ABSTRACT

An artificial heart assembly comprising a pair of ventricles, a pair of atria or inflow means, a pair of sinus or outflow means for pumped blood, and fluid pumps to drive the ventricles. In a modification, a single ventricle is used as a ventricular assist device. Each ventricle has a shell providing a ventricular cavity and at least one pumping chamber in the shell. The chamber has a flexible non-stretching wall and a rigid wall sealed to each other. The rigid wall has an aperture to permit entry of the pumping fluid into the chamber. A blood-compatible material covers all blood-exposed surfaces in the cavity.

27 Claims, 9 Drawing Figures
FIG. 2

FIG. 3

FIG. 4

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SHEET 2 OF 5

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ARTIFICIAL HEART ASSEMBLY AND HEART ASSIST DEVICE

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation in part of application Ser. No. 72,628, filed Sept. 16, 1970 now abandoned.

BACKGROUND OF THE INVENTION

This invention relates to an artificial heart assembly that is implantable in a human being or an animal for functioning similarly to the natural heart, and also relates to a heart assist device for supporting a natural heart. Either assembly can function over an extended period of time, providing controllable pressure, volume, and rate control. Both assemblies are blood-compatible and require little, if any, anticoagulation. Implantation is relatively easy and convenient.

Devices are known which use pneumatic or hydraulic pressure as a motive force to activate an artificial heart or heart assist. The single ventricle of the assist or each of the two ventricles used in a total prosthesis usually has comprised a double walled chamber with an inner bladder representing the ventricular cavity, pressure being applied in the outer chamber. The outer wall, whether rigid or flexible, has had a tubulation for transmission of the gas or fluid medium, but there has been no specific control of the pump volume, and the expansion and elasticity of the pneumatic or hydraulic chamber has required excessive pumping and relief time, due to expansion of the outer chamber and compressibility of the medium. The atrial connection chambers have usually been attached to the ventricles, and the ventricles have been connected in a way that has tended to cause difficulties in the surgical procedure for installation of the artificial heart.

The above difficulties are overcome by the device of the present invention, and other advantages will become apparent from the description which follows. For instance, the ventricle of the present invention provides a precise and predetermined pump volume; the pumping chamber walls are flexible and non-elastic and as a result provide a more constant and uniform supply of blood under controllable pressure and at a controlled rate. The atria and sinuses as part of the prostheses are detachable from the ventricles so that at the time of surgery, attachment of these parts to the atrial remnants and arteries after removal of the heart or to the apex of the left ventricle (in the case of the assist) is more readily accomplished. The blood-contacting surfaces of this new device are blood-compatible with minimal embolic risk.

BRIEF SUMMARY OF THE INVENTION

The present invention provides an artificial heart assembly or a heart assist device which can be implanted in an animal or human body and which provides a constant and uniform pulsing flow of blood, with minimal risks of coagulation, embolism or infection, and with optimal ease of installation and use.

The invention provides a ventricle containing one or more pumping chambers. A means for introducing a fluid, either gas or liquid, is provided for each pumping chamber. A prosthetic heart assembly includes one or two such ventricles while a heart assist uses a single ventricle. The pumping fluid is kept separated from the blood, and there is means for connecting the blood outlet from each ventricle to one of the body's arterial systems. An atrium connects the ventricle to the patient's venous system in the total heart device. In the heart assist, a special connection joins the patient's left ventricle to the assist device. In both devices, there are inflow and outflow valves located in the inflow and outflow means, respectively.

Each pumping chamber comprises a rigid outer wall and a flexible, non-stretching diaphragm wall, the two walls being secured together at or adjacent their edges, as by sutures or by cement or by compression seal, to define a generally ovoid bladder when inflated. When deflated, the flexible membrane lies against the rigid wall while the central space or blood-flow chamber of the ventricle, in which the pumping space is disposed, fills with the blood to be pumped. The walls of the blood-flow chamber and any other surfaces of the device or assembly which are exposed to blood are provided with a blood-compatible covering, advantageously Dacron velour. The rigid wall is made of a physiologically compatible material such as stiffened silicone rubber, resin-impregnated glass-fiber cloth, or a suitable plastic or metal.

The present invention provides separate impervious non-stretching pumping chambers of the exact size desired. While a single chamber may be used, two pumping chambers are preferably used for each ventricle, in order to economize size and movement and to provide central flow of blood in the ventricle. One side of each chamber — the outer side — is made rigid to force expansion to take place only in the desired direction, which is inwardly. Fluid or gas passages are provided in this rigid shell so that the movable diaphragm is uncomplicated in form in the interest of extending flexural fatigue life. The diaphragm membrane is non-stretching and is impervious to liquid and gas, to provide controlled pressure, volume, and position in the ventricle and to separate the pumping fluid from the blood by separating the pumping chamber from the blood-flow chamber. Prefabrication of the pumping chambers enables their pretesting to assure freedom from leaks.

The pumping chambers are assembled into the ventricle, usually being placed at an angle to give the most economical use of space, and to prevent their touching opposing walls when fully expanded to minimize red cell trauma. This enables control of the volume and pressure. When more than one expansion or pumping chamber is used in a single ventricle, the expansion or pumping chambers are preferably interconnected at the base or tip of the ventricle to a common gas or liquid conduit. A separate conduit is provided for each ventricle. The ventricle is preferably shaped to be round or oval laterally, to accommodate the expansion or pumping chambers in the side wall or walls, and the inflow and outflow valves fit naturally into the spaces at the top of the ventricle. The entire ventricle is lined with an impervious lining, such as velour, especially Dacron velour, or other blood-compatible material.

The atria and sinus, which may be part of the inflow and outflow means, may be fabricated separately, so that the ventricle may be attached to them by suitable connectors which mate with connectors on top of the ventricle. This attachment is done after the atria and sinus are surgically attached to the patient or animal. This technique results in easier surgical insertion and manipulation.
When a single ventricle is used as a heart assist device, the patient's own heart is left intact in this application. A suitable connector is placed in the apex of the left ventricle to draw blood out of the patient's left ventricle into the artificial ventricle via a flexible plastic tube such as a Dacron tube. The artificial ventricle or heart assist may be placed in the abdominal cavity, inferior to the diaphragm or it may be left outside the body. The artificial ventricle then pumps blood through a suitable flexible tube into the descending aorta. Valves are located at the top of the artificial ventricle. This device relieves the load on a patient's own heart for an indefinite period of time permitting his own heart to recover sufficiently to resume its full capacity.

Other objects and advantages of the invention will appear from the following description of some preferred embodiments.

**BRIEF DESCRIPTION OF THE DRAWINGS**

FIG. 1 is a partially exploded view in side elevation of an artificial heart ventricle, embodying the principles of the invention, with a prosthetic valve and an atrium shown ready for insertion and attachment. A detachable sinus and outflow prosthetic valve are shown connected. The attachment to a pump is broken and is shown partly diagrammatically.

FIG. 2 is a view in section, taken along the line 2—2 in FIG. 1, with the pumping chambers collapsed. FIG. 3 is a view similar to FIG. 2 with the pumping chambers expanded to a maximum.

FIG. 4 is a view in section, taken along the line 4—4 in FIG. 1, with the pumping chambers expanded as in FIG. 3.

FIG. 5 is a view in perspective of two of the ventricles of FIG. 1 attached to each other to provide a complete heart prosthesis.

FIG. 6 is an exploded enlarged fragmentary view in section of a portion of the apparatus showing the connectors and a valve between the atrium and the ventricle.

FIG. 7 is a view similar to FIG. 6 with the parts assembled.

FIG. 8 is a fragmentary view partially in section of the heart assist device embodying the principles of the invention, completely connected to the patient's heart and descending aorta.

FIG. 9 is a view in section of an apex connector used with the heart assist device.

**DESCRIPTION OF SOME PREFERRED EMBODIMENTS**

An entirely totally artificial heart 10 (see FIG. 5) of this invention comprises two identical artificial ventricles 11 and 12, two atria 13 and 14 serving as blood in-flow means into their respective ventricles 11 and 12, and two sinus 15 and 16 serving as the outflow means for blood from the respective ventricles 11 and 12.

Each of the two identical ventricles 11 and 12 has an air bleeder line 17 (see FIG. 1) and gas or fluid lines 18 or 19 for the pumping fluid, leading to a pump 20 (FIG. 1). Between each atrium 13, 14 and its ventricle 11, 12 is an inflow or atrioventricular valve 21, located where a flanged connector 22 on the atrium 13 meets and mates with a flanged connector 23 on the ventricle 11. The atrium 13 has a wall 24 at its other end for attachment to the patient's residual atrial walls after removal of the recipient's heart. Between each ventricle 11, 12 and its sinus 15 or 16 is an outflow or sinuventricular valve 25 housed in similar flanged connectors 26 and 27. The sinus 15 and 16 also have tubulation 28 for connection to the patient's aorta or pulmonary artery. The flanged connectors 22, 23 and 26, 27 greatly ease the technical problem of insertion of the prosthesis 10 at the time of surgery, since the atrium 13 and sinus 15 can be surgically implanted individually, unencumbered by the ventricle 11. Connection of the ventricle 11 to its atrium 13 and sinus 15 is simplified in that one merely "plugs" the parts together, securing the flanges to one another with sutures threaded into holes provided in the flanges as described below. After the prosthetic heart 10 is fully assembled, it is filled with blood, and any air is removed via the bleeder line 17, which is then sealed. The gas or fluid line 18 (or 19) is brought out through the body wall 29 and connected to a suitable power source or pump 20 for continued operation of the device. Individual power sources are used for each ventricle 11, 12 since the pressure requirements for the arterial and pulmonary circulations are different.

The ventricle 11 shown in FIGS. 1—4 has an outer shell 30 made of rigid material, preferably fiberglass-reinforced epoxy resin, though it may be made from other rigid plastics, or from metal, so long as these are biologically compatible, or the shell 30 may be made so biologically compatible by covering or coating a rigid material with a compatible material such as stiff silicone rubber. The shell 30 provides a ventricular cavity 31, and, disposed within the cavity 31 is at least one pumping chamber, preferably two pumping chambers 32 and 33 connected to respective gas passages 34 and 35. The chambers 32 and 33 are separated from the blood by two fluid impervious membranes 36 and 37, preferably made from silicone rubber impregnated Dacron fabric or other suitable non-stretching, flexible material. The membranes 36 and 37 are preferably wrapped around the edges and bonded to the back surfaces of inner shells 38 and 39 respectively. These inner shells are preferably made of material similar or identical to that of the outer shell 30. Openings 40 and 41 are provided in the inner shells 38 and 39 to enable fluid to enter the chambers 32 and 33.

The enclosed pumping chambers 32 and 33 are thus bounded partly by the inner shell 38 and 39 and partly by the fluid-impervious but flexible diaphragms or membranes 36 and 37. The blood exposed surfaces of the diaphragms 36 and 37 and of the outer shell 30 are covered by a blood compatible material 42 such as Dacron velour, by impregnating one side of the velour — without filling the pile on the other side — with a suitable medical rubber impregnant and then adhesively attaching the velour 42 to the diaphragms 36 and 37 and the shell 30. Also the tube 18 which connects the power source 20 to the gas passages 34 and 35, preferably via a Y-shaped connector 43, is preferably exteriorly coated with Dacron velour 44.

The pressure chambers 32 and 33 are preferably placed so as to be on a slight angle to the vertical centerline of the ventricular cavity 31 — that is, they diverge from each other and from the blood flow chamber 45 upwardly and outwardly from the lower end 46 of the shell 30 — so that when the chambers 32 and 33 are fully expanded, their flexible diaphragm walls 36 and 37 do not touch each other, minimizing blood trauma. The pumping chambers 32 and 33 may be
placed in position and affixed to the interior surface of the outer shell 30, for example, by cementing the inner shells 38 and 39 to the outer shell 30 with a medical rubber cement.

At the top of ventricle 11 is a blood inlet area 47 and a blood outlet area 48. FIGS. 6 and 7 show the configurations of the connectors 22, 23 between the ventricle 11 and the atrium 13, and the connectors 26 and 27 are substantially the same as the connectors 22 and 23. The body 50 of the ventricular or male connector 23 can be an integral part of the ventricle shell 30 or can be made from another piece and bonded or welded to the shell 30. An anular recess 51 with a shoulder 52 is provided in the body 50 of the connector 23 in which the valve 21 is seated and is mechanically locked in position by press fit. The valve 21 is preferably a Wada-Cutter tilting disc valve but may be any suitable prosthetic or tissue valve. The blood compatible lining 42 is continued right up to the valve 21. The atrial or female connector 22 has a body 53 with an annular receptacle 54 having a cylindrical wall 55 and a shoulder 56, against which end wall 57 of the body 50 abuts, the bodies 50 and 53 nesting together tightly.

Against a shoulder 61 of the body 50, a flange 60 is mounted so that it can be rotated relatively to the body 50, and the flange 60 mates with a flange 62 on the body 53, preferably fixed to the body 53. These flanges 60 and 62 are made of rigid material such as stainless steel or other suitable material such as rigid plastic or fiberglas-reinforced epoxy resin. The flanges 60 and 62 each have a spaced series of holes 63 and 64 respectively, distributed around the peripheries of the flanges 60 and 62 so that the two flanges 60 and 62 can be sutured together, thereby firmly securing the two connectors 22 and 23 together. The flange 60 can be rotated about the vertical axis so as to align the holes 63 and 64. The generally cone-shaped atrium 13 is preferably constructed from silicone rubber sheet 65 (which may be reinforced with fabric) and along with a blood compatible lining 66, preferably Dacron velour, is bonded to the body 53 of the connector 22. The connectors 26 and 27 between the sinus 15 and the ventricle 11 are identical to the connectors 22 and 23 except that the outflow valve 25 is a flipped-over valve 21 so as to function properly.

In surgery the surgeon connects to the patient an external heart-lung machine to maintain the patient's circulation and oxygenation while the operation is in progress. By one method, he takes out the patient's natural heart and puts in the first or lower atrium 13, suturing it to the atrial remnant. The second atrium 14 is then sutured to the other atrial remnant. The arterial graft tubing 28 attached to the sinus 15 is sutured to the pulmonary artery, and the second sinus 16 is attached to the aorta via additional arterial graft tubing 28. The connectors 23 and 27 of the ventricles 11 and 12 are then "plugged" into the atrial and sinus connectors 22 and 26, securing them by sutures through the holes 63 and 64 in the connector flanges 60 and 62. The ventricles 11 and 12 are then attached to each other by straps 67 of silicone impregnated Dacron cloth, which are bonded to each ventricle and are then sewn to each other.

In another embodiment, a single ventricle 11 can be used as a heart assist device. FIG. 8 shows the configuration of the attachment to the patient's left ventricle 70 and his descending aorta 71. Blood is removed from the apex 72 of the heart 73 via a suitable apex connector 74.

This apex connector 74 (see also FIG. 9) is provided with an internal radial extension 75 for positioning the apex connector 74 flush with the inner surface of the heart 73. The apex connector 74 also has another radial extension, a sewing flange 76 for suturing the apex connector 74 to the heart muscle.

As shown in FIG. 9, the apex connector 74 preferably has a thin metal or plastic tube 77 for stiffening the apex connector 74. The inner and outer surfaces of the tube 77 are covered with adhesive 78 such as silicone rubber, to bond it to an exterior sleeve 80 of blood compatible material and an inner sleeve 81 of blood compatible material, both sleeves preferably being Dacron velour. The radial extensions 75 and 76 may have fillers 82 and 83, such as silicone rubber sheet, to provide bulk. The sewing flange 76 may be attached to the body of the apex connector 74 by suturing through holes 84 provided around the periphery of a flange 85 that is part of the rigid tubing 77. A tubular extension 86 is provided for attachment by suture to arterial graft tubing 87.

This tubing 87 is, in turn, sutured to a heart assist outflow adapter 88, which, like a heart assist outflow adapter 89, is constructed essentially from the same materials as the atrium 13 and sinus 15, i.e., silicone rubber sheeting lined with blood compatible material, preferably Dacron velour. Built into the assist adapters 88 and 89 are connectors 90 and 91 like the connector 22 of FIGS. 6 and 7 for easy attachment to the connectors 23 and 27 on the ventricle 11. As in the total heart 10, inflow and outflow valves are housed inside the connectors 23 and 27 on top of the ventricle 11. Arterial graft tubing 92 is sewn onto the heart assist outflow adapter 89 and to the patient's descending aorta 71. Both arterial graft tubings 87 and 92 are made of flexible, non-collapsing materials, for example, spirally wound metal wire covered with silicone with an interior bonded covering of Dacron velour.

At the time of surgery a hole is punctured in the apex 72 of the patient's heart 73, and the apex connector 74 is inserted. The sewing flange 76 is sutured to the heart muscle. Holes 93 and 94 are cut in the patient's diaphragm 95, and the arterial graft tubes 87 and 92 are inserted through these holes 93 and 94. The tube 87 is sutured to the apex connector 74, and the tube 92 is sutured to the descending aorta 71. The assist adapters 88 and 89 may be attached by suturing to the tubes 87 and 92 at this point, or they may have been sutured prior to surgery. The connectors 23 and 27 of the ventricle 11 are then "plugged" into the connectors 90 and 91 of the adapters 88 and 89 and secured by sutures. The fluid pressure line 18 is brought out through the body wall 29 as in FIG. 1 and is attached to the power source 20 as described previously.

The above specific description and the drawings have been furnished for illustrative purposes only, and variations and modification can be made without departing from the spirit and scope of the invention.

What is claimed is:

1. An improved artificial ventricle including in combination:

a) generally rigid ventricle shell means providing a ventricular cavity and having inlet means and outlet means for blood, said ventricle shell means comprising an outer shell and an inner shell,
pumping means providing at least two pumping chambers within said cavity and comprising a diaphragm for each pumping chamber secured between said inner and outer shells and dividing the pumping chamber from a blood-flow chamber in said cavity, each said diaphragm being a flexible, non-stretching, impervious membrane, said inner shell having aperture means enabling entrance of pumping fluid into said pumping chambers, said inner shell being sealed at its back side to each said diaphragm and to said outer shell.

blood-compatible material covering all blood-exposed surfaces of said ventricle shell and said diaphragm, and

condut means connected to said aperture means for conducting pumping flow to said chamber, said pumping chambers enabling central flow of blood chamber.

2. The ventricle of claim 1 wherein said pumping chambers are so disposed that when fully expanded the flexible membranes do not touch each other, thereby minimizing red cell trauma.

3. The ventricle of claim 1 wherein said pumping chambers are disposed to diverge from each other upwardly and outwardly from a lower end of said shell means.

4. The ventricle of claim 1 wherein said shell means is made from stiff silicone rubber.

5. The ventricle of claim 1 wherein said shell means is made from glass fiber cloth impregnated with epoxy resin.

6. The ventricle of claim 1 wherein said shell means is made from metal.

7. The ventricle of claim 1 wherein blood-exposed surfaces are all covered with Dacron velour.

8. The ventricle of claim 1 wherein said flexible membrane is of flexible silicone rubber.

9. The ventricle of claim 1 wherein said flexible membrane is of elastomer-impregnated non-expandable cloth.

10. The ventricle of claim 1 having valves in both said inlet and outlet means.

11. The ventricle of claim 1 having an artificial atrium detachably connected to said inlet means.

12. The ventricle of claim 11 having an artificial sinus detachably connected to said outlet means.

13. The ventricle of claim 12 wherein both said detachable connections comprise a pair of rings, one rotatably mounted to said ventricle, the other being secured in one instance to said sinus and in the other instance to said atrium, each ring of each pair having a flange with suture openings therethrough, the rotatable mounting of said one ring of each pair enabling alignment of its suture openings with those of the other ring of that pair.

14. The ventricle of claim 13 wherein a valve is seated by press fit in an annular shouldered recess in each said ring that is mounted to said ventricle.

15. An artificial heart assembly comprising in combination:

a. a pair of ventricles,

b. a pair of atria, one connected to each said ventricle,

c. a pair of sinuses, one connected to each said ventricle,

d. means to provide pumping fluid to said assembly,

e. outflow means for pumped blood, including a valve for each ventricle,

f. intake means for blood to be pumped, including a valve for each ventricle,

g. each said ventricle comprising:

1. a rigid outer shell providing a ventricular cavity,

2. at least two pumping chambers disposed in said cavity and having one flexible nonstretching diaphragm wall separating each said pumping chamber from a blood-flow chamber in said cavity and a more rigid inner shell sealed to each said diaphragm and secured to said outer shell,

3. said inner shell having an aperture therein to permit entry of pumping fluid into said pumping chamber,

4. blood-compatible material covering all blood-exposed surfaces in said cavity; and

5. means to conduct pumping fluid to said pumping chamber,

6. said chambers being of predetermined capacity.

16. The assembly of claim 15 wherein said blood-compatible material is Dacron velour.

17. The assembly of claim 15 wherein each said ventricle has two connectors, each having a body with an annular shouldered recess, and a stiff radial flange rotatably mounted to said body and having circumferentially spaced holes therethrough, one said valve being seated and held in each said recess, a connector for each atrium and each sinus mated with a connector on said ventricle and each having a radial flange with circumferentially spaced holes therethrough and alignable with those of a flange on the ventricle's connector, by rotation of the flange on the ventricle's connector, for suturing said flanges together.

18. The assembly of claim 17 wherein each said valve is a low-profile valve having an annular housing press fitted into said recess.

19. An artificial heart ventricle assembly comprising in combination:

a. a ventricle,

b. an atrium separate from said ventricle and separately attachable to a patient's atrial remnant before attachment to said ventricle,

c. an atrioventricular valve enclosed between said atrium and said ventricle upon attachment of said atrium to said ventricle,

d. a sinus separate from said ventricle and separately attachable to a patient's aorta or pulmonary artery before attachment to said ventricle,

e. a sinuventricular valve enclosed between said sinus and said ventricle upon attachment of said sinus to said ventricle,

f. means for providing pumping fluid for said ventricle,

each said ventricle comprising:

1. a rigid shell providing a ventricular cavity,

2. at least two pumping chambers disposed in said cavity each having one flexible nonstretching wall and one rigid wall sealed to each other,

3. each said rigid wall secured to said shell and having an aperture for entry of pumping fluid into said chamber,

4. each said flexible wall dividing said pumping chamber from a blood-flow chamber in said cavity,

5. blood-compatible material covering all blood-exposed surfaces in said cavity; and
6. means for conducting said pumping fluid to said pumping chamber,
7. said chambers being of predetermined capacity.
20. The assembly of claim 19 wherein said blood-compatible material is Dacron velour.
21. The assembly of claim 19 wherein said atrium and said sinus each have a female connector having an annular socket receptacle and a radial flange having a plurality of spaced openings therethrough and said ventricle has two male connectors each pluggable into a said socket receptacle and having a radial flange mounted rotatably to said male connector and having a plurality of spaced openings therethrough like those of said flange of said female connector alignable therewith by rotation relative to said male connector, for suturing together of said mating connectors.
22. The assembly of claim 21 wherein each said male connector has an annular shouldered recess, one receiving said atrioventricular valve and one receiving said sinus ventricular valve for press fit therewith.
23. A heart assist device, comprising in combination a. an artificial ventricle comprising
   1. a rigid shell providing a ventricular cavity,
   2. at least two pumping chambers disposed in said cavity, each having one flexible nonstretching wall and one rigid wall sealed to each other,
   3. each said rigid wall secured to said shell and having an aperture for entry of pumping fluid into said chamber,
   4. said flexible wall dividing said pumping chamber from a blood-flow chamber in said cavity,
   5. blood-compatible material covering all blood-exposed surfaces in said cavity,
   6. means for conducting said pumping fluid to each said pumping chamber,
   7. inflow and outflow valves for blood flowing to and from said blood-flow chamber,
   b. an apex connector, covered with blood-compatible material, having means enabling suture of said connector to a patient's heart and providing a channel for removal of blood from that heart, and
c. conduit means for connecting said apex connector to said artificial ventricle and for connecting said ventricle to the patient's descending aorta.
24. The device of claim 23 wherein said conduit means comprises arterial graft tubing.
25. The device of claim 23 wherein each said conduit means is connected to said ventricle by a connector assembly comprising a male connector and a female connector, each having a body and a radial flange with identically spaced perforations therethrough, one said radial flange being rotatable relative to its said body.
26. The device of claim 23 wherein said apex connector comprises a rigid tube lined exteriorly and interiorly with blood compatible material and having a terminal radial flange for engaging the interior wall of the patient's heart, and a radial sewing flange spaced away from said terminal flange and sutureable to the heart muscles.
27. The device of claim 26 wherein said rigid tube has a radial flange to which said sewing flange is sutured.

* * * * *
UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION


Inventor(s) Paul Kahn and Ronald C. Brown

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

Item [56], References Cited, in the heading, right-hand column, line 5, "Fnt. Organs" should read --Int. Organs--.

Column 6, line 34, "venricle" should read --ventricle--.

Column 6, line 66, "said verticle shell" should read --said ventricle shell--.

Column 7, line 11, at the end of this paragraph, "shell." should read --shell.--

Signed and sealed this 6th day of August 1974.

(SEAL)
Attest:

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Attesting Officer Commissioner of Patents