PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M	A2	(11) International Publication Number: WO 99/34847
		(43) International Publication Date: 15 July 1999 (15.07.99)

(21) International Application Number: PCT/US99/00636

(22) International Filing Date: 11 January 1999 (11.01.99)

(30) Priority Data:
60/071,123 12 January 1998 (12.01.98) US

(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Application
US 60/071,123 (CIP)
Filed on 12 January 1998 (12.01.98)

(71)(72) Applicant and Inventor: KLEIN, Enrique, J. [US/US]; 1686 Christina Drive, Los Altos, CA 94024 (US).

(74) Agents: HESLIN, James, M. et al.; Townsend and Townsend and Crew LLP, Two Embarcadero Center, 8th floor, San Francisco, CA 94111–3834 (US).

(81) Designated States: JP, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
Without international search report and to be republished upon receipt of that report.

(54) Title: IMPROVED SEALLESS BLOOD PUMP

(57) Abstract

A sealless implantable rotary blood pump including a number of features which improve its performance over the prior art. Such features include a fully floating shaft on magnetic bearings to avoid thrombus formation, a split blood flow path allowing for improved motor efficiency, a brushless motor operating in the left ventricle independently from the pump impeller, an axial/radial flow impeller coaxially mounted with the motor and operating within a portion of the housing placed outside the heart and means for imparting pulsatility to the output of a rotary pump.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

IMPROVED SEALLESS BLOOD PUMP

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to medical devices and methods. More particularly, the present invention relates to an implantable blood pump having a sealless fully magnetically suspended rotor.

A sealless centrifugal blood pump is described in published PCT application WO 97/29795 and U.S. Patent No. 5,695,471. The pump is driven by an electric motor and incorporates radial magnetic bearings and stationary axial thrust bearings having contacting surfaces with the shaft or rotor. The purpose of the pump is to provide a left ventricular assist device operating over extended periods of time for the treatment of congestive heart failure.

While the design proposed in the PCT application and U.S. Patent has numerous advantages, it also has certain limitations. For example, it will be difficult to provide suitable axial bearings to limit axial motion of the shaft and/or rotor in such a way as to avoid thrombus formation and hemolysis at the bearing surfaces. Moreover, balancing of axial forces due to hydraulic reaction forces, axial force components of the proposed magnetic radial support system, and forces in the axial gaps of the flat motor will be extremely difficult. Furthermore a combination of both the flat motor and the centrifugal pump designs into one unit will impose complex design constraints. The performance of an electric motor having iron and/or permanent magnets in the rotor and stator is sensitive to changes in the gap between the rotor and the stator. In the case of flat motors with two independent gaps, this could lead to destabilizing axial forces. Moreover, in a blood pump having a flat motor, balancing the axial forces may be problematic depending on the relative magnitudes of the forces in the axial motor gap(s) and the hydraulic and axial magnetic bearing forces. Shock and vibration, such as might occur when the patient performs high impact exercise, must also be considered in the design. An axial shuttle motion of the shafts proposed in the prior art implies that there is either a gap between the end(s) of the shaft and the fixed axial bearing(s) or that at least

one of the axial bearings is spring-loaded to eliminate the gap(s). In the first case, the shaft with the radial magnetic bearings, carrying the cantilevered pump impeller and motor/rotor combination may become misaligned (angled) causing problems with the motor gap(s). In the second case, there would be constant contact between the shaft end(s) and the axial bearing(s), potentially giving rise to additional thrombus formation and hemolysis. Combination of an axial motor with a centrifugal pump imposes some additional constraints on the optimum design of both. Compromises are mainly due to the small width of the motor gap(s), needed for improved efficiency, and the need to provide magnetic components as well as flat motor-pump impeller combination.

It would therefore be desirable to provide improved designs for sealless blood pumps having magnetic radial and axial bearings to attain a truly floating rotor having no contact with the stator at any time. In particular, it would be desirable for the pump to be unaffected by extraneous or intrinsic destabilizing axial forces. It would be further desirable to eliminate all friction bearings, for example by eliminating axial friction bearings. It would be still further desirable to improve hydraulic efficiency by reducing the hydraulic intake losses and by providing improved hydraulic impeller designs. It would still be further desirable to separate the motor from the impeller so that both designs could be improved and optimized for size, performance and efficiency. It would still be further desirable to reduce the overall sized of the implantable device.

2. Description of the Background Art

WO 97/29795 and U.S. Patent No. 5,695,471 have been described above. One type of radial magnetic bearings is described in U.S. Patent No. 4,072,370. The full disclosures of each of these documents are incorporated herein by reference.

SUMMARY OF THE INVENTION

The present invention is an improved design for a sealless rotary blood pump. In a first aspect of the present invention, the design separates the motor from the hydraulic impeller, where the motor is of the coaxial and/or concentric stator and rotor type and is preferably located in the left ventricle while the impeller which is mounted on the same shaft, remains external to the heart. The support of the shaft carrying the rotor and the pump impeller has been improved by using a combination of magnetical cylindrical and conical end bearings that can suspend the shaft in a floating configuration. The pump impeller includes a combination of axial and radial vanes to improve

performance. The motor is suspended by bearings at each end and is not cantilevered. The impeller is cantilevered relative to bearings. In another aspect of the present invention, the blood flow into the pump is divided in two paths in order to provide a large entry duct for the primary path and a smaller secondary flow path through the decreased motor gap to optimize the motor design. Alternatively, a hollow shaft or an external intake are used for the primary blood path. The shape of the pump casing has been further improved to fit within the apex of the heart. Pulsatile flow can be achieved by varying the angular velocity of the rotor shaft, at a preferred frequency of from 0.5 Hz to 1.5 Hz, more preferably from 1 Hz to 1.3 Hz. The direction (sense) of rotation of the pump can be chosen so that the reaction torque of the heart to which the pump is attached mimics the pulsatile torque of a normal heart. Additionally, the sound of a pulsatile flow rotary pump would likely be less objectionable than the sound of a continuously operating pump.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 illustrates a first embodiment of a sealless blood pump constructed in accordance with the principles of the present invention.

Figs. 2A and 2B illustrate the magnetic bearing utilized in the pump of Fig. 1.

Fig. 3 is an external perspective view of the blood pump of Fig. 1.

Fig. 4 illustrates an alternative magnetic bearing.

Fig. 5 illustrates an alternative blood pump constructed in accordance with the principles of the present invention.

Fig. 6 is a schematic illustration of a gating system for achieving pulsatile flow.

Fig. 7 illustrates certain flow characteristics of the pulsatile flow blood pump.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

A blood pump according to present invention is illustrated in Fig. 1. The blood pump incorporates a brushless radial motor 1 flanked by modified magnetic bearings 2 having lateral ferromagnetic pole pieces 3 that provide for balanced axial constraint. A primary blood flow path is through an eccentric intake nozzle 4, and a

hydraulic impeller 5 may be of the thick web type or may be a modified Kaplan turbine-type pump impeller, having both axial and radial flow components, as shown.

The intake nozzle 4 is preferably provided with a large cross-section and a short length, e.g. just longer than the muscle thickness of the apex of the heart, in order to reduce the hydraulic losses of the intake flow when compared to the annular path along the radial magnetic bearings of the prior art. Since the primary blood flow is through intake nozzle 4, radial gap 4a between the rotor and stator for both the motor and the radial magnetic bearings, may be substantially reduced when compared to the prior art. This design improves the magnetic efficiency and allows for a more compact design. Decreasing the size of the radial gap will also improve the stiffness of the radial bearing making the device less susceptible to shock and vibration while minimally impacting hemolysis or thrombus formation in the gap.

The radial annular gap 4a provides a secondary parallel blood flow path for the pump. The cross sectional area of this decreased annular gap will have a much reduced blood flow capacity both due to the reduced cross sectional area of the smaller annulus and due to the greater effect of the boundary layers. Thus, gap 4a mainly allows for the design of a floating rotor with no contacting surfaces between the rotor magnetic bearings or the shaft, against any of the stationary components of the pump for all operating conditions.

The magnetic bearings 2 may be similar to those described in U.S. Patent No. 4,072,370, full disclosure of which has been previously incorporated herein by reference. The disks 2a in Fig. 1 are axially magnetized permanent magnets assembled next to pole pieces, with equal poles facing each other resulting in a flux pattern wherein the poles of the stator and the rotor repel each other. As proposed in the '370 patent, the inner pole pieces on each side of the motor also provide magnetic shielding so that the magnetic bearing flux will not significantly interfere with the magnetic motor flux.

Referring now to Figs. 2A and 2B, where Fig. 2a represents only a portion of one of the magnetic bearings, by modifying the conventional inner and outer pole pieces 2a of the magnetic bearings into modified lateral pole pieces 2b on each side of the rotor it is possible to provide a balanced axial constraint for the shaft and the rotor assembly in addition to the radial constraint. Fig. 2A shows one bearing cell with the modified lateral pole pieces 2b. The pole pieces P_1 and P_2 are both shown as magnetic South poles and will repel each other with a force F_a which has a radial component F_r

(Fig. 2B), where opposing radial forces cancel each other axisymmetrically, and an axial component F_{ax} which will be balanced by the equal and opposite axial component $-F_{ax}$ on the opposite lateral bearing (not shown), thus making axial contacting bearings unnecessary. Thus, by including magnetic bearings that impart balanced opposite axial forces to the rotor, the entire rotor assembly can be fully suspended without physical contact between the rotor and the stator. Such opposite, balanced forces also stabilize the rotor when subjected to destabilizing axial forces imparted by the pump impeller and/or by shock and vibration.

The cross-section of the outer end pole piece is shown with more material toward the outer end, and the gap is shown with a slight conical angle mismatch to even out the flux repulsion across the gap. An alternate axial bearing design is shown hereinafter.

Heat transfer from the motor to the blood in the annular gap should not be significantly affected since the gap will still have significant blood flow. Heat from the windings in the stator will also be efficiently dissipated through conduction to the housing and to the blood stream in the left ventricle. As shown previously and in the perspective view of Fig. 3, an intake nozzle 4b need not be axisymmetric. It may also be preferably oriented toward the free wall of the left ventricle.

Another feature of the present device is that it permits forming a "waist" or annular constriction in radially narrowed region 6a in the main housing to provide improved anchoring in the muscle at the apex of the heart. Moreover, the base of the impeller housing may better conform to the shape of the apex of the heart. Usually, loops or anchors will be provided in the housing (not shown) to permit suturing to hold the pump in place.

The hydraulic impeller design is no longer constrained by the need to serve also as the rotor of a flat motor as in the prior art. Thus, other impellers may be used, such as a ship's screw rotor or a modified Kaplan turbine-type impeller having both axial and radial flow, while still inside a centrifugal pump housing. Such designs would have less surface exposed to the blood than the thick web impeller of the prior art. Furthermore, even if hemostasis should become a problem between the end of the impeller shaft and the secondary housing 6, it is possible to drill one or more holes in the impeller to provide leakage paths 7 for the blood. While this would minimally decrease pumping efficiency, it may be an advantageous compromise. Usually, titanium will be

used for all housings because of its high strength and low weight, as well as its natural damping characteristics and biocompatibility. The principal housing 8, secondary housing 6, and end cap 9 can all be formed from titanium by investment casting and machining, or in the case of end cap 9, by machining from stock. The permanent magnets 10 can be made of a high energy rare earth, such as iron-neodymium or samarium-cobalt. Pole pieces can be made from pure or very low-carbon iron and then plated or coated to inhibit corrosion and enhance biocompatibility.

The blood pump can be assembled in stages as follows. The stator (motor and magnetic bearings) could be installed in the principal housing 8, all except for pole piece 3 which is pre-assembled within cap 9. The impeller and shaft is then introduced in the stator assembly and the motor and bearing portions of the rotor are assembled onto the impeller shaft. The end cap subassembly (components 9 and 3) is then assembled onto the principal housing 8. The secondary housing 6 is assembled onto the principle housing, to complete the construction. All joints should be permanent and preferably done with press fits and adhesives in a manner similar to assembly techniques used in the disk drive motor industry. The implantable device will usually be coated with an anti-thrombotic coating.

Referring now to Fig. 4, an alternate magnetic bearings design is illustrated. In that figure, a portion of a bearing cell is illustrated. The bearing cell in Fig. 4 differs from that in Fig. 2A by the addition of an annular permanent magnet 22 and annular end pole 20 which jointly may augment the axial repulsion forces between angled pole pieces 24 in the static and the rotating portions of the pump. The actual forces can be verified first analytically by using magnetic Finite Element Analysis (FEA) and then experimentally. A similar arrangement with added permanent magnet and pole piece is used at the opposite end of the magnetic bearing (not shown) to balance the axial forces.

An alternative implantable pump design is illustrated in Fig. 5 (where like components are numbered the same as in Fig. 1). This design incorporates many of the features of the previously described pump, but differs in that a primary blood flow path 30 is routed to the impeller 5 through a hollow shaft 11, thus eliminated the need for a separate entry nozzle 4 or 4b as shown in Figs. 1 and 3. This embodiment takes advantage of the shaft 11 and the entire rotor assembly being truly floating (i.e., having no physical contact during rotation). It is furthermore advantageous because the efficiency of the motor is minimally impacted by the loss of magnetic material in the

center of the rotor. Such a design could not be implemented in a configuration incorporating axial contacting bearings acting on a shaft as taught by the prior art.

Referring now to Fig. 6, the centrifugal pumps of the present invention (as well as those of the prior art) can be modified to operate so as to provide pulsatile blood flow into the aorta, which may be clinically advantageous in certain respects. In particular, pulsatile flow more closely matches or mimics the natural cycle of a beating heart. While certain positive displacement heart pumps are able to achieve pulsatile flow, rotary pumps as proposed in the prior art and including temporary pumps placed in the aorta, are normally associated with continuous (non-pulsatile) flow. Pulsatile flow can be achieved with a rotary pump, however, by varying the rotational speed, preferably at a frequency between 0.5 Hz to 1.5 Hz, more preferably at 1 Hz and 1.3 Hz, which corresponds to heart rates in the range from 30 to 90 and 60 to 80 beats per minute, respectively. Furthermore, using analog or digital and other easily configured control systems, the frequency of rotational pulsatility can be gated to the output of the coronary sinus node through the use of appropriate sensors. Alternatively, when fitting the patient with a pacemaker, a modified pacemaker can be used to gate or pace the pump through pacemaker leads as shown schematically in Fig. 6.

Typically, the pulsatile cycle of the rotary pump will be triggered a fraction of a second ahead of the ventricles in order to best synchronize the output of the pump into the aorta with the pulsation of the ventricles since the acceleration of the rotary pump may be slower than the contraction of the ventricles. While it may not be practical to exactly match the pulsatile flow rate of a normal heart with an electrically controlled rotary pump, it may be possible to approximate the average flow rate when using a pacemaker as shown in Fig. 6 together with the appropriate pump motor drivers.

Moreover, as shown in Fig. 7, the aortic flow velocity and the volume stroke in a healthy heart is depicted by a solid line. When accelerating a rotary pump shaft and impeller and its hydraulic load, it may be difficult to achieve the same steep pressure rise. To compensate for this, the peak flow rate may be increased, as shown in a broken line 40, or the delivery cycle may be lengthened, as shown in the broken line 42, or some combination of both as shown in the broken line 44. The objective will be to mimic the stroke volume per cycle, i.e., the area under the curves as illustrated in Fig. 7. Another advantage to gating the rotary pump with a pacemaker, if the pacemaker is a rate-responsive device, is that the pacemaker in combination with the pump motor drivers

can control the actual cardiac output through separate sets of algorithms. Such rate-responsive pacemakers are currently made to control heart rate only.

A normal heart contracts and expands with every cycle, and also twists around an axis running approximately through the apex and the root of the aorta. Such periodic twisting motion would be partly mimicked by a left ventricular assist device having a rotary pump with a shaft aligned with the axis of the heart and controlled to deliver pulsatile flow. As the motor/impeller accelerates, the housing, which is tied into the apex of the heart, experiences a reaction torque which is transmitted to the heart. This reaction is opposite to the shaft sense of rotation. Thus, it may be desirable that the normal direction of rotation of the pump shaft be opposite of that of the periodic twisting of the heart. With the same device having only a constant angular velocity shaft, there would be no pulsatile reaction torque.

Finally, the sound of a pulsatile rotary pump may also be less objectionable to a patient than the constant hum of the constant velocity pump, particularly if the pulsatile action mimics the normal heartbeat.

While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the invention which is defined by the appended claims.

WHAT IS CLAIMED IS:

1. An improved sealless blood pump of the type including a pump housing, a hydraulic impeller mounted for rotation within the housing, and magnetic bearings for radially supporting the hydraulic impeller, wherein the improvement comprises:

at least two blood flow paths through the housing to a hydraulic impeller.

2. An improved sealless blood pump as in claim 1, wherein one blood flow path passes through a gap in the magnetic bearings.

3. An improved sealless blood pump as in claim 2, wherein a second blood flow path passes coaxially through a rotor shaft supported by the magnetic bearings, wherein the rotor shaft supports the hydraulic impeller.

4. An improved sealless pump as in claim 2, wherein the second blood flow path bypasses a rotor shaft supported by the magnetic bearings, wherein the rotor shaft supports the hydraulic impeller.

5. An improved sealless blood pump of the type including a pump housing, a rotor mounted for rotation within the housing, magnetic bearings for radially supporting the rotor within the housing, and a combined motor/impeller within the housing for driving the rotor, wherein the improvement comprises:

a motor positioned within a portion of the pump housing which lies within the left ventricle when the pump is fully implanted in the heart.

6. An improved sealless blood pump as in claim 5, wherein the rotor comprises a hydraulic impeller, on a shaft, wherein the impeller is within a portion of the housing which lies outside of the heart when the pump is fully implanted in the heart and wherein the shaft and the motor lie within a portion of the housing lying within the left ventricle when the pump is fully implanted in the heart.

7. An improved sealless blood pump as in claim 6, wherein the two portions of the housing are joined by a waist which lies in the apex of the heart when the pump is fully implanted in the heart.

8. An improved sealless blood pump of the type including a pump housing, a rotor mounted for rotation within the housing, and magnetic bearings for radially supporting the rotor within the housing, wherein the improvement comprises:

magnetic bearings which are configured to both radially support and axially constrain the shaft.

9. An improved sealless pump as in claim 8, wherein the magnetic bearings comprise inner pole pieces attached to a shaft of the rotor and outer pole pieces attached to the housing, wherein at least some of the inner and outer pole pieces are configured to impart balanced axial forces between the rotor shaft and the housing.

10. An improved sealless pump as in claim 9, wherein the pump does not include a contacting axial bearing between the rotor shaft and the housing.

11. An improved sealless blood pump of the type including a pump housing, a rotor mounted for rotation within the housing, and magnetic bearings for radially supporting the rotor wherein the improvement comprises:

a hydraulic pump impeller which operates in both an axial and radial manner.

12. An improved sealless blood pump of the type including a pump housing, a rotor mounted for rotation within the housing, and magnetic bearings for radially supporting the rotor wherein the improvement comprises:

a pump housing having an annular constriction configured to fit within an opening in an apex of a heart.

13. An improved sealless blood pump of the type including a pump housing, a rotor mounted for rotation within the housing, and magnetic bearings for radially supporting the rotor wherein the improvement comprises:

magnetic bearings which impart balanced radial and axial forces on at least one side of the motor so that the motor is not cantilevered.

14. An improved sealless blood pump of the type including a pump housing, a rotor mounted for rotation within the housing, and magnetic bearings for radially supporting the rotor wherein the improvement comprises:

a control system for gating and rotating the rotor in a pulsatile manner at a pulse frequency range from 0.5 Hz to 1.5 Hz.

15. A blood pump system, said system comprising:
an implantable rotary blood pump; and
means for operating the blood pump to provide pulsatile flow.

16. A blood pump system as in claim 15, wherein the operating means mimics a natural heartbeat.

17. A blood pump system as in claim 15, wherein the operating means comprises a pacemaker.

18. A blood pump system as in claim 15, wherein the operating means comprises electronically controlled motor drivers.

19. A blood pump system as in claim 15, wherein the operating means senses the output of the coronary sinus node and gates the blood pump motor drivers in response to said output.

20. An improved sealless blood pump of the type including a pump housing, a rotor mounted for rotation within the housing, and magnetic bearings for radially supporting the rotor wherein the improvement comprises:
means for operating the pump in a manner which mimics the natural heartbeat.

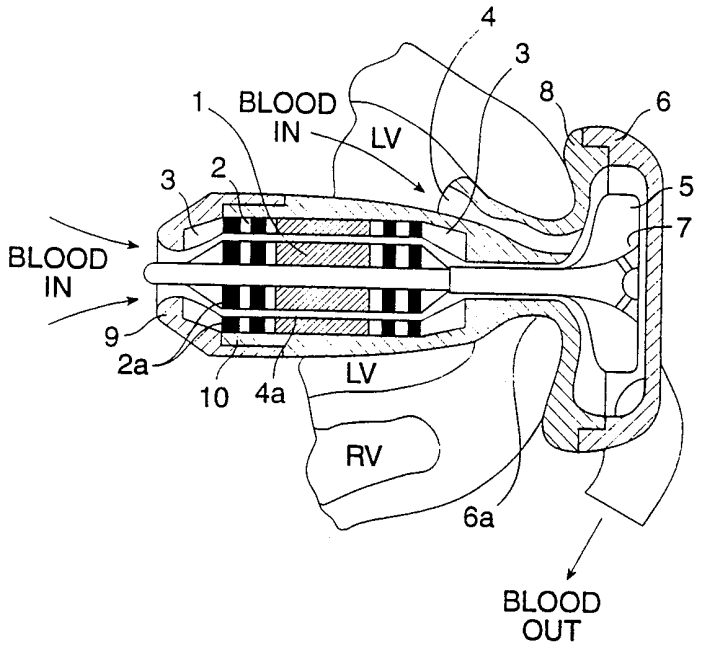


FIG. 1

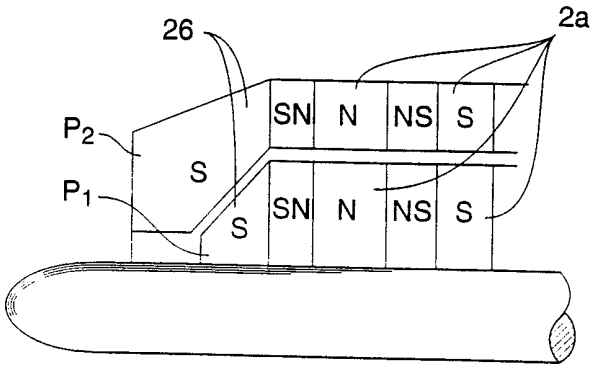


FIG. 2A

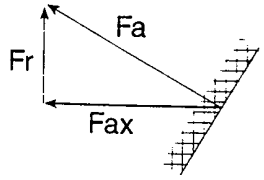


FIG. 2B

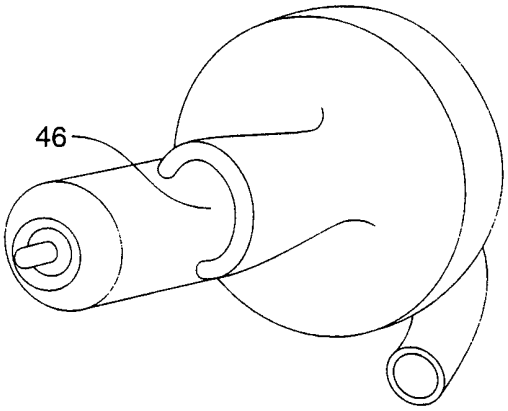


FIG. 3

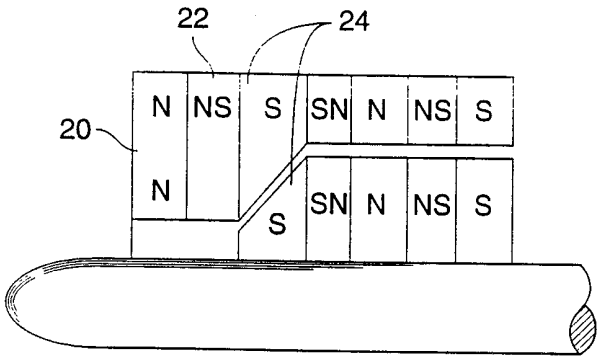


FIG. 4

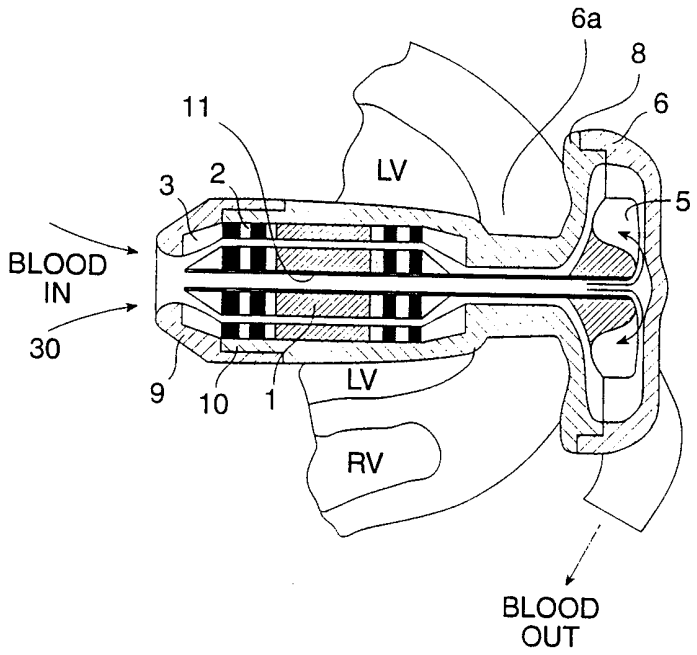


FIG. 5

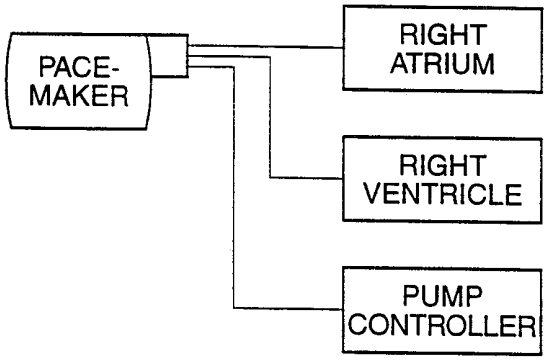

PACE-
MAKER
RIGHT
ATRIUM
RIGHT
VENTRICLE
PUMP
CONTROLLER

FIG. 6

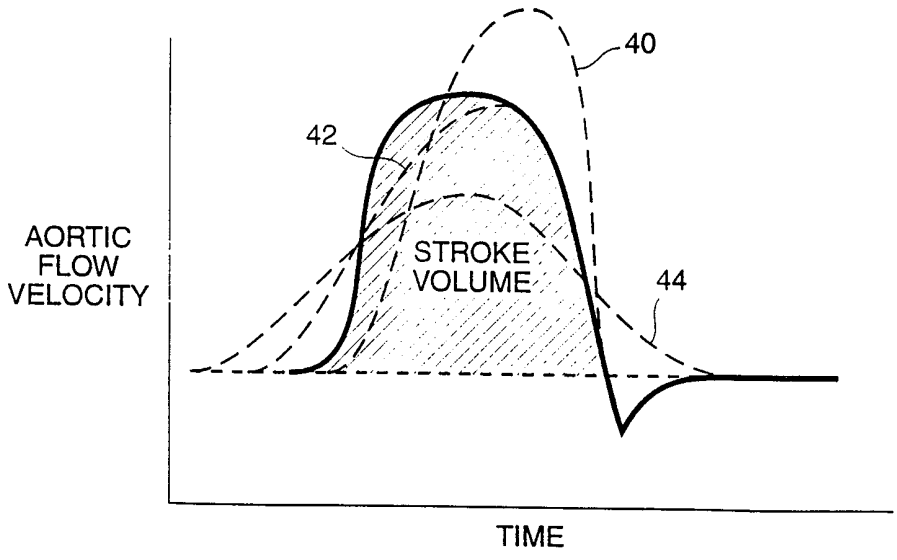

40
42
AORTIC
FLOW
VELOCITY
STROKE
VOLUME
44
TIME

FIG. 7