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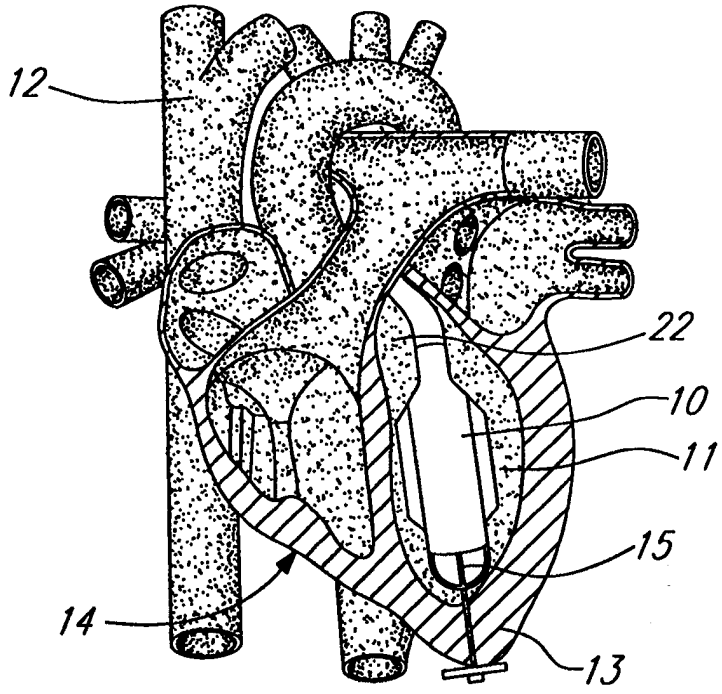
(54) Title: VENTRICULAR ASSIST DEVICE COMPRISING AN ENCLOSED–IMPELLER AXIAL FLOW BLOOD PUMP

(57) Abstract

The axial flow blood pump comprises a stationary housing structure, and an impeller rotatably mounted in the stationary housing structure about an axis of rotation to produce a flow of blood along this axis of rotation. The impeller includes a generally cylindrical shroud centered on the axis of rotation, a plurality of impeller blades extending inwardly from the inner surface of the shroud to intersect with each other at the axis of rotation, and a central hub centered on the axis of rotation and formed by the intersection of the impeller blades. The axial flow blood pump further comprises an electric motor drive incorporated in both the generally cylindrical shroud and the stationary housing structure. More specifically, the electric motor drive comprises a set of windings enclosed in the stationary housing structure, and a set of elongated axial permanent magnets embedded in the shroud. The axial flow blood pump can be used in an implantable ventricular assist device. The enclosed–impeller axial flow geometry of the pump, as well as the small diameter of the central hub substantially increase the volume of blood the pump is capable of containing and therefore of pumping.



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VENTRICULAR ASSIST DEVICE COMPRISING AN ENCLOSED-IMPELLER AXIAL FLOW BLOOD PUMP

BACKGROUND OF THE INVENTION

1. Field of the invention:

The present invention relates to a ventricular assist device and more particularly to an enclosed-impeller axial flow blood pump.

The present disclosure refers to a number of documents, the content of which is herein incorporated by reference.

2. Description of the prior art:

In North America, heart related diseases are still the leading causes of death. Among the causes of heart mortality are congestive heart failure, cardiomyopathy and cardiogenic shock. The incidence of congestive heart failure increases dramatically for people over 45 years. In addition, a large part of the population in North America is now entering this group of age. Thus, the number of people who will

need treatment for these types of diseases will reach a larger proportion of the population. Many complications related to congestive heart failure including death could be avoided and many years of life could be saved if proper treatments were available.

The type of treatments for heart failure depends on the extent and severity of the illness. Many patients can be cured with rest and drug therapy but there is still severe cases that require heart surgery including heart transplantation. Actually, the mortality rate for patients with cardiomyopathy who received drug therapy is about 25 % within 2 years and there still is some form of theses diseases that cannot be treated medically. One of the last options that remain for these patients is heart transplantation. Unfortunately, according to the procurement agency UNOS (United Network for Organ Sharing in United States) the waiting list for heart transplantation grows more than 2 times faster than the number of heart donors.

Considering these arguments, it appears imperative to offer alternative treatments to heart transplantation. The treatment should not only provide life extent but also improve quality of life. In this context, mechanical circulatory support through Ventricular Assist Devices (VAD) is a worthwhile alternative in front of a large deficiency in the number of available organ donors. In the 1980's, successful experiments with mechanical hearts and VAD serving as bridge to transplantation increased significantly. The accumulated knowledge in all aspects of patient care, device designs and related problems led to the use of VAD as permanent implants. Now, it appears appropriate to address the

problem of end stage heart failure with permanent mechanical heart implants. Among the various mechanical supports, axial flow VAD which aims at durability of 5 to 10 years is a very interesting approach. It is estimated that 2 000 patients per year in Canada and 30 000 patients per year in the United States could benefit from VAD.

In 1980, the National Heart, Lung and Blood Institute (NHLBI) of the United States defined the characteristics for an implantable VAD (Altieri, F.D. and Watson, J.T., 1987, "Implantable Ventricular Assist Systems", *Artif Organs*, Vol. 11, pp. 237-246). These characteristics include medical requirements that are to restore hemodynamic function (pressure and cardiac index) avoid hemolysis, prevent clot formation infection and bleeding, and minimize anti-coagulation requirement. More technical characteristics include: small size, control mode, long durability (> 2 years), low heating, noise and vibration.

VADs can be used in several circumstances where a patient has poor hemodynamic functions (low cardiac output, low ejection fraction, low systolic pressure). Whatever the origin of the cardiac failure, the goal of the VAD is to help the heart in his pumping action. The VAD unloads the heart by producing an enhanced circulation and thus restoring the hemodynamic functions which will provide good end organ perfusion. Many devices can achieve these goals; however they are not optimal, and hemolysis and thrombus formation are still important problems to investigate.

In the 1970's, the first approach to solve the problem of mechanical support was to imitate as much as possible the heart physiology. This resulted in the development of several pulsatile devices, some of these initial designs are still used. The first developments were pneumatically driven devices while a second generation of pumps was electrically actuated. In the 1990's, a new generation of pumps has emerged which addresses certain problems associated with previous devices (size and power consumption). These pumps are non-pulsatile devices divided into two main categories, centrifugal blood pumps and axial flow blood pumps.

In a non-pulsatile VAD, an impeller is enclosed in a housing and continuously rotates to produce a pumping action. The faster the rotation, the higher the blood flow. These devices are called non-pulsatile or continuous because they operate at constant speed. Most axial flow blood pumps operate around 10 000 rpm (Rotations Per Minute). However, in in-vivo conditions, there is a dynamic range (about 1000 rpm around the operating point) over which the output flow is pulsatile. Since the native heart is still contracting, a pressure difference between the ventricle (inlet) and the aorta (outlet) is created. This pressure variation will produce a variation in the pump flow. The range of rotational speed (rpm) over which pulsatile flow occurs is small; at lower speed back flow is observed (in diastole) and at higher speed the heart is completely unloaded. In the latter case, no pressure variation occurs resulting in non-pulsatile flow.

Many advantages are associated with the use of non-pulsatile VADs and they all have a strong impact on the physiology as well as on the clinical management. These advantages include:

Size: Non-pulsatile VADs present a much smaller volume than pulsatile ones, around 25 cc for an axial blood flow pump, and 100 cc for a centrifugal pump compared to 150 cc and more for pulsatile devices. For the sake of comparison a complete axial-flow VAD is usually smaller than the graft used for pulsatile pump. The clinical impact is the possibility to use this type of VADs in small adults as well as in children. Also, the small dimensions enable to place the pump in a more orthotopic position; that is, in the thorax near the heart instead of the upper abdomen. This eliminates the use of long cannula passing through the diaphragm. Furthermore, for axial flow VADs, the shape and size can be made to place the VAD in an intra-ventricular position.

Power: The electrical power required to drive a non-pulsatile VAD is lower than for pulsatile VADs.

Simplicity: Non-pulsatile VAD are mechanically simpler than pulsatile VADs; they do not require complex structures such as valves, diaphragms, blood sacs, vents or compliance chambers. Non-pulsatile continuous VADs

are made of a simple motor to which is coupled an impeller contained in an housing. One important advantage of a simple mechanical design is that it enables better durability. Durability as long as 5 to 10 years (Nosé, Y., 1995a, "Can We Develop a Totally Implantable Rotary Blood Pump? ", *Artificial Organs*, Vol. 19, pp. 561-562; and Jarvik, R.K., 1995, "System Consideration Favoring Rotary Artificial Hearts with Blood-Immersed Bearing", *Artificial Organs*, Vol. 19, pp. 565-570) could be achieved with continuous VAD compared with two years for pulsatile VAD (Pierce, W.S., Sapirstein, J.S. and Pae, W.E., 1996, "Total Artificial Heart: From Bridge to Transplant to Permanent Use", *Ann Thorac Surg*, Vol. 61, pp. 342-346). In principle, this would allow not only to use it as a bridge to transplantation but also as long term mechanical support.

Hemolysis: Hemolysis or tearing of the red blood cells can be estimated with a parameter called the Normalized Index of Hemolysis (NIH). The NIH of most pulsatile VADs is around 0.04 mg/dL (Nosé, Y., 1995a, "Can We Develop a Totally Implantable Rotary Blood Pump? ", *Artificial Organs*, Vol. 19, pp. 561-562) whereas for continuous VADs the NIH drops to a range between 0.002 to 0.004 mg/dL, that is about 10 to 20 times smaller. As a

consequence, these non-pulsatile VADs are less traumatic for blood.

Infection: Interestingly, probability of infection with continuous VADs is reduced. Since the transcutaneous vent of pulsatile VADs is an open door for opportunist infections daily cleaning is required.

Patient considerations: Non-pulsatile VADs require less maintenance allowing the patient a greater autonomy. Also, as it is now known, most patients with a VAD are discharged from the hospital and returned to a normal life after about a month. Presently, because of the vent in pulsatile VADs, patients cannot take a bath or swim since water could enter the motor compartment. Continuous VADs are less restrictive and allow the patient to practice more activities.

Centrifugal blood pumps were first used in cardio-pulmonary bypass for heart surgery. Based on results obtained with the Bio-Medicus pump (Medtronic Bio-Medicus Inc., Eden Prarie, MN), several groups decided to develop much smaller centrifugal pumps so that they could be totally implantable. In centrifugal blood pumps, the rotation of the impeller produces a centrifugal force that drags blood from the inlet port on top to the outlet port at the bottom side. To produce rotation of the impeller, the impeller is coupled to an electric motor. This coupling is made either (a) magnetically by means of permanent

magnets located under the impeller and on the rotor of the motor or (b) mechanically by means of a shaft interposed between the impeller and the motor's rotor. Magnetically coupled devices generally show better functionality because no seal is required between the motor and the impeller shaft.

A problem related to centrifugal pumps is that although they are much smaller than pulsatile pumps, they are still too large to be totally implanted in a human thorax thus eliminating any intra-ventricular implantation.

To overcome the above mentioned problem related to centrifugal pumps, axial flow ventricular assist blood pumps were developed. These axial flow blood pumps can decrease the hemolysis rate by decreasing the time of exposure of the blood to friction forces and by reducing the intensity of these forces. Another interesting advantage is that axial flow blood pumps are generally much smaller than centrifugal pumps.

The first commercially available axial flow blood pump was the Hemopump (Medtronic Inc. Minneapolis, MN) used as short term circulatory support. Based on the good results obtained with this pump, several groups have initiated the development of totally implantable axial flow VADs for long term uses.

A few axial flow VADs are presently under intensive development. Examples are: - the Jarvik 2000, by Jarvik Research Inc.

(New York, NY) and Transicoil Inc. (Valley Forge, PA), - DeBakey/NASA by the Baylors College of Medicine in conjunction with the NASA Johnson Space Center, - The Heart Institute of Japan, Waseda University and Sun Medical Research, and - AxiPump, developed by Nimbus Inc. (Rancho Cordova, CA) in cooperation with the Schools of Medicine and Engineering from the University of Pittsburgh. All of these groups have already started in-vivo experiments on animals although they still perform in-vitro trials.

An important issue about these types of pumps is the bearing system that supports the impeller. The impeller must rotate easily with minimal wear and resistance. Three technologies are available (Jarvik, 1995) to support the impeller: blood-immersed bearing (Jarvik 2000 and DeBakey/NASA), sealed bearing (Japan Heart Institute and Nimbus) and magnetically suspended rotor. Presently, the latter is being studied by a few groups but the technology is still at the research stage. Concerning the blood-immersed bearing, there is a tendency for thrombus formation around the bearing location. To minimize this adverse effect, high speed flow has to be provided in order to produce a good bearing washout. For the case of sealed bearing, there is usually thrombus formation at the interface of seal and contacting surface. Also, a purge port is required, through which a sterile solution is injected at continuous pressure and flow to ensure that blood elements do not enter the sealed area.

Jarvik 2000

This axial flow blood pump comprises two stators, one at the inflow and one at the outflow. These stator have two functions: they support the bearing shaft around which the impeller will rotate (middle part) and they modify the blood flow path. The inflow stator initiates the rotation of the flow so that the blade tip of the rotor does not create too much shear stress on the blood cells. The outflow stator straightens the flow so that blood from the pump enters the blood stream with a generally axial profile. Permanent magnets are enclosed in the center of the impeller and two motor windings are located in the casing on each side of the rotor. This configuration constitutes a DC brushless motor; this is a simple and durable motor which minimizes the number of mechanical parts. The power cable is connected directly to the DC brushless motor controller to change motor speed.

To implant the device, the chest is opened by means of a left thoracotomy and no cardiopulmonary bypass is used. The pump axial outflow is anastomosed to the aorta with a Dacron graft. Then a ventriculotomy is made to insert the pump into the ventricle through a sewing ring attached to the apex.

DeBakey/NASA

The DeBakey/NASA VAD is very similar to the Jarvik-2000 design. Indeed, this concept of VAD is based on a DC brushless motor with blood-immersed bearings, a central impeller and two fixed side pieces. The DeBakey/NASA VAD is described in US patent No. 5,527,159.

Blood enters on the left side and passes through a flow straightener preventing pre-rotation thereof. Then, the blood reaches the inducer/impeller; the inducer initiates rotation of blood before this blood reaches the impeller. However, it should be noted that the impeller produces the effective pumping action. Finally a flow diffuser converts the tangential flow into an axial flow. The inducer comprises three blades and the impeller is provided with six blades. The three blades of the inducer co-extend with three associated blades of the impeller. Each blade of the impeller contains eight cylindrical permanent magnets. Finally, a winding is placed outside the pump to complete the motor assembly, and the rotor is supported by a pair of bearings.

Japan Heart Institute

The axial flow blood pump developed by this group is quite different from the two previous ones. This axial flow pump is a sealed-bearing type pump whose motor is separated from the impeller. This axial flow pump has a so called dry motor configuration compared to the Jarvik 2000 and DeBakey/NASA pumps presenting a so called wet motor configuration. The impeller is coupled to the motor by a driving shaft. Blood enters the pump through four holes provided at its base, passes through the impeller and the flow straightener to finally exits the pump through a tapered end thereof. The pump is designed to produce a gradient of pressure along its geometrical axis.

The surgical placement of the pump is quite different from the other VADs. An incision is made at the apex and the pump is

inserted in the left ventricle until the base of the motor is in contact with the apex. The motor stays outside the heart and is sutured to the heart. The outlet port of the pump is passed through the aortic valve and since blood ejects directly in the aorta, no outflow cannula is required.

The main problem with this VAD is the presence of the seal of the driving shaft that requires continuous infusion of sterile solution in the sealed area to prevent blood from entering. This requires an external refillable bag to contain the sterile solution and a transcutaneous cannula connected to the pump purge port.

AxiPump

This pump is similar to the DeBakey/NASA and the Jarvik 2000 pumps. It is placed next to the heart and is connected between the apex of the heart and the aorta. It is also a sealed-bearing type pump and, accordingly, requires a purge system. This system has a second pump which injects 15 ml/day of sterile solution in the sealed area. A pump without purge system is now under development. Three animals have been supported for 1 month with the AxiPump (Konishi, H., Antaki, J.F. et al., 1996b, "Long-term Animal Survival with an Implantable Axial Flow Pump as a Left Ventricular Assist Device", *Artificial Organs*, vol. 20, pp. 124-127).

All the axial flow ventricular assist devices described herein above are very attractive but they all have limitations: in the Japan Heart Institute pump, the sealed bearing approach requires a purge

system and a transcutaneous fluid delivery system. Also, there is thrombus formation at the seal location. In the Jarvik 2000 and the DeBakey/NASA pumps, poor bearing washout results in thrombus formation at the bearing locations.

Other axial flow blood pumps have been proposed. For example, US patent No. 5,205,721 (Isaacson) discloses an axial flow blood pump having a hydrodynamically suspended rotor centrally positioned with respect to the stator. Hydrodynamic bearings are created by two spaces in which blood must flow to create the hydrodynamic support; this in turn produces shearing forces applied to the blood. Isaacson teaches three types of impeller blades which significantly add to the volumetric contribution of the hub.

In US patent No. 5,211,546, Isaacson et al. teach an axial flow blood pump which is similar to that of US patent No. 5,205,721. A rotor is suspended radially by hydrodynamic bearings. In certain embodiments, a radially centered thrust bearing element is located within the outlet directed surface of the pump stator inlet section and acts to stabilize the rotation of the suspended rotor. However, the volumetric contribution of the hub and vanes is significant.

US patent No. 5,290,227 (Pasque), on the other hand, proposes an axial flow blood pump having a rotor assembly described generally as a hollowed-out cylinder provided with rotor vanes which extend from the inner surface of the hollowed cylindrical rotor towards the central rotation axis of the rotor. This design generates two pumping

zones inside the pump, one of these zones being an outer annulus which is expected to create substantial shearing of the blood in the outer part of the rotor.

OBJECTS OF THE INVENTION

A first object of the present invention is to provide an axial flow blood pump and a VAD including this axial flow blood pump which eliminate the drawbacks of the prior art.

Another object of the present invention is to provide a VAD of simple design, small size, and including a control mode and a potential for long term durability (> 2 years), low heating and minimized vibrations.

A third object of the invention is to provide (a) a VAD comprising an enclosed impeller axial flow blood pump optimizing pumping efficiency while which restoring hemodynamic functions, minimizing hemolysis, minimizing anti-coagulant requirements and preventing clot formation, infection, and bleeding, and (b) such a VAD provided with a heart implantable design.

SUMMARY OF THE INVENTION

More specifically, in accordance with the present invention, there is provided an axial flow blood pump comprising:

a stationary housing structure; and

an impeller rotatably mounted in the stationary housing structure about an axis of rotation to produce a flow of blood along this axis of rotation. The impeller includes a generally cylindrical shroud centered on the axis of rotation and defining an inner surface, a plurality of impeller blades extending inwardly from the inner surface of the shroud to intersect with each other at the axis of rotation, and a central hub centered on the axis of rotation and formed by the intersection of the impeller blades.

The enclosed-impeller geometry of the axial flow blood pump, as well as the small diameter of the central hub substantially increase the volume of blood the pump is capable of containing and therefore of pumping.

In accordance with a preferred embodiment of the invention, the axial flow blood pump further comprises an electric motor drive incorporated in both the generally cylindrical shroud and the stationary housing structure. More specifically, the electric motor drive comprises a set of windings enclosed in the stationary housing structure, and a set of elongated axial permanent magnets embedded in the shroud. Preferably, the permanent magnets are parallel to each other

and each pair of laterally adjacent permanent magnets are spaced apart from each other by the same distance.

According to another preferred embodiment of the axial flow blood pump:

-the generally cylindrical shroud has first and second opposite ends;

- the stationary housing structure comprises a first annular stator coaxial with the generally cylindrical shroud, having an inner surface and located adjacent to the first end of the generally cylindrical shroud;

- the stationary housing structure comprises a second annular stator coaxial with the generally cylindrical shroud, having an inner surface and located adjacent to the second end of the generally cylindrical shroud; and

- the inner surfaces of the generally cylindrical shroud, the first annular stator and the second annular stator define a generally continuous, smooth inner surface of the pump;

- the inner surface of the shroud is generally cylindrical and has a constant first diameter;

- the inner surface of the first annular stator has a proximate end located adjacent to the first end of the generally cylindrical shroud and having a second diameter equal to the first diameter; and

- the inner surface of the second annular stator has a proximate end located adjacent to the second end of the generally cylindrical shroud and having a third diameter equal to said first and second diameter.

According to a further preferred embodiment of the axial flow blood pump, the central hub comprises two axial end pivots, and the stationary housing structure comprises a pair of support members for rotatably supporting the two end pivots of the central hub in view of rotatably mounting the impeller in the stationary housing structure.

In a preferred embodiment where the axial flow blood pump is destined to be implanted in one ventricle of a living heart:

- the stationary housing structure comprises a blood inlet and a cage extending over the blood inlet to prevent an inner wall of the ventricle to close the blood inlet;

- the stationary housing structure comprises a fixation mechanism for preventing the axial flow blood pump to displace into the ventricle, this fixation mechanism preferably including an elongated needle member passing through the wall of the heart from the inside of the ventricle to the outside of the heart, and a fixation member mounted on the free end of the needle member on the outside of the heart.

The present invention further relates to a ventricular assist system comprising an axial flow blood pump according to the invention implanted in one ventricle of a living heart. An electric energy

source supplies the electric motor drive with electric energy, and a controller unit controls supply of electric energy to the electric motor drive in order to control at least the speed of rotation of the impeller of the axial flow blood pump.

The objects, advantages, and other features of the present invention will become more apparent upon reading of the following non-restrictive description of a preferred embodiment thereof, given as a non limitative example only with reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

In the appended drawings:

Figure 1 is a cross sectional view of a human heart in which an axial flow blood pump according to the present invention is installed;

Figure 2 is a side elevational view of the axial flow blood pump of Figure 1;

Figure 3 is a side elevational, cross sectional view of the axial flow blood pump of Figure 1;

Figure 4 is a cross sectional view of the axial flow blood pump of Figure 1, taken along line 4-4 of Figure 2;

Figure 5 is a side elevational, cross sectional partial view of the axial flow blood pump of Figure 1; and

Figure 6 is a schematic view of a VAD system implanted in a human being and comprising the axial flow blood pump of Figure 1.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The originality of the present invention is at least in part related to the axial flow blood pump itself, although the pump is only one element of the complete VAD system. In the following sections, important aspects of the pump design are addressed. In particular, the pump design takes into account anatomical and physiological considerations combined to mechanical, electrical and material requirements. Then, following this discussion, the global characteristics of the VAD system are presented.

It should first be reminded that the axial flow blood pump of the present invention is not restricted to an application to an implantable VAD system. Other possible applications are liver perfusion, active perfusion PTCA-catheter, bladder draining, etc. Since the axial flow blood pump according to the invention overcomes a number of

drawbacks of the blood pumps of the prior art, those of ordinary skill in the art will understand that such an axial flow blood pump can be used as part of an intra-corporal system such as an intra-ventricular VAD, or an extra-ventricular VAD (i.e. a VAD located in the abdomen), or alternatively as a para-corporal or extra-corporal VAD, often used in bridge to heart transplantation. It shall also be understood that the axial flow blood pump of the present invention can be used in temporary VADs (ie. bridge to heart transplant) or permanent VADs. A non limitative example of permanent VAD is the intra-ventricular VAD in accordance with the present invention.

In the following description, an example of permanent or temporary intra-ventricular VAD is disclosed. For certainty, it shall be understood that the concept of the axial flow blood pump described herein is adaptable to other types of VADs. Furthermore, it should be understood that the intra-ventricular VAD disclosed in the following description is a preferred embodiment and hence could be modified at will within the scope of the appended claims.

ANATOMICAL PHYSIOLOGICAL AND SURGICAL CONSIDERATIONS

As previously discussed, bleeding is an important problem associated with patients who receive a VAD; in fact 30 % of patients suffer from this problem (Defraigne, J.O., Limet, R., 1996a, "Les assistances circulatoires: Partie I. Indications et description des systèmes", *Rev Med Liege*, Vol. 51, pp.295-306). The risk of infection is another quite important problem. Consequently, for medical and surgical

considerations, a first objective was to have a completely intra-ventricular pump. Indeed this position eliminates the need for inflow and outflow grafts and their anastomoses which reduce the risk of bleeding and infection. This has also the obvious advantage of considerably reducing the implantation time. Figure 1 illustrates the proposed position of the axial flow blood pump 10 in the left ventricle 11.

The axial flow blood pump 10 according to the present invention has also been designed to fit in small adults and in teens. Thus the size of the axial flow blood pump 10 is limited in regard to the ventricular dimension of humans to a BSA (Body Surface Area) of 1.5 m^2. Since the physical size and shape of the axial flow blood pump 10 are greatly influenced by the desired location of the pump 10, a good description of the ventricle anatomy is required. Feigenbaum, Harvey, "Echocardiography", 5th edition, 1994, Lea & Febiger, Philadelphia, presents several dimensions of the heart normalized by the BSA (Body Surface Area). These anatomical dimensions have been statistically determined and are known to represent 95 % of the population. Thus a ventricular dimension for humans corresponding to a BSA of 1.5 m^2 was used.

It will be understood that the physical size and shape of the axial flow blood pump 10 could also be adapted to meet the anatomical dimensions of individuals falling outside this 95% of the population. Similarly, the size and shape could be adapted to specific and particular individuals and heart conditions.

The internal diameter of the left ventricle 11 ranges from 37 to 46 mm in diastole and between 22 to 31 mm in systole. This diameter is determined at the center of the ventricular length (segment AB in Figure 1). The diameter near the apex at the first third of the ventricular length is about 1.5 cm (segment CD of Figure 1). The internal length of the ventricle from the apex to mitral valve ranges from 55 to 70 mm. Finally, the other important parameter is the surface of the aortic valve opening which ranges from 2.5 to 4 cm^2.

In a surgical point of view, the favored insertion procedure is to use the same approach as with valve replacement. According to this procedure, an incision is made at the root of the aorta 12 (Figure 1) and the axial flow blood pump 10 is inserted though the aortic valve and then into the left ventricle 11. The axial flow blood pump is then pushed until its base reaches the myocardium at the apex 13. In order to prevent motion thereof, the axial flow blood pump 10 should be fixed. Also in accordance with a preferred embodiment, an outflow cannula should pass through the aortic valves to further reduce bleeding.

One of the main roles of the axial flow blood pump 10 is to restore a hemodynamic function in patients with cardiac failure. Depending on the severity of the failure and the BSA, the pump 10 is susceptible to work at flow rates between 1 to 10 l/min against a pressure as high as 200 mmHg and, more commonly, at a flow rate between 3 to 5 l/min against a pressure of 100 mmHg.

Another important consideration for blood pump design is the hemolysis rate. Hemolysis is the tearing of red blood cells which empties the content of the cells in the blood stream resulting in free hemoglobin; the normal level of plasma free hemoglobin is around 10 mg/dl. A blood pump with a normalized index of hemolysis (NIH) of 0.005 g/100 l and lower is considered to be almost athromatic for red blood cells. A NIH of about 0.05 g/100 l could be tolerated. A NIH situated between 0.005 g/100 l to 0.05 g/100 l is envisaged for a VAD according to the present invention. Preferably, the NIH will be as close to 0.005 g/100 l as possible. The platelets are other important blood elements; their activation by high hydromechanical forces should be avoided in order to prevent clot formation.

AXIAL FLOW BLOOD PUMP DESIGN: Mechanical aspect

This section of the disclosure is divided into parts A and B. Part A describes the external shape and size of a preferred embodiment of the axial flow blood pump according to the invention and part B describes the internal conception of this axial flow blood pump.

Part A: External design requirements

The external design (shape and size) of the axial flow blood pump 10 (Figure 1) depends on the anatomic dimensions of the left ventricle 11. Figure 2 illustrates the external shape of the axial flow blood pump 10 and the critical geometric parameters thereof.

Inflow cage

Figure 1 shows that the preferred embodiment of the axial flow blood pump 10 sit at the bottom of the left ventricle 11, in the region of the apex 13 of the heart 14. In order to prevent the inner walls of the left ventricle 11 from obstructing blood intake, an inflow cage 15 (Figures 1 and 2) is mounted on the intake end of the axial flow blood pump 10. As can be seen in Figures 1 and 2, the inflow cage 15 presents the general configuration of an hemisphere. The diameter of the inflow cage 15 is set to 15 mm, which is smaller than the segment CD (Figure 1) and suitable to limit the level of pressure on the walls of the left ventricle 11 near the apex 13.

Outflow cannula

At the outflow end of the axial flow blood pump 10, the outflow diameter 16 (Figure 2) is reduced so as to reduce as much as possible the obstruction caused by an outflow cannula 17 to the operation of the aortic valves (not shown); since the function of the axial flow blood pump 10 is to assist blood circulation, blood flow contribution from the natural contraction of the heart 14 should be maintained. In a preferred embodiment, the diameter of the outflow cannula 17 is of 1.3 cm^2.

A blood diffuser 18 is formed at the distal end of the cannula. The function of diffuser 18 is to reduce the shear stress on blood cells. Without diffuser 18, the velocity of blood ejected from the pump 10 is higher than the velocity of blood ejected from the heart 14. The difference in velocity between these two blood flows will result in shear stress proportional to this difference. Since the velocity is inversely

proportional to the cross-section area, a solution for reducing the relative velocity of the blood flows from the pump 10 and from the heart 14 is (a) to increase the area of the orifice 19 of the cannula 17 to reduce the velocity of the flow of blood from the pump 10, and (b) to decrease the area occupied by the blood flow from the heart to increase the velocity of the latter blood flow. This is exactly the role of diffuser 18. Of course, parameters such as the angle of opening and the length of the diffuser 18 can be adjusted at will to fit the mechanical characteristics of the pump 10 in view of minimizing the shear stress on the blood cells.

Housing

The diameter of the axial flow blood pump 10 is a compromise between pumping requirements and minimal interference with heart contraction. In a preferred embodiment, the maximum allowable diameter 20 is about 22 mm which is the diameter of the left ventricle 11 in systole. This dimension is reasonable since people with heart failure have dilated ventricles.

The maximum length 21 of the axial flow pump 10, as illustrated in Figure 2, is set in regard of the average distance between the apex 13 and the mitral valve 22 of the heart 14. In a preferred embodiment, the length 21 of the axial flow blood pump 10 is about 55 mm. As shown in Figure , a reduction of the pump diameter (see 23) toward the outflow increases the mitral valve clearance in order to minimize interference with the mitral valve function.

Since in this preferred embodiment the axial flow blood pump 10 will be completely located inside the left ventricle 11, blood will circulate around the casing 24 of this pump 10. As a consequence, the external surface of the casing 24 should be as smooth as possible and avoid as much as possible abrupt deviations to thereby minimize vortices, turbulence and recirculation zones which may be at the origin of clot formation.

Fixation mechanism

At the pump inflow, a fixation mechanism 25 is provided. As an example, fixation mechanism 25 comprises:

- an elongated needle member 26 which is, from the inside of the left ventricle 11, through the myocardium and the epicardium at the apex 13 of the heart 14; and
- a fixation disk 27 fastened to the free end of the needle member 26 on the outside of the heart 14 to firmly fix the axial flow blood pump 10 in place.

Of course, it is within the scope of the present invention to employ any other fixation mechanism.

Electrical supply

The required electrical supply for the operation of the motor (to be described in the following description) is made through a wire that could, for example, extend from the pump 10 along the needle member 26 to reach the controller and the energy source.

Part B: Internal design characteristics

In the design of the internal components, the general concept of axial flow blood pumps have been retained. It should be first mentioned that the axial flow blood pump 10 comprises a stationary housing structure comprising a first stationary inflow stator 28, a second stationary stator 31 and a cylindrical pump stator 40. At the inflow, the first stationary stator 28 (inflow stator) induces a rotation (see arrow 29) to the blood flow about the longitudinal axis 32 of the axial flow blood pump 10. This initial rotation 29 minimizes abrupt changes in the blood flow path when it reaches the impeller 30 (rotor). At the outflow, the second stationary stator 31 is used to transform the rotational motion (see arrow 31) of the flow about the longitudinal axis 32 into a translational motion (see arrow 33); in other words, the second stator 31 acts as a flow straightener 34.

As previously mentioned, the pump design should minimize shearing stress in order to minimize hemolysis. In that context, reduction of the rotational speed would obviously contribute to reduce hemolysis. However, reduction of the rotational speed while pumping the same volume of blood requires an increase of the volume of blood contained in the rotor zone of the pump 10. The volume of blood contained in the rotor zone can be increased by minimizing the volume of the central hub of the pump rotor.

Current wet motor axial flow blood pumps use permanent magnets inserted either in the central hub or in the impeller blades. Both methods require important compromises. Insertion of the permanent magnets in the central hub requires a large hub to locate the

permanent magnets close to the motor windings for obvious electromagnetic coupling reasons; in contrast a small hub is preferred to increase the pumped blood volume. Insertion of the permanent magnets in the impeller blades yields a compromise since the geometry of the blades must be curved for pumping efficiency. As a consequence, some of the embedded magnets get farther away from the windings as the blade is curving.

The approach proposed in the present invention eliminates the compromises and drawbacks discussed in the two preceding paragraphs, while still providing both an optimal electromagnetic coupling between the windings and the permanent magnets, and an optimal pumping volume. For that purpose, the axial flow blood pump 10 presents an enclosed-impeller axial flow configuration. In the preferred embodiment of this configuration as illustrated in Figure 4, the impeller 30 comprises a set of four blades such as 35 enclosed in a shroud 36 whereby these blades are locked with one another. This enables a reduction of the strength, and therefore of the dimensions of the central hub 37 to obtain an optimal pumping volume while providing the required structural support for the blades 35. In addition, elongated permanent magnets such as 38 can be inserted axially in the shroud 36, thereby providing optimal electromagnetic coupling between the permanent magnets 38 and motor windings such as 39, inserted into the cylindrical pump casing 40 extending between the stators 28 and 31 and surrounding the shroud 36.

Still referring to Figure 7, the four blades 35 intersect at the central hub 37 protruding at both ends from the impeller 30 to form end pivots 41 and 42 (Figure 3). The function of the end pivots 41 and 42 (Figure 3) is to support the impeller 30 at each extremity. The end pivots 41 and 42 are respectively inserted into respective bushings 43 and 44. Bushing 43 is mounted on the inflow stator 28 through a number of radial arms 45 schematically illustrated in Figure 3. In the same manner, bushing 44 is mounted on the stator 31 through a number of radial arms 46 schematically illustrated in Figure 3. The bearings formed by the bushing and pivot assemblies 41,43 and 42,44 are the only mechanical parts subject to wear. Therefore, these parts are expected to be mostly responsible for the life of the axial flow blood pump 10.

Of course, the number of blades 35 and their shape (curvature and angulation) should be optimally determined in relation to pumping performance and other hydrodynamic considerations. In particular, the influence of the blade angulation on the level of shearing stresses, turbulence and cavitation responsible for red blood cell damage and increase of hemolysis rate should be carefully investigated.

Figure 5 shows that the internal diameter of the shroud 36 is the same as the internal diameter of the stators 28 and 31. Therefore, the inner surfaces of the shroud 36 and the stators 28 and 31 defines an inner continuous and smooth surface of the axial flow blood pump 10, to prevent as much as possible abrupt irregularities responsible for flow perturbations.

Still referring to Figure 5, the cylindrical shroud 36 of the impeller 30 is inserted in the cylindrical pump casing 40; this could be viewed as a double casing configuration. The gap 47 separating the outer cylindrical surface of the shroud 36 from the inner cylindrical surface of the pump casing 40 should be sufficiently large to prevent mechanical shocks and produce sufficient blood flow in order to increase washout and prevent clot formation. On the other hand, too large a gap will reduce the pump efficiency and may result in higher hemolysis.

As shown in Figure 5, blood flow through the gap 47 between the outer cylindrical surface of the shroud 36 and the inner cylindrical surface of the pump casing 40 can be reduced by bevelling outwardly the annular edge surface 48 of stator 28 and bevelling inwardly the annular edge surface 49 of the stator 31.

Electrical Aspects

The axial flow blood pump 10 will be actuated by means of a brushless DC (direct current) motor. This brushless configuration presents the advantage of minimal wear. Two other interesting characteristics of brushless DC motors are high rotational speed and high torque. In the axial flow blood pump 10, the brushless DC motor is composed of the elongated axial permanent magnets 38 inserted in the shroud 36 and the windings 39 inserted in the cylindrical pump casing 40.

As discussed previously, the configuration in which the blades 35 are embedded in the shroud 36 to increase the pumping

volume has also an advantage related to the electromagnetic coupling between the permanent magnets 38 and the motor windings 39. In the proposed design, the permanent magnets 38 are embedded in the shroud 36 and the windings 39 are embedded in the cylindrical pump casing 40. The insertion of the permanent magnets 38 in the shroud 36 very close to the windings 38 provides for an optimal electromagnetic coupling and obviously minimizes electrical losses. When compared to the configurations of the prior art including permanent magnets embedded in the blades, the configuration according to the present invention does not restrict the number of magnets to the number of blades.

Selection of the materials

The choice of materials for an implantable device is crucial and several properties of the available materials should be considered: strength, durability, hardness, elasticity, wear resistance, surface finish and biocompatibility. Biocompatibility is very important to minimize irritation, rejection and thrombogenesis. The interaction between the surface of the material and the biological tissues is very complex. In several cases, treatments of the surface with human proteins, certain drugs like heparin or other biocompatible material may considerably increase the biocompatibility and minimize thrombus formation.

VAD SYSTEM

Figure 6 schematically illustrates an embodiment of implantable VAD system including an axial flow blood pump 10. The VAD system is composed of four main parts:

- the axial flow blood pump 10 implanted in the left ventricle 11 of the patient 53;
- an internal controller 50;
- two energy sources, i.e. an internal rechargeable battery 51 and an external rechargeable battery 52; and
- a Transcutaneous Energy and Information Transmission (TEIT) system 54.

The TEIT system 54 works as a transformer. System 54 is composed of two electrical coils, namely an external transmission coil 55 and an internal reception coil 56. A RF (Radio Frequency) signal is applied to the external transmission coil 55 by a transmission circuit 57 supplied by the external battery 52, and the RF signal is transmitted to the internal reception coil 56. The transmitted energy will be used to supply all the internal components of the VAD system. The same TEIT system could eventually be used for transferring to the controller 50 operational data as well as programmable parameters.

The VAD system includes three external components advantageously incorporated to a belt 58 or suspenders (not shown). The first external component is a source of energy in the form of a rechargeable battery 52 of good mobility (the external source of energy can also be fixed when the patient is stationary for example during sleeping time). The second external component is a transmission circuit

which converts the DC voltage from the external energy source into a RF signal. Finally, the third external component is the transmission coil 55 which transmits the RF signal to the reception coil 56.

The VAD system also requires the implantation of four internal components. The first internal component is the axial flow blood pump 10 itself. The second internal component is the sub-cutaneous reception coil 56. The third internal component is the rechargeable battery 51. As a consequence, when the patient removes the belt 58 or his suspenders (not shown), and therefore the associated external components, the internal battery 51 will provide the required power for a sufficiently long period of time. The fourth internal element is the controller 50. Controller 50 is a very important part of the system and achieves several functions. The main function of the controller 50 is to determine the blood flow rate to be delivered by the pump 10 considering the BSA and the level of activity of the patient (estimated by the heart rate). The controller 50 will adjust the speed of rotation of the axial flow blood pump 10 in relation to heart rate measurements. Most of the other functions of the controller 50 are related to power management. The controller 50 converts the RF signal from the internal coil 56 into DC power. This DC power is used by the controller 50 to supply power to the pump 10 and to recharge the internal battery 51 when required. The controller 50 also monitors the pump energy consumption. Interestingly, perturbation in energy consumption of the axial flow blood pump may serve to diagnose mechanical problems. For example, a slow but constant increase in energy consumption may reveal bearing wear or thrombus formation interfering with the pump operation. Another

possibility is a sudden increase in energy consumption which may reveal a significant obstruction of the pump 10. The last function of the controller 50 is to communicate information. In that context it is used to receive external programmable parameters and to monitor and transfer data to a computer for processing thereof.

Because the controller 50 is the central component of the VAD system, its reliability is imperative. To minimize risks of hazards and malfunctions, several strategies must be combined. First, the redundancy of critical electronic components of the controller 50 is recommended, and a watch dog circuit to detect erratic behaviours of the controller 50 is proposed. Finally, the watch dog circuit can be coupled to a backup circuit whose function it to fix a blood flow in case of major problems with the controller 50.

To conclude, ventricular assist devices (VADs) are now being used worldwide and their utilization is becoming more and more accepted as a solution to treat end stage heart failure. It is generally accepted that VADs extend life of patients while improving quality of life of these patients. A pool, made with patients who received VADs, concerning their quality of life revealed that these patients would have preferred a heart transplant but prefer their situation than having to be on dialyses.

It is also now being accepted that VAD is becoming a cost effective solution considering the fact that patients are discharged from the hospitals more rapidly and may return to normal life occupations.

In the United States, several insurance companies are now reimbursing the implantation of VADs.

Finally, the axial flow blood pump 10 according to the invention provides an excellent bridge to heart transplant and aims at long term implant. The new proposed axial flow blood pump 10 should answer most of the remaining problems and limitations of the prior art axial flow blood pumps, especially those related to hemolysis and bleeding.

Although the present invention has been described hereinabove by way of a preferred embodiment thereof, this embodiment can be modified at will, within the scope of the appended claims, without departing from the spirit and nature of the present invention.

WHAT IS CLAIMED IS:

1. An axial flow blood pump comprising:

a stationary housing structure; and

an impeller rotatably mounted in the stationary housing structure about an axis of rotation to produce a flow of blood along said axis of rotation, said impeller including:

a generally cylindrical shroud centered on said axis of rotation and defining an inner surface;

a plurality of impeller blades extending inwardly from the inner surface of the shroud to intersect with each other at said axis of rotation; and

a central hub centered on said axis of rotation and formed by the intersection of the impeller blades.

2. An axial flow blood pump as recited in claim 1, further comprising an electric motor drive incorporated in both the generally cylindrical shroud and the stationary housing structure.

3. An axial flow blood pump as recited in claim 2, wherein said electric motor drive comprises:

a set of windings enclosed in said stationary housing structure; and

a set of elongated axial permanent magnets embedded in the shroud.

4. An axial flow blood pump as recited in claim 3, in which the permanent magnets are parallel to each other and in which each pair of laterally adjacent permanent magnets are spaced apart from each other by the same distance.

5. An axial flow blood pump as recited in claim 1, wherein:

the generally cylindrical shroud has first and second opposite ends;

the stationary housing structure comprises a first annular stator coaxial with the generally cylindrical shroud, having an inner surface and located adjacent to the first end of the generally cylindrical shroud;

the stationary housing structure comprises a second annular stator coaxial with the generally cylindrical shroud, having an inner surface and located adjacent to the second end of the generally cylindrical shroud; and

the inner surfaces of the generally cylindrical shroud, the first annular stator and the second annular stator define a generally continuous, smooth inner surface of the pump.

6. An axial flow blood pump as recited in claim 5, wherein:

the inner surface of said shroud is generally cylindrical and has a constant first diameter;

the inner surface of the first annular stator has a proximate end located adjacent to the first end of the generally cylindrical shroud and having a second diameter equal to said first diameter; and

the inner surface of the second annular stator has a proximate end located adjacent to the second end of the generally cylindrical shroud and having a third diameter equal to said first and second diameter.

7. An axial flow blood pump as recited in claim 1, wherein said central hub comprises two axial end pivots, and wherein the stationary housing structure comprises a pair of support members for rotatably supporting the two end pivots of the central hub in view of rotatably mounting the impeller in the stationary housing structure.

8. An axial flow blood pump as recited in claim 1, wherein the axial flow blood pump is destined to be implanted in one ventricle of a living heart and wherein the stationary housing structure comprises a blood inlet and a cage extending over the blood inlet to prevent an inner wall of said one ventricle to close the blood inlet.

9. An axial flow blood pump as recited in claim 1, wherein the axial flow blood pump is destined to be implanted in one ventricle of a living heart, and wherein the stationary housing structure comprises a fixation mechanism for preventing the axial flow blood pump to displace into said one ventricle, said fixation mechanism including:

an elongated needle member passing through the wall of the heart from the inside of said one ventricle to the outside of the heart; and

a fixation member mounted on the free end of the needle member on the outside of the heart.

10. A ventricular assist system, comprising:

an axial flow blood pump as recited in claim 2 implanted in one ventricle of a living heart;

an electric energy source for supplying the electric motor drive with electric energy; and

a controller unit for controlling supply of electric energy to the electric motor drive in order to control at least the speed of rotation of the impeller of the axial flow blood pump.

11. A ventricular assist device as recited in claim 10, wherein the controller unit is implanted inside a patients body, the electric power source comprises an inner rechargeable battery implanted inside the patient's body, the electric energy source comprises an outer source unit situated outside the patient body, and a transcutaneous transmission link for transmitting electric energy from the outer source unit to the controller unit in view of supplying the electric motor drive and recharging the inner rechargeable battery.

12. A ventricular assist device as recited in claim 11, wherein said controller unit comprises means for acquiring information about operation of the axial flow blood pump, said information being transmitted to the outside of the patient's body through the transcutaneous transmission link.

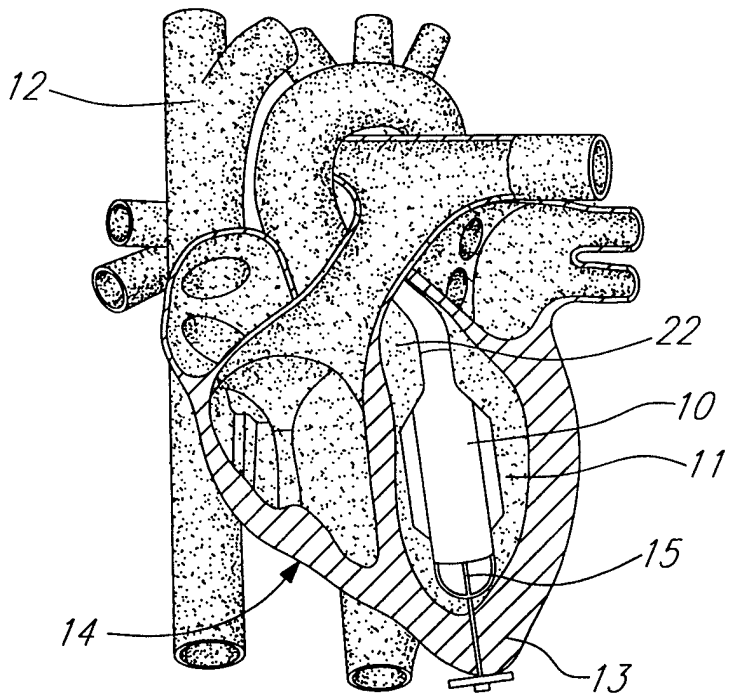

FIG. 1

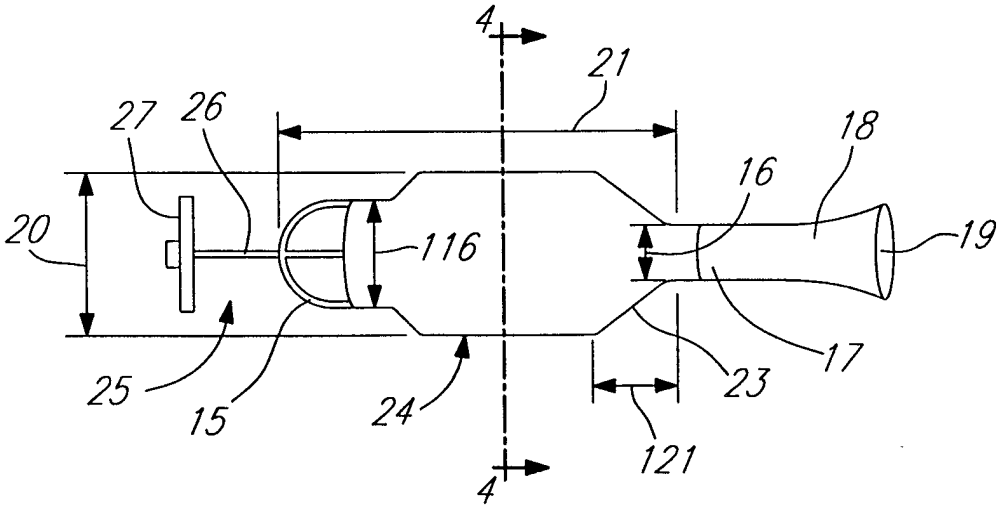

FIG. 2

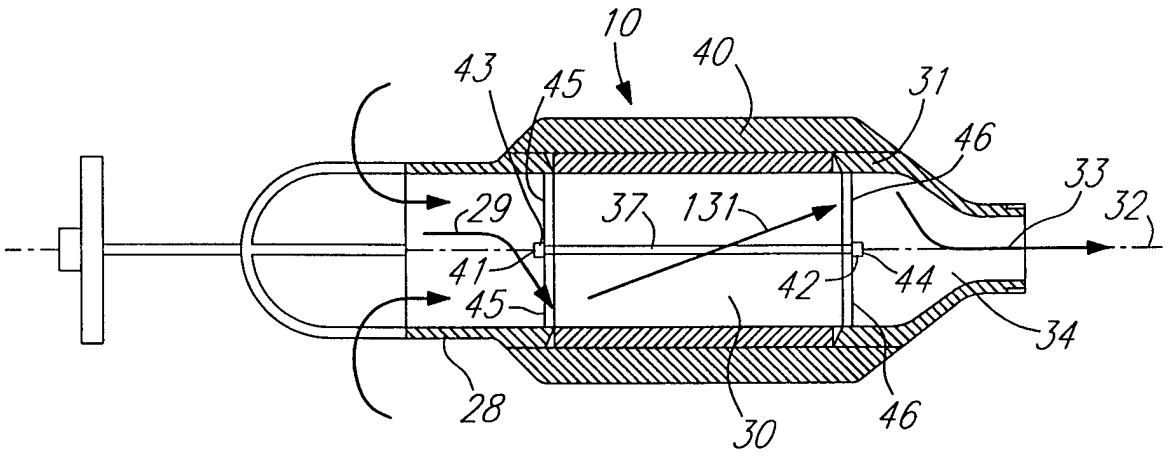
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Fig. 3

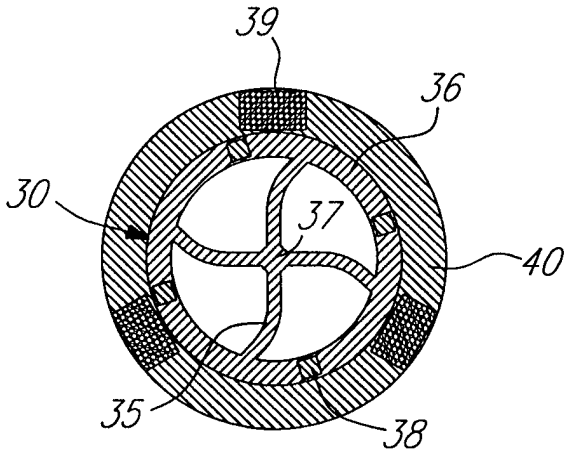
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Fig. 4

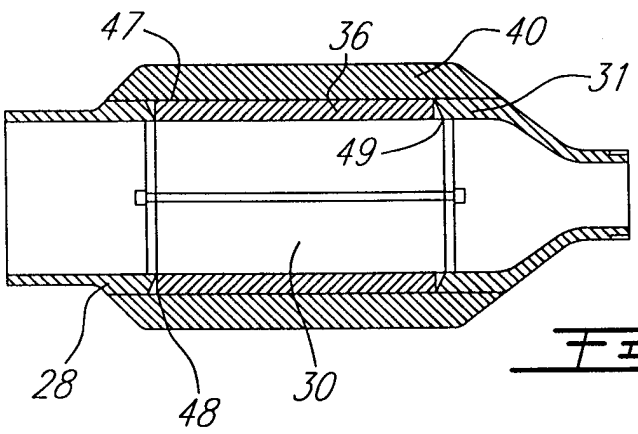

Fig. 5

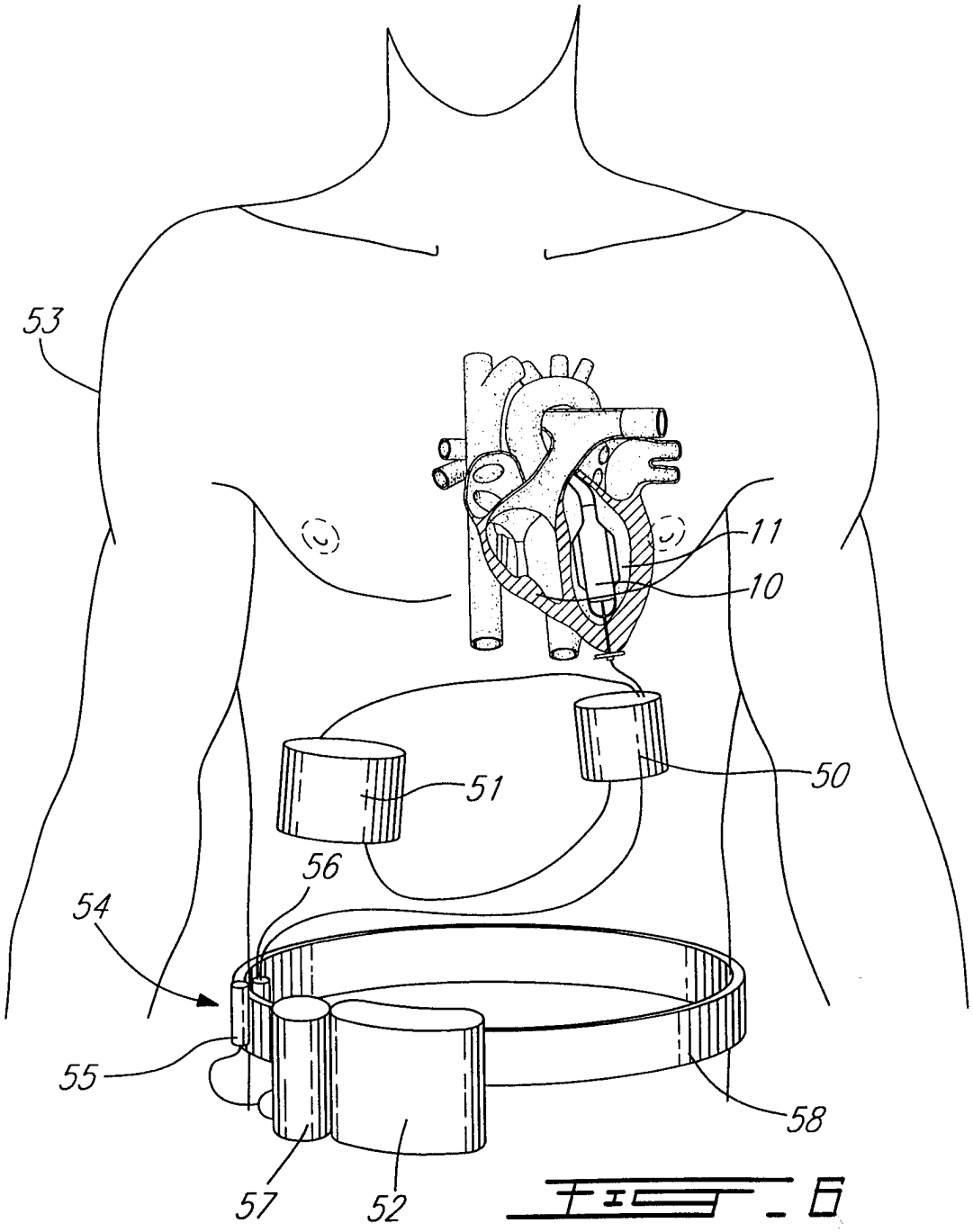

Fig. 6

INTERNATIONAL SEARCH REPORT

Inte. .onal Application No
PCT/CA 98/00534

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M1/10 F04D13/06

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 F04D

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.
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X	EP 0 060 569 A (BRAMM) 22 September 1982 see page 11, line 7 - page 13, line 12 see figure 2	1-3
Y	--- -/--	10-12

[X] Further documents are listed in the continuation of box C.

[X] 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

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"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
1 October 1998	09/10/1998

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	Schönleben, J

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Inte. ational Application No
PCT/CA 98/00534

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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