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Kitrilakis et al.

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[54] **NONTRAUMATIC HEART PUMP**

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[73] Assignee: **Tecna Corporation,** Berkeley, Calif.

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[21] Appl. No.: **177,264**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 77,291, Oct. 1, 1970, abandoned.

[52] **U.S. Cl.** **417/383,** 417/430, 417/478

[51] **Int. Cl.** **F04b 35/02,** F04b 21/06

[58] **Field of Search** 417/567, 394, 387, 389, 417/383, 430, 478; 137/332; 3/1; 128/DIG. 3

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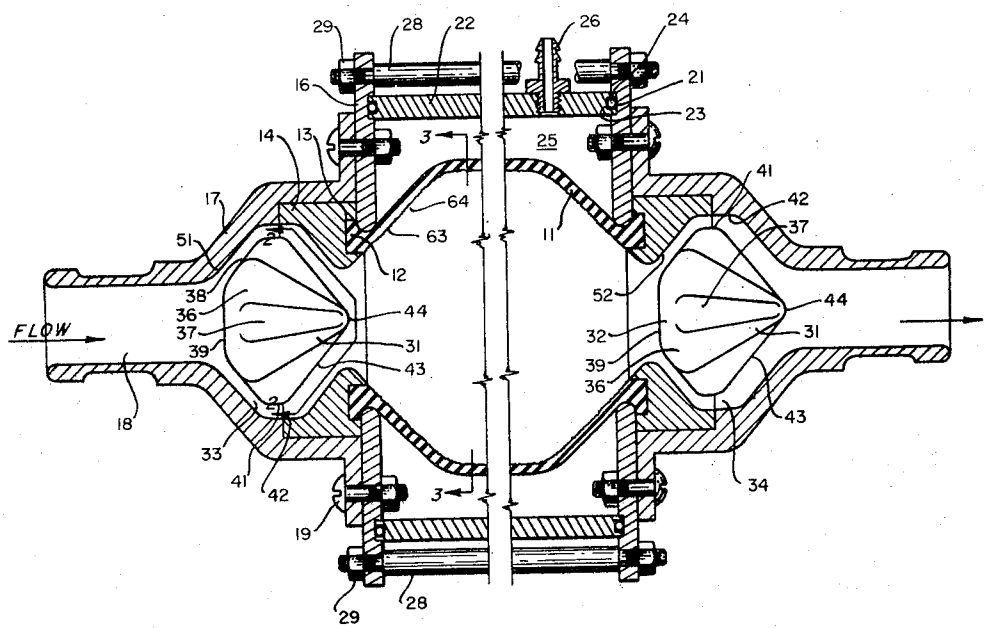
[57] **ABSTRACT**

A blood pump including a pumping chamber provided with in-flow and out-flow valves substantially aligned with the axis of the pumping chamber. The valves are especially designed to eliminate protrusions which may act as sites of possible thrombus formation, to minimize turbulence and areas of stasis and to provide a smooth flow of blood past the valve and through the pumping chamber. The inner lining of the pump includes a surface which contains microcavities to facilitate the attachment of fibrin and cellular deposits to provide a pseudointimal lining compatible with blood.

10 Claims, 6 Drawing Figures



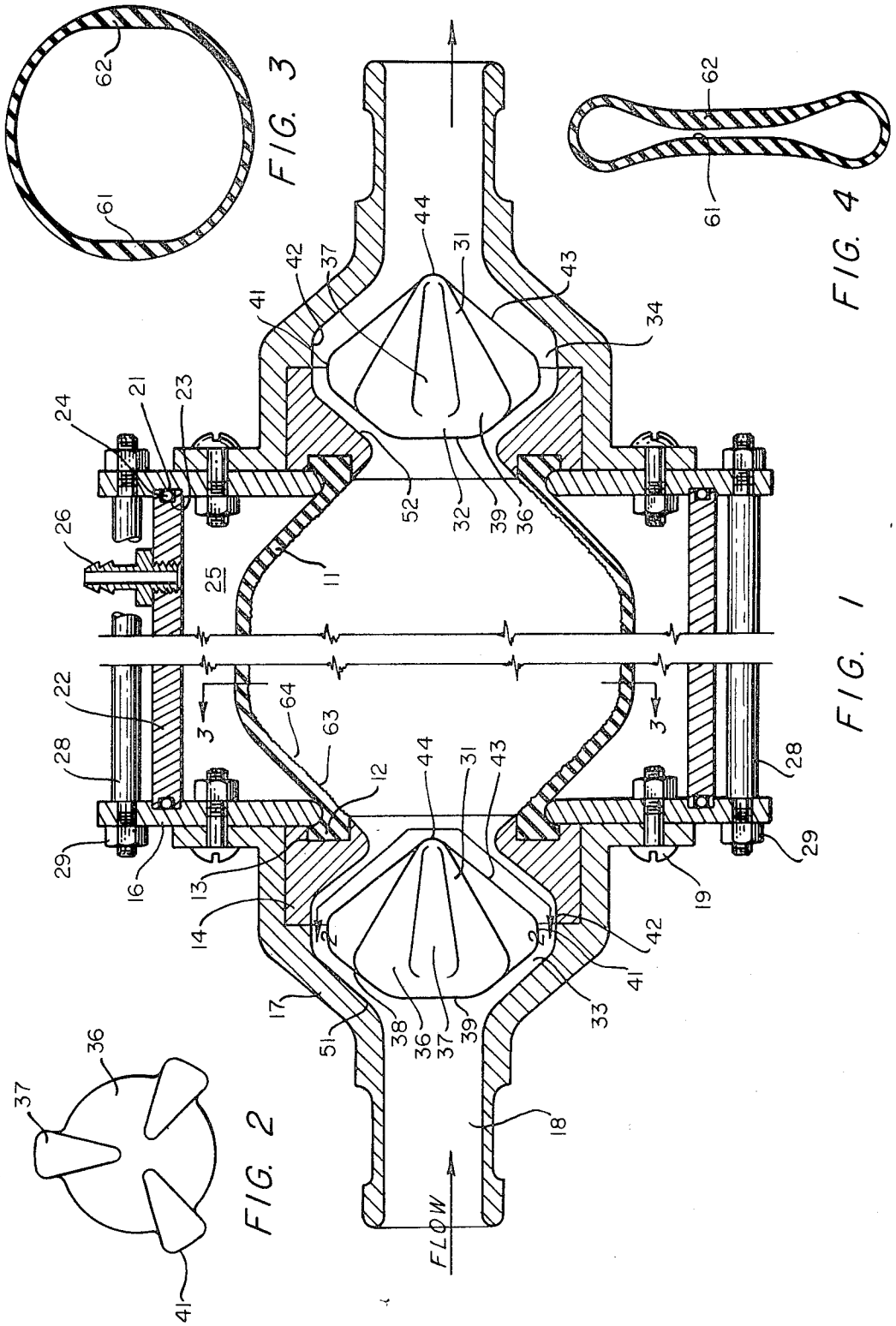


FIG. 1

FIG. 3

FIG. 4

FIG. 2

NONTRAUMATIC HEART PUMP

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of our copending application Ser. No. 77,291, filed Oct. 1, 1970 now abandoned.

BACKGROUND OF THE INVENTION

This invention relates generally to a nontraumatic blood pump.

In the course of the last ten years, the pumping of blood by artificial means has been frequently used in connection with cardio-vascular surgery and for emergency support in certain disease and accidental injury situations. Although high blood damage in the form of red cell destruction, loss of platelets, protein denaturation, the formation of thromboemboli and the like results from such pumping, the procedure continues to be used with increased frequency since very often the alternative is death. The duration of pumping is limited by the damage to blood elements which must not exceed the upper limit imposed by the body's ability to dispose of the debris of blood damage. Currently available blood pumping systems can be used for periods up to 4 to 6 hours, an amount of time adequate for the majority of open heart operations. There are many instances, however, in which longer pumping time is required; for example, circulatory support following heart failure or circulatory support for accident victims with cardiac or pulmonary damage. The need for artificial pumping may continue for several days while the natural healing process allows the heart or lung to resume normal functioning.

None of the currently available roller pumps nor the more recently marketed pulsating pumps are capable of prolonged circulatory support primarily because of the damage they cause to the blood elements. A need, therefore, exists for a pump capable of pumping blood for an indefinite period of time with low, physiologically tolerable blood trauma.

As far as is known at this time, two general types of action are responsible for damage to the blood elements. Biochemical processes are initiated when certain blood elements come in contact with a foreign, nonbiologic surface resulting in the destruction of the elements. The second type of damage is mechanical in nature and results from mechanical action or shear exerted on various blood elements, especially the red blood cells. Squeezing or pressing of blood elements between pump components or surfaces and excessive turbulence are sources of mechanical damage to the blood. It follows then that the key considerations which must be taken into account in the design and construction of a blood pump are that the surfaces of the pump which interface with the blood must not induce biological changes in blood elements, i.e., they must not be thrombogenic and that the fluid dynamics of the pump be designed to avoid turbulence, shear, stagnation, flow separation and the like which cause mechanical damage.

OBJECTS AND SUMMARY OF THE INVENTION

It is a general object of the present invention to provide a nontraumatic blood pump which includes a blood interface which promotes anchoring of the fibrin and cellular deposits from the blood stream resulting in coverage of the internal structure by biologic material and having a smooth flow of the blood through the pump thereby minimizing mechanical damage to the blood components.

The foregoing objects are achieved by a blood pump comprising a flexible bladder, having in-flow and out-flow openings, defining a pumping chamber, an in-flow valve associated with said in-flow opening and an out-flow valve associated with said out-flow opening, said in-flow and out-flow valves each including a valve seat, a valve adapted to cooperate with said seat, guide means for guiding said valve between its open and closed positions, and means for limiting the movement of the valve, each of said valve means comprising a central core having a surface portion adapted to seat on said valve seat and outwardly extending vanes cooperating with the guide means for guiding the valve between its open and closed positions, and further defining a plurality of flow channels for the flow of blood past the valve in a smooth even flow pattern free of protrusions in the form of pins or other retaining structures thereby minimizing turbulence and resulting mechanical damage to the blood.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a partial elevational view in section showing a blood pump in accordance with the invention.

FIG. 2 is an end view of the valve taken along the line 2—2 of FIG. 1.

FIG. 3 is a sectional view taken along the line 3—3 of FIG. 1 showing the bladder defining the pumping chamber.

FIG. 4 is a sectional view showing the bladder in its collapsed position.

FIG. 5 is a sectional view of another embodiment of the invention.

FIG. 6 is a sectional view of a disposable blood pump in accordance with the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to the embodiment of FIG. 1, flexible bladder 11 forms the pumping chamber. Each end of the bladder includes a rim 12 adapted to fit in a groove 13 formed in the retaining and valve stop member 14. The rim 12 is held in the groove 13 by means of disc 16 which is received by member 17 which cooperates with and holds the retaining member 14. The member 17 forms the in-flow connection 18. A plurality of screws 19 serve to secure the disc 16 to the member 17 and thereby hold the bladder in the member 14 which is, in turn, held in the member 17. The out-flow assembly is similar in construction and has like reference numerals applied to like parts.

The spaced discs 16 each include a circular groove 21 adapted to receive the end of cylinder 22. The end of the cylinder includes groove 23 and is provided with O-rings 24 to thereby form a seal between the end of the cylinder and the associated disc. The bladder 11, cylinder 22 and disc 16 define a chamber 25 which surrounds the bladder and communicates with inlet 26 whereby air pressure or vacuum may be applied to the chamber 25 to collapse or expand the bladder for pumping. The pumping chamber is maintained in assembled relationship by means of a plurality of spacers

28 which extend through the spaced members 16 and threadably receive nuts 29.

Valves 31 and 32 are disposed in the chambers 33 and 34 defined by the inclined opposed portions of the members 14 and 17.

The valves 31 and 32 each include a core portion 36 provided with outwardly extending fins 37. The front or leading edge 38 of the fins 37 defines a continuous surface with the front face 39 of the core 36. The outer edges 41 of the fins lie on a surface of revolution which is coaxial with the valve body. The outer edges 41 are adapted to cooperate with the cylindrical portion 42 of the valve chambers 33 and 34. The other end of the fins merges with the end of the valve body. The trailing edge 44 of the fins is rounded and the fins taper towards the downstream end to thereby provide a smooth transition for the flow of blood around the fins. The downstream inclined area of the surrounding housings 14 or 17 acts as the valve stop while the upstream end acts as the valve seat. It is to be observed that the in-flow and out-flow valves are identical and, therefore, like reference numerals are applied to like parts. In the case of the in-flow valve, the valve seat is at 51 and formed in the member 17, while in the case of the out-flow valve, the valve seat is at 52 and formed in the member 14. The valve core or body and vanes are so formed that there is a substantially constant cross-sectional area of the flow passage between the valves and associated chamber to thereby minimize the turbulence.

The formation of stagnant pools of blood within the pump is avoided by the streamlined configuration of the pump and chamber. The valves and their housing, as previously described, are designed with nearly constant cross-section for flow which minimizes acceleration and associated turbulence in the flowing blood as it passes through the various passages and channels around the valve. Preferably, the angle of the valve seats 51 and 52 is less than 50°, the limit which has been experimentally found necessary for the avoidance of major separation and recirculation of blood in this area. The blood flowing through the passages formed by the vanes washes the central core 36 in the process of flow. The use of the vanes and inclined surface as a valve stop provides a smooth shape which prevents significant acceleration, turbulence and flow separation and replaces the less satisfactory, more turbulent valve guide struts or other protrusions found in the prior art.

The guide vane portions 41 of the valve keep the valve positioned along the axis of the pump by coacting with the cylindrical portion 42 of the passage. The vanes are slightly tilted with respect to the axis of the valve so that a certain amount of rotation occurs each time the valve travels from left to right as it opens and closes. This ensures that uniform contacting occurs between the valve and its seat and that wear or deformation areas do not form in the lining of the valve seat or along the valve retaining walls. The shape of the valve guiding vanes and the central core portion provide adequate washing to avoid the formation thrombus and they are also so designed as to minimize turbulence eddies and the like. The above precaution is necessary because the valve is not coated with material that allows the formation of biologic lining.

The bladder itself is essentially a right cylinder in its central portion and tapered at the two ends which define the ridges 12. The cylindrical walls preferably include two thick portions 61 and 62 along the length on diametrically opposite sides to permit preferential collapse as shown in FIG. 4. By including these thickened portions, uniform and reproducible collapse of the bladder is assured. This is an important feature which assures that the maximum displacement volume is obtained without the risk of the opposite walls of the bladder surface touching one another and damaging the blood.

The inclined portions 63 of the bladder should have a thickness adapted to avoid excess stress concentration which would result in rupture, fatigue or permanent deformation. We have found it preferable to make the angle of inclination about 40°. In general, the flexing of the bladder during collapse takes place primarily at the point 64 which minimizes the excess stress concentration.

In accordance with another feature of the present invention, the bladder, the valve housing and the inlet and outflow members are preferably lined with a material which is compatible with the blood and which includes a plurality of microcavities which promote anchoring fibrin and cellular deposits from the blood stream resulting in complete coverage by biologic material within a short time. These deposits eventually result in a pseudointimal lining which is sufficiently thin to remain adherent and flexible and is nourished from the blood flowing past it.

A preferable lining for such purpose is a lining containing a plurality of microcavities such as are formed in accordance with the process set forth in copending application Ser. No. 77,289, filed Oct. 1, 1970.

In operation of the pump, air pressure is applied to chamber 25 through the inlet 26 to thereby collapse the bladder whereby the inlet valve is closed and the outlet valve is opened to provide the flow of blood outwardly. The amount of air applied to the chamber 25 is closely controlled whereby the walls 61 and 62 collapse and come close to one another for maximum volume displacement but yet do not touch whereby the blood elements are damaged. Thereafter, the pressure is removed and a vacuum may be applied to the chamber 25 thereby expanding the bladder to draw blood into the pumping chamber.

The blood pump shown in FIG. 5 operates in substantially the same manner as that just described with reference to FIGS. 1 through 4 and like reference numerals are applied to like parts. The chamber 25 comprises an oval shaped shell 71 having threaded ends 72 and 73 and inlet 26. The threaded ends 72 and 73 receive couplings 74 and 76, respectively. Flexible disposable bladder 11 is accommodated in the chamber 21 and includes retaining flanges 77 and 78. The bladder 11 extends beyond the flanges and is shaped to define valve chambers 33 and 34 with inlet and outlet connections 79 and 81 which can be connected directly to the patient. This provides a single material in contact with the blood. The material is suitably lined as, for example, a lining of the type described in said copending application. The embodiments of FIGS. 5 and 6 utilize a one-piece blood interface lining which incorporates the flexible bladder and the valve linings. This one-piece structure is an improvement over the multi-segment blood interface of the pump in FIG. 1. It is an improvement because the hydrodynamic effects of small nonuniformities such as gaps or steps at joints between parts

create local eddies, flow separation, or stasis. These in turn lead to thrombus formation or thick pseudonitimal lining development at these locations. A second advantage in a one-piece liner is the continuity of the microporous blood interface which prevents ridges or fibrin deposits associated with an interface discontinuity. Retainers **82** and **83** are engaged by the couplings and retain the lining by sandwiching the flanges **77** and **78** between surfaces **86, 87** and **88, 89,** respectively. The retainers are shaped to receive the bladder and provide a housing for the valve chambers **33** and **34.** The valves **31** and **32** are constructed as described above.

The blood pump may be constructed with a disposable housing. One example of such a pump is shown in FIG. **6.** The housing is formed of two pieces of plastic **91** and **92** which are snapped together at **93.** The disposable flexible bladder includes valve chambers **33** and **34** which are formed by shaping the ends of the housing to define one end wall **94** and **96** and by providing ridges **97** and **98** on the bladder to define the other wall of the chamber. The space between the bladder and the housing is sealed at the ends by applying suitable adhesive to the bladder and housing in the regions **101** and **102.** The valves **31** and **32** may be of the type previously described. The bladder is suitably lined as described above.

In summary then, there is provided a nontraumatic pump in which the lining permits deposition and permanent anchoring of a pseudointimal lining to avoid contact between blood elements and foreign surfaces. The design of the pump chamber and valves provides a substantially constant blood flow velocity with minimum acceleration, deceleration and associated turbulence and no areas of stagnation. The valve is designed to promote such constant velocity and is continuously washed by the blood flowing past the same. The valve is rotated by the flow whereby to provide substantially uniform wear in the pseudointimal lining on the valve housing and the valve seat.

We claim:

1. A blood pump comprising an external housing, a flexible bladder disposed in said housing, said bladder and housing defining a pumping chamber therebetween, said bladder including an inflow and outflow opening, an inflow valve assembly associated with said inflow opening and an outflow valve assembly associated with said outflow opening, said inflow and outflow valve assemblies each including a valve chamber and a valve disposed in said chamber, said valve chamber including a valve seat upstream in said chamber, said valve adapted to cooperate with said seat, said valve chamber cooperating with said valve for defining a constant flow path across section for constant flow velocity therethrough for minimizing flow turbulence, each of said valves comprising a central core having an upstream surface portion adapted to seat on said valve seat and downstream outwardly extending vanes cooperating with the valve chamber for guiding the valve and limiting its movement between its seated and unseated position.

2. A blood pump as in claim **1** in which said vanes are inclined in the axial direction whereby the flow of blood past the valve causes the valve to maintain even contact with said valve seat and minimize wear therebetween.

3. A blood pump as in claim **1** in which said flexible bladder includes a central cylindrical portion with the ends inclined inwardly to form said inflow and outflow openings, said cylindrical portion including thick portions extended along diametrically opposite sides for providing preferential collapse when subjected to pumping pressure.

4. A blood pump as in claim **1** in which the inner surface of said flexible bladder and in-flow and out-flow assemblies are provided with a surface containing microcavities to promote anchoring of fibrin and cellular deposits to form a pseudointimal lining.

5. A blood pump comprising a cylindrical housing having first and second open ends, a flexible bladder disposed in said housing, said bladder including an inflow and outflow opening extending beyond said first and second open ends for presenting a continuous internal surface to fluids flowing through for minimizing flow turbulence, an inflow valve assembly associated with said inflow opening and an outflow valve assembly associated with said outflow opening, said inflow and outflow valve assemblies each including a valve chamber, a valve seat surrounding the upstream ends of said valve chambers, a valve disposed in each of said chambers, each of said valves including a central core having an upstream surface adapted to engage said valve seat and down stream outwardly extending vanes cooperating with the valve chamber to guide the valve and serving to define with said chamber a plurality of flow passages providing a constant flow path cross section through said valve chambers for constant flow velocity therethrough thereby minimizing flow turbulence, and means for sealing the space between the housing and the bladder near said open ends to provide a pumping chamber surrounding the bladder, and an inlet to said pumping chamber.

6. A blood pump as in claim **5** in which said vanes are inclined in the axial direction whereby the flow of blood past the valve causes the valve to rotate and attain a new seating orientation.

7. A blood pump as in claim **5** in which said bladder has a substantially cylindrical central portion when distended and in which said cylindrical portion includes thick portions extended along diametrically opposite sides to provide for preferential collapse of said flexible bladder.

8. A blood pump as in claim **5** wherein te inner surface of said bladder contains microcavities to promote anchoring of fibrin and cellular deposits to form a pseudointimal lining.

9. A blood pump as in claim **5** wherein said housing comprises first and second disposable portions adapted to be connected to one another to form the cylindrical housing and wherein said flexible bladder is disposable and said means for sealing comprises means for permanently adhering the bladder to the housing near said open ends.

10. A blood pump as in claim **5** wherein the ends of the housing and the bladder are shaped to form said valve chambers.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,814,547 Dated June 4, 1974

Inventor(s) Sotiris Kitrilakis et al.

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Insert FIGURES 5 and 6, as part of Letters Patent.

Signed and sealed this 7th day of January 1975.

(SEAL)
Attest:

McCOY M. GIBSON JR.
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents

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