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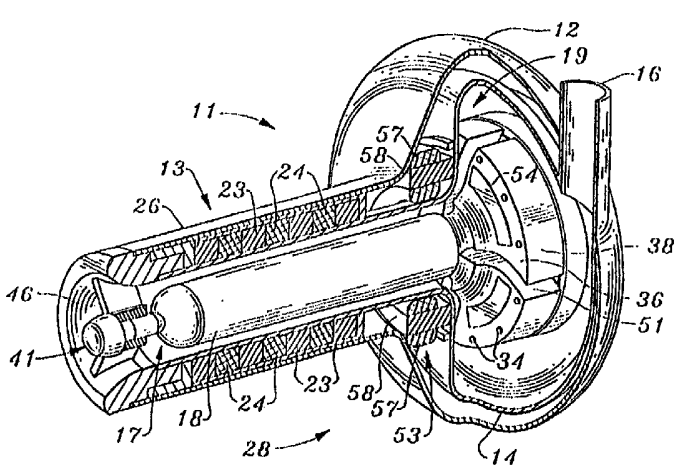
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(54) Title: SEALLESS ROTARY BLOOD PUMP WITH PASSIVE MAGNETIC RADIAL BEARINGS AND BLOOD IMMERSED AXIAL BEARINGS		
(57) Abstract This invention is an implantable rotary blood pump without a shaft seal. The pump includes rotary element (18) having a pump impeller (38) at one end. The rotary element and the impeller are maintained in radial alignment by respective, passive magnetic bearings (23, 24).		
		

**SEALLESS ROTARY BLOOD PUMP WITH PASSIVE MAGNETIC
RADIAL BEARINGS AND BLOOD IMMERSSED AXIAL BEARINGS**

Field Of The Invention

5 The invention relates generally to the field of blood pumps. More specifically, the invention pertains to continuous flow pumps of rotary design, suitable for permanent implantation in humans, for use as chronic ventricular assist devices.

10 Background Of The Invention

 Thousands of heart patients who suffer from severe left ventricular heart failure could benefit from cardiac transplantation. However, owing to a shortage of donor hearts, most of these patients face a foreshortened life span characterized by frequent hospitalizations, severe
15 physical disability, and death from congestive failure or cardiogenic shock. If a left ventricular assist device ("LVAD") were available for chronic use, many of these patients could be returned to prolonged and productive lives.

 Prior art LVADs, now in clinical trials, provide a cyclic or pulsating delivery of blood, designed to emulate the natural pulsatile blood
20 flow through the heart. This design approach has resulted in a variety of anatomic and engineering problems. Cyclic delivery systems tend to be physically large, making implantation difficult or impossible for some patients. Cyclic delivery systems also employ artificial valves, having special material, longevity, and performance requirements. All of these characteristics make
25 cyclic blood pumping devices both complex and expensive.

 It is apparent that if the requirement of pulsatile blood flow is eliminated, the LVAD could be much smaller, simpler, and less expensive. Rotary pumps, whether of centrifugal or axial flow design, provide substantially continuous liquid flow, and potentially enjoy a number of the
30 listed advantages over cyclic delivery systems. However, the prior art has not

developed a durable rotary blood pump, owing to unique problems with the rotary pump's driveshaft seal. In a blood environment, such driveshaft seals have a short life, and contribute to a premature failure of the pump. Prior art driveshaft seals may also cause embolisms, resulting in a stroke or even death for the patient.

5 Accordingly, it is an object of the present invention to provide an improved rotary blood pump, be eliminating the necessity for a driveshaft seal;

It is a further object of the present invention to provide a compact, rotary blood pump using passive, magnetic radial bearings to maintain an impeller and its support shaft for rotation about an axis;

10 It is yet a further object of the present invention to provide a rotary blood pump having bi-stable operation, in which the impeller and the support shaft shuttle as a unit, between two predetermined axial positions;

It is another object of the present invention to provide blood immersed axial thrust bearings which are regularly washed by fresh blood flow to prevent thrombosis from
15 occurring;

It is yet another object of the present invention to provide a unique thick bladed pump impeller, which houses both motor magnets and radial bearing magnets, and includes narrow, deep, blood flow passages;

It is yet another object of the present invention to provide a pump impeller which is
20 effective pumping viscous liquids, such as blood, at low flow rates, and which minimizes hemolysis of the blood by using only a few pump impeller blades.

Summary of the Invention

According to the present invention there is provided a centrifugal blood pump comprising:

25 a casing having an inlet and an outlet; and

a disc-shaped impeller located within said casing and having an upper face, a lower face, and a plurality of blade sectors, each of said sectors being separated from an adjacent sector by a channel extending continuously from said upper face to said lower face, said channel serving as a continuous fluid path through the impeller from said upper
30 face to said lower face and functioning to increase the effective working area of the impeller.

In accordance with the present invention, rotary blood pump includes a housing and a pump rotor. A centrifugal pump impeller is attached to an impeller support shaft, or spindle, to form the pump rotor. The pump



housing includes an elongated inlet tube surrounding the shaft, and a scroll-shaped casing, or volute, with a discharge outlet, enclosing the impeller.

The shaft and the impeller are specially suspended within the housing. Radial magnetic bearings of passive design, maintain the support
5 shaft and the impeller about a rotational axis. The magnetic bearing which levitates the shaft includes a plurality of permanent ring magnets and pole pieces arranged along surrounding portions of the inlet tube, and a plurality of permanent disc magnets and pole pieces within the shaft itself. Radially adjacent pairs of these magnets are of like polarity. One part of the magnetic
10 bearing, which maintains the impeller about a rotational axis, includes a plurality of permanent rod or arcuate magnets disposed in spaced, circular relation around blade sectors of the impeller; another part of the bearing includes a pair of permanent ring magnets outside the casing, on either side of the impeller. Adjacent portions of the rod and ring magnets are of opposite
15 polarity.

The shaft and impeller are axially restrained by a magnetic and hydrodynamic forces in combination with mechanical thrust bearings, or touchdowns. The magnets of the magnetic bearing in the inlet tube and shaft may be arranged in slightly offset axial relation, to produce a translational
20 loading force, or bias, along the longitudinal axis of the rotor. This bias substantially counteracts the axial force resulting from the hydraulic thrust of the rotating impeller. However, the hydraulic thrust will vary as a function of the cardiac cycle and additional restraints are desirable to ensure that pump operation is stable and controlled. For this purpose, a pair of blood immersed
25 thrust bearings is provided. These thrust bearings may be located at either end of the rotor, although other arrangements are feasible.

One thrust bearing is included at the upstream end of the support shaft, and the other thrust bearing is located on the bottom, or downstream side of the impeller. A spider within the inlet tube includes a

touchdown, or thrust surface, against which the end of the shaft periodically touches. Another touchdown is provided on an inner surface of the casing base, adjacent a downstream terminus of the impeller. A predetermined amount of spacing is included between the two touchdowns, so as to allow the
5 shaft/impeller assembly axially to shuttle back and forth, in response to the user's cardiac cycle. This shuttling motion will produce a pumping action, frequently exchanging blood in the touchdown area with fresh blood from the circulation. This pumping action minimizes the likelihood of blood thrombosis in the thrust region, by maintaining the blood at an acceptable temperature
10 and by shortening its residence time in the thrust bearing gap.

The impeller is of unique configuration and characteristics, owing to the special requirements of the present application. Contrary to conventional centrifugal pump design, the present invention uses relatively few impeller blades, generally resembling pie-shaped sectors. Moreover, the blades
15 are made quite thick in an axial direction, having deep and narrow, arcuate channels between adjacent blades for the passage of blood through the impeller. The substantial height of the blades provides a relatively large blade working surface, ensuring efficient pump operation. These structural features decrease hemolysis of the blood, while maintaining useful efficiency in a pump
20 using so few impeller blades.

Sealed, hollow chambers are provided within the thick impeller blades to reduce the density of the impeller. These chambers reduce gravity induced loads on the thrust bearings, which in turn reduces the likelihood of thrombosis of the blood used to lubricate the bearings.

25 The thick impeller blades are also used advantageously to house magnets used in the pump drive system. Torque drive is imparted to the impeller by magnetic interaction between arcuate, permanent magnetic segments imbedded within each impeller blade sector, and a circular electromagnetic stator, affixed to the casing. Back-EMF sensing is used to

commutate the brushless motor stator, providing attractive and repulsive forces upon the magnetic segments. A control unit and a portable power supply, worn on the user, power the pump drive system. The control unit allows the speed and drive cycle of the motor either to be programmed or
5 interactively determined by the user's physical activity or condition.

Brief Description Of The Drawings

Figure 1 is a left front perspective of the blood pump of the present invention;

10 Figure 2 is a fragmentary, cross-sectional view of the pump of Figure 1, showing a plurality of ring magnets comprising part of the magnetic bearing assembly;

Figure 3 is a fragmentary, cross-sectional view of the pump of Figure 1, showing the shaft and an impeller;

15 Figure 4 is a view as in Figure 1, but with the shaft and impeller shown removed from the housing;

Figure 5 is a simplified, fragmentary, representation of a human heart, showing the pump implanted within the left ventricle of the heart;

20 Figure 6 is a transverse, cross-sectional view of the housing, impeller, and impeller chamber, taken along the line 6-6, shown in Figure 1;

Figure 7 is a longitudinal, cross-sectional view of the pump, taken along the line 7-7, shown in Figure 1; and,

25 Figure 8 is a longitudinal, cross-sectional view of a simplified, schematic representation of the pump, showing respective polarities of the magnets and the pole pieces of the passive radial magnetic bearings, and the elements of the pump motor, including rotor magnets and a motor stator.

Detailed Description Of The Preferred Embodiment

Turning now to the drawings, a sealless rotary blood pump 11 includes a housing 12, having an elongated inlet tube 13 and a scroll-shaped impeller casing or volute 14. A discharge tube 16 extends through the housing
5 to communicate with the interior periphery of casing 14. Tube 16 has a tangential orientation with respect to a radius of the casing, for effectively channeling the blood output from the pump.

A pump rotor 17 is located within housing 12, and includes an elongated, right-circular cylindrical support shaft or spindle 18, attached to a
10 disc-shaped impeller 19. Rotor 17 is mounted for rotation about a longitudinal axis which extends both through shaft 18 and impeller 19. It should be noted that the preferred embodiment disclosed herein includes an impeller and a casing of centrifugal design. However, many of the structural features and aspects of operation of the present invention may also be adapted
15 advantageously to rotary blood pumps of axial flow design.

The pump 11 of the present invention includes a forward magnetic bearing 21 and a rearward magnetic bearing 22 to levitate rotor 17 and maintain it in proper radial alignment with respect to its longitudinal axis. A radial magnetic bearing construction is shown in U.S. Patent No. 4,072,370,
20 issued to Wasson. The '370 Patent is hereby expressly incorporated by reference. The forward magnetic bearing 21 herein may be constructed entirely in accordance with the teachings of the '370 Patent. However, several simplifications and improvements to the construction shown in the '370 Patent are disclosed herein. For example, it has been determined that the radially
25 polarized ring magnets (numerals 44 and 46) of the '370 device, are not necessary for successful practice of the invention herein. In addition, as will be explained below, the axially magnetized ring magnets (numeral 22) of the '370 device may advantageously be replaced with axially magnetized disc magnets for purposes of the present invention.

Accordingly, the forward magnetic bearing 21 includes a plurality of rings, comprising ferromagnetic pole pieces 23 and axially polarized permanent magnets 24. As shown most clearly in Figures 7 and 8, pole pieces 23 and magnets 24 are arranged in contingent, alternating fashion, and are
5 located between outer sidewall 26 and inner sidewall 27 of inlet tube 13. The polarization of opposing magnets is the same, inducing an identical polarization into a respective pole piece therebetween. A combination of high strength adhesive and surrounding tube sidewalls, maintains the arrangement of magnets and pole pieces in contingent relation, despite strong magnet
10 forces attempting to urge the rings apart.

Forward magnetic bearing 21 also includes a plurality of discs, comprising ferromagnetic pole pieces 28 and axially polarized permanent magnets 29. Pole pieces 28 and magnets 29 are also arranged in contingent, alternating fashion, so as to form a magnetic structure which mirrors the
15 polarity and axial position of respective pieces and magnets of the surrounding rings. This magnetic structure is first assembled and secured together using high strength adhesive, and is then installed within the hollow volume of shaft or spindle 17. The magnetic polarizations and repulsive forces produced by the magnets and the pole pieces of forward magnetic bearing 21 are such that
20 magnetic levitation of support shaft 18 results.

To provide additional radial restraint for rotor 17, rearward magnetic bearing 22 is also provided. Bearing 22 includes a first ring magnet 31 mounted on an outer wall of casing 14, and a second ring magnet 32 imbedded within a circular casing base 33. The bottom portion of casing 14
25 is attached and sealed to base 33, to form a fluid impervious enclosure for impeller 19 (see Figure 7). Both magnets 31 and 32 are axially polarized, but each has a different polarization facing impeller 19. Bearing 22 also includes a plurality of rod magnets 34, transversely extending from an upper face portion 36 to a lower face portion 37 of impeller 19. Rod magnets 34 are

arranged in spaced, circular fashion, adjacent an outer periphery 38 of impeller 19. The polarizations between the ends of magnets 34 and the adjacent surfaces of magnets 31 and 32 are respectively opposite, creating attractive, but equal and opposite magnetic forces acting on the impeller. In
5 this manner, rearward magnetic bearing 22 acts to maintain the impeller end of rotor 17 in axial alignment.

It should also be noted that other configurations, locations, numbers, and polarization orientations may be used for the components forming rearward magnetic bearing 22. For example, magnets 34 may be
10 arcuate segments, rather than rods. Also, the polarizations of the magnets 31, 32, and 34 may be arranged to effect respective repulsive forces, rather than the attractive forces specifically disclosed herein.

Although the drawings show magnets 32 and 34 as if portions thereof are directly immersed in blood, in actual practice, a thin-walled non-
15 magnetic jacket or a plastic coating would be placed over these portions, to prevent contact between the magnets and the blood. Such contact, if it were allowed, would likely cause an undesirable chemical reaction, to the detriment of the blood. However, for clarity, the referenced jacket or coating, is not shown in the drawings.

20 To provide mechanical limitations on axial, translational excursions of the rotor, a first thrust bearing 39 and a second thrust bearing 41 are provided. First thrust bearing 39 includes a threaded plug 42, installed within casing base 33. Plug 42 is screw adjustable along the longitudinal axis of rotor 17, and includes a recessed bearing surface 43. Surface 43 is
25 contoured to accommodate a corresponding bearing tip 44, in the lower face portion of impeller 19. It should be noted that the particular configuration of bearing 39 is not critical, and planar bearing surfaces may alternatively be used in this application.

Second thrust bearing 41 is secured within the blood entry end of inlet tube 13, and includes a spider 46, adjustment knob 47, and ball 48. Rotation of knob 47 will translate ball 48 along the longitudinal axis of rotor 17.

5 Alternative locations and constructions for second thrust bearing 41 are also contemplated. For example, an annular thrust bearing surface could be provided on the inner wall of casing 14, adjacent the upper face portion 36 of impeller 19. In this arrangement, portion 36 would slidably contact the annular thrust bearing surface. By eliminating spider 46 and the
10 associated components of the upstream thrust bearing, the possibility of blood deposits forming on these structures would be eliminated.

 It will be appreciated that thrust bearings 39 and 41 are effective not only to provide limit stops to axial movement of rotor 17, but also to adjust certain operational aspects of the pump. In the drawings, the upstream
15 end of support shaft 18 is shown in contact with ball 48. However, this will not always be the case during the course of operating the pump. For example, it is desirable for the two thrust bearings to be adjusted so that the distance between them, is slightly greater than the overall length of the rotor. This will allow the rotor to "shuttle", back and forth between the axial constraints
20 provided by the thrust bearings with each cardiac cycle of the user. Each such cycle will produce a pumping action, bringing fresh blood into the touchdown, or thrust bearing area.

 The present invention does not use a journal bearing to restrain the rotor. Of necessity, a journal bearing radially encases at least a portion of
25 the rotor's support shaft or spindle. It is within this thin, annular volume between the shaft and the bearing surface, where thrombosis can occur in prior art devices as a consequence of heat and excessive residence time within the bearing. The bi-stable operation of the pump and rotor of the present invention, continuously flushes the blood around each thrust bearing, avoiding

thrombosis effects of prior art journal bearings.

There is also an important physical relationship which exists between the rotor and the magnetic bearings of the device disclosed herein. This relationship is established and maintained by proper axial placement of
5 the adjustable thrust bearings. In operation of the pump, the pressure gradient produced by the rotating impeller imparts an upstream axial force on the rotor. This force needs to be substantially counterbalanced, to ensure that cardiac pulses will create sufficient pressure variances through the pump, to effect bi-stable operation. By adjusting the axial relationship of the pole pieces
10 23 and the magnets 24 with respect to the pole pieces 28 and magnets 29, a downstream axial force will be produced. Since the forces within forward magnetic bearing 21 are repulsive, the desired downstream loading or bias will be effected when the magnets and pole pieces within the shaft are translated slightly downstream from the magnets and pole pieces in the inlet tube (See,
15 Figures 7 and 8). Thus, second thrust bearing 41 is effective to shift, or offset the rotor downstream a sufficient amount so the resultant, repulsive magnetic forces substantially counterbalance the hydrodynamic axial force produced by the rotating pump impeller.

We can now turn to the special design considerations and
20 operational characteristics of impeller 19. As will be noted particularly in Figure 6, the impeller includes a plurality of large blade sectors 49. Owing to its relatively high viscosity and susceptibility to damage from heat and mechanical action, blood is a uniquely difficult liquid to pump.

It is generally preferable in a large centrifugal pump, to have a
25 substantial number of thin, sharp impeller blades with relatively large voids or passages, between the blades, for the passage of low viscosity liquid. However, such a conventional design is not desirable, for a small centrifugal pump which has to pump a viscous liquid, such as blood.

When blood flows axially into the leading edges of impeller blades it tends to be damaged by the mechanical action and turbulence associated with the impeller blades. Thus, one of the design considerations of the present invention is to reduce such hemolysis, by minimizing the number
5 of impeller blades.

To maintain efficiency in a small pump with so few blades, the effective working area of the blades needs to be increased. This was accomplished in the present design by modifying the size and configuration of conventional blades in two significant aspects. First, blade sectors 49 are made
10 relatively wide or expansive through a rotational aspect (see Figure 6). In other words, the outer periphery of each blade sector 49 assumes approximately 80 to 85 degrees of rotation. It should be noted that an alternative design contemplated herein includes only two blade sectors, each of which assumes approximately 175 degrees of rotation. In either case, the
15 width of the impeller blade sectors of the present invention differ significantly from known prior art blades.

The second modification pertains to the thickness or height of the blade sectors. As shown particularly in Figures 4 and 7, blade sectors 49 are relatively thick in an axial direction. As a consequence of these
20 modifications, a narrow and deep impeller blood flow path or passageway 51 is defined between adjacent edges of blade sectors 49. By increasing the thickness of the blade sectors and narrowing the blood passageway, the ratio between the area of working surface of the blades and the volume of the passageway is increased. Also, the average distance of the liquid in the
25 passageway from the working surface of the blades is decreased. Both of these beneficial results provide a small pump for blood which has few blades for damaging blood, yet maintains acceptable efficiency.

The size and configuration of the impeller blades also allows the structural integration of a number of features directly within the impeller 19.

For example, the previously discussed rearward magnetic bearing 22 includes a plurality of rod magnets 34 of considerable length. Owing to the thickness of the blade sectors, these magnets are readily accommodated within the sectors. The sectors may also be provided with respective hollow chambers 52, to reduce the mass of the impeller and the gravity induced loads on the thrust bearings (see, Figure 6).

Lastly, a brushless rotor motor 53 includes arcuate magnetic segments 54, imbedded within the upper face portion 36 of blade sectors 49. As discussed above, the portions of segments 54 which would otherwise be in fluid communication with the pumped blood, are encased in a jacket or a coating (not shown) to prevent any chemical reaction between the blood and the magnetic segments. Making reference to Figures 6 and 8, segments 54 have alternating orientations in their polarities, and are directed toward an adjacent motor stator 56. Included within stator 56 are windings 57 and a circular pole piece 58, mounted on the outer surface of impeller casing 14. Windings 57 are interconnected by means of percutaneous wires to a controller 59 and a power supply 61, as shown in Figure 5. It is contemplated that controller 59 and power supply 61 may be worn externally by the user, or alternatively, they may be completely implanted in the user.

Controller 59 may include circuitry as simple as a variable voltage or current control, manually adjusted or programmed to determine the running rate of pump. However, controller 59 may also have interactive and automatic capabilities. For example, controller 59 may be interconnected to sensors on various organs of the user, automatically and instantaneously to tailor operation of the pump to the user's physical activity and condition.

The windings 57 are energized by the electrical output of controller 59 to produce an electromagnetic field. This field is concentrated by pole piece 58, and is effective to drive magnets 54 and the rotor 17, in rotary fashion. The back EMF resulting from the magnets 54 passing by the

windings is detected by the controller. The controller uses this back EMF voltage to continue generation of the electromagnetic field in synchronism with further rotation of the rotor. Brushless operation of the motor 53 is effected, then, by electromagnetic interaction between the stator and magnets
5 imbedded within the pump's impeller blades.

Rotation of the rotor 17, including shaft 18 and impeller 19, causes blood to flow through inlet tube 13 in the direction of arrows 62. The blood continues its path from the upper edge of passage 51 to the interior of casing 14. Discharge tube 16 allows the blood to be expelled from the casing
10 an into the user's cardiovascular system.

Anatomical placement of the pump 11 is shown in Figure 5. The simplified representation of a human heart 63, includes a left ventricle 64 and an aorta 67. The inlet tube 16 serves as the inflow cannula and is placed into the apex of the left ventricle 64. An arterial vascular graft 66 is connected on
15 one end to tube 16 and on the other end to the aorta 67 through an end to side anastomosis.

The centrifugal design of the pump allows a considerable amount of flexibility during implantation. Owing to the axial inflow and radial outflow of the pump, a 90 degree redirection of the blood is effected without
20 the necessity of a flow-restrictive elbow fitting. Moreover, the pump can be rotated on its longitudinal axis to adjust the orientation of the discharge tube and minimize kinking and hydraulic losses in the vascular graft. Good anatomic compatibility is possible since the pump casing is compact and disc-shaped, fitting well between the apex of the heart and the adjacent diaphragm.

25 It will be appreciated, then, that I have provided an improved sealless blood pump including magnetic bearings and thrust bearing suspension to minimize thrombosis, and an impeller having a blood flow path therethrough which is calculated to minimize hemolysis.

The claims defining the invention are as follows:

1. A centrifugal blood pump comprising:
a casing having an inlet and an outlet; and
a disc-shaped impeller located within said casing and having an upper face, a lower
5 face, and a plurality of blade sectors, each of said sectors being separated from an
adjacent sector by a channel extending continuously from said upper face to said lower
face, said channel serving as a continuous fluid path through the impeller from said upper
face to said lower face and functioning to increase the effective working area of the
impeller.
- 10 2. A centrifugal blood pump according to claim 1 further comprising:
a plurality of permanent magnets unitary with and located within said blade sectors.
3. A centrifugal blood pump according to claim 1 wherein
said impeller is thick in the axial direction and
said impeller blade sectors define sealed, individual hollow chambers to reduce the
15 density of the impeller.
4. A centrifugal blood pump according to claim 1 further comprising:
a motor including a plurality of permanent magnets carried by said impeller, and a
motor stator including an electrically conductive coil, said motor stator having a ring-
shaped configuration and surrounding said impeller.
- 20 5. A centrifugal blood pump according to claim 1 further comprising:
a motor including a plurality of permanent magnets located within said impeller and
extending axially, and a motor stator including an electrically conductive coil, said motor
stator having a ring-shaped configuration and located within said casing.
6. A centrifugal blood pump according to claim 1 further comprising:
25 a motor rotor on a surface of said impeller; and
a motor stator within said casing adjacent said surface of said impeller, for
producing an electromagnetic field.
7. A centrifugal blood pump according to claim 1 further comprising:
a permanent magnet motor rotor on a surface of said impeller;
30 an electromagnetic motor stator within said housing adjacent said surface of said
impeller; and
a power supply having an electrical output in connection with said motor stator.



8. A centrifugal blood pump substantially as hereinbefore described with reference to the drawings.

Dated 7 June, 1999

Kriton Medical, Inc.

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Patent Attorneys for the Applicant/Nominated Person

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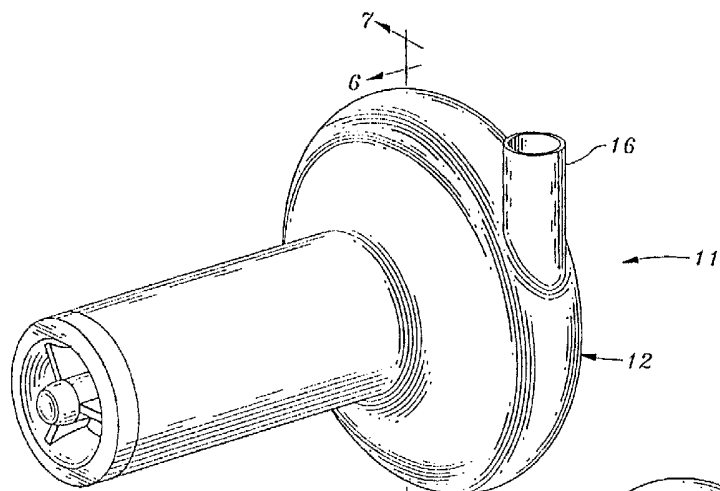


Fig. 1

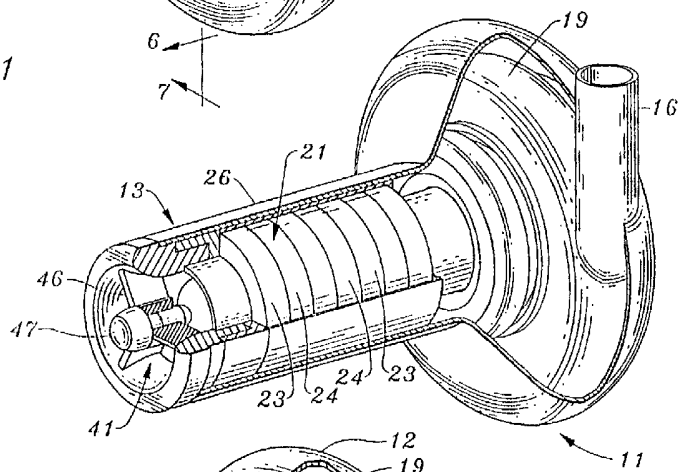


Fig. 2

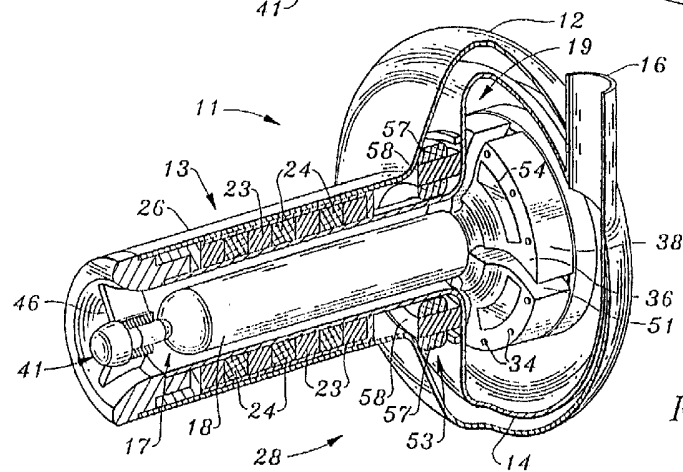
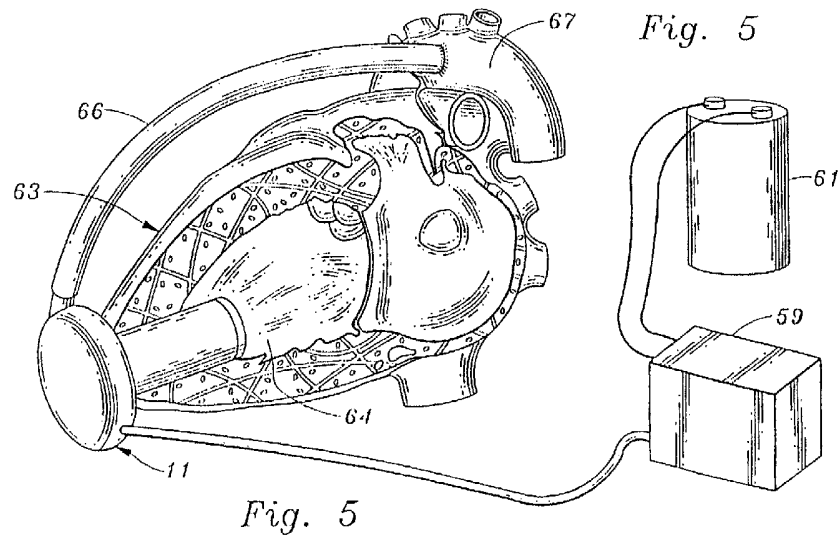
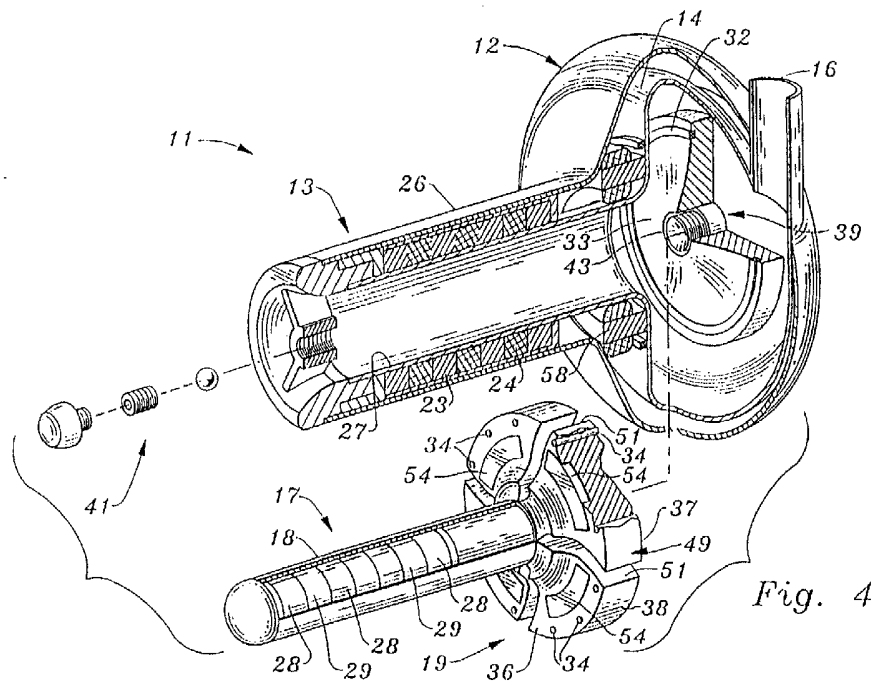


Fig. 3

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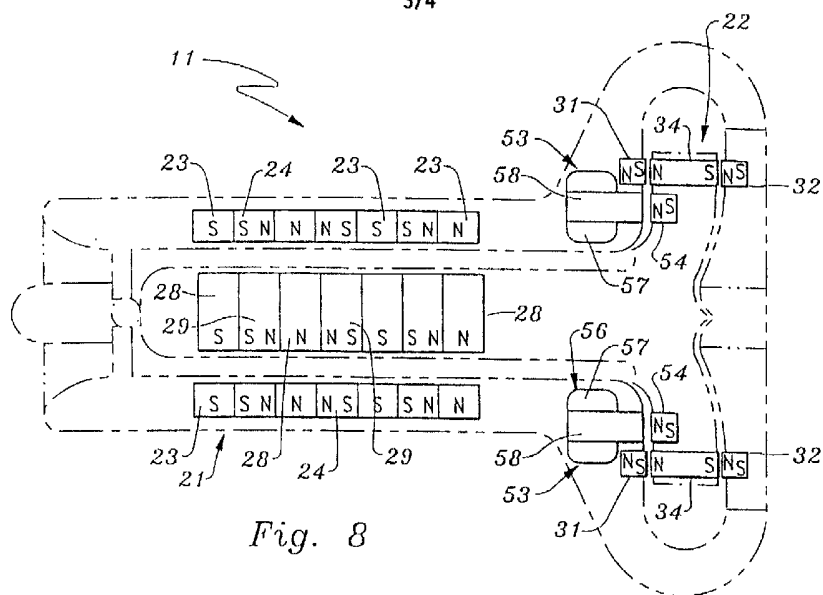


Fig. 8

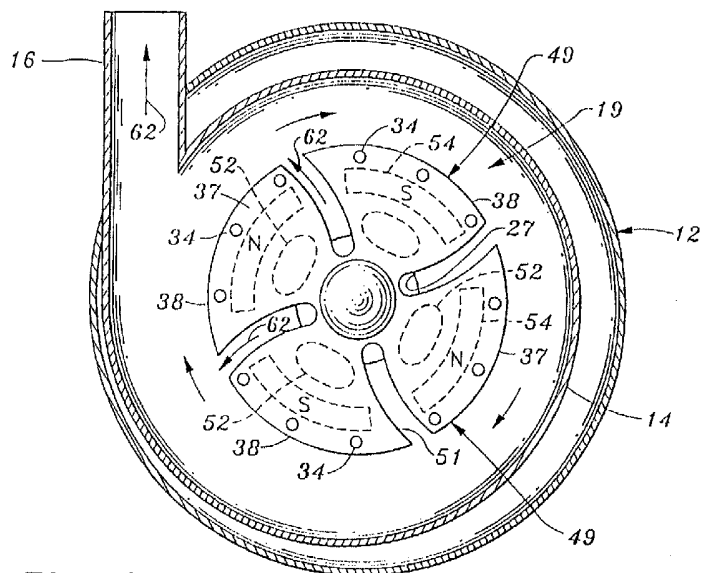


Fig. 6

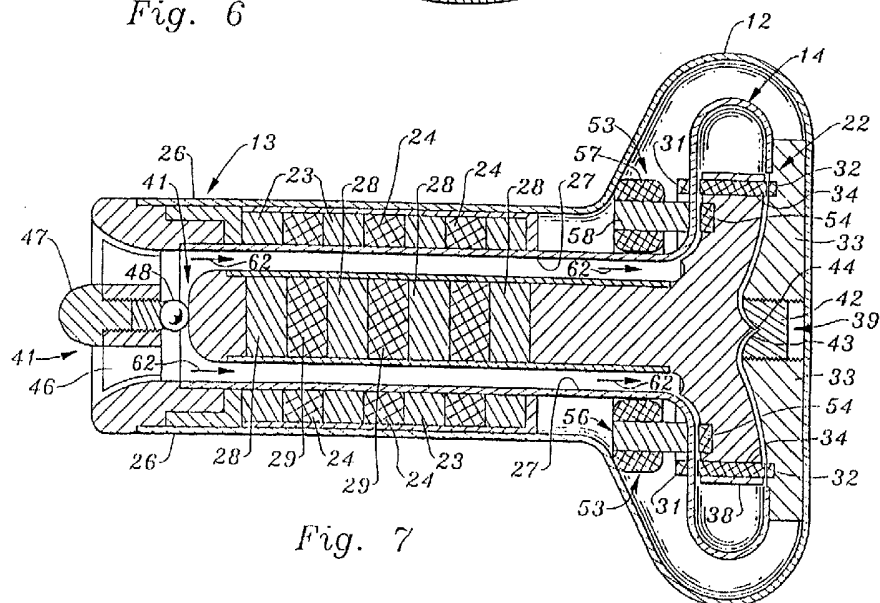


Fig. 7