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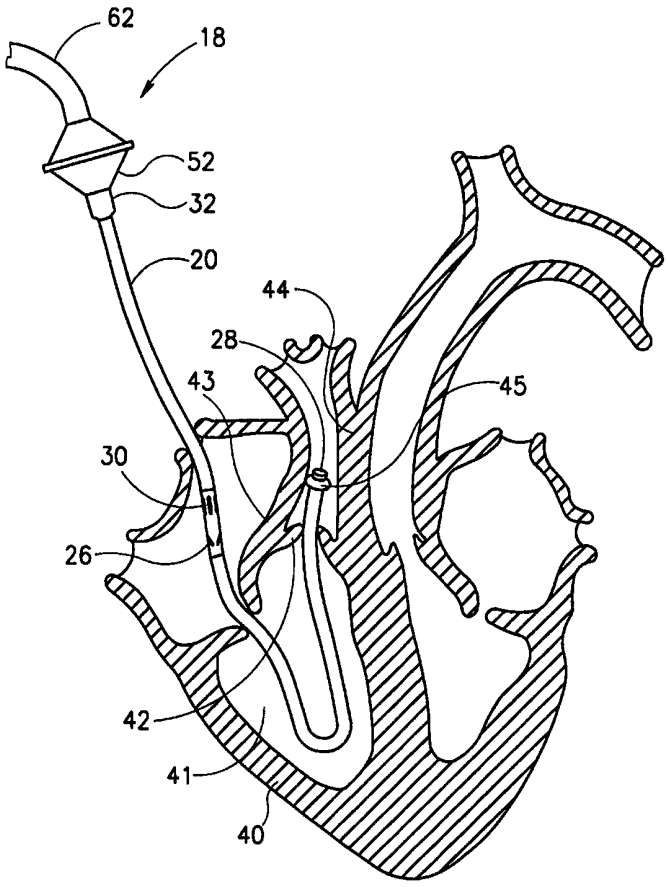
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(57) Abstract

A heart assistance pump system comprising a cannula having a distal end, an intake valve associated with the cannula, an outlet valve associated with the cannula, and an extensible protrusion, such as an inflatable balloon, adjacent the distal end of the cannula. Alternatively, a heart assist pump system comprising a cannula having a distal end and including an intake valve and an outlet valve and a guide, having a distal end, for guiding the cannula, the guide comprising an extensible protrusion, such as an inflatable balloon, adjacent the distal end of the guide. Alternatively or additionally, the pump is suitable for pumping blood directly from an atrium such as the right atrium or a vein associated with the atrium, such as the vena cava, to an artery associated with the same side of the heart as the atrium, such as the pulmonary artery.



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HEART ASSIST SYSTEM WITH CANNULA PUMP

FIELD OF THE INVENTION

The present invention relates generally to devices and systems for augmenting cardiac output, and specifically to intra-ventricular cardiac assist pumps.

BACKGROUND OF THE INVENTION

Intra-aortic and intra-ventricular cardiac assist devices are well known in the art. These devices are generally used to reduce the heart's work load after or during insult or surgery. They may also be used to increase blood flow from the left ventricle of the heart into the aorta in cases of insufficient cardiac output due, for example, to acute or chronic heart ailments or to interference with normal cardiac function during surgery.

One of the best-known and most widely-used intra-aortic pump systems is the Intra-Aortic Balloon Pump (IABP), comprising a catheter, having an inflatable balloon at its distal end, which is inserted through an artery into the aorta. The balloon is then alternately inflated and deflated by an external pump drive, so as to alternately block and unblock blood flow through the aorta, in synchrony with the beating of the heart, in order to assist the left ventricle in propelling blood into the arterial system. The IABP, however, provides only limited augmentation of the heart's natural, unassisted output, and is not adequate for overcoming heart failure.

U.S. patent 4,014,317, which is incorporated herein by reference, describes a cardiocirculatory assist cannula with a balloon pump and cardiac pacing electrode. The cannula is inserted percutaneously via the aorta so that its distal end is inside the left ventricle of the heart. During systole, inlet valves on the cannula inside the left ventricle open, and the contraction of the ventricle forces blood to flow into the cannula. Then, during diastole, the blood flows out, into the aorta, through one or more outlet valves along the cannula downstream from the inlet valve. A gas-filled balloon, similar in function to the IABP described above, is connected to the cannula downstream of the outlet valves. The balloon is typically inflated during diastole and deflated during systole, to assist in perfusion of the coronary arteries. The cannula has a small stroke volume, however, and relies on the contractile force of the heart to pump the blood. It is therefore of limited usefulness in augmenting the blood output of a weakened or failing heart.

PCT publication WO97/02850, the disclosure of which is incorporated herein by reference, describes a heart assist system based on a catheter system in which the distal end of the cannula is inserted into the left ventricle via the aorta. An intake valve draws blood from

the ventricle and an outlet valve delivers blood to the aorta. A hydraulic pump mechanism external to the body, at the proximal end of the catheter, acts as a pump and reservoir for blood drawn from the ventricle. However, this system, while it is useful for the alleviation of heart insufficiency in a wide range of problems, suffers from the limitation that the diameter of the catheter is limited by the arterial path the catheter must travel on its way to the ventricle. Furthermore, the catheter is inserted against the direction of the leaves in the aortic valve, which may sometimes be problematical.

In PCT application PCT/IL97/00201, the disclosure of which is incorporated by reference, a cannula valve was described in which the inlet and output valves are formed in a unit which is situated between two tubular sections of a cannula.

In the Hemopump Cardiac Assist System, distributed by Johnson & Johnson Interventional Systems, a cannula containing a special, miniature rotor pump mechanism is inserted into the aorta. The pump is driven by a drive unit outside the body, to pump blood continuously from the aorta into the rest of the arterial system, thereby supplementing the heart's natural output rate. A system of this type is similarly described in U.S. patent 5,092,844, which is incorporated herein by reference. While continuous-flow devices are useful for short-term augmentation of cardiac output, however, it is medically known that pulsatile pumps provide more effective long-term support, since they approximate more closely the natural pump action of the heart.

All of the above references relate to pumps for augmenting flow of blood from the left side of the heart.

Catheters which utilize a balloon to aid in the movement of a catheter in a stream of blood. However, such balloon aided movement is not used with pumping systems at least partly because cannulas used in such systems are generally inserted in a direction opposite to the flow of blood.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a cardiac assist pump for improving blood flow from the heart.

In a first aspect of the invention, a heart assist pump is utilized to pump blood into the pulmonary artery. In some preferred embodiments of the invention, the pump pumps the blood directly from the vena cava. In some aspects of the invention, the pump pumps blood directly from the right atrium. In some aspects of the invention, the pump pumps blood from the right ventricle.

In a second aspect of the invention, a heart assist system is provided in which the cannula is inserted into the pulmonary artery from the right ventricle. Preferably the cannula enters the body via the jugular vein, the femoral vein and/or the vena cava and therefrom to the right ventricle. Such systems are especially useful where the heart is manipulated during bypass surgery.

In a third aspect of the present invention, wherein the pump comprises a cannula, one-way valve structures are provided in the sides of the cannula so as to reliably control the alternate inflow and outflow of blood therefrom.

In a fourth aspect of the invention, a cannula pump with an attached extensible protrusion, such as a balloon, is provided. The pump is designed to blood between one position thereon and another position thereon and the balloon structure is so constructed that it provides sufficient impediment to blood flow that the tip of the cannula is guided or carried in the direction of the flow.

In preferred embodiments of the present invention, an intraventricular cardiac assist pump comprises a cannula, whose distal end is inserted, preferably through via the vena cava and the right ventricle, into the pulmonary artery. It also comprises a pulsatile drive unit, coupled to the cannula at the proximal end thereof. The cannula comprises an outer sheath, defining and enclosing an internal lumen, having at least one output valve, adjacent to and preferably communicating with the cannula's distal end, and one or more intake valves, disposed radially along the length of the cannula, downstream from the intake valve. The pulsatile drive unit alternately reduces and increases blood pressure in the cannula. When the pressure is reduced, the at least one intake valve opens, while the one or more outlet valves are closed, and blood flows through the intake valve into the lumen of the cannula. The pressure in the cannula is then increased, causing the intake valves to close and the outlet valve to open, so that blood flows out of the lumen into the pulmonary artery. Cannula of generally similar structure may also be used to provide pumping from the left ventricle to the aorta, with the cannula being inserted via the apex of the left ventricle.

In preferred embodiment of the present invention, a balloon is attached at or near the distal end of the cannula. This balloon is inflated during placement of the cannula. In the inflated configuration, the balloon presents a resistance to the blood flow and is thus carried along by the flowing blood. This helps to guide the end of the cannula through curves in the right atrium and ventricle and into the pulmonary artery. Similarly, the balloon may be used to

aid in the placement of the cannula tip in the aorta when the cannula is inserted from the left ventricle into the aorta.

Since the cannula is inserted into the pulmonary artery via the vena cava and right ventricle, the cannula may be very large in diameter in comparison with prior art heart assist devices, especially if it enters the blood stream via the main vena cava. The assist pump differs from published prior art cannula pumps in that the outlet valve is at or communicates with the distal end of the cannula and the intake valve is proximal to the outlet valve. Furthermore, the output valve may be (and preferably is) coaxial with the cannula such that the output from the valve is unobstructed by the walls of the artery into which the blood is pumped. This allows for higher pressure and flow to be applied to the vascular system than in assist devices of the prior art. Furthermore, while the intake valves are generally on the sides of the cannula, the valve is in the vena cava or right ventricle and the intake valves are substantially unobstructed. Since the path through the ventricle includes many curves, the cannula may have a different diameter at the intake and outlet portions. The intake portion of the catheter is preferably of a large diameter to enable high flow rates which are normally limited by suction pressure and cavitation. The distal portion of the cannula is preferably thinner and more flexible to aid in guidance of the cannula.

In some preferred embodiments of the present invention, the pulsatile drive unit includes a fluid reservoir, comprising first and second chambers, separated by a flexible diaphragm, each chamber having a fluid port. The fluid port of the first chamber is connected to the proximal end of the cannula, so that blood may flow between the chamber and the cannula. The fluid port of the second chamber is connected to a hydraulic mechanism, which alternately increases and decreases the pressure, and hence the volume, of a control fluid in the second chamber. The flexible diaphragm couples pressure changes from the second to the first chamber, without direct contact between the fluid in the second chamber and the blood in the first chamber, thereby controlling the flow of blood into and out of the lumen of the cannula, as described above. Such pumps are described, for example, in the aforementioned PCT publication. The use of the hydraulic mechanism enables substantially greater volumes of blood to be pumped, with greater efficiency, than pneumatic pump drive mechanisms that are commonly used in other cardiac assist pumps known in the art. However, the invention is not limited to such pumps and other pumping systems, as known in the art, may be advantageously be a utilized in the present invention.

It will be appreciated that in preferred embodiments of the present invention, as described above, the blood being pumped remains entirely inside the cannula and in the first chamber of the fluid reservoir connected thereto, without circulating substantially outside the body. Preferably, the cannula and fluid reservoir are disposable, intended for a single use, so as to reduce the likelihood of infection.

In preferred embodiments of the present invention, the cannula is capable of pumping at least 50 cc, and preferably up to 80 cc of blood, in each stroke of the pulsatile drive unit. It will be appreciated, however, that depending on clinical requirements, the cardiac assist pump may be adjusted to pump a smaller volume in each stroke, for example 20 cc. The pulsatile drive unit is preferably operated substantially at the rate of the human heart beat, and the rate and volume are adjusted so that adequate flow is maintained. The drive is preferably synchronized with the heart beat, so as to draw blood into the lumen of the cannula during systole and eject the blood into the artery during diastole.

Alternatively, the drive may be counter-synchronized, so as to draw blood into the lumen during diastole and eject it during systole, or the drive may be operated asynchronously, independent of the heart beat.

In preferred embodiments of the present invention, the cannula comprises a flexible, resilient tube having a diameter in the range of 15-45 French (5-15 mm) or even larger. It is preferably inserted from the vena cava during surgery or percutaneously from the jugular or femoral veins through the right atrium into the right ventricle and then through the pulmonary valve into the pulmonary artery.

In some preferred embodiments of the present invention, the intake valve and outlet valve are comprised in a valve unit constructed of a rigid external tube with radial holes and a flexible internal structure. The internal flexible structure includes flexible leaflet type outlet valve and a cylindrical sleeve which covers the holes from inside the tube forming an intake valve.

Preferably, a fluid reservoir, having a variable fluid volume, is connected to the proximal end of the cannula, such that blood may flow between the lumen and the reservoir and a pump drive coupled to the fluid reservoir and controlling the fluid volume in said reservoir is provided such that the pump mechanism alternately increases and decreases the fluid volume in the reservoir to produce a pulsatile pumping action of blood through the cannula.

There is thus provided, in accordance with a preferred embodiment of the invention, a heart assistance pump system comprising:

a cannula having a distal end;

an intake valve associated with the cannula;

an outlet valve associated with the cannula; and

an extensible protrusion, such as an inflatable balloon, adjacent the distal end of the cannula.

There is further provided, in accordance with a preferred embodiment of the invention, a heart assist pump system comprising:

a cannula having a distal end and including:

an intake valve; and

an outlet valve; and

a guide, having a distal end, for guiding the cannula, the guide comprising:

an extensible protrusion, such as an inflatable balloon, adjacent the distal end of the guide.

There is further provided, in accordance with a preferred embodiment of the invention, a heart assistance pump system comprising:

a cannula having a distal end;

an intake valve, having an inlet from the circulatory system, associated with the cannula; and

an outlet valve, having an outlet to the circulatory system, associated with the cannula;

wherein the distance between the inlet and outlet is such that when the cannula is placed in the right side of the heart the outlet is in the pulmonary artery and the inlet is in the right atrium or the vena cava.

There is further provided, in accordance with a preferred embodiment of the invention, a heart assistance pump system for pumping blood from an atrium of the heart or a vein associated with the atrium to an artery exiting a ventricle on the same side of the heart as the atrium, comprising:

a cannula having a distal end;

an intake valve associated with the cannula; and

an outlet valve associated with the cannula.

In a preferred embodiment of the invention, the atrium is the right atrium and the pump is configured to pump blood from the right atrium to the pulmonary artery.

In an alternative preferred embodiment of the invention the atrium is the right atrium and the pump is configured to pump blood from the vena cava to the pulmonary artery.

In another preferred alternative of the invention, the atrium is the left atrium and the pump is configured to pump blood from the left atrium to the aorta.

In a preferred embodiment of the invention, the outlet valve communicates with an opening at or adjacent to the distal end of the cannula and the intake valve communicates with an opening proximate to the opening with which the outlet valve communicates.

Preferably, the outlet valve is an axial valve communicating with an opening at the distal end of the cannula.

Preferably, the outlet valve is a leaflet valve having a plurality of leaves.

Preferably, the intake valve comprises a valve through which blood enters the cannula via orifices in a wall of the cannula. Preferably, the orifices are formed in a portion of the cannula which has a cylindrical inner wall and the said inlet valve comprises an inner flexible tube. Preferably, the inner flexible tube closes the orifices in the absence of a pressure differential. Preferably, the inner flexible tube is moved away from the orifices by negative internal pressure relative to the outside of the cannula, uncovering the orifices. Preferably, the inner flexible tube is integrally formed with the outlet valve.

Preferably, the cannula has a substantially greater diameter at the intake valves than at the distal end thereof.

There is further provided, in accordance with a preferred embodiment of the invention, a method of augmenting the blood flow from an atrium of a heart or a vein leading into the atrium to an artery exiting an associated ventricle of the heart, the method comprising:

inserting a cannula having a distal end and a proximal end, into the heart and the artery such that the distal end of the cannula is in the artery and a more proximal portion of the cannula is in the atrium or vein; and

transferring blood from the atrium or vein to the artery via a lumen of the cannula.

Preferably, the method comprises providing an intake valve communicating with an opening in the cannula proximate to the distal end of the cannula.

Preferably, the method comprises providing an outlet valve communicating with an opening at the distal end of the cannula. Preferably, providing an outlet valve comprises providing an axial outlet valve communicating with an opening at the distal end of the cannula.

In a preferred embodiment of the invention, the method providing an outlet valve communicating with an opening in the cannula distal to the opening with which the intake valve communicates.

Preferably, transferring blood comprises drawing blood from the atrium or vein, through the intake valve by reducing the pressure within the cannula and ejecting blood from the cannula through the outlet valve into the artery by increasing the pressure in the cannula.

Preferably, inserting a cannula into the heart and artery comprises inserting the cannula via a heart valve from the ventricle into the artery. Preferably, the method comprises guiding the cannula through the ventricle to the artery. Preferably, guiding comprises:

providing an extensible protrusion, such as a balloon, adjacent the distal end of the cannula;

extending the extensible protrusion, as by inflating the balloon; and

allowing the cannula to advance at least partially under the influence of the effect of the blood flow on the extended protrusion.

In a preferred embodiment of the invention, the atrium is the right atrium and the artery is the pulmonary artery. Preferably, blood is transferred directly from the right atrium to the pulmonary artery via the cannula.

In a preferred embodiment of the invention, the vein is the vena cava and the artery is the pulmonary ventricle. Preferably, blood is transferred directly from the vena cava to the pulmonary artery via the cannula.

In a preferred embodiment of the invention, the atrium is the left atrium and the artery is the aorta. Preferably, blood is transferred directly from left right atrium to the aorta via the cannula.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be more clearly understood with reference to the following detailed description of non-limiting preferred embodiments of the invention in which:

Fig. 1 is a schematic, sectional representation of a cardiac assist pump, in accordance with a preferred embodiment of the present invention;

Fig. 2 is a schematic representation of a cannula in accordance with a preferred embodiment of the present invention, illustrating the insertion of the cannula into the heart;

Fig. 3A is a sectional representation of a valve assembly in accordance with a preferred embodiment of the present invention, including intake and outlet valves, shown in a first configuration in which the intake valves are closed and the outlet valve is open;

Fig. 3B is a sectional representation of the valve assembly of Fig. 3A shown in a second configuration in which the intake valves are open and the outlet valve is closed;

Fig. 3C is a sectional representation of an alternative valve assembly in accordance with a preferred embodiment of the invention; and

Fig. 3D is a sectional representation of further alternative valve assembly in accordance with a preferred embodiment of the invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Reference is now made to Fig. 1, which is a schematic, sectional representation of a cardiac assist pump system 18, in accordance with a preferred embodiment of the present invention. The system comprises an intra-aortic cannula 20, having an outer sheath 22, which defines and encloses an inner lumen 24. Preferably cannula 20 has a diameter in the range of 15-45 French (5-15 mm) and is made of flexible, resilient material, for example, polyurethane reinforced with stainless steel wire, so that it may be inserted into and passed through major veins of the human body. This size may be reduced when the cannula is inserted via smaller veins. Cannula 20 further includes an outlet valve 26, preferably a leaflet valve and preferably axially disposed, connected to an outlet at or near its distal end 28, and one or more intake valves 30, radially disposed along sheath 22 of the cannula.

Outlet valve 26 and intake valves 30 are preferably one-way valves, so that blood may flow into and out of cannula 20 substantially only in a single direction: entering through intake valve 30 and exiting through outlet valve 26 (corresponding to the direction of blood flow in the body, as will be described below). In the preferred embodiment of the present invention shown in Fig. 1, the intake valves comprise mechanical flap valves, which rotate about hinges 36 to open and shut as desired.

Preferably, outlet valve 26 comprises a leaflet valve. However, in other preferred embodiments of the invention, it may comprise other types of valves such as valves similar to valves 30, but which open outwardly. Such leaflet valves are known in the art for use in heart-assist devices, as described, for example, in a PCT publication WO 97/41808, whose disclosure is incorporated herein by reference. Alternatively, valves described in PCT Application PCT/IL97/00386, entitled "Apex Cannula Pump," filed November 24, 1997, whose disclosure is incorporated herein by reference, may be used.

In other preferred embodiments of the present invention as, for example, will be described below, other types of intake valves may similarly be used.

In preferred embodiments of the present invention, cannula 20 incorporates an extensible protrusion, such as a balloon 45 situated at or near the distal end of the cannula. Balloon 45 is connected via a tube 46 to a source of air or other fluid (not shown) for inflating balloon 45. Balloon 45 is useful for guiding cannula 20, as described below.

Fig. 2 shows, schematically, the use of cannula 20 in a human heart 40. Preferably the cannula is inserted through the vena cava, the right atrium and the right ventricle 41 and passed downstream through pulmonary valve 42 into pulmonary artery 44. The length of cannula 20 is preferably approximately 120 cm, which is generally sufficient so that when distal tip 28 is positioned in pulmonary artery 44, proximal end 32 remains outside the body, adjacent to an incision in the jugular or femoral vein.

During insertion of the distal end of the cannula into the vena cava or jugular or the femoral veins, the distal end must pass through the right atrium and ventricle. Since control of the direction of the movement of the cannula is difficult in the open chest and impossible in the closed chest without a guiding system, balloon 45 is utilized to aid in positioning the distal end of cannula 20, in accordance with a preferred embodiment of the invention. Balloon 45 is designed to open outward, when filled with a gas, as closely as possible to the shape shown in Fig. 1. When the balloon has this shape, it has a high resistance to flow and thus is carried along with the blood flow. Thus, it will be carried along from the right atrium to the right ventricle and, most importantly, within the right ventricle through valve 42. This use of the blood flow to position a heart pump is believed to be unique and is based in part on the direction of insertion of the cannula which allows for the use of the blood flow in positioning the cannula. Alternatively, an extensible protrusion, such as balloon 45 may be attached to a guide wire along which the cannula is guided. In this embodiment of the invention, the extended protrusion aids in the positioning the guide wire and the guide wire is removed when the cannula is in place.

Once cannula 20 is in place, intake valves 30 are opened, and blood flows from the right atrium into lumen 24. Preferably outlet valve 26 is kept closed while the blood fills the lumen. Proximal end 32 may be temporarily opened, to vent out air or fluid that was inside cannula 20 before its insertion. Then intake valve 30 is closed and outlet valve 26 is opened, so that the blood may flow out of the lumen and into pulmonary artery 44. Alternatively, the inlet valve is placed in the right ventricle instead of in the right atrium.

In the preferred embodiment of the invention illustrated in Fig. 1, intake valves 30 and outlet valve 26 preferably open and shut in response to pressure exerted through pump system

18 to cannula 20, in the following manner. Proximal end 32 of cannula 20 is connected to a first chamber 50 of a fluid reservoir 52 through a first fluid port 54. Fluid reservoir 52 further includes a second chamber 56, which is separated from first chamber 50 by a flexible diaphragm 58. Diaphragm 58, which is preferably made of flexible polyurethane, deforms to alter the respective volumes of chambers 50 and 56, so as to substantially equalize the fluid pressures in the two chambers, but prevents mingling of the fluids in the first and second chambers.

Second chamber 56 preferably contains a substantially incompressible liquid, such as water or, alternatively, any other suitable fluid, such as normal saline solution. Chamber 56 is coupled via a second fluid port 60 through a tube 62 to a pump drive 64. A piston 66 in pump drive 64 moves alternately up and down to correspondingly increase and decrease the fluid pressure in reservoir 52, thereby pumping blood out of and into lumen 24.

It will be appreciated that the maximum volume of blood that may be pumped in a single stroke of piston 66 is roughly determined by the volume of reservoir 50. Preferably this maximum single stroke pumping volume is at least 50 cc, and more preferably up to 80 cc, although piston 66 may also be operated with a shorter stroke to pump a smaller volume of blood if desired. Preferably, the stroke is adjusted so that when pump drive 64 is operated at or about the heart's natural rate, sufficient blood can be pumped to perfuse substantially all of the person's body.

It will further be appreciated that blood may enter cannula 20 and flow into first chamber 50 only up to diaphragm 58. No blood flows through tubing 62 or into pump drive 64. Preferably, cannula 20 and reservoir 52 are disposable and made for single use only, to prevent transfer of infections and contamination.

Pump drive 64 is preferably driven by a servo mechanism 68, under the control of an computer 70, which regulates the rate and stroke volume of piston 66. Preferably, computer 70 receives physiological signal inputs, such as ECG and blood pressure signals, and uses these signals in optimally controlling pump drive 64, preferably to drive piston 66 at the rate of the heart beat.

Preferably, computer 70 further adjusts the delay of the piston stroke relative to the systolic stroke of the heart. This delay may be adjusted so that cannula 20 pumps blood out synchronously with the heart's systole; countersynchronously, during diastole; or at any suitable phase therebetween. Alternatively, the rate of piston 66 may be set to be independent

of the heart rate, for example in order to maintain steady perfusion during arrhythmia or fibrillation.

The assist pump of preferred embodiments of this aspect of the invention thus differs from pumps described in the public literature in that the outlet valve is at the distal end of the cannula and the intake valve is proximal to the distal end. Since the cannula is inserted into the pulmonary artery from the right ventricle, the cannula may have a very large diameter in comparison with prior art heart assist devices. Furthermore, the output valve may be coaxial with the cannula such that the output from the valve is unobstructed by the walls of the artery. This allows for higher pressure and flow to be applied to the vascular system than in assist devices of the prior art. Furthermore, while the intake valves are generally on the sides of the cannula, the valve is in the atrium or vena cava and the intake valves are substantially unobstructed. Since the path through the ventricle includes many curves, the cannula may have a different diameter at the intake and outlet portions. The intake portion of the catheter (placed in the atrium or vena cava) is preferably of a large diameter to enable high flow rates which are normally limited by suction pressure and cavitation. The distal portion of the cannula is preferably thinner and more flexible to aid in guidance of the cannula.

Furthermore, it is understood that the cannula pump of the invention must be designed and constructed for its intended use. For example, the distances between the inlet to the cannula via the inlet valve and the outlet from the cannula must be the correct distance for placement of the inlet and outlet in desired positions in the circulatory system.

Figs. 3A and 3B illustrate schematically construction of a combined intake and outlet valve 80, in accordance with a preferred embodiment of the invention. Valve unit 80 comprises a preferably rigid tube 82 made of a bio-compatible plastic material such as, for example, polycarbonate (Lexan) or metal (such as stainless steel) or other suitable bio-compatible material. Holes 86 are formed on sleeve 82.

An insert or inner part 81 is preferably formed of a flexible bio-compatible material such as, for example, polyurethane or silicone rubber of other suitable material. It preferably comprises an axial outlet leaflet valve 83 such as a bi- or tri-leaflet and a cylindrical intake valve section 84.

Section 84 is aligned with holes 86 such that section 84 and holes 86 comprise an intake valve. Attachment of inner part 81 to tube 82 is preferably by gluing the upper part of section 84 to tube 81 or by other means such as crimping.

Fig. 3A illustrates the valve configuration when pressure is applied to the valve unit such that blood is injected from the pump into the pulmonary artery. Leaflet valve 83 is open and section 84 is pressed against holes 86 closing them, such that no blood enters the pump from the atrium. This pressure is preferably aided by the unstressed shape of section 84 which acts to close holes 86.

Fig. 3B illustrates valve unit 80 during a suction period, in which blood is sucked from the vena cava or right atrium. In this configuration valve 83 is closed and segment 84 is forced by the suction into the lumen, such that blood can enter the lumen through holes 86 from the atrium.

Fig. 3C illustrates a portion of a cannula in which inlet valve 84 and outlet valve 83 are formed of separate pieces. Fig. 3D illustrates a cannula with multiple rows of inlet valves. The use of several rows of such valves results in better suction and in reduced sensitivity to placement of the valves in the vena cava or atrium.

Preferably, as described in PCT application PCT/IL96/00044, the disclosure of which is incorporated herein by reference, valve 83 is partially open in the absence of differential pressure and the closure of the valve as illustrated in Fig. 3B is the result of the suction of the pump.

It should be understood, that while the valves shown in Figs. 1 and 3 are preferred, other intake and outlet valves as known in the art may be used.

It should be understood that the present invention is described in conjunction with preferred embodiments thereof. Various combinations of the elements shown in the various embodiments, alternatively or additionally with other elements as known in the art or combinations having only some of the features or elements shown in the preferred embodiments may be used in certain alternative forms of the invention. It should be understood that the scope of the invention is thus defined by the following claims and not by the preferred embodiments described above.

CLAIMS

1. A heart assistance pump system comprising:

a cannula having a distal end;

an intake valve associated with the cannula;

an outlet valve associated with the cannula; and

a radially extensible protrusion adjacent the distal end of the cannula.

2. A heart assist pump system comprising:

a cannula having a distal end and including:

an intake valve; and

an outlet valve; and

a guide, having a distal end, for guiding the cannula, the guide comprising:

a radially extensible protrusion adjacent the distal end of the guide.

3. A heart assistance pump according to claim 1 or claim 2 wherein the extensible protrusion is an inflatable balloon.

4. A heart assistance pump system comprising:

a cannula having a distal end;

an intake valve, having an inlet from the circulatory system, associated with the cannula; and

an outlet valve, having an outlet to the circulatory system, associated with the cannula;

wherein the distance between the inlet and outlet is such that when the cannula is placed in the right side of the heart the outlet is in the pulmonary artery and the inlet is in the right atrium or the vena cava.

5. A heart assistance pump system for pumping blood from an atrium of the heart or a vein associated with the atrium to an artery exiting a ventricle on the same side of the heart as the atrium, comprising:

a cannula having a distal end;

an intake valve associated with the cannula; and

an outlet valve associated with the cannula.

6. A heart assist pump according to claim 5 wherein the atrium is the right atrium and the pump is configured to pump blood from the right atrium to the pulmonary artery.

7. A heart assist pump according to claim 5 wherein the atrium is the right atrium and the pump is configured to pump blood from the vena cava to the pulmonary artery.

8. A heart assist pump according to claim 5 wherein the atrium is the left atrium and the pump is configured to pump blood from the left atrium to the aorta.

9. A heart assist pump according to any of the preceding claims wherein the outlet valve communicates with an opening at or adjacent to the distal end of the cannula; and

the intake valve communicates with an opening proximate to the opening with which the outlet valve communicates.

10. A heart assist pump according to any of the preceding claims wherein the outlet valve is an axial valve communicating with an opening at the distal end of the cannula.

11. A heart assist pump according to any of the preceding claims wherein the outlet valve is a leaflet valve having a plurality of leaves.

12. A heart assist pump according to any of the preceding claims wherein the intake valve comprises a valve through which blood enters the cannula via orifices in a wall of the cannula.

13. A heart assist pump according to claim 12 wherein said orifices are formed in a portion of the cannula which has a cylindrical inner wall and wherein said inlet valve comprises an inner flexible tube.

14. A heart assist pump according to claim 13 wherein the inner flexible tube substantially closes the orifices in the absence of a pressure differential.

15. A heart assist pump according to claim 14 wherein the inner flexible tube is moved away from the orifices by negative internal pressure relative to the outside of the cannula, uncovering the orifices.

16. A heart assist pump according to any of claims 13-15 wherein the inner flexible tube is integrally formed with the outlet valve.

17. A heart assist pump according to any of the preceding claims wherein the cannula has a substantially greater diameter at the intake valves than at the distal end thereof.

18. A method of augmenting the blood flow from an atrium of a heart or a vein leading into the atrium to an artery exiting an associated ventricle of the heart, the method comprising:

inserting a cannula having a distal end and a proximal end, into the heart and the artery such that the distal end of the cannula is in the artery and a more proximal portion of the cannula is in the atrium or vein; and

transferring blood from the atrium or vein to the artery via a lumen of the cannula.

19. A method according to claim 18 and including:

providing an intake valve communicating with an opening in the cannula proximate to the distal end of the cannula.

20. A method according to claim 18 or claim 19 and including providing an outlet valve communicating with an opening at the distal end of the cannula.

21. A method according to claim 20 wherein providing an outlet valve comprises providing an axial outlet valve communicating with an opening at the distal end of the cannula.

22. A method according to any of claims 18-21 and including providing an outlet valve communicating with an opening in the cannula distal to the opening with which the intake valve communicates.

23. A method according to any of claims 18-22 wherein transferring blood comprises:

drawing blood from the atrium or vein, through the intake valve by reducing the pressure within the cannula; and

ejecting blood from the cannula through the outlet valve into the artery by increasing the pressure in the cannula.

24. A method according to any of claims 18-23 wherein inserting a cannula into the heart and artery comprises:

inserting the cannula via a heart valve from the ventricle into the artery.

25. A method according to claim 24 and including guiding the cannula through the ventricle to the artery.

26. A method according to claim 25 wherein guiding comprises:

providing an radially extensible protrusion adjacent the distal end of the cannula;

radially extending the protrusion; and

allowing the cannula to advance at least partially under the influence of the effect of the blood flow on the protrusion.

27. A method according to claim 26 wherein the protrusion is a balloon and extending the protrusion comprises inflating the balloon.

28. A method according to any of claims 18-27 wherein the atrium is the right atrium and the artery is a pulmonary artery.

29. A method according to claim 28 wherein blood is transferred directly from the right atrium to the pulmonary artery via the cannula.

30. A method according to any of claims 18-27 wherein the vein is the vena cava and the artery is the pulmonary ventricle.

31. A method according to claim 30 wherein blood is transferred directly from the vena cava to the pulmonary artery via the cannula.

32. A method according to any of claims 18-27 wherein the atrium is the left atrium and the artery is the aorta.

33. A method according to claim 32 wherein blood is transferred directly from left atrium to the aorta via the cannula.

AMENDED CLAIMS

[received by the International Bureau on 9 September 1998 (09.09.98); original claims 1-33 replaced by new claims 1-26 (4 pages)]

1. A heart assistance pump system configured for pumping blood from the vena cava of the heart to a pulmonary artery exiting the right ventricle comprising:

a cannula having a distal end;

an inlet from the circulatory system, associated with the cannula; and

an outlet to the circulatory system, associated with the cannula;

wherein the distance between the inlet and outlet is such that when the cannula is placed in the right side of the heart the outlet is in the pulmonary artery and the inlet is in the vena cava.

2. A heart assistance pump system configured for pumping blood from the left atrium of the heart to the aorta, comprising:

a cannula having a distal end;

an intake associated with the cannula; and

an outlet associated with the cannula;

wherein the distance between the inlet and outlet is such that when the cannula is placed in the left side of the heart the outlet is in the aorta the inlet is in the aorta.

3. A heart assistance pump according to claim 1 or claim 2 and including:

an inlet valve associated with the inlet; and

an outlet valve associated with the outlet.

4. A heart assistance pump system comprising:

a cannula having a distal end;

an intake valve associated with the cannula;

an outlet valve associated with the cannula; and

a radially extensible protrusion adjacent the distal end of the cannula.

5. A heart assist pump system comprising:

a cannula having a distal end and including:

an intake valve; and

an outlet valve; and

a guide, having a distal end. for guiding the cannula, the guide comprising:

a radially extensible protrusion adjacent the distal end of the guide.

6. A heart assistance pump according to claim 4 or claim 5 wherein the extensible protrusion is an inflatable balloon.

7. A heart assist pump according to any of the preceding claims wherein the outlet valve communicates with an opening at or adjacent to the distal end of the cannula; and

the intake valve communicates with an opening proximate to the opening with which the outlet valve communicates.

8. A heart assist pump according to any of the preceding claims wherein the outlet valve is an axial valve communicating with an opening at the distal end of the cannula.

9. A heart assist pump according to any of the preceding claims wherein the outlet valve is a leaflet valve having a plurality of leaves.

10. A heart assist pump according to any of the preceding claims wherein the intake valve comprises a valve through which blood enters the cannula via orifices in a wall of the cannula.

11. A heart assist pump according to claim 10 wherein said orifices are formed in a portion of the cannula which has a cylindrical inner wall and wherein said inlet valve comprises an inner flexible tube.

12. A heart assist pump according to claim 11 wherein the inner flexible tube substantially closes the orifices in the absence of a pressure differential.

13. A heart assist pump according to claim 12 wherein the inner flexible tube is moved away from the orifices by negative internal pressure relative to the outside of the cannula, uncovering the orifices.

14. A heart assist pump according to any of claims 11-13 wherein the inner flexible tube is integrally formed with the outlet valve.

15. A heart assist pump according to any of the preceding claims wherein the cannula has a substantially greater diameter at the intake valves than at the distal end thereof.

16. A method of augmenting the blood flow in the heart comprising:

inserting a cannula having a distal end and a proximal end, into the heart and pulmonary artery such that the distal end of the cannula is in the artery and a more proximal portion of the cannula is in the vena cava; and

transferring blood from the vena cava to the artery via a lumen of the cannula.

17. A method of augmenting the blood flow in the heart comprising:

inserting a cannula having a distal end and a proximal end, into the heart and aorta such that the distal end of the cannula is in the aorta and a more proximal portion of the cannula is in the left atrium; and

transferring blood from the left atrium to the aorta via a lumen of the cannula.

18. A method according to claim 16 or claim 17 and including:

providing an intake valve communicating with an opening in the cannula proximate to the distal end of the cannula.

19. A method according to any of claims 16-18 and including providing an outlet valve communicating with an opening at the distal end of the cannula.

20. A method according to claim 19 wherein providing an outlet valve comprises providing an axial outlet valve communicating with an opening at the distal end of the cannula.

21. A method according to any of claims 16-20 and including providing an outlet valve communicating with an opening in the cannula distal to the opening with which the intake valve communicates.

22. A method according to any of claims 16-21 wherein transferring blood comprises:

drawing blood through the intake valve by reducing the pressure within the cannula; and

ejecting blood from the cannula through the outlet valve into the artery by increasing the pressure in the cannula.

23. A method according to any of claims 16-22 wherein inserting a cannula into the heart and artery comprises:

inserting the cannula via a heart valve from the ventricle into the artery.

24. A method according to claim 23 and including guiding the cannula through the ventricle to the artery.

25. A method according to claim 24 wherein guiding comprises:

providing an radially extensible protrusion adjacent the distal end of the cannula;

radially extending the protrusion; and

allowing the cannula to advance at least partially under the influence of the effect of the blood flow on the protrusion.

26. A method according to claim 25 wherein the protrusion is a balloon and extending the protrusion comprises inflating the balloon.

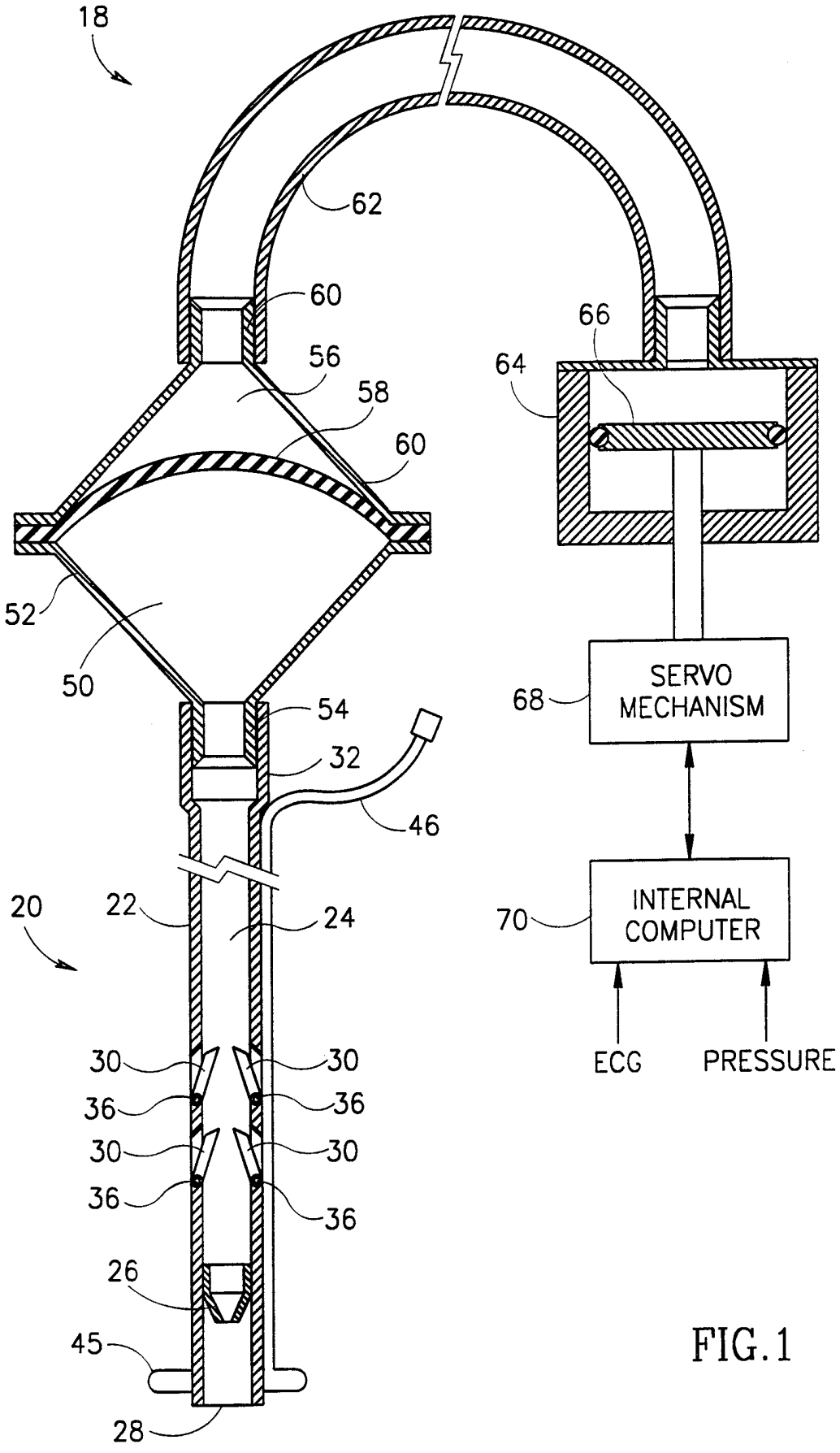

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ECG
PRESSURE

FIG.1

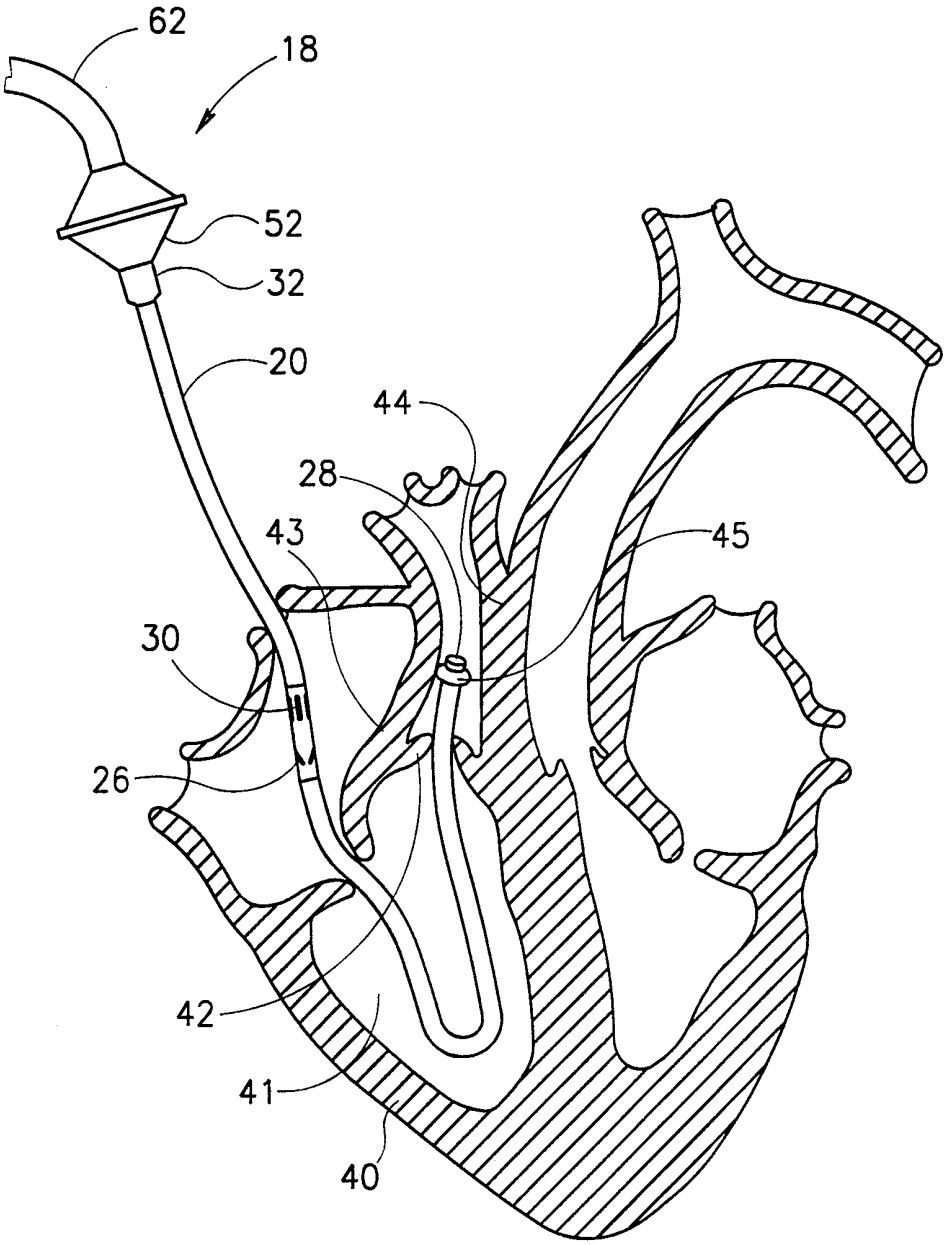


FIG.2

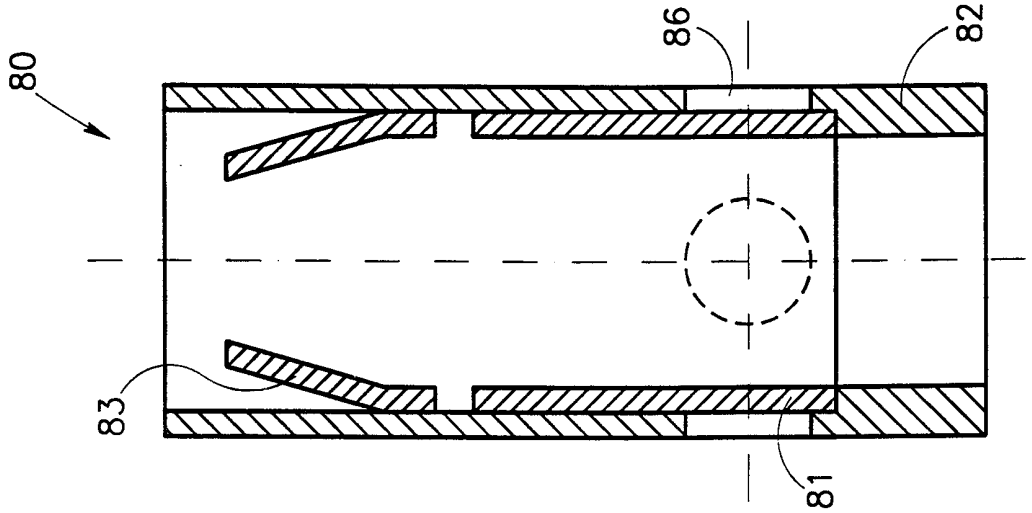


FIG.3C

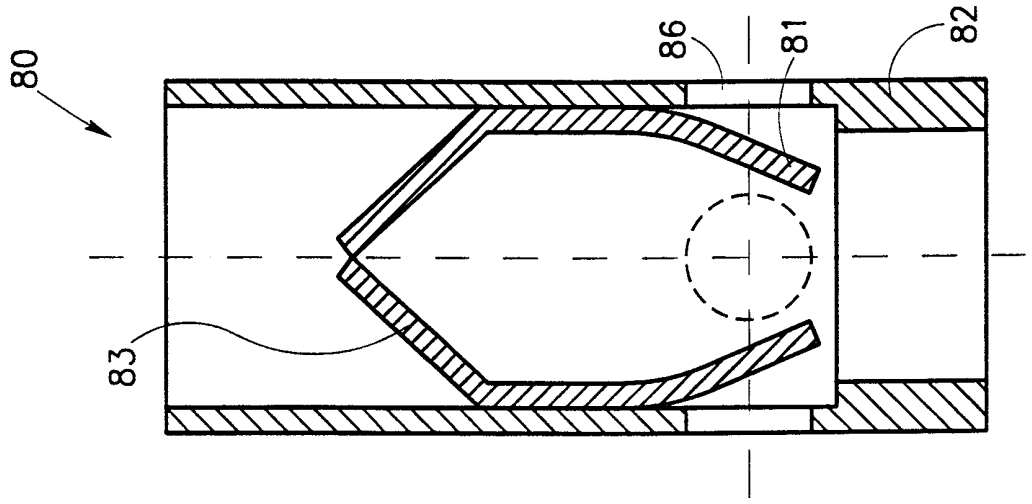


FIG.3B

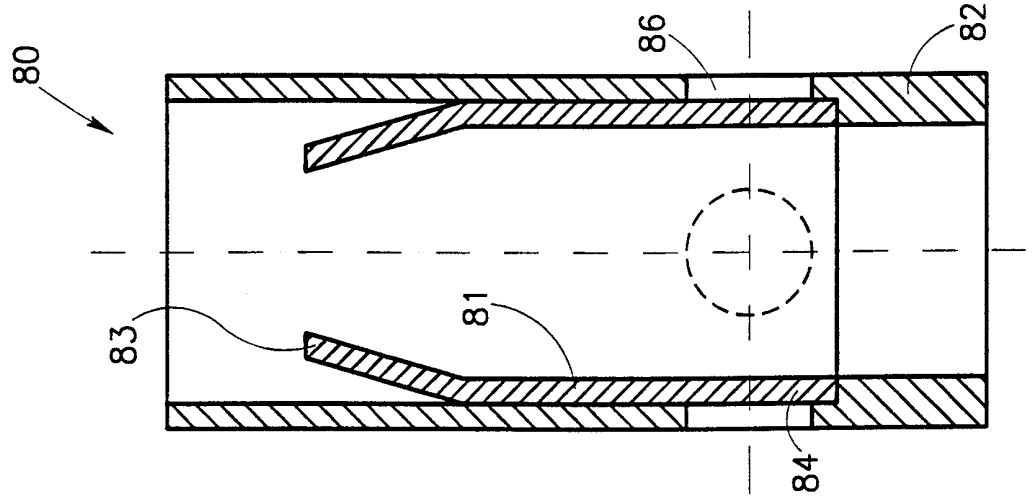


FIG.3A

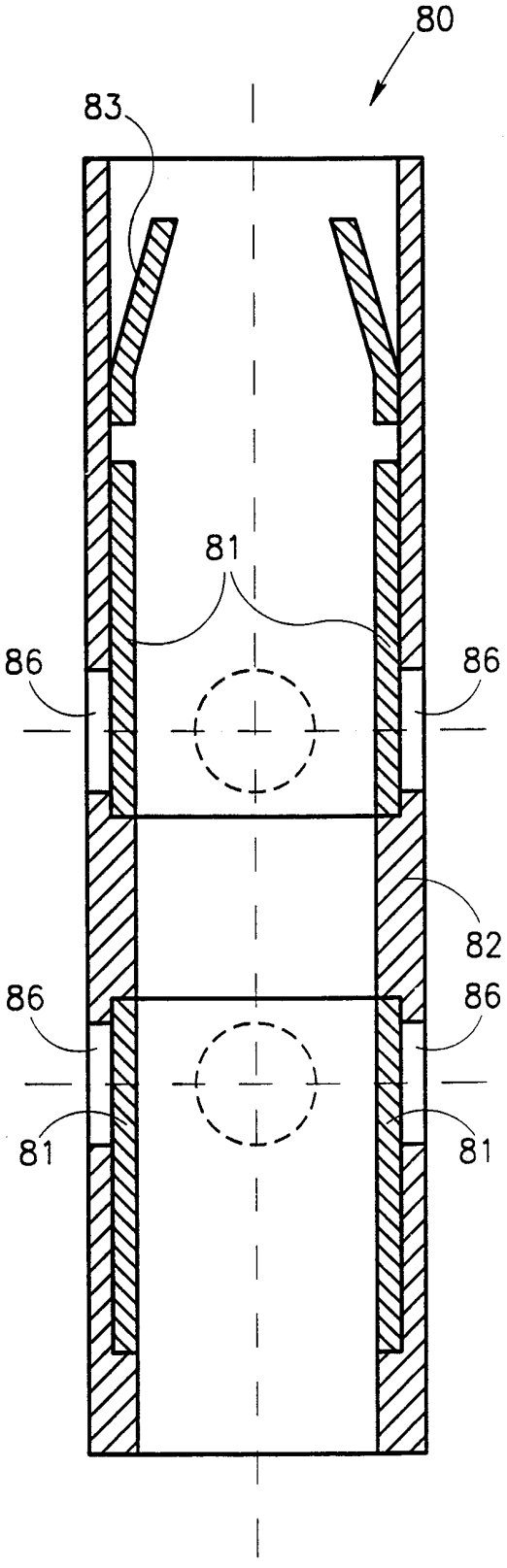


FIG.3D

INTERNATIONAL SEARCH REPORT

Intern. al Application No
PCT/IL 98/00142

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M1/10

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 97 02850 A (RDC RAFAEL DEVELOPMENT) 30 January 1997 cited in the application see the whole document	1-7,9, 10, 12-15,17
Y	US 4 985 014 A (OREJOLA) 15 January 1991 see column 3, line 55-61; figure 3 see column 4, line 45-49	1-7,9, 10, 12-15,17
A	GB 1 528 073 A (BRUNO) 11 October 1978 see figure 2	11
A	EP 0 445 782 A (MISUZU) 11 September 1991 see abstract; figure 1	8

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 July 1998	11. 08. 98

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Papone, F

3

INTERNATIONAL SEARCH REPORT

Inte. .ational application No.
PCT/IL 98/00142

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 18-33
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

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

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

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

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internal Application No
PCT/IL 98/00142

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9702850 A	30-01-1997	AU 6317596 A	10-02-1997
		EP 0837704 A	29-04-1998
US 4985014 A	15-01-1991	NONE	
GB 1528073 A	11-10-1978	US 4014317 A	29-03-1977
		DE 2613696 A	13-10-1977
		FR 2344277 A	14-10-1977
		GB 1528072 A	11-10-1978
EP 445782 A	11-09-1991	JP 1913283 C	09-03-1995
		JP 4126158 A	27-04-1992
		JP 6036821 B	18-05-1994
		AT 109664 T	15-08-1994
		CA 2037622 A	09-09-1991
		DE 69103295 D	15-09-1994
		DE 69103295 T	01-12-1994
		US 5147388 A	15-09-1992
		US 5275580 A	04-01-1994
		AU 638339 B	24-06-1993
		AU 7922391 A	06-02-1992