Dec. 22, 1970 R. G. KISCHER 3,548,417

HEART VALVE HAVING A FLEXIBLE WALL WHICH ROTATES BETWEEN OPEN AND CLOSED POSITIONS

Filed Sept. 5, 1967 2 Sheets-Sheet 1

FIG. 1.

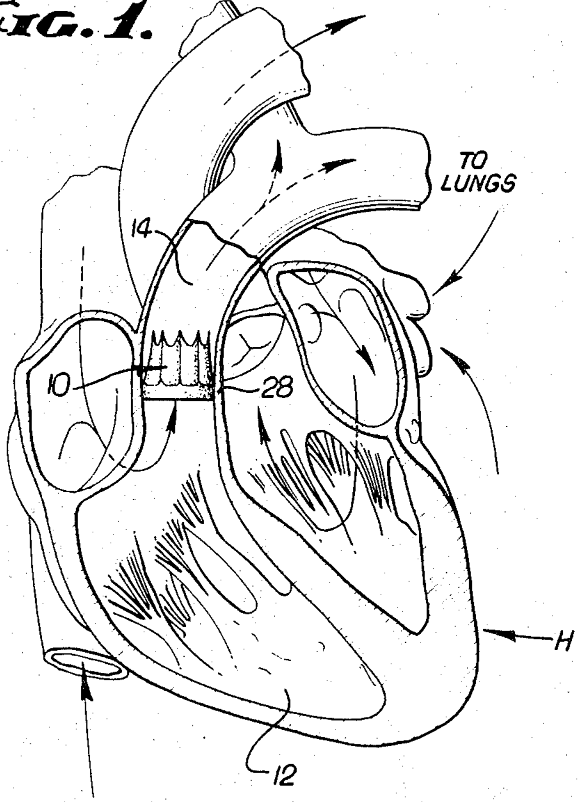


FIG. 2.

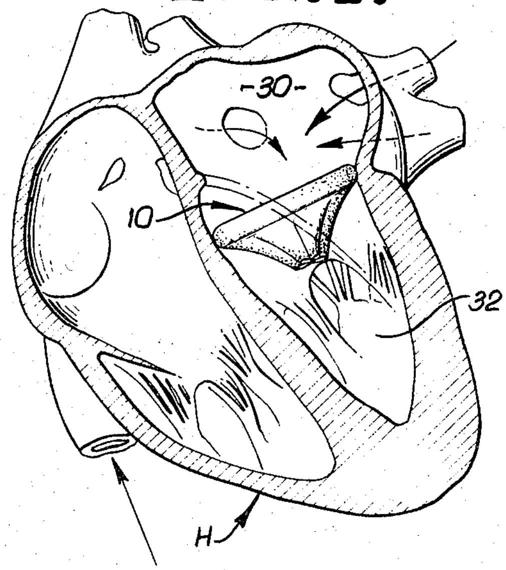


FIG. 3.

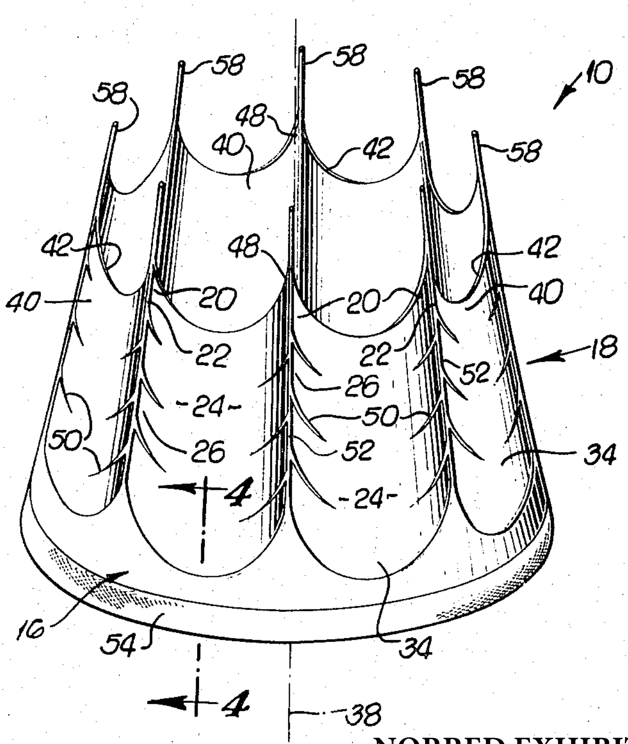
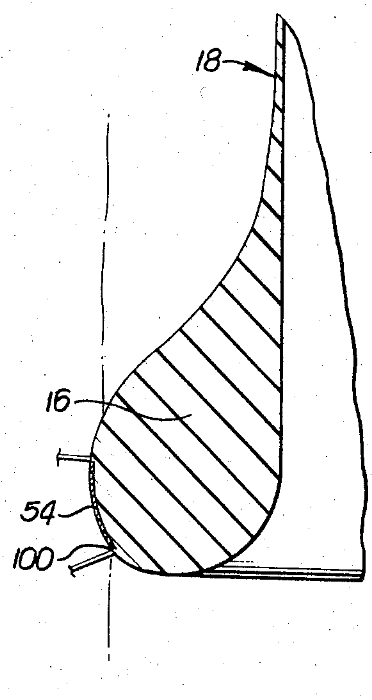


FIG. 4.



INVENTOR.
RONNIE G. KISCHER

By White & Haefliger

ATTORNEYS

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FIG. 5.

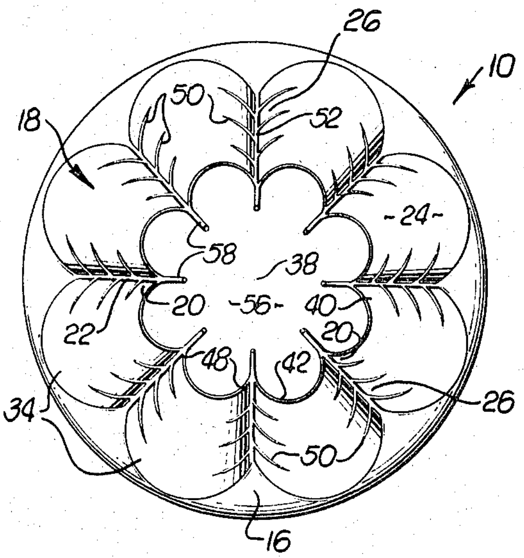


FIG. 7.

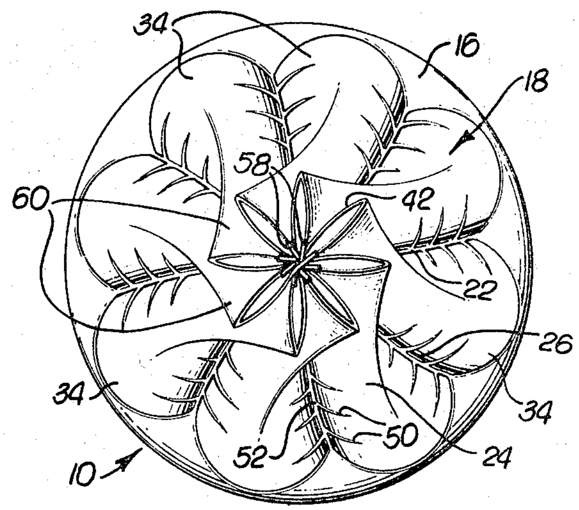


FIG. 6.

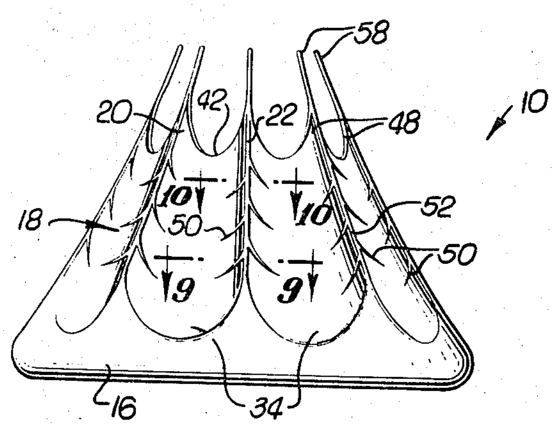


FIG. 8.

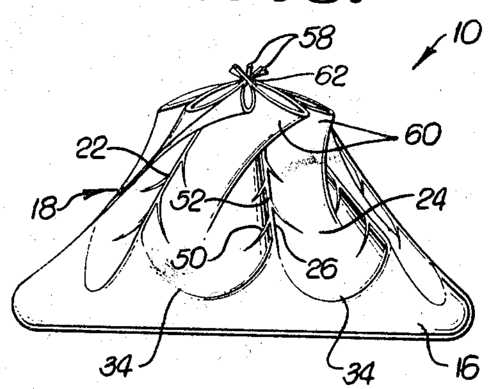


FIG. 10.

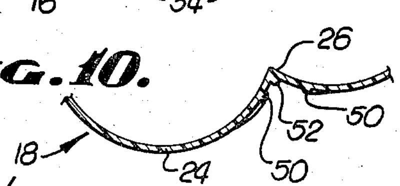
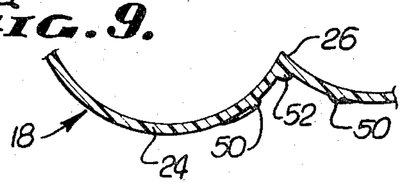


FIG. 9.



INVENTOR.
RONNIE G. KISCHER

BY White & Haefliger

ATTORNEYS.

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3,548,417

HEART VALVE HAVING A FLEXIBLE WALL WHICH ROTATES BETWEEN OPEN AND CLOSED POSITIONS

Ronnie G. Kischer, La Habra, Calif.; Jane N. Kischer, widow of said Ronnie G. Kischer, deceased
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Int. Cl. A61f *1/22;* A16k *15/14*
U.S. Cl. 3—1 13 Claims

ABSTRACT OF THE DISCLOSURE

A cardiac valve having a winding and unwinding movement between open and closed positions and including thin sheet material extending about a central axis and having at one time a first position in which the material is openly extended to define a blood passage and at another time a second position in which the material is collapsed and pleated and partially rotated about the central axis to close the passage for blocking reverse flow of blood.

BACKGROUND OF THE INVENTION

Field of the invention

This invention is concerned with prosthetic devices and particularly with valves useful in replacement of natural heart valves. As is known the human heart includes four cavities. Communication therewith is controlled by valves specifically the aortic, tricuspid, mitral and pulmonary valves. These valves are remarkably similar in construction consisting of triangular cusps or leaflets, the free ends of the mitral and tricuspid valves being supported by delicate tendons, the chordae tendinae, which insert into the papillary muscles, thus to prevent wrong way opening of these antrioventricular valves. Defective natural valves, those which have been narrowed or surface roughened or which close incompletely, are desirably replaced. For successful replacement, the extremely critical opening and closing characteristics of the healthy natural valve must be approximated as closely as possible.

Prior art

Prior developments in the art may be classified as either blood passing valves intended for use in mechanical "heart" pumps used in surgery or heart valves properly so-called, i.e. those attached to and operative within the heart. It is with the latter group that the present invention is concerned. In U.S. Pat. 3,130,418 to Head, et al., a specially woven and plastic impregnated valve device is disclosed. In U.S. Pat. 3,197,788 to Segger a valve device is described which, like the Head, et al. invention, tried to simulate the action of the natural valve by a physical approximation of the natural valve cusps. U.S. Pat. 3,263,239 to Edwards et al., utilizes the well known ball valve and cooperating seat combination to accomplish the check valve function of the natural valves.

In the present invention an entirely different type of valve is produced. The design is predicated on a simulation of the function of the natural heart valve, without imitation of the structure of the natural valves, the simulation being found particularly in the aspect of positive and complete closure following pumping discharge of blood therethrough without mechanical abuse of the blood.

SUMMARY OF THE INVENTION

It is the major object of the present invention to provide a prosthetic heart valve suitable for the replacement of any of the natural heart valves. It is a further object to achieve opening and closing of the valve with a novel

In general, the invention may be succinctly described as a valve comprising a thin sheet material defining a through passage, flow through which is controllable by a winding pleated or accordion fold of the material.

In particular, the invention provides a cardiac valve comprising thin sheet material impervious to blood and resistant to body fluids and which extends about a central axis, thus to define an open passage to pass blood; the material at another time has a second position in which it is collapsed to form pleats and is also at least partially rotated about the central axis. In the second position the material closes the passage and blocks reverse flow of blood therethrough.

Collapse in the desired manner is facilitated by provision of stiffening support for the sheet material in constraining relation to induce the material to rotate in its movement between its first and second position. Also, structure may be provided for implanting the valve in the heart, such as a base ring from which the sheet material may extend in the direction of natural blood flow.

In certain preferred embodiments, the sheet material is frusto-conical when open and is provided with plural ribs which extend generally longitudinally of the material and in planes extending axially of the conical material. Such ribs may be formed integrally with the wall forming sheet material as thickened areas thereof and serve to define circumferentially alternating relatively flexible and relatively rigid wall portions, the former to follow and the latter to lead in the winding collapse of the valve material to produce overlapping, pleated flaps.

The relative size of the rigid wall portions is controllable by provision in the ribs of webs extending away from midribs, the webs having differential lengths as will be explained. Also, the wall may have plural cusps opposite its base which move helically on opening and closing movement of the valve and from which the midribs may proceed directionally toward the base. The latter may be reinforced against radial crushing by ventricular contractions, such reinforcement being spaced from the rib lower termini to facilitate the winding movement of the sheet material above the base, relative to the base and about the valve longitudinal axis.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. 1 is a sectional view of a human heart showing the valve device of the present invention in open position in the place of the pulmonary valve;

FIG. 2 is a view like FIG. 1 showing the present valve device in closed position in the place of the mitral valve;

FIG. 3 is an enlarged perspective view of the artificial heart valve shown in FIG. 1;

FIG. 4 is an enlarged view in section taken along line **4—4** in FIG. 3;

FIG. 5 is a plan view of the valve shown partially closed;

FIG. 6 is a view in elevation of the partially closed valve shown in FIG. 5;

FIG. 7 is a view like FIG. 5 showing the valve fully closed;

FIG. 8 is a view like FIG. 6 showing the valve fully closed;

FIG. 9 is a sectional view of the valve wall taken along line **9—9** in FIG. 6; and

FIG. 10 is a view like FIG. 9 taken along line **10—10** in FIG. 6.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

With reference to the attached drawings in which one condition, substituted for the natural pulmonary valve, between the right ventricle **12** and the pulmonary artery **14** for controlling flow of blood from the heart, H, to the lungs and avoiding regurgitation or partial return flow from the artery to the right ventricle. The heart contraction pumps blood through the valve which can be seen to include (FIG. 3) a base portion **16** and a wall portion **18** having plural cusps **20** from which ribs **22** extend directionally toward the base circumferentially dividing the wall into relatively flexible sections **24** and relatively rigid sections **26**. The valve is sutured at the base **16** to the artery wall **28** as by thread extending about or through the base, and typically about reinforcement **54** as seen at **100** in FIG. 4.

The versatility of the present valve device is illustrated by its substitution in FIG. 2 for the mitral valve. This location is more critical than the pulmonary valve position and thus requires extreme precision and reliability in operation when mounted as shown across the relatively wide opening between the left atrium **30** and the left ventricle **32**, illustrated in the closed position.

With particular reference to FIG. 3 the cardiac valve **10** shown may be described as frusto-conical and composed of plural conical segments **34** which abut at spaced locations about the valve circumference to provide a wall **18** extending about a central axis **38**. The segments **34** are relatively wider at their bottoms adjacent the base **16** than at their upper edge portions **40**. The edge portion **40** of each segment **34** terminates in an arcuate edge **42** giving the valve a scalloped appearance with the circularly arranged peaks or cusps **20** at the abutment of adjacent segments **34**.

The wall **18** has relatively flexible portion **24** formed centrally of segments **34** and relatively rigid portion indicated at **26** and corresponding generally to the line of abutment between adjacent segments. Stiffening support may be provided at the junctions between segments **34** in the form of ribs **22** which as shown proceed directionally from cusps **20** downward toward the base portion **16**, which base portion the ribs may or may not meet, depending upon collapsing characteristics desired. The ribs **22** may also project beyond the peaks **48** of the cusps **20** as shown in FIG. 3.

The ribs **22** may be of any material compatible with the use environment of the valve such as stainless steel or high modulus plastic, secured by adequate means to the wall **18**. Preferably, ribs **22** are formed integrally with the molded plastic wall **18** by providing selectively increased thickness in the wall according to a predetermined pattern to provide a localized increase in stiffness, which will be generally proportionate to the thickness increase. In order better to control areas of the adjacent segments **34** beyond the immediate junction thereof, the ribs **22** are provided with webs **50** which radiate preferably in dendroid array from the central portions or midribs **52** of the ribs. The webs **50** generally are base directed, i.e., proceed toward the base **16** of the valve, regardless of the in-heart orientation of the valve device **10**. The function of the webs **50** is to provide stiffening fingers outward from the midrib **52** to facilitate the desired mode of collapse of the wall **18**. Accordingly, the webs **50** will be relatively longer progressively as they increase in proximity to the base **16** along the midrib **52** due to the greater circumference of the valve wall **18** proximate the base.

Ribs **22** are tapered to a minimum cross-section adjacent the cusps **20** and as such are sometimes termed banners. Webs **50** are similarly tapered, outward from midribs **52** to extinction on the wall **18**. The wall itself is also preferably tapered frusto-conically upwardly from the base **16**, the taper of the wall **18** and a rib **22** being shown in the fragmentary views of FIGS. 9 and 10. The maximum and minimum thicknesses of the wall **18** and the ribs **22** and webs **50**, as well as their taper, will be

material and the orientation and strain factors likely to be encountered in molding or otherwise shaping the valve.

With reference to FIG. 4, the base **16** may typically be ring like or toroidal, and the wall **18** may extend from the outer edge thereof. The base **16** may be formed as an annular ring apart from the wall **18** and fastened thereto or may, in preferred practice, be integrally molded with or to the wall **18** in the valve manufacturing operation. Reinforcement of the base **16** against radial crushing may be desirable, particularly where the valve is integrally molded and intended for use as an aortic valve. A preformed ring of metal, plastic or a combination thereof may be used, or fibers, preferably woven, e.g., Dacron cloth may be employed for reinforcement, and as an example an annular preformed Dacron cloth **54** is shown embedded in the periphery of base **16** in FIG. 4.

With reference now to FIGS. 5–8, the movement of the valve of the present invention between open and closed positions will be described. Noted above was the requirement in a heart valve for fail-proof actuation of the valve by pressure of the blood on either side thereof and with minimum mechanical abuse of the blood. It is a feature of the present valve device that opening and closing movement is effected over a very long surface relative to the diameter of the valve. This permits lowering of pressure per unit of area in closing the valve and minimizes risk of blood damage.

The present valve movement is a winding movement, that is the valve **10** is at least partially rotated about its axis; the cusps **20** of the valve traveling helical paths. The slack or relatively flexible portions **24** of the valve wall **18** fold on themselves between the relatively rigid wall portions **26** which thus converge on one another so that adjacent flexible portions **24** double over and overlap with one another to a greater or lesser extent as the valve wall **18** is flattened.

In FIGS. 5 and 6, the normal open position of the valve **10** is shown. Cone segments **34** of the wall **18** are coaxial with the axial plane of the valve and define a valve passage **56** into which ends **58** of ribs **22** project slightly. The valve position shown in FIGS. 5 and 6 is the result of a pressure differential between the interior and exterior of the valve **10** in favor of the valve interior as is the case for example for an aortic valve during a pumping contraction of the left ventricle. Upon cessation of the pumping, the back pressure produced by the blood pumped through the valve tends to cause regurgitation or blood return, quickly reversing the pressure differential in favor of the valve exterior. At this point the valve **10** must close, or else already pumped blood must be repumped imposing in all likelihood an intolerable burden on the heart.

In the present valve closure is quick and sure. The shift of incremental pressure to the exterior of valve **10** immediately causes an inward collapse of the valve wall **18**. Because the wall is not uniformly collapsible owing to the circularly alternate flexible and rigid portions **24** and **26**, the wall **18** tends to wind either right or left in collapse, depending on the predisposition built into the wall by arrangement of the ribs **22** or other selective stiffening feature, relative to the base. The base **16** remains stationary and the wall **18** rotates with respect thereto and at least partially about the axis **38** of the wall.

With the reduction in the height of the wall **18** occasioned by the collapse, the flexible wall portions **24** move from between the rigid portions **26** forming flaps **60** projecting inwardly or outwardly and preferably outwardly as shown. Continued exertion of reverse flow pressure on the flaps **60** forces the flaps to lie flat, upon one another to an extent dependent on the concavity of the cone segments **34** which is a matter of design.

On a further pumping contraction of the heart, the inner valve pressure will again exceed the outer and the

It will be seen in FIGS. 7 and 8 that the rib ends meet at a common point **62** lying on the axis **38** and the flaps **60** resemble pleats or accordion folds.

The present valve device can be formed of many materials known to the art including olefin polymers and copolymers, polyamides, polyesters, silicones and the like solely or in combination with other materials of a plastic or metallic nature for specific properties, e.g., rigidifying the selected areas of the valve wall **18**.

The present design is advantageous in being readily formable in a single molding operation, with mold insert if desired, e.g., the preformed annular cloth **54**.

What is claimed is:

1. Cardiac valve comprising a generally annular base carrying means for securing the valve in a heart blood passageway and a frusto-conical wall of flexible sheet material extending from the base and about a longitudinal axis, said wall having circularly alternating relatively rigid and relatively flexible longitudinally extended portions to rotate relative to the base about said axis in response to relatively greater interior pressure in the valve to a first position in which the wall is extended openly relative to said axis to define an open passage to pass blood, and in response to relatively greater exterior pressure on the valve to a second position in which the wall is collapsed by the relatively rigid wall portions converging on one another and the relatively flexible wall portions therebetween folding on themselves to form pleats to close said passage for blocking reverse flow of blood therethrough.

2. Cardiac valve according to claim **1** including also plural circularly spaced stiffening support means carried in local constraining relation with said sheet material to define said rigid portions and to induce said rotation in response to movement of the wall material from said first to said second positions.

3. Cardiac valve according to claim **2** in which each of said stiffening support means extends along the sheet material in the plane of said axis when the wall is in said first position.

4. Cardiac valve according to claim **1** including also cloth secured to said base to define said means for securing said valve to the heart.

5. Cardiac valve according to claim **2** in which said stiffening support means comprise ribs and in which said flexible portions between said ribs are cone segments.

6. Cardiac valve according to claim **5** in which said base is rigid relative to said sheet material.

7. Cardiac valve according to claim **5** including also midribs and plural webs extending from said ribs in dendroid arrangement.

8. Cardiac valve according to claim **7** in which said ribs are formed integrally with said sheet material.

9. Cardiac valve according to claim **5** in which said ribs are spaced from said base.

10. Cardiac valve according to claim **1** in which said wall includes plural terminal cusps at the opposite end of the wall from the base.

11. Cardiac valve according to claim **10** in which said relatively rigid portions comprise thickened areas forming ribs in said wall and include raised midribs extending directionally from said cusps toward said base and raised webs extending away from said midribs and at opposite sides thereof, webs closer to said base being longer than webs closer to said cusps.

12. Cardiac valve according to claim **11** in which said base and wall consists of integrally molded plastic material.

13. Cardiac valve according to claim **12** in which said base includes reinforcement means to resist radial crushing forces.

14. Cardiac valve according to claim **14** in which said base includes reinforcement structure to resist radial crushing forces.

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RICHARD A. GAUDET, Primary Examiner

R. L. FRINKS, Assistant Examiner

U.S. Cl. X.R.

137—525.1

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