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(54) **DEVICE AND METHOD PROVIDING ARTERIAL BLOOD FLOW FOR PERFUSION OF ISCHEMIC MYOCARDIUM**

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Publication Classification

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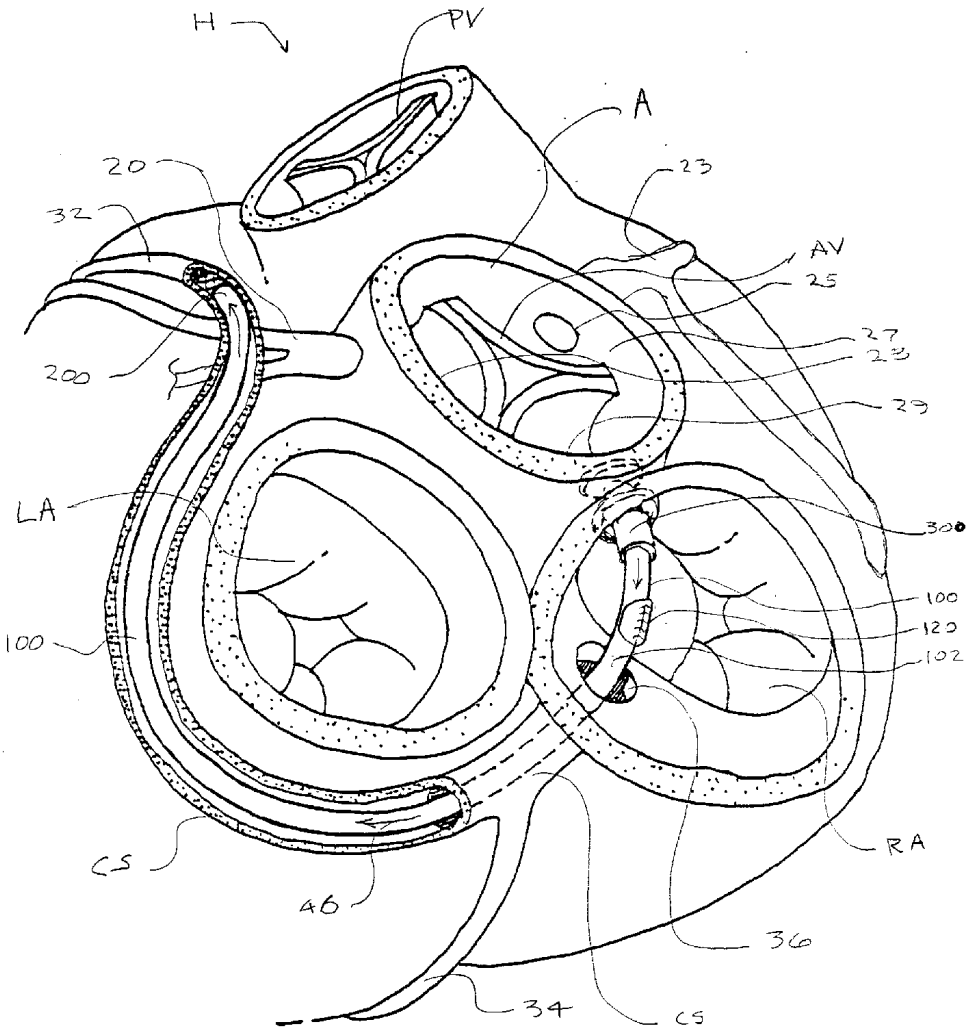
(57) **ABSTRACT**

The present invention generally relates to methods and apparatus for use in endovascular and intraoperative procedures providing arterial blood flow for perfusion of ischemic myocardium. Aspects of the present invention provide a conduit between a non-coronary sinus of the aorta and a coronary vein. The conduit traverses a portion of the right atrium and the coronary sinus, and is located entirely within the heart and aorta. Arterial blood flows from the aorta through the conduit and into the coronary venous circulation towards the ischemic region of the heart. All procedures described herein may be performed endovascularly, and further may be performed while the patient's heart is beating.



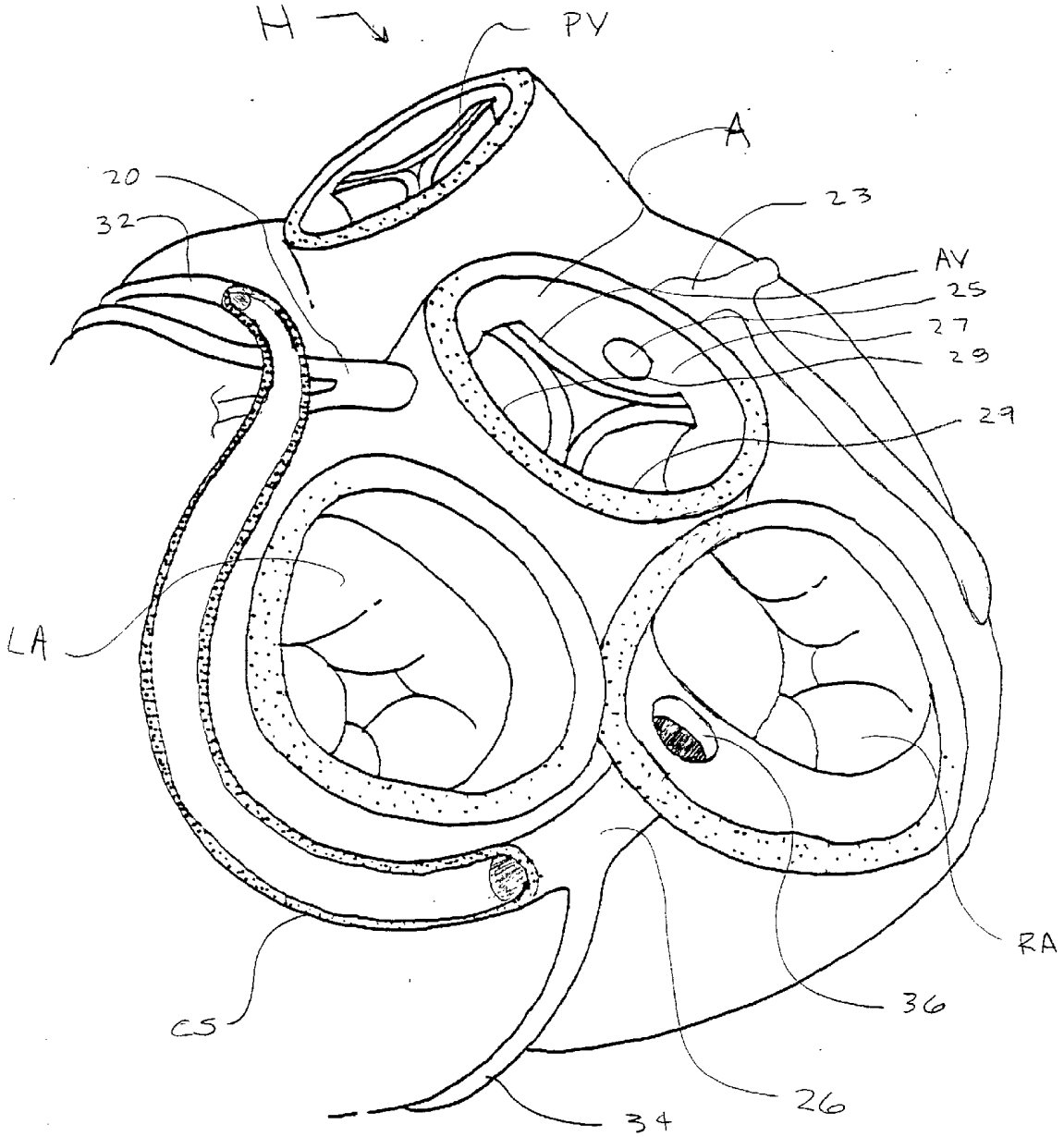


FIG. 1

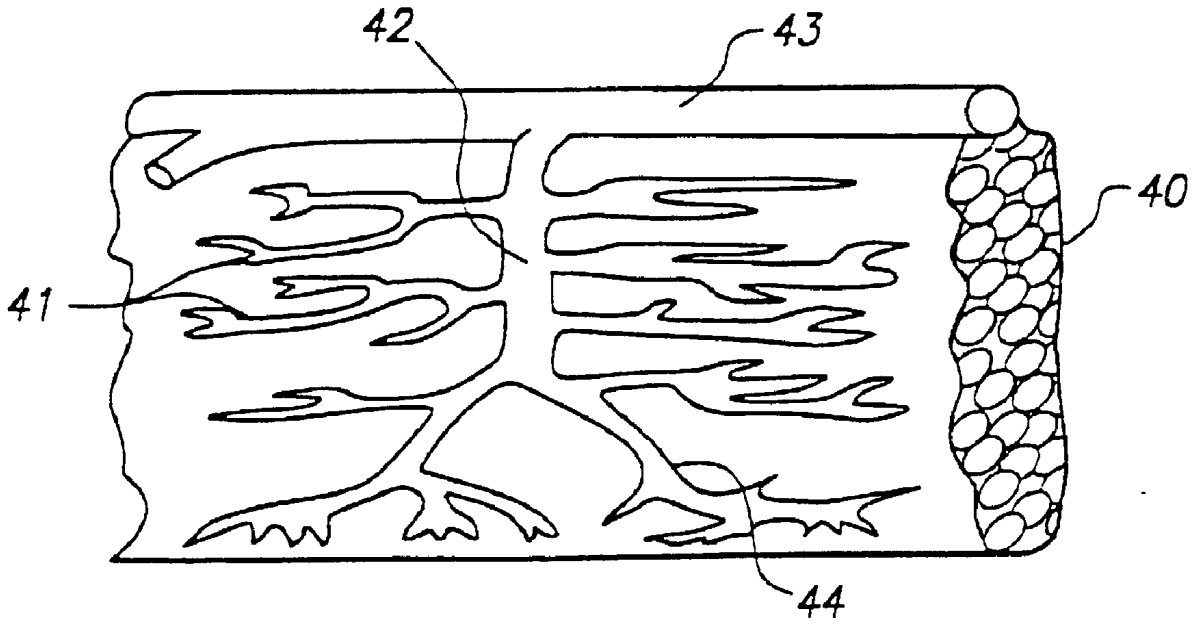


FIG. 2.

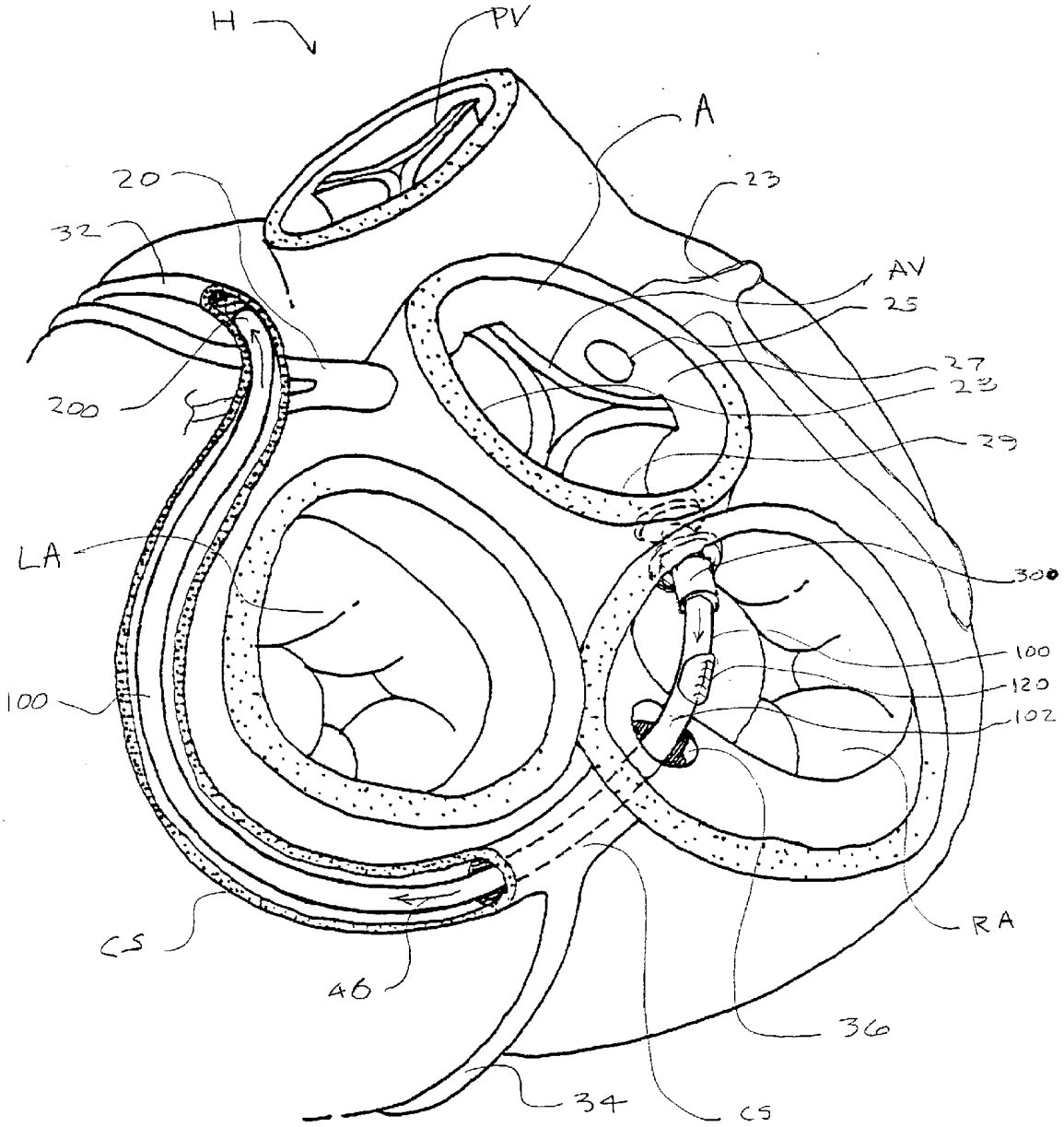

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FIG. 3

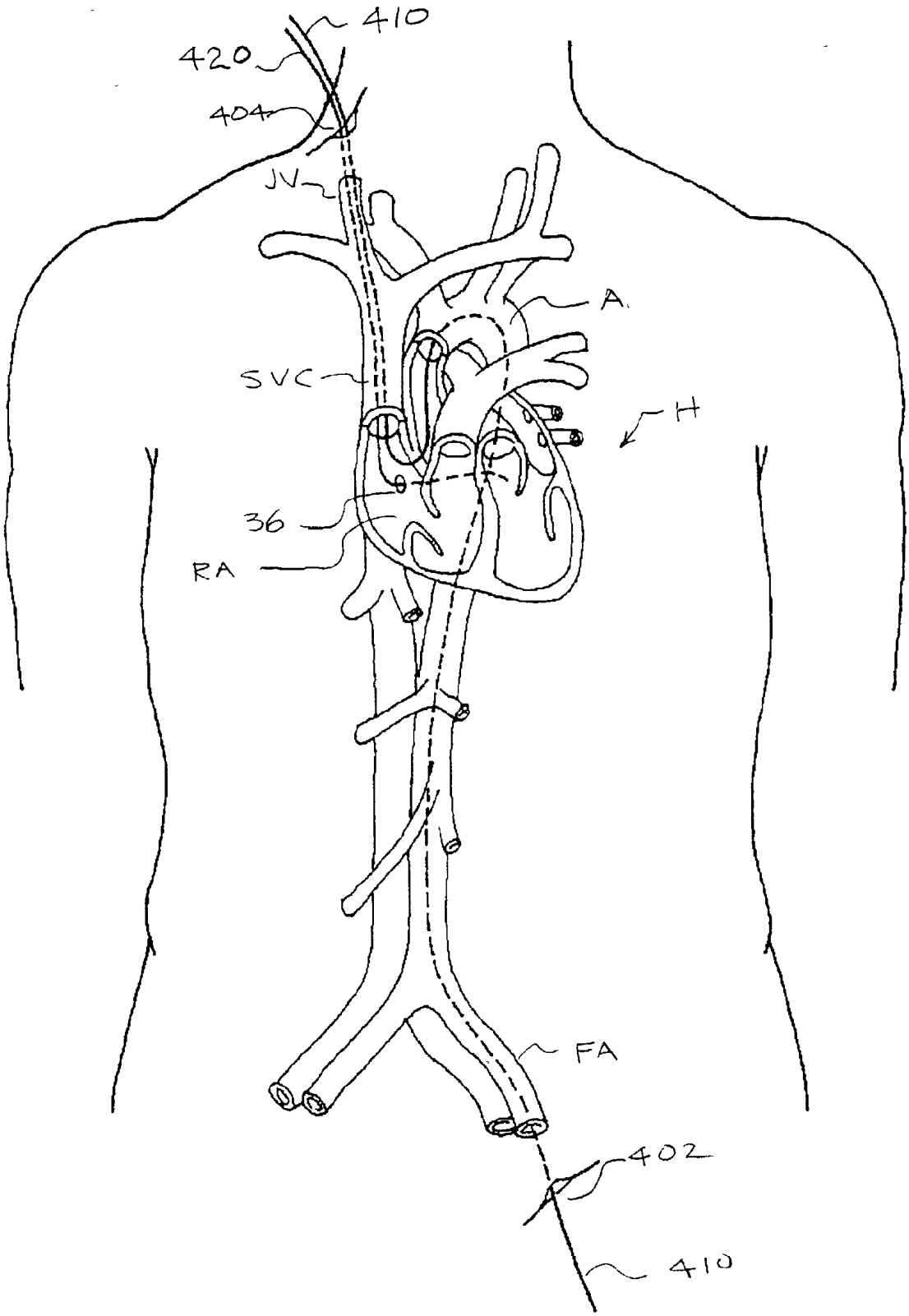
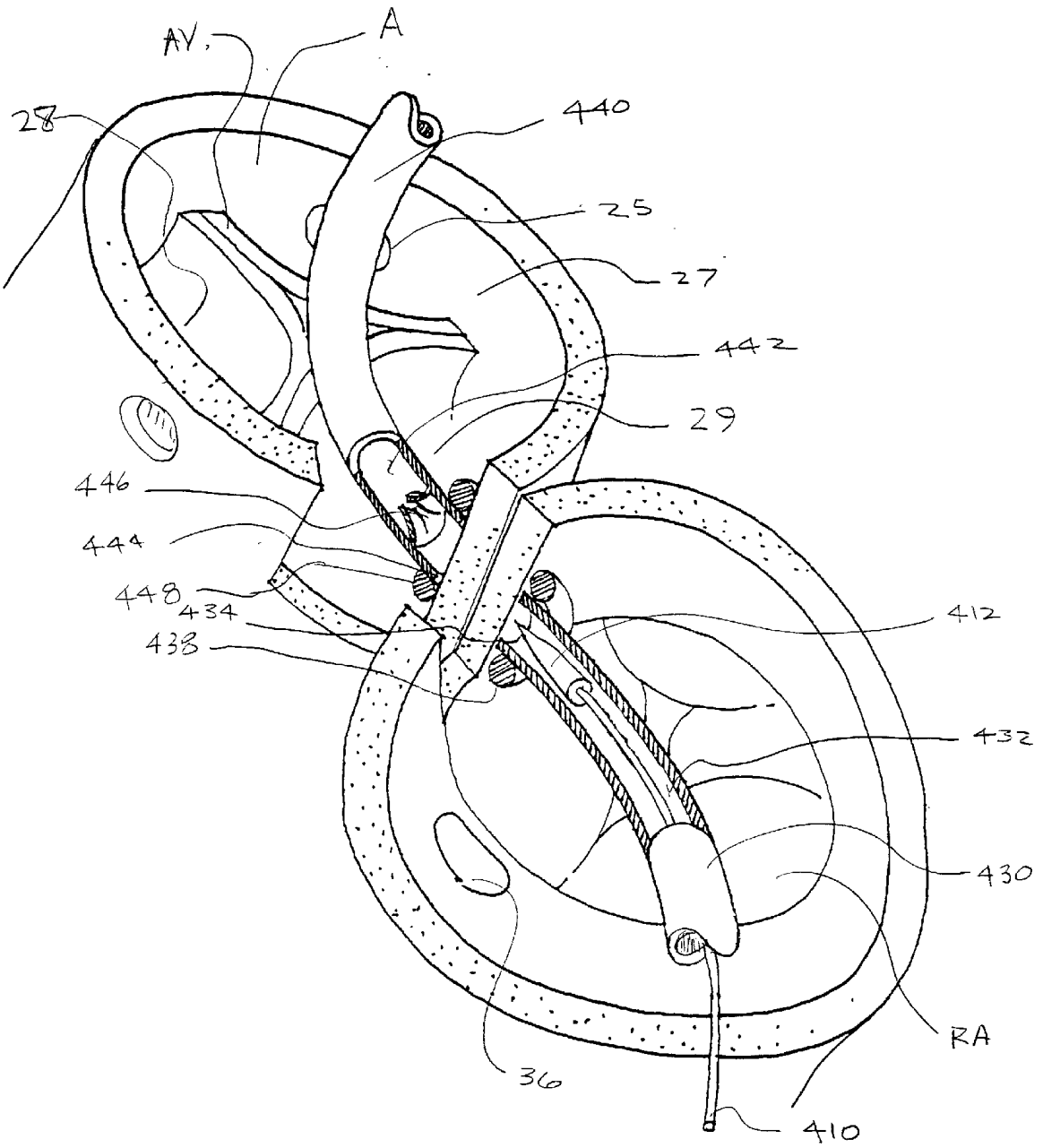


FIG 4



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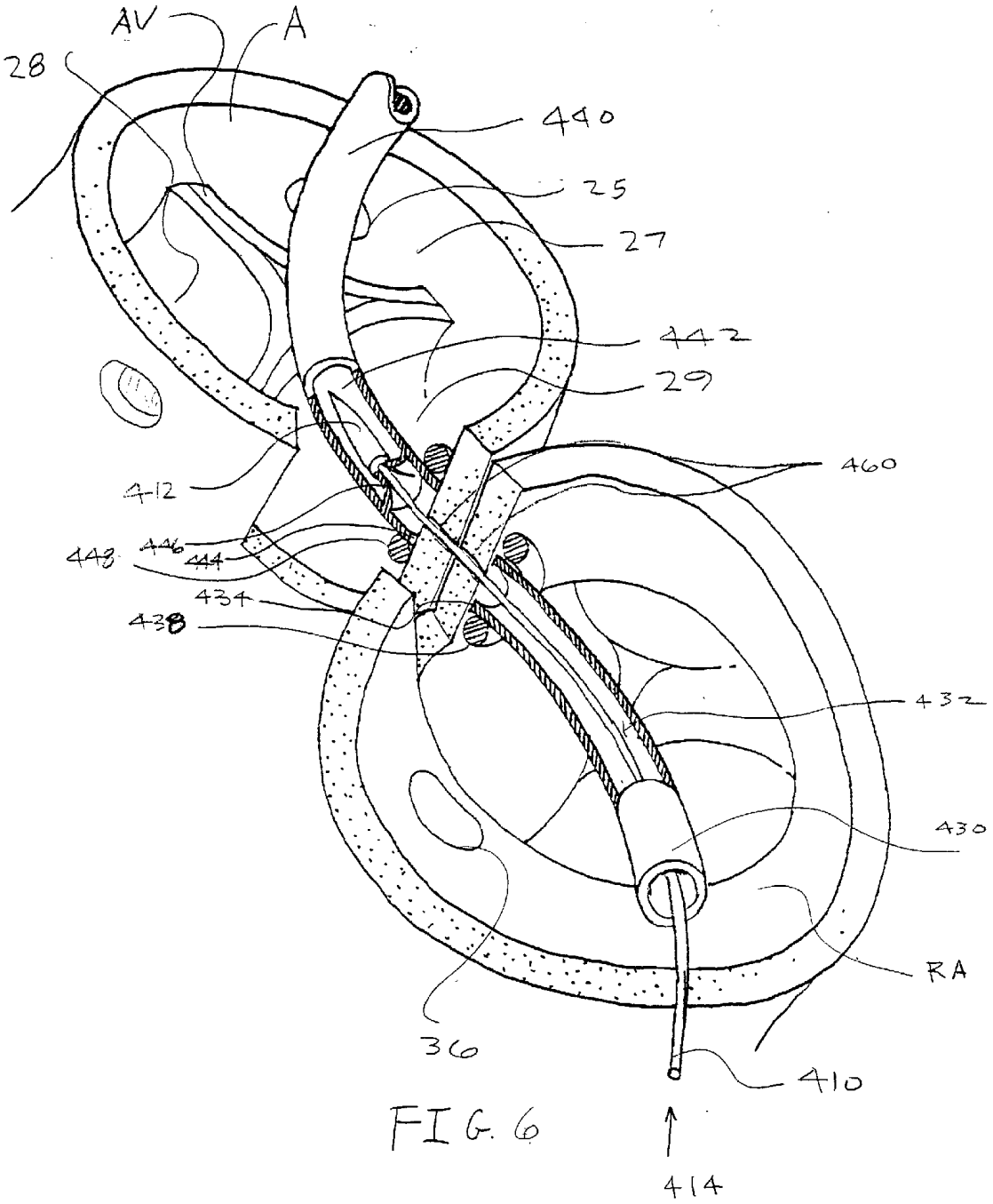
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FIG. 6

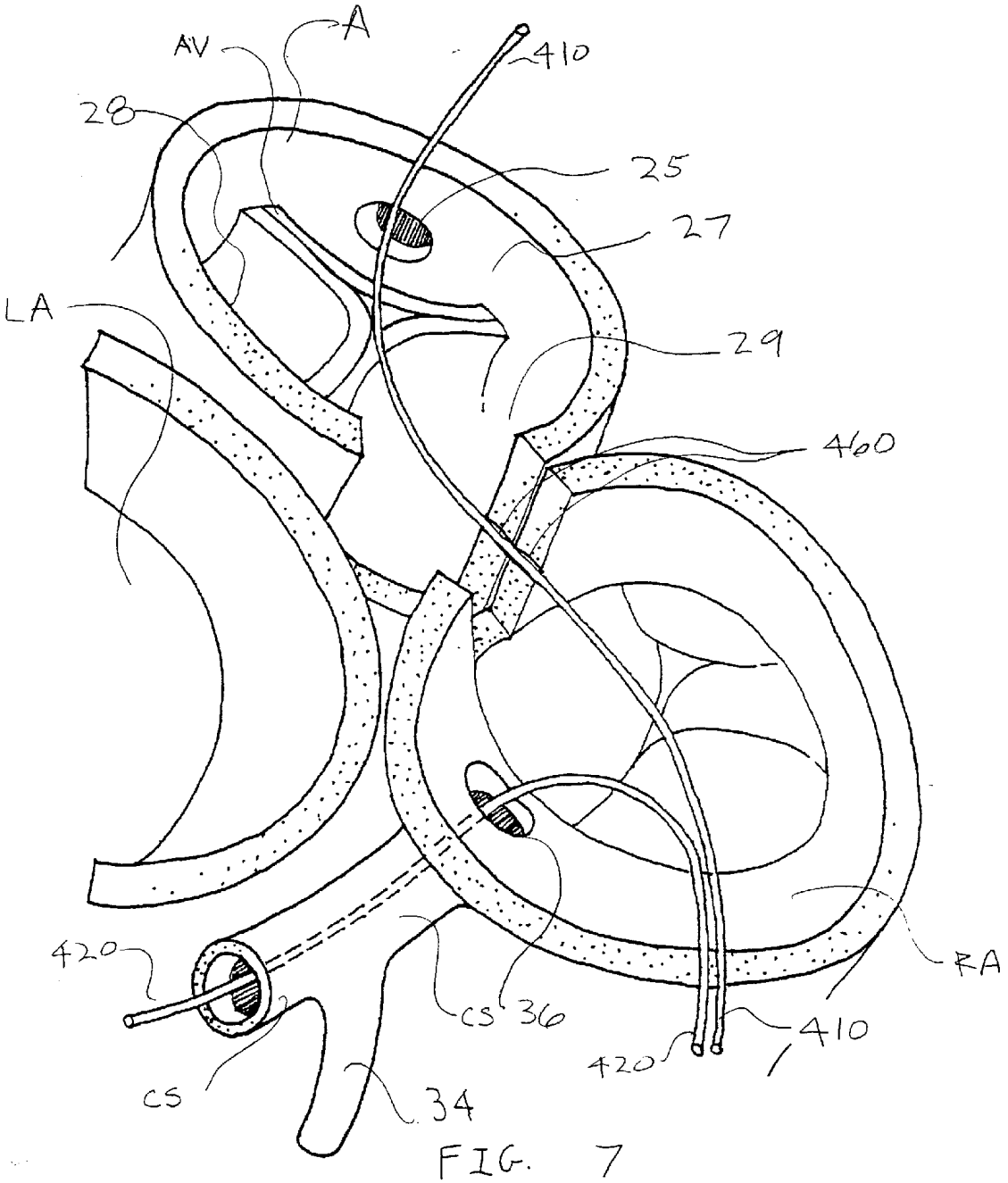

FIG. 7

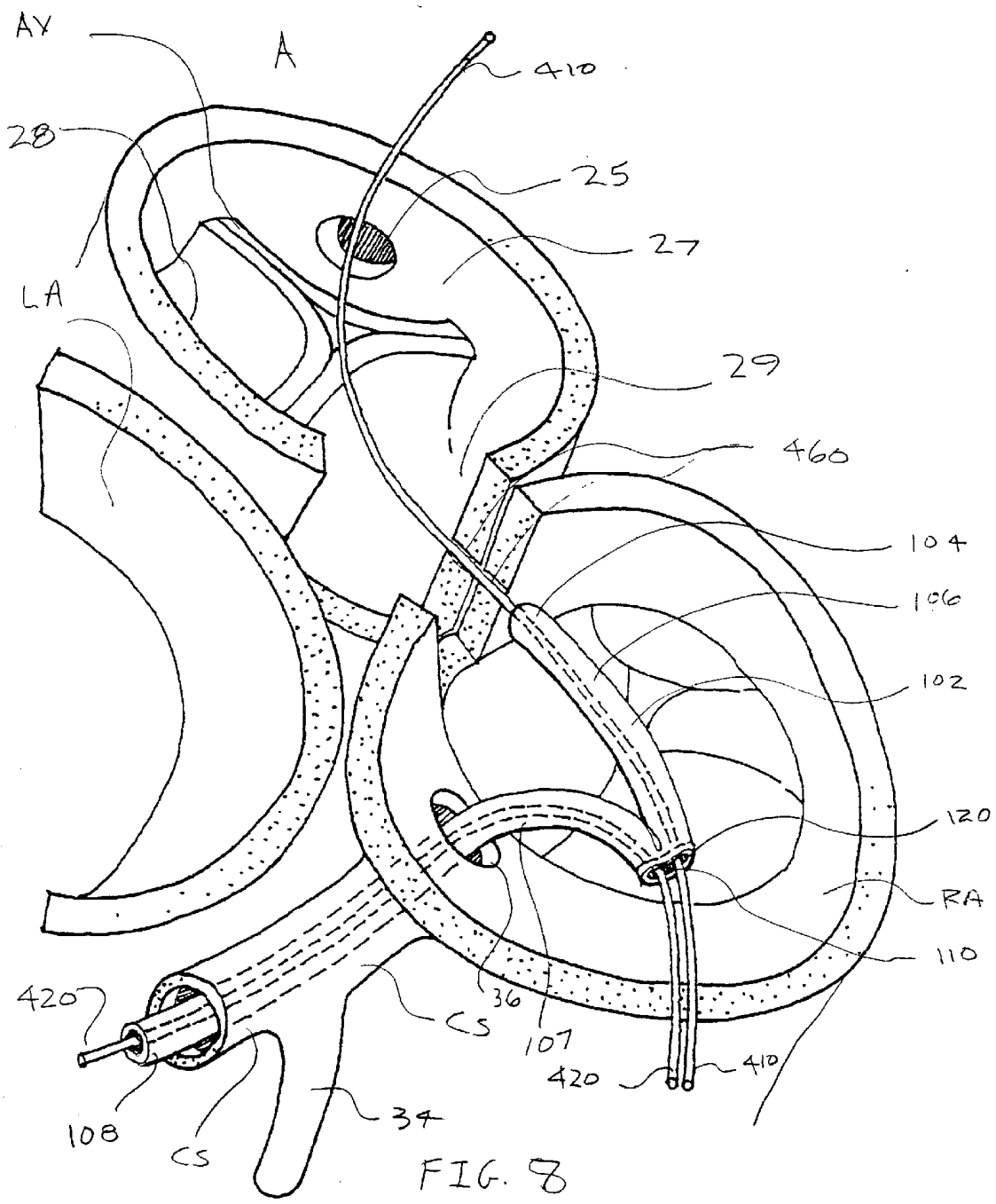
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FIG. 8

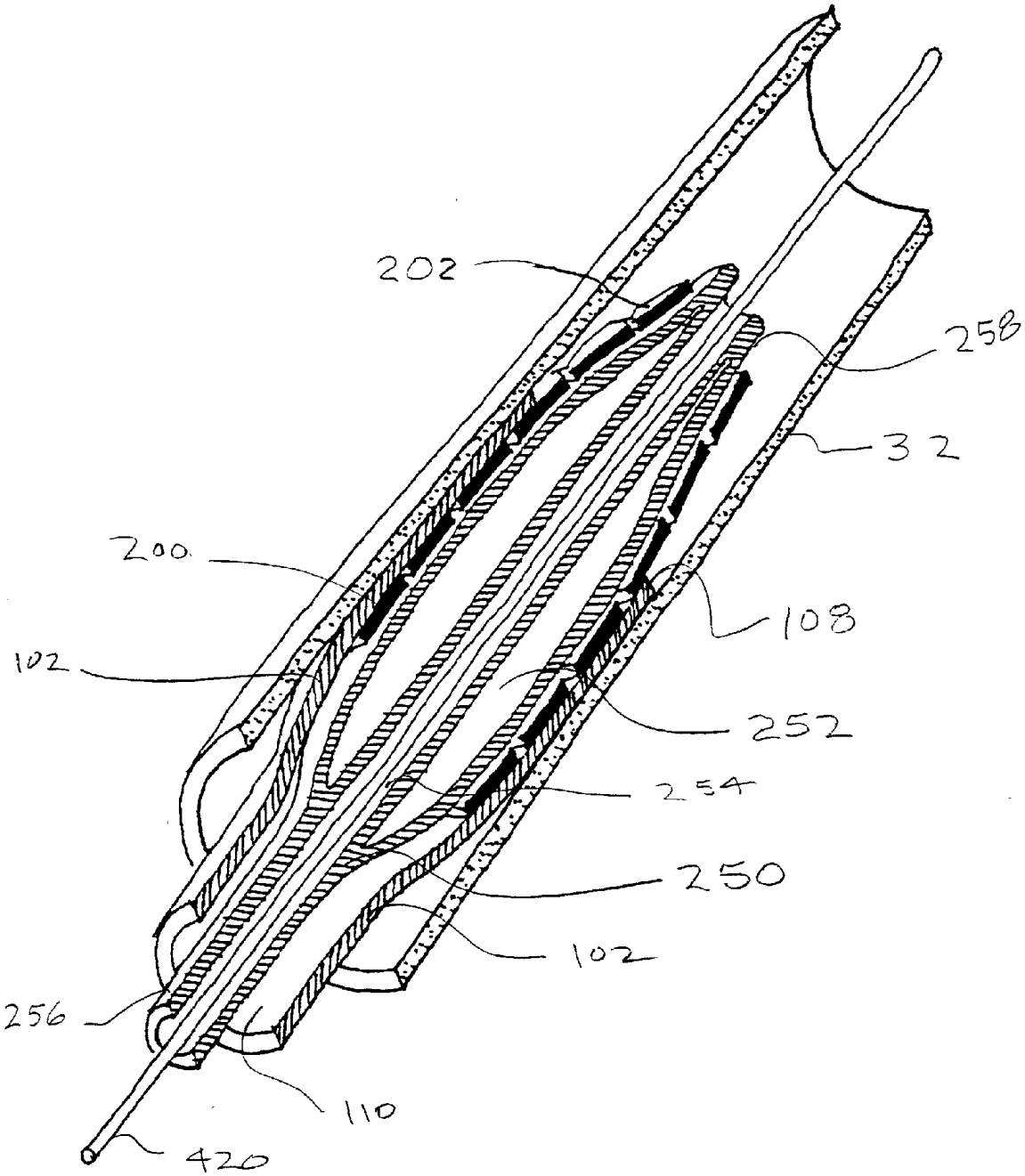

FIG. 9

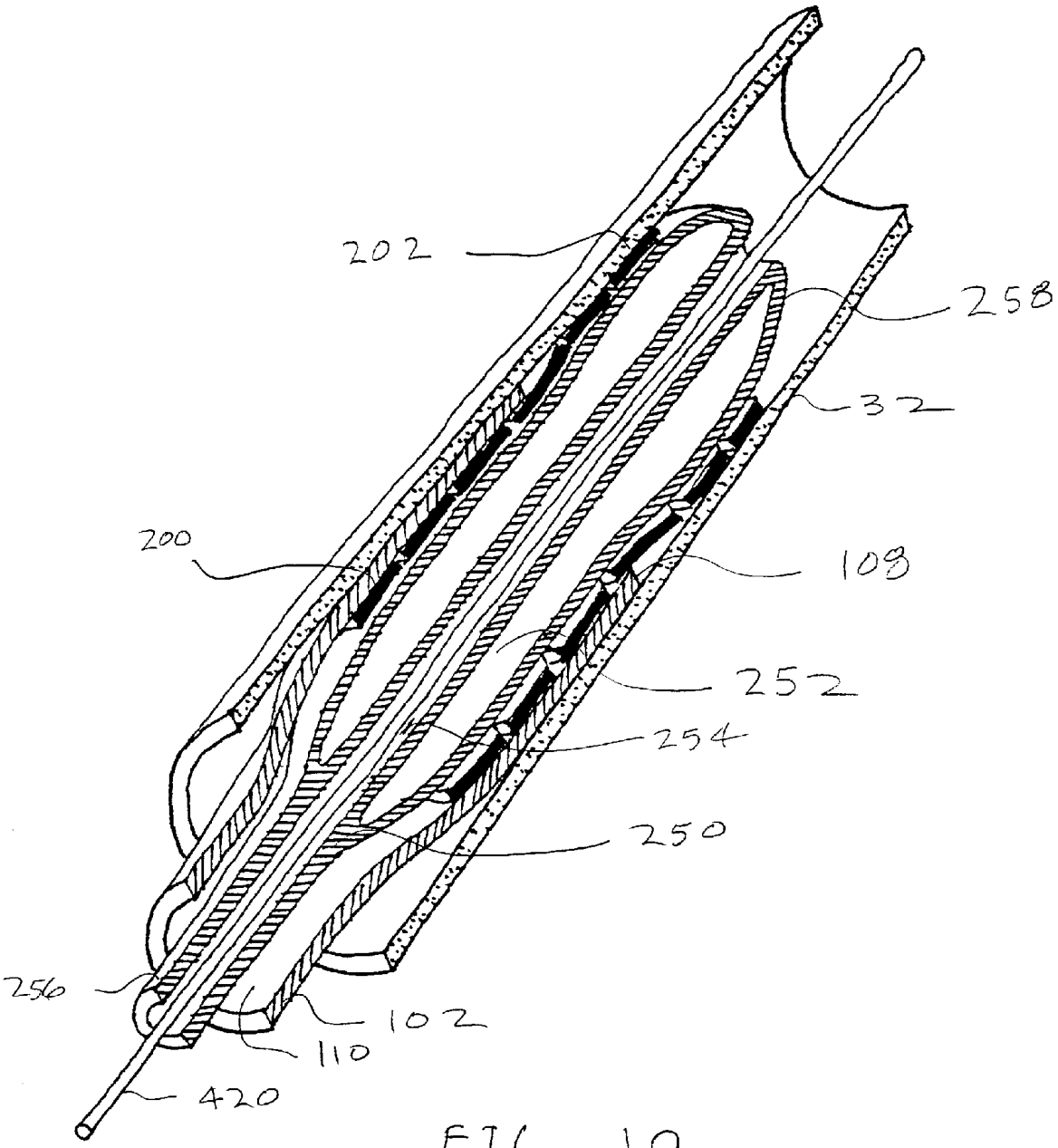

FIG. 10

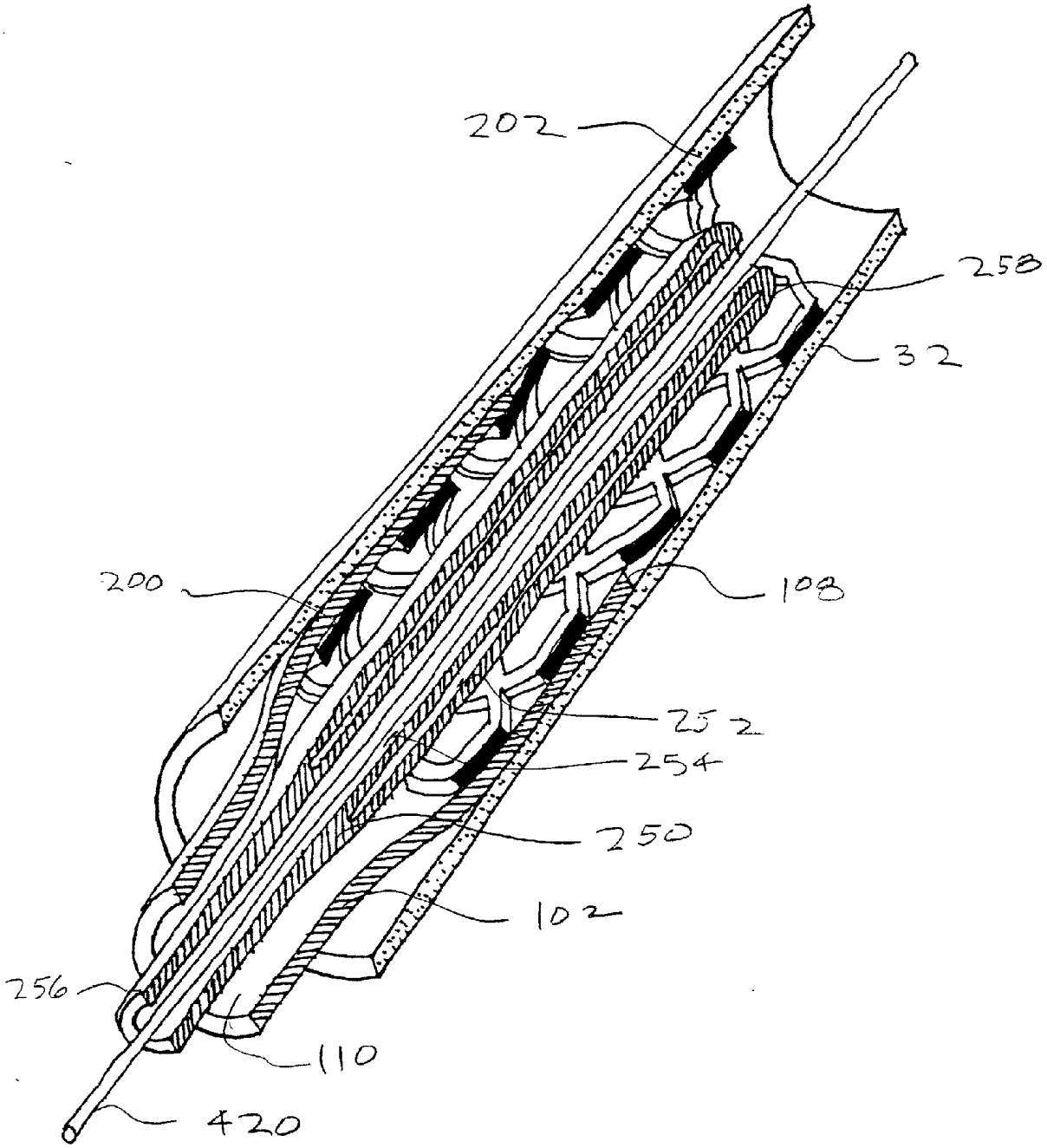

FIG. 11

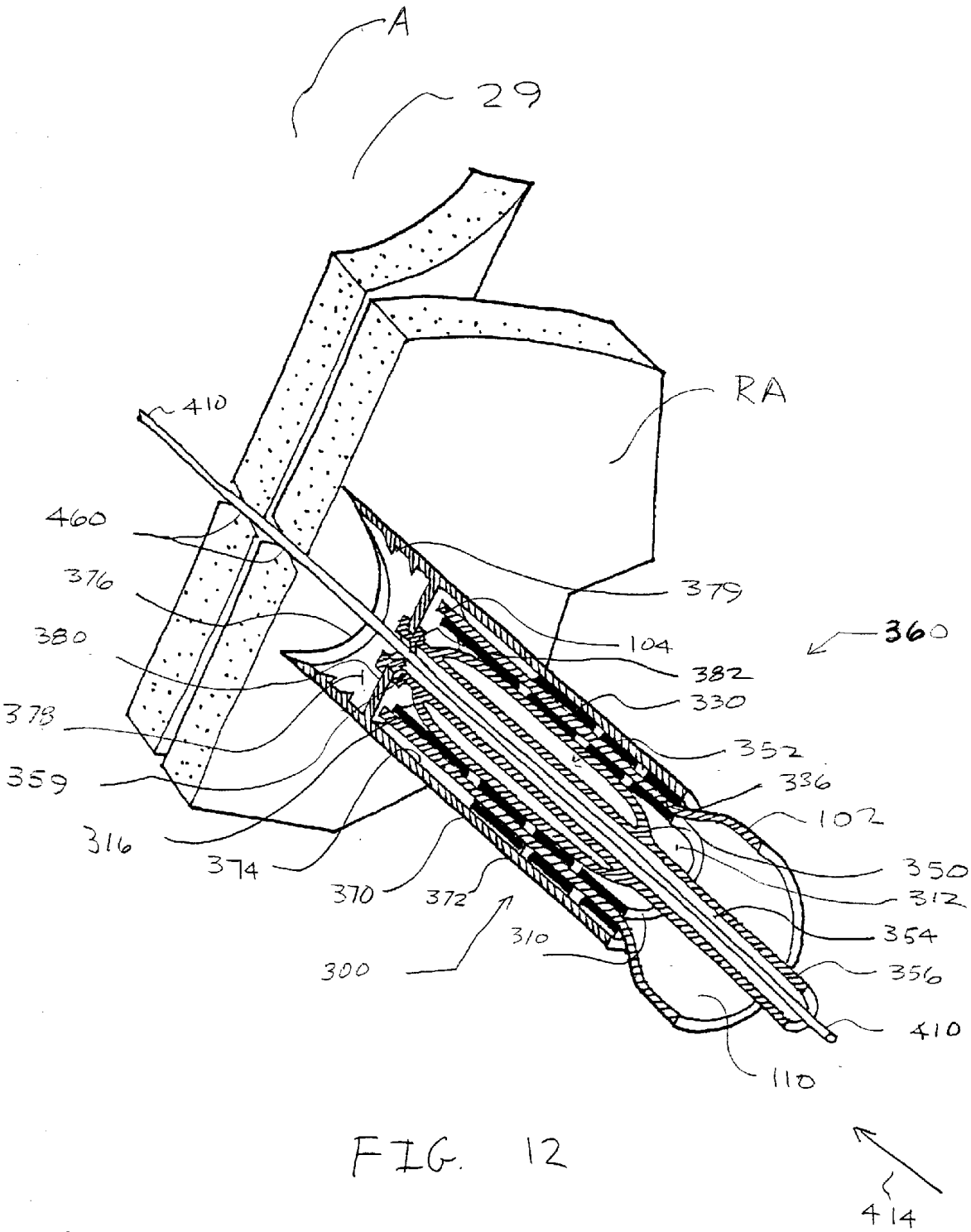
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FIG. 12

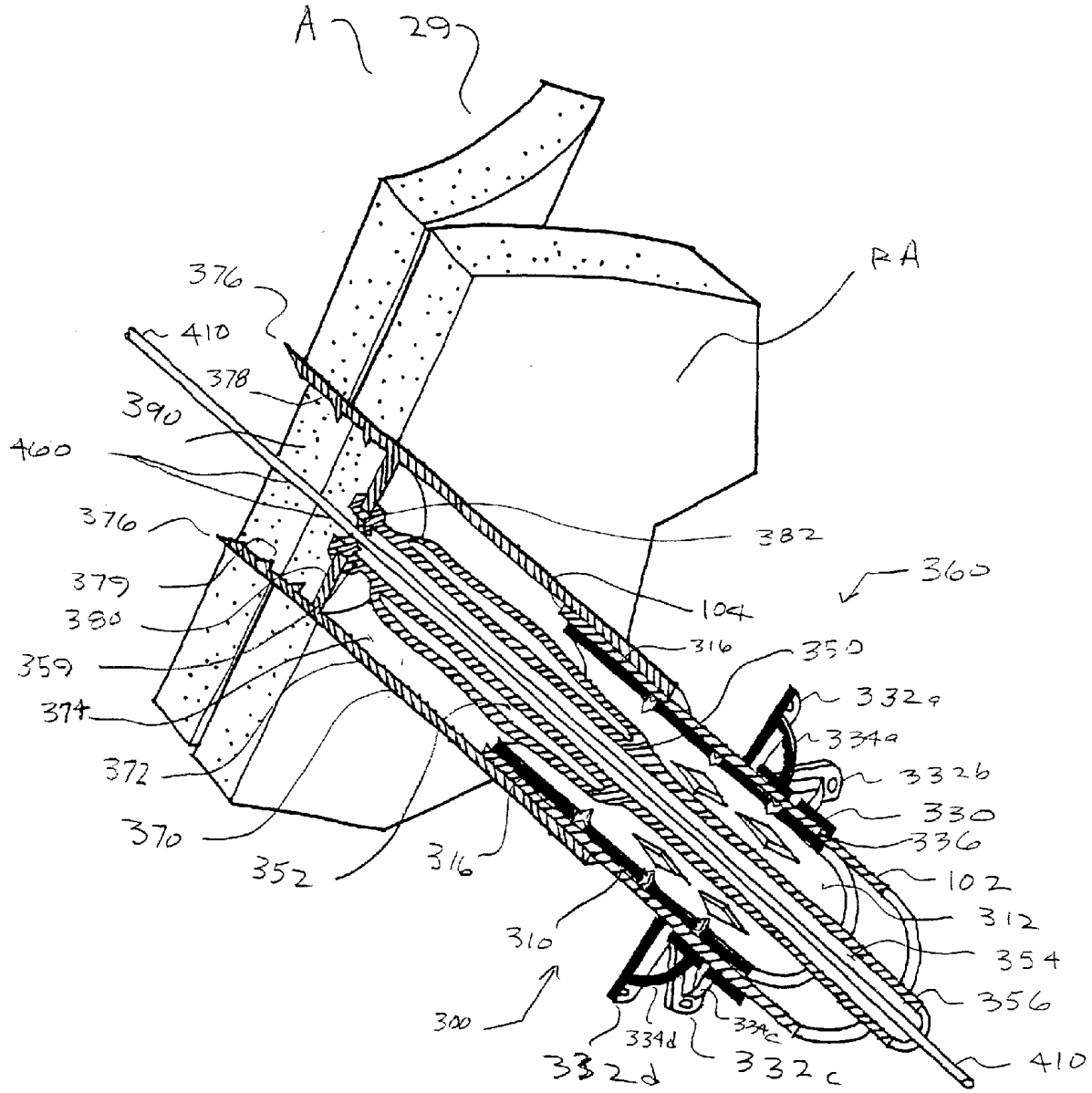
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FIG. 13

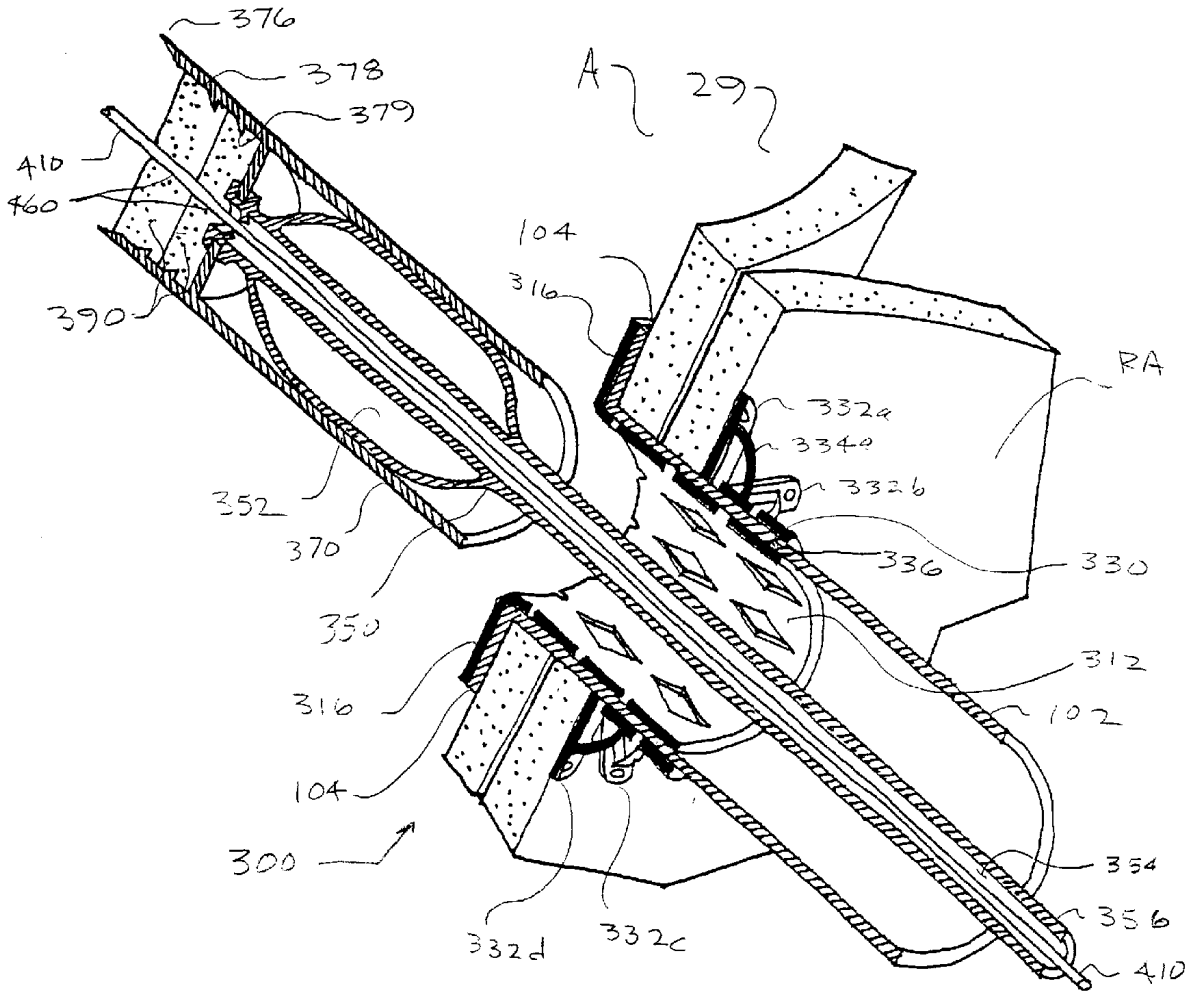
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FIG. 14

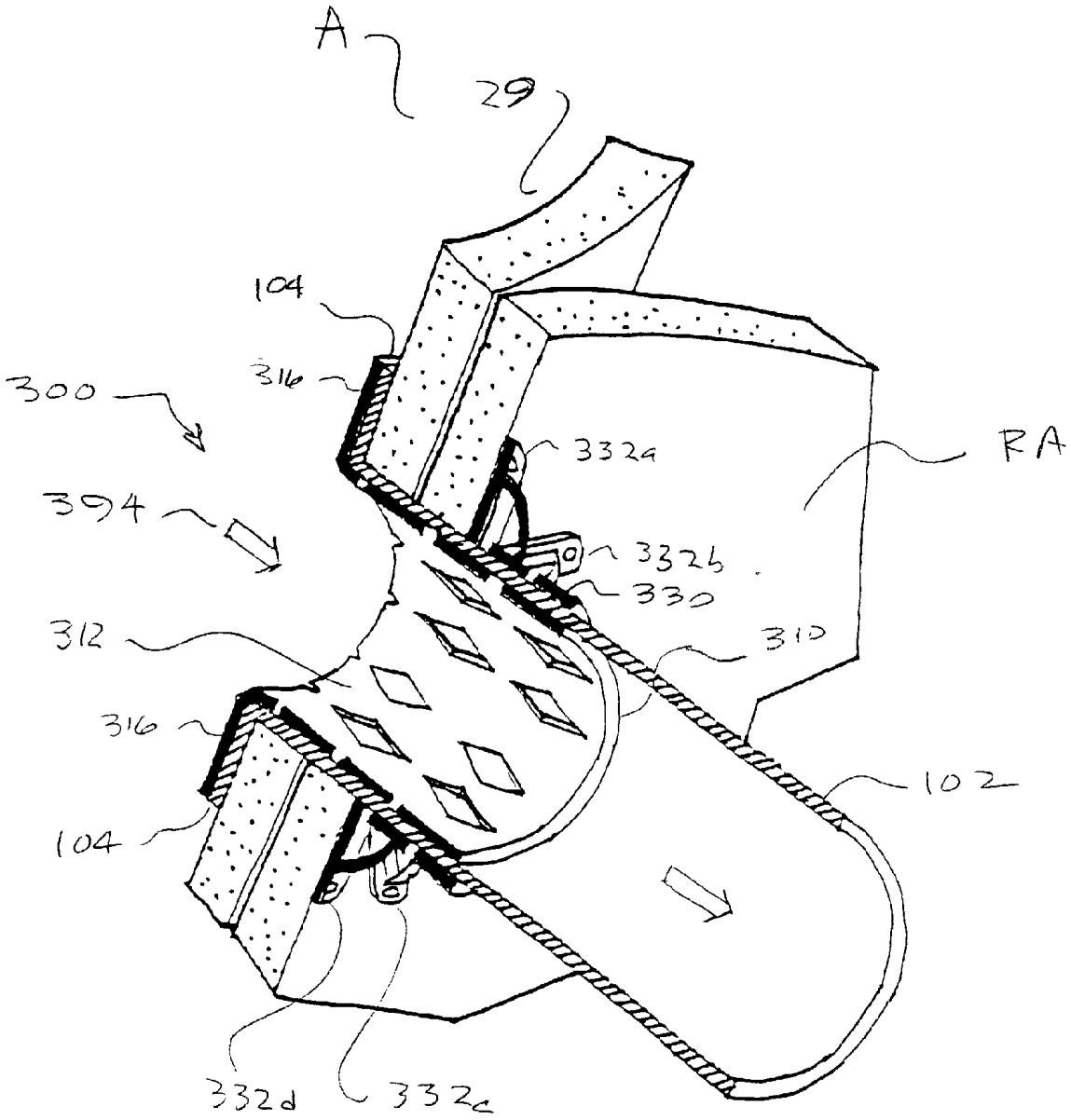
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FIG. 15

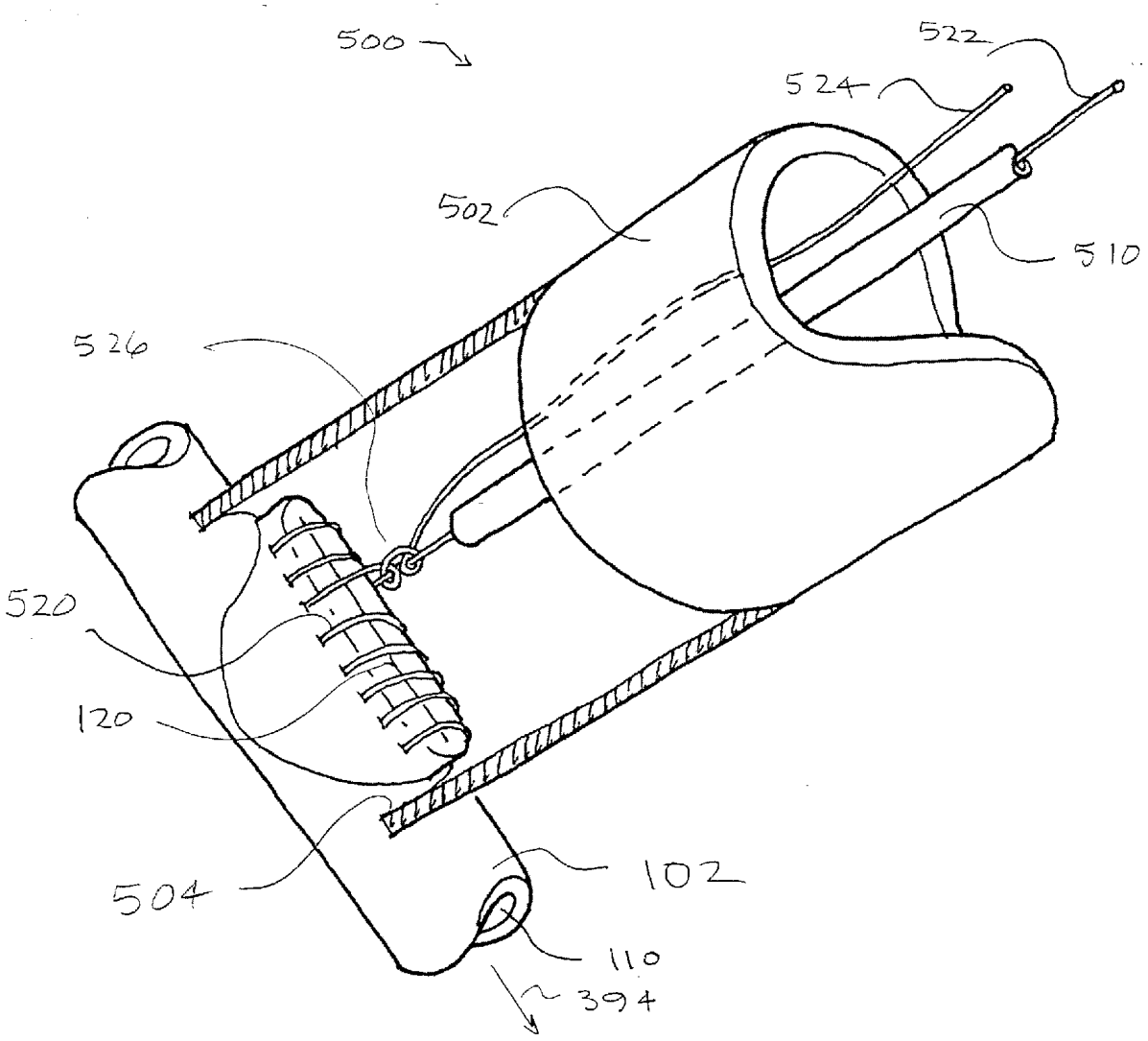

FIG. 16

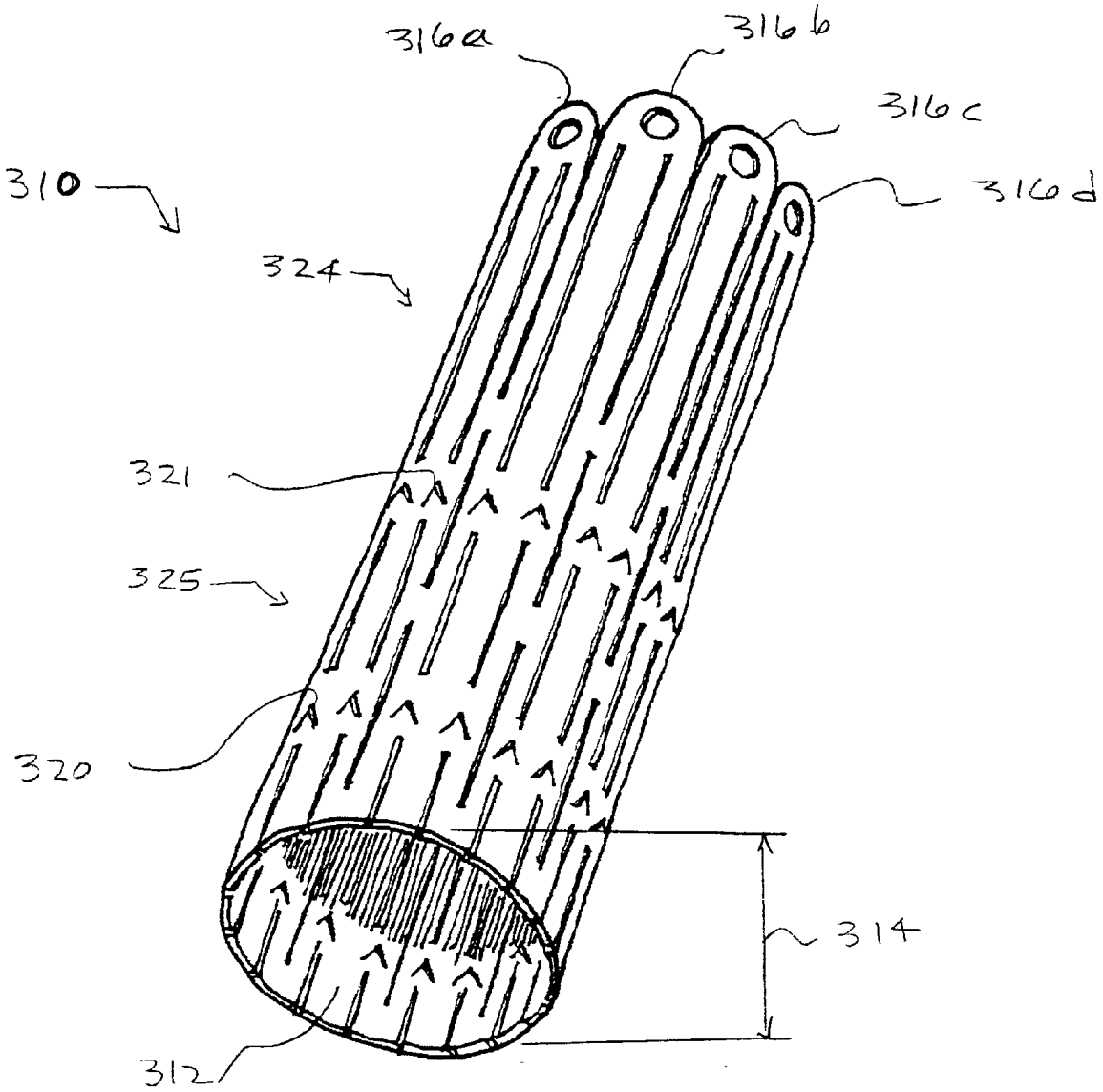

FIG. 17

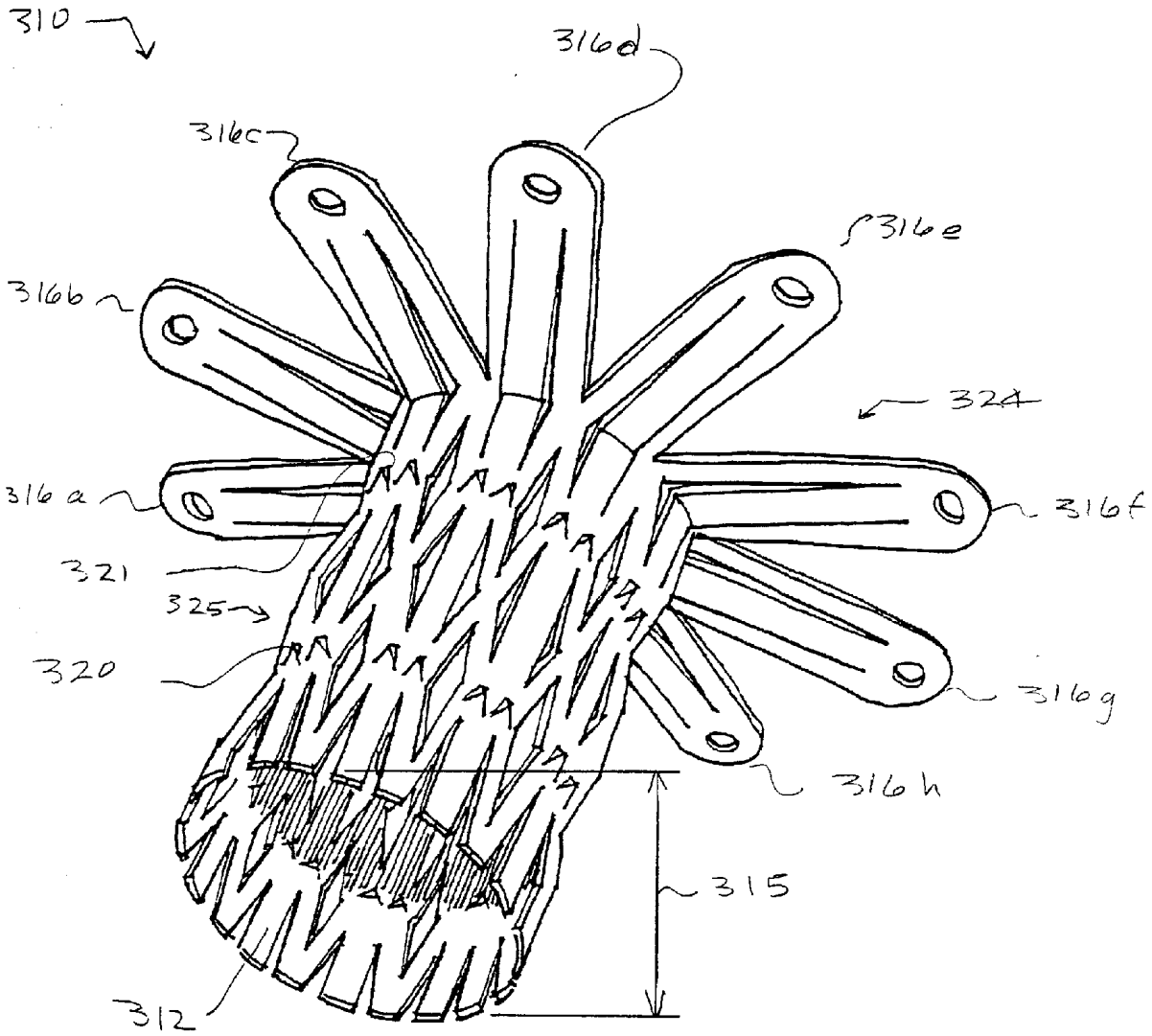
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FIG. 18

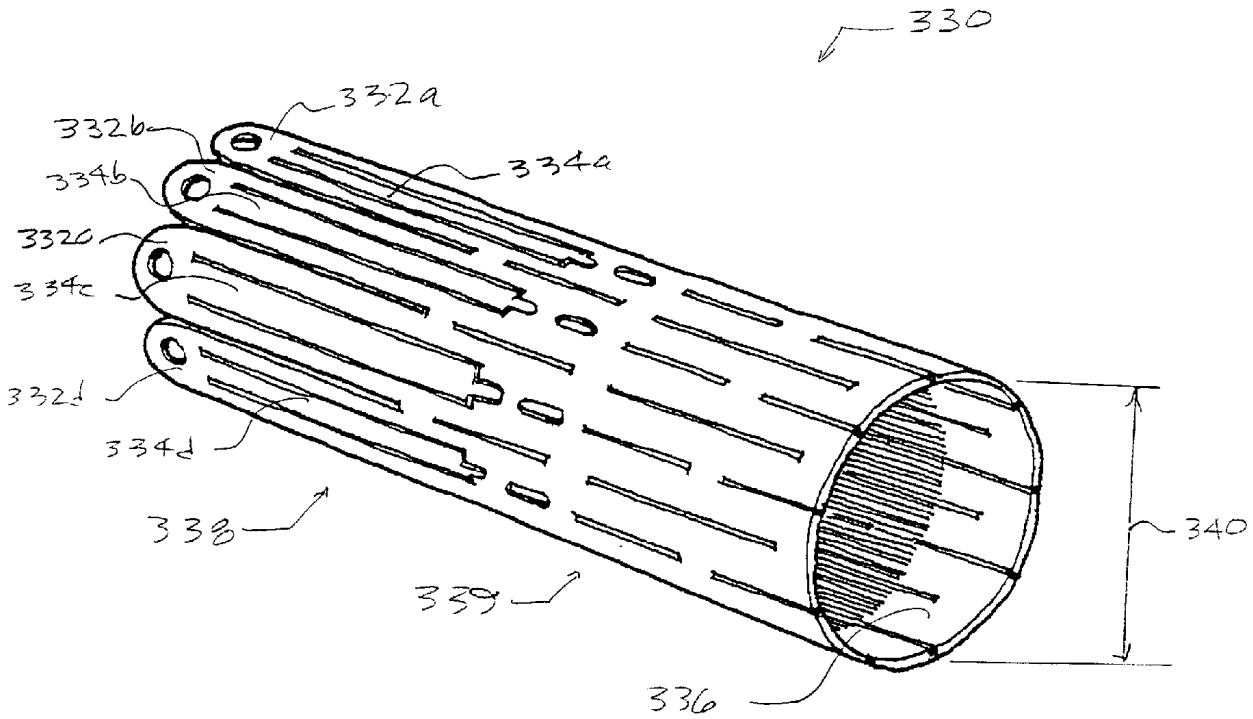

FIG. 19

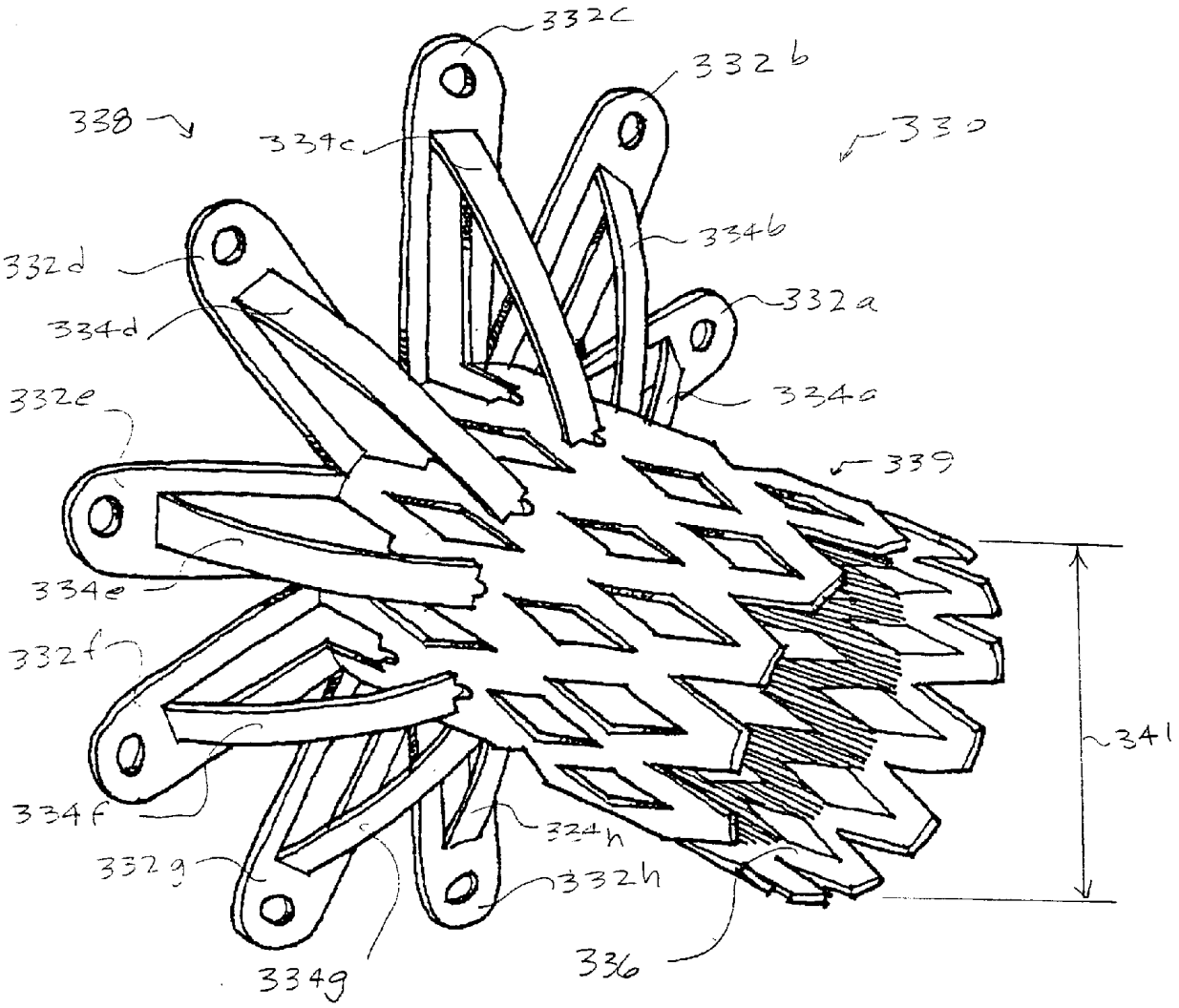
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FIG 20

DEVICE AND METHOD PROVIDING ARTERIAL BLOOD FLOW FOR PERFUSION OF ISCHEMIC MYOCARDIUM

PRIORITY

[0001] This application claims the priority of Provisional Application No. 60/388,005 filed Jun. 11, 2002, entitled "Method and Apparatus for an Aorta to Atrium Anastomosis for Venous Retroperfusion of Ischemic Myocardium."

FIELD OF THE INVENTION

[0002] The present invention relates generally to methods and apparatus for treating ischemic heart disease. More particularly, the invention relates to endovascular devices and methods of providing arterial blood flow from the aorta to a portion of the coronary vascular system for perfusion of ischemic myocardium.

BACKGROUND

[0003] Coronary artery disease (CAD), also known as ischemic heart disease, affects more than 12.5 million Americans according to the American Heart Association (AHA). CAD is the leading cause of death and disability in the United States, killing over half a million people in 1999. This is a progressive disease that causes narrowing of the arteries that supply blood to the heart muscle, thus diminishing cardiac perfusion. Eventually, the delivery of blood is not sufficient to maintain proper function of the heart. The most common manifestation of the disease is angina pectoris or chest pain, which can be severe. The AHA estimates that well over six million Americans suffer from angina pectoris, with over 400,000 new cases each year. However, complications that are even more serious can develop including myocardial infarction (heart attack), arrhythmia (irregular or lack of a heart beat), sudden death from cardiac arrest, and heart failure.

[0004] The cardiac perfusion system is composed of two coronary arterial vessels, the left and right coronary arteries, which perfuse the myocardium from the epicardial surface inward towards the endocardium. Perfused blood flows through the capillary systems, into the coronary veins, and then into the right atrium via the coronary sinus. Additional systems, such as the lymphatic and the Thebesian, also provide drainage pathways for coronary blood. The venous system has extensive collaterals and, unlike the coronary arteries, does not occlude in atherosclerotic disease.

[0005] Current options to treat CAD caused, for example by atherosclerosis, include medical therapy/lifestyle changes, percutaneous intervention such as percutaneous transluminal coronary angioplasty (PTCA) often with coronary stenting, and surgical intervention such as coronary artery bypass grafting (CABG). PTCA and CABG have emerged as the leading treatments for coronary artery disease when drug therapy and lifestyle modification fail or are inadequate. The goal of both types of treatment is to restore the flow of arterial blood through the arteries and down to the level of the microcirculation. These treatments have been highly successful in reducing or eliminating symptoms and improving the quality of life for those suffering.

[0006] Best known of the current surgical techniques is CABG, wherein a thoracotomy is performed to expose the patient's heart, and one or more blocked coronary arteries are bypassed with saphenous veins. In preparation for the bypass grafting, the heart is arrested using a suitable cardioplegia solution, while the patient is placed on cardiopulmonary bypass (i.e., a heart-lung machine) to maintain circulation throughout the body during the operation. Typically, a state of hypothermia is induced in the heart muscle during the bypass operation to reduce oxygen utilization, thereby preserving the tissue from further necrosis. Alternatively, the heart may be perfused throughout the operation using either normal or retrograde flow through the coronary sinus, with or without hypothermia. Once the bypass grafts are implanted, the heart is resuscitated, and the patient is removed from cardiopulmonary bypass. Drawbacks of conventional open heart surgery are that such surgery is time-consuming and costly, involves a significant risk of mortality, requires a lengthy period of recuperation, and involves significant discomfort to the patient.

[0007] As a result of the foregoing drawbacks to the above surgical techniques, other less invasive surgical techniques have been developed that permit coronary bypass grafting to be performed endoscopically, i.e., using elongated instruments inserted through incisions located between the ribs. A drawback of these keyhole techniques, however, is that they can be used only for coronary arteries that are readily accessible, and not, for example, those located posteriorly.

[0008] Alternatively, techniques such as PTCA have been developed for reopening arteries, such as the coronary arteries, that have become constricted by plaque. In these techniques, a balloon catheter is typically inserted into the stenosis and then inflated to compress and crack the plaque lining the vessel, thereby restoring patency to the vessel. Additionally, a vascular prosthesis, commonly referred to as a "stent," may be inserted transvascularly and expanded within the vessel after the angioplasty procedure, to maintain the patency of the vessel.

[0009] A drawback of the foregoing transvascular approaches is that the treatment device, e.g., the balloon catheter or the stent delivery system must be inserted in the vessel before it can be expanded. Occasionally, a stenosis may occlude so much of a vessel that there is insufficient clearance to advance a guidewire and catheter within the stenosis to permit treatment. In addition, arterial blockages treatable using PTCA techniques are restricted to the portions of the anatomy where such techniques can be beneficially employed.

[0010] Moreover, the above-described technique-both open—surgery and transvascular—are useful only where the stenosis is localized, so that the bypass graft or PTCA procedure will restore near normal blood flow to the effected areas. Yet, current technology offers little relief or hope for a population of patients suffering from diffuse atherosclerosis where blockages exist throughout much of the coronary arterial system. Others in the population have, for example, extensive diffuse arterial disease with no good distal arterial target, persistent recurrent restenosis, or small vessels with no good target for arterial revascularization. Some of these patients may have already had one or more failed PTCA and CABG procedures. Some may be candidates for CABG but are excluded due to surgical risk and co-morbidity. For a large number of this patient population in the later phases of CAD, and particularly diffuse athero-

sclerotic disease, current technology offers little relief or hope. In such instances, humanely extending the patient's life for additional months may provide significant physical and emotional benefits for the patient.

[0011] Estimates of the size of this patient population vary, but several reports indicate it to be around 10% of those needing revascularization. Some of these patients may be considered for heart transplantation, though their numbers far exceed the supply of suitable hearts, and many patients could not tolerate such an invasive surgical procedure. Recently, some of these "no option" patients have been involved in a variety of new experimental therapies including trials of direct myocardial revascularization (DMR), percutaneous myocardial revascularization (PMR), gene or protein injections for angiogenesis, and coronary venous retroperfusion. Direct percutaneous myocardial revascularization and angiogenesis trials have met with mixed results. Some patients report feeling better, but the therapeutic benefits of these techniques have yet to be established. One criticism has been that the creation of new vasculature in the neighborhood of the microcirculation is ineffective because the problem lies upstream in the larger blocked arterial conduits. The arterial blood supply will still be limited by the stenosis or stenoses in the larger vessel or vessels.

[0012] The coronary veins are attractive as conduits to chronically deliver oxygenated blood to ischemic myocardium in patients with severe CAD. First, the atherosclerotic process that impairs the arteries virtually never affects the veins. Second, the coronary venous system is easily accessed via the coronary sinus, which is located in the right atrium. Third, a redundant drainage system (coronary sinus, Thebesian system, anterior cardiac veins) in the heart allows for retroperfusion and delivery of oxygen at the capillary level while still providing a means for draining blood. Lastly, ample experimental evidence and limited clinical evidence indicate that coronary venous retroperfusion can reduce or eliminate myocardial ischemia and angina due to impaired arterial inflow. It is also worthy to note that retroperfusion of the coronary sinus is considered a standard method to preserve myocardium during cardiopulmonary bypass. A procedure that could permanently bring arterial blood to the coronary venous system in a minimally invasive way has the potential to help improve the symptoms and quality of life of numerous CAD patients who currently have no proven alternatives.

[0013] Over the past several decades, surgeons have occasionally used a coronary vein as a means of oxygenating myocardium when a suitable arterial target could not be found. In many patients, the aorta-coronary vein bypass (CVBG) or internal mammary artery (IMA) to coronary vein bypass surgical procedures provides relief from angina. Follow up examination in some cases has shown open grafts several years after the surgery. Researchers working with surgical animal models have shown short-term and long-term benefit to coronary venous retroperfusion in the presence of arterial occlusion. Long-term graft patency and nutritive flow to the myocardium have been demonstrated. Recently, a percutaneous approach to retroperfusion has been successfully used in a small group of patients. In these people, a portion of a functioning coronary artery was connected to an adjacent coronary vein to provide blood flow for venous retroperfusion. Follow-up data indicate improvement in symptoms and persistent patency. With this documentation of safety and feasibility, there is now a foundation to explore additional endovascular approaches to cardiac venous retroperfusion.

[0014] Percutaneous approaches to coronary venous retroperfusion are being explored. An approach is to bring oxygenated blood from the left ventricle through the venous system to the ischemic myocardium. This approach requires creating holes or channels between coronary vessels and ventricular heart chambers. Other disadvantages of this approach are that the blood flowing from the left ventricle is out of phase with the normal cardiac arterial supply, the blood pressure is too high, and there is a tendency of the blood to flow back into the left ventricle during the relaxation phase. As a result, pressure limiting and back flow preventing valves must be implanted in an effort to approximate natural or normal blood flow. Another approach involves bringing oxygenated blood from a coronary artery that is adjacent or near the target vein. A significant disadvantages of this technique is encountered when a suitable vein does not lie in close proximity to the proximal end of the diseased segment of coronary artery.

[0015] In view of the foregoing, it would be desirable to provide methods and apparatus for endovascular implantation in a beating heart that provide arterial blood flow for venous retroperfusion to ischemic myocardium, particularly for the population of patients having few other options. It would further be desirable to provide methods and apparatus that enable patients suffering the later phases of diffuse ischemic heart disease to experience renewed vigor, reduced pain, and improved emotional well being during the remainder of their lives.

SUMMARY

[0016] An embodiment of the present invention includes a device that provides arterial blood flow from aorta to coronary venous system for venous retroperfusion of myocardium. The device includes an aorta-right atrium traversing connector arranged to receive arterial blood flow from the aorta, an arterial blood conduit in fluid communication with the traversing connector and a portion of the venous system, the conduit arranged for placement within the right atrium and the coronary sinus, and a venous connector arranged to couple the conduit with the coronary venous system. The aorta-right atrium traversing connector may include an inlet member arranged for receiving arterial blood flow from the aorta and for traversing a first aperture in an aortic wall and a second aperture in a right atrium wall, and having a channel providing fluid communication.

[0017] The arterial blood conduit may include a tubular member having a first end, a second end, and a lumen providing fluid communication between the ends, the tubular material comprising a flexible material. The arterial blood conduit may further include a member having a first end adapted to be coupled to the aorta-right atrium traversing connector, a second end adapted to be coupled to the venous connector, an intermediate portion located between the ends, a lumen providing fluid communication between the ends, a first region near the first end adapted to be placed in the right atrium and a second region near the second end adapted to be placed into a portion of the venous system, the member comprising a flexible material. The intermediate portion of conduit may include a self-sealing diaphragm.

The conduit may include a biocompatible material that comprises at least one from the group consisting of polyvinyl chloride, polyethylene, polytetrafluoroethylene (PTFE), and ePTFE.

[0018] The venous connector may include a radially expandable elongated structure that includes a portion arranged for annular enlargement and configured for disposition around the inside of a lumen of the coronary venous system, and which, when annularly enlarged within the lumen, engages the conduit with the vascular lumen. The device may include arrangement for endovascular implantation, which may further be in a beating heart.

[0019] The invention further provides an aorta-right atrium traversing connector. The connector includes an inlet member arranged for receiving arterial blood flow from the aorta and for traversing a first aperture in an aortic wall and a second aperture in a right atrium wall, and having a channel providing fluid communication. The first aperture may occur at a point proximate to a non-coronary aortic sinus. The inlet member may include arrangement for coupling with a conduit arranged to carry the arterial blood flow. The inlet member may further include an annularly enlargeable structure that, when annularly enlarged within a portion of a conduit arranged to carry the arterial blood flow, couples the inlet member to the conduit. The inlet member may include arrangement to move from a first configuration for endovascular placement in the first and second apertures to a second configuration of implantation in the first and second apertures. A portion of the inlet member may include arrangement for self-annular expansion after deployment from a sheath. A portion of the inlet member may further include arrangement for annular enlargement by expansion of an inflatable expandable structure positioned within the portion of the inlet member. The inlet member may include at least one element that extends radially outward and arranged to engage an interior portion of the aortic wall. The channel may include a portion of arterial blood conduit arranged around a portion of the inlet member. The connector may include arrangement for endovascular implantation, which may be in a beating heart.

[0020] The invention still further provides an aorta-right atrium traversing connector. The traversing connector includes an inlet member arranged for receiving arterial blood flow from the aorta and for traversing a first aperture in an aortic wall and a second aperture in a right atrium wall, and having a channel providing fluid communication, and a positioning member arranged to maintain the inlet member in a selected position. The inlet member may include arrangement for engaging the aorta. The positioning member may include an element for engaging an interior wall of the right atrium, and may include arrangement for engaging the right atrium and the inlet member. The positioning member may include at least one element extending radially outward, and arranged to engage an interior portion of the right-atrial wall and position the inlet member relative to the right-atrial wall. The radially extending element may include arrangement for moving from a first configuration for endovascular placement to a second configuration for engagement. A portion of the positioning member may include arrangement to resist annular enlargement.

[0021] The inlet member may include an element for engaging an aortic interior wall, and the positioning member may include an element for engaging a right-atrial interior wall, and when a portion of the positioning member engages a portion of the inlet member, the inlet member engaging element and the position member engaging element are arranged to cooperatively compress tissue radial of the apertures between them. The compression may limit blood leakage from at least one of the aorta and the right atrium.

[0022] The invention also provides an assembly for use in creating a guidewire pathway between two body structures each having a cavity. The assembly includes a first catheter having a distal tip arranged for placement into a cavity of a body structure and a lumen, a second catheter having a distal tip arranged for placement into a cavity of another body structure and a lumen, and a tissue penetrating element deployable from one lumen and arranged to create a guidewire pathway by penetrating tissue. The cavity of a body structure may include a lumen of a vascular structure, or may include a cardiac chamber. One catheter may include arrangement for transvascular placement in an arterial structure, or for transvascular placement in a venous structure. Alternatively, one catheter may include arrangement for transvascular placement in an arterial structure and another catheter may include arrangement for transvascular placement in a venous structure. One distal tip may carry a magnetic member arranged to attract and align with a magnetic member carried on another distal tip. One distal tip may carry an electrical signal source and another distal tip may carry an electrical signal sensor. One distal tip may carry an ultrasound source and another distal tip may carry an ultrasound sensor. One distal tip may carry a light source and another distal tip may carry a light sensor. One distal tip may include a substance viewable with an imaging device. Further, one catheter may be arranged to deploy the penetrating element, and another may be arranged to engage the penetrating element when the penetrating element is deployed from another catheter. One catheter may be arranged to deploy the penetrating element, and another catheter may further include member arranged to snare the penetrating element. One catheter may include an additional lumen arranged to eject a substance viewable with an imaging device.

[0023] The penetrating element may be carried on a guidewire. The penetrating element may include a penetration aid selected from a group consisting of a thermal heating element, a laser energy emitter, a RF cutting device, and a vibration device. The penetrating element may include a hollow needle and a guidewire arranged for advancement through tissue penetrated by the hollow needle. The penetrating element may include arrangement for penetrating between an aorta and a right-atrium.

[0024] The invention also provides an instrument for forming an aperture between cavities of two proximate body structures and deploying a connector in the aperture. The instrument includes a tubular structure arranged for placement in one of the cavities and having a sheath for deploying the connector, a tissue-cutting member arranged to form the aperture in tissue between the cavities, a guidewire following member, and a sheath arranged for deploying the connector in the aperture. The instrument may include a cut-tissue retention member. The instrument may further include a movement control member having an extracorporeal portion and arranged for moving the instrument along a guidewire, and the movement control member may include

a radially expandable structure. The connector may include arrangement for traversing between lumens of an aorta and a right atrium. The tissue-cutting member may include a cutting aid selected from a group consisting of a thermal heating element, a laser energy emitter, a RF cutting device, and a vibration device. The guidewire following member may include arrangement for engaging a guidewire moved in a direction relative to the instrument. The instrument may include arrangement for endovascular use, and may be used in a beating heart.

[0025] The invention yet further provides an intra-luminal venous connector for fluid coupling a conduit placed in a cardiac vascular lumen to the vascular lumen. The connector includes an annularly enlargeable structure that, when annularly enlarged within a portion of a conduit arranged to carry arterial blood flow, couples the conduit with the vascular lumen. The structure includes arrangement for annular enlargement by a radially expandable structure placed within a portion of the elongated structure. When the structure is annularly enlarged and coupling the conduit with the vascular lumen, blood flow from the conduit into a right atrium is limited. The connector may include arrangement for endovascular implantation, and may be implanted in a beating heart.

[0026] The invention further provides an assembly for use in implanting an aorta-right atrium traversing connector. The assembly includes a guidewire path creation subassembly arranged for creating a guidewire pathway between an aorta and a right atrium, the subassembly including a first catheter having a distal tip arranged for placement into a cavity of a body structure and a lumen, a second catheter having a distal tip arranged for placement into a cavity of a body structure and a lumen, and a guidewire deployable from one catheter lumen and receivable by another catheter lumen and having a tissue penetrating element arranged to create a guidewire pathway by penetrating tissue between the lumens. The assembly further includes a guidewire guided instrument arranged for creating an aperture in response to the guidewire pathway between the aorta and the right atrium, and deploying a connector in the aperture. The guidewire-guided instrument may include a tubular structure arranged for endovascular placement, a sheath arranged for carrying and deploying the traversing connector, a tissue-cutting element, and a guidewire following member. The guidewire-guided instrument may include a movement control member for moving the instrument along a guidewire and having an extracorporeal portion. The assembly may further include a device arranged to provide arterial blood flow from the aorta to coronary venous system for venous retroperfusion of myocardium. The device includes an aorta-right atrium traversing connector arranged to receive arterial blood flow from the aorta, an arterial blood conduit in fluid communication with the traversing connector and a portion of the venous system, the conduit arranged for placement within the right atrium and the coronary sinus, and a venous connector that couples the conduit to the coronary venous system. The assembly may include arrangement for endovascular implantation, and may be implanted in a beating heart.

[0027] The invention provides a method of providing venous retroperfusion of myocardium. The method includes steps of acquiring arterial blood flow from an aorta, conveying the arterial blood flow through a right atrium, through a coronary sinus, and into a portion of a coronary venous system, and discharging the arterial blood flow in a portion of the coronary venous system for venous retroperfusion of a myocardium. The arterial blood flow may be acquired from the non-coronary aortic sinus. The step of acquiring the arterial blood flow may include the further step of directing the blood flow into an arterial blood conduit. The step of conveying the arterial blood flow may include the further step of routing an arterial blood conduit from acquisition in the aorta to a point of discharge in the coronary venous system. The step of providing the arterial blood flow may include the further step of coupling an arterial blood conduit with a lumen of the coronary venous system. The discharged arterial blood flow may include normal cardiac arterial blood flow phasing, and may include normal cardiac arterial blood pressure. The steps may be performed endovascularly, and may be performed in a beating heart.

[0028] The invention further provides a method of implanting a device that provides arterial blood flow from an aorta to a portion of a coronary venous system for venous retroperfusion of myocardium. The method includes the steps of placing an arterial catheter in the non-coronary aortic sinus at a position proximate to an aortic wall, placing a venous catheter in the right atrium at a position proximate to an atrium wall, and in approximate opposition to the arterial catheter, passing an arterial guidewire between the venous catheter and the arterial catheter, the guidewire passing through both the aortic wall and the atrium wall and having a proximal end, and placing a distal end of a venous guidewire into a lumen of the coronary venous system, the venous guidewire having a proximal end located adjacent to the proximal end of the arterial guidewire. The method also includes the steps of mounting portions of a lumen of the device moveably over the adjacent proximal ends of the venous guidewire and the arterial guidewire, a first portion being mounted on the arterial guidewire and the second portion being mounted on the venous guidewire, moving the mounted device along the guidewires into the right atrium, deploying the aorta-right atrium connector in the pathway and in fluid communication with the aorta, and deploying the venous connector in the selected portion of the venous system. The device may include an arterial blood flow conduit having a first portion with an aorta-right atrium traversing connector arranged to receive arterial blood from the aorta mounted on one end and second portion with a venous connector arranged to couple the conduit into a lumen of the coronary venous system mounted on a second end.

[0029] The invention additionally provides a device that provides venous retroperfusion of myocardium. The device includes means for acquiring an arterial blood flow from an aorta, means for conveying the acquired arterial blood flow through a right atrium and into a coronary sinus, and means for discharging the arterial blood flow into a portion of a coronary venous system.

[0030] The invention proves still another device that provides arterial blood flow from the aorta to a vascular structure for perfusion of cardiac tissue. The device includes a connector arranged to receive arterial blood flow from the aorta, an arterial blood conduit in fluid communication with the connector and the vascular structure, the conduit arranged for placement within a heart chamber and the

vascular structure, and a connector arranged to couple the conduit with the vascular structure. The vascular structure may be a vein or an artery. The device may be arranged for endovascular implantation in a beating heart.

[0031] These and various other features as well as advantages that characterize the present invention will be apparent from a reading of the following detailed description and a review of the associated drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0032] The features of the present invention which are believed to be novel are set forth with particularity in the appended claims. The invention, together with further objects and advantages thereof, may best be understood by making reference to the following description taken in conjunction with the accompanying drawings, in the several figures of which like referenced numerals identify like elements, and wherein:

[0033] **FIG. 1** depicts a human heart from above without the non-coronary vascular structures;

[0034] **FIG. 2** depicts a myocardium of a human heart including a lattice of capillaries that drain deoxygenated blood into intramyocardial veins and the Thebesian system;

[0035] **FIG. 3** illustrates the heart of **FIG. 1** after implantation of a device providing arterial blood flow for venous retroperfusion of ischemic myocardium, in accordance with the invention;

[0036] **FIG. 4** is a front view of a patient illustrating a guidewire pathway created between the aorta and the right atrium, the guidewires are in a position for implantation of the device providing arterial blood flow, and percutaneous endovascular introduction sites, in accordance with the invention;

[0037] **FIG. 5** is a view similar to **FIG. 1** and illustrates distal tips of a venous side catheter and an arterial side catheter in position for a guidewire to create a guidewire pathway between the right atrium and the non-coronary aortic sinus portion of the aorta, in accordance with the invention

[0038] **FIG. 6** is a view similar to **FIG. 1** and illustrates final steps of creating the guidewire pathway using a guidewire, in accordance with the invention;

[0039] **FIG. 7** is a view similar to **FIG. 1** and illustrates placement of the guidewires in preparation for placing the device providing arterial blood flow in the heart, in accordance with the invention;

[0040] **FIG. 8** is a view similar to **FIG. 1** and illustrates the arterial blood flow conduit slideably carried on the guidewires and placed in the heart in preparation for implantation, in accordance with the invention;

[0041] **FIG. 9** is a cross-sectional perspective view illustrating a venous connector in an initial configuration partially mounted on the distal end of an arterial blood flow conduit and carried on a partially expanded balloon catheter, in accordance with the invention;

[0042] **FIG. 10** is similar to **FIG. 9**, and illustrates a venous connector in a fully expanded configuration engaging the distal end of the arterial blood flow conduit with the vascular lumen of the great cardiac vein, in accordance with the invention;

[0043] **FIG. 11** is similar to **FIG. 9**, and illustrates a configuration where the balloon catheter has been deflated to an unexpanded configuration for removal from the patient, in accordance with the invention;

[0044] **FIG. 12** is a cross-sectional perspective view illustrating an initial step for cutting an aperture through tissue between cavities of two body structures employing an assembly moveably carried on a guidewire, in accordance with the invention;

[0045] **FIG. 13** is similar to **FIG. 12**, and illustrates intermediate steps in cutting an aperture through tissue between cavities of the right atrium and the aorta, and an initial step in deploying the traversing connector, in accordance with the invention;

[0046] **FIG. 14** is similar to **FIG. 12**, and illustrates another intermediate step in cutting an aperture through tissue between the right atrium and the aorta, and another step in deploying the traversing connector, in accordance with the invention;

[0047] **FIG. 15** is similar to **FIG. 12**, and illustrates a final configuration of the traversing connector implanted in apertures created between the right atrium and the non-coronary aortic sinus, in accordance with the invention;

[0048] **FIG. 16** illustrates an assembly employing a knot pusher for sealing a sealable exit opening of an arterial blood flow conduit, in accordance with the invention;

[0049] **FIG. 17** is a perspective view illustrating the inlet member in a compressed and pre-deployment configuration, in accordance with the invention;

[0050] **FIG. 18** is similar to **FIG. 17**, and illustrates the inlet member in an expanded and deployed configuration, with engaging elements radially extended, in accordance with the invention;

[0051] **FIG. 19** is a perspective view illustrating the positioning member in a compressed and pre-deployment configuration, in accordance with the invention; and

[0052] **FIG. 20** is similar to **FIG. 19**, and illustrates the positioning member in an expanded and deployed configuration with engaging elements and braces radially extended, in accordance with the invention.

DETAILED DESCRIPTION

[0053] In the following detailed description of exemplary embodiments of the invention, reference is made to the accompanying drawings, which form a part hereof. The detailed description and the drawings illustrate specific exemplary embodiments by which the invention may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention. It is understood that other embodiments may be utilized, and other changes may be made, without departing from the spirit or scope of the present invention. The following detailed description is therefore not to be taken in a limiting sense, and the scope of the present invention is defined only by the appended claims.

[0054] Throughout the specification and claims, the following terms take the meanings explicitly associated herein unless the context dictates otherwise. The meaning of "a", "an", and "the" include plural references. The meaning of "in" includes "in" and "on." Referring to the drawings, like numbers indicate like parts throughout the views. Additionally, a reference to the singular includes a reference to the plural unless otherwise stated or inconsistent with the disclosure herein.

[0055] Briefly stated, aspects of the present invention generally relate to methods and apparatus for use in endovascular and intraoperative procedures providing arterial blood flow for perfusion of ischemic myocardium. Aspects of the present invention provide a conduit between a non-coronary sinus of the aorta and a coronary vein, the conduit traversing a portion of the right atrium. The conduit is located entirely within the heart and aorta. Arterial blood flows from the aorta through the conduit and into the coronary venous circulation towards the ischemic region of the heart. All procedures described herein may be performed endovascularly, and further may be performed while the patient's heart is beating.

[0056] The description of the present invention is organized as follows: First, the anatomy of a heart, and its arterial and coronary vascular systems relevant to the present invention are described. Next, a heart illustratively treated with methods of and apparatus in accordance with the present invention is described. This is followed by a description of a method for placing an apparatus of the present invention within the heart, including several components of various embodiments of the apparatus of the present invention. Finally, additional details are illustrated of several components of various embodiments of the invention.

[0057] **FIGS. 1 and 2** describe various features of the human heart relevant to the present invention. **FIG. 1** depicts a human heart H from above without the non-coronary vascular structures. The illustration includes the aortic valve AV, the pulmonary valve PV, the right atrium RA, and the left atrium LA. The coronary arterial system comprises a left coronary artery **20** and a right coronary artery **23**, which branch into sub-branches supplying the heart with oxygenated blood. Both coronary arteries receive blood flow from openings in the coronary sinuses, the right coronary artery **23** being supplied by opening **25** in the coronary sinus formed with the right semilunar cusp **27** of the aortic valve AV. The left coronary artery **20** is supplied by an opening (not shown) in the coronary sinus formed with the left semilunar cusp **28** of the aortic valve AV. The non-coronary sinus is formed with the posterior semilunar cusp **29** (hereafter called the non-coronary aortic sinus **29**), and does not have an arterial opening. The non-coronary aortic sinus **29** is located relatively close to the right atrium RA, the walls of both structures being nearly in contact. The blood flow to the coronary arteries **20** and **23** at the level of the coronary aortic sinuses **27** and **28** occurs during diastole.

[0058] The heart H receives deoxygenated blood from the venous system into right atrium RA. The coronary sinus CS discharges deoxygenated blood flowing in the coronary venous system through the coronary ostium **36** and into the right atrium RA. The coronary sinus CS provides drainage for great cardiac vein **32**, middle cardiac vein **34**, and other veins that are not shown. The cardiac venous system further includes cardiac veins that drain directly into the right atrium RA as described in **FIG. 2**.

[0059] With respect to **FIG. 2**, myocardium **40** includes a lattice of capillaries **41** that drain deoxygenated blood into intramyocardial veins **42**. From intramyocardial veins **42**, a fraction of the blood drains into the cardiac veins via subepicardial veins **43**, while the remainder drains through the Thebesian veins **44** directly into the atrial and ventricular cavities It has been reported in healthy human hearts that approximately 70% of the deoxygenated blood is drained through the coronary sinus CS, while the remaining 30% is drained into the heart via the lymphatic system and the Thebesian veins **44**. It has likewise been reported that when individual components of the venous system (i.e., the coronary sinus, lymphatic system and Thebesian veins) are occluded, the flow redistributes itself through the remaining unoccluded channels.

[0060] In **FIG. 3**, the heart H of **FIG. 1** is shown after implantation of a device providing arterial blood flow **100** for venous retroperfusion of ischemic myocardium, in accordance with the invention. The device **100** includes an arterial blood flow conduit **102**, a venous connector **200**, and a traversing connector **300**. The conduit **102** has been routed through the right atrium RA and the coronary sinus CS, terminating in the great cardiac vein **32**. The traversing connector **300** acquires arterial blood flow **46** from the non-coronary aortic sinus **29** of the aorta A and provides it to the conduit **100**. Venous connector **200** couples the blood flow **46** of conduit **102** into the lumen of great cardiac vein **32** for venous retroperfusion of myocardium, and limits the blood flow from flowing toward the right atrium RA.

[0061] FIGS. **4-7** illustrate steps employing endovascular methods for placing a guidewire **410** between aorta A and right atrium RA, and a guidewire **420** into the coronary sinus CS and the great cardiac vein **32** of the coronary vascular system, in accordance with the invention. FIGS. **5-7** are views similar to **FIG. 1**.

[0062] Various imaging modalities may be used to aid in accomplishing the positioning of the various apparatus and devices described herein, such as fluoroscopy with angiography or ultrasound (intravascular or intracardiac) or a combination of the two. Alternatively, other imaging technologies may be used. The devices and apparatus may include substances that enhance imaging. While preparation for and implantation of the device **100** is described herein by endovascular methods, device **100** may be implanted by another method or procedure, including an open surgical setting or other interventional cardiology setting.

[0063] **FIG. 4** is a front view of a patient illustrating the heart H and vascular system after creation of a guidewire pathway between the aorta A and the right atrium RA, and placing the guidewires **410** and **420** in a position for implantation of device **100**. **FIG. 4** also illustrates using femoral artery FA for an arterial percutaneous endovascular introduction site **402** and a jugular vein JV for a venous endovascular introduction site **404**. Possible other arterial introduction sites include the radial artery or aorta. Possible other venous introduction sites include subclavian vein, femoral vein, or superior vena cava SVC.

[0064] **FIG. 5** is a view similar to **FIG. 1** illustrating distal tips of a venous side catheter **430** and an arterial side

catheter **440** in position for a guidewire **410** to create a guidewire pathway between the right atrium RA and the non-coronary aortic sinus **29** portion of aorta A, in accordance with the invention. The catheters **430** and **440** are arranged for endovascular use and are preferably steerable. Each catheter has a lumen, **432** and **442**, respectively, for passage of guidewires, and a distal tip, **434** and **444**, respectively. The catheters may be made of any material suitable for endovascular cardiac procedures. The distal tips **434** and **444** are arranged for alignment of the distal portions of lumens **432** and **434** in vivo, such that a guidewire deployed from one lumen can be received in the other lumen. In an embodiment illustrated in **FIG. 5**, catheter **430** is arranged to deploy the guidewire **410**, and catheter **440** is arranged to receive it. Catheter **440** includes a catching member **446** arranged to engage guidewire **410** when it enters lumen **442**. Catching member **446** may be any mechanism or device arranged to engage either the guidewire **410** or the penetrating element **412** and preclude movement of the guidewire **410** other than in the direction of advancement **414**. In an alternative embodiment, the catching member **446** may be a lasso mechanism arranged to snare the guidewire **410** after it passes through the aortic and atrial tissue layers. Catheters **430** and **440** may each be arranged for the specific vascular or cardiac structures into which they are intended for placement. For example, the distal tip **434** of catheter **430** may be formed to aid in placing it proximate to a preselected portion of the right atrium wall. Likewise, the distal tip **444** of arterial catheter **440** may be formed to aid in placing it in the non-coronary aortic sinus **29** and against the aortic wall.

[**0065**] The distal tips **434** and **444** may carry alignment devices **438** and **448**, respectively. Alignment devices **438** and **448** may be any device or combination of devices suitable for in vivo alignment of the distal portions of the lumens **432** and **434**, such that a guidewire deployed from one lumen can be received in the other lumen. Alignment devices **438** and **448** are illustrated in **FIG. 5** as magnets **438** and **448** carried on distal tips **434** and **444**. The polarization of magnets **438** and **448** is arranged for self-alignment of the distal portions of the lumens **432** and **434**. The magnets **438** and **448** can have any shape suitable for the intended use, such as a donut shape. The magnets are arranged to attract and align with each other in only one configuration, such that when the guidewire **410** with its penetrating element **412** is deployed from the lumen **432** of catheter **430** it is receivable by the lumen **442** of catheter **440**. In alternative embodiments, one alignment device may be an electrical signal source and the other an electrical signal sensor; one alignment device may be an ultrasound source and the other an ultrasound sensor; or one alignment device may be a light source and the other a light sensor. In these alternative embodiments, the source and the sensor are used to guide the distal tips **434** and **444** into proximity. The distal tips **434** and **444** may include a substance viewable with an imaging device. In a further alternative embodiment, one or both lumens **432** and **442** may be usable for ejecting a substance viewable with an imaging device, or an additional lumen may be provided in one or both catheters for ejecting a viewable substance. The ejected viewable substance may be used to guide the distal tips **434** and **444**.

[**0066**] Guidewire **410** includes a penetrating element **412** arranged to penetrate tissue between distal tips **434** and **444**, and which may be further arranged to engage catching member **446**. Guidewire **410** may be any size, shape, and configuration suitable for use in vascular procedures. In an embodiment, guidewire **410** is approximately 0.014 inches in diameter. The penetrating element **412** may be a sharpened distal end of guidewire **410**, or may be an element carried preferably on the distal end of guidewire **410**. Penetrating element **412** may include a device to aid penetration, such as a thermal heating element, a laser energy emitter, a RF cutting device, or a vibration device. In an alternative embodiment, the penetrating element **412** may include a hollow needle deployed from a distal tip and a guidewire arranged for advancement through tissue penetrated by the hollow needle.

[**0067**] **FIG. 5** also illustrates initial steps in percutaneous endovascular implantation of device **100**. A step includes introducing the distal tip **444** of arterial catheter **440** at site **404**, and the distal tip **434** of the venous catheter **430** at site **404**. These sites are illustrated in **FIG. 3**. The distal tip **444** is steered into the aorta A to a position at a level of the non-coronary sinus **29** and proximate to an aortic wall. The distal tip **434** is steered into the right atrium RA to a position adjacent to the non-coronary sinus **29**. Steering may be by any method, including visualization methods. After the above step, the distal tips **434** and **444** are in proximity to each other, separated by the tissues of the aortic wall and the right atrium wall.

[**0068**] Another initial step includes aligning the distal portions of the lumens **432** and **442**. Once in proximity to each other, the magnets **438** and **448** carried on the distal tips will attract and align with each other, cause the distal tips **434** and **444** to contact the walls, and align the distal portions of lumens **432** and **442**, such that a guidewire deployed from one lumen can be received in the other lumen. If an alternative embodiment is used where the alignment is aided by a signal source, the source, preferably carried in the distal tip **444** of arterial catheter **440**, is activated and the distal tip of the other catheter, is maneuvered until a maximum signal is sensed by the sensor, indicating alignment. If a light source is used, the source is also preferably carried in the distal tip **444** of arterial catheter **440**. The sensor may be an optical lens or photo sensor carried on the other distal tip, which is maneuvered until a maximum light is received, indicating alignment.

[**0069**] **FIG. 6** illustrates final steps of creating the guidewire pathway **460** using guidewire **410**. The guidewire **410** can be introduced into the heart H using either the venous catheter **430** at site **404** or the arterial catheter **440** at site **402**. **FIG. 6** illustrates introducing the guidewire **410** using the venous catheter **430**. A step includes advancing the guidewire **410** and its penetrating element **412** through the lumen **432** and into proximity with a tissue wall of the right atrium RA. Another step includes further advancing the guidewire **410** to deploy the penetrating element **412** from a lumen **432** and to penetrate through the right atrial wall and the aortic wall tissue between the deploying lumen **432** and the receiving lumen **442**. If the penetrating element **412** includes a device to aid penetration, the device is activated. If the penetrating element **412** includes a hollow needle, the guidewire **410** may be advanced after penetration by the hollow needle. The needle can be retracted after the guidewire **410** is advanced into the receiving catheter. The guidewire **410** and its penetrating elements **412** are small enough to minimize bleeding when penetrating tissue, and the penetration is anticipated to be self-healing.

[0070] As used in these specifications, "guidewire pathway" means any guiding path or pathway between the right atrium RA and the non-coronary aortic sinus **29**, and typically will have sufficient diameter for passage of a guiding device, such as a guidewire. A "guidewire pathway" may include any kind of guiding path arranged to guide movement of any device between the right atrium RA and the non-coronary aortic sinus **29**.

[0071] In a further step, the guidewire **410** is advanced into the lumen **442** of the arterial catheter **440**. If the receiving catheter **440** includes a catching member **446**, the guidewire **410** is advanced until the catching member **446** or the penetrating element **412** engages it. Guidewire **410** is further advanced until a portion of the guidewire **410** and the penetrating element **412** is exteriorized as illustrated in **FIG. 4**. At this point, the guidewire **410** extends from outside the body at site **402** into the arterial catheter **430**, through the aortic wall and the right atrial wall, into the venous catheter **440**, and outside the body again at site **404**. Alternatively, instead of advancing the guidewire **410** to exteriorize it, after the guidewire **410** engages the catching member **446**, the receiving catheter **440** may then be withdrawn from the patient. This will exteriorize the guidewire **410**.

[0072] **FIG. 7** is a view similar to **FIG. 1**, and illustrates placement of the guidewires **410** and **420** in preparation for placing the device **100** in the heart H. **FIG. 7** illustrates guidewire **410** placed in guidewire pathway **460** as described above. A step includes withdrawing both catheters **430** and **440** from the patient.

[0073] Guidewire **420** may be any size, shape, and configuration suitable for use in vascular procedures. In an embodiment, guidewire **420** is approximately 0.035 inches in diameter.

[0074] A step in placing the guidewire **420** includes introducing a coronary venous guiding catheter (not shown) at site **404** of **FIG. 4**, and advancing the catheter to the coronary sinus ostium **36** in the right atrium RA. The coronary venous guiding catheter is further advanced into the coronary sinus CS, and to a position that is proximate to a selected location in the coronary venous system for discharging the arterial blood flow **46**. Once the coronary venous catheter is in position, the guidewire **420** is advanced in a lumen of the coronary venous catheter until its distal end (not shown) is placed in the selected location, or preferably slightly distal thereof. As another step, the coronary venous catheter is then removed from the patient leaving the guidewire **420**.

[0075] **FIG. 8** is a view similar to **FIG. 1** and illustrates a step where the arterial blood flow conduit **102** of device **100** is slideably carried on the guidewires **410** and **420** and placed in the heart H in preparation for implantation, in accordance with the invention. The venous connector **200** and the traversing connector **300** are omitted from **FIG. 8** for clarity. The arterial blood flow conduit **102** of device **100** comprises a tubular member having a first end **104** adapted to be coupled to the aorta-right atrium traversing connector **300** (not shown), a second end **108** adapted to be coupled to the venous connector **200** (not shown), an intermediate portion located between the ends **104** and **108** and including a first region **106** near the first end **104** adapted to be placed in the right atrium RA and a second region **107** near the second end **108** adapted to be placed into the coronary ostium **36**, through the coronary sinus CS and into a portion of the venous system. The arterial blood flow conduit **102** also comprises a lumen **110** arranged to provide fluid communication between the ends **104** and **108**, and comprising a flexible material. The intermediate portion of conduit **102** includes a sealable exit opening **120** allowing passage over guidewires **410** and **420**. The sealable exit opening **120** may be arranged for sealing against blood leakage by any method known to those in the art, including a purse string suture as illustrated in **FIG. 16**, or a self-sealing diaphragm, such as used for introducer sheets in interventional procedures. The arterial blood conduit **102** may be formed from an autologous vein or artery, or a non-autologous or a synthetic material. Possible autologous veins include a saphenous vein. Possible synthetic materials include any biocompatible material known to those in the art, including polyvinyl chloride, polyethylene, polytetrafluoroethylene (PTFE), and ePTFE. The conduit **102** will be approximately 8 cm long, depending on the selected location for placement of the venous connector **200**, and will have an inside diameter of approximately 3 mm.

[0076] The device **100** is placed within the right atrium RA in preparation for implantation. An initial step includes placing portions of the lumen **110** of the device **100** slideably over adjacent extracorporeal portions of the guidewires **410** and **420** at site **404**. The extracorporeal portion of the guidewire **410** is placed in the lumen **110** of the first end **104** with the aorta-right atrium traversing connector **300** (not shown) mounted, and the extracorporeal portion of the guidewire **420** is placed in the lumen **110** of the second end **108** with the venous connector **200** (not shown) mounted. As the device **100** and the ends **104** and **108** are initially advanced, the extracorporeal portions of the guidewires **410** and **420** both pass out of the lumen **110** at a sealable exit opening **120** and remain extracorporeal. The ends **104** and **108** of the device **100** are advanced over the guidewires **410** and **420** into the jugular vein at site **404**, into the superior vena cava SVC, and toward the right atrium RA of the heart H. The ends **104** and **108** are advanced using any pushing apparatus known to those in the art, such as two balloon catheters with the expandable portions partially inflated near the distal ends (**104**, **108**) of the conduit **102** to engage it. Alternatively, the pushing apparatus may be a small caliber tubular structure of a given stiffness or with a hollow center that allows stylets of different stiffness to be introduced. The device **100** is advanced into the right atrium RA and the coronary sinus CS until it is placed approximately as illustrated in **FIG. 8**.

[0077] FIGS. **9-11** are cross-sectional perspective views illustrating the connector **200** and the second distal end **108** of conduit **102** carried on a balloon catheter **250** and moveable along the guidewire **420** for placement in the great cardiac vein **32**, in accordance with the invention. **FIG. 9** is a cross-sectional perspective view illustrating the connector **200** in an initial configuration, partially mounted on the distal end **108** of conduit **102** and carried on the balloon catheter **250**, which is in a partially expanded configuration.

[0078] Venous connector **200** is a balloon expandable structure, such as a stent, and its distal end may include a tapered tip portion **202** arranged to facilitate advancement into the venous system. The venous connector **200** may have the configuration of a conventional vascular stent with added features to ensure the connector is partially in contact with

the inside of the vein and creates a partial or complete seal with the vein. The connector **200** may be laser cut Nitinol or stainless steel tube expanded into a mesh-like structure. The connector **200** may include members to facilitate engagement between the connector, the conduit **102**, and the venous system, such as barbs.

[**0079**] The balloon catheter **250** includes a lumen **254** arranged for following a guidewire, an expansion member **252**, and an elongated shaft **256** having an extracorporeal portion arranged for advancing and retracting the balloon catheter **250**. The balloon catheter **250** may be any type of expandable catheter suitable for endovascular use, and those having a relatively short length and larger diameter may be particularly suited for use in accordance with the invention. The catheter **250** and the connector both may have tapered distal ends (**202**, **258**), which may facilitate advancement through the venous structures and the heart H.

[**0080**] Prior to insertion into the venous structure used to access the right atrium RA, the distal end **108** of the conduit **102** is placed over an outside periphery of the unexpanded connector **200** covering approximately one-half of its length as generally illustrated in **FIG. 9**. Another step prior to insertion includes placing the expansion member **252** of the balloon catheter **250** into the sealable exit opening **120** and advancing it toward the distal end **108** until positioned within unexpanded connector **200**, such that expanding the expansion member **252** will expand the connector **200**. The expansion member **252** is then partially expanded to engage connector **200** and to annularly enlarge connector **200** sufficient to engage a portion of the conduit **102** proximate to the distal end **108**, and forming a connector assembly **260**.

[**0081**] Another step includes placing the extracorporeal end of guidewire **420** inside the lumen **254** of the balloon catheter **250** at its tapered distal end **258**, thus slideably engaging the guidewire **420**. The connector assembly **260** is advanced along guidewire **420** into the coronary sinus CS and the great cardiac vein **32** as described in conjunction with **FIG. 8**. The tapered end **258** of the balloon catheter **250** is advanced along guidewire **420** to a preselected location in the great cardiac vein **32** for discharge of arterial blood flow from the device **100** for venous retroperfusion of ischemic myocardium of the heart H. The progress and position of the tapered end **258** of the balloon catheter **250** may be monitored by X-ray fluoroscopy.

[**0082**] Once the distal end **108** is at the preselected location in the great cardiac vein **32**, another step involves fully expanding the balloon catheter **250**. When the balloon catheter **250** is in a fully expanded configuration, the connector **200** is annularly enlarged within the conduit **102** and engages the distal end **108** of the conduit **102** with the vascular lumen of the great cardiac vein **32**. The annularly expanded connector **200** also directly engages the vascular lumen of the great cardiac vein **32**. **FIG. 10** is a cross-sectional perspective view illustrating this intermediate step. The vascular lumen of a cardiac vein has a normal diameter of about 4 to 4.5 mm when under typical venous pressure, and might expand further in response to expansion of the connector **200**. The connector **200** may be annularly enlarged to a diameter greater than the normal vascular lumen diameter to aid engagement between the conduit **102**, the connector **200**, and the vascular lumen of the great cardiac vein **32**.

[**0083**] **FIG. 11** is similar to **FIG. 9**, and illustrates a configuration where the balloon catheter **250** has been deflated to an unexpanded configuration. Once the connector **200** has been annularly enlarged and is directly engaging the vascular lumen, and is further engaging the conduit **102** with the vascular lumen, a final step includes deflating the balloon catheter **250** to an unexpanded configuration for removal. This unexpanded configuration leaves the connector **200** in place and engaging the conduit **102** with the vascular lumen, thus fluid coupling the conduit **102** to the vascular lumen. The engagement may be confirmed by visualization methods. Another final step includes withdrawal of the balloon catheter **250** and the guidewire **420** out of the conduit **102** at sealable exit opening **120** and from the patient. The fluid coupling of conduit **102** to the wall of the vein **32** forms a fluid tight seal directing aortic blood flow from conduit **102** into the vein **32**. Retrograde flow through the conduit **102** will be largely or completely directed toward the venous microcirculation instead of the right atrium RA.

[**0084**] FIGS. **12-15** are cross-sectional perspective views illustrating employing an assembly **360** for cutting an aperture through tissue between cavities of two body structures and deploying a traversing connector **300** in the aperture, in accordance with the invention. In FIGS. **12-15**, aspects of the invention are illustrated cutting an aperture between a right atrium and an aorta, and deploying the traversing connector **300** using endovascular methods.

[**0085**] **FIG. 12** is a cross-sectional perspective view illustrating the assembly **360** moveably carried on a guidewire **410** and located proximate to a portion of the right atrium interior wall. The guidewire **410** passes through the guidewire pathway **460** that is proximate to the non-coronary aortic sinus **29**, and both ends of which are outside of the patient's body in an arrangement similar to FIGS. **4**, and **9-11**. Assembly **360** includes a tissue cutter and deployment instrument illustrated as a cutter/deployer **370**, a traversing connector **300** in a collapsed configuration, and a balloon catheter **350**, all arranged for endovascular procedures in a beating heart.

[**0086**] The tissue cutter/deployer **370** includes a tubular structure **372**, a sheath **374**, a tissue-cutting member **376**, a cut-tissue retention member **378**, a guidewire following member **380**, and a guidewire engaging member **382**. While illustrated as a round elongated structure, the tubular structure **372** may have any shape suitable for its intended use, and typically may be round with an outside diameter of between approximately 4 to 4.5 mm, and may be made from any suitable material, such as stainless steel. The tissue-cutting member **376** has a sharpened circumferential edge arranged to cut an aperture when advanced through tissue, and typically will be formed on the tubular structure **372**. While illustrated as formed on a perpendicular cross-sectional plane, the cutting member **376** may be formed on any plane, may have a pointed portion to make initial contact with a small portion of tissue, and may have an irregular edge. Further, the cutting member **376** may be a separate apparatus carried on the tubular structure **372**. The cutting member **376** may include a device to aid cutting, such as a thermal heating element, a laser energy emitter, a RF cutting device, or a vibration device. The cut-tissue retention member **378** retains for removal the cut tissue **390**, and prevents the cut tissue **390** from being released into the patient. The tissue retention member **378** may be a chamber in the tubular

structure **372** proximate to the cutting member **376**, and retention of the cut tissue **390** may be assisted by one or more other members, such as barbs **379**.

[**0087**] The guidewire following member **380** may be any structure allowing the cutter/deployer **370** to follow a guidewire, and is illustrated as a portion of the tubular structure **372** having an opening dimensioned for following a guidewire. The guidewire engaging member **382** is arranged for engaging a guidewire moved in a direction relative to the cutter/deployer **370**. The engaging member **382** may be a pawl that frictionally engages the guidewire. The guidewire engaging member **382** is illustrated in FIGS. **12-14** incorporated into the balloon catheter **350**. The sheath **374** is arranged to carry the traversing connector **300** in a collapsed configuration for endovascular delivery into an aperture cut by the cutting member **376**, and for deployment therein. The sheath **374** may be an interior cavity of cutter/deployer **370** having a periphery arranged to carry the traversing connector **300**, and further arranged to allow deployment by a method compatible with the configuration of the traversing connector **300**.

[**0088**] Traversing connector **300** is illustrated in **FIG. 12** in a collapsed configuration for endovascular placement and in **FIG. 15** in a deployed and implanted configuration in the apertures cut by the cutting member **376**. Traversing connector **300** includes an inlet member **310**, and a positioning member **330**.

[**0089**] The inlet member **310** is arranged for receiving arterial blood flow from the aorta A, traversing the apertures cut by the cutting member **376**, engaging an interior portion of the aorta wall, and providing the arterial blood flow to the conduit **102**. Inlet member **310** includes a channel **312** for providing the arterial blood flow, and an element **316** extending radially and arranged to engage a portion of the aorta interior wall. The channel **312** may be formed by placing a portion of conduit **102** proximate to the first end **104** about an outer periphery of a portion of the inlet member **310**. Additional description of the inlet member **310** is provided in conjunction with **FIGS. 17 and 18**.

[**0090**] The positioning member **330** includes an interior periphery **336** arranged to engage a portion of the inlet member **310** and a portion of conduit **102** proximate to the first end **104** by resisting annular expansion of the inlet member **310**. Additional description of the positioning member **330** is provided in conjunction with **FIGS. 19 and 20**.

[**0091**] The balloon catheter **350** may be similar to the balloon catheter **250**, and includes a lumen **354** arranged for following a guidewire, an expansion member **352**, a cutter/deployer engaging member **359**, and an elongated shaft **356** having an extracorporeal portion arranged for advancing **414** and retracting the balloon catheter **350**. **FIG. 12** illustrated an embodiment where the guidewire engaging member **382** is carried by the balloon catheter **250** instead of the tubular structure **372**. The balloon catheter **350** may be any type of expandable catheter suitable for endovascular use, and those having a relatively short length and larger diameter may be particularly suited for use in accordance with the invention. The cutter/deployer engaging member **359** includes arrangement for transmitting advancement **414** and retraction movements of the elongated shaft **356** to the cutter/deployer **370**.

[**0092**] Assembly **360** comprises the balloon catheter **350** coupled to the cutter deployer **370** by engaging member **359**. The assembly **360** further comprises the inlet member **310** sheathed within a portion of the conduit **102** proximate to the first end **104**, which is further sheathed within positioning member **330**, which is further sheathed within the sheath **374** of the cutter deployer **370**. When so sheathed, the inlet member **310** is arranged to exert an radially expansive force that compresses and engages the portion of conduit **102**, the positioning member **330**, and the sheath **374**. The balloon catheter **350** may be partially expanded against the channel **312** of the inlet member **310** to provide additional radial expansive force and keep the assembly **360** together while it is advanced into the right atrium RA.

[**0093**] An initial step in placing the assembly **360** within the right atrium RA includes placing the extracorporeal venous end of the guidewire **410** inside the opening in guidewire following member **380**, and advancing the venous end into to the lumen **354** of balloon catheter **350**, thus slideably engaging the guidewire **410** in the manner described in conjunction with **FIG. 8**. The assembly **360** is advanced into the right atrium RA also in the manner described in conjunction with **FIG. 8**. The tissue-cutting member **376** may be rendered inoperative during placement of the assembly **360** in the right atrium to limit damage to vascular structures. **FIG. 12** illustrates the assembly **360** advanced along guidewire **410** and adjacent to the wall of a right atrium RA at guidewire pathway **460**. This position is an initial step in cutting an aperture through tissue between the right atrium RA and the aorta, and deploying the traversing connector **300**.

[**0094**] **FIG. 13** illustrates intermediate steps in cutting an aperture through tissue between cavities of the right atrium RA and the aorta, and an initial step in deploying the traversing connector **300**. The expansion member **352** is shown retracted for clarity in **FIG. 13**, but retraction at this step may not be required. An intermediate step includes partially withdrawing assembly **360** from the sheath **374** sufficient for a right atrium wall engaging element **334** to deploy in a configuration for engaging the wall of the right atrium RA and limiting advancement **414** of the inlet member **310**. The engaging member **316** of inlet member **310** is prevented from expanding by its continued presence in the sheath **374**.

[**0095**] The guidewire engaging member **382**, illustrated as a pawl, is arranged to engage guidewire **410** when the extracorporeal arterial end is withdrawn a distance from the patient. Another intermediate step includes advancing the cutter/deployer **370** by moving the extracorporeal arterial end of the guidewire **410** a short distance in the advancement direction **414**. This causes the engaging member **382** to engage the guidewire **410**, and advance the tissue-cutting member **376** through the right atrial wall and the aortic wall. This forms apertures in the walls of the aorta A and the right atrium RA. The cutting forms cut tissue **390**.

[**0096**] **FIG. 14** illustrates another intermediate step in cutting an aperture through tissue between the right atrium RA and the aorta, and another step in deploying the traversing connector **300**. As the arterial extracorporeal end of guidewire **410** is further advanced, the cutter/deployer **370** fully advances into the aorta A. An initial portion of this advancement causes the right atrium wall engaging element **330** to engage the inside of the right atrium wall, stopping further advancement of the inlet member **310**.

[0097] With advancement of inlet member **310** stopped, continued advancement of tissue cutter/deployer **370** completes unsheathing the inlet member **310**, and deploys the aorta wall engaging element **316**. The deployment allows element **316** to move from a collapsed configuration to an expanded configuration, which includes radially extending elements **316** to engage the aorta wall. The engagement compresses the first end **104** of conduit **102** against the aorta wall as a step in forming a fluid seal. The deployment also allows the portion of the inlet member **310** located within the cut apertures to self or automatically radially expand and annularly enlarge. This compresses a portion of the conduit **102** against the apertures in the right atrium RA and the aorta A as another step in forming a fluid seal. The inlet member **310**, the conduit **102**, and the position member **330** are structurally connected by the radial expansion force provided by the inlet member **310**. The connection may be aided or provided by barbs, hooks, or other members located on the inlet member **310** or position member **330**.

[0098] In addition, the spatial relationship between the engaging element **316** and **332** is arranged such that elements **316** and **332** compress tissue of the right atrium RA and aortic A walls together as another step in forming a fluid seal and implanting the connector **300**. The combined tissue thickness is approximately 2 mm.

[0099] In another embodiment, an alternative embodiment of the traversing connector **300** may be delivered over the guidewire **410** and implanted into the guidewire pathway **460** without first forming apertures in the right atrium RA and the aorta A. If some dilation of guidewire pathway **460** is required for implanting the alternative embodiment of the traversing connector **300**, a mechanical dilation may precede deployment of the traversing connector **300**. For example, a small balloon catheter may be advanced over the guidewire **410** and placed in the guidewire pathway **460**. Inflation of the balloon will dilate the tissue surrounding guidewire pathway **460** sufficient for implantation of the alternative embodiment of inlet member **310**. Alternatively, a tapered non-balloon instrument or series of such instruments could be advanced over the guidewire **410** to dilate the right atrial wall and aortic wall. The dilating apparatus may be removed before or after deployment of the traversing connector **300**. Therefore, the traversing connector **300** can be delivered over the guidewire **410** with or without preparatory steps to increase the diameter of guidewire pathway **460**, such as dilation or cutting an aperture between the right atrium and aorta. In a further alternative embodiment, the traversing connector **300** may be configured to include a dilating apparatus that widens the guidewire pathway **460** as traversing connector **300** is advanced over guidewire **410**. In the alternative embodiment, the distal end **108** of conduit **102** may be coupled to a portion of traversing connector that extends into the right atrium RA.

[0100] **FIG. 15** illustrates a final configuration of the traversing connector **300** implanted in apertures created between the right atrium RA and the non-coronary aortic sinus **29**, in accordance with the invention. The inside diameter of the portion of the channel **312** of inlet member **310** located within the cut apertures is approximately 5 mm, which is greater than the approximately 4 to 4.5 mm outside diameter of the cutter/deployer **370**. This allows the cutter/deployer **370** to be withdrawn back through the inlet member channel **312**. A final step includes withdrawing the cutter/deployer **370** from the patient by withdrawing the balloon catheter **350** from the patient at venous introduction site **404** in a direction opposite to advancement **414**. In an alternative embodiment, the cutter/deployer **370** may be withdrawn from the patient by advancement **414** until it emerges from the patient at the introduction site **402**.

[0101] **FIG. 16** illustrates an assembly **500** employing a knot pusher **510** for sealing the sealable exit opening **120** of arterial blood flow conduit **102**, in accordance with the invention. After removal of the pushers such as balloons **250** and **350**, and the guidewires **410** and **420** from the sealable exit opening **120** of the conduit **102**, the sealable exit opening **120** in the tubular body of the conduit may be sealed to prevent the aortic blood flow **394** from leaking. A guidewire (**410**, **420**) may be in left within or in proximity to the sealable exit opening **120** to aid in the positioning of a catheter **502** introduced for the purpose of sealing or plugging the aperture.

[0102] Assembly **500** includes the catheter **502**, and a knot pusher **510**, which may be any devices known in the art suitable for endovascular use within the heart H. **FIG. 16** also illustrates sutures **520**, suture post end **522**, and suture loop end **524**. Sutures **522** may be any suture material suitable for use with the conduit **102**, and may depend on the material used for the conduit **102**. In an embodiment illustrated in **FIG. 16**, sutures **522** were pre-placed proximal to the opening **120** prior to the conduit **102** being inserted in the patient, and the ends **522** and **524** were secured to prevent interfering with implantation of the conduit **102** in the heart H. Any suitable suture pattern may be used, including the continuous over-and-over pattern illustrated or a purse-string pattern.

[0103] Once the opening **120** is ready for closing, the distal tip **504** of catheter **502** is placed over the extracorporeal post and loop ends **522** and **524**, and guided adjacent to opening **120**. The distal tip **504** may be guided by a guidewire (**410**, **420**) prior to it being removed from opening **120**. Knot-tying techniques known to those in the art are used extracorporeally to create loops by looping loop end **524** around the post end **524**, and using knot pusher **510** to advance the loops down the post and form knot **526**.

[0104] In another embodiment, the sealable exit opening **120** includes a self-sealing device, such as a vascular introducer sheath that includes a one-way diaphragm arranged to prevent bleeding. The vascular introducer sheath will seal automatically after removal of the pushers such as balloons **250** and **350**, and the guidewires **410** and **420** from the sealable exit opening **120** of the conduit **102**. In a further embodiment, a prosthesis is introduced over one of the guidewires (**410**, **420**) from the venous entry site **404** to cover or plug the sealable exit opening **120**.

[0105] When all of the apparatus are removed and the sealable site opening **120** is sealed, arterial blood flow **394** will flow from the aorta A through the conduit **102** and into the coronary venous circulation towards the myocardium. The implant is a permanent means to perfuse ischemic myocardium with arterial blood from an aortic source, and does not require an open chest procedure of any kind.

[0106] **FIGS. 17 and 18** are perspective views illustrating additional features of the inlet member **310**, in accordance with the invention. **FIG. 17** illustrates the inlet member **310**

in a compressed and pre-deployment configuration. **FIG. 18** illustrates the inlet member **310** in an expanded and deployed configuration, with engaging elements **316** radially extended. Inlet member **310** includes channel **312**, a compressed (or collapsed) inside diameter **314**, an expanded inside diameter **315**, radially extending, aortic wall engaging element **316** (shown as a plurality of elements **316***a-h*), a first plurality of engaging members **320**, optionally a second plurality of engaging members **321**, and axially spaced first and second portions **324** and **325**, respectively.

[**0107**] Inlet member **310** may be made from any material suitable for use in the heart and cardiac venous system, such as Nitinol, stainless steel, tantalum, tungsten, and platinum. Inlet member **310** may be produced by starting with a single, unitary metal tube and removing selected material until only the structure shown in **FIG. 17** remains. For example, laser cutting may be used to remove material from the starting tube in order to produce inlet member **310**. The tube size and any initial plastic expansion of the laser cut tube is selected to result in the inlet member **310** being radially contractible to the compressed inside diameter **314** and being self or automatically radially expandable to at least the expanded inside diameter **315**.

[**0108**] Inlet member **310** is arranged to be annularly compressed to the compressed inside diameter **314** for placement in the sheath **374** of cutter/deployer **370**. The compressed inside diameter **314** will be approximately 3.5 to 4 mm. In its expanded state, the second portion **325** is arranged to annularly enlarge to the expanded inside diameter **315**. The expanded inside diameter **315** is approximately 5 mm. The inlet member **310** has an initial pre-deployment length of about 5 mm, and a material thickness of about 0.004 inches.

[**0109**] First portion **324** includes a first plurality of annularly spaced members **316***a-h* that have free end portions, and that are arranged for engaging the interior wall of aorta A. The annularly spaced members **316***a-h* are further arranged such, that when compressed into the sheath **374** and then deployed, they will elastically and radially move from the compressed configuration illustrated in **FIGS. 12 and 17** to the expanded configuration illustrated in FIGS. **14-15**, and **18**, and to engage the interior wall of the aorta A.

[**0110**] Second portion **325** provides a structure allowing its annular dimension to be enlarged to an expanded inside diameter **315** or reduced to the compressed inside diameter **314**, and when reduced typically by compression, the structure provides an elastic force seeking to enlarge the annular dimension. Second portion **325** is particularly arranged to be radially and elastically contracted to the compressed inside diameter **314**, and then to automatically and elastically radially expand upon deployment to expanded inside diameter **315**. The radially expandable and contractible structure is provided by making the inlet member **310** with a plurality of annularly adjacent, annularly enlargeable portions. For example, a typical enlargeable portion includes annularly spaced, adjacent, and interconnected longitudinal members, the axially spaced ends of which are connected to one another. A portion of the longitudinal members may have free ends. A plurality of these enlargeable portions is connected side-to-side and end-to-end on second portion **325**. The structure is annularly enlargeable by radial expansion, which annularly enlarges the portions, as shown for example in **FIG. 18**. As second portion **325** annularly enlarges, it generally axially shortens. Once the second portion **325** is plastically annularly enlarged to at least inside diameter **315**, the enlargeable portions are also elastically and annularly compressible, permitting radially contracting the second portion **325** to inside diameter **314** for placement in the sheath **374**.

[**0111**] Second portion **325** also includes a plurality of engagement facilitating members, arranged in a first band **320** and optionally a second band **321**. The engagement facilitating members in bands **320** and **321** may include outward deflected material arranged to form barbs, hooks, or other shapes that facilitate coupling between the inlet member **310**, the conduit **102**, and the position member **370**.

[**0112**] The outward deflection of engaging elements **316***a-h*, and engagement facilitating members **320** and **321** as illustrated in **FIG. 18** may be produced by putting the inlet member **310** on a mandrel and plastically displacing them. In another embodiment, the inlet member **310** may be formed in such a way that second portion **325** is annularly enlargeable by inflation of a balloon catheter **350** that is temporarily disposed in the channel **312**.

[**0113**] In use, the inlet member **310** is formed into the configuration illustrated in **FIG. 18**. Inlet member **310** is prepared for incorporation into assembly **360** by bringing the engaging elements **316***a-h* of the first portion **324** into axial alignment and by annularly compressing the second portion **325**. The inlet member **310** as part of assembly **360** is then sheathed in sheath **374** for deployment. Upon deployment, the inlet member **310** deploys as illustrated in FIGS. **14-15**, and **18**, and engaging elements **316***a-h* engage the interior wall of the aorta A. The deployment further allows the second portion **325** to annularly enlarge and cause the inlet member to compressively oppose the expanded inside diameter **341** of the positioning member **330** (shown in **FIG. 20**). The annular enlargement provides a compressive force that fluid couples inlet member **310** and a portion of the first end **104** of the conduit **102**, and further mechanically couples the second portion **325** to the positioning member **330**. This annular enlargement also causes the second portion **325** to compressively oppose the tissue of the aperture formed between the right atrium RA and the aorta A.

[**0114**] **FIGS. 19 and 20** are perspective views illustrating additional features of the positioning member **330**, in accordance with the invention. **FIG. 19** illustrates the positioning member **330** in a compressed and pre-deployment configuration. **FIG. 20** illustrates the positioning member **330** in an expanded and deployed configuration, with engaging elements **332** and braces **334** radially extended.

[**0115**] The positioning member **330** is substantially similar to inlet member **310** in construction and arrangement. The positioning member **330** includes radially extending right atrium wall engaging element **332** (shown as a plurality of elements **332***a-h*), bracing element **334** (shown as a plurality of bracing elements **334***a-h*), a compressed (or collapsed) inside diameter **340**, an expanded inside diameter **341**, and axially spaced first and second portions **338** and **339**, respectively.

[**0116**] The positioning member **330** may be made from the same material and made in the same manner as inlet member **310**, and arranged to be compressed to the com-

pressed inside diameter **340** for placement in the sheath **374** of cutter/deployer **370**. The compressed inside diameter **340** will be approximately 3.5 to 4 mm and the expanded inside diameter **341** is approximately 5.5 mm. In its expanded state, the second portion **339** is arranged to radially expand to the inside diameter **341** and to oppose further expansion. The limitation on expansion causes the positioning member **330** to compressively oppose further expansion of the inlet member **310**, cooperatively providing a compressive force coupling the second portion **325** of inlet member **310** to the second portion **339** of the positioning member **330**. The compressive force also provides fluid coupling of the inlet member **310** to a portion of the first end **104** of the conduit **102**. The positioning member **330** has an initial pre-deployment length of about 5 mm, and a material thickness of about 0.004 inches.

[**0117**] In use, the positioning member **330** is formed into the configuration illustrated in **FIG. 20**. Positioning member **330** is prepared for incorporation into assembly **360** by bringing the engaging elements **332***a-h* and braces **334***a-h* into axial alignment, and by compressing second potion **339**. The positioning member **330** as part of assembly **360** is then sheathed in sheath **374** for deployment. Upon deployment, the positioning member **330** deploys as illustrated in FIGS. **13-15**, and **20**, and engaging elements **332***a-h* engage the interior wall of the right atrium RA.

[**0118**] While the present invention has been described in certain preferred embodiments, other embodiments of the invention include an apparatus and method for providing arterial blood for arterial perfusion of ischemic myocardium. These embodiments include arrangement of the apparatus and method for implantation in a beating heart.

[**0119**] Although the present invention has been described in considerable detail with reference to certain preferred embodiments, other embodiments are possible. Therefore, the spirit or scope of the appended claims should not be limited to the description of the embodiments contained herein. It is intended that the invention resides in the claims hereinafter appended.

What is claimed is:

1. A device that provides arterial blood flow from the aorta to a vascular structure for perfusion of cardiac tissue, the device comprising:

a connector arranged to receive arterial blood flow from the aorta;

an arterial blood conduit in fluid communication with the connector and the vascular structure, the conduit arranged for placement within a heart chamber and the vascular structure; and

a connector arranged to couple the conduit with the vascular structure.

2. The device of claim 1, wherein the device is arranged for endovascular implantation.

3. The device of claim 1, wherein the device is arranged for endovascular implantation in a beating heart.

4. A device that provides arterial blood flow from aorta to coronary venous system for venous retroperfusion of myocardium, the device comprising:

an aorta-right atrium traversing connector arranged to receive arterial blood flow from the aorta;

an arterial blood conduit in fluid communication with the traversing connector and a portion of the venous system, the conduit arranged for placement within the right atrium and the coronary sinus; and

a venous connector arranged to couple the conduit with the coronary venous system.

5. The device of claim 4, wherein the aorta-right atrium traversing connector comprises an inlet member arranged for receiving arterial blood flow from the aorta and for traversing a first aperture in an aortic wall and a second aperture in a right atrium wall, and having a channel providing fluid communication.

6. The device of claim 4, wherein the arterial blood conduit comprises a tubular member having a first end, a second end, and a lumen providing fluid communication between the ends, the tubular material comprising a flexible material.

7. The device of claim 4, wherein the arterial blood conduit comprises a member having a first end adapted to be coupled to the aorta-right atrium traversing connector, a second end adapted to be coupled to the venous connector, an intermediate portion located between the ends, a lumen providing fluid communication between the ends, a first region near the first end adapted to be placed in the right atrium and a second region near the second end adapted to be placed into a portion of the venous system, the member comprising a flexible material.

8. The device of claim 7, wherein the intermediate portion of conduit includes a self-sealing diaphragm.

9. The device of claim 4, wherein the arterial blood conduit includes a biocompatible material that comprises at least one from the group consisting of polyvinyl chloride, polyethylene, polytetrafluoroethylene (PTFE), and ePTFE.

10. The device of claim 4, wherein the arterial blood conduit includes a vascular structure.

11. The device of claim 10, wherein the vascular structure includes an autologous vein.

12. The device of claim 4, wherein the venous connector comprises:

a radially expandable elongated structure that includes a portion arranged for annular enlargement and configured for disposition around the inside of a lumen of the coronary venous system, and which, when annularly enlarged within the lumen, engages the conduit with the vascular lumen.

13. The device of claim 4, wherein the device includes arrangement for endovascular implantation.

14. The device of claim 4, wherein the device includes arrangement for endovascular implantation in a beating heart.

15. An aorta-right atrium traversing connector comprising an inlet member arranged for receiving arterial blood flow from the aorta and for traversing a first aperture in an aortic wall and a second aperture in a right atrium wall, and having a channel providing fluid communication.

16. The aorta-right atrium traversing connector of claim 15, wherein the first aperture occurs at a point proximate to a non-coronary aortic sinus.

17. The aorta-right atrium traversing connector of claim 15, wherein the inlet member includes arrangement for coupling with a conduit arranged to carry the arterial blood flow.

18. The aorta-right atrium traversing connector of claim 17, wherein the inlet member includes an annularly enlargeable structure that, when annularly enlarged within a portion of a conduit arranged to carry the arterial blood flow, couples the inlet member to the conduit.

19. The aorta-right atrium traversing connector of claim 15, wherein the inlet member includes arrangement to move from a first configuration for endovascular placement in the first and second apertures to a second configuration of implantation in the first and second apertures.

20. The aorta-right atrium traversing connector of claim 15, wherein a portion of the inlet member includes arrangement for self-annular expansion after deployment from a sheath.

21. The aorta-right atrium traversing connector of claim 15, wherein a portion of the inlet member includes arrangement for annular enlargement by expansion of an inflatable expandable structure positioned within the portion of the inlet member.

22. The aorta-right atrium traversing connector of claim 15, wherein the inlet member includes at least one element that extends radially outward and arranged to engage an interior portion of the aortic wall.

23. The aorta-right atrium traversing connector of claim 15, wherein the channel comprises a portion of arterial blood conduit arranged around a portion of the inlet member.

24. The aorta-right atrium traversing connector of claim 15, wherein the connector includes arrangement for endovascular implantation.

25. The aorta-right atrium traversing connector of claim 15, wherein the connector includes arrangement for endovascular implantation in a beating heart.

26. An aorta-right atrium traversing connector, the traversing connector comprising:

an inlet member arranged for receiving arterial blood flow from the aorta and for traversing a first aperture in an aortic wall and a second aperture in a right atrium wall, and having a channel providing fluid communication; and

a positioning member arranged to maintain the inlet member in a selected position.

27. The aorta-right atrium traversing connector of claim 26, wherein the inlet member includes arrangement for engaging the aorta.

28. The aorta-right atrium traversing connector of claim 26, wherein the positioning member includes an element for engaging an interior wall of the right atrium.

29. The aorta-right atrium traversing connector of claim 26, wherein the positioning member includes arrangement for engaging the right atrium and the inlet member.

30. The aorta-right atrium traversing connector of claim 26, wherein the positioning member includes at least one element extending radially outward, and arranged to engage an interior portion of the right-atrial wall and position the inlet member relative to the right-atrial wall.

31. The aorta-right atrium traversing connector of claim 30, wherein the radially extending element includes arrangement for moving from a first configuration for endovascular placement to a second configuration for engagement.

32. The aorta-right atrium traversing connector of claim 26, wherein a portion of the positioning member includes arrangement to resist annular enlargement.

33. The aorta-right atrium traversing connector of claim 26, wherein the inlet member further comprises an element for engaging an aortic interior wall, and the positioning member includes an element for engaging a right-atrial interior wall, and when a portion of the positioning member engages a portion of the inlet member, the inlet member engaging element and the position member engaging element are arranged to cooperatively compress tissue radial of the apertures between them.

34. The aorta-right atrium traversing connector of claim 33, wherein the compression limits blood leakage from at least one of the aorta and the right atrium.

35. An assembly of catheters having magnetically alignable lumens, the assembly comprising:

a first catheter arranged for placement into a cavity of a body structure and having a first distal tip, a first magnetic member carried proximate to the first distal tip, and a first lumen having a distal entrance;

a second catheter arranged for placement into a cavity of another body structure and having a second distal tip, a second magnetic member carried proximate to the second distal tip, and a second lumen having a distal entrance, the magnetic member of one catheter being arranged to attract and align with the magnetic member of the other catheter, such that, when the magnetic members align, the distal entrances of the first and second lumens also align.

36. The assembly of claim 35, wherein at least one cavity is a lumen of a vascular structure.

37. An assembly of catheters having alignable lumens, the assembly comprising:

a first catheter arranged for placement into a cavity of a body structure and having a first distal tip, a first alignment member carried proximate to the first distal tip, and a first lumen having a distal entrance; and

a second catheter arranged for placement into a cavity of another body structure and having a second distal tip, a second alignment member carried proximate to the second distal tip, and a second lumen having a distal entrance, the alignment member of one catheter being arranged to align with the alignment member of the other catheter, such that, when the alignment members align, the distal entrances of the first and second lumens also align.

38. The assembly of claim 37 wherein one alignment member is an electrical signal source and another alignment member is an electrical signal sensor.

39. The assembly of claim 37, wherein one alignment member is an ultrasound source and another alignment member is an ultrasound sensor.

40. The assembly of claim 37, wherein one alignment member is a light source and another alignment member is a light sensor.

41. An assembly for use in creating a guidewire pathway between two body structures, the assembly comprising:

a first catheter arranged for placement into a cavity of a body structure and having a first distal tip, a first alignment member carried proximate to the first distal tip, and a first lumen having a distal entrance; and

a second catheter arranged for placement into a cavity of another body structure and having a second distal tip,

a second alignment member carried proximate to the second distal tip, and a second lumen having a distal entrance, the alignment member of one catheter being arranged to align with the alignment member of the other catheter, such that, when the alignment members align, the distal entrances of the first and second lumens also align; and

a guidewire deployable from one lumen and receivable by the other lumen.

42. The assembly of claim 41, wherein at least one cavity includes a lumen of a vascular structure.

43. The assembly of claim 41, wherein one cavity includes a cardiac chamber.

44. The assembly of claim 41, wherein one catheter includes arrangement for transvascular placement in an arterial structure.

45. The assembly of claim 41, wherein one catheter includes arrangement for transvascular placement in a venous structure.

46. The assembly of claim 41, wherein one catheter includes arrangement for transvascular placement in an arterial structure and another catheter includes arrangement for transvascular placement in a venous structure.

47. The assembly of claim 41, wherein both alignment members are a magnetic, and are arranged to attract and align with each other.

48. The assembly of claim 41 wherein one alignment member is an electrical signal source and another alignment member is an electrical signal sensor.

49. The assembly of claim 41, wherein one alignment member is an ultrasound source and another alignment member is an ultrasound sensor.

50. The assembly of claim 41, wherein one alignment member is a light source and another alignment member is a light sensor.

51. The assembly of claim 41, wherein guidewire further includes a penetrating portion for penetrating tissue lying between the entrances to the lumens.

52. The assembly of claim 51, wherein one catheter further includes an element arranged to snare the penetrating portion.

53. The assembly of claim 51, wherein the penetrating portion includes a penetration aid selected from a group consisting of a thermal heating element, a laser energy emitter, a RF cutting device, and a vibration device.

54. The assembly of claim 51, wherein the penetrating portion includes a hollow needle and the guidewire is arranged for advancement through tissue penetrated by the hollow needle.

55. The assembly of claim 51, wherein the penetrating portion includes arrangement for penetrating between an aorta and a right-atrium.

56. The assembly of claim 41, wherein one distal tip includes a substance viewable with an imaging device.

57. The assembly of claim 41, wherein one catheter further includes an additional lumen arranged to eject a substance viewable with an imaging device.

58. An instrument for forming an aperture between cavities of two proximate body structures and deploying a connector in the aperture, the instrument comprising:

a tubular structure arranged for placement in one of the cavities and having a sheath for deploying the connector;

a tissue-cutting member arranged to form the aperture in tissue between the cavities;

a guidewire following member; and

a sheath arranged for deploying the connector in the aperture.

59. The instrument of claim 58, further including a cut tissue retention member.

60. The instrument of claim 58, further including a movement control member having an extracorporeal portion and arranged for moving the instrument along a guidewire and.

61. The instrument of claim 60, wherein the movement control member includes a radially expandable structure.

62. The instrument of claim 58, wherein the connector includes arrangement for traversing between lumens of an aorta and a right atrium.

63. The instrument of claim 58, wherein the tissue-cutting member includes a cutting aid selected from a group consisting of a thermal heating element, a laser energy emitter, a RF cutting device, and a vibration device.

64. The instrument of claim 58, wherein the guidewire following member includes arrangement for engaging a guidewire moved in a direction relative to the instrument.

65. The instrument of claim 58, wherein the instrument includes arrangement for endovascular use.

66. The instrument of claim 58, wherein the instrument includes arrangement for endovascular use in a beating heart.

67. An intra-luminal venous connector for fluid coupling a conduit placed in a cardiac vascular lumen to the vascular lumen, the connector comprising an annularly enlargeable structure that, when annularly enlarged within a portion of a conduit arranged to carry arterial blood flow, couples the conduit with the vascular lumen.

68. The venous connector of claim 67, wherein the structure includes arrangement for annular enlargement by a radially expandable structure placed within a portion of the elongated structure.

69. The connector of claim 67, wherein when the structure is annularly enlarged and coupling the conduit with the vascular lumen, blood flow from the conduit into a right atrium is limited.

70. The connector of claim 67, wherein the connector includes arrangement for endovascular implantation.

71. The connector of claim 67, wherein the connector includes arrangement for endovascular implantation in a beating heart.

72. An assembly for use in implanting an aorta-right atrium traversing connector, the assembly comprising:

a guidewire path creation subassembly arranged for creating a guidewire pathway between an aorta and a right atrium, the subassembly including a first catheter having a distal tip arranged for placement into a cavity of a body structure and a lumen, a second catheter having a distal tip arranged for placement into a cavity of a body structure and a lumen, and a guidewire deployable from one catheter lumen and receivable by another catheter lumen and having a tissue penetrating element arranged to create a guidewire pathway by penetrating tissue between the lumens; and

a guidewire guided instrument arranged for creating an aperture in response to the guidewire pathway between the aorta and the right atrium, and deploying a connector in the aperture.

73. The assembly of claim 72, wherein the guidewire guided instrument includes a tubular structure arranged for endovascular placement, a sheath arranged for carrying and deploying the traversing connector, a tissue-cutting element, and a guidewire following member.

74. The assembly of claim 72, wherein the guidewire guided instrument includes a movement control member for moving the instrument along a guidewire and having an extracorporeal portion.

75. The assembly of claim 72, further including a device arranged to provide arterial blood flow from the aorta to coronary venous system for venous retroperfusion of myocardium, the device including:

an aorta-right atrium traversing connector arranged to receive arterial blood flow from the aorta;

an arterial blood conduit in fluid communication with the traversing connector and a portion of the venous system, the conduit arranged for placement within the right atrium and the coronary sinus; and

a venous connector that couples the conduit to the coronary venous system.

76. The assembly of claim 72, wherein the assembly includes arrangement for use in a beating heart.

77. The assembly of claim 72, wherein the assembly includes arrangement for endovascular use.

78. A method of providing venous retroperfusion of myocardium, the method including the steps of:

acquiring arterial blood flow from an aorta;

conveying the arterial blood flow through a right atrium, through a coronary sinus, and into a portion of a coronary venous system; and

discharging the arterial blood flow in a portion of the coronary venous system for venous retroperfusion of a myocardium.

79. The method of claim 78, wherein the arterial blood flow is acquired from the non-coronary aortic sinus.

80. The method of claim 78, wherein the step of acquiring the arterial blood flow includes the further step of directing the blood flow into an arterial blood conduit.

81. The method of claim 78, wherein the step of conveying the arterial blood flow includes the further step of routing an arterial blood conduit from acquisition in the aorta to a point of discharge in the coronary venous system.

82. The method of claim 78, wherein the step of providing the arterial blood flow includes the further step of coupling an arterial blood conduit with a lumen of the coronary venous system.

83. The method of claim 78, wherein the step of discharging arterial blood flow includes normal cardiac arterial blood flow phasing.

84. The method of claim 78, wherein the discharged arterial blood flow includes normal cardiac arterial blood pressure.

85. The method of claim 78, wherein the steps are performed in a beating heart.

86. The method of claim 78, wherein the steps are performed endovascularly.

87. A method of implanting a device that provides arterial blood flow from an aorta to a portion of a coronary venous system for venous retroperfusion of myocardium, the method including the steps of:

placing an arterial catheter in the non-coronary aortic sinus at a position proximate to an aortic wall;

placing a venous catheter in the right atrium at a position proximate to an atrium wall, and in approximate opposition to the arterial catheter;

passing an arterial guidewire between the venous catheter and the arterial catheter, the guidewire passing through both the aortic wall and the atrium wall and having a proximal end;

placing a distal end of a venous guidewire into a lumen of the coronary venous system, the venous guidewire having a proximal end located adjacent to the proximal end of the arterial guidewire;

mounting portions of a lumen of the device moveably over the adjacent proximal ends of the venous guidewire and the arterial guidewire, a first portion being mounted on the arterial guidewire and the second portion being mounted on the venous guidewire;

moving the mounted device along the guidewires into the right atrium;

deploying the aorta-right atrium connector in the pathway and in fluid communication with the aorta; and

deploying the venous connector in the selected portion of the venous system.

88. The method of claim 87, wherein the device includes an arterial blood flow conduit having a first portion with an aorta-right atrium traversing connector arranged to receive arterial blood from the aorta mounted on one end and second portion with a venous connector arranged to couple the conduit into a lumen of the coronary venous system mounted on a second end.

89. A device that provides venous retroperfusion of myocardium, the device comprising:

means for acquiring an arterial blood flow from an aorta;

means for conveying the acquired arterial blood flow through a right atrium and into a coronary sinus; and

means for discharging the arterial blood flow into a portion of a coronary venous system.

* * * * *

专利名称(译)	提供用于灌注缺血心肌的动脉血流的装置和方法		
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摘要(译)

本发明一般涉及用于血管内和术中程序的方法和装置，其提供用于灌注缺血心肌的动脉血流。本发明的各方面提供了主动脉的非冠状窦和冠状静脉之间的导管。导管穿过右心房的一部分和冠状窦，并且完全位于心脏和主动脉内。动脉血液从主动脉通过导管流入冠状静脉循环，朝向心脏的缺血区域。本文描述的所有程序可以在血管内进行，并且可以在患者的心脏搏动时进一步进行。