United States Patent

Tindal

[15] **3,668,708**

[45] **June 13, 1972**

[54] ARTIFICIAL HEART

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[73] Assignee: **North American Rockwell Corporation**

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[21] Appl. No.: **887,566**

[52] **U.S. Cl.** 3/1, 3/DIG. 2, 417/389, 417/394

[51] **Int. Cl.** **A61f 1/24**

[58] **Field of Search**.....3/1, DIG. 2; 128/1, 214; 417/389, 394

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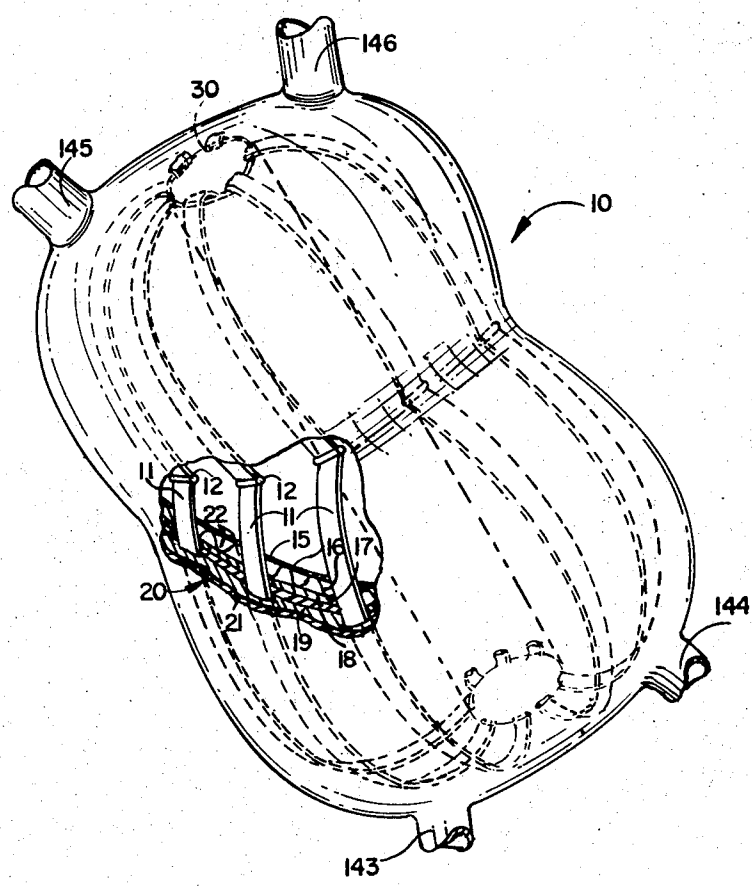
[57] **ABSTRACT**

An artificial heart has a number of flat structural members arranged circumferentially about a central support. An inner layer of material confines blood to chambers of the artificial heart and an outer layer of material, which fully encloses the flat structural members, defines cavities between the inner layer of material and the outer layer. Fluid is pumped into the cavities for expanding the structural members to cause heart pumping action in response to measured values of preselected blood chemistry parameters. The structural members contact to their original positions to complete the pumping action.

8 Claims, 25 Drawing Figures



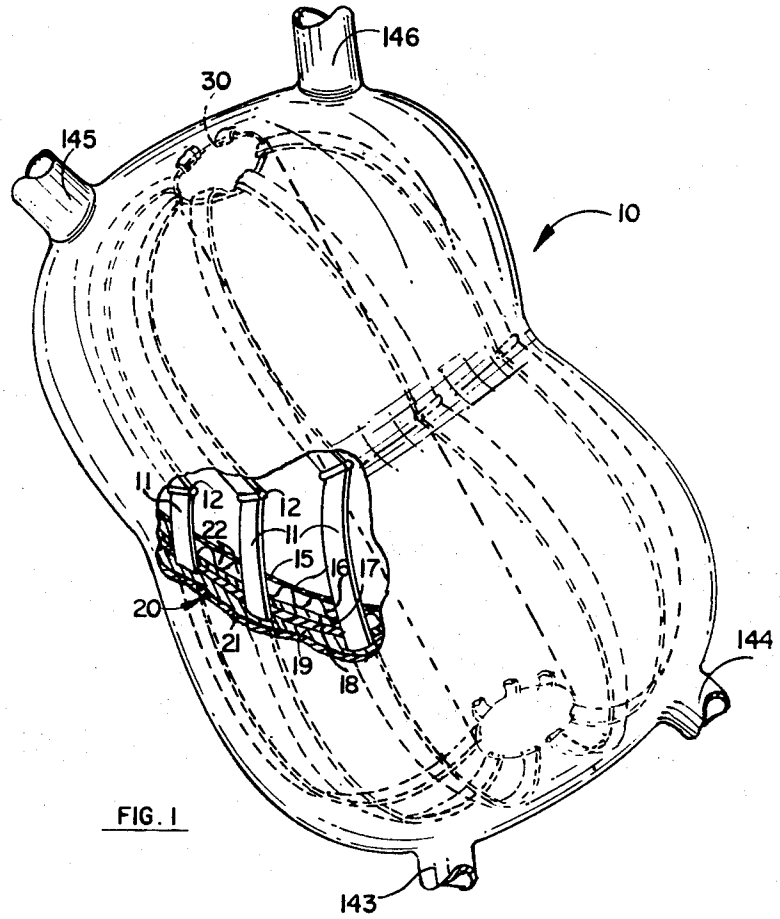


FIG. 1

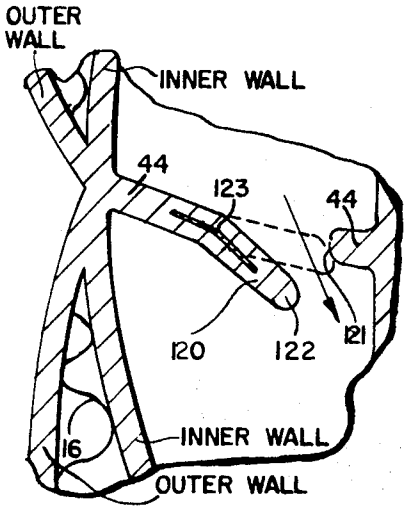


FIG. 7

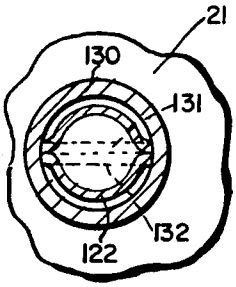


FIG. 8b

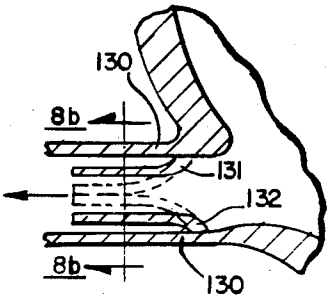


FIG. 8a

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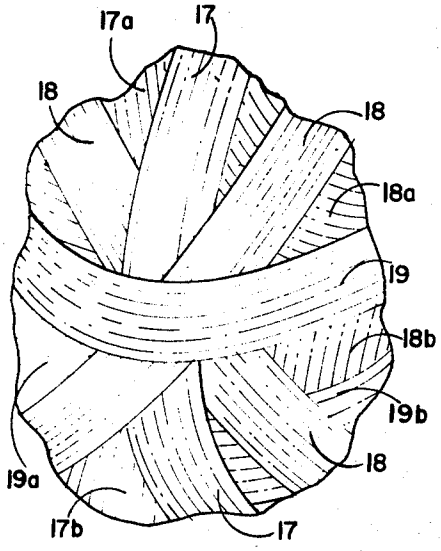

FIG. 2

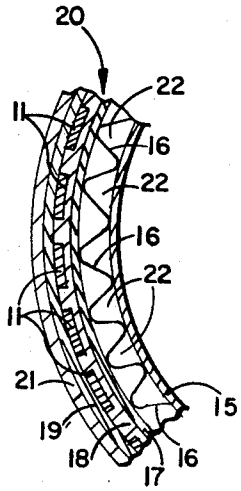

FIG. 3a

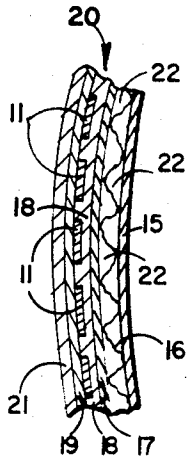

FIG. 3b

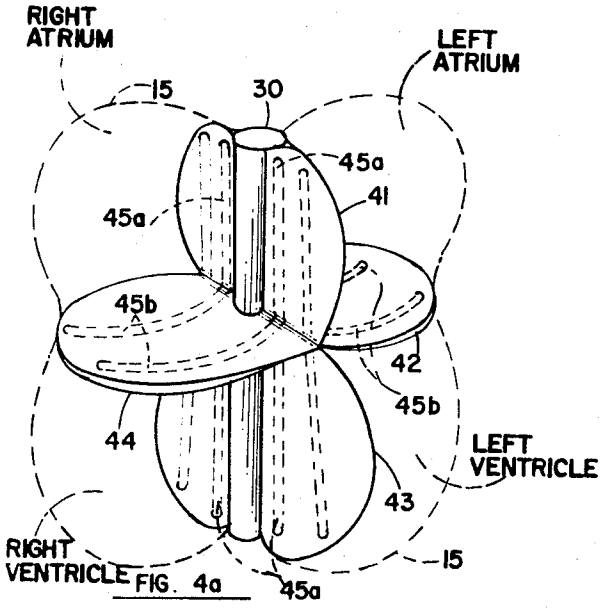

FIG. 4a

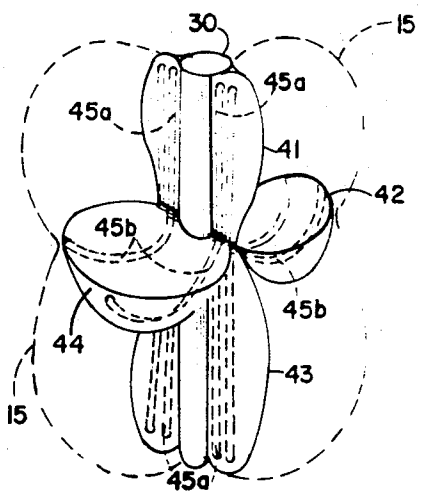

FIG. 4b

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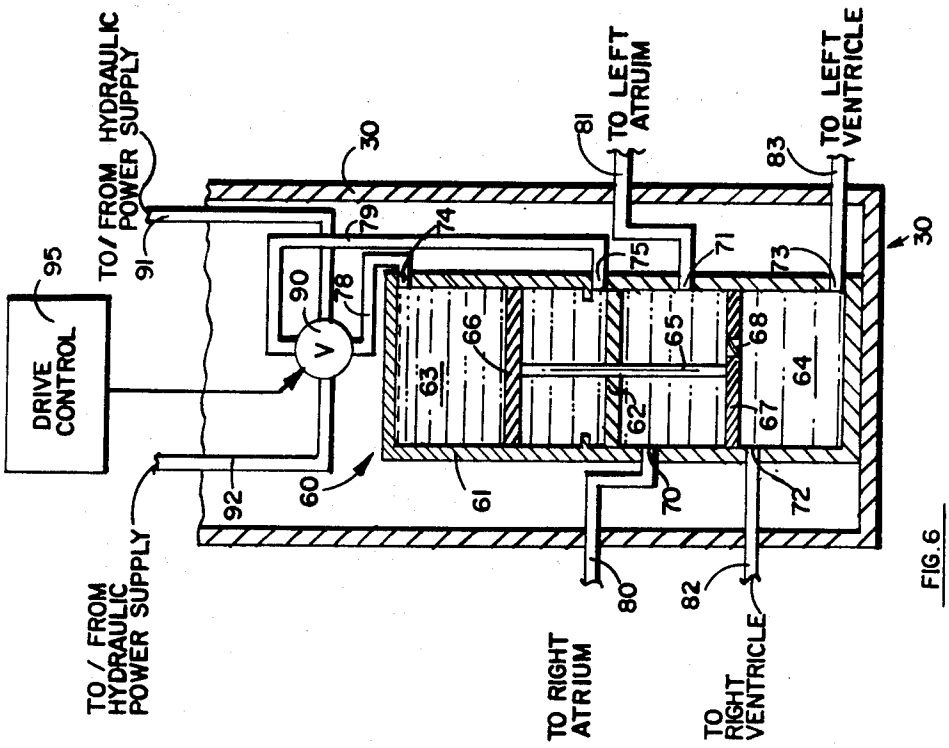

FIG. 6

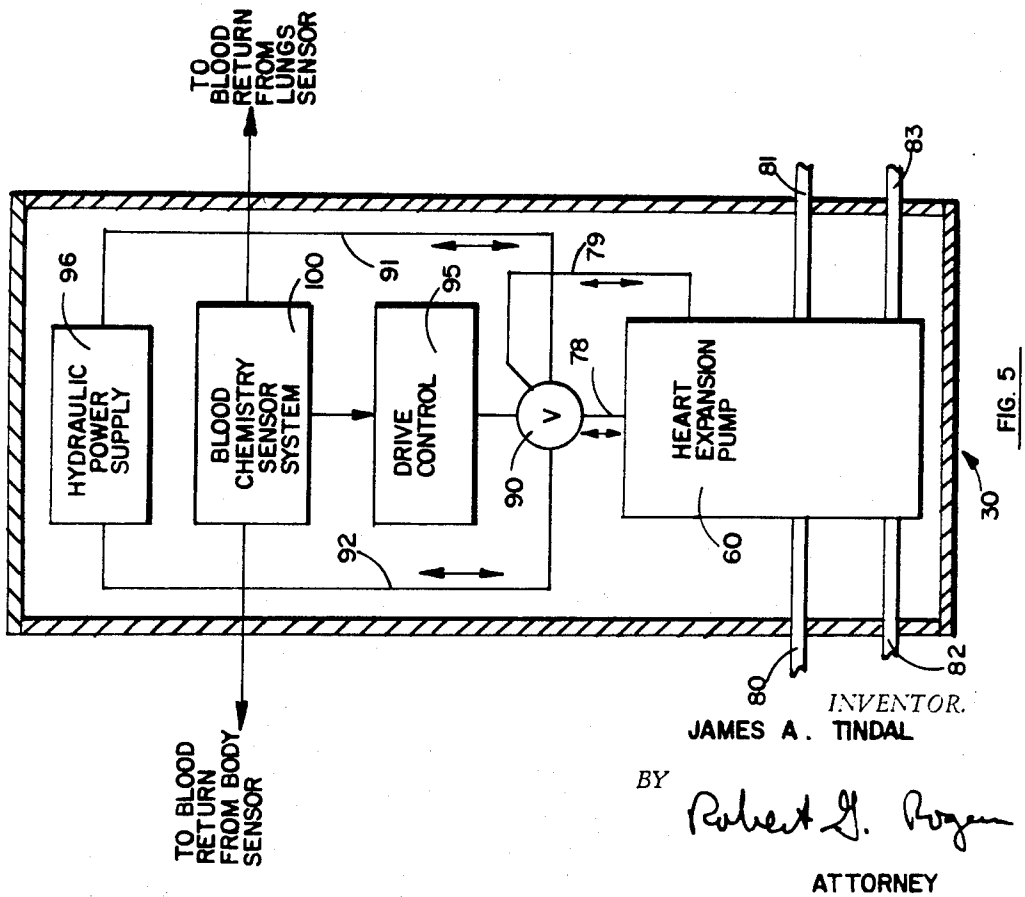

FIG. 5

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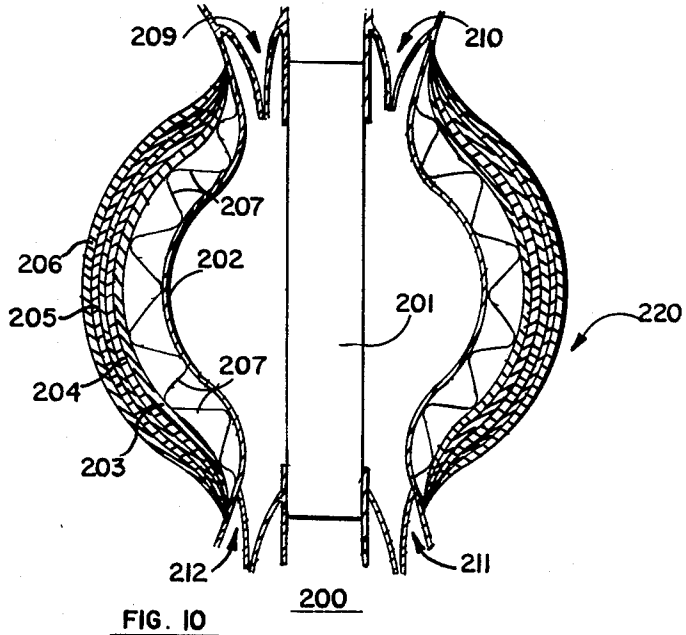

FIG. 10

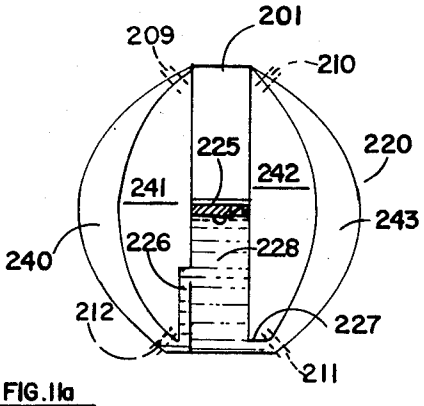

FIG. 11a

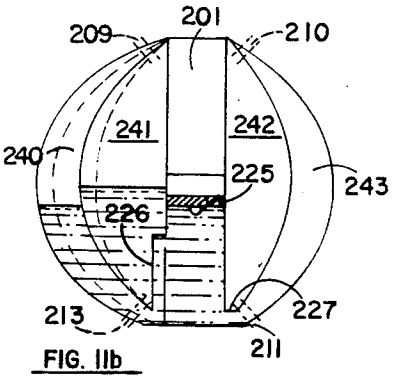

FIG. 11b

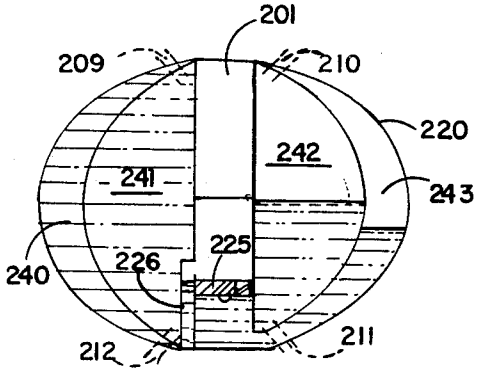

FIG. 11c

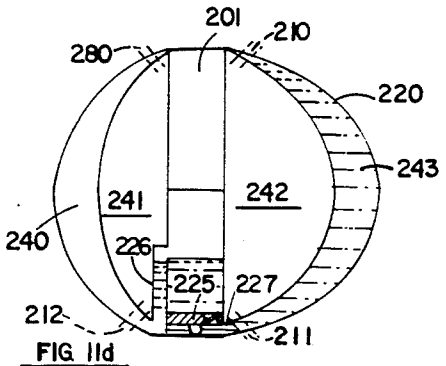

FIG. 11d

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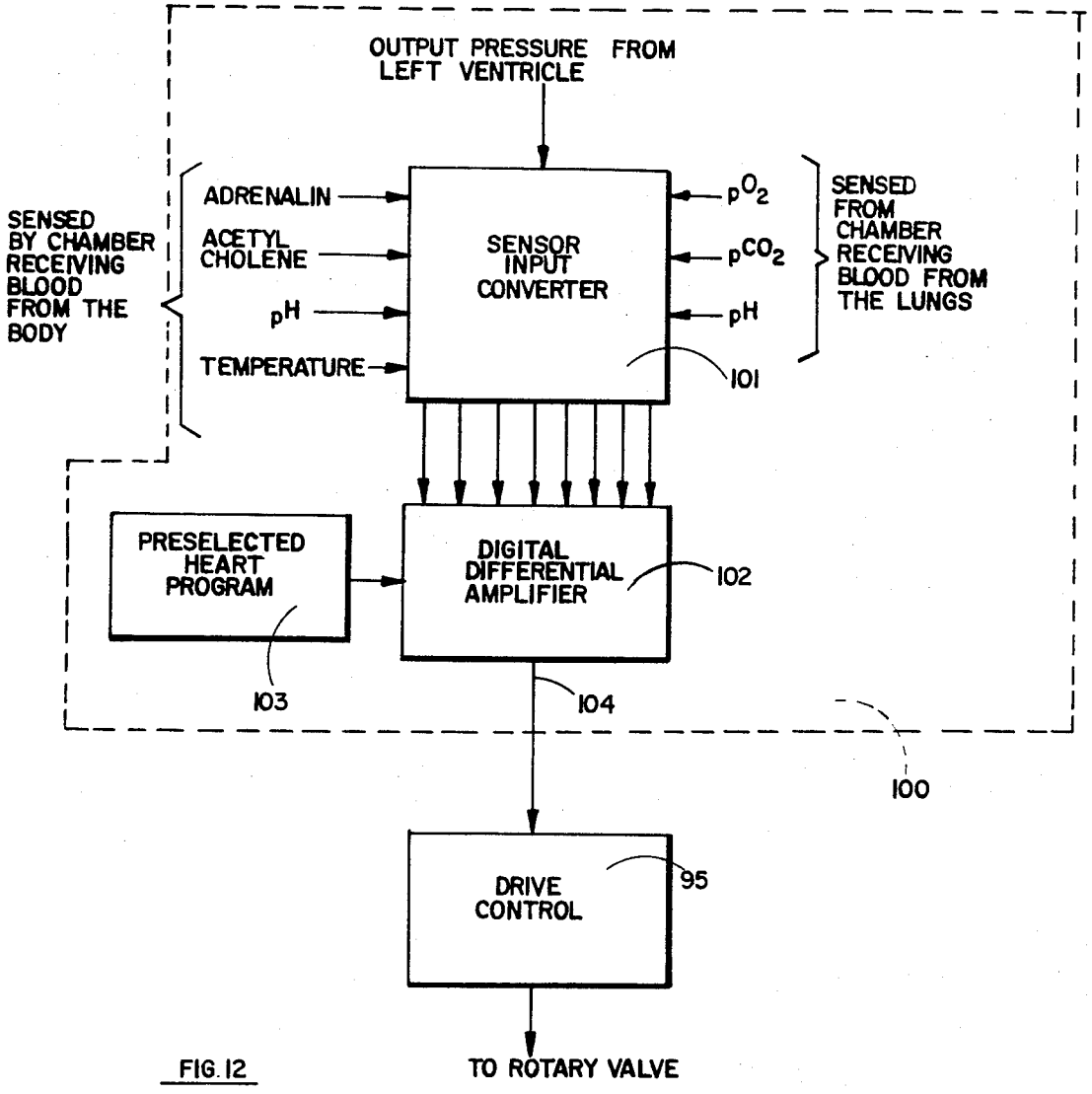

FIG. 12

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ARTIFICIAL HEART

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention pertains to an artificial heart and more specifically to an artificial heart having enclosed structural members circumferentially disposed around heart blood chambers for simulating natural heart pumping action when expanded by a fluid.

2. BACKGROUND OF THE INVENTION

Much effort has been recently devoted in the medical fields to implantation devices. Particular interest has developed concerning implantation of portions of a natural heart or implantation of a complete natural heart. It is well known that several implantation operations have been performed using human hearts, and that several transplantations have been performed using artificial heart valves or other portions of an artificial heart.

Transplantations of hearts and heart devices can be broadly categorized into two types. One type concerns transplantation of hearts from other humans or animals into a living being. In this particular field of medical practice there have been transplants with full hearts of deceased humans into the chest of living persons as well as transplanation of, for instance, the valves from a heart of a pig into a living person.

Another broad categorization can be made with respect to use of natural or artificial heart valves and devices. Into this category falls implantations of artificially manufactured heart valves; certain types of pacemakers, and devices that simulate arteries, veins and heart wall structures.

A broad form of categorization for heart implantation devices can also be made with respect to whether or not the implanted device is designed to accurately mimic the performance of a natural device or whether the device is to merely perform the same heart function without necessarily mimicking a natural device. For instance, a pacemaker may be simply a fixed pulsation device operating with response to body demands. A fixed period pacemaker is not designed to accurately mimic a natural heart since a natural heart responds to various parameters of the body. Similarly, a heart device that merely functions as a blood pump without regard to blood volume and pressure demands could be classified as a non-mimicking device.

Many of the artificially designed heart valves do, however, strive to accurately mimic the performance of a natural heart valve. Such valves are designed to close and open at prespecified pressures and to allow predetermined amounts of flow through a given channel.

Optimum success with any implanted device when considered from a functional point of view (that is, without regard to rejection and other nonfunctional problems) is when such device accurately mimics the operation of the natural device. The best practical manufactured device could be classified, as noted above, as an artificial mimicking device. It is within this category that the instant invention can be placed. The instant device will serve as a completely responsive self-sufficient implantable heart that contains all necessary functional elements to duplicate the physiological functions of a natural heart process in addition to merely serving as a heart pump.

SUMMARY OF THE INVENTION

The major structure of the present invention comprises a number of resiliently flexible flat structural members disposed around a central support. The flexible flat structural members are attached to the central support and define the basic form of the artificial heart. An inner layer of flexible, elastic material is supported between the flexible structural member and the central support. The inner laver forms the basic cavity of the artificial heart and may be divided into a number of chambers, such as two or four.

An outer laver of flexible elastic material encapsulates the flexible structural members. The outer layer is comprised of strips of elastic material that are cross-laced to simulate the muscle structure that surrounds a natural heart. Various ones of the outer layers are crisscrossed in the horizontal, vertical and oblique directions to form a single laminate laver of interlacing flexible strips.

The outer layer and the inner layer define a number of cavities between them. The number of cavities is the same as the number of chambers of the heart. The cavities are outside the chambers and conform to the external surface of the heart chambers. As fluid flows to and from the cavities the heart chambers sequentially expand and contract.

The central support tube houses a pump, working fluid, control equipment and fluid flow ports. The pump causes the working fluid to flow in the cavity between the inner and outer layers of the artificial heart.

Flow of working fluid in a preselected manner to various cavities of the artificial heart causes pumping action similar to that of a natural heart. The fluid causes expansion of the heart chambers and the natural contraction of the flexible outer layer and flexible structural members causes contraction of the chambers. Sequentially causing the expansion and contraction to the various heart chambers results in heart pumping action.

Physiological sensors located in the blood flow stream returning from the body and from the lungs sense body chemistry parameters. The sensor through appropriate circuitry drive the pump that regulates the pumping rate of the artificial heart.

It is therefore an object of this invention to provide an artificial heart.

It is another object of this invention to provide an artificial heart that fully simulates the physiological functions of a natural heart.

It is yet another object of this invention to provide an artificial heart that requires power only in the expansion stroke of the artificial heart.

It is still another object of this invention to provide an artificial heart that responds to sensed parameter changes of measured values in the blood.

Another object of this invention is to provide an artificial heart comprising a number of flexible structural members arranged around a central support member.

Additional object of this invention is to provide an artificial heart with an outer layer that closely approximates muscle action of a natural heart.

These and other objects of the invention will become more apparent from the description of the drawings, a brief description of which follows:

DESCRIPTION OF THE DRAWINGS

FIG. **1** is a cutaway view showing the basic components of the artificial heart of the present invention.

FIG. **2** is a cutaway drawing showing one embodiment of the orientation of the longitudinal, horizontal and oblique outer "muscle" fiber layers.

FIG. **3***a* and **3***b* is a cross-sectional view of the inner and outer wall structure of the artificial heart in expanded and contracted positions respectively.

FIG. **4***a* and **4***b* show the internal wall structure of the artificial heart that divides the heart into four chambers in expanded and contracted positions respectively.

FIG. **5** shows the central support structure housing a hydraulic pump for moving the working fluid to and from cavities around the inner layer of the artificial heart.

FIG. **6** is a cross-sectional view of one embodiment of a heart expansion pump.

FIG. **7** is one embodiment of a valve that would be suitable for use between an atrium and a ventricle chamber.

FIG. **8***a* shows one embodiment in cross-section of a valve that is suitable for permitting one way passage of blood between the artificial heart and the systemic circulation system.

FIG. **8***b* is a cross-sectional view cut in the plane of the diameter of the valve of FIG. **8***a*.

FIGS. 9*a* through 9*h* depicts a four chamber artificial heart of the instant invention during a normal cycle of operation.

FIG. 10 shows an embodiment of an artificial heart having two chambers.

FIG. 11*a* through 11*d* diagrammatically represents the two chamber heart of the instant invention during a complete pumping sequence.

FIG. 12 shows the functional relationship of the blood chemistry sensor system.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIG. 1 there is shown a cutaway sectional view of the artificial heart **10** of the instant invention. The primary structure consists of a central tube **30** to which is affixed a number of shaped structural members **11**. The structural members **11** are connected to both ends of a central tube **30**. Each structural member **11**, usually leaf springs, may be made of machinable metal, plastic, or other material that exhibits lead spring characteristics. The strips are shown as flat of substantially rectangular cross-section, however, a particular cross-sectional configuration is not mandatory. Articulated joint **12** couples the upper and lower strip sections to form a continuous strip that extend the full length of the artificial heart **10**. A continuous strip with a suitable machine junction would also serve well as an articulated junction. As will be described later for a two chamber artificial heart, an articulated structural member may be eliminated. The structural members **11** extend fully around the central tube **30** and form the principal structure and define the shape of the artificial heart. The structural members **11** may be quite close together or somewhat separated. FIG. 1 shows the members somewhat separated so that the cross-section of the layers is clearer. Furthermore, any convenient number of structural members may be used.

The flat structural strips or springs are preshaped and connected to provide the expansion and contraction limits of the heart. One-half of the lower springs carry one-fifth of the tension or temper of the other half of the lower springs. The weaker springs are grouped on one side of the central tube **30** while the stronger springs are grouped on the opposite side of the device. This compares to a human heart and approximates the requirements for simulating the natural functions of the heart. As is well known, the pressures realized in the left ventricle of a natural heart exceeds by several times the pressures realized in the right ventricle (See Cardiac Diagnosis, Noble O. Fowler, M.D., published by Hoeber Medical Division of Harper and Row Inc., copyright 1968, at page 16)

The difference in the tension of the two sides of the artificial heart also insures a necessary pressure differential between the two halves of the heart when it is in operation.

Besides tension variations in the lower portion of the structural members **11**, the upper structural members of both sides are about one-tenth as strong as the lower structural members. This also approximates the relationship between the atriums of the heart and the respective ventricles of the heart. The upper sections operate the receiving chamber while the lower sections operate as blood distribution chambers as will be more fully described in FIGS. 9*a* through 9*h*. Internal structuring of the compartments of the heart are shown more fully in FIG. 4.

The flexible structural members **11** are surrounded by layers comprising the outer covEr **20**. Outer layer **20** is preferably comprised of fiberous elastic substance which is laminated to form a three layer laminate. Many types of material are suitable for application as "muscle" material, the major requirement being the elasticity and response of the material. The material must also be inert and possess properties approximately equivalent to a natural heart. A material such as crepe latex possesses many of these properties.

The laminated layers are the equivalent of natural heart muscles and achieve similar functions. One layer **17** has fibers running longitudinal to the heart **10**, one layer **18** has fibers running obliquely to the heart **10**, and one layer **19** has fibers running transversely to the heart **10**. It is substantially a matter of choice in what order the transverse, longitudinal and oblique layers occur in relationship to the outer layer. They form a laminated layer and perform as an integrated sheet of material. Thus calling layer **17** the longitudinal layer is merely for convenience and layer **17** might well be either the transverse or oblique layer.

The structural members **11** are fully enclosed in the outer layer comprised by layers **17**, **18** and **19**. The structural members could occur between layers **19** and **18** or between layers **17** and **18** with little matter being dependent on the particular position selected. The structural members **11** could merely be attached to the innermost surface of outer layer **20** without even being embedded in layer **20** if so desired.

A final layer **21** completely encloses the entire artificial heart and is laminated or otherwise bonded to the outermost "muscle" fiber layer **19**. Layer **21** is not required if layer **19** provides adequate covering for the heart as well as serving as a fibrous "muscle" layer.

An inner layer **15**, also made of fibrous elastic substance exists interior to the structural members **11** and outer layer **20**. The inner layer **15** is separated from the laminated outer layer and a cavity **22** exists between these layers **15** and **20**. The cavity **22** will increase and decrease during normal operation of the heart as will be more fully described later.

Connection means **16** exists between the inner layer **15** and the outer laminated layer **20** so that on expansion of the heart proper relationship is maintained between these two layers. The connection means **16** is preferably a thin ribbon or string of inert material interwoven between the inner and outer layers. This material must be inert and should occupy small volume compared to the total volume of the cavity **22**. This insures that little resistance to a flow stream will occur and that flow will be rapid with good circulation throughout the cavity during operation of the heart.

FIG. 2 shows one embodiment of the longitudinal, oblique and transverse layers as comprise that portion of the outer layer of the artificial heart which simulates the muscle functions of the natural heart. Longitudinal layer **17**, oblique layer **18**, and transverse layer **19** are laminated to form a single structural member that contains the structural member strips **11** as discussed in FIG. 1. The order of the longitudinal, oblique and transverse layers is immaterial so long as the resulting laminated layer approximates the muscle action of the heart.

The particular embodiment of FIG. 2 shows each layer being comprised of many strips of elastic material wound around the heart. This is somewhat different in construction from the single layer per orientation representation of FIG. 1. In operation, however, both composite layers perform in the same manner. The composite outer layer will continue to be represented as in FIG. 1 because of the simplicity achieved in making cross-sections of the outer layer.

FIG. 3 is a cross-sectional view of the inner wall **15** and the outer wall **20** of the artificial heart of the instant invention. FIG. 3*a* shows the cross-section of the heart wall when the heart is in an expanded condition with the cavity **22** expanded. FIG. 3*b* shows the walls with the heart in a contracted state. The operation concerning wall expansion and heart action is fully described in FIG. 9. The purpose of FIG. 3 at this juncture is to clearly illustrate all the components of the heart.

The layers depicted in FIGS. 3*a* and 3*b* are identical to the layers described for FIG. 1. The outer wall **20** is comprised of outer layer **21**, laminated "muscle" layers **17**, **18**, and **19**, wall restraining material **16** and inner layer **15**. Structural members **11** are shown embedded between laminate layers **18** and **19**. As has been noted the structural members **11** could just as well be between laminate layers **17** and **18** or fully enclosed in either one of the other layers.

The cavity **22** is greatly compressed when the heart is in the relaxed condition of FIG. 3*b* and greatly expanded in FIG. 3*a* where the contiguous heart chamber is expanded. The cross-sectional representation of FIG. 3*a* and 3*b* is identical for all

wall areas of the artificial heart except where the union of the inner and outer wall occurs. Each chamber of the heart functions in a similar manner and is comprised of the same layers of material.

FIGS. 4*a* and 4*b* show the internal wall structure that divides the artificial heart into four chambers. The internal wall structure is integral with and attached to the inner wall structure **15** described in FIGS. **1** and **3**. Suitable valve means exists between each chamber and will be more fully discussed in FIGS. 7, 8*a* and 8*b*.

FIG. 4*a* shows the inner chamber walls when the chambers are expanded while 4*b* shows the inner chamber walls when the heart is relaxed. Note how walls **42** and **44** flex to tolerate the expansion and contraction of the heart. Walls **42** and **44** are more concave in the relaxed condition than in the expanded condition.

The chamber wall structures surround central support tube **30** and are attached to the support tube **30**. Chamber walls **41**, **42**, **43**, and **44** respectively divide the heart into four chambers, two atrium and two ventricle chambers by junctioning with the inner surface of the inner wall **15**. Structural support strips **45** and 45*b* are embedded in the material that serves to make up the chamber walls. Structural strips 45*a* and 45*b* may be made of any suitable material that will generally maintain structure rigidity along the major axis of the structural member.

Structural strips 45*a* that exist in chamber walls **41** and **43** are strong enough to prevent deformation to any significant degree of these chamber walls. The structural strips that are in chamber walls **42** and **44** are not as rigid as the structural strips **41** and **43**.

The structural support strips 45*a* and 45*b* may be made of metal, plastic, or other suitable material. The wall material comprising the chamber walls might be made of a material similar to the cross-laced laminate comprising the outer wall **20** of the heart. Of course such material must be medicinally sterile, must not interact with blood, must be somewhat elastic, and must be able to be joined with the inner wall to form a tight seal.

Although the FIG. 4*a* and 4*b* show two structural support members in each of the horizontal and lateral chamber walls, the number of structural support members for any given design is a matter of discretion. It is important, however, that the structural support members **45**a in the longitudinal walls provide rigidity to those walls since, as discussed earlier, there is a five to one pressure differential between the two sides of the heart. Such a pressure differential is the same differential that is encountered in a natural heart. The longitudinal support members 45*a* are placed in the manner indicated so as to offer no resistance to the expansion and contraction strokes of a heart while providing longitudinal stability.

The structural support members 45*b* in the lateral walls are preshaped so that they cause the lateral walls to be slightly depressed into the ventricles. As can be seen in FIG. 4*b* the the lateral walls **42** and **44** are deeply depressed into the ventricles in the fully compressed condition.

The lateral wall structural members 45*b* offer resistance to the expansion of the heart chambers and must be carefully designed to approximate the actual resistance encountered in a natural heart. In consideration for overall design of strength members comprising the artificial heart a force balance must be achieved between the lateral chamber members **42** and **44**, the outer layer **20**, and the structural support members **11**. In actual design the total strength of the structural support members **11** (see FIGS. **1** and **2**) in conjunction with the outer wall structure **20** must be very carefully balanced mechanically against the prime mover means. As will be more fully discussed later, fluid is caused to flow in the cavity **22** (shown in FIGS. 3*a* and 3*b*) between the inner layer **15** and the outer layer **20**. As hydraulic fluid flows in cavity **22** force differential is established that causes the structural support members **11** and the heart walls to become more concave. The increased concavity causes expansion of the heart chambers. Minimum power is expanded in causing this expansion stroke if the forced balance between the combined outer layer **20** and the structural support members **11** and the lateral structural members 45*b* is such that the effort required to move one against the other is small. Under such a design condition the prime mover output need be sufficient to merely exceed the force difference to expand the unit.

Each inner chamber of the artificial heart has a corresponding cavity outside it. The cavity defined between the inner and outer layers of the heart is partitioned to correspond to the inner chambers. No communication of hydraulic fluid is permitted between the respective cavities.

To keep some sort of consistency in discussing the various cavities and chambers of the artificial heart, chamber refers to a volume normally containing blood, i.e. an atrium or ventricle. Cavity is used to designate the spaces between the inner wall and the outer wall of the heart. The cavities contain the hydraulic fluid that actuates the heart chambers.

To summarize briefly then one embodiment of the artificial heart of the instant invention comprises a four chambered device. The four chambers approximate the right and left atriums and right and left ventricles of the natural heart. The primary structure comprises an inner layer and an outer layer wherein the inner and outer layers define a cavity between them. The outer layer comprises a laminate of plastic material that simulates the muscle structure of the natural heart as well as flat structural members that provide structural definition and support for the artificial heart. A hydraulic fluid, preferably other than blood, is caused to flow in the cavity between the inner and outer layers of the artificial heart. Blood is undesirable as a hydraulic fluid because of its poor resistance to damage under varying pressures and flows. This flow of fluid under pressure causes a change in volume of respective heart chambers. Releasing pressure of the hydraulic fluid between the cavities causes the cavity to contract and thereby forces the fluid from the cavity. The contraction stroke is a result of natural contraction of the outer "muscle" structure layer of the artificial heart. The blood pumped by the heart comes in contact only with the inner layer of the primary heart structure and the inner chamber walls. No blood comes in contact with the outer layer of the heart, with the flat structural members, or with the cavity defined between the inner and outer layers. Thus the chambers of the heart accommodate blood, while the hydraulic cavities accommodate only hydraulic fluid.

FIG. **5** represents the devices contained in the central tube **30** (see FIG. **1**) of the artificial heart. Sufficient preliminary structure has been discussed that consideration may now be given to pump requirements and actual pumping operation of the heart.

FIG. **5** is a schematic representation of components enclosed within central tube **30**. The components enclosed in central tube **30** provide control means, power supply, and hydraulic fluid for operation of the artificial heart.

Heart expansion pump **60** provides fluid under pressure to the various cavities defined by inner and outer layers of the artificial heart. Fluid under pressure is provided to the cavity outside each heart chamber. Four hydraulic fluid cavities exist between the inner and outer layers of the four chambered artificial heart, one around each of the four inner chambers. Hydraulic fluid paths **80**, **81**, **82**, and **83** lead respectively to the left and right atrium and left and right ventricle of the artificial heart.

Blood chemistry sensor system **100** receives inputs from blood returning from general body circulation and blood returning from circulation around the lungs. Preselected parameters of blood are sampled at the sensor sample points and computer interrogated to determine proper heart rate based on sensed values of the parameters. The output from the blood chemistry sensor system **100** is fed to drive control **95**. Drive control **95** provides a driving positional command to rotary valve **90**. Rotary valve **90** ports working fluid under pressure from hydraulic power supply **96** to opposite sides of a

double action piston in heart expansion pump **60**. The details concerning the heart expansion pump are described more fully with reference to FIG. **6**.

Drive control **95** provides the positional control for rotary valve **90**, the commands of which set the heart rate of the artificial heart. The logic connected to drive control **95** is contained in blood chemistry sensor system **100** as shown in FIG. **12**.

Drive control **95**, in one preferred embodiment, is merely a flip-flop circuit whose change in electrical sense causes a change in the position of rotary valve **90**. In such an arrangement, rotary valve **90** would be responsive to electrical signals.

A mechanical actuation of rotary valve **90** could also be provided by drive control **95**. A mechanical linkage between drive control **95** and rotary valve **90** could be positionally controlled by electrical signals from blood chemistry sensor system **100**. The linkage could comprise a link pivoted to the periphery of a variable speed, continuously rotating disc in drive control **95**. The other end of the link could be pivoted to a pin on rotary valve **90**. The design of the linkage could convert the full rotational motion of drive control **95** to 90° arc motion of a familiar and standard rotary valve **90**.

Naturally many embodiments of drive controls exist and the above discussions of one embodiment of electrical and one embodiment of mechanical controls are merely illustrative of two.

Hydraulic power supply **96** provides working fluid under pressures to the heart expansion pump **60**. Hydraulic lines **91** and **92** lead to rotary valve **90**. From rotary valve **90** hydraulic fluid under pressure travels via path **78** or **79** to the heart expansion pump. When either of paths **78** or **79** is porting hydraulic fluid under pressure, the other path is porting return fluid from the heart expansion pump **60**.

FIG. **6** is a cross-sectional view of the detail of one embodiment of the heart expansion pump **60**.

The heart expansion pump **60** is contained in the center support means **30** of the artificial heart. Casing **61** contains a power piston that is slidably mounted interior to the casing **61**. Structural member **62** divides the heart expansion pump into two distinct and fluid isolated sections **63** and **64**. The power piston is of the double acting variety and has two piston flanges **66** and **67** mounted to a central shaft **65**.

The shaft **65** of power piston passes through the structural member **62**. Sliding contact is maintained between the shaft **65** and structural **62**. Sliding contacts is also maintained between the piston surfaces **66** and **67** and the inner surfaces of casing **61**.

The upper chamber **63** of heart expansion pump **60** contains **74** and **75** for hydraulic fluid entry and exit to either side of the piston **66**.

Hydraulic fluid under pressure is delivered by hydraulic power supply **96** (see FIG. **5**) by lines **91** and **92** to rotary control valve **90**. The labeling of line **91** as "from hydraulic power supply" is for convenience because either of **91** or **92** could serve as a source or return line. The positioning of rotary control valve **90** will deliver hydraulic fluid under pressure to either side of power piston flange **66** in hydraulic cavity **63**. Proper positioning of rotary control valve **90** is provided by drive control **95**. Thus as hydraulic fluid under pressure is ported through orifice **74** to the upper side of power piston flange **66** the piston is caused to move down and hydraulic fluid is vented through orifice **75**, The porting of hydraulic fluid under pressure through orifice **75** to the underside of piston flange **66** causes the piston to rise in cavity **63**. Venting of hydraulic fluid would then occur through orifice **74**.

The lower cavity **64** of heart expansion pump **60** is the fluid cavity that contains fluid for heart actuation. The response of piston flange **67** is naturally a function of the positional relationship of piston flange **66**.

Check valve **68** in piston flange **67** allows heart actuation fluid to port through the check valve when the piston is returning to a position adjacent structure **62**. Fluid entry and exit ports **70**, **71**, **72**, and **73** provide for passage of fluid from cavity **64** to the respective heart chambers and return therefrom.

In operation descent of power piston flange **66** forces the lower piston flange **67** to descend. Hydraulic fluid is forced through orifices **70**, **71**, **72** and **73** to the appropriate heart cavities. The amount of fluid that flows to each cavity is a function of the positional relationship of the orifices **70**, **71**, **72**, and **73** along the casing **61** and the resistance of the respective walls of the heart to deformation. Fluid will naturally start to flow earliest into chamber cavities that offer the least resistance to deformation and therefore to flow to the fluid. Thus the balance previously discussed between the strength of the flat structural members **11** (see FIG. **1**) and the inner **15** and outer layer **21** of the artificial heart is once more apparent.

As piston flange **67** descends in cavity **64**, fluid is ported first through cavity **70** to the right atrium of the artificial heart. Lower volumes of flow also starts in each of the other chambers through ports **71**, **72**, and **73** but flow through them is quite slight, again because of structural design. As the piston flange **67** passes orifice **70** sufficient fluid has ported through left orifice **70** to fill the cavity around the right atrium and causes the right atrium chamber to fully expand. As piston flange **67** further descends, fluid is allowed to return behind piston **67** from orifice **70** while fluid continues to flow through orifices **71**, **72**, and **73**. The cavity around the left atrium of the artificial heart is filled with hydraulic fluid as piston flange **67** approaches orifice **71**. Similarly as piston flange **67** continues to descend towards the bottom of cavity **64** the cavity around the right ventricle is filled through orifice **72** and finally the cavity around the left ventricle is filled through orifice **73**. The sequencing of filling and draining the heart chambers will be more fully described in discussions concerning FIG. **9**.

The porting of hydraulic fluid under pressure to the bottom surface of piston flange **66** in the chamber **63** caused both piston flange **66** and piston flange **67** to return to the top of their respective chambers. Check valve **68** allows the passage of hydraulic fluid through piston flange **67** with minimum resistance so that expansion of heart chambers does not occur during the return stroke.

FIG. **7** shows one form of valve that would be appropriate for porting bLood from an atrium chamber to a ventricle chamber in the artificial heart. Lateral chamber wall **44** is severed to form flap **120**. The size of flap **120**, and thus the opening through lateral chamber wall **44**, is a function of heart volume blood flow requirements based on pressure differentials between the atrium and the ventricle. Naturally the size of the passageway when flap **120** is open could not be large enough to cause substantial strength loss to lateral chamber wall **44**.

A hinge reinforcing member **123** is implanted in lateral chamber wall **44** at a point where flap **120** will hinge to lateral chamber wall **44**. The strength member **123** will allow for proper flexing of flap **120**.

Sealing surface exists between flap **120** and the lateral chamber wall **44** at faces **121** and **122**. The design of flap **120** will be such that when no pressure differential exists across lateral chamber wall **44** positive sealing of flap **120** will occur. Of course, no blood flow from the atrium to the ventricle will occur when flap **120** is shut.

FIG. **8***a* describes a valve that is appropriate for allowing one way flow of blood into the circulatory system and from a ventricle of the artificial heart. Tubular channel **130** is fixedly attached to outer layer **20** of the artificial heart. Mounted to the inner surface of channel **130** are flaps **131** and **132**. Flaps **131** and **132** are flexibly mounted to channel **130** such that as a pressure differential exists across the length of flaps **131** and **132**, the flaps open and allow fluid to pass. Once the pressure differential along the lengths of **131** and **132** subsides, flaps **131** and **132** close shutting off all flow.

FIG. **8***b* is a cross-sectional view of the valve of **8***a* in an open position. The dashed lines superimpose position of the flap **131** and **132** when closed.

The valves described in FIGS. **7**, **8***a*, and **8***b* are merely representative of possible valves for the described application.

Of course there are many types of valves and many new designs of heart valves that would serve as well as those indicated in FIGS. 7, 8*a* and 8*b*.

FIG. 9 shows the sequential operation of a four chamber artificial heart of the instant invention through a complete cycle of operation.

In FIG. 9*a* all chambers of the heart are devoid of blood. The cavities defined by the inner and outer layers are also devoid of any hydraulic fluid. Piston 67 is also at top position and ready to commence a downward stroke. The hydraulic chamber 64 contains the hydraulic fluid for actuation of the heart chambers. Chamber 64 is shown as occupying the entire lower half of central support 30 for clarity and convenience only. The actual fluid chamber may actually be much smaller.

As piston 67 starts to descend, hydraulic fluid flows through tube 80 to cavity 26 between the inner and outer layers of the right atrium. Slight amounts of hydraulic fluid also start to flow in each of the other chamber cavities 27, 28, and 29. As the hydraulic fluid enters cavity 26 the right atrium expands causing an intake of blood through valve 145.

In FIG. 9*b* the piston 67 has descended further and the right atrium is approximately half full of blood due to expansion. The piston 67 has not yet cut off hydraulic flow up to cavity 26.

Referring now to FIG. 9c, when piston 67 passes orifice 70 the flow of hydraulic fluid to the right atrium cavity 26 is secured and flow to the cavity 27 of the left atrium has caused the left atrium to fill to approximately one-half full of blood. The flow of fluid through orifice 71 into the cavity 27 of the left atrium causes the left atrium to expand and an intake of blood into the left atrium through valve 146.

It can be seen that in FIG. 9d as piston 67 continues towards the bottom of the heart expansion pump chamber 64, flow is cut off to the left atrium cavity 27 and flow increases to the right ventricle cavity 28. As piston 67 fully passes orifice 70, hydraulic fluid under pressure from the natural contraction of the outer layer 20 of the right ventricle starts to return through orifice 70 behind piston 67. This return of the hydraulic fluid and the natural compression of the right atrium forces blood from the right atrium to the right ventricle through valve 141. The flow of blood from the right atrium to the right ventricle is, of course, assisted by the expansion of the left ventricle under action of hydraulic fluid from orifice 72 flowing into cavity 28. The left atrium has continued to expand and fill with blood during this period. In FIG. 9d the right atrium and right ventricle are approximately one-half full while the left ventricle is full.

Flow to the right ventricle is stopped when continued descent of piston 67 cuts off orifice 72 as shown by FIG. 9*e*. By the time this occurs, the right atrium has fully relaxed and emptied the blood of the right atrium to the right ventricle through valve 141. The expansion of the left ventricle is also approximately one-half completed at this point and blood is flowing from the left atrium to the left ventricle through valve 142. The flow of blood from the left atrium to the left ventricle is under the influence of two factors, the natural compression of the left atrium and the expansion of the left ventricle.

In FIG. 9*f* when the piston 67 is at the bottom of the stroke all fluid has been discharged into the respective cavities 26, 27, 28 and 29. The right ventricle is emptying its hydraulic fluid behind piston 67 and blood from the right ventricle is flowing through valve 143 under natural action of compression of the right ventricle. The left ventricle is full of blood as well as the left ventricle cavity 29 being full of hydraulic fluid.

Actuation of a rotary valve 90 (see FIG. 6) causes hydraulic fluid pressure to flow on the lower side of piston flange 66 causing piston 67 to rise in the casing of heart expansion pump 60. The check valve in piston 67 allows for passage of the hydraulic fluid through the piston as it returns to the top of the chamber. Referring to FIG. 9*g*, as the piston 67 returns to the top of the hydraulic chamber 64, the left ventricle compresses under natural contraction of outer layer 20 forcing blood to flow from the left ventricle to the body through valve 144.

In FIG. 9*h* the heart is in its normal condition with all chambers and cavities devoid of fluid preparatory to starting a new artificial heart cycle.

It is to be clearly understood that FIGS. 9*a* through 9*h* are schematic only and do not represent proportional area and volumes between the heart chambers and cavities. Further, no attempt has been made to scale the relationship of a full chamber to an empty chamber in the artificial heart.

FIG. 10 shows an artificial heart of the present invention that has two chambers rather than four. A two chambered heart of the present invention is completely feasible and operable with the same efficiencies as a four chambered heart. The difference between the two chambered heart and the four chambered heart is that the pressure and flow outputs produced by a two chambered heart substantially varies from that of a natural heart. However, the two chambered heart fully performs and meets the physiological requirements of a human. The four chambered heart, of course, is designed to produce output characteristics identical to a natural heart.

The two chambered heart 200 has an outer layer 220 that is substantially identical to the outer layer of the four chambered heart previously described (see FIGS. 1, 2, and 3). The outer layer has an outer covering 206. Elastic material layers in the longitudinal, transverse and oblique directions comprise layers 203, 204, and 205 as described for the four chambered heart and as shown in FIG. 2. As was noted in the description of the outer layer for the four chambered heart the ordering of the laminated layers is generally not too critical.

Structural support members 208 are shown laminated between layers 205 and 204. The structural support member 208 does not have an articulated joint as was necessary for the structural support 11 of the four chambered heart. The structural support members 11 and 208 are otherwise similar in design and function.

Inner layer 202 is connected to the first material layer 203 of the outer layer by membranes 207. Membranes 207 insure that the relative position of the inner and outer layers is properly maintained during expansion and contraction of the cavity. The cavity defined by inner layer 202 and the inner surface of the first material layer 203 is for the passage of hydraulic fluid in much the same manner as was the passages for the four chambered heart.

The left and right chambers of the two chambered heart are identical except that strength differences might be incorporated into each chamber through design of the support members 208 and the inner and outer layers. That is to say, the volumetric output of the left chamber under proper pressure would be so as to approximate the volumetric output at the pressure of the left ventricle of a natural heart and the right chamber would approximate the output at the pressure of the right ventricle of a natural heart.

Valves 209 and 210 provide for one way blood flow input to the chambers of the artificial heart and valves 210 and 212 provide for one way blood flow out of the chambers of the artificial heart.

FIGS. 11*a* through 11*d* schematically represents a pumping cycle for a two chambered heart. The heart actuation fluid pump would be identical to the pump and system described in FIG. 5 and FIG. 6 for the four chambered heart except that few fluid ports and tubes are required.

In FIG. 11*a*, piston 225 (which is double acting as described in FIG. 6) is at the top of the stroke with both the cavities and the heart chambers devoid of fluids. As piston 225 descends central tube 201, hydraulic fluid is ported through tubes 226 and 227 to heart chamber cavities 240 and 243 respectively. The strength designs of the respective cavities once again provides for proper flow of fluid to the respective chambers. Referring to FIG. 11*b*, fluid flows substantially at first through line 226 to cavity 240 with slight flow through line 227. The flow of fluid through cavity 240 causes expansion of chamber 241 allowing blood to enter the chamber through valve 209. In FIG. 11c, there is shown the piston 225 passing line 226 and stopping the flow of hydraulic fluid to cavity 240. At that point

the chamber **241** is full of blood. When the chamber **241** is full of blood chamber **242** is approximately one-half full of blood due to partial expansion caused by hydraulic flow into cavity **243** via line **227**.

As piston **225** continues to the bottom of central tube **201** as shown by FIG. **11**d, chamber **242** completely expands and fills with blood. As the piston **225** passes duct **226** hydraulic fluid commences to flow behind piston **225** as chamber **241** naturally contracts. During the natural contraction of chamber **241** blood is forced from chamber **241** through valve **212** to the body. As piston **225** is returned to the top of the stroke to commence another pumping cycle, natural contraction of the chamber **242** forces blood from chamber **242** through valve **211** to the body. The piston **225** is then in a position to commence another pumping stroke.

FIG. **12** shows the functional relationship of the components comprising the blood chemistry sensor system **100** previously shown in FIG. **5**. Sensor input converter **101** receives eight inputs from sensors located in the artificial heart. Adrenalin, acetyl colene, pH and temperature are sensed by sensors located in the chamber receiving blood from the body, i.e. the left atrium. Sensors located in the right atrium, i.e. the chamber receiving blood from the lungs senses 0_2, $p^{cv}{}_2$, and pH. The output pressure from the left ventricle is also sensed. There are, of course, many other parameters that may be sensed depending upon the physiological demands of a particular patient.

The sensor input converter electronically processes the sensed inputs to provide information that is useful by digital differential analyzer **102**.

Control of the entire artificial heart is accomplished by the miniturized digital differential analyzer **102**. The digital differential analyzer **102** is programmed to provide **70** equally timed signals per minute to drive control **95** under normal operating conditions.

Signals received by the digital differential amplifier **102** from the sensor input converter **101** are processed with preselected heart program signals **103**. The heart program is a tailored program that indicates proper heart rate based on the aggregate values of the sensed parameters. When any of the sensors indicate an out of tolerance condition the digital differential analyzer **102** performs a decision of adding to or substracting from the number of normal output pulses being fed to drive control **95**. By comparing the sensed input signals to a preselected heart program and thereby regulating the heart functions, the artificial heart can approach natural heart in operation.

There are at least two ways of varying the output of the artificial heart. One way, as illustrated by the drawings, is by varying the rate of heart operation, i.e., the "pulse rate" of the artificial heart. Increased blood demands would therefore result in an increased heart rate. An alternate means of changing the flow of blood from the artificial heart would be to vary the amount of blood per pump stroke of the heart expansion pump. This type of variation can be accomplished by changing the rate of flow of hydraulic fluid to and from the heart expansion pump. A quite complicated valving arrangement is required to accomplish a change in heart capacity where the pump stroke remains constant, however. The orifice size must be regulated to restrict when lower flow demands are made.

An advantage of an artificial heart of the instant design is that an artificial heart can be designed to fit the specific need of a particular patient. The tailoring of the heart can be accomplished by machining of the flexible support members that comprise the major structure of the heart. Further tailoring can be accomplished by suitably programming the preselected heart program for use by the digital differential analyzer. The machining of the heart springs can simulate strength and performance outputs of the individual's natural heart in a normal condition. Similarly, by knowing normal sensed parameters of the particular patient, response by the digital differential analyzer can be geared to those normal responses.

The entire heart pump system and blood chemistry sensor system, drive control means and hydraulic power supply can be miniturized to be enclosed in the central support tube **30** of the artificial heart (see FIGS. **1**, **5** and **6**). Small power supplies are also available that would allow the heart to be completely self-sufficient by having an internally implanted power supply for driving the hydraulic piston. Of course power supplies other than those implanted in the body could also be used such as the portable power packs now in use, and external belly plungers for exerting pressure on hydraulic fluids.

Power for the artificial heart may also be supplied by implantable devices that generate their own electric power. These devices could be remote from the heart but would be connected to it by insulated conductors.

There are also two methods currently known, where the artificial heart could generate sufficient power for its own operation. In one scheme, it is possible to employ a small portion of the oxygenated blood to supply the necessary power. In this scheme the oxygen is chemically extracted from the blood to create a gaseous vapor.

A second source of oxygen for use in driving a small turbine could be obtained by passing hydrogen peroxide through a cadmium-cobalt screen to free the oxygen from the peroxide. The oxygen could then be recovered without coming in contact with the patient.

The gaseous vapor is then used to drive a small generator that provides power to the miniturized circuits of the heart control system.

A second method could employ a fluid with a vapor point slightly below normal body temperature. By circulating the fluid through tubing around the outside of the heart vaporization of the fluid could be realized through the use of normal body heat. The released vapor could be conducted through a turbine wheel that drives a generator. The current from the generator could supply power to the miniturized circuits.

With the use of a non-blood fluid for providing the vapor the exhaust of the turbine could not be channeled back into the blood stream. The exhaust would have to be channeled through a cooling reservoir where it could be condensed back to its fluid state. The coating reservoir could, of course, be fully closed. The coolant itself could be some liquid such as kerosene where a slight temperature change creates a slight change of viscosity which sets up a convective cooling current in the liquid itself.

An alternate means of providing motion to the hydraulic prime mover fluid that flows to an from the cavities around the chamber walls of the artificial heart is the use of a free floating piston. The free floating piston, configured much like the double acting piston of FIG. **6**, is composed of highly magnetic material and is slidably mounted in a cylinder which is either wound to act as a solenoid body or built-in insulated sections to perform the function of a solenoid. Windings around the case to affect the solenoid function are double functioning such that a magnetic pull can be applied to cause motion of the piston in either direction.

Control of the length of piston stroke in a magnetic piston device is accomplished through variations in current and the length of time that current is applied. The application of current to the cylinder windings or body attracts the piston such that it progresses from one end of the cylinder to the other. Motion of the piston would port fluid much as illustrated by FIG. **6**

What is claimed is:

1. An artificial heart comprising a central support,

resiliently flexible flat structural members disposed around said central support, an inner layer of flexible elastic material supported between said flexible flat structural members and said central support, said inner layer forming a first cavity for said artificial heart, said cavity being divided into a plurality of heart chambers,

inlet and outlet valve means communicating with the chambers of said heart cavity,

outer layer of flexible elastic material encapsulating the flexible flat structural members, connecting means between said inner and outer layers,

a plurality of second cavities formed between said inner and outer layers for selectively receiving and discharging a pressure imparting fluid for flexing said flat structural members outwardly and inwardly whereby blood is enabled to flow through said artificial heart via said valve means and heart cavity in response to outward and inward flexing of said outer layer

2. The artificial heart according to claim 1 wherein said flexible flat structural members comprise leaf springs arranged circumferentially about said central support.

3. The artificial heart of claim 1 wherein said outer layer is composed of strips of flexible, elastic material cross-laced perpendicularly and obliquely to each other and bonded to form a laminate.

4. The artificial heart recited in claim 1 including a plurality of first cavity partitioning means forming said chambers inside said heart cavity, and

drive means for forcing fluid into a selected second cavity for applying pressure to said flexible flat structural members whereby aid chamber is expanded.

5. The artificial heart recited in claim 1 wherein said connecting means comprises a layer of material interconnecting said inner and outer layers of material for maintaining a spaced relationship between said inner and outer layers of material when fluid is received by said cavities between said inner and outer layers.

6. The artificial heart recited in claim 5 wherein said partition means form four chambers inside said first cavity and further comprising:

first valve means for permitting the flow of blood into two of said four chambers;

second valve means for permitting the flow of blood from said two of said four chambers into the remaining two of said four chambers, and

third valve means for permitting the flow of blood from said remaining two of said four chambers.

7. A device for simulating a natural heart comprising:

inner and outer flexible elastic coverings substantially closed on themselves, said coverings defining a cavity therebetween, connecting means between said inner and outer coverings;

at least two strips of resiliently flexible material attached to one of said coverings;

prime mover means for causing a fluid to flow into said cavity between said inner and outer covering;

partition means internal to and integral with said inner coverings, said partition means defining at least two cavities internal to said inner covering inlet and outlet valve means communicating with said internal cavities whereby blood can flow through said internal cavities; and

sensing and control means for driving said prime mover means in a manner substantially similar to the rate of a natural heart.

8. The device according to claim 7 and further comprising power system means, said power system providing driving power to said sensing and control means.

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