

[54] **PROSTHETIC HEART VALVE**

[72] Inventor: **Richard K. Rapp**, 1251 Imperial Dr., Glendale, Calif. 91207

[22] Filed: **Sept. 15, 1970**

[21] Appl. No.: **72,449**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 880,674, Nov. 28, 1969, abandoned.

[52] U.S. Cl. 3/1, 3/DIG. 3, 137/527.8, 137/512.1, 137/527

[51] Int. Cl. **A61f 1/22**

[58] Field of Search.....3/1, DIG. 3; 137/527, 527.4, 137/527.8, 512.1

[56] **References Cited**

UNITED STATES PATENTS

3,445,863	5/1969	Wada	3/1
3,438,394	4/1969	Nakib	3/1 X
3,314,420	4/1967	Smith et al.	3/1 UX
3,448,465	6/1969	Pierce et al.	3/1
3,370,305	2/1968	Goott et al.	3/1

FOREIGN PATENTS OR APPLICATIONS

452,298	5/1968	Switzerland	3/DIG. 3
1,500,461	9/1967	France	3/DIG. 3

OTHER PUBLICATIONS

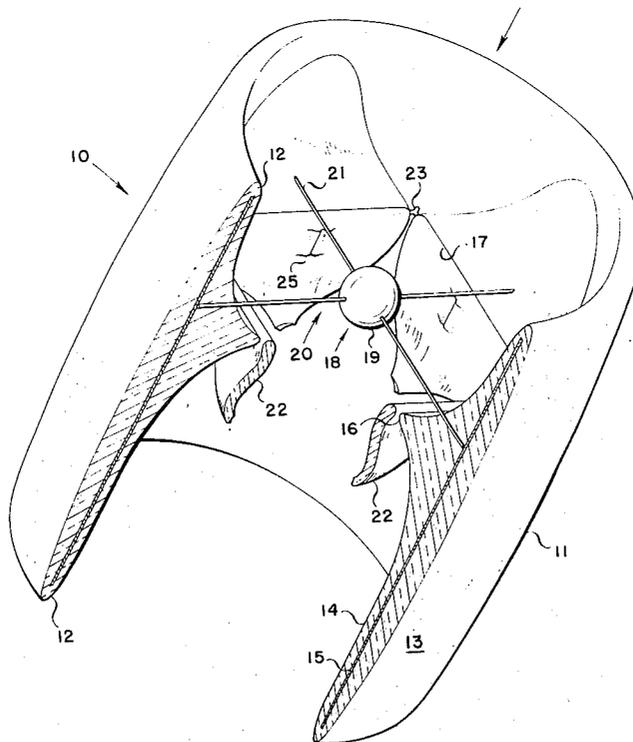
" A Hinged Prosthetic Cardiac Valve Fabricated of Rigid Components" by W. S. Pierce et al., The Journal of Thoracic & Cardiovascular Surgery, Vol. 56, No. 2, Aug. 1968, pp. 229- 235.

Primary Examiner—Richard A. Gaudet
Assistant Examiner—Ronald L. Frinks
Attorney—Matthew P. Lynch

[57] **ABSTRACT**

A prosthetic heart valve consisting of a cylindrical housing having a substantially rectangular opening therein and a plurality of triangular flaps pivotally secured to the housing within the opening. The flaps are adapted to pivot open in response to the flow of blood from the heart and pivot to a sealing position, in abutment to a sealing ball which controls the position of the flaps, in response to the back flow of the blood, thereby providing uni-directional flow.

17 Claims, 6 Drawing Figures



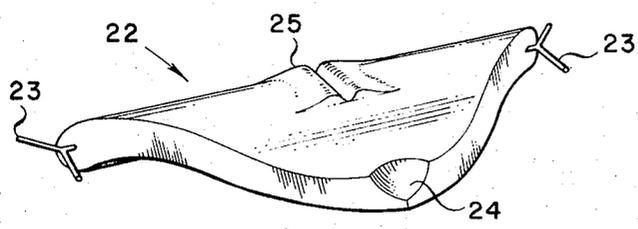
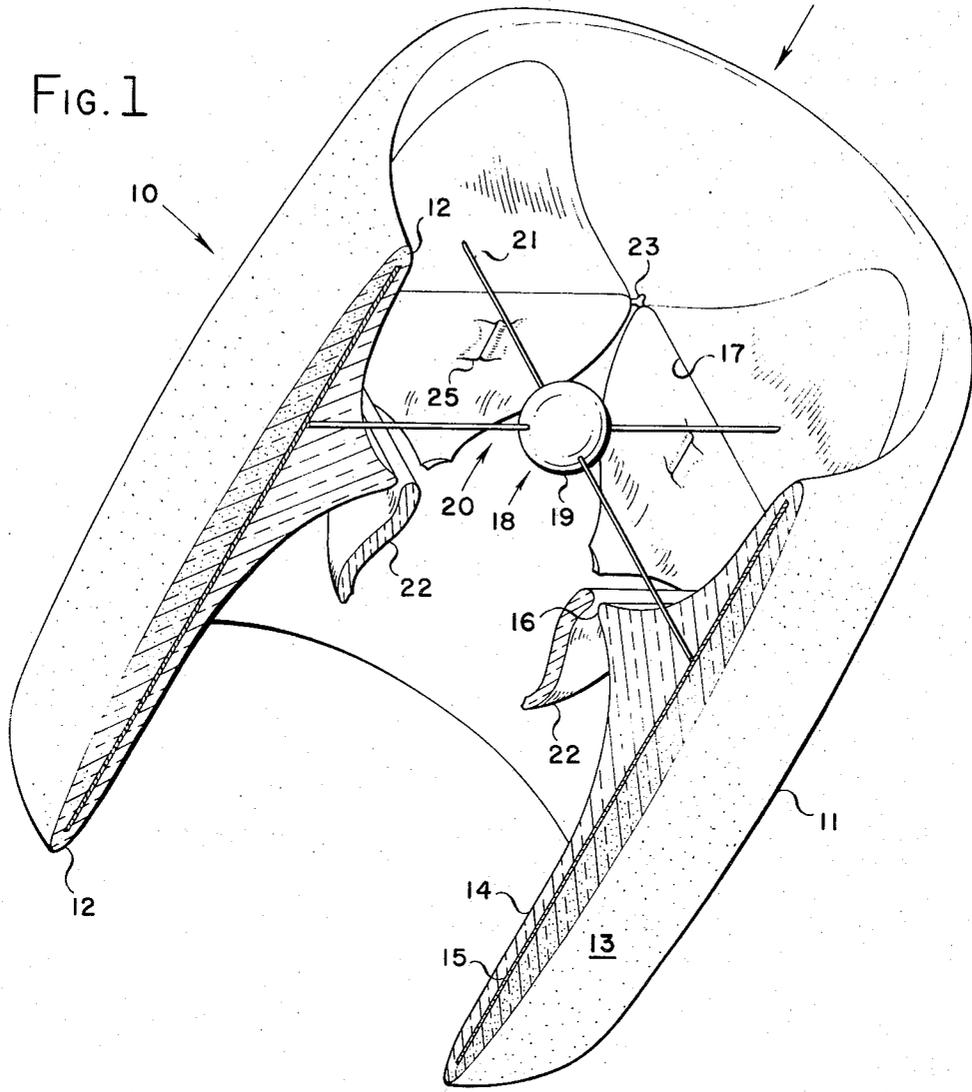


FIG. 3

INVENTOR.
RICHARD K. RAPP
BY *Matthew P. Lynch*
Attorney

FIG. 5

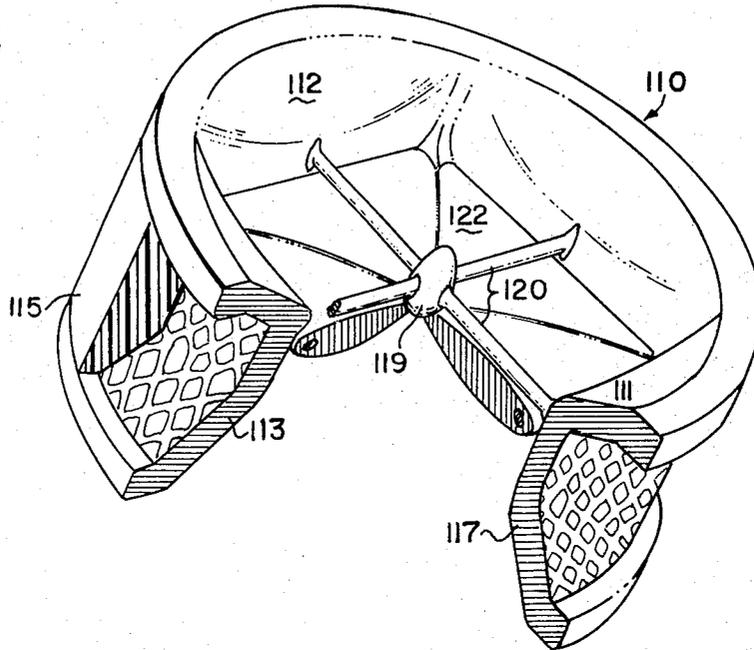
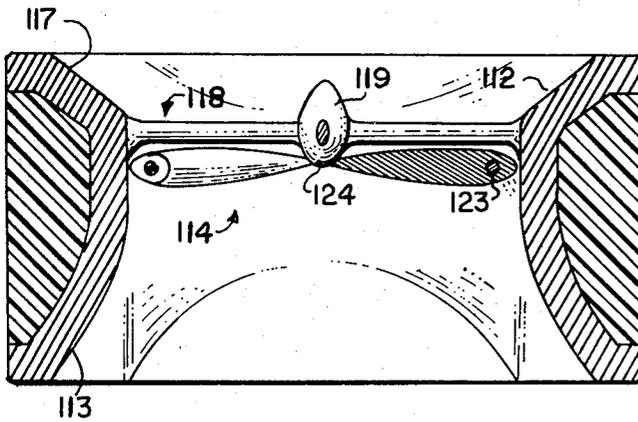


FIG. 6



RICHARD K. RAPP
INVENTOR

By *Matthew P. Lynch*
ATTORNEY

PROSTHETIC HEART VALVE

RELATED APPLICATIONS

This application is a continuation-in-part of application Ser. No. 880,674, filed Nov. 28, 1969, entitled "Prosthetic Heart Valve" and now abandoned.

BACKGROUND OF THE INVENTION

In the human body, blood enters the right auricle from the superior and inferior vena cavae which drain most of the body. It passes through the tricuspid valve to the right ventricle and is pumped to the lungs during systole or contraction of the heart. Blood returns from the lungs by way of the pulmonary veins to the left auricle passes into the left ventricle through the mitral valve and during contraction is pumped out into the aorta, which is a large elastic vessel whose endothelial lining is continuous with that of the heart. Located within the heart where the aorta connects to same is an aortic heart valve which is in essence a on-way valve. When operating correctly, the aortic heart valve will allow blood to pass from the left ventricle of the heart through the aortic heart valve into the aorta and thence throughout the arterial branches during heart contractions or systole and will prevent the blood from flowing back into the heart; when the flow or pressure of the blood is reversed due to the heart ceasing to contract and proceeding to expand. Since the back pressure of the blood on the aortic heart valve during the heart's resting cycle reaches a magnitude of about 200 millimeters of mercury (200 mm Hg) or 3.87 pounds per square inch, it is imperative that the aortic valve be capable of preventing the back-rushing blood from entering the heart where it would cause irreparable damage and possibly death.

In many instances the aortic valves become diseased or damaged in some way, thereby preventing them from operating in a normal manner, particularly with regard to preventing the back flow of blood into the heart. During the last few years great strides have been made in the area of heart surgery, particularly with regard to the replacing of malfunctioning heart valves with artificial prosthetic valves. The most commonly used of these artificial prosthetic heart valves is the ball and cage type which is inserted in place of an excised section of the descending aorta. The ball and cage valve utilizes an elastomer ball which relies, for extended use, upon the continuing elastomeric properties of the ball. In addition, such ball valves require a "cage" or retaining struts to maintain the ball in close proximity to its valve seat and these retaining struts extend into and across the blood stream, thus hindering the free flow of blood and causing undesirable turbulence. Additionally, when such ball valves are open, the flow of blood must pass around the ball which is a relatively bulky object and which takes up a significant portion of the cross-section of the normal blood flow channel. Further, when the ball valve closes after each systole it does so with an audible click, causing severe psychological neuroses in the transplant patient and even more serious is that the ball, in closing, crushes red blood corpuscles which is a known cause of disease.

In order to solve the aforementioned problems, attempts have been made to design uni-directional flap valves. Flap valves, however, while solving some of the problems associated with the ball and cage valve, have

other inherent disadvantages and defects. A particular problem is in the area of providing areas or pockets which are not constantly subjected to the washing or flushing action of the flow of blood therethrough, such pockets provide prime blood clot forming areas and are highly undesirable and dangerous to the well being of the patient. Another major problem with such flap valves is the fact that in all known flap valves a portion of the flap, when in its open position, extends into the oncoming flow of blood, causing the blood to flow in a swirling turbulent pattern which precludes the desirable laminar flow and additionally causes a fluttering of the valve flaps and a further eddying of the blood flow, all of which causes severe pressure differentials about the valve and a resulting insufficiency of blood flow, particularly in the extremities.

SUMMARY OF THE INVENTION

The present invention overcomes the aforementioned problems by providing a prosthetic heart valve having an annular housing with a substantially rectangular opening therein. A plurality of triangular flaps are pivotally secured to the inner walls of the housing forming the opening, the apexes of the flaps meeting in complementary sealing relationship in the center of the opening. The flaps are contoured and pivotally affixed in a manner such as to be completely responsive to the flow of blood without causing turbulence or restricting the flow of said blood while allowing a complete washing or flushing of the valve and only permitting uni-directional flow. Disposed in the center of the valve is a sealing ball which is adapted to complementarily receive the apexes of the flaps to hold them in sealing orientation to prevent the back flow of blood. The flaps and inner surface of the valve housing are constructed from an inert, impervious material and the outer surface of the valve housing is constructed from an inert, porous material in order to allow the living tissue of the aorta and heart to grow into the outer surface of the housing while precluding it from clogging the opening within the housing or interfering with the functioning of the flaps.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view, partially cut-away, of the prosthetic heart valve in its open position.

FIG. 2 is a perspective view, partially cut-away, of the prosthetic heart valve in its closed position.

FIG. 3 is a perspective view of one of the flaps.

FIG. 4 is a view along line 4-4 of FIG. 2.

FIG. 5 is a perspective view, partially cut-away, of an alternate embodiment of the prosthetic heart valve.

FIG. 6 is a transverse cross-sectional view of FIG. 5.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawings, wherein like reference numbers designate like or corresponding parts throughout the several views, there is shown in FIGS. 1 and 2 a prosthetic heart valve 10.

The valve 10 is adapted to be inserted into the heart as a replacement for the aortic heart valve or the mitral valve; therefore, it is preferred that the valve have a housing 11 which conforms to the shape of its receiving

member. However, since both the heart and the aorta are of an elastic nature, the shape of the valve housing is not critical. As a preferred embodiment, the housing 11 has been illustrated as having a substantially cylindrical exterior configuration. The diameter of the housing 11 will be determined by the diameter of the heart and aorta of its ultimate recipient; however, since the valve 10 has an expected unlimited useful life it is within the realm of feasibility that a larger valve will be utilized in young recipients by stretching the diameters of the receiving members in order to allow the recipients organs to grow without requiring that the transplanted valve be replaced with a larger valve. It will be noted that the housing 11 has a varying outer diameter in that the outer diameter tapers inwardly as it approaches either end of the cylinder and that the ends of the cylinder have a radius 12. The tapered and radiused ends of the housing 11 facilitate the insertion of the valve 10 into the heart and aorta and additionally assist in providing a relatively obstruction-free smooth vessel for the blood to flow through.

The housing 11 consists of an outer surface 13 which is of a porous nature and an inner surface 14 which is impervious. The outer surface 13 and the inner surface 14 can be bonded together directly to form an integral structure or they can be bonded together by means of a metalized layer 15 as illustrated. The utilization of an outer porous surface 13 allows the living tissue of the heart and aorta to grow into the housing 11 and permanently retain the valve 10 in its correct position. It is extremely undesirable, however, for the tissue to extend through the entire housing into the valve opening itself because then the tissue would tend to interfere with the operation of the valve and disrupt the flow of blood therethrough. Therefore, the inner surface should be impervious in order to preclude this from happening.

The inner surface 14 of the housing 11 is configured to converge to a radiused lip 16, which forms a substantially rectangular opening 17 at a point intermediate the ends of the housing 11. It will be noted by referring to the drawings, that a square opening has been illustrated. This is because, while any rectangular opening will work, a square opening is preferred. The contour of the inner surface 14 converging to form the opening 17 is designed to preclude the blood flowing through the opening 17 from eddying while still allowing the blood to flow over all parts of the valve to provide a continuous washing or flushing action in order to eliminate blood clotting pockets and areas of stagnation. In addition to the angle and contour of the slope of the inner surface 14, the radiused edge 16 of the rectangular opening 17 assists in the ensuring of laminar blood flow through the opening 17.

Disposed within the housing 11 substantially centrally of the opening 17 and adjacent thereto is a sealing means 18. In the preferred embodiment, as illustrated in FIGS. 1, 2 and 4, the sealing means 18 comprises a ball 19 of a substantially spherical configuration which is rigidly held in position by a plurality of support members 20. While the sealing means 18 has been illustrated in the preferred embodiment as a sphere, it will be obvious to someone skilled in the art that the sealing means 18 can assume other configurations such as an ellipse or a cone, among others. The

support members 20, which hold the ball 19 in position, should have as small a cross section as possible in order not to hinder the flow of blood while having sufficient strength and rigidity to maintain the ball 19 in a constant position within the housing 11. In the preferred embodiment, the support members 20 comprise small diameter wires 21 which are embedded in the housing 11 on one end and secured to the ball 19 on their opposite ends.

Pivotaly secured to the inner surface 14 of the housing 11 are four flaps 22. The flaps 22 are constructed to have a compound curvature which resembles a sinusoidal curve in order to be immediately responsive to the flow of the blood from the heart and to assist in the complete flushing of all the components of the valve 10 by the flowing blood. The flaps 22 are pivotaly connected to the housing 11 by substantially Y-shaped support pins 23. As illustrated in FIGS. 1 and 3, one end of the support pin 23 is pivotaly affixed to a corner of a flap 22, another end of the pin 23 is pivotaly affixed to a corner of an adjacent flap 22 and the leg of the pin 23 is fixedly secured within the inner surface 14 of the housing 11. In other words, the four flaps 22 are pivotaly secured to the housing 11 by four support pins 23, each of the support pins pivotaly connecting one end of two adjacent flaps to the housing 11. The leg of each pin 23 is disposed within the housing 11 at each corner of the rectangular opening 17 so that when the flaps 22, which are of a substantially triangular configuration, are pivotaly supported by the pins 23, one side of each flap lies in juxtaposition to one of the radiused lips 16 which form the rectangular opening 17. It is an important aspect of the applicant's invention that the flaps 22 all be of a complementary configuration and that their manufacturing tolerances be such that when all four flaps are pivotaly connected to the housing and in juxtaposition to each other that they substantially close and seal the rectangular opening 17. Research has shown, however, that due to the viscosity of the blood that a clearance of approximately 10 microns can be tolerated between the adjacent flaps in order to allow non-binding action while still providing complete sealing of the opening 17. In order to provide complete closing and sealing of the opening 17 when the flaps 22 are in juxtaposition, the apexes of the flaps are not radiused. FIG. 4 shows the compound curvature of the flaps 22 and their complementary juxtaposition relationship to the radiused lip 16.

Referring now to FIG. 3, it will be noted that the flap 22 has a concave depression 24 along its free apex. As illustrated, the depression represents a segment of a sphere and is specifically configured to mate in complementary abutment with the underside of the ball 19 when the flaps 22 are in juxtaposition in their closed position, as best shown in FIG. 4. Disposed on the upper surface of the flap 22 along a plane coinciding with the wire 21 is a flap guide 25. The flap guide 25 comprises a raised surface having a groove therein, the groove having a concavity sufficient to accept and partially surround the wire 21.

Referring now to FIGS. 5 and 6, there is shown an alternate embodiment of the prosthetic heart valve 10 indicated generally by the numeral 110. The valve 110 comprises a housing 111 which is annular and has a substantially C-shaped exterior configuration. The con-

cave exterior surface of the housing 111 is roughened or knurled to allow the attachment thereto of a polyethylene terephthalate (Dacron) or Teflon cloth layer 115 to which the living tissue of the aorta can be secured when the valve is placed within the body of its user. If a Teflon or Dacron cloth layer is utilized then it is not necessary to provide that the exterior surface of the housing 111 be porous since the living tissue of both the heart and aorta will be securely connected to the inert cloth layers and it is not necessary that they be able to grow into the outer surface of the housing. It will be noted by referring to the drawing that all the edges of the housing 111 are rounded or radiused in order to facilitate laminar flow of the blood therethrough. The housing 111 may be constructed from any type of material which is inert and capable of safe acceptance by the human body; however, the internal surface 114 should be impervious to preclude the growth of living tissue therethrough. The inner surface 114 of the housing 111 is of a modified hour glass configuration, wherein the upper inner portion 112 has a conical configuration which progressively decreases in diameter to terminate in a substantially rectangular opening 117, which is located intermediate the ends of the housing 111. The opening 117 extends downwardly for a distance less than one-half of its shortest side and then terminates to form the lower inner surface 113 which has a conical configuration, the diameter of which increases as it extends away from the opening 117.

Disposed within the housing 111 substantially centrally of the opening 117 is a sealing means 118. The sealing means 118 comprises a ball 119 having a substantially elliptical configuration which is rigidly held in the center of the housing by a plurality of support members 120, which also have a substantially elliptical configuration. The support members 120 are secured to both the ball 119 and the inner surface 114 of the housing 111 and have as small a lateral cross section as possible in order not to impede the flow of blood while still supporting the ball. In order to preclude the possibility of turbulent flow about the support members 120 at the points where they are secured to the ball 119 or the inner surface 114 of the housing 111, the support members 120 are flared at their attachment points, thereby facilitating laminar flow by such points.

Pivotaly secured to the inner surface 114 of the housing 111 are four flaps 122. The flaps 122 have a substantially triangular configuration and are pivotaly connected to the housing 111 by support pins 123 in a manner similar to flaps 22. The flaps 122 are disposed in complementary relationship to each other and to the housing walls forming the opening 117 in a manner such that when they are in the position illustrated in FIGS. 5 and 6 they completely seal the opening 117 in the same manner as hereinbefore described. Each of the flaps has a surface contour designed to provide the least resistance to the flow of blood through the valve 110 when the flaps 122 are in their open position. The most efficient contour can be determined by tests conducted under a varying range of parameters including blood viscosity, opening dimensions, rate of flow, amount of flow, response time required both for opening and closing and flow pressure. Tests conducted by applicant have shown that under most conditions the

most efficient flap surface configuration is as illustrated, wherein the upper and lower surfaces are convex and symmetrical about a center line through the support pin 123. The cross sectional configuration of the flaps 122 is effectively an airfoil which tapers to an edge not only along their free apex but also along the complementary juxtaposed sides. The flaps 122, in a manner similar to the flaps 22 of FIG. 3, have a concave depression 124 at their free apex. The configuration of the depression 124 is designed to allow the apex of the flap 122 to mate with the lower surface of the ball 119 in complementary sealing abutment when the flaps are in their sealing position, as shown in FIGS. 5 and 6.

Since the subject valve of applicant's invention is primarily intended to be used in a human body, all parts of the prosthetic heart valve must be constructed of materials which are inert, non-toxic, non-irritating, capable of sterilization and not subject to corrosion or other attack by body fluids. In addition to the aforementioned requirements, the materials must be compatible with each other and possess sufficient rigidity and strength to function indefinitely without damage. There are all too few materials that possess all of the required attributes; however, some known suitable materials are high chromium stainless steel, titanium, etc., and plastics, such as reinforced inert thermosetting plastics, including glass reinforced polyesters and epoxys, acrylic resins, polycarbonate resin, formaldehyde polymers and polyamides; while all of the above materials will work, the preferred materials for applicant's device are vitrified carbon or aluminum oxide for the entire housing and the flaps and "Vitalium", the composition of which is specifically described in Aeronautical Material Specification No. 5385c as promulgated by the Society of Automotive Engineers, for the sealing means and support pins. Vitrified carbon and aluminum oxide are ideally suited for constructing the housing 11 because they can be made in both a porous manner for the outer surface 13 and in an impervious manner for the inner surface 14.

In operation during systole, blood is forced from the heart, in the direction of the arrow, impinging upon the flaps and forcing them downward about the support pins, as shown in FIG. 1. When the flaps are in their downward position the entire rectangular opening is open to allow the flow of blood therethrough and since the sealing means occupies a minute area, as compared to the opening, the blood is not restricted thereby in its flow. Due to the curvature of the flaps they are very responsive to the blood flow and present negligible resistance; additionally, when the flaps are in their open position they provide a gap between the wall of the rectangular opening and the side of the flap in juxtaposition thereto, thereby allowing blood to flow through the gap and wash the undersurface of the flap. When the heart comes to rest and proceeds to expand, the blood starts to back-flow towards the heart, at which time the blood applies a force against the underside of the flaps and, due to the curvature of the flaps, they are forced upwardly into contact with the ball. The configuration of the flaps is designed so that their reaction time to the back-flowing blood is almost instantaneous or in the order of four-tenths of a second for the flaps to move from a fully open position to a

fully closed position. In one embodiment, when the flaps approach a fully closed position in abutting relationship to the underside of the ball, the flap guide 25 engages the wire 21, thereby correcting any misalignment of the flaps relative to the sealing means 18. When the flaps are all in their upward closed position the concave depressions at the apexes of the flaps encircle and abut the lower surface of the ball in a complementary manner, thereby serving a dual purpose, namely sealing and alignment. It will be apparent that there is no area of the valve over which flow does not take place either during normal forward flow or back flow and this concept is important in assuring that all interior surface areas are washed to prevent stagnation and clot formation. After the prosthetic heart valve is inserted into the recipient's heart there will be a period of time during which the valve must be artificially secured to the heart and the aorta in order to give the living tissue sufficient time to grow into the porous outer surface of the housing when it is utilized. For this reason, at the time of insertion of the valve which utilizes a porous outer surface, it is wrapped with a cloth sewing ring made of polyethylene terephthalate (Dacron) fabric or other synthetic plastic fabric such as polytetrafluoroethylene and the receiving member is sutured to the cloth sewing ring to temporarily hold the valve in place.

For the purposes of exemplification, particular embodiments of the invention have been shown and described according to the best present understanding thereof. However, it will be apparent that changes and modifications in the arrangement and construction of the parts thereof may be resorted to without departing from the spirit and scope of the invention.

What is claimed is:

1. A prosthetic heart valve comprising:
 - an elongated housing having top and bottom end surfaces and being provided with a rectangular opening therein intermediate said end surfaces;
 - a sealing means secured within said housing and located generally axially of said opening; and
 - a plurality of substantially triangular flaps, pivotally secured to the inner surface of said housing within said rectangular opening, said flaps being substantially rigid and sized to at least substantially seal said opening and adapted to open in response to the flow of blood from the heart and close in response to the back flow of blood towards the heart, an apex of said flaps abutting said sealing means when said flaps are in their closed position.
2. A prosthetic heart valve in accordance with claim 1, wherein said housing has an impervious inner surface.
3. A prosthetic heart valve in accordance with claim 2, wherein said housing has a porous outer surface.
4. A prosthetic heart valve in accordance with claim 1, wherein said flaps have a depression along one of their apexes, said depression being complementary to the sealing means for abutment therewith when said flaps are in their closed position.
5. A prosthetic heart valve in accordance with claim 1, wherein said sealing means comprises:
 - a ball disposed centrally of the opening within said housing; and

support members secured between said ball and said housing for rigidly retaining said ball in position.

6. A prosthetic heart valve in accordance with claim 5, wherein said ball has a substantially elliptical configuration.
7. A prosthetic heart valve in accordance with claim 1, wherein said flaps have a compound curvature.
8. A prosthetic heart valve in accordance with claim 7, wherein said flaps have a sinusoidal configuration.
9. A prosthetic heart valve in accordance with claim 1, wherein said flaps have a convex upper and lower surface tapering towards their free apexes.
10. A prosthetic heart valve in accordance with claim 9, wherein said flaps are tapered towards their free apex and towards the two sides forming said apex.
11. A prosthetic heart valve in accordance with claim 1, further comprising:
 - a plurality of support pins, said pins having a substantially Y-configuration, one end pivotally secured to a corner of one flap, another end pivotally secured to a corner of an adjacent flap and the leg fixedly secured to the housing, whereby said flaps are pivotally secured to said housing by said support pins.
12. A prosthetic heart valve in accordance with claim 2, wherein said impervious inner surface slopes inwardly to form the rectangular opening.
13. A prosthetic heart valve in accordance with claim 1, wherein said housing is annular and has a substantially C-shaped exterior configuration.
14. A prosthetic heart valve in accordance with claim 13, further comprising:
 - a layer of polyethylene terephthalate disposed within the concave portions of said housing forming said C-shaped exterior configuration.
15. A prosthetic heart valve in accordance with claim 1, further comprising:
 - a flap guide disposed upon said flap and adapted to coact with said sealing means, whereby said flaps are guided into complementary juxtaposition to each other and in abutment to each other and in abutment to said sealing means.
16. A uni-directional prosthetic valve comprising:
 - an elongated housing having top and bottom end surfaces and being provided with a rectangular opening therein intermediate said end surfaces;
 - a sealing means secured within said housing adjacent to and centrally of the rectangular opening;
 - a plurality of triangular flaps pivotally secured to the inner surface of said housing and within said rectangular opening, said flaps being substantially rigid and sized to at least substantially seal said opening and adapted to open away from said sealing means in response to a flow of fluid in one direction and to close in abutment to said sealing means thereby sealing the rectangular opening in response to flow in a contra direction.
17. A uni-directional prosthetic valve in accordance with claim 16, wherein said flaps have a depression along an apex, each depression complementary conforming to the shape of said sealing means, whereby said sealing means rests partially within said complementary depression when said flaps are in abutment thereto.

* * * * *