertrophy. In hypertensive left ventricular hypertrophy, the ventricle cannot relax normally in diastole. Thus, to produce the necessary increase in ventricular input, especially during exercise, there is an increase in left atrial pressure rather than the normal reduction in ventricular pressure, which produces a suction effect as described above. This can lead to an increase in pulmonary capillary pressure that is sufficient to induce pulmonary congestion. The rise in atrial pressure can also lead to atrial fibrillation, and in hypertrophied ventricles dependent on atrial systole the loss of atrial transport can result in a significant reduction in stroke volume and pulmonary oedema. Exercise induced subendocardial ischemia can also produce an “exaggerated” impairment of diastolic relaxation of the hypertrophied myocardium. Although available antihypertensive drugs are all successful in lowering blood pressure in some patients, others are known to be resistant to hypertension medications and there are currently no alternative therapies to help manage these patient’s hypertension.

[0006] As the efficiency of the left ventricle decreases, blood pressure tends to increase to compensate for the efficiency loss. In turn, this further contributes to the deterioration of the left ventricle.

[0007] What is needed is a new treatment method that helps break the cycle of these chronically deteriorating conditions to better maintain the health of the left ventricle.

[0008] Mitral valve regurgitation— also called mitral regurgitation, mitral insufficiency or mitral incompetence — is a condition in which your heart's mitral valve doesn't close tightly, allowing blood to flow backward in your heart. If the mitral valve regurgitation is

significant, blood can't move through your heart or to the rest of your body as efficiently, making you feel tired or out of breath. Heart surgery or interventional devices can be used to repair or replace the valve for severe leakage or regurgitation. Left untreated, severe mitral valve regurgitation can cause heart failure or heart rhythm problems (arrhythmias). There are some patients suffering from MR that may be excluded from surgery or existing interventional procedures and a new treatment method that helps reduce or eliminate the MR is needed.

SUMMARY OF THE INVENTION

[0009] The present invention is generally directed to methods and devices of treating or preventing hypertension or mitral regurgitation.

[0010] This prevention or treatment is achieved in one embodiment by creating a shunt between the aorta to another region of lower pressure. This lower pressure passage effectively decreases the arterial resistance and allows for pressures within the heart, such as the left atrium and left ventricle, to be reduced by offloading some of the volume of blood exiting the left ventricle to other areas. The reduced pressure/volume may have several advantages, such as reducing mitral valve regurgitation, reducing left ventricle thinning, and/or reducing left ventricle wall thickening, or dilation. The closer the shunt is created to the aortic valve the less impedance the shunted blood flow will experience and the greater the potential for the shunt to decrease the characteristic impedance of the arterial circuit. This reduction in impedance of the arterial circuit impacts the amount the left ventricle is offloaded as well as the magnitude and timing of impact the reflective waves have on the left ventricle.

[0011] In one example, one or more shunts can be created between the aorta and the left atrium, the aorta and the right atrium, the aorta and the pulmonary artery, the aorta and the superior vena cava, and the aorta and the azygous vein.

[0012] In another embodiments, other locations that do not include the aorta are also possible to reduce this pressure, such as between the brachiocephalic vein and the carotid artery, brachiocephalic vein and the left common carotid, brachiocephalic vein and the left internal jugular, the right internal jugular vein and the right subclavian artery, or the subclavian vein and subclavian artery. All of these embodiments are shunting blood

from the arterial circuit to the venous circuit and effectively reducing arterial vascular resistance and therefore impacting arterial pressures.

[0013] In another embodiment, the present invention is directed to a target catheter that is configured to position itself within the base of the aorta, near the aortic valve. The target catheter may include one or more devices for assisting in positioning of a second delivery catheter on an opposite side of the tissue as the target catheter (e.g., magnets). Optionally, the target catheter also include material extending across a loop or similar shape to help prevent a guidewire or other device from penetrating too far into the aorta.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] These and other aspects, features and advantages of which embodiments of the invention are capable of will be apparent and elucidated from the following description of embodiments of the present invention, reference being made to the accompanying drawings, in which

[0015] Fig. 1 is a view of a heart with a shunt located between the aorta and left atrium according to the present invention.

[0016] Fig. 2 is a side view of an aorta and aortic valve with possible shunt locations according to the present invention.

[0017] Fig. 3 a top view of an aorta and aortic valve with possible shunt locations according to the present invention.

[0018] Fig. 4. is a view of a shunt creation method within a heart according to the present invention.

[0019] Fig. 5 is a side view of an aorta and target catheter according to the present invention.

[0020] Fig. 6 is a top view of an aorta and target catheter according to the present invention.

[0021] Fig. 7 is a top view of an aorta and target catheter according to the present invention.

[0022] Fig. 8 is a top view of an aorta and delivery catheter according to the present invention.

[0023] Fig. 9 is a top view of an aorta and shunt scaffold according to the present invention.

[0024] Fig. 10 is a side view of a delivery catheter according to the present invention.

[0025] Fig. 11 is a side view of a delivery catheter according to the present invention.

[0026] Figs. 12A, 12B, and 13 illustrates views of a shunt scaffold according to the present invention.

[0027] Fig. 14 is a perspective view of a shunt scaffold according to the present invention.

[0028] Figs. 15A and 15B illustrate views of a shunt scaffold according to the present invention.

[0029] Figs. 16A and 16B illustrate views of a valve mechanism for a shunt scaffold according to the present invention.

[0030] Figs. 17A and 17B illustrate views of a valve mechanism for a shunt scaffold according to the present invention.

[0031] Fig. 18 illustrates a method of creating a shunt between an aorta and a left atrium according to the present invention.

[0032] Fig. 19 is a view of multiple shunt locations according to the present invention.

[0033] Fig. 20 is a view of a shunt location according to the present invention.

[0034] Fig. 21 is a view of a shunt location according to the present invention.

[0035] Fig. 22 is a view of a magnetic alignment system according to the present invention.

[0036] Fig. 23 is a view of a magnetic alignment system according to the present invention.

[0037] Fig. 24 is a view of a surgically placed shunt according to the present invention.

[0038] Fig. 25 is a view of a blood diffuser for a shunt according to the present invention.

[0039] Fig. 26 is a view of a shunt with a deflector according to the present invention.

DESCRIPTION OF EMBODIMENTS

[0040] Specific embodiments of the invention will now be described with reference to the accompanying drawings. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. The terminology used in the detailed description of the embodiments illustrated in the accompanying drawings is not intended to be limiting of the invention. In the drawings, like numbers refer to like elements.

[0041] The present invention is generally directed to methods and devices of treating or preventing hypertension or mitral regurgitation. This prevention or treatment is achieved in one embodiment by creating a shunt between the aorta to another region of lower pressure. This lower pressure passage effectively decreases the arterial resistance and allows for pressures within the heart, such as the left atrium and left ventricle, to be reduced by offloading some of the volume of blood exiting the left ventricle to other areas. The reduced pressure/volume may have several advantages, such as reducing mitral valve regurgitation, reducing left ventricle thinning, and/or reducing left ventricle wall thickening or dilation.

[0042] The aorta can be shunted to many different locations within the body to help achieve the reduced pressure within the left atrium and left ventricle. For example, one or more shunts can be created between the aorta and the left atrium, the aorta and the right atrium, the aorta and the pulmonary artery, the aorta and the superior vena cava, the aorta and the inferior vena cava, and the aorta and the azygous vein. Other locations that do not include the aorta are also possible to reduce this pressure, such as between the brachiocephalic vein and the carotid artery, brachiocephalic vein and the left common

carotid, brachiocephalic vein and the left internal jugular, the right internal jugular vein and the right subclavian artery, or the subclavian vein and subclavian artery.

[0043] Turning first to Figure 1, a heart 10 is illustrated with a shunt 100 between an aorta 14 and a left atrium 18. In the case of hypertension or similar conditions, blood flows into the left atrium 18 and then is pumped through the mitral valve 21 and into the left ventricle 19. The increased blood pressure and thickening, thinning, or dilation of the left ventricle 19 as well as any degenerative damage to the mitral valve 21 can cause mitral valve regurgitation in which blood is forced backwards through the mitral valve 21 and back into the left atrium 18.

[0044] As the heart 10 contracts during systole and pushes blood from the left ventricle 19 into the aorta 14, the pressure in the left ventricle 19 momentarily increases and causes the pressure in the aorta 14 to momentarily increase as well. The pressure in the left atrium 18 during this phase of the cardiac cycle is lower than the pressure in the left ventricle 19 as well as the aorta 14. Since the shunt 100 communicates with the left atrium 18, this passage decreases the pressure within the aorta 14. In turn, the decreased pressure in the aorta 14 decreases the resistance and pressure that the left ventricle 19 must work against, effectively making it easier for the left ventricle 19 to function. This shunted blood flow from the aorta 14 to the left atrium 18 decreases the pressure gradient between the left ventricle 19 and the aorta 14 while decreasing the pressure gradient between the left atrium 18 and the left ventricle 19, therefore forcing more of the blood volume out of the left ventricle 19 and into the aorta 14 rather than past the mitral valve 21 and into the left atrium 18 thereby reducing the amount of mitral regurgitation.

[0045] As discussed in more detail later in this specification, this effect can be created with shunts between the aorta 14 and other locations having a lower pressure during systole. However, other locations may have other characteristics and benefits.

[0046] Figures 2 and 3 illustrate two to three possible locations of the shunt 100 shown in Figure 1. Figure 2 illustrates a side view of the aorta 14 and aortic valve 22 and Figure 3 illustrates a top view of the aorta 14 and aortic valve 22. In both figures, two possible shunts 100A and 100B are shown opening from the aorta 14 into the left atrium 18. Specifically, a shunt 100A can be created through the area immediately above the non coronary cusp 22A or a shunt 100B can be created through the area immediately above

the left coronary cusp 22B, since both cusps 22A, 22B are positioned adjacent the left atrium 18, while the right coronary cusp 22C is not. Also, a shunt 100C is shown through the area immediately above the right coronary cusp 22C and into the pulmonary artery 20. Preferably, only one shunt is created, although the creation of multiple shunts either into the left atrium 14 or other locations, is also possible.

[0047] Figure 4 illustrates an arterial and venous approach in which a target catheter 110 is positioned in the aorta 14 to help position and snare a piercing guidewire 108 (e.g., a radio frequency guidewire) that penetrates the aorta 14 from the pulmonary artery 20. First, the target catheter's own aortic guidewire 107 is advanced into the aorta 14 so that the distal end is positioned near or across the aortic valve 22. The target catheter 110 is advanced over the target catheter's aortic guidewire 107 so that its distal end is positioned near or adjacent the aortic valve 22.

[0048] As seen in the side view of the aortic valve 22 in Figure 5, the target catheter 110 can include an outer catheter sheath 116 and an inner catheter 112 that can move distally out of the sheath 116 (or alternately the sheath 116 can be withdrawn proximally). The distal end of the inner catheter 112 preferably includes a positioning member 114. In one embodiment, this positioning member 114 is a loop of wire with both ends connected to the inner catheter 112. The loop of wire is formed into a center ridge 114A with two adjacent lobes 114B that are each sized and shape to conform to the cusps 22A and 22C. In this respect, when the inner catheter 112 and positioning member 114 are deployed, they tend to position and center themselves within cusps 22A and 22C. Each loop could be deployed to a diameter range of 5 to 20 mm. The loops would be separated by a gap ranging from 2 to 10 mm. Alternatively, the loops could be normally biased to overlap, therefore allowing them to purchase across the native valvular commissure and clearly define the commissure location. An alternative targeting catheter design may contain 3 loops rather than 2 that center themselves in 1 of the three valvular cusps. The wire loops can be made of but not limited to materials such as nitinol, radiopaque plastics or stainless steel.

[0049] In one embodiment, positioning member 114 includes a magnet 113 attached to it to help position a piercing guidewire 108, discussed below, that pierces into the aorta 14. For example, the piercing guidewire 108 may also have a magnet at its distal tip or

be composed of a magnet attracting metal to help align/position it in the pulmonary artery 20. Alternately, the magnet 113 can be positioned on the distal tip of the inner catheter 112.

[0050] Optionally, the positioning member 114 may be formed from the above-described loop with a fabric, mesh, or similar material extended across it. This material may act as a "snare" to catch the piercing guidewire 108 when it pierces through the wall of the aorta 14. The material may also be such that it resists piercing from the piercing guidewire 108 and thereby can prevent the piercing guidewire 108 from passing through both sides of the aorta 14 and therefore completely through the aorta 14 or prevent the piercing of the aortic valve 22.

[0051] Alternately, instead of a positioning member 114, the piercing guidewire 108 can be aligned with two similar sized catheters 240A and 240B, as seen in Figure 22, each of which has a magnetic ring 242 around their lumen opening at their distal tip (or alternately one or more magnets positioned around the opening). The magnetic rings 242 allow the distal tips to be aligned with each other through various tissue. The piercing guidewire 108 can be advanced through the lumen of the first catheter 240, through any tissue, and then into the lumen of the second catheter 240B.

[0052] Returning to Figure 4, the piercing guidewire 108 is advanced through the inferior vena cava 12 (or optionally through the superior vena cava 16), into the right atrium 16, across the tricuspid valve, into the right ventricle and into the pulmonary artery 20. Once in the pulmonary artery 20, the distal tip of the piercing guidewire 108 is curved around and directed towards the aorta 18. In one embodiment, as previously mentioned, the piercing guidewire 108 can have a magnet or magnet sensitive material on it so that the magnetic forces will help align the sharp tip of the piercing guidewire 108 with the magnet 113 of the positioning member 114.

[0053] As seen in the top view of Figure 6, when the distal tip of the piercing guidewire 108 is aligned, it can be further advanced to pierce through the aorta wall and into the aorta 14. Again, if the positioning member 114 includes snare material stretched across it, it can act as a protective barrier to stop the piercing guidewire 108 from advancing too far across the aorta 14 and out the aorta's opposite side or piercing or damaging the aortic valve 22.

[0054] Once the piercing guidewire 108 is positioned through the aorta wall, a delivery catheter 120 is advanced over the piercing guidewire 108, as seen in Figure 7. Optionally, the delivery catheter 120 has a tapered tip to assist in expanding or dilating the pierced location or a separate dilation catheter can first be advanced to the site to open up the pierced location. The delivery catheter 120 is advanced through the pierced location and into the aorta 14.

[0055] Next, a shunt scaffold or stent-like structure can be deployed in the pierced location to maintain its size and prevent closure from healing. One such shunt scaffold 130 is depicted in Figures 8-11. In Figures 8 and 10, an outer sheath of the delivery catheter 120 is withdrawn to expose the shunt scaffold 130. The scaffold 130 is preferably positioned so that about half of its length is positioned in the aorta 14 and about half its length is positioned in the pulmonary artery 20.

[0056] As seen in Figure 9 and 11, the scaffold 130 is expanded within the pierced location, leaving a passage through the scaffold 130 and between the aorta 14 and left atrium 18. The scaffold 130 can self-expand or the delivery catheter 120 can include a balloon 124 that can be inflated to expand the scaffold 130. Once in place, the delivery catheter 120 and the target catheter 110 can be withdrawn, leaving the scaffold 130 to maintain the opening of the shunt 100.

[0057] Any of the embodiments of the present invention may further include implanting scaffold devices into an incision created surgically or by interventional techniques. Examples of such devices can be found in U.S. App. No. 16/576,704 filed September 19, 2019 and entitled Method and Technology for Creating Connections and Shunts between Vessels and Chambers of Biological structures, and in U.S. App. No. 16/785,501 filed February 7, 2020 and entitled Rivet Shunt and Method of Deployment, both of which are incorporated by reference.

[0058] In one embodiment, the scaffold 130 can expand from a relatively uniform cylindrical shape to a shape with a narrowed middle section (e.g., an hourglass shape), as seen in Figures 12A, 12B, and 13. In Figure 12A, the scaffold 130 is shown in a radially compressed configuration having a relatively long length 131 and a relatively small, uniform diameter 133. As the shunt 130 is deployed and expanded (Fig. 12B), its length substantially decreases to 131' and its diameter increases. More specifically, end portions

130A increase to a maximum radial diameter of 133' and then decrease in diameter towards a middle region 130B, which has a diameter of 203''. In one embodiment, the device is composed of a super elastic material such as Nitinol.

[0059] In one example, when compressed, the shunt 130 has a length 131 of about 20 mm and a diameter 133 of about 1.5 mm, and when expanded the shunt 130 has a diameter 133' of the end portions 130A of about 8 mm and a diameter 133'' of the middle region 130B of about 5 mm.

[0060] In another example, when compressed, the shunt 130 has a length 131 of about 30 mm and a diameter 133 of about 2.2 mm, and when expanded the shunt 130 has a diameter 133' of the end portion 130A of about 8 mm and a diameter 133'' of the middle region 130B of about 3 mm.

[0061] The shunt 130 includes a plurality of tubular radial bands that are each formed from a plurality of uniform, alternating waves that create the shunt passage 130C. Put another way each radial band 137 comprises a plurality of straight regions 137B joined together to create a pattern of triangular peaks 137A that alternate their longitudinal directions. The peaks 137A of each radial band 137 are aligned with each other and connected via a small, straight portion 139, which effectively creates diamond-shaped cells 132 when radially compressed. As a result of this design, the angle of each peak 137A increases as the shunt 130 is radially expanded and the radial bands 137 become closer together to each other, which causes longitudinal foreshortening (i.e., a decrease in length of the shunt 130).

[0062] One mechanism for causing the radial flaring of the ends 130A of the shunt 130 is by creating a pattern of cells 132 in which some cells 132 are longer in their proximal-to-distal length than other cells 132 (i.e., they have longer straight regions 137B). Preferably, cells 132 in the middle of the shunt 130 have the smallest length and each row of cells 132 progressively increase in length the further away from the middle they are. Alternately, larger length cells 132 can be located only near the ends of the shunt 130. Additionally, the radial flaring can be assisted or caused by using an hourglass-shaped balloon 124 (Figs. 10 and 11) that has larger diameter end portions 124A and 124B relative to the smaller diameter middle portion 124C when inflated.

[0063] One variation on the delivery technique of the shunt 130 allows for the passage through the shunt 130C (i.e., the narrowed middle region 130B) to be resized after delivery, if needed. Specifically, the shunt 130 can be delivered as previously described, but the narrowed middle region 130B is expanded to an initial diameter that is smaller than the middle region 130B is capable of expanding to. This may be achieved, for example, by limiting the expansion size of the middle region 124C of the balloon 124 in Figures 10 and 11. If the physician determines that increasing the size of the middle region 130B of the shunt 130 would be beneficial, the middle region 130B can be further expanded in diameter by either a different portion of the balloon (e.g., 124A or 124B) or by a second balloon catheter that inflates to a desired passage diameter.

[0064] Alternately, if the physician determines that the middle region 130B of the shunt 130 was initially deployed with a diameter that is larger than desired, a second delivery catheter may be used to deliver a tubular spacer having a thickness that reduces the size of the passage through the middle region 130B. In one example, the tubular spacer may be a second shunt 130, similar to the shunt initially deployed but deployed inside of the first shunt.

[0065] This ability to resize the shunt 130 after delivery allows a physician to customize the amount of shunted fluid for each individual patient. It also allows the shunt 130 to be modified at a later date if the patient's hemodynamic needs change.

[0066] In an alternate embodiment, the balloon catheter may include two or three separate, independently inflatable balloons that can be inflated to different sizes to achieve a similar hourglass shape. This may allow the physician to limit expansion of the middle of the shunt 130 to a desired diameter while ensuring the ends of the shunt 130 radially expand sufficiently to engage the surrounding tissue.

[0067] Another example shunt scaffold can be seen in Figure 14 which illustrates a shunt device 140 having a fenestrated body 142 defining a lumen 144 therethrough and anchoring features 146 and 148 on either side of the device 140. Anchoring features 146 and 148 are embodied as a plurality of petals. The device 140 is shown with an optional cover 154 spanning between the various features of the device 140. The cover 154 aids in anchoring the device 140 and preventing leakage of fluids around the device. In one embodiment, the device is composed of a super elastic material such as Nitinol.

[0068] Another example shunt scaffold 170 can be seen in Figures 15A and 15B. Depending on the position that the shunt is created, there may be little space for a lower portion of the flange of the scaffold to engage within the aorta 14 without contacting or otherwise interfering with the leaflets of the aortic valve 22. The scaffold 170 can be similar to either of the prior scaffolds 130, 140 (or those incorporated by reference), but can include a relatively smaller lower flange and one or more upper arms 174. The scaffold 170 and the arm 174 can be composed of a laser cut super elastic metal (nitinol) or can be braided from super elastic wires to have a heat set shape similar to that shown in the figures. Hence, the arm 174 is positioned to extend away from the valve 22 and provide additional anchoring force. Optionally, the tip of the arm 174 can curl or include other features that make it atraumatic.

[0069] The scaffolds 130, 140, or 170 (or those incorporated by reference) may further incorporate a flow control device that allows flow through the lumen in only one direction or allows flow through the lumen in only one direction and only if certain parameters are met. Alternatively, the device may further incorporate a flow control device that allows flow through the lumen in both directions, but only when certain parameters are met. The parameters that must be met in a first direction for fluid flow to be established may be the same or different than the parameters that must be met for fluid to flow in a second direction.

[0070] Adaptive shunt designs vary the flow profile based upon the pressure drop across the device. The principal of an adaptive shunt is such that the degree of shunting conferred by the device can be changed by intrinsic local conditions in response to a change in hemodynamic and/or anatomic parameters around which the device is placed. Such parameters may include, but are not limited to pressure, pressure gradient, absolute flow or flow gradients. The relationship between shunting and stimulus-response can be linear or nonlinear depending on the requirements of the individual situation. In addition to linearity/nonlinearity, thresholds can be built into such a shunt which function to begin or cease shunt at specific local conditions. These are ‘onset’ or ‘offset’ thresholds. In each case, for example, pressure or flow acts to change the effective shunt lumen size (open, close, other). The opening, if made highly nonlinear, can affect a ‘snap open’ or ‘snap closed’ result, effectively being a gating function of flow, pressure, or another regulated parameter.

[0071] The purpose of adaptive shunting is to protect organs or biologic tissues from pressure or flow damage. This protection may be conferred by limiting pressures at either the source or receiving end of the connection. For example, if the source of flow is the right atrium, this chamber cannot sustain prolonged elevated pressures and a "bleed off" shunt could be used to drop pressures which are approaching or exceeding a specified threshold value. Such a threshold value may be variable and inherently built into the device such that the pressure-flow relationship is linear, or nonlinear of any sort to accommodate physiologic benefit.

[0072] Adaptive shunts may thus be used as regulators for a pressure-flow relationship and would thus be made to function in an "autoregulatory mode". This feature is useful to maintain healthy and safe pressures (for example) or other parameters by shunting flow (or other parameters) into lower resistance, or higher compliance chambers or channels.

[0073] In one example an adaptive shunt shunts more blood to the low-pressure chamber at higher pressures, feeding back on the source and lowering source pressure as it attempts to increase. Similarly, if pressure drops to lower levels the shunt will contract and shunt less blood from high-to-low pressure chamber, hence preventing the pressure to drop too low which would potentially dangerously reduce cardiac output.

[0074] Alternately, an adaptive shunt may reduce, limit, diffuse, or deflect blood flow to the low-pressure chamber at higher pressures. Creating a shunt from a high-pressure zone (e.g., in the aorta) to a low-pressure zone (e.g., in the left atrium) may result in a high velocity jet of blood flow from one chamber to the other. If the high velocity jet hits the native vessel or chamber wall it will result in a high amount of shear stress on the tissue cells which may induce a biological response causing the formation of endothelial or scar tissue growth and ultimately vessel stenosis.

[0075] Stent-like devices, like the shunt devices 130 or 140, can include valve mechanisms within their central passages to provide the previously discussed adaptive flow shunting. In one example, a conical member 150 composed of elastic material can be mounted within the central passage of a shunt device, moving from a relatively closed position (Figure 16A) to a relatively open position (Figure 16B). In another example, a relatively flat disc 160 can include a plurality of slits 162 that move from a closed position

(Figure 17A) to an open position (Figure 17B). Other example mechanisms include spring mechanisms attached to a valve member, flaps, braided structures biased to a closed position that can be forced open, and other similar mechanisms.

[0076] Stent-like devices, like the shunt devices 130 or 140, can also or alternately include a diffuser mechanism to prevent a high velocity jet to occur through the central passage of the shunt. For example, Figure 25 illustrates a diffuser 260 which is composed of a flexible material that extends across the central passage of a shunt. The material includes a plurality of small apertures 262 that limit the amount of blood that can pass through and spread out the locations the blood passes through. In other words, the blood flow is diverted to several smaller locations that may decrease the shear stress on the tissue in the low-pressure chamber.

[0077] Stent-like devices, like the shunt devices 130 or 140, can also or alternately include a deflector that helps deflect the high velocity jet of blood in a direction in which it will not cause high shear stress on nearby tissue. For example, Figure 26 illustrates a shunt 130 with a deflector 170 located on its end in the low-pressure chamber. The deflector 170 is preferably curved and therefore can be oriented in a desired off-axis direction relative to the shunt's internal passage.

[0078] In one embodiment, the deflector 170 can be a shape-memory loop of wire with a sheet of flexible material fixed across (e.g., a polymer sheet). The loop can be heat set to expand to the desired curved shape. In another example, the deflector 170 can be formed from a plurality of heat-set, shape memory wires woven into a mesh with an optional material sheet fixed over it. If the low-pressure chamber is a vessel, such as the pulmonary artery 20, the deflector 170 can be oriented so that the shunted blood is deflected in the same direction as natural blood flow (e.g., away from the pulmonary valve).

[0079] The deflector 170 can be located fully or partially within the passage of the shunt 130. In such a configuration, the deflector 170 may be a similar curved structure as discussed above or alternately a large rounded bump on only a portion of the inner circumference within the passage (i.e., the bump does not symmetrically extend entirely around the entire passage).

[0080] To be clear, any of the shunts of the present specification can include any combination of valves, diffusers, and/or deflectors. For example, one shunt may have a valve and a deflector. Another shunt may have a diffuser and a deflector.

[0081] While the previously described method is performed by advancing a delivery catheter 120 through the pulmonary artery 20 and into the aorta 14 towards the target catheter 110, it is also possible that the delivery catheter 120 be advanced within the aorta 14 towards the target catheter 110 located within the left atrium 18. The method is performed similar to the previously described technique of Figures 1-9. For example, a target catheter 110 can be advanced through the inferior vena cava 12 or superior vena cava 16, across the atrial septum 17, and into the left atrium 18 (Fig. 18). An aortic guidewire 107 can be advanced into the aorta 14 so that its distal end is near the aortic valve 22 and then pierces the aortic wall at either a location immediately above the non coronary cusp 22A or the left coronary cusp 22B. Again, the target catheter 110 can be used to help target the desired location to cross into the left atrium 18 (e.g., magnets) and/or can include a loop of wire 114 with material across it to help snare the second guidewire. A delivery catheter 120 can be advanced over the aortic guidewire 107 within the aorta 14 and into the pierced location in the wall of the aorta 14. Finally, a shunt scaffold can be deployed within the pierced location to maintain the size of the opening.

[0082] Similar methods using a target catheter and a delivery catheter can be used in other locations in a similar manner. Several alternative locations can be seen Figures 19-21.

[0083] Turning first to Figure 19, a shunt can be created between the brachiocephalic vein 30 at locations 208 and connected to the right common carotid artery 34, the left common carotid artery 35, or the left subclavian artery 37. A shunt can also be created between the right internal jugular vein 38 and the right common carotid artery 34 at location 206. Turning to Figure 20, a shunt may also be located between the subclavian vein 16 and subclavian artery 28 at location 210, near the internal jugular vein 30. Finally, in Figure 21, a shunt can be created between the aorta 14 and the azygous vein 40 at locations 212A and 212B.

[0084] Some of these locations may benefit from using two catheters 250A and 250B with side openings to allow the piercing guidewire 108 to pass through tissue at the

desired location, as seen in Figure 23. Both catheters 250A, 250B have magnetic rings 242 surrounding distal side openings 244A, 244B into their internal lumens (or alternately one or more magnets disposed around the openings). The magnetic rings 242 allow the distal ends of each catheter to be positioned near each other and attract each other through the target tissue. The piercing guidewire 108 can be advanced through the lumen of one catheter 250A, out its distal opening 244A, into the distal opening 244B of catheter 250B, and out the distal tip of the catheter 250B.

[0085] In one embodiment, the shunt 100 shown in Figure 1 can be created surgically by first creating access transapically with an incision between the 5th and 6th intercostal space. An introducer sheath would be advanced through this incision and into the apex of the left ventricle. A guidewire would be tracked from the introducer sheath into the left ventricle 19 and into the aorta 14. A steerable, pre-shaped catheter, or the introducer itself can be guided over the guidewire and directed toward the left atrium 18. A target catheter or dye shots can be performed in the left atrium 18 to help target the crossing location between the left atrium 18 and the aorta 14. The guidewire can be crossed between the aorta 14 and the left atrium 18 and the shunt can be deployed.

[0086] In another embodiment, the shunt 100 shown in Figure 1 can be created surgically in an open-chest or open-heart procedure. Direct access via incision to the aorta and/or left atrium can allow for visualization of the puncture step and subsequent shunt creation or placement. The shunt can also be created in a manner similar to Coronary Artery Bypass Graft surgery by sewing a graft to the aorta and then to the desired chamber for shunting (left atrium, right atrium, SVC, etc.).

[0087] One specific example can be seen in Figure 24 in which a shunt 101 has been surgically implanted between the aorta 14 and the pulmonary artery 20. This shunt 101 can be made by first creating an incision via scalpel or needle in both the aorta 14 and pulmonary artery 20. The openings can be increased to a desired size, as needed, with a dilator tool, and then the shunt 101 can be connected. In one embodiment, the shunt 101 is sewn via stitches 103. In another embodiment, any of the shunt scaffold devices described in this specification can be used.

[0088] In the case of any of the shunts in this specification, the patient may have several evaluations taken to help determine the patient's condition and whether a shunt

would be an effective treatment. In a mitral regurgitation patient, echo, fluoroscopy, CT, and/or MRI can be used to determine anatomical volume and structure measurements, as well as blood flow and the amount of mitral regurgitation. Invasive hemodynamic measurements can be performed in order to determine cardiac pressures such as left atrial, left ventricle, pulmonary artery, pulmonary capillary wedge pressure, arterial, central venous pressure, or similar measurements. Heart rate and EKG may also be recorded.

[0089] In the case of hypertensive, diastolic dysfunction, hypertrophic cardiomyopathy, or any patient who is suffering from a disease that is negatively impacted by high left ventricular afterload, similar procedures as outlined above can be performed. Additional focus may be directed toward pressure volume loop evaluations or left ventricular structure and function.

[0090] During the procedure, hemodynamic data will be the most valuable to determine the impact of the therapy. Once the shunt is implanted, the pressure in the aorta and the adjoined chamber (e.g., left atrium), will be taken to determine the shunt's effect. An expected decrease in aortic pressure would be monitored.

[0091] If a greater pressure reduction is desired, the shunt size can be increased, as previously discussed in this specification. If a lesser pressure reduction or shunt volume is desired, then the shunt size can be decreased.

[0092] Although the invention has been described in terms of particular embodiments and applications, one of ordinary skill in the art, in light of this teaching, can generate additional embodiments and modifications without departing from the spirit of or exceeding the scope of the claimed invention. Accordingly, it is to be understood that the drawings and descriptions herein are proffered by way of example to facilitate comprehension of the invention and should not be construed to limit the scope thereof.

What is claimed is:

1. A method of treating a patient, comprising:

creating a shunt between a first location in an aorta of the patient and a second location located in a chamber having a pressure lower than the aorta; and,

decreasing arterial resistance so as to reduce pressures within a cardiovascular system of the patient.

2. The method of claim 1, wherein the creating a shunt is preceded by evaluating the patient and diagnosing a condition of hypertension, mitral valve regurgitation, or conditions relating to either hypertension or mitral valve regurgitation.

3. The method of claim 1, wherein the second location is located in a pulmonary artery.

4. The method of claim 3, wherein creating the shunt comprises advancing a target catheter within the aorta of the patient, advancing a piercing guidewire within the pulmonary artery of the patient, advancing the piercing guidewire into the aorta, advancing a delivering catheter from the pulmonary artery into the aorta, and delivery a shunt scaffold to create the shunt.

5. The method of claim 1, wherein the second location is located in a left atrium.

6. The method of claim 5, wherein the creating the shunt comprises advancing a target catheter within the left atrium of the patient, advancing a piercing guidewire within the aorta of the patient, advancing the piercing guidewire into the left atrium, advancing a delivery catheter from the aorta into the left atrium, and delivering a shunt scaffold to create the shunt.

7. The method of claim 1, wherein the second location is located in a right atrium.

8. The method of claim 1, wherein the second location is located in a superior vena cava.

9. The method of claim 1, wherein the second location is located in an azygous vein.

10. The method of claim 1, wherein the first location is located in the area immediately above the aortic valve.

11. The method of claim 1, wherein creating the shunt further comprises deploying a positioning member having an expandable snare with fabric or mesh extending across it.

12. The method of claim 1, wherein creating the shunt further comprises deploying a positioning member and wherein the positioning member comprises a loop shaped to conform to cusps of the aortic valve.

13. The method of claim 1, wherein creating the shunt further comprises aligning magnets on a first catheter at the first location with magnets on a second catheter at a second location.

14. A method of treating a patient, comprising:

creating a shunt between a first location in a brachiocephalic vein of the patient and a second location located in a chamber having a pressure higher than the brachiocephalic vein; and,

decreasing arterial resistance so as to reduce pressures within the heart.

15. The method of claim 14, wherein the second location is located in the carotid artery.

16. The method of claim 14, wherein the second location is located in the left common carotid artery, brachiocephalic artery, and/or the left subclavian artery.

17. A method of treating a patient, comprising:

creating a shunt between a first location in an internal jugular vein of the patient and a second location located in a subclavian artery; and,

decreasing arterial resistance so as to reduce pressures within a cardiovascular system of the patient.

18. A method of treating a patient, comprising:

creating a shunt between a first location in a subclavian vein of the patient and a second location located in a subclavian artery; and,

decreasing arterial resistance so as to reduce pressures within a cardiovascular system of a patient.

19. A device for snaring a piercing guidewire, comprising:

an elongated body; and,

a wire loop located at a distal end of the elongated body, the wire loop expanding to a first lobe and a second lobe that are adjacent a center ridge;

wherein the first lobe and the second lobe are sized and shaped to conform to cusps of an aortic valve.

20. The device of claim 19, wherein the wire loop further comprises a third lobe.

21. A system for creating a shunt, comprising:

a first catheter having a first lumen and a first lumen opening at a distal end of the first catheter; wherein one or more magnets disposed around the first opening;

a second catheter having a second lumen and a second opening at a distal end of the second catheter; wherein one or more magnets are disposed around the second opening; and,

wherein the one or more magnets disposed around the first opening are configured to magnetically attract the one or more magnets disposed around the second opening.

22. The system of claim 21, wherein the first lumen opens at a terminal tip of the first catheter, and wherein the second lumen opens at a terminal tip of the first catheter.

23. The system of claim 22, wherein the first lumen opens on a side of the first catheter and wherein the second lumen opens on a side of the second catheter.

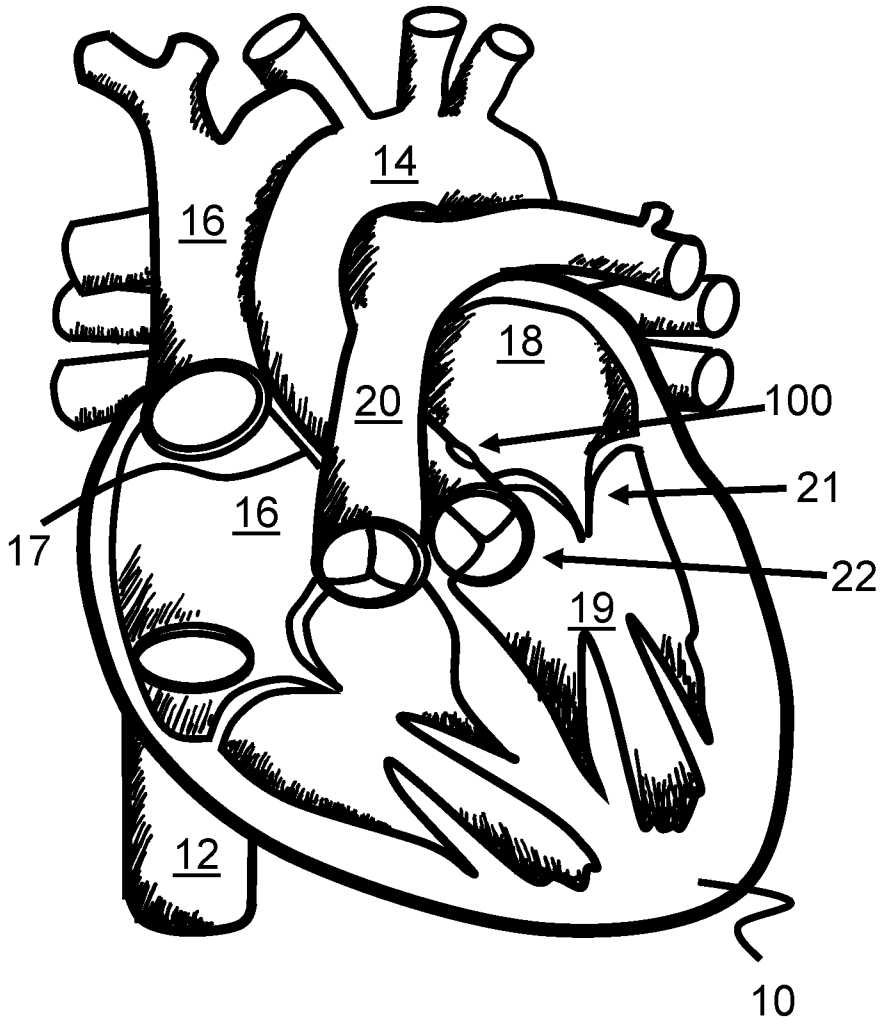


Figure 1

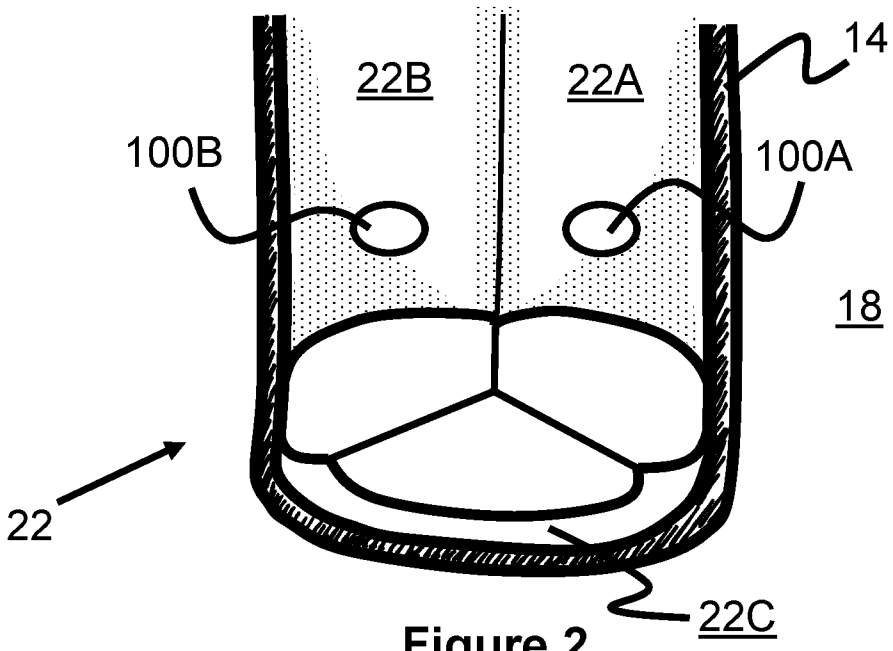


Figure 2

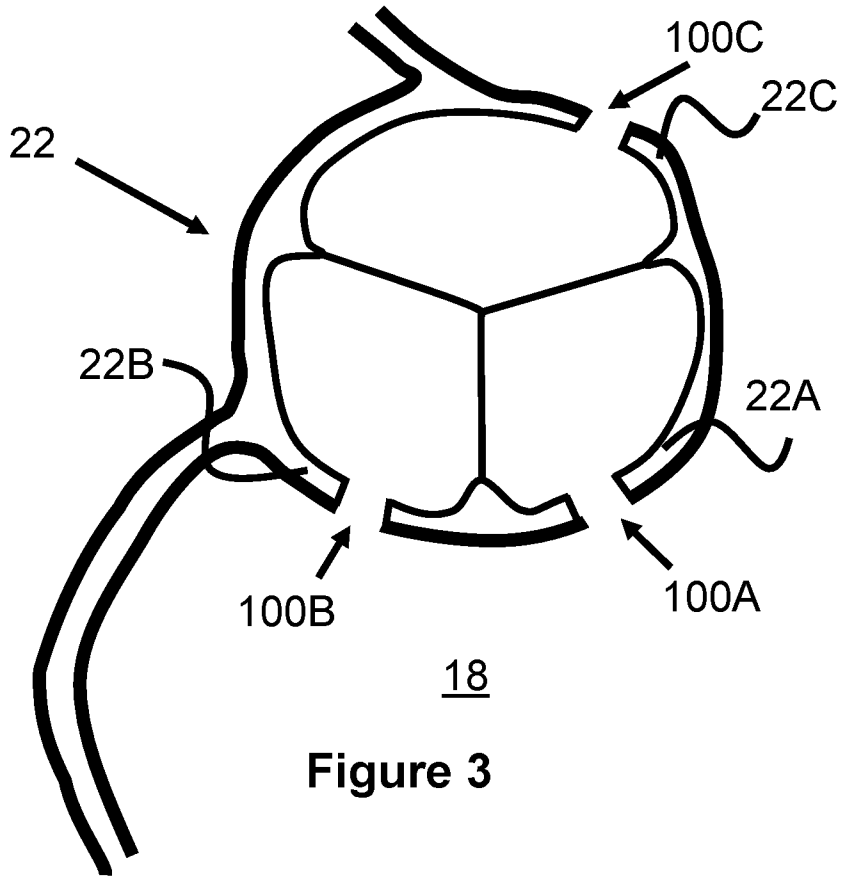


Figure 3

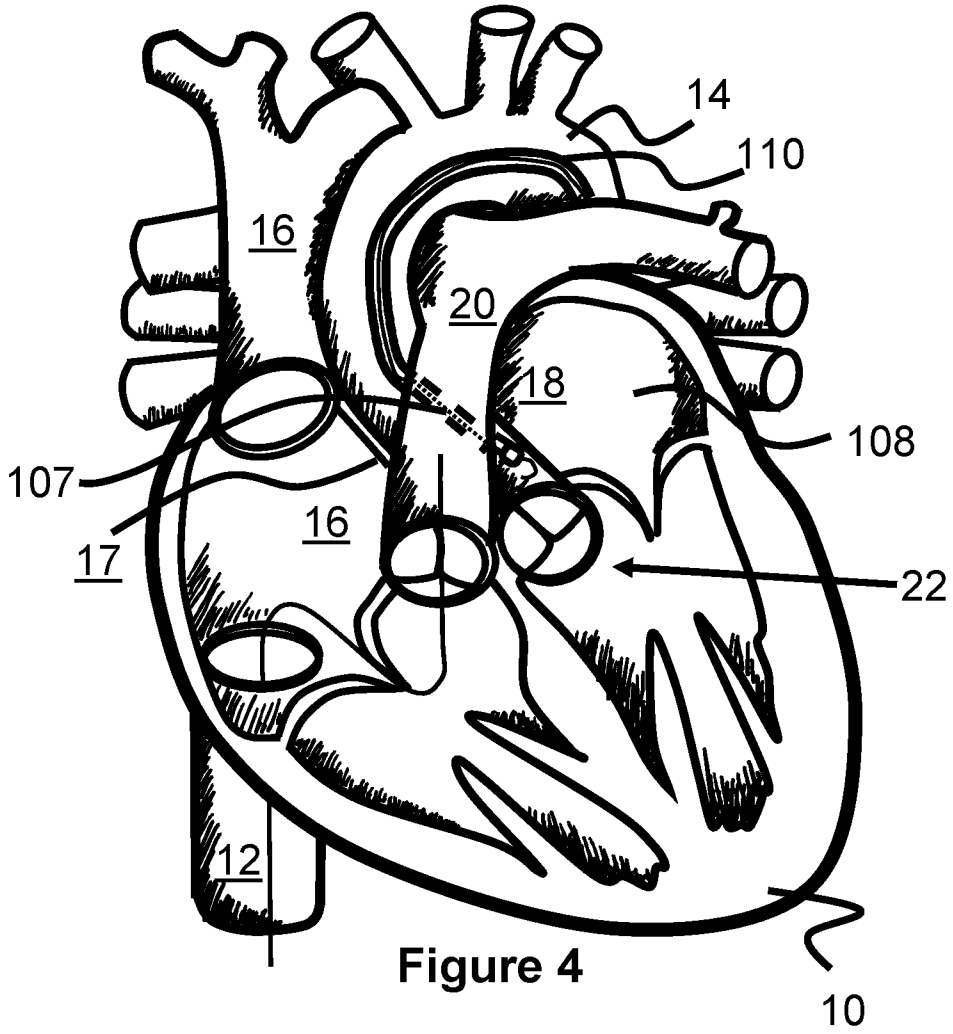


Figure 4

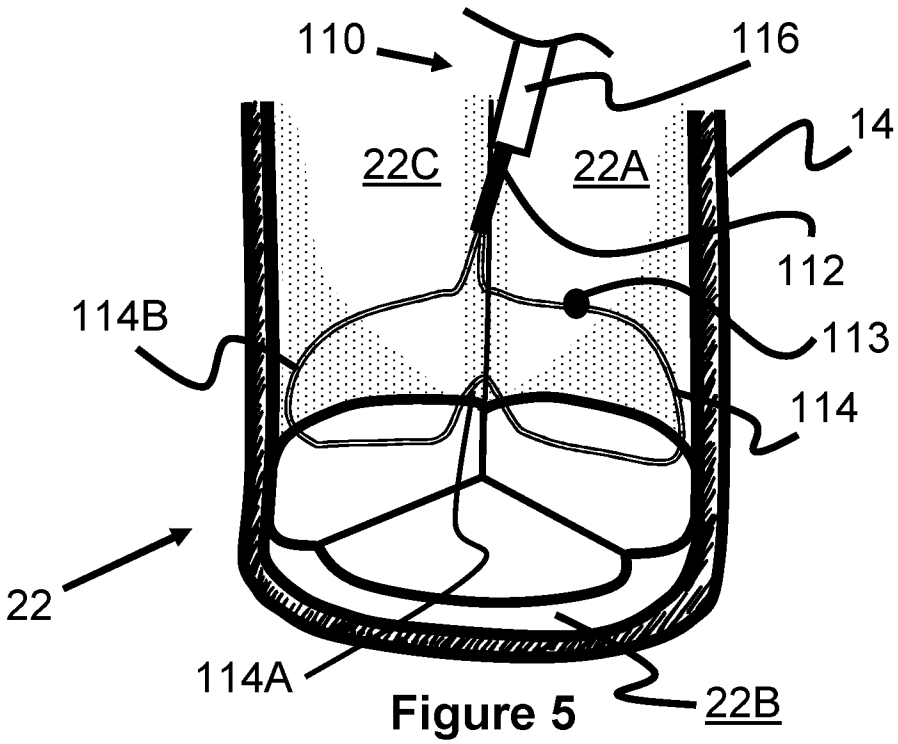


Figure 5

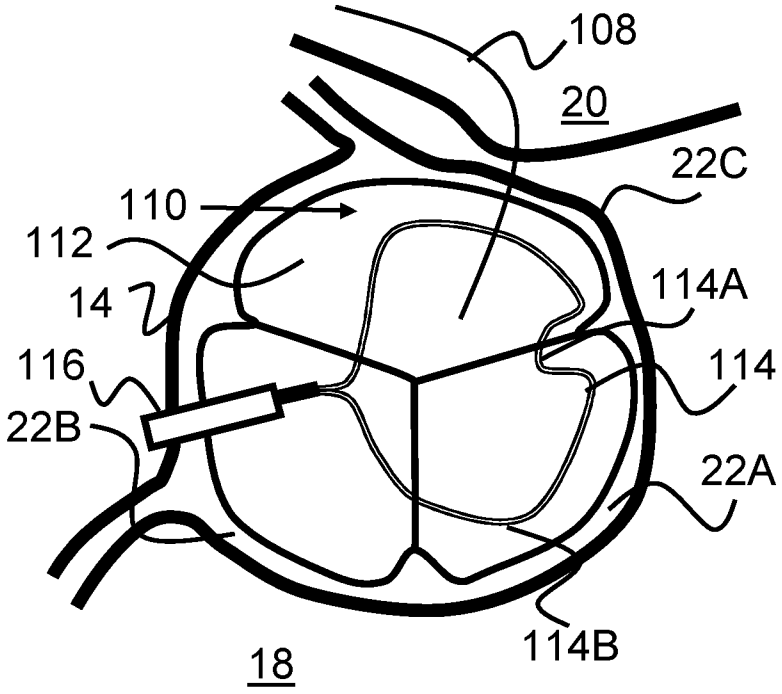


Figure 6

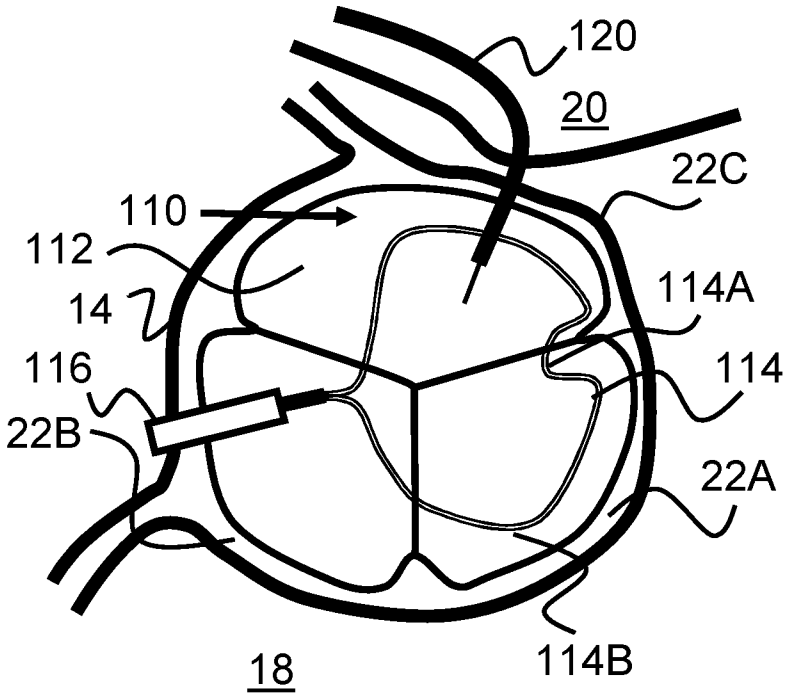


Figure 7

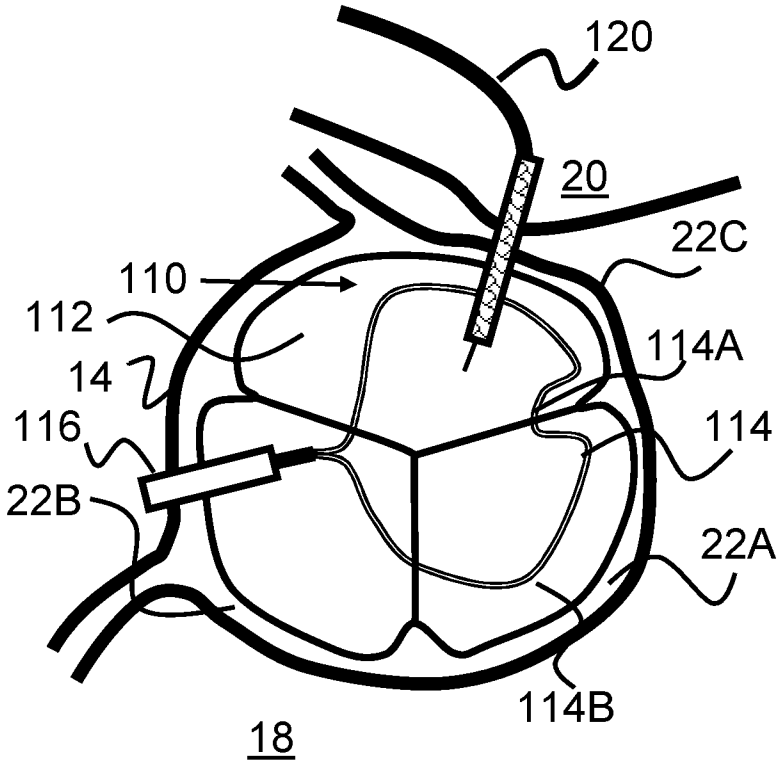


Figure 8

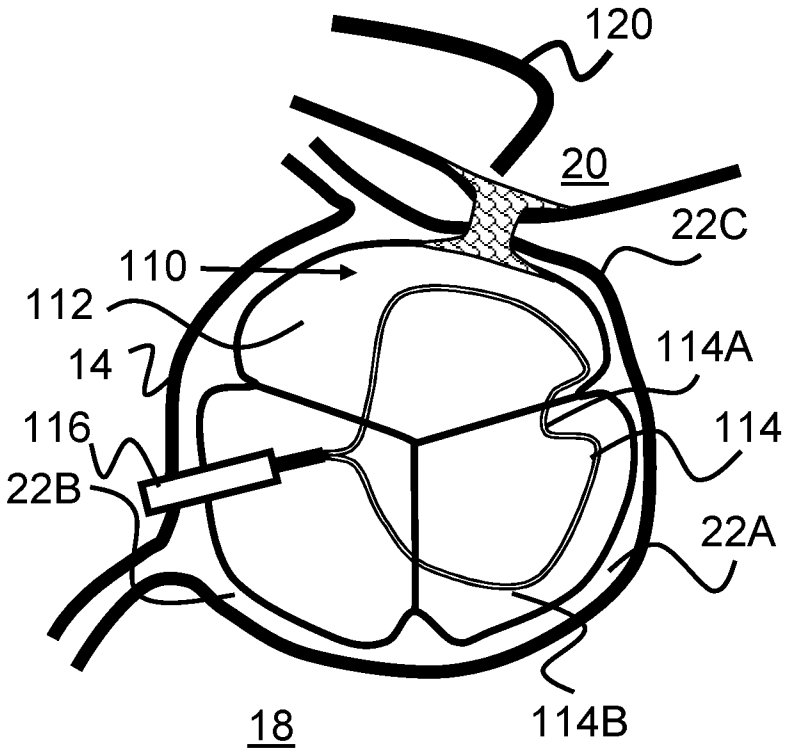


Figure 9

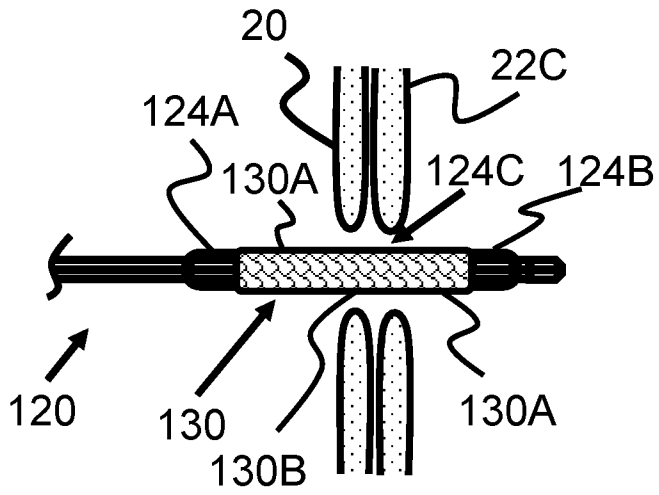


Figure 10

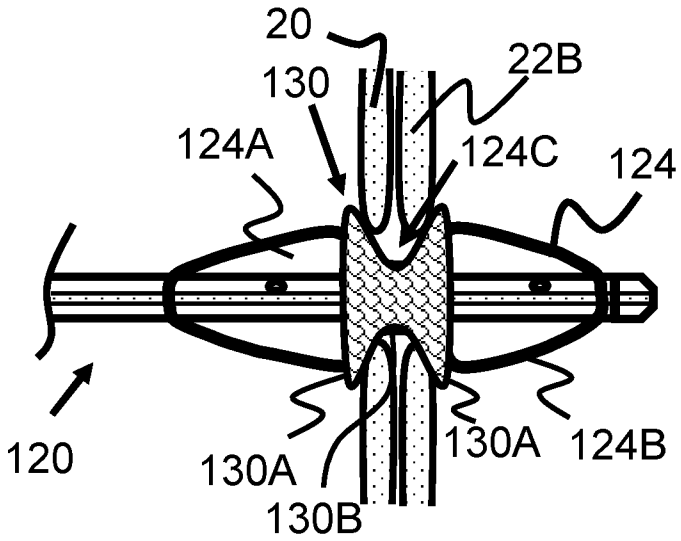


Figure 11

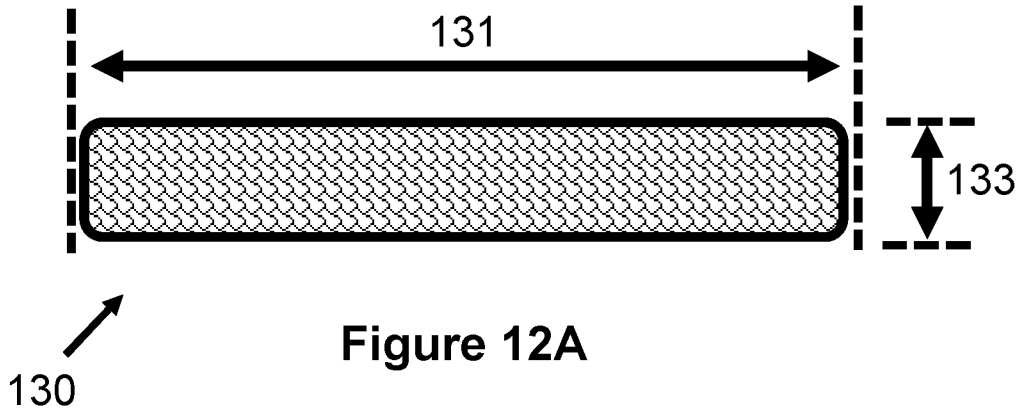


Figure 12A

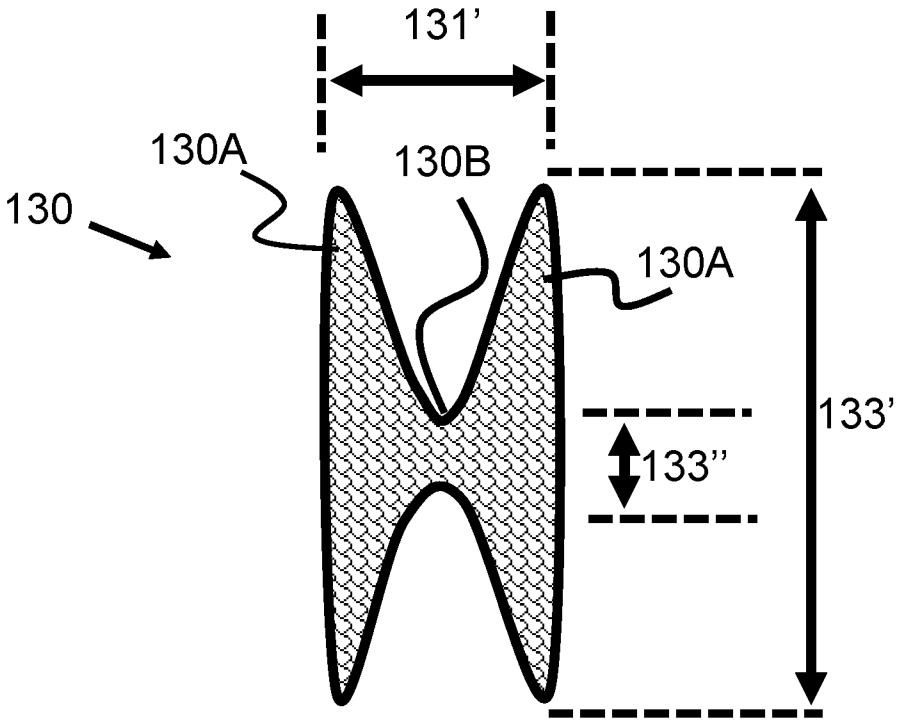


Figure 12B

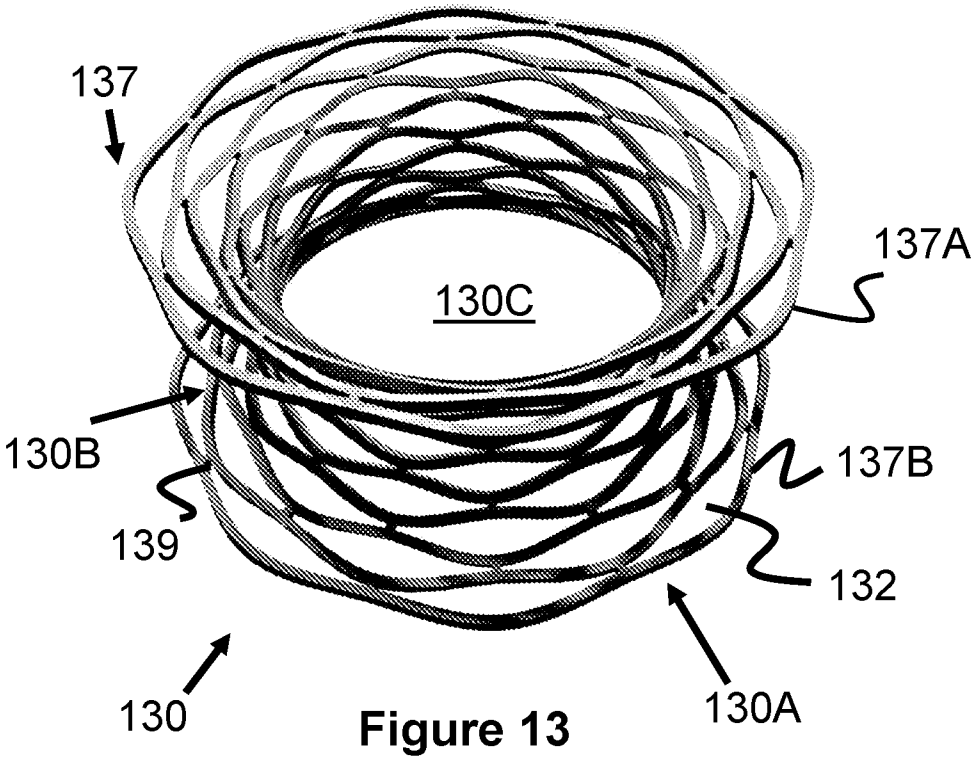


Figure 13

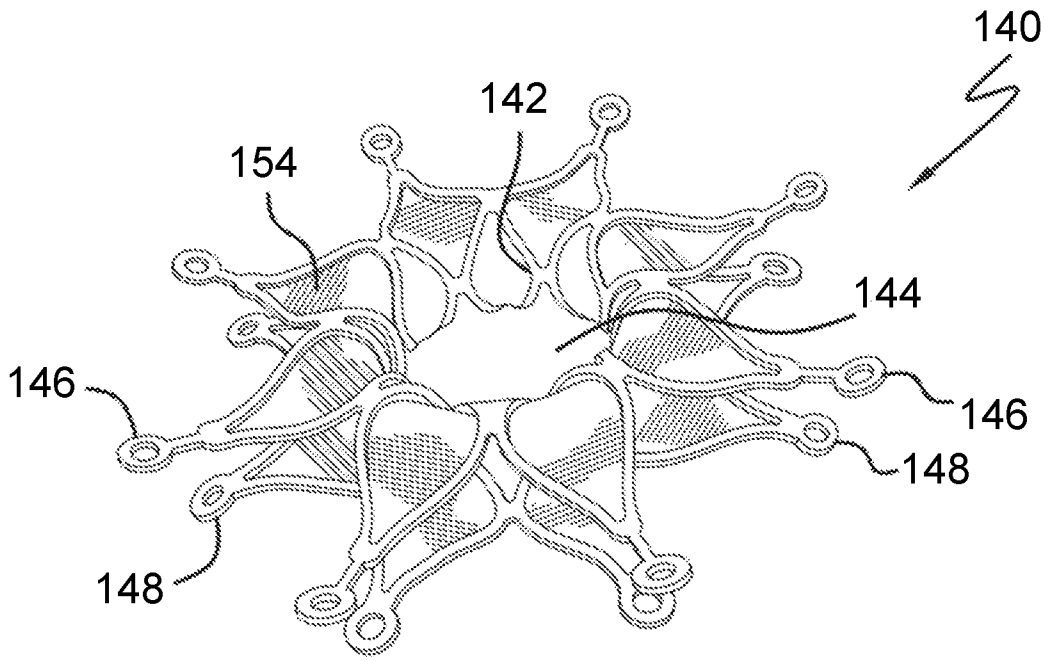


Figure 14

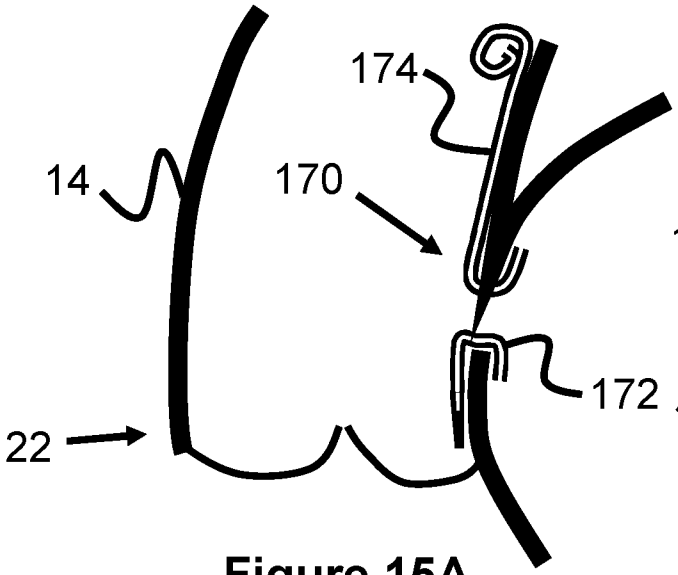


Figure 15A

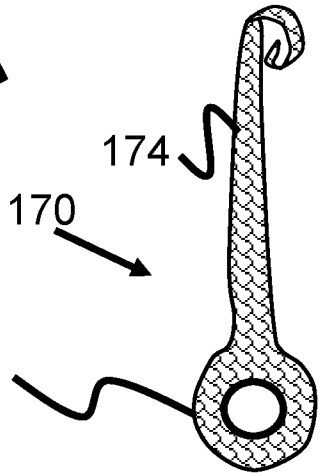


Figure 15B

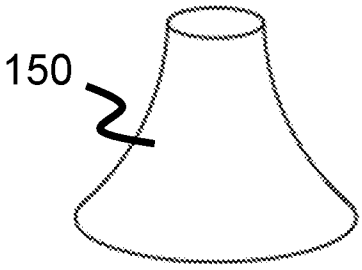


Figure 16A

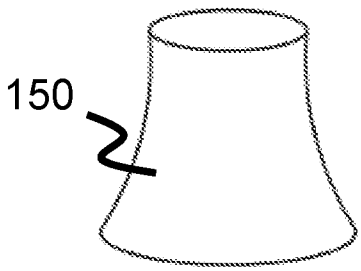


Figure 16B

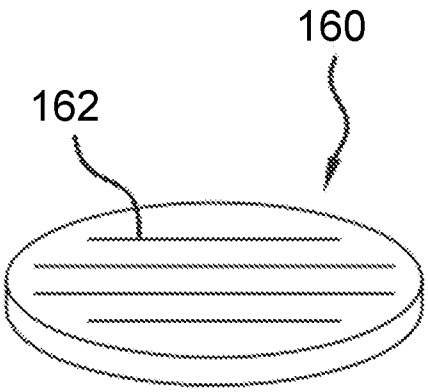


Figure 17A

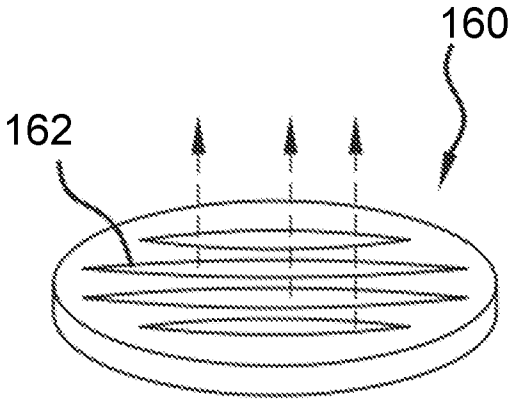
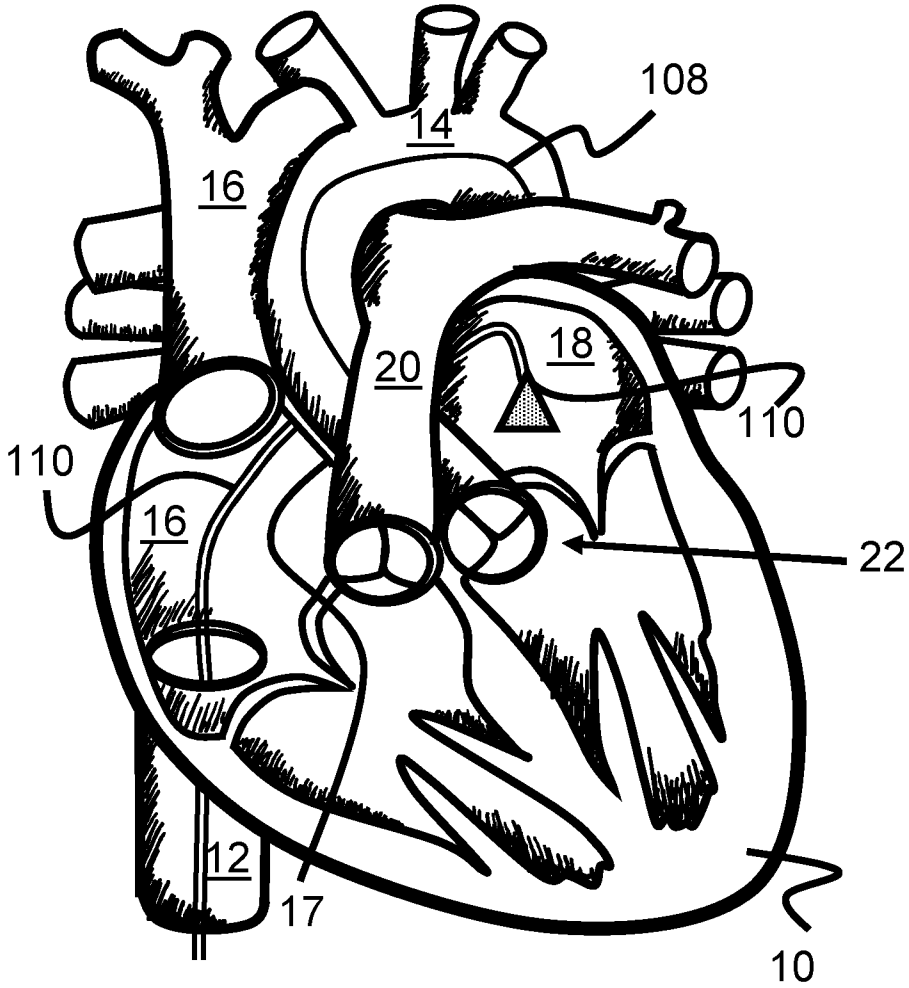


Figure 17B



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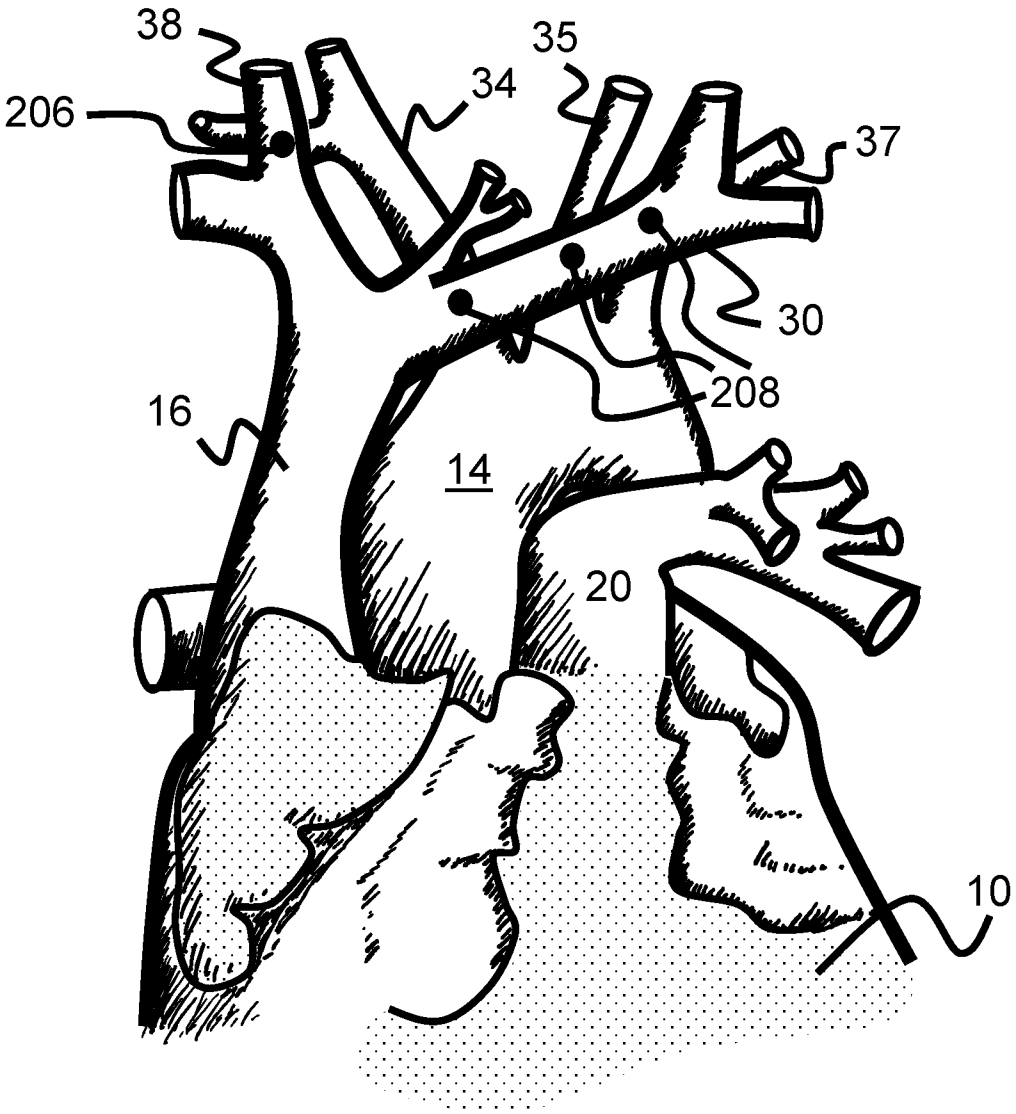

Figure 19

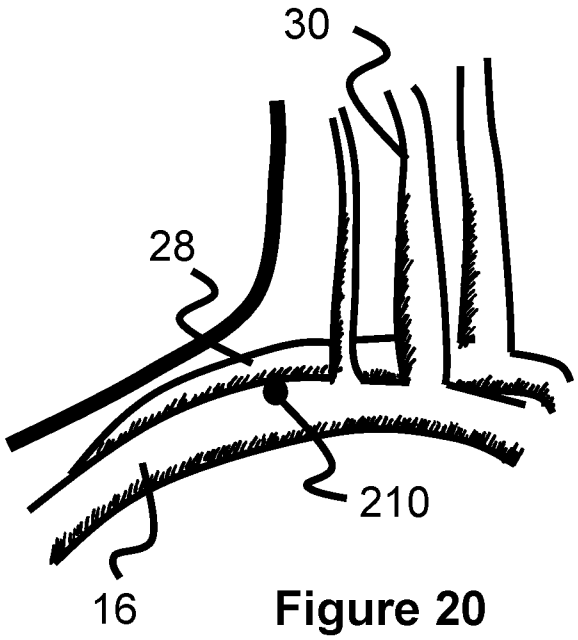

Figure 20

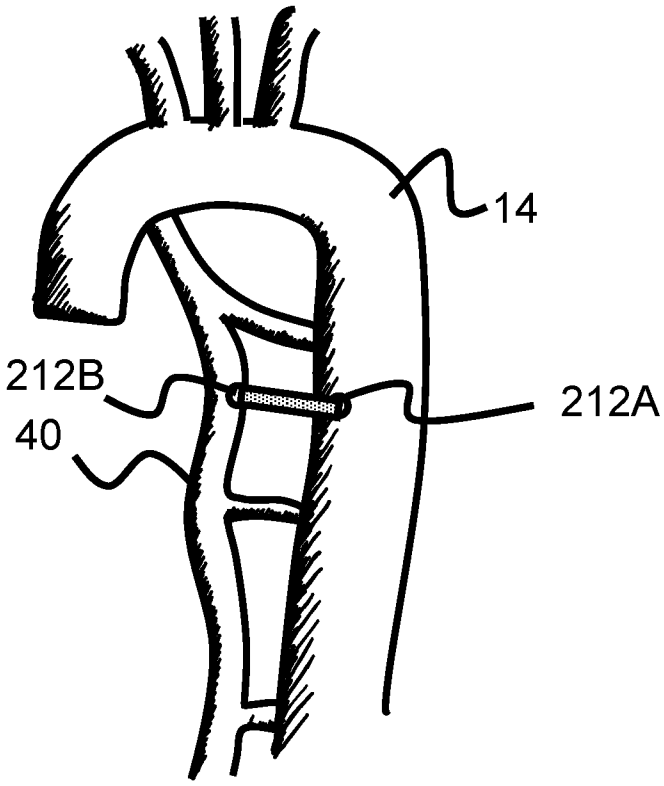

Figure 21

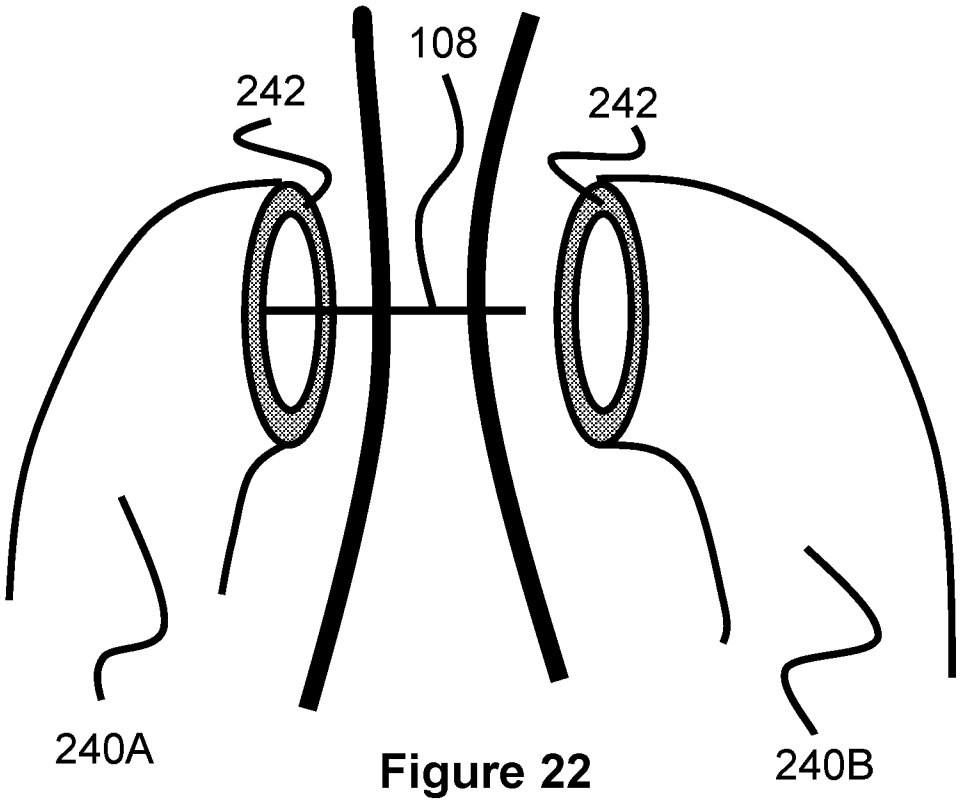

Figure 22

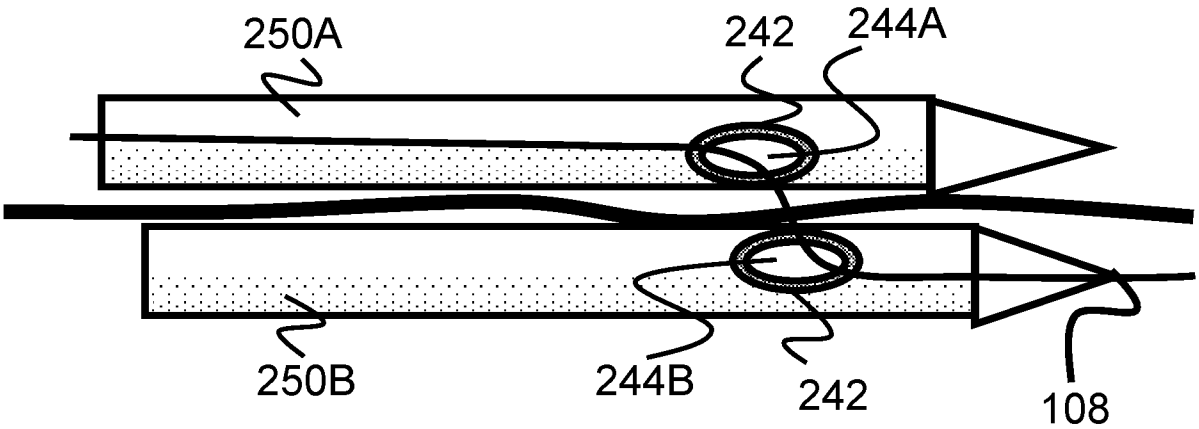

Figure 23

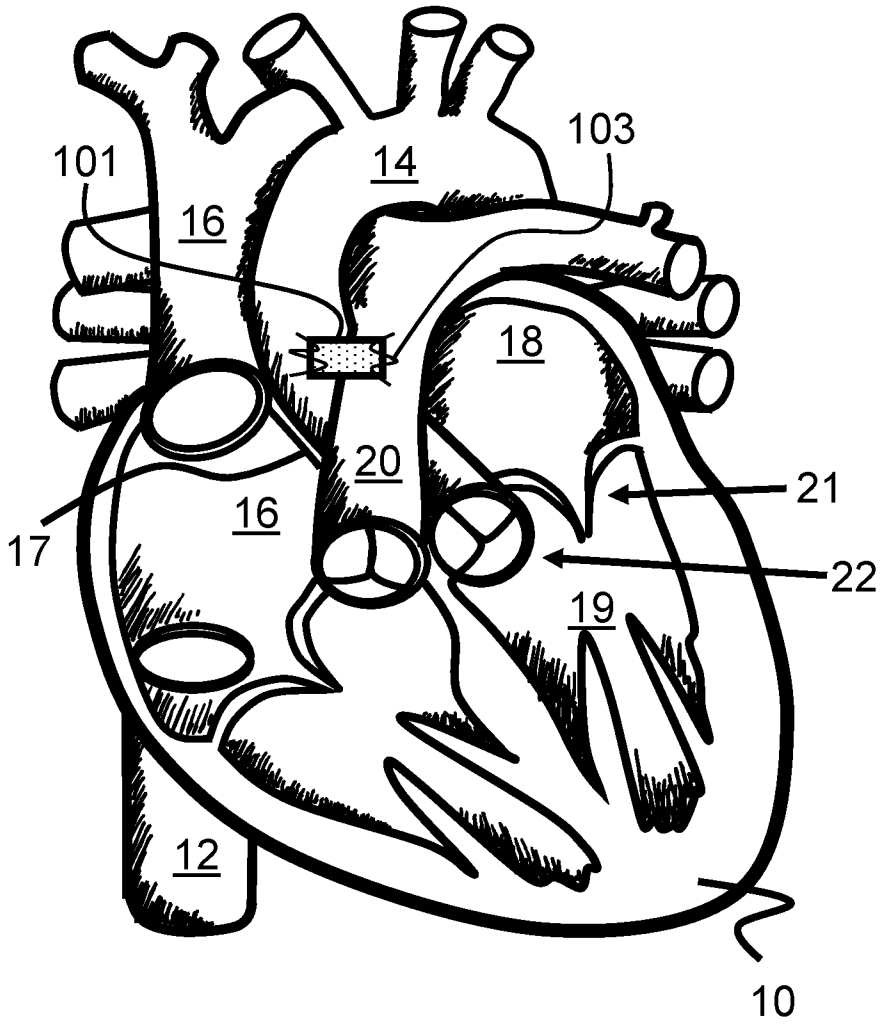

Figure 24

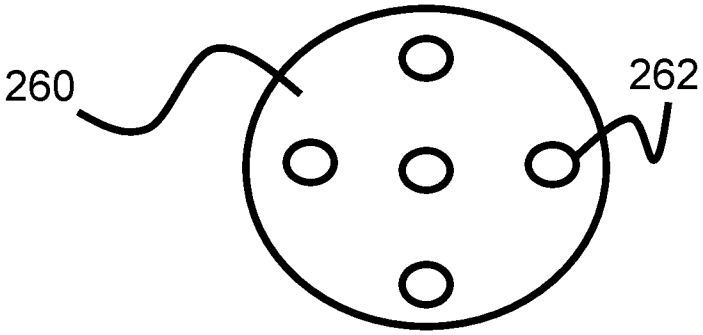

Figure 25

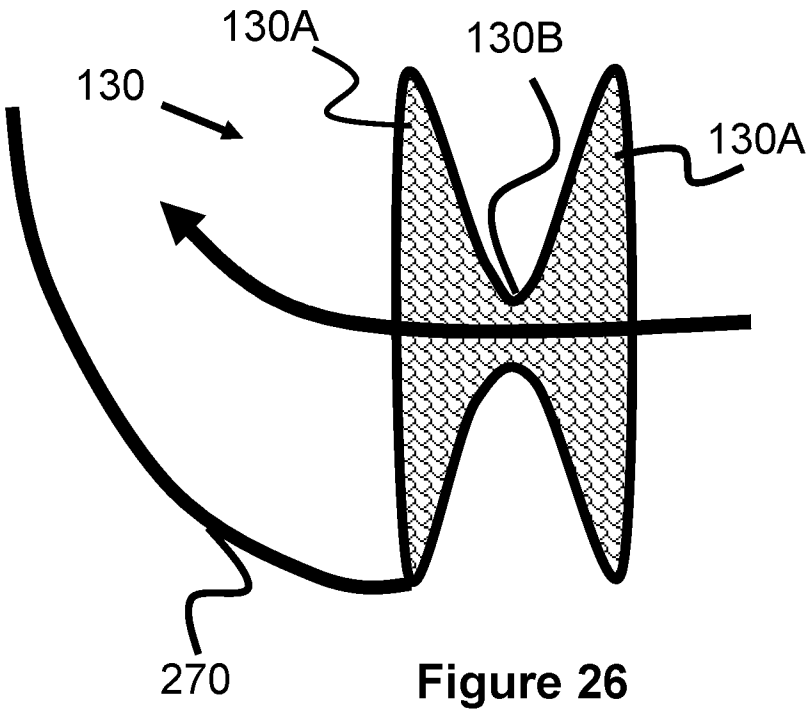

Figure 26

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/033218

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/11; A61B 17/00; A61B 17/03; A61B 17/12; A61F 2/06 (2020.01)
CPC - A61B 17/11; A61B 17/00; A61B 2017/00252; A61B 2017/1107; A61B 2017/1139; A61B 17/12; A61F 2/06 (2020.08)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
see Search History document

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2015/0148731 A1 (MCNAMARA et al) 28 May 2015 (28.05.2015) entire document	1-10
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Y		11-13
X	US 2007/0299384 A1 (FAUL et al) 27 December 2007 (27.12.2007) entire document	14-18
Y	US 2007/0167974 A1 (CULLY et al) 19 July 2007 (19.07.2007) entire document	11
Y	US 2011/0218620 A1 (MEIRI et al) 08 September 2011 (08.09.2011) entire document	12
Y	US 2003/0181843 A1 (BIBBER et al) 25 September 2003 (25.09.2003) entire document	13
A	US 2002/0010411 A1 (MACOVIAK et al) 24 January 2002 (24.01.2002) entire document	1-18
A	US 2005/0277967 A1 (BRENNEMAN et al) 15 December 2005 (15.12.2005) entire document	1-18

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

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
08 September 2020	14 OCT 2020
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver Telephone No. PCT Helpdesk: 571-272-4300

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/033218

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

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

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

See extra sheet(s).

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-18

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/033218

Continued from Box No. III Observations where unity of invention is lacking

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-18, are drawn to a method of treating a patient, comprising: creating a shunt between a first location in an aorta of the patient and a second location located in a chamber.

Group II, claims 19-20, are drawn to a device for snaring a piercing guidewire, comprising: an elongated body.

Group III, claims 21-23, are drawn to a system for creating a shunt, comprising: a first catheter having a first lumen and a first lumen opening at a distal end of the first catheter.

The inventions listed as Groups I, II and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature of the Group I invention: creating a shunt between a first location in an aorta of the patient and a second location located in a chamber having a pressure lower than the aorta; and, decreasing arterial resistance so as to reduce pressures within a cardiovascular system of the patient as claimed therein is not present in the invention of Groups II and III. The special technical feature of the Group II invention: an elongated body; and, a wire loop located at a distal end of the elongated body, the wire loop expanding to a first lobe and a second lobe that are adjacent a center ridge; wherein the first lobe and the second lobe are sized and shaped to conform to cusps of an aortic valve as claimed therein is not present in the invention of Groups I or III. The special technical feature of the Group III invention: a first catheter having a first lumen and a first lumen opening at a distal end of the first catheter; wherein one or more magnets disposed around the first opening; a second catheter having a second lumen and a second opening at a distal end of the second catheter; wherein one or more magnets are disposed around the second opening; and, wherein the one or more magnets disposed around the first opening are configured to magnetically attract the one or more magnets disposed around the second opening as claimed therein is not present in the invention of Groups I or II.

Groups I, II and III lack unity of invention because even though the inventions of these groups require the technical feature of creating a shunt in a patient, this technical feature is not a special technical feature as it does not make a contribution over the prior art.

Specifically, US 2002/0010411 A1 to Macoviak et al. teaches creating a shunt in a patient (the perfusion shunt apparatus is configured as an aortic perfusion shunt apparatus for deployment within a patient's aortic arch, para. 0008).

Since none of the special technical features of the Group I, II or III inventions are found in more than one of the inventions, unity of invention is lacking.