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Wang et al.

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(54) **APEX TO AORTA CANNULA ASSEMBLY**

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(51) **Int. Cl.**
A61M 1/10 (2006.01)

(52) **U.S. Cl.** **600/16**; 623/3.13; 623/3.15

(58) **Field of Classification Search** 623/3.13, 623/3.15; 600/160, 16
See application file for complete search history.

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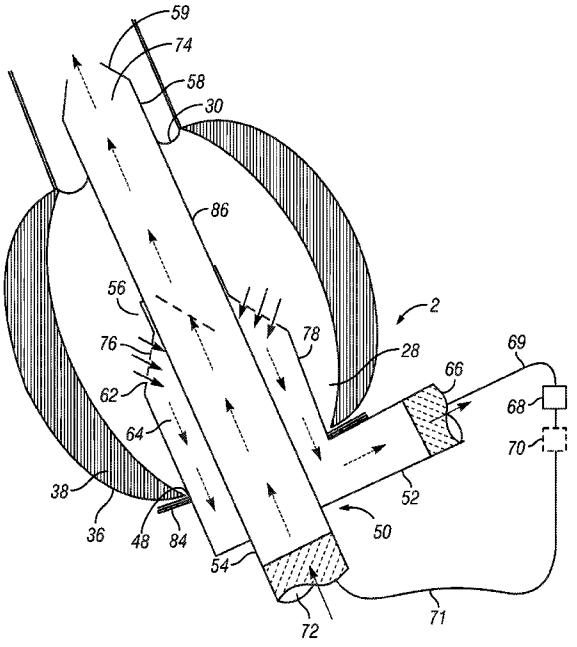
(57) **ABSTRACT**

An apparatus, system, and method for assisting a heart in circulating blood that has been damaged, for example, by a myocardial infarction. In at least one aspect, an apparatus, system, and method are used for inserting a single cannula assembly comprising at least an inner and outer cannula into the left ventricle, advancing the inner cannula portion of the cannula assembly past the aortic valve, and into the aorta without requiring a secondary cannula insertion through an external portion of the aorta. In another aspect, an intraventricular assistant device (IVAD) having a motor and impeller can be inserted directly into the heart, such as in the left ventricle. The IVAD uniquely provides a pump within the heart through a single insertion that can reduce thrombosis and lessen the complexities typically associated with such efforts.

18 Claims, 4 Drawing Sheets



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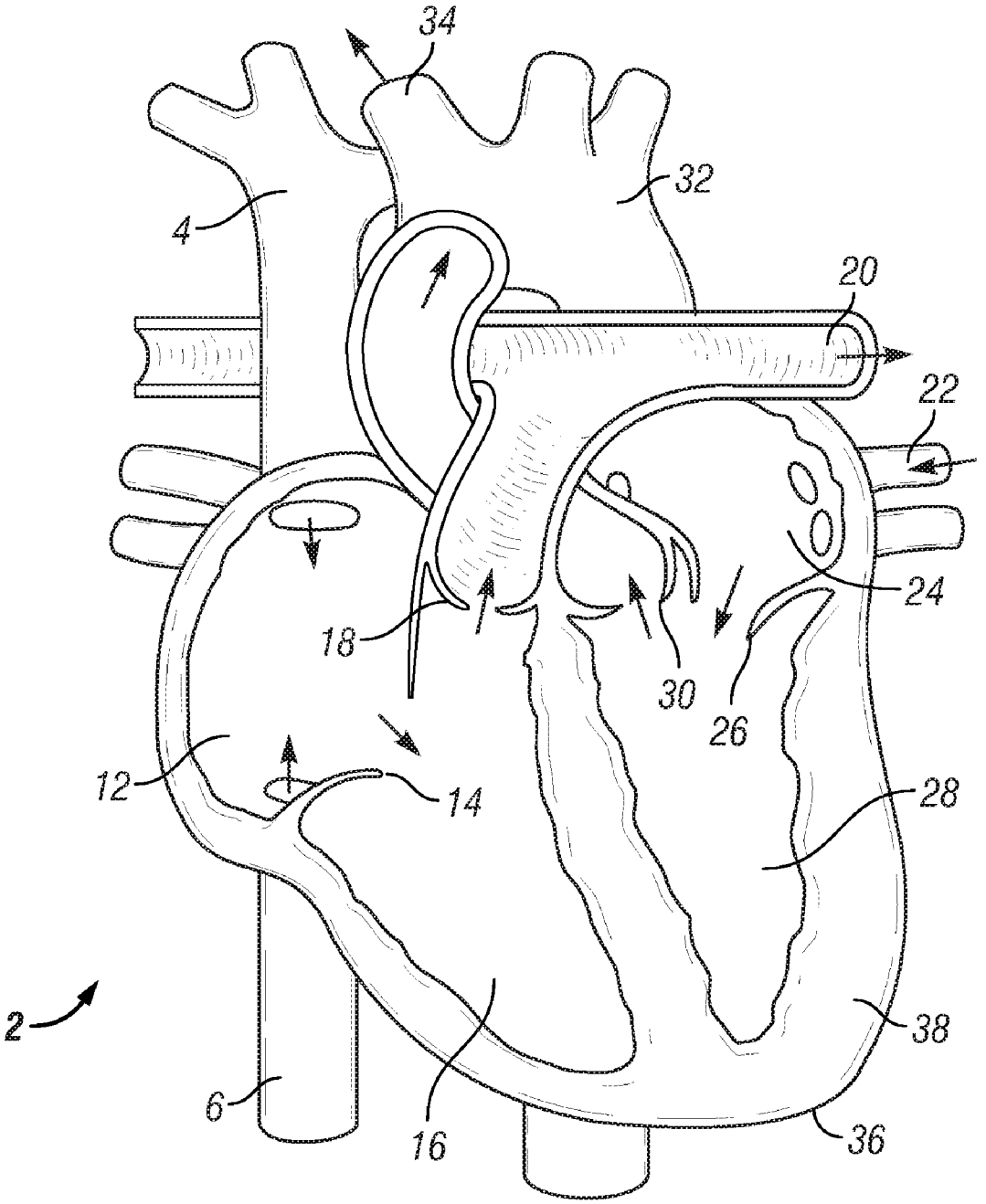

FIG. 1
(Prior Art)

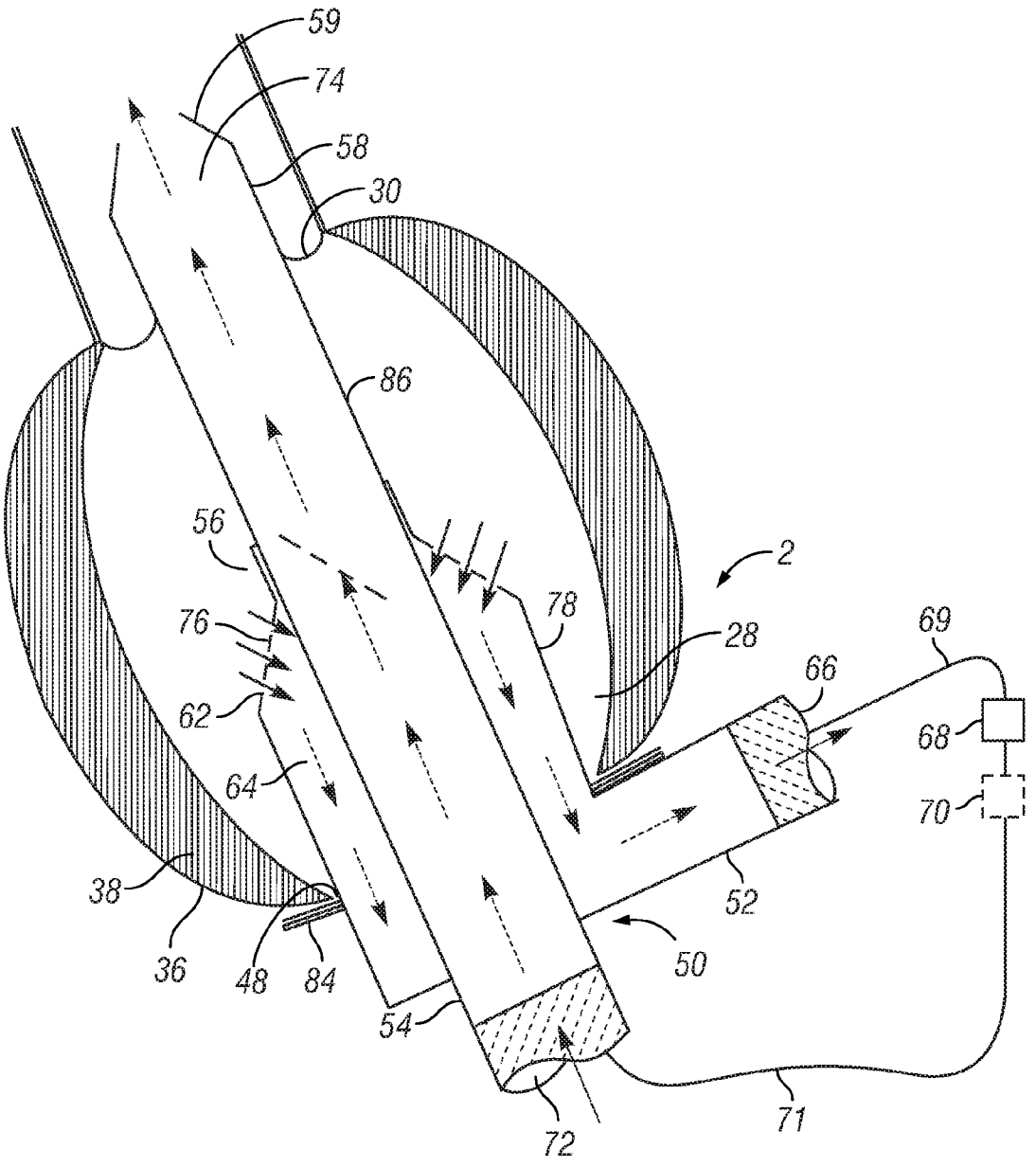

FIG. 2

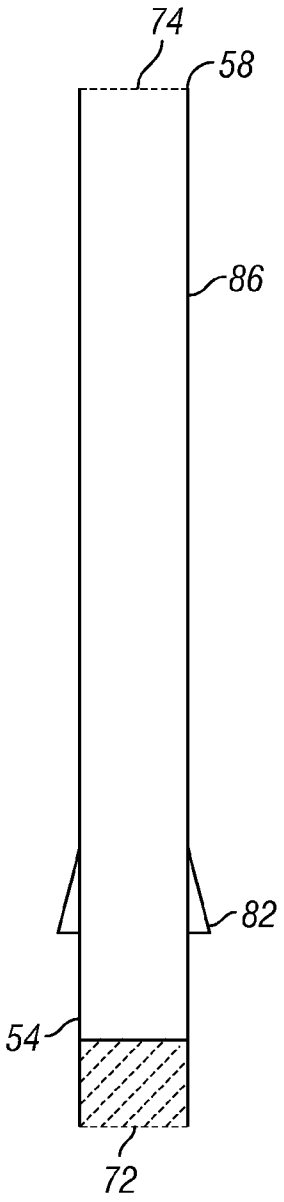

FIG. 3A

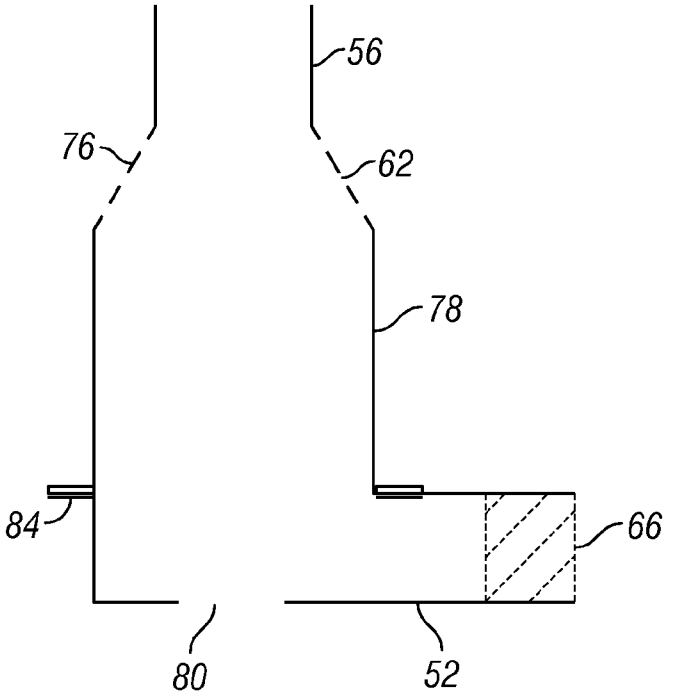

FIG. 3B

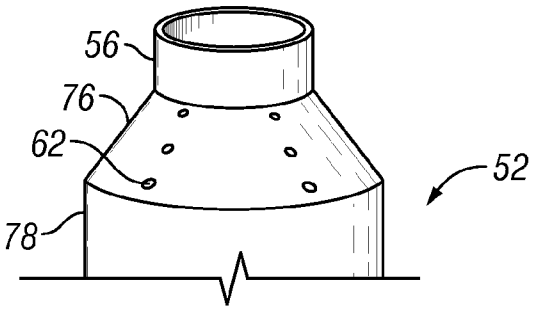

FIG. 3C

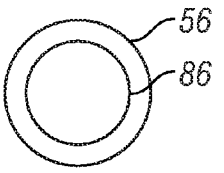

FIG. 4B

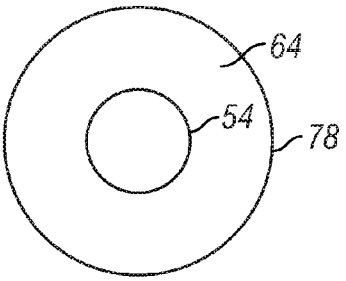

FIG. 4C

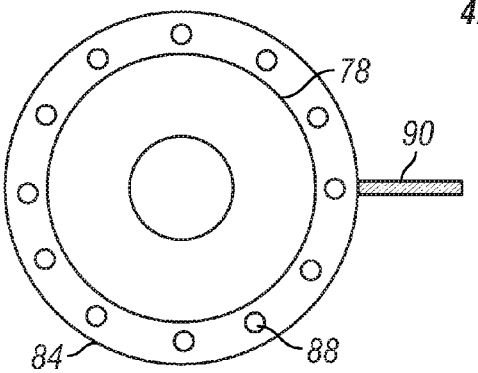

FIG. 4D

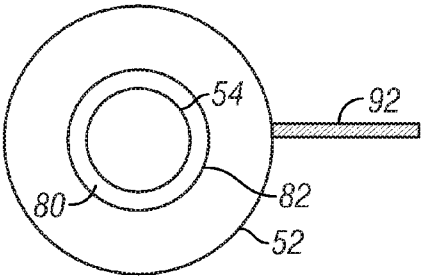

FIG. 4E

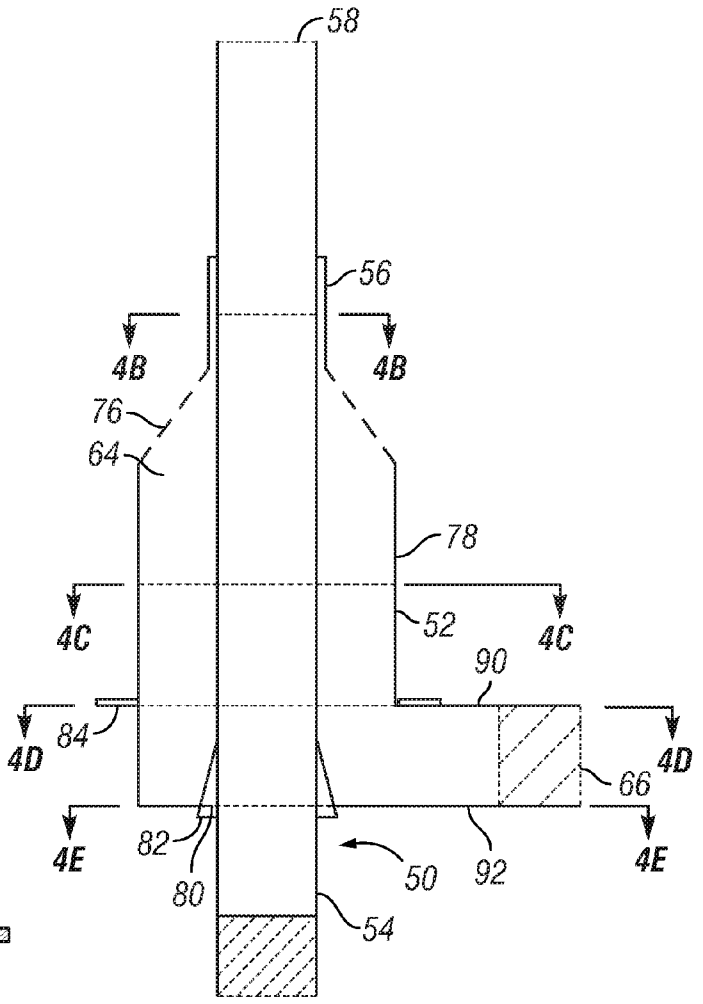

FIG. 4A

APEX TO AORTA CANNULA ASSEMBLY

This application claims the benefit of U.S. Provisional Application Ser. No. 60/543,799, filed Feb. 11, 2004.

FIELD OF THE INVENTION

The invention relates to the field of medical devices. More specifically, the invention relates to the design and use of cardiac medical devices.

BACKGROUND OF THE INVENTION

Tissue decay in a heart typically results from a myocardial infarction (MI). Often, the decay results in chronic heart degradation and ultimate failure, as the damaged portion is unable to be restored. The deterioration is especially acute when the damage occurs to the left ventricle, which functions at a high pressure during systolic contractions to pump the blood received from the left atrium and the mitral valve, through the aortic valve and into the aorta for distribution throughout the body. The damaged tissue, operating under high pressures, eventually fails. Even without a failure, the heart is unable to function at a performance level prior to the MI, resulting in less circulation and lower blood oxygen levels.

Although cutting edge, critical care technology has been applied in the treatment and restoration of the cardiac tissues after an MI, the typical procedures are traumatic to many patients and sometimes result in mortality. Less tissue decay can result from immediate and efficient cardiac or combined cardiac and pulmonary support, but the current technology is lacking in both aspects. Current technology, including a left ventricle assist device (LVAD), extracorporeal membrane oxygenation (ECMO), and cardiopulmonary support (CPS), is either less efficient or too complicated and traumatic to already impaired anatomical systems.

Veno-Arterial (V-A) ECMO with peripheral arterial venous access using percutaneous cannulae has been available for cardiopulmonary support for several decades. Typically, a cannula is inserted into a vena cava, blood is routed through the cannula to an ECMO system for oxygenation, and the blood is returned to an artery. The multiple insertions causes trauma, can result in bleeding especially by the return path to the arterial system, and the flow rates are limited by high resistance. ECMO is also time limited, generally to less than four weeks, and has been shown to induce damage to the red blood cell (RBC). Further, ECMO does not unload the left ventricle, resulting in contractions and continued stress on the cardiac tissues. Thus, the left ventricle is unable to relax to allow at least partial healing of the muscle tissues by, for example, new growth.

LVAD systems have been used for longer-term, left ventricular support and reduced damage to the RBC. The LVAD removes blood flowing into the left ventricle, so that the left ventricle contracts at a significantly lower pressure in a more relaxed state. The blood flows to the LVAD pump and is pumped back into the aorta at an increased pressure to reduce the load on the left ventricle. However, current technology typically requires LVAD systems to be inserted into both the left ventricle to remove the blood and then returned to the aorta by a separate anastomosis of another cannula. The outlet cannula anastomosed to the aorta can especially cause complications because of the no-flow segment of the aorta root below the anastomosis, and has the possibility of clotting, thrombosis, and strokes.

Some efforts have resulted in a pump routed to the left ventricle by inserting a cable attached to an impeller into a location below the iliac artery and routing the impeller back up into the aorta, back through the aortic valve and into the left ventricle. The motor is typically located external to the body or at least the artery. The motor rotates the cable, which in turn rotates the impeller to supplement the pumping of the left ventricle. The cable, the arterial insertion, and the impeller can cause physical damage and thrombosis.

An insertion from the apex of the heart directly to the aorta was proposed about three decades ago, but the complexities of insertion and advancement to the aorta proved to be unfeasible in practice and thus did not enable the concept. Further, the cannula was not able to penetrate the chest wall and subsequently connect to a paracorporeal blood pump and oxygenator.

Even if the above procedures result in no adverse consequences, they are often performed at a subsequent time, when damage to the heart has largely occurred, due to their complexity. Further, the procedures are expensive and unavailable to many persons in need. The prognosis for healing after an MI can be greatly affected by the efficiency and availability of providing rapid assistance to the heart to encourage its healing and to provide oxygenation and circulation to supply blood to the anatomy.

Therefore, there remains a need for a simple, relatively easily accessible system and method for rapid provision of assistive devices for cardiac and/or pulmonary support.

SUMMARY OF THE INVENTION

The present invention provides an apparatus, system, and method for assisting a heart in circulating blood that has been damaged, for example, by a myocardial infarction. In at least one aspect, the invention provides an apparatus, system, and method for inserting a single cannula assembly comprising at least an inner and outer cannula into the left ventricle, advancing the inner cannula of the cannula assembly past the aortic valve, and into the aorta without requiring a secondary cannula incision through an external portion of the aorta. Certain shapes and flow paths reduce thrombosis and help ensure sealing into the apex and through the aortic valve. Blood entering the left ventricle through the mitral valve is withdrawn at a sufficient rate to allow the left ventricle to either not contract or to contract at a sufficient low pressure that can help the damaged area in restoration.

In another aspect, the invention provides an intraventricular assistant device (IVAD) having a motor and impeller that can be inserted directly into the heart, such as in the left ventricle. The IVAD uniquely provides a pump within the heart through a single insertion that can reduce thrombosis and lessen the complexities typically associated with such efforts

The disclosure provides a method of withdrawing blood from a heart of a body, the heart having an apex in proximity to a left ventricle and an aortic valve fluidicly disposed between the left ventricle and an aorta, the aorta providing a distribution of blood to the body, comprising: obtaining a cannula assembly having a first cannula and a second cannula; creating an incision in proximity of the apex of the heart; inserting the cannula assembly through the incision and into the left ventricle of the heart, the first cannula being disposed in the left ventricle and fluidicly coupled to the left ventricle; inserting a portion of the second cannula through the aortic valve of the heart; and allowing blood to be withdrawn from the left ventricle through the first cannula separate from a blood flow through the second cannula.

The disclosure further provides a system for withdrawing blood from a heart of a body, the heart having an apex in proximity to a left ventricle and an aortic valve fluidicly disposed between the left ventricle and an aorta, the aorta providing a distribution of blood to the body, comprising: a cannula assembly having an outer cannula and an inner cannula, comprising: the inner cannula having an outer perimeter disposed inside an inner perimeter of the outer cannula, and having a tapered tip adapted to be introduced through the heart apex and extended through the aortic valve; and the outer cannula having a transition portion having a first introductory inner perimeter disposed toward a portion of the cannula assembly adapted to be introduced through an incision in the apex of the heart, the introductory inner perimeter being sized in proximity to an outer perimeter of the inner cannula to reduce blood flow therebetween, the transition portion further having a second inner perimeter larger than the first introductory perimeter and distal from the portion to be introduced through the incision, the outer cannula forming an annulus around the inner cannula fluidicly separate from the inner cannula, the outer cannula having at least one port to allow blood to be withdrawn from the left ventricle to flow through the annulus to an outlet of the outer cannula.

The disclosure further provides a method of circulating blood in a heart of a body, the heart having an apex in proximity to a left ventricle and an aortic valve fluidicly disposed between the left ventricle and an aorta, the aorta providing a distribution of blood to the body, comprising: obtaining an intraventricular device, having a cannula and a pump coupled to the cannula, the pump having an inlet and an outlet; creating an incision in proximity of the apex of the heart; inserting the intraventricular device at least partially through the incision and into the left ventricle of the heart to fluidicly couple the pump inlet to the left ventricle; inserting a portion of the cannula through the aortic valve of the heart to fluidicly couple the pump outlet to the aorta; and allowing blood to be withdrawn from the left ventricle into the inlet of the pump in the left ventricle.

The disclosure also provides a system of circulating blood in a heart of a body, the heart having an apex in proximity to a left ventricle and an aortic valve fluidicly disposed between the left ventricle and an aorta, the aorta providing a distribution of blood to the body, comprising an intraventricular device, comprising: a cannula adapted to be inserted into the left ventricle through an incision in the heart and a portion of the cannula adapted to be inserted through the aortic valve using the same incision; and a pump coupled to the cannula, the pump having an inlet and an outlet, the pump being adapted to be at least partially inserted into the left ventricle with the cannula, the inlet being fluidicly coupled to the left ventricle and the outlet being fluidicly coupled to the aorta.

BRIEF DESCRIPTION OF THE DRAWINGS

A more particular description of the invention, briefly summarized above, may be had by reference to the embodiments thereof which are illustrated in the appended drawings and described herein. It is to be noted, however, that the appended drawings illustrate only some embodiments of the invention and are therefore not to be considered limiting of its scope, because the invention may admit to other equally effective embodiments.

FIG. **1** is a diagram of a heart showing the various portions relevant to the present invention.

FIG. **2** is a diagram of a cannula assembly that can be inserted through the apex into the left ventricle and through the aortic valve directly into the aorta root.

FIG. **3**A illustrates a cross sectional schematic of an inner cannula.

FIG. **3**B illustrates a cross sectional schematic of an outer cannula.

FIG. **3**C illustrates a cross sectional schematic of an upper portion of the outer cannula.

FIG. **4**A illustrates the cannula assembly in an assembled condition.

FIG. **4**B illustrates a cross sectional schematic at an interface of the outer cannula and inner cannula.

FIG. **4**C illustrates a cross sectional schematic of the flow area between the outer cannula and the inner cannula.

FIG. **4**D illustrates a cross sectional schematic of a securing plate coupled to the outer cannula.

FIG. **4**E illustrates a cross sectional schematic of the cannula assembly where the inner cannula is inserted into the outer cannula.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

In general, the invention provides a cannula assembly having a double wall to create a readily installed, high-flow, low-resistant apex-to-aorta shunt that allows for rapid attachment to a blood-pumping device such as a ventricular assistant device, or a combination ventricular assistant device/oxygenator. The procedure for placement of the present invention cannula assembly is generally relatively simple, less time consuming, and less invasive than previous methods. In another aspect, the present invention provides a single lumen cannula with a built-in intraventricular pump that can be inserted at the apex of the heart and pumps blood from the left ventricle across the aortic valve to the ascending aorta.

FIG. **1** is a diagram of a heart showing various portions relevant to the present invention. The following brief summary of the heart's circulatory system is included to provide a better understanding of the present invention. In general, a heart **2** receives blood from veins, pumps the oxygenated blood through the lungs, where the blood is returned to the heart as oxygenated blood. The heart then pumps the oxygenated blood through the aorta to the various arteries throughout the body. More specifically, the heart **2** receives blood from the superior vena cava **4** and the inferior vena cava **6** into the right atrium **12**. The right atrium **12** then contracts to force the blood through the tricuspid valve **14** into the right ventricle **16**. The right ventricle **16** contracts at a relatively small contraction pressure to force the blood through the pulmonary valve **18** into the pulmonary artery **20**. The pulmonary artery **20** directs blood to the lungs (not shown) where the blood is oxygenated. From the lungs, the oxygenated blood is returned to the heart **2** through pulmonary vein **22** into the left atrium **24**. The left atrium **24**, again operating a low pressure, such as less than 18 mm of mercury, pushes the blood through the mitral valve **26** into the left ventricle **28**. The left ventricle **28** provides the main pumping chamber for the heart at a higher pressure of approximately 100 mm of mercury. The blood pumped from the left ventricle exits through the aortic valve **30** into the aorta **32** in the lower region known as the aortic root. The aorta **32** then acts as a distribution chamber for the various greater arteries **34**.

Acute heart failure can occur in either ventricle, but generally is more problematic in the left ventricle, because the left ventricle provides the primary pressure to the artery system of the body. Sometimes, the tissues of the heart can at least partially be restored by draining the blood supply, or "unloading", from the particular ventricle, so that the contraction pressure is minimized. Generally, when a patient is

undergoing heart surgery, the heart is by-passed by taking blood from the vena cava, pumping it through an extracorporeal oxygenator, and then returned via an arterial cannula into the root of the ascending aorta emanating from the aortic arch. Additional methods may employ cannulating through the outer heart tissue **38** in the vicinity of a lower portion of the heart, known as the apex **36**, and unloading the heart thusly. As described in the background, some systems unload the blood from the left ventricle, circulate to an extracorporeal pump and recirculate it to yet another cannula inserted through the wall of the aorta with the problems described above.

A. Apex-to-Aorta Cannula Assembly

FIG. **2** is a diagram of a cannula assembly that can be inserted through the apex into the left ventricle and through the aortic valve directly into the aorta. In general, the insertion is made through a single incision without the need for another cannula inserted through the aorta wall. The present invention provides a cannula assembly **50** that generally includes two primary components to form a double wall cannula assembly: an outer cannula **52** and an inner cannula **54** coupled to the outer cannula. In at least one embodiment, the inner cannula is slidably coupled to the outer cannula.

The outer cannula **52** includes a larger portion **78** that is larger than the inner cannula **54** to form an annulus **64** therebetween. An upper portion of the outer cannula **52** forms a lumen **56**. The lumen **56** is sized to fit closely to an upper portion of the inner cannula **54**. The inner cannula forms a lumen **86** as a blood flow path for returning the blood to the body through the aortic valve into the aorta as described herein. The inner cannula **54** includes a portion herein termed a tip **58** that is sufficiently long to be inserted through the aortic valve **30** above the left ventricle **28** toward the aorta. A transition portion is formed in the outer cannula **52** between the lumen **56** and the larger portion **78**. In one embodiment, the transition portion can be a cone **76**. The cone **76** includes one or more ports **62** that are fluidicly coupled to the annulus **64**. Other locations of the ports **62** can be formed in the outer cannula **52**. For example, one or more ports **62** can be located toward a lower portion of the outer cannula to provide the ability to withdraw blood from a position closer to the apex **36**. Alternatively, the ports **62** in the cone **76** or at other locations can be located closer to the apex **36** by locating the outer cannula **52** at a different position relative to the heart **2** and the apex **36**. Further, ports can also be formed in the tip **58** above the aortic valve **30**. In general, the blood flow path is generally designed to reduce stagnant areas of blood flow and lower the risk of thrombosis.

The outer cannula **52** includes an outlet **66** that is coupled to a tubing **69**. The outlet can form a "tail" portion as a side outlet, with the understanding that various angles can be used without limitation. The tubing **69** can be coupled to a pump **68** and an optional oxygenator **70**. The outlet of the pump **68** (and/or oxygenator **70**) is coupled to a return tubing **71**. The return tubing **71** is coupled to an inlet **72** of the inner cannula **54**.

A securing plate **84** can be coupled to the outer cannula **52**. The securing plate can be used to suture the cannula assembly **50** to heart to maintain a fixed location of the cannula assembly.

In operation, a small incision **48** is made in the region of the apex **36** through the heart tissue **38** of the heart **2**. The outer cannula lumen **56** is inserted into the incision **48**. The transition piece, such as the cone **76**, can then expand the incision **48** to allow the larger portion **78** of the cannula assembly to be inserted into the left ventricle. The lumen **86** of the inner cannula **54** can be slidably coupled with the outer cannula **52**, so that the tip **58** can be advanced through the left ventricle cavity and through the aortic valve **30**. The tip **58** can include an introducer **59** to assist in smoothly engaging the aortic valve **30**. The outlet **56** of the outer cannula **52** can be coupled to the pump **68** and possibly an oxygenator **70**, where one or both of the instruments can be located percutaneously or extracorporeally.

In another embodiment, the inner cannula **54** can already be position in an extended mode in the outer cannula **52** and sealingly coupled to the outer cannula **52**. Thus, upon insertion of the cannula assembly **50** through the incision **48**, the tip **58**, and any introducer **59** included therewith, first enters the incision **48** followed by the lumen **56**, the cone **76**, and the larger portion **78**. As the outer cannula is advanced and then seated, the inner cannula **54** is also advanced through the aortic valve **30** into the aorta.

Blood entering the left ventricle **28** readily flows into the annulus **64** through the ports **62** of the outer cannula **52** separate from flow through the inner cannula. The blood then flows out of the cannula outlet **66** through the tubing **69**, pump **68**, optional oxygenator **70**, tubing **71**, and into the inlet **72** of the inner cannula **54**. The blood then flows directly through the aortic valve **30** into the aorta (not shown) through the outlet **74** of the inner cannula **54**.

The incision **48** in the left ventricle is generally aligned with the aortic valve **30** so that the lumen **86** can be readily inserted therethrough. This incision is in an area of the heart **2** that is generally used to unload from the left ventricle during cardiac surgery. Thus, it is believed that many physicians will readily adapt to the disclosed concept upon understanding the present invention. The readily available placement of the cannula assembly can reduce cost in providing assistant devices as well as provide less trauma to the patient by providing a single insertion, because the cannula assembly can extract and inject blood through only one incision. It is believed that the location of the single insertion, coupled with the unloading of the left ventricle, allows for the left ventricle to either not contract at all or to contract at a much lower contraction pressure that reduces ischemia or circulatory instability. Further, the more relaxed state of the left ventricle will allow it to more readily restore with time if indeed restoration is possible. Still further, an external cannula assembly, typical with prior art, is unnecessary with the present invention. Thus, the risk of post-operative thrombosis and need for corrective surgery due to post-operative bleeding is reduced.

FIGS. **3**A-**3**C illustrate various details of the inner cannula and outer cannula in disassembled form for at least one embodiment.

FIG. **3**A illustrates a cross sectional schematic of the inner cannula. The inner cannula **54** forms a lumen **86** having an inlet **72** and an outlet **74**. A circumferential seal **82**, such as a seal formed of silicone or other sealing material known to those with ordinary skill in the art, is disposed on the inner cannula **54**, on the outer cannula **52**, or both. The seal **82** is used to sealingly engage an opening in the outer cannula **52** described herein. An introducer **59**, shown in FIG. **2**, can be coupled to the tip **58** of the inner cannula **54** to assist in engaging the aortic valve **30**, and potentially the incision **48**, if inserted first.

FIG. **3**B illustrates a cross sectional schematic of the outer cannula. The outer cannula **52** includes a lumen **56** sized to approximate the outer periphery of the inner cannula **54**. The relative close dimensions can reduce blood flow therebetween. A transition piece, such as cone **76**, can transition from the cross-sectional area of the lumen **56** to a larger portion **78**

of the outer cannula **52**. In at least one embodiment, the cone **76** includes one or more ports **62** through which the blood can enter the outer cannula **52**. An outlet **66** is fluidicly disposed opposite the port **62** and the lumen **56**. The outer cannula **52** also includes an opening **80** sized to accept the inner cannula **54** and to form a seal therewith in conjunction with the seal **82** when assembled.

The outer cannula **52** can also include a securing plate **84**. The securing plate **84** can be used to secure the cannula assembly **50** to the cardiac tissues, such as shown in FIG. **2**.

FIG. **3**C illustrates a cross sectional schematic of an upper portion of the outer cannula **52**. The outer cannula **52** includes the lumen **56**, a transition cone **76** having one or more ports **62** that is coupled to a larger portion **78**. Further, the angle of the transition piece and its associated length can vary in accordance with the desired flow rates, and flow locations, to avoid thrombosis and other deteriorating factors. The number of ports **62** can vary depending on the particular application, the rate of flow, size of an annulus between the outer cannula **52** and inner cannula **54**, and other factors. Further, various physiological factors can be considered in sizing the ports, annulus, as well as the pump, tubing sizes, outlets, and other flow channels. Such factors include without limitation, the avoidance or reduction of hemolysis, that is, the destruction of the red corpuscles due to disadvantageous flow rates. Flow should be sufficient so as to induce high shear forces at the surfaces, yet not create turbulence or vortices that will occasion clotting and thrombus formation. Flows are generally in the 3-5 liters/min. range, although other flow rates are possible.

FIGS. **4**A-**4**E will be described in conjunction with one another, and are included to show various cross-sectional details of the cannula assembly.

FIG. **4**A illustrates the cannula assembly in an assembled state. The cannula assembly **50** includes the outer cannula **52** and the inner cannula **54**. In at least one embodiment, the inner cannula **54** is assembled with the outer cannula **52** through an opening **80**. The opening **80** can be sealed with a seal **82**. The seal **82** is disposed around the periphery of the inner cannula **54**, or alternatively, around the opening **80**, or a combination thereof. In at least one embodiment, the seal **82** can be formed at an angle to form a transitional sealing surface. If a surgeon wishes to advance the inner cannula **54** into the aortic valve shown in FIG. **2**, after the insertion of the outer cannula **52** in the ventricle, then the seal **82** can be advanced into a sealing position upon proper placement of the inner cannula **54**. A securing plate **84** can be coupled at some location on the outer cannula **52** to help attach the cannula assembly **50** to the cardiac tissues. Further, an upper portion **90** of the outlet of the outer cannula **52** can be coupled with a lower portion **92** of the outlet of the outer cannula **52** for manufacturing convenience. The upper portion **90** coupled with the lower portion **92** can form an outlet **66** in the shape of a "tail" of the outer cannula to assist in coupled the tubing **69** thereto. In at least one embodiment, the tail can extend in a sideways direction from the longitudinal axis of the inner cannula, although other angles can be used. Alternatively, the outlet **66** can be formed and attached to the outer cannula by forming an opening in the side of the larger portion **78** and sealingly coupling the tail thereto.

FIG. **4**B illustrates a cross sectional schematic at an interface of the outer cannula and inner cannula. The lumen **56** on the outer cannula **52** is shown in close proximity to the outer periphery of the inner cannula **54**. The close proximity minimizes blood flow by-pass between the lumen **56** and the inner cannula **54**.

FIG. **4**C illustrates a cross sectional schematic of the flow area between the outer cannula and the inner cannula. The change in relative cross sections is shown between the inner periphery of the larger portion **78** of the outer cannula **52** compared to the outer periphery of the inner cannula **54** to create the annulus **64**. The annulus **64** is generally sized to permit high blood flow with low resistance. This sizing can help protect red blood cells from hemolysis.

FIG. **4**D illustrates a cross sectional schematic of a securing plate coupled to the outer cannula. The securing plate **84** is generally coupled to an outer periphery of the larger portion **78** of the outer cannula **52**. The securing plate **84** can include one or more suture holes **88** that allow a surgeon to couple the securing plate and associated cannula assembly **50** to tissue, such as cardiac tissue. A top portion **90** of the outer cannula **52** outlet is also shown in FIG. **4**D. The tail forming the outer cannula outlet **66** can have a variety of shapes as is customary to the art. In other embodiments, the outlet **66** can simply be inserted directly into the larger portion **78** of the outer cannula **52**, such as a circular member inserted through the sidewall of the outer of the larger portion **78**.

FIG. **4**E illustrates a cross sectional schematic of the cannula assembly where the inner cannula is inserted into the outer cannula to form the double wall cannula assembly. The seal **82** engages and seals the opening **80** in the outer cannula **52** with the inner cannula **54** inserted therethrough.

Various basics of the invention have been explained herein. The various techniques and devices disclosed represent a portion of that which those skilled in the art would readily understand from the teachings of this application. Details for the implementation thereof can be added by those with ordinary skill in the art. Such details may be added to the disclosure in another application based on this provisional application and it is believed that the inclusion of such details does not add new subject matter to the application. The accompanying figures may contain additional information not specifically discussed in the text and such information may be described in a later application without adding new subject matter. Additionally, various combinations and permutations of all elements or applications can be created and presented. All can be done to optimize performance in a specific application.

The various steps described herein can be combined with other steps, can occur in a variety of sequences unless otherwise specifically limited, various steps can be interlineated with the stated steps, and the stated steps can be split into multiple steps. Unless the context requires otherwise, the word "comprise" or variations such as "comprises" or "comprising" or the word "includes" and variations, should be understood to imply the inclusion of at least the stated element or step or group of elements or steps or equivalents thereof, and not the exclusion of any other element or step or group of elements or steps or equivalents thereof.

Further, any documents to which reference is made in the application for this patent as well as all references listed in any list of references filed with the application are hereby incorporated by reference. However, to the extent statements might be considered inconsistent with the patenting of this invention such statements are expressly not to be considered as made by the applicant(s).

Also, any directions such as "top," "bottom," "left," "right," "upper," "lower," and other directions and orientations are described herein for clarity in reference to the figures and are not to be limiting of the actual device or system or use of the device or system. The device or system may be used in a number of directions and orientations.

The invention claimed is:

1. A method of withdrawing blood from a heart of a body, the heart having an apex in proximity to a left ventricle and an aortic valve fluidicly disposed between the left ventricle and an aorta, the aorta providing a distribution of blood to the body, comprising:

a. obtaining a cannula assembly having an outer cannula and an inner cannula, the outer cannula having a transition portion from a first introductory inner perimeter of the outer cannula to a second inner perimeter of the outer cannula, the first introductory inner perimeter being sized in proximity to an outer perimeter of the inner cannula and the second inner perimeter being sized larger than the first introductory inner perimeter, the second inner perimeter forming an annulus around a length of the inner cannula to establish a flow path through the annulus fluidicly separate from a flow path through the inner cannula, the transition portion having a port to allow blood flow into the annulus;

b. creating an incision in proximity of the apex of the heart;

c. inserting the cannula assembly through the incision and into the left ventricle of the heart, at least a portion of the outer cannula comprising the transition portion and at least a portion of the annulus being disposed in the left ventricle and fluidicly coupled to the left ventricle;

d. inserting a portion of the inner cannula through the aortic valve of the heart; and

e. allowing blood to be withdrawn from the left ventricle into the port and through the annulus to an outlet of the outer cannula to establish a downstream direction in the annulus flow path along the length of the inner cannula disposed inside the outer cannula while restricting blood flow downstream of the transition portion within the heart along the annulus flow path from external to the outer cannula into the annulus, wherein a portion of the outer cannula downstream of the transition portion is disposed within the heart.

2. The method of claim 1, further comprising discharging blood into the aorta through the inner cannula.

3. The method of claim 1, further comprising reducing a contracting pressure of the left ventricle by allowing the blood to be withdrawn.

4. The method of claim 1, wherein inserting the portion of the inner cannula comprises sliding the inner cannula relative to the outer cannula.

5. The method of claim 1, further comprising pumping the blood through a pump and an oxygenator fluidicly coupled between the first cannula and the second cannula.

6. The method of claim 1, further comprising extending an introducer coupled to the inner cannula initially through the aortic valve to reduce a risk of damage to the aortic valve.

7. The method of claim 1, further comprising securing the cannula assembly with a securing plate to the heart.

8. The method of claim 1, wherein creating the incision comprises creating the incision in relative alignment with the aortic valve.

9. A system for withdrawing blood from a heart of a body, the heart having an apex in proximity to a left ventricle and an aortic valve fluidicly disposed between the left ventricle and an aorta, the aorta providing a distribution of blood to the body, the system comprising a cannula assembly comprising:

a. an inner cannula having an outer perimeter disposed inside an inner perimeter of an outer cannula, and having an introducer adapted to be introduced through the heart apex and extended through the aortic valve; and

b. an outer cannula disposed around a length of the inner cannula and having a transition portion disposed toward a portion of the cannula assembly adapted to be introduced through an incision in the apex of the heart, the transition portion having an introductory inner perimeter being sized in proximity to an outer perimeter of the inner cannula to reduce blood flow therebetween, the transition portion further having a second inner perimeter larger than the first introductory inner perimeter and distal from the portion to be introduced through the incision, the second inner perimeter of the outer cannula forming an annulus around the inner cannula to establish a flow path through the annulus fluidicly separate from a flow path through the inner cannula, the transition portion of the outer cannula having at least one port to allow blood to be withdrawn from the left ventricle to flow into the port and through the annulus to an outlet of the outer cannula to establish a downstream direction in the annulus flow path, and the outer cannula being further adapted to restrict blood flow downstream of the transition portion within the heart along the annulus flow path from external to the outer cannula into the annulus, wherein a portion of the outer cannula downstream of the transition portion is disposed within the heart.

10. The system of claim 9, further comprising a pump for circulating the blood, a first conduit coupled from an outlet of the outer cannula to the pump, and a second conduit coupled from the pump to the inner cannula.

11. The system of claim 9, further comprising an oxygenator coupled to the pump.

12. The system of claim 9, further comprising a securing plate coupled to the cannula assembly and adapted to secure the cannula assembly to the heart.

13. The system of claim 9, wherein inner cannula is a separate component from the outer cannula and is coupled to the outer cannula through an opening in the outer cannula.

14. A system for withdrawing blood from a body, the system comprising a cannula assembly comprising:

a. an inner cannula having an outer perimeter disposed inside an inner perimeter of an outer cannula, and having an introducer adapted to be introduced into a blood flow path of the body; and

b. an outer cannula disposed around a length of the inner cannula and having a transition portion disposed toward a portion of the cannula assembly adapted to be at least partially inserted into the body, the transition portion having an introductory inner perimeter being sized in proximity to an outer perimeter of the inner cannula to reduce blood flow therebetween, the transition portion further having a second inner perimeter sized larger than the first introductory inner perimeter and distal from the portion to be inserted into the body, the second inner perimeter of the outer cannula forming an annulus around the inner cannula to establish a flow path through the annulus fluidicly separate from a flow path through the inner cannula, the transition portion having at least one port to allow blood to be withdrawn from the blood flow path to flow into the port and through the annulus to an outlet of the outer cannula to establish a downstream direction in the annulus flow path, and the outer cannula being further adapted to restrict blood flow downstream of the transition portion within the heart along the annulus flow path from external to the outer cannula into the annulus, wherein a portion of the outer cannula downstream of the transition portion is disposed within the blood flow path.

15. The system of claim 14, wherein the inner cannula is slidably disposed in the outer cannula.

16. The system of claim 14, wherein the inner cannula is coupled to the outer cannula through an opening in the outer cannula and sealed therewith.

17. The system of claim 14, further comprising a pump for circulating the blood, a first conduit coupled from the outlet of the outer cannula to the pump, and a second conduit coupled from the pump to the inner cannula.

18. The system of claim 17, further comprising an oxygenator coupled to the pump.

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