

Oct. 20, 1970

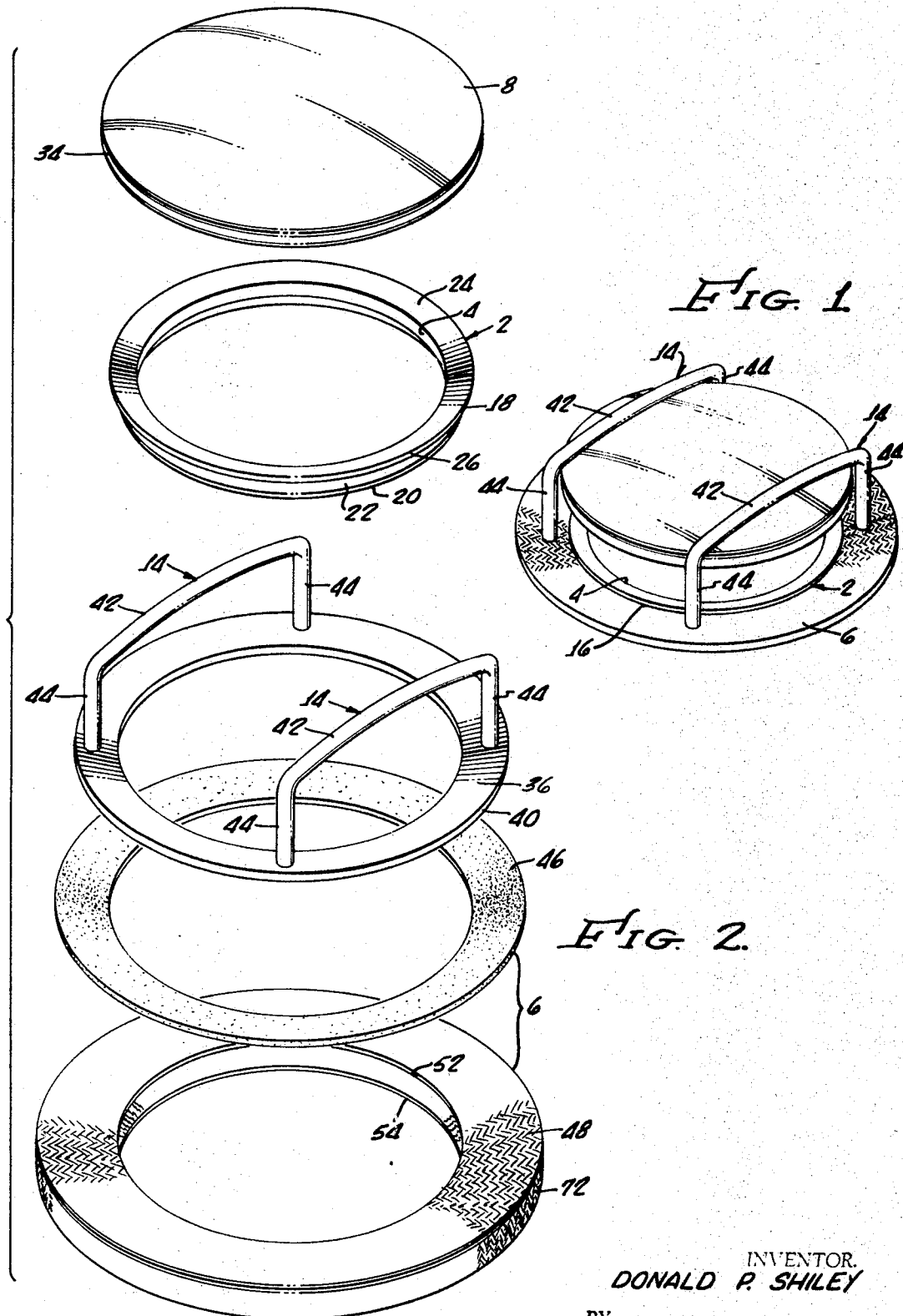
D. P. SHILEY

3,534,411

CLOTH COVERED HEART VALVE

Filed Oct. 5, 1967

3 Sheets-Sheet 1



INVENTOR.
DONALD P. SHILEY
BY
FOWLER, KNOBBE
& MARTENS
ATTORNEYS.

Oct. 20, 1970

D. P. SHILEY

3,534,411

CLOTH COVERED HEART VALVE

Filed Oct. 5, 1967

3 Sheets-Sheet 2

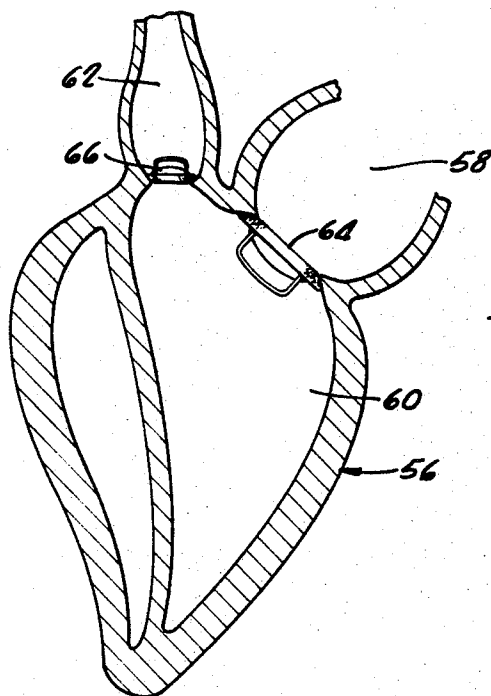


FIG. 3.

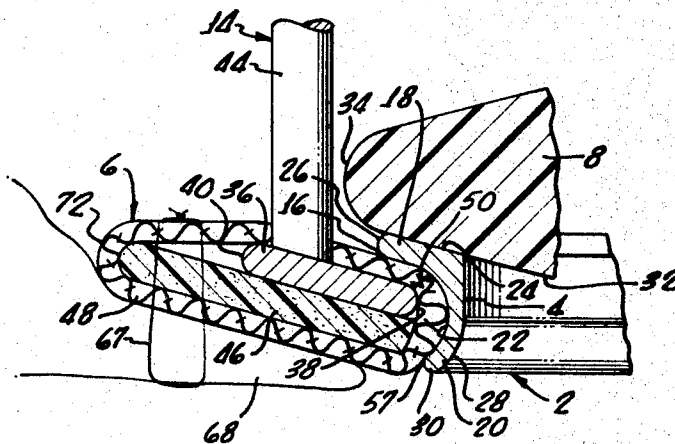


FIG. 4.

INVENTOR
DONALD P. SHILEY

BY
FOWLER, KNOBBE
& MARTENS
ATTORNEYS.

Oct. 20, 1970

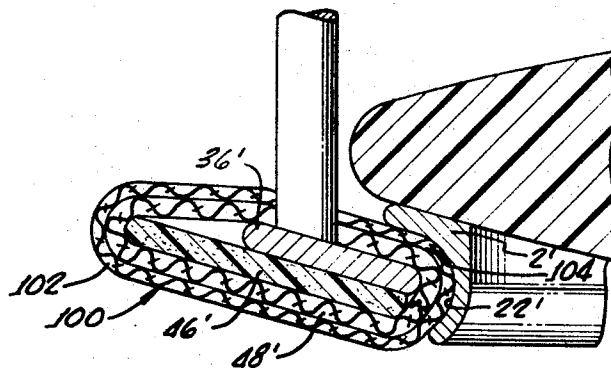
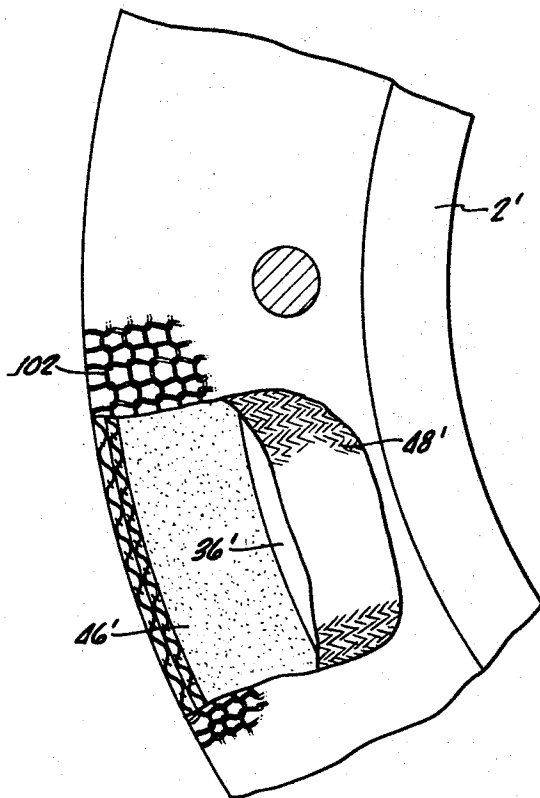
D. P. SHILEY

3,534,411

CLOTH COVERED HEART VALVE

Filed Oct. 5, 1967

3 Sheets-Sheet 3



INVENTOR
DONALD R. SHILEY

BY
FOWLER, KNOBBE
& MARTENS
ATTORNEYS.

1

3,534,411

CLOTH COVERED HEART VALVE
Donald P. Shiley, 11022 Hunting Horn,
Santa Ana, Calif. 92705

Filed Oct. 5, 1967, Ser. No. 673,144
Int. Cl. A61f 1/22

U.S. Cl. 3—1

19 Claims

ABSTRACT OF THE DISCLOSURE

A prosthetic heart valve has a cage for guiding the movable disc mounted on a frusto-conical, annular retaining ring circumscribing the valve ring. The retaining ring is covered by a cloth suture ring. The movable disc closely overlays the downstream cloth/metal margin so that seating pressure inhibits thrombus growth. The cloth suture ring is relatively thin and wide. In one embodiment the outer cloth is loosely woven to encourage tissue ingrowth.

BACKGROUND OF INVENTION

Although cardiac valvular replacement has been quite successful in recent years, one recurring problems has been thrombus formation on and around the prosthesis. The typical prosthetic heart valve includes a metal valve body surrounded by a cloth suture ring. The cloth is sutured to the heart tissue at the annulus where the natural valve was removed. Prior art valve structures require a relatively wide exposed metal portion, causing the cloth/metal margin to be disposed a substantial distance from the orifice of the valve. Thrombus growth then tends to accumulate at the cloth/metal margin because it is located in an area of low velocity flow where the thrombus formation is not subjected to periodic washing by high velocity blood. Often this problem is aggravated by valve structure which creates a low velocity cul-de-sac at the cloth/metal margin.

Another focal point for thrombus formation in many prior art valves is found at the outer periphery of the cloth suture ring. If the ring is too thick, a cul-de-sac at the periphery results and causes an area of blood stasis conducive to thrombus growth.

Still another problem with some prior art prosthetic valves is insufficient post-operative tissue ingrowth into the suture ring. Tissue ingrowth increases the effectiveness of the suture and improves the seal around the valve.

SUMMARY OF INVENTION

This invention provides a prosthetic heart valve directed toward reducing the problems noted above. In accordance with the invention, the legs which extend alongside the movable valve member to guide its movement as it periodically closes the orifice of the annular body member are mounted outward of the margin between the valve body and the suture cloth which is affixed to the valve body. This permits the cloth/metal margin to be located close to the orifice where it is washed by high velocity flow. Moreover, this structure permits sizing the movable valve member so as to overlay the cloth/metal margin and subject that margin to the periodic seating pressure of the movable member. The seating pressure effectively prevents thrombus growth at the cloth/metal margin.

2

Preferably the guide legs are mounted on a washer-shaped retaining ring covered by the cloth suture ring and received in a peripheral groove around the valve body.

In the preferred embodiment, the cloth ring is of relatively large radial extent, but is quite thin, being of approximately the same thickness as the valve body. This shape reduces the problem of cul-de-sacs at the outer periphery of the suture ring and at the cloth/metal margin, while providing sufficient flexibility to conform to the heart tissue to which it is attached. Moreover, the small volume of cloth reduces the risk of thrombus formation, yet allows an adequate bed for ingrowth of tissue.

In one embodiment of the invention, tissue ingrowth is encouraged by use of a loosely woven cloth sleeve covering the tightly woven suture cloth. Thus, the inner cloth provides strong support for the sutures, and the outer cloth aids the support by bonding with the healed tissue.

These and other features and advantages of this invention will be apparent from the following detailed description when read with reference to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a prosthetic heart valve constructed in accordance with this invention with the valve illustrated in its open position;

FIG. 2 is an exploded view of the heart valve illustrated in FIG. 1;

FIG. 3 is a diagrammatic cross-sectional view of a human heart illustrating prosthetic heart valves constructed in accordance with this invention used as both mitral and aortic prosthetic valvular replacements;

FIG. 4 is a cross-section through a portion of the prosthetic heart valve illustrating its internal structure and its position relative to the valvular annular of the heart;

FIG. 5 is a cross-section through a portion of a prosthetic heart valve constructed in accordance with another embodiment of this invention; and,

FIG. 6 is a plan view of a portion of the heart valve of FIG. 5 with portions removed for clarity.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENT

Referring to FIGS. 1 and 2, the prosthetic heart valve includes an annular valve ring or body 2 having an orifice 4 providing a passage for fluid flow. A cloth suture ring 6 connected to the valve body extends outwardly for receiving the sutures to implant the valve in the heart. A movable check valve disc 8 is disposed on the downstream side of the valve body and closes the orifice against fluid flow from the downstream side of the valve body to the upstream side. Parallel cage struts 14 disposed outward of the cloth/body margin 16 guide the disc in its reciprocating movement and limit its excursion.

Referring now primarily to FIGS. 2 and 4, the valve body 2 is an annular member preferably fabricated of a metal such as Stellite. Upper and lower flanges 18 and 20 extend outwardly from the valve body to define a peripheral groove 22 of radial cross-sectional configuration. The top surface 24 of the upper flange is inclined and forms a frusto-conical seating surface extending from the

3

orifice 4 to the outer edge 26 of the flange. The lower flange 20 extends outward only a very short distance in relation to the upper flange. The orifice wall is beveled at 28 out to the lower flange so that the lower flange has very little exposed undersurface 30 outside the orifice.

The movable disc check valve member 8 has a frusto-conical seating surface 32 on its underside which mates with the seating surface 24 on the valve body to close the orifice 4 against backflow. The disc 8 is larger in diameter than the upper flange 18 of the valve body so that the disc overhangs the outer periphery 26 of the valve body. The outer edge 34 of the disc and the outer edge of the upper flange are both rounded in section and their respective points of tangency to the seating surfaces 24 and 32 are approximately opposite each other. Preferably, the disc is made of a silicone material such as Silastic as is known in the prior art heart valves.

A frusto-conical washer-shaped retaining ring 36, preferably constructed of a somewhat springy metal, is received in the peripheral groove 22 formed on the valve body. The inner edge 38 of the thin, annular retaining ring preferably is approximately the same in diameter as the outer edge of the lower flange 20. The outer edge 40 of the retaining ring terminates a substantial distance outward from the valve body 2.

Each of the two cages 14 includes a stop portion 42 which limits excursion of the disc and a pair of legs 44 which support the stop portion and extend down alongside the disc member to guide it during reciprocation. The lower ends of the legs are connected to the retaining ring 36, for example either integrally or by welding. The cages preferably are fabricated of the same metal as the body.

The cloth suture ring 6 includes a cloth pad 46 and a cloth sleeve 48. The pad is a flat annular piece of cloth extending along the lower face of the retaining ring 36 and terminating a substantial distance outward from the retaining ring. The cloth sleeve 48 is an annular cloth member covering the annular retaining ring 36 and the cloth pad 46. For ease in assembly, the cloth sleeve is not sewn at the circumferential butt joint 50, but rather the two edges 52 and 54 of the sleeve are butted interior of the groove 22 and the cloth is held in place by the pinching action between the annular retaining ring 36 and the groove wall. A small incision is made in the cloth to receive each cage leg 44 and the cloth is folded around the legs so that the legs extend through the cloth. Both the cloth pad and the cloth sleeve are preferably of a rather strong fabric to provide sufficient strength of attachment, the polytetrafluoroethylene fiber known as Teflon having been found to be a particularly suitable fabric.

In assembling the valve, the retaining ring 36 is covered with the cloth suture ring 6 and is then snapped over the lower flange 20. Since the inside diameter of the retaining ring is approximately the same as the outside diameter of the lower flange, the retaining ring must be forced over the lower flange working circumferentially around the flange and taking advantage of the springy character of the ring and the compressibility of the cloth.

Referring now to FIG. 3, the human heart 56 is shown having a left atrium 58, a left ventricle 60, and the aorta artery 62 which communicates with the left ventricle. For purposes of illustration, both mitral 64 and aortic 66 valvular prosthesis are shown in location so as to illustrate the relative size and placement of the two types of valve configurations. Thus, a mitral disc valve 64 is located between the left atrium 58 and the left ventricle 60, and an aortic disc valve 66 is located between the aorta 62 and the left ventricle.

As is shown in FIG. 4, each valve is installed with the heart tissue 68 which forms the annulus extending along the underside of the suture ring 6 to a position relatively close to the valve body 2. The fixation sutures 67 extend through the cloth sleeve 48, the cloth pad 46, and the heart tissue 68 at the remaining cuff of the natural valve. 75

4

The suture ring 6 is relatively thin and flexible in the direction generally along the axis of the orifice, but is wide in the radial direction to provide a large surface contact with the heart tissue for tissue ingrowth. Moreover, since the cloth suture ring is approximately the same thickness as the valve body, cul-de-sacs at the upper and lower cloth metal margins 16 and 57 are minimized. The thinness also reduces the cul-de-sac at the outer periphery 72.

Because the upstream cloth/metal margin 57 is located very close to the orifice 4 and is in an area of a relatively high velocity flow, the cloth/metal margin is continuously washed by the flowing fluid and thrombus growth is minimized. On the downstream side of the valve, the disc 8 closely overlays the cloth/metal margin 16 and each time the disc seats it applies pressure to the cloth/metal margin and tends to inhibit thrombosis growth. Moreover, substantially the entire upper surface 24 of the valve body is subjected to the seating pressure. The end result is that the cloth area is completely covered with ingrowth, and is accepted in the body. The small amount of metal exposed is well washed and provides a well defined seat area for the disc. The full diameter orifice is maintained without being reduced through build-up of tissue on the metal defining the orifice.

Referring now to FIGS. 5 and 6, the cloth suture ring 100 in that embodiment includes an outer cloth sleeve 102 covering the first sleeve 48' and similarly having its edges butted at 104 in the peripheral groove 22' of the valve body 2'. This sleeve 102, like the inner cloth sleeve 48' and the pad 46', is held in place by the pinching action of the retaining ring 36' against the valve body 2'. In this embodiment, the inner sleeve 48' and cloth pad 46' again are made up of Teflon for strength of attachment, but the outer sleeve 102 is fabricated of a loosely woven fabric to encourage tissue ingrowth into the fabric. A velour of polyethylene terephthalate textile fibers such as Dacron has been found to be a particularly suitable fabric for the outer sleeve.

Often in the above description and in the following claims, the terms upper and lower have been used to indicate the two sides of the valve. It is to be understood that this is for convenience in description only, and the valve can of course be installed upside down such as is illustrated with respect to the mitral valve in FIG. 3.

What is claimed is:

1. A prosthetic heart valve, comprising:

a valve body having an orifice providing a passage for fluid flow, said valve body having an upstream side and a downstream side;

a suture cloth connected to the valve body so as to form a peripheral margin between the cloth and the valve body and said suture cloth extending outward from said body;

a movable check valve member closely overlying the cloth/body margin on the downstream side of the valve so as to subject said margin to periodic seating pressure of said movable member; and

means for limiting the excursion of said movable valve member away from the downstream side of the valve to permit said movable member to move between an open and a closed position.

2. A prosthetic heart valve comprising:

a valve body having an orifice providing a passage for fluid flow, said valve body having an upstream and a downstream side;

a suture cloth connected to the valve body so as to form a peripheral margin therebetween and extending outward therefrom;

a movable check valve member closely overlying the cloth/body margin on the downstream side of the valve; said movable valve member being larger in diameter than the downstream side of the valve body; and

a cage structure for limiting excursion of said movable

valve member, said cage structure being mounted to extend downstream from said valve body.

3. A prosthetic heart valve in accordance with claim 2, wherein:

the valve body has a seating surface on its downstream side extending substantially to said cloth/body margin; and,

the movable member engages the valve body seating surface closely adjacent the cloth/body margin to inhibit thrombus growth on the downstream side of the valve.

4. A prosthetic heart valve in accordance with claim 2, and wherein said cage structure comprises guide legs disposed outward of said cloth/body margin and extending alongside the movable member to guide the movable member and limit its excursion.

5. A prosthetic heart valve in accordance with claim 4, and further comprising:

an annular retaining ring covered by the suture cloth and disposed around the periphery of the valve body to fix the suture cloth to the body, the guide legs being mounted on the retaining ring.

6. A prosthetic heart valve in accordance with claim 2, wherein:

the valve body includes a frusto-conical seating surface extending substantially over all of the downstream side of the valve body; and,

the movable check valve member is a disc including a frusto-conical surface which engages substantially the entire seating surface of the valve body.

7. A prosthetic heart valve, comprising:

an annular valve body having an orifice therein;

a movable valve member adapted to periodically close the orifice of the body member;

a suture cloth affixed to the valve body and extending outward therefrom to form an annular margin with the valve body;

a plurality of legs mounted outward of the suture cloth/valve body margin and extending alongside the movable valve member to guide its movement into seating engagement with the valve body over the cloth/body margin; and

a stop means supported by said legs for limiting excursion of said valve member away from said valve body.

8. A prosthetic heart valve comprising:

an annular valve body having an orifice therein;

a movable valve member adapted to periodically close the orifice;

a mounting member is affixed to the valve body and covered by a suture cloth to form an annular cloth/body margin;

a plurality of legs connected to the mounting member outward of said margin to guide the valve member movement; and

stop means on said legs.

9. A prosthetic heart valve in accordance with claim 8, wherein the mounting member is a separable annular retaining ring circumscribing the valve body.

10. A prosthetic heart valve, comprising:

a valve body having an orifice therethrough and upper and lower outwardly extending flanges defining a peripheral groove on the outer surface of the body;

a movable valve member adapted to periodically close the orifice of the valve body;

means for limiting the excursion of the valve member away from the orifice of the valve body and for defining a path for movement of the movable member away from the valve body;

a washer-shaped retaining ring having its inner edge near the groove wall and its outer edge a substantial distance outward from the groove;

a thin cloth suture pad extending along one face of the retaining ring and terminating a substantial distance outward therefrom; and,

a cloth suture sleeve covering the suture pad and the retaining ring.

11. A prosthetic heart valve in accordance with claim 10, wherein the suture sleeve is pinched between the inner portion of the retaining ring and the valve body groove wall.

12. A prosthetic heart valve in accordance with claim 11, wherein two edges of the suture sleeve are juxtaposed interior of the groove.

13. A prosthetic heart valve in accordance with claim 10, wherein the suture pad comprises

an inner cloth member of a tightly woven, relatively strong fabric for holding the sutures; and,

the suture sleeve comprises an outer cloth member of a looser woven fabric for encouraging tissue ingrowth.

14. A prosthetic heart valve in accordance with claim 13, wherein the outer cloth member is Dacron velour fabric.

15. A prosthetic heart valve in accordance with claim 13, and further comprising a second inner cloth member, one of the inner cloth members being a thin pad extending along one face of the retaining ring and terminating a substantial distance outward therefrom, and the other inner cloth member being a cloth suture sleeve covering the pad and the retaining ring.

16. A prosthetic heart valve in accordance with claim 15, wherein the inner sleeve and the cloth pad are Teflon fabric.

17. A prosthetic heart valve in accordance with claim 10, wherein said limiting means comprise cage legs mounted on the retaining ring and extending through the cloth suture sleeve past the upper flange of the valve body to guide movement of the movable valve member.

18. A prosthetic heart valve comprising:

a metal valve body having a central orifice providing a passage for fluid flow and upper and lower outwardly extending flanges defining a groove around the periphery of the valve body, the lower flange and the groove wall being arcuate in cross-sectional configuration, and the upper flange being substantially larger in diameter than the lower flange;

a frusto-conical seating surface on the upper flange extending from the orifice to the outer edge of the flange;

a movable disc check valve member disposed above the valve body and having a frusto-conical seating surface on its under side which mates with the seating surface on the valve body to close the orifice against back flow, the disc being larger in diameter than the upper flange of the valve body so as to overhang the outer periphery of the valve body, the outer edge of the disc and the outer edge of the upper flange both being rounded in section and their respective points of tangency to the seating surfaces being approximately opposite each other;

a thin frusto-conical annular retaining ring of a springy metal disposed around the valve body between the flanges, with the inner edge of the retaining ring downward, the smaller diameter of the retaining ring being approximately the same as the diameter of the valve body lower flange, and the outer edge of the retaining ring terminating a substantial distance outward from the valve body upper flange;

a pair of parallel cages each including a stop portion which limits excursion of the disc and a pair of legs which extend downwardly along side the disc and are connected to the retaining ring; and

a cloth suture ring including a cloth pad and at least one cloth sleeve, the pad being a flat annular piece of cloth extending along the lower face of the retaining ring and terminating a substantial distance outward from the retaining ring, and the cloth sleeve being an annular cloth member covering the retaining ring and the cloth pad and having its two edges

butted interior of the groove and held in place by pinching action between the annular retaining ring and the groove wall.

19. A prosthetic heart valve in accordance with claim 18 and further comprising a second cloth sleeve covering the first cloth sleeve, the first sleeve and the pad being Teflon fabric, and the second cloth sleeve being polyethylene terephthalate textile fiber.

References Cited

UNITED STATES PATENTS

3,263,239	8/1966	Edwards et al.	3—1
3,464,065	9/1969	Cromie	3—1
3,371,252	3/1968	Siposs et al.	3—1
3,396,409	8/1968	Melrose	3—1
3,445,863	5/1969	Wada	3—1

FOREIGN PATENTS

1,180,087	10/1964	Germany.
-----------	---------	----------

OTHER REFERENCES

"Stainless Steel Disc Valve For Cardiac Valve Replacement," by K. R. Williams et al. Journal of Thoracic And Cardiovascular Surgery, vol. 49, No. 4, April 1965, pp. 540-549.

"Comparative Study of Some Prosthetic Valves for Aortic and Mitral Replacement," by C. A. Hufnagel et al., Surgery, vol. 57, No. 1, January 1965, pp. 205-210.

"A New Caged-ball Aortic and Mitral Valve and Monitoring and Controlled Respiration in Critically Ill Patients," by D. E. Harken, Mt. Sinai Hospital Journal, vol. 32, 1965, pp. 93-106. Copy in Group 335.

"Aortic Valve Prosthesis Incorporating Lightweight Titanium Ball, Dacron Velour Covered Cage and Seat," by D. A. Cooley et al., Transactions Amer. Soc. For Artificial Internal Organs, vol. XIII, Apr. 15 and 16, 1967, pp. 93-100.

RICHARD A. GAUDET, Primary Examiner

20 R. L. FRINKS, Assistant Examiner