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(54) **IMPLANTABLE CARDIAC ASSIST DEVICE WITH A PHASED ELECTRODE ARRAY**

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(60) Provisional application No. 60/464,766, filed on Apr. 23, 2003.

**Publication Classification**

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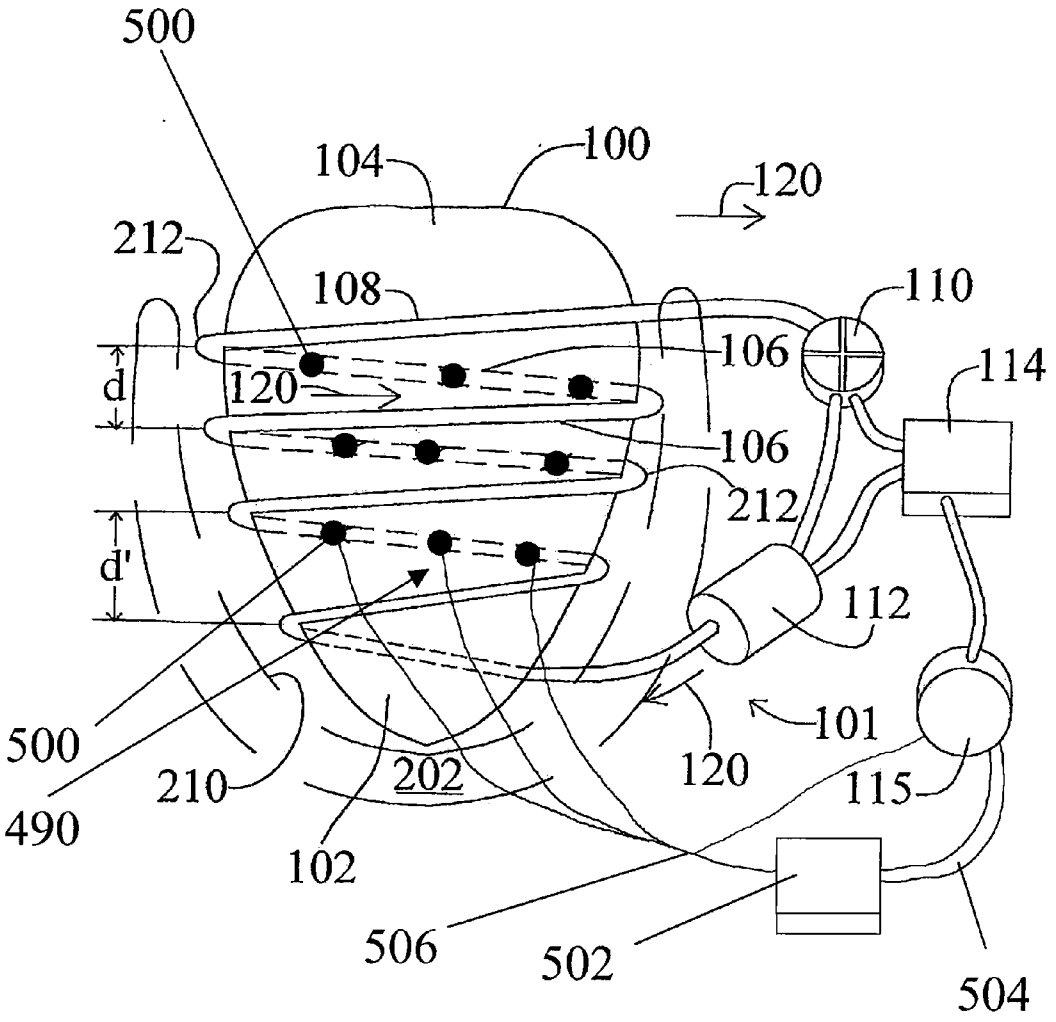
(52) **U.S. Cl.** ..... **600/16**

(57) **ABSTRACT**

The present invention provides a fully implantable cardiac massage apparatus having a phased electrode array. The cardiac massage apparatus of the invention can provide both "active" contraction of the heat, wherein the device electrically stimulates the heart to contract, or "passive" contraction of the heart, wherein the device squeezes the heart in a coordinated fashion so that the heart is massaged in a natural fashion from the apex to the base of the heart.



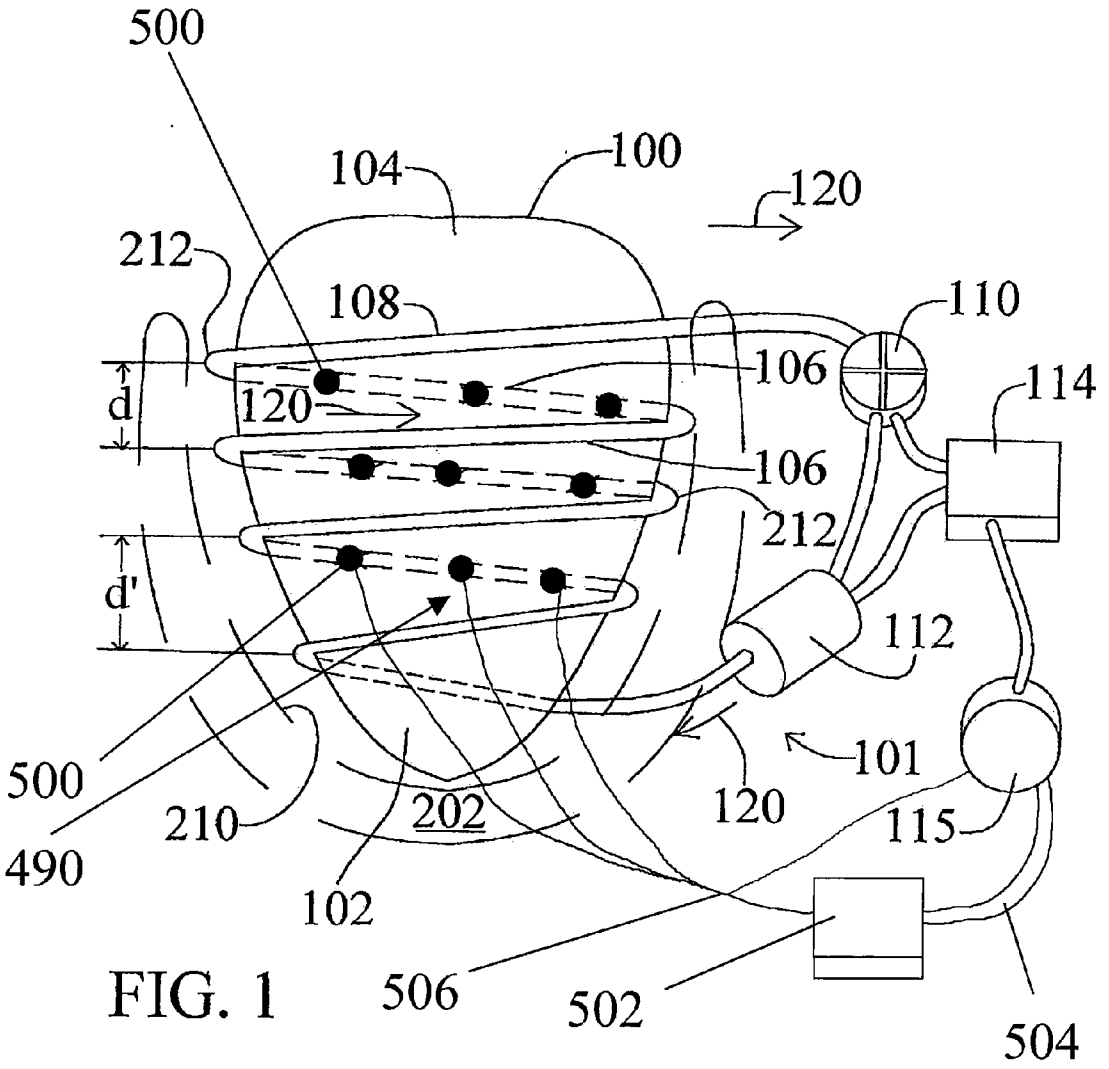

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FIG. 1

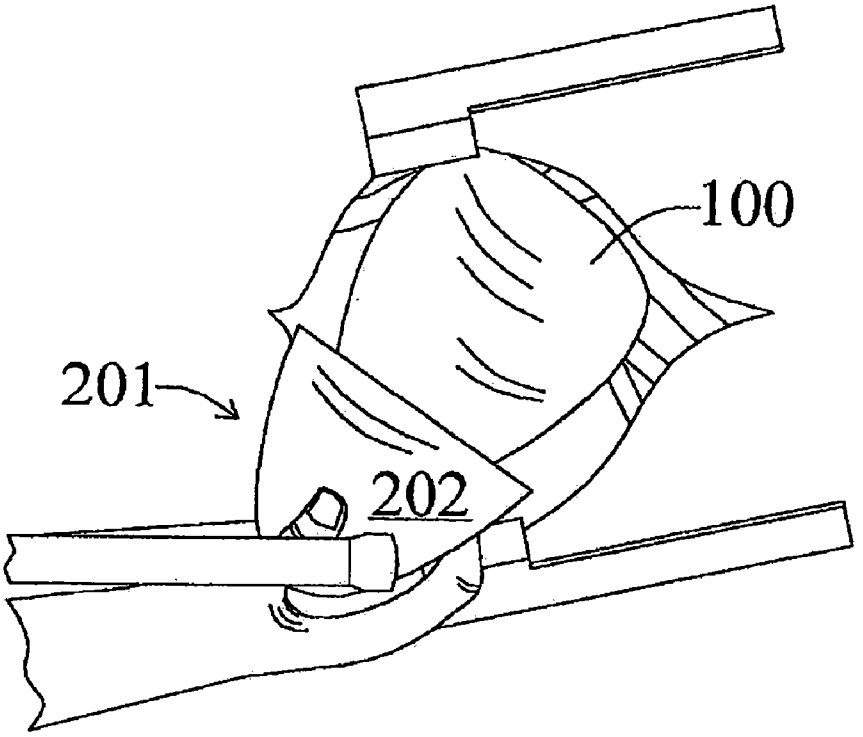



FIG. 2

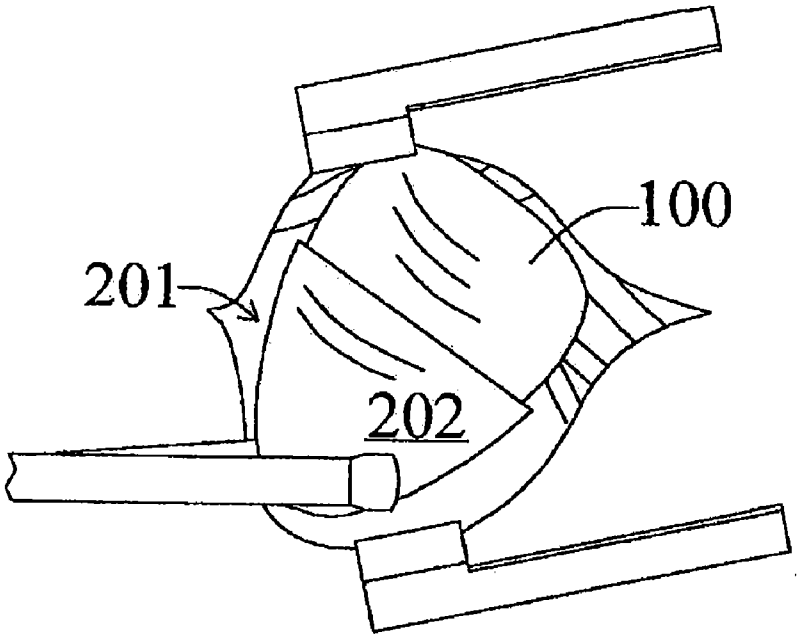



FIG. 3

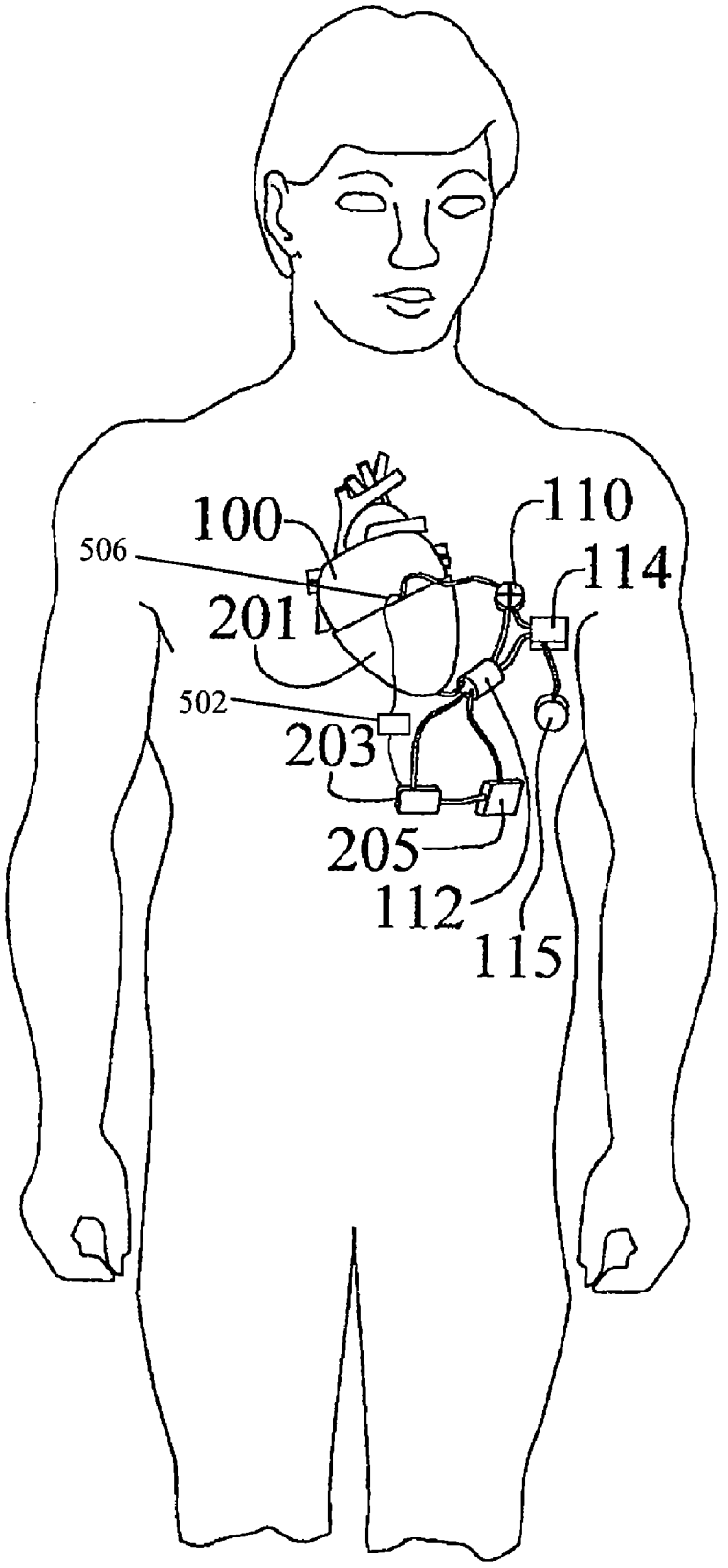
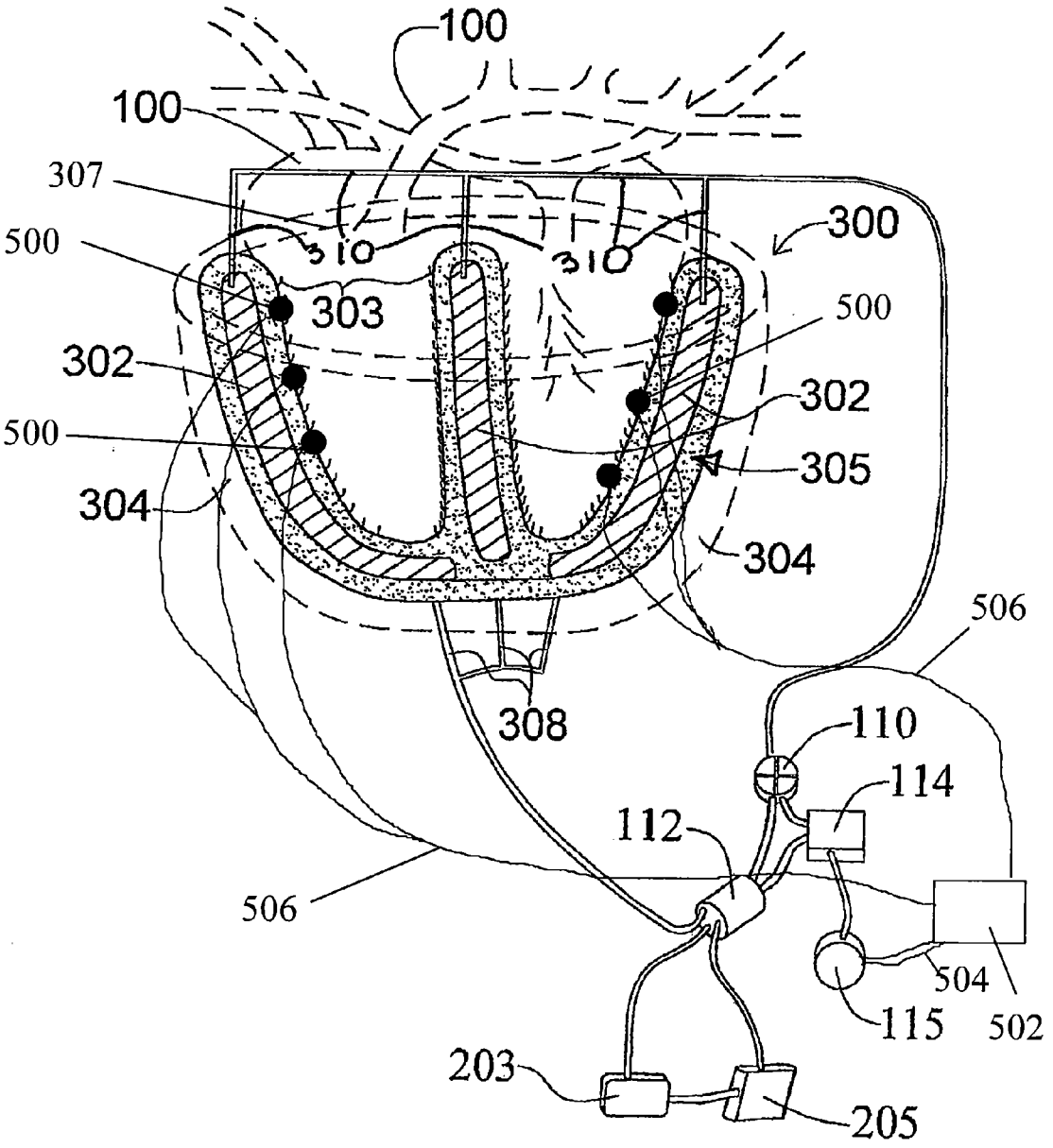



FIG. 4

FIG. 5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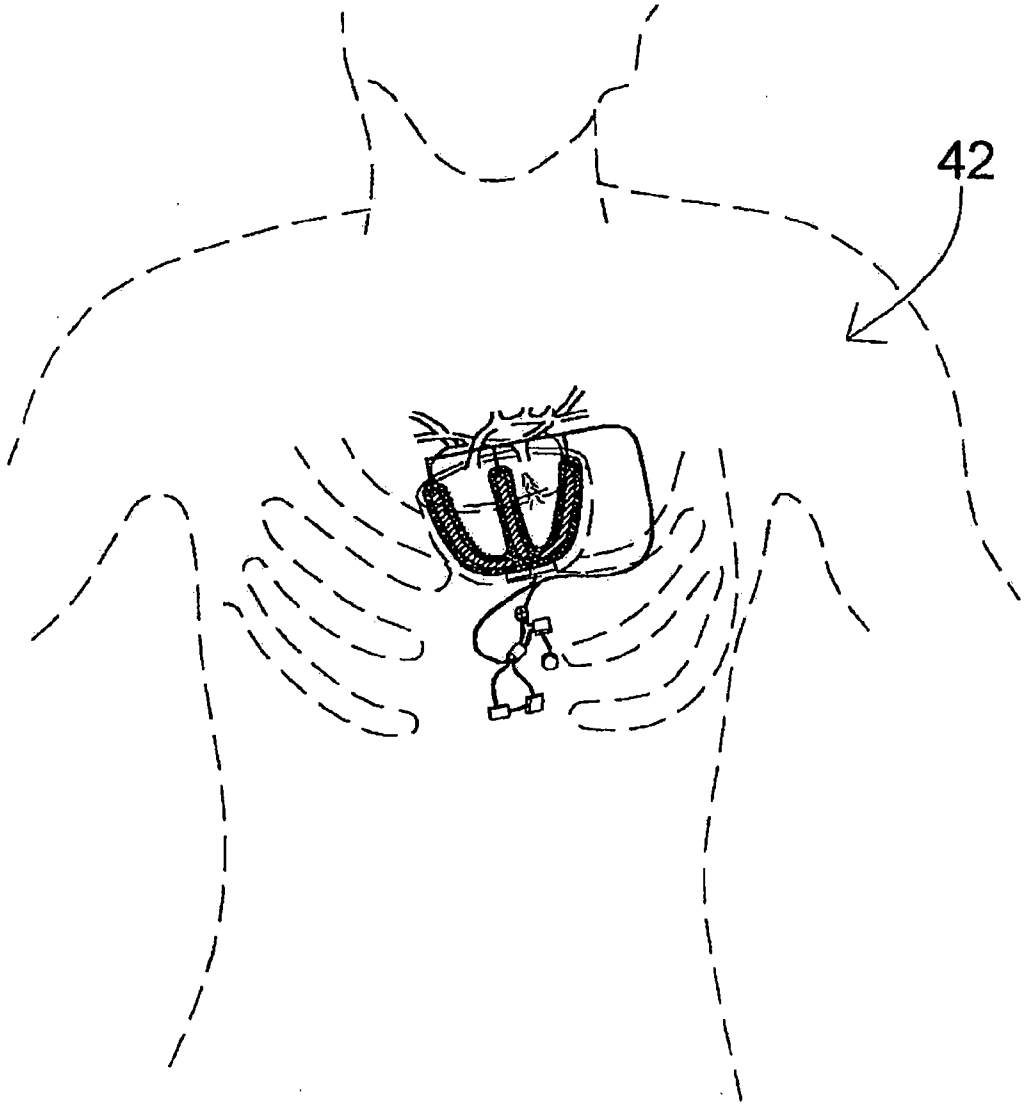


FIG. 6

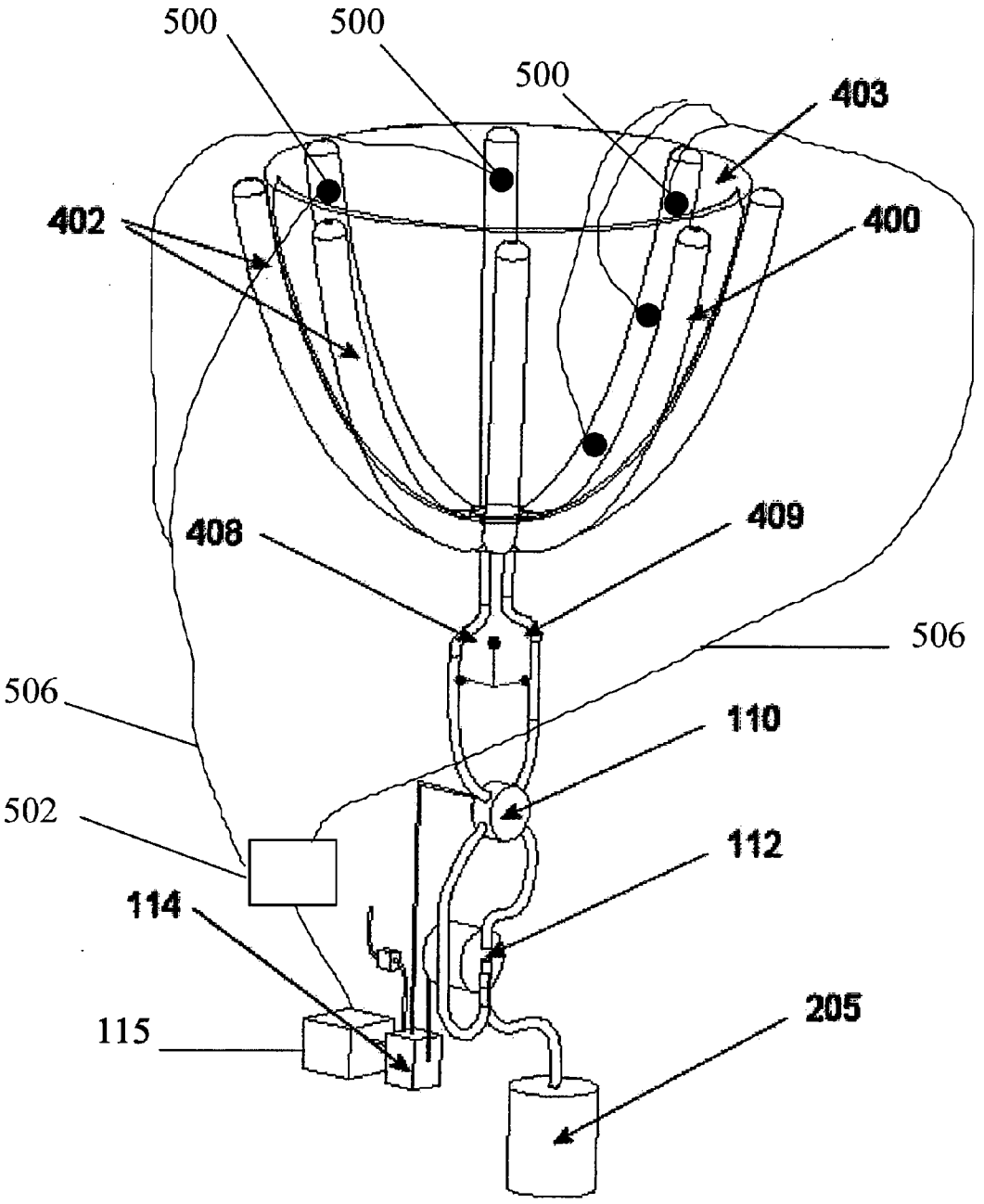


FIG. 7

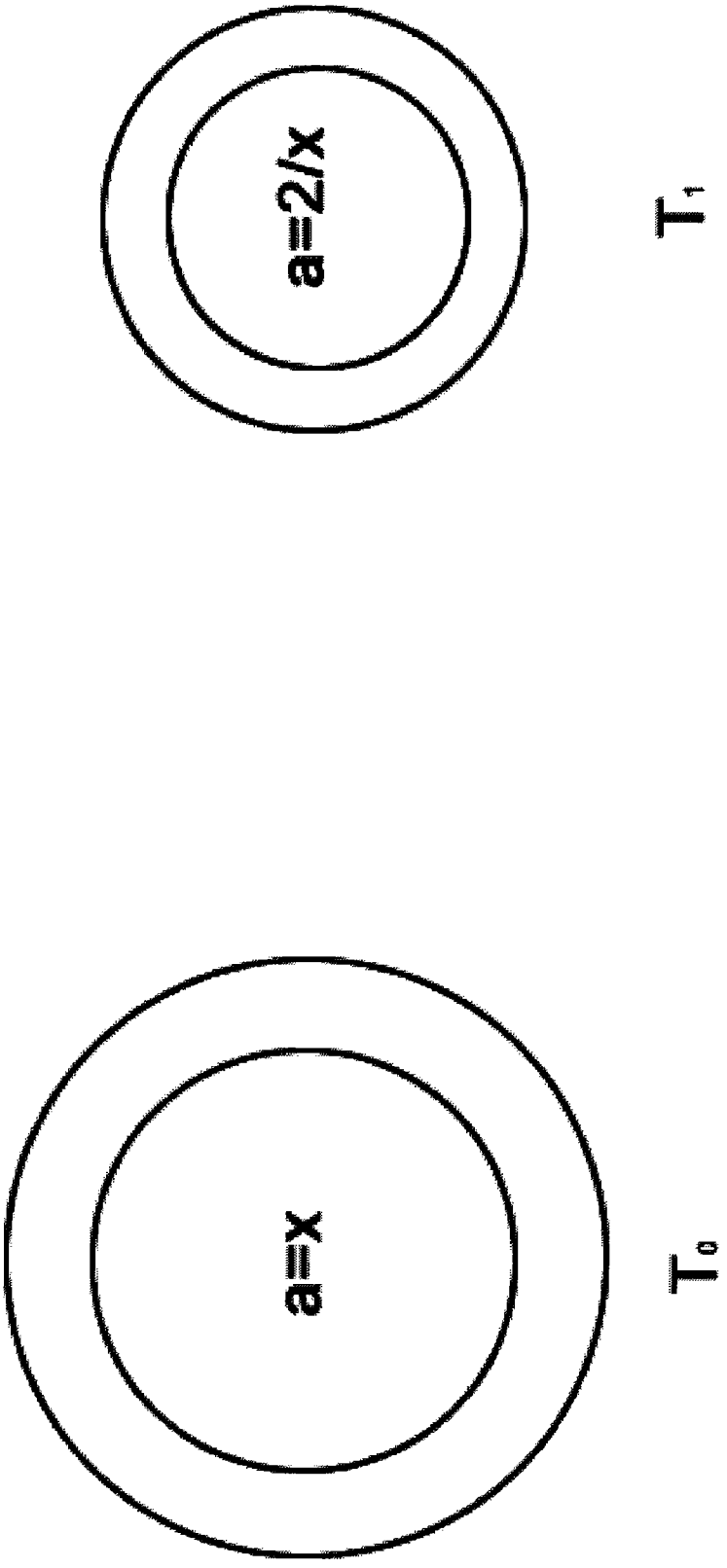


FIG. 8

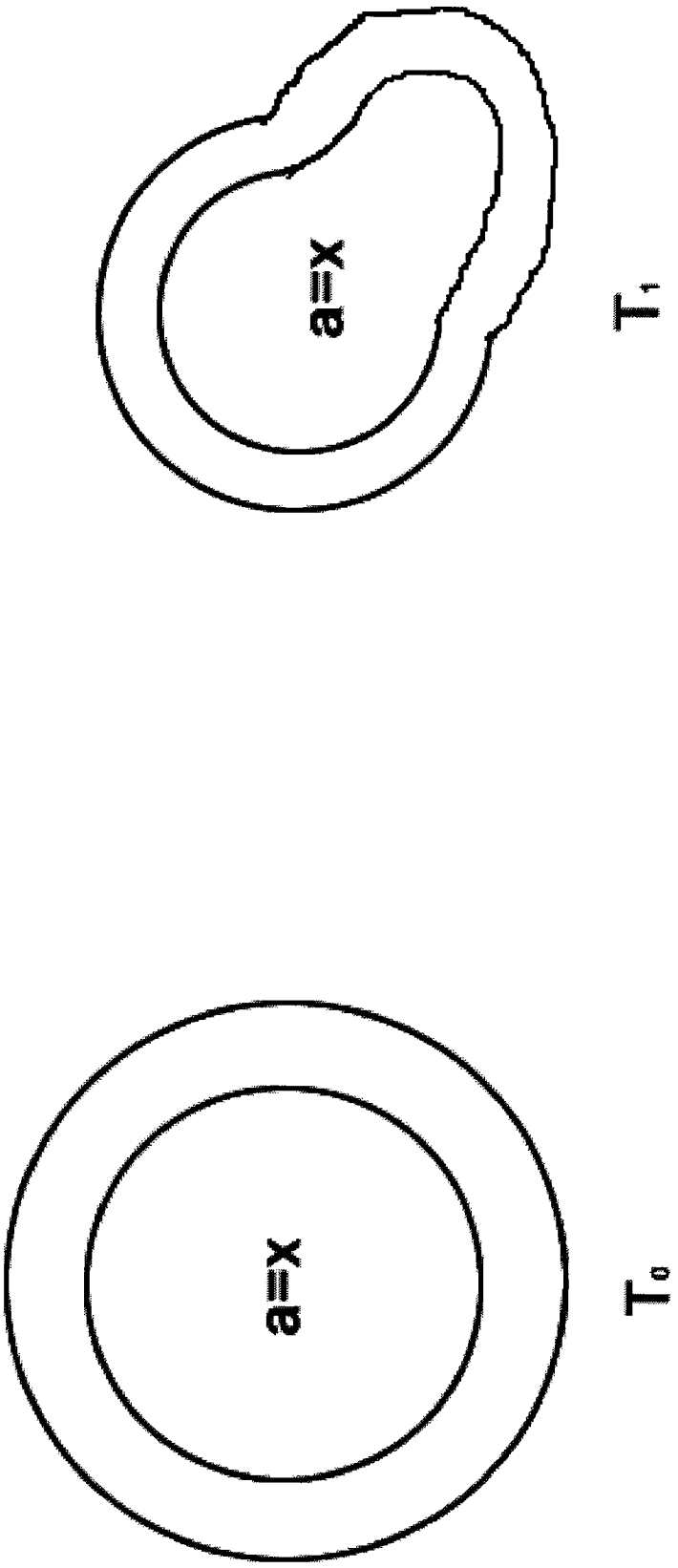


FIG. 9

# IMPLANTABLE CARDIAC ASSIST DEVICE WITH A PHASED ELECTRODE ARRAY

## CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part application of U.S. patent application Ser. No. 10/829,573 filed Apr. 22, 2004, which claims priority to U.S. Provisional Patent Application Ser. No. 60/464,766, filed Apr. 23, 2003, the applications being incorporated herein by reference, in their entirety.

## STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] None

## FIELD OF THE INVENTION

[0003] The present invention relates to therapeutic devices to work in conjunction with a diseased or failing heart to satisfy the hemodynamic needs of a patient. More particularly, the invention relates to a fully implantable device for assisting a heart to pump blood by intermittently applying pressure to at least a portion of the ventricular surface of the heart (if not the entire surface), preferably both the atrial and ventricular surfaces, at predetermined or possibly pre-programmed intervals to assist the heart to provide adequate hemodynamic output by sensing demand of the human body. In short, the present invention assists the maintenance of, or reestablishes, the normal contraction sequence of a healthy heart.

[0004] The present device is designed to restore to normal the electrical excitation pathways and mechanical contraction sequence of the failing heart. Where necessary, this restores the normal spread of electrical excitation pathways with a phased array electrical stimulation coupled with a phased array mechanical compression to restore the normal excitation/contraction sequence to a failing heart.

## BACKGROUND OF THE INVENTION

[0005] The human heart is a very complex organ that relies on both mechanical and electrical operation in order to perform properly. As with any complex mechanism, problems can and often do arise, with the heart. For example, areas of the ventricle may lose their normal excitation pathways causing some parts of the ventricle to not contract when they are supposed to, losing, thereby, the circular compression and allowing some areas to "bulge." This decreases efficiency. These areas of heart muscle are intrinsically contracting mechanically, but lack the correct electrical input. In addition, in some failing hearts the muscle of the heart no longer contracts the ventricles to a sufficient extent. Insufficient ventricular contraction can produce a dangerous reduction in the amount of blood flow.

[0006] Numerous attempts have been made to assist these diseased or failing hearts by applying external pressure directly to the heart. One such example is direct manual compression of the heart by a person's hand during open chest cardiopulmonary resuscitation. Often, however, the patient requires cardiac or circulatory support or assist for extended periods of time, such as hours, days, weeks, or for the rest of the patient's life. Thus, manual manipulation of the heart is not a solution to the problem in most cases.

[0007] Mechanical devices have been developed to apply external pressure directly to the heart. Some of these devices utilize an inflatable liner that surrounds the heart. For example, U.S. Pat. No. 5,119,804 Anstadt discloses a cup that is provided with an elastomeric liner. The heart is held in place within the liner, which is cyclically inflated and deflated to apply external pressure to the heart. While this device provides an improvement in hemodynamics for a diseased or failing heart, the device is not fully implantable. U.S. Pat. No. 5,131,905 Grooters and U.S. Pat. No. 6,238,334 Easterbrook, III et al. are further examples of external (as opposed to implantable) cardiac assist devices.

[0008] U.S. Pat. No. 6,464,655 Shahinpoor, at FIG. 6d and FIG. 7, illustrates an embodiment of the "Electrically-Controllable Multi-Fingered Resilient Heart Compression Device" disclosed therein. In the embodiment shown artificial muscles, specifically electro-active polymers, are used to create "soft fingers" that can be directly electrically powered and computer controlled by wires. See eg., U.S. Pat. No. 6,464,655 at column 8, lines 19-38,: The teachings of Shahinpoor are specifically incorporated by reference herein.

[0009] Another shortcoming inherent in the prior art devices results from the fact that relatively high pressures are applied almost exclusively to the central portion of the ventricles' outer surfaces. This causes the heart to deform into an unnatural, generally hourglass, shape and may even eventually cause trauma (e.g., bruises) to the heart, especially if one of the prior art devices is operated for an extended period of time.

## SUMMARY OF THE INVENTION

[0010] The present invention provides a fully implantable cardiac massage apparatus having a phased electrode array. The cardiac massage apparatus of the invention can provide both "active" contraction of the heat, wherein the device electrically stimulates the heart to contract, or "passive" contraction of the heart, wherein the device squeezes the heart in a coordinated fashion so that the heart is massaged in a natural fashion from the apex to the base of the heart.

[0011] The cardiac massage apparatus comprises a chamber array, the array comprising a series or locus of spaced-apart, fluidically coupled, chambers or helices. In one embodiment the array comprises helically-wound chambers, helices, or loops located closely adjacent or on the epicardium. The array further has fluid input and output ports. The chambers or helices collectively define an interior surface which closely conforms to the exterior surface of a heart when implanted. In another embodiment the array can be comprised of a series of spaced apart chambers that are vertically oriented with respect to the heart. In one embodiment the array fluid input port is located adjacent to the apex of the heart to be massaged and the fluid output port is located adjacent to the base of the heart to be massaged.

[0012] The cardiac massage apparatus also comprises a phased electrode array comprising a series of electrodes, the electrodes in contact with the heat and capable of providing electronic stimulation to the heart and capable of sensing cardiac output data of the heart. In one embodiment the electrodes are located in the interior surface of the chambers of the chamber array, in another embodiment they are separate from the chambers of the chamber array. The

electrodes of the phased electrode array can also be connected to a phased electrode array controller means. The phased electrode array controller means is an electronically-powered microprocessor and can be a separate component, or be integral to either the cardiac activity sensor/input means or a controller means for the chamber array. The phased electrode array controller means controls the electrical discharge of the electrodes so that a coordinated electrical stimulation of the heart can be obtained to restore the hearts normal contraction sequence bringing about a normalization of the active phase of contraction

[0013] The cardiac massage apparatus of the present invention can also include coupled valve means, pump means, the chamber controller means, and the cardiac activity sensor/input means. The valve means is fluidly or hydraulically coupled to the chamber array input port and output port and, in turn, is coupled to the pump means. The pump means and valve means are both electronically coupled to the chamber controller means. In one aspect, the chamber controller means is an electronically-powered microprocessor. The chamber controller means of the present invention is adapted to actuate the pump means and valve means so that fluid is pumped substantially continuously through the input port while intermittently cycling the discharge. In this manner the fluidly-coupled chambers or helices are inflated and deflated starting at the apex of the heart and continuing toward the base of the heart to create a rhythmic cardiac massage which substantially imitates the natural contraction sequence of the heart.

[0014] A cardiac massage apparatus of the present invention further includes a cardiac activity sensor/input means which monitors or senses cardiac output. The cardiac activity sensor/input means sends the cardiac output data to both the phased electrode array controller means and the chamber controller means. Depending on the cardiac output data, the phased electrode array controller means and the chamber controller means can determine, based on preprogrammed parameters for cardiac output data, whether the cardiac massage apparatus needs to trigger either an "active" contraction of the heart by signaling the activation of the phased electrode array, or a "passive" contraction of the heart by having the chamber array contracting in a controlled fashion around the heart.

[0015] In a further embodiment, the massage apparatus can include a separately-implanted source of electrical energy such as, for example, a rechargeable battery and an optional fluid reservoir.

## BRIEF DESCRIPTION OF THE DRAWINGS

[0016] Some of the features and advantages of the invention having briefly been stated, others will appear from the detailed description which follows, when taken in connection with the accompanying drawings in which:

[0017] FIG. **1** is a perspective view of one embodiment of an apparatus of the present invention.

[0018] FIG. **2** is a perspective view of a heart massage cup (or apparatus) of the present invention being inserted over a heart.

[0019] FIG. **3** is a perspective view of the heart massage apparatus of FIG. **2** in place on a heart.

[0020] FIG. **4** is a schematic view of the entire system implanted within the human body.

[0021] FIG. **5** is a schematic view in partial section, as a second embodiment of the present invention.

[0022] FIG. **6** shows the invention of FIG. **5** fully implanted within the human chest cavity.

[0023] FIG. **7** is a schematic view of another embodiment of the invention.

[0024] FIG. **8** is a cross-sectional representation of normally functioning heart before and after contraction.

[0025] FIG. **9** is a cross-sectional representation of an abnormally functioning heart before and after contraction.

[0026] Before the embodiments of the invention are explained in detail, it is to be understood that the invention is not limited in its application to the details of construction and the arrangements of the components set forth in the following description or illustrated in the drawings. The invention is capable of other embodiments and of being practiced or being carried out in various ways. Also, it is understood that the phraseology and terminology used herein are for the purpose of description and should not be regarded as limiting. The use of "including", "having" and "comprising" and variations thereof herein is meant to encompass the items listed thereafter and equivalents thereof as well as additional items and equivalents thereof.

## DETAILED DESCRIPTION OF THE INVENTION

[0027] The present invention provides a cardiac massage apparatus that provides assistance to a heart. The cardiac massage apparatus does not interfere with the normal contraction pattern or rhythm of the heart as long as the "normal" pattern provides sufficient cardiac output of blood (e.g., from about 1.5 to about 3 liters per minute) to sustain and support the activities in which the patient wishes to engage. As shown in FIG. **8**, when a heart is functioning normally, all areas of the heart contract at the same time. Before contraction (at a time $T_0$) the internal area (a=x) of the heart is larger by half than the internal area (a=2/x) of the heart during contraction (at a time $T_1$). However, when areas of a heart do not receive the proper electrical impulse to contract (as shown in FIG. **9**), when the properly functioning areas of the heart contract it causes the heart to bulge around the "malfunctioning" area. In this instance internal area (a=x) of the heart during contraction (at a time $T_1$) is approximately the same as the internal area of the heart (a=x) in an uncontracted state. Such a situation does not provide the necessary cardiac output of blood to the body. In such situations the present device provides cardiac assist by increasing blood flow by either mechanically contracting the heart or electronically stimulating it. Active contraction of the heart is done by causing the heart muscle itself to contract by electrically stimulating the heart by the use of a phased electrode array. This coordinated stimulation can be done to stimulate specific areas of the heart muscle that need to be stimulated, as determined by a sensing means, to provide the desired pumping action. The cardiac massage device can also "passively" contract the heart by mechanically or hydraulically contracting the heart by the contraction motion of a chambered array positioned around the heart. Such contraction is deemed "passive" as the heart is

in a passive state, in that it is not contracting on its own, but contacts when acted on by the pumping action of the device. This hydraulic compression is done from the apex or tip of the heart to its base (or top) without abnormal compression of generally the middle portion of the heart.

[0028] One embodiment of the present invention is shown in FIG. **1**. FIG. **1** shows an embodiment of an apparatus or cardiac assist device **101** of the present invention. A patient's heart **100** is shown schematically. Enveloping or enshrouding heart **100** from its apex **102** to its base **104** is a helically wound length of tubing or a bladder array **106**, the tubing segments on the back side of heart **100** being shown in dashed lines. Alternatively, the array **106** could comprise an arrangement, locus, or series of fluidically coupled chambers. The individual helices **108** of the tubing array **106** shown in FIG. **1** are separated by distances d and d': Distances d, d' are variable and can be adjusted by the physician (e.g., by selecting a device with wider or narrower "d" spacing) to create a more natural mimic of the heart's rhythmic contractions as is described below. Also shown in phantom in FIG. **1** is an optional heart-shaped, supporting cup or envelope **202**. The heart-shaped cup member **202** is constituted of a somewhat rigid, but flexible material. The material (preferably translucent) of cup-shaped member **202** should have adequate rigidity so that it does not collapse during diastolic actuation. Further, it should not expand radially to any great extent when pressurized fluid is introduced into chambers **108** in accordance with the method of the present invention. This cup shaped member **202** provides a supporting envelope for efficiently assisting the mechanical compression of the heart **100**. The cup **202** can apply substantially uniform fluid pressure against the exterior surface of at least a portion of the ventricular portion of the heart **100** during the systolic phase. The cup **202** is designed to not unduly deform the natural shape of the heart **100** during the mechanical or hydraulic compression of the heart **100**. As is shown in FIG. **1**, the inside surface **210** of cup **202**, in this embodiment, is in contact with the outer-most surface of chambers **108** so as to support them, to keep the segments or chambers separated from each other, and to direct inwardly (to compress heart **100**) any pulsatile or pump surge input thereto. The cup **202** can be installed in its operative position with minimal movement of the heart **100**. Suitably the cup **202** can be sutured or otherwise attached to the heart **100** so as to prevent device migration during use.

[0029] Also shown in FIG. **1** to be in fluid communication with chamber array **106** are a pressure regulator **110** and a pump **112**. The regulation of chamber pressure may be achieved by a relief valve coupled to the fluid circuit, a pressure regulator, or possibly, by "pump surge." Pressure regulator **110** and pump **112** are electrically coupled to a controller means or module **114**, e.g., a microprocessor. (Under circumstances where added complexity is permissible, a solenoid valve could be substituted for a pressure regulator **110**). Microprocessor **114** is programmed to receive input information as to the status and performance characteristics of heart **100** from a cardiac activity sensor/input means **115**. Assuming heart **100** is providing adequate cardiac output i.e., it is beating sufficiently frequently, with sufficient efficiency, the assist system shown in the FIG. **1** provides no stimulation or assistance to heart **100**. However when microprocessor **114** receives input that the cardiac output of heart **100** is inadequate for the patient's activity and matches certain preprogrammed parameters that call for "passive" constriction, the microprocessor **114** activates pump **112** and valve **110**.

[0030] Pump **112** causes a fluid, preferably an incompressible, low viscosity, biocompatible fluid such as saline to flow into the individual helices **108** starting at the heart's apex **102** and flowing toward its base **104**. (It is conceivable that compressed gas could be used to activate the helices or chambers according to this invention). This creates a wave form or wave front which travels from the apex toward the base which causes the heart (specifically the ventricles) to contract in rhythmic fashion. This contraction wave form tends to mimic normal cardiac depolarization but with enhanced or accelerated fluid blood flow from the ventricles. The speed of pump **112** (which preferably is either a kinetic or centrifugal pump, a peristaltic or positive displacement pump but may be of any type including axial turbine or a radial pump) is coordinated with pressure regulator **110** to create a sequence or series of wave forms or pulses of fluid in chambers **108** causing at least the ventricles (but preferably both the ventricles and the atria) to be rhythmically massaged or compressed. In this manner cardiac output is substantially enhanced with the assistance of this device. A device of this invention has the capability of assisting left and right ventricles (i.e., compressing or massaging) essentially simultaneously or sequentially.

[0031] The intensity of the compression step can be adjusted by adjusting pump speed and pressure regulator **110** timing. The intensity of the compression step can also be adjusted by the selection of stiffness and diameter of the bladder or tube elements used to create the array **106**. The number of chambers **108** wrapped around heart **100** and their separation distance (discussed above), also determines the intensity and extent of assist provided to the heart. One skilled in the art will appreciate that some amount of experimentation regarding bladder characteristics may be needed to optimize the natural pumping efficiency of the heart using a device of this invention.

[0032] The cardiac assist device also contains a phased electrode array **490** having a series of electrodes **500**. The electrodes **500** can be positioned on the interior (facing the heart) of the tubing array **106** as shown or can be placed adjacent the heart in other positions. The electrodes **500** are electronically connected to a phased electrode array controller means **502** by means of wires **506**. In one embodiment the electrodes can also be connected to a cardiac activity sensor/input means **115**. To aid in the clarity of the drawing the wires **506** to only a few of the electrodes **500** are shown, though all the electrodes have such wires. The phased electrode array controller means **502** is suitably a microprocessor and is programmed to receive input information as to the status and performance characteristics of heart **100**. The controller **502** can receive this information from feedback from the electrodes **500** themselves and/or from the cardiac activity sensor/input means **115** by way of the connection **504**. In another embodiment, the phased electrode controller means can be the same microprocessor (i.e. same part) used for the controller **114** for the tubing array, and can also be the same microprocessor as the sensing/input means. Assuming heart **100** is providing adequate cardiac output i.e., it is beating sufficiently frequently, with sufficient efficiency, the assist system shown in the FIG. **1** provides no stimulation or assistance to heart **100**.

However when phased electrode array controller means **502** receives input that the cardiac output of heart **100** is inadequate for the patient's activity and matches certain preprogrammed parameters that call for "active" contraction, the controller **502** electronically stimulates the appropriate electrodes **500** in the phased electrode array **490** to produce the desired contraction response, based on the cardiac output data received by the sensor/input means **115**.

[**0033**] It also is to be appreciated that the physiological factor (or factors) observed or monitored by sensor/input means **115** to provide input to control means **114** may include many (if not all) of the parameters normally observed appurtenant to electrical sensing and/or pacing of the heart. Thus general body activity, oxygen saturation, pulse, peak-to-peak T-wave separation and numerous other indicia of cardiac activity may be observed in order to trigger e.g., via the microprocessor **114**, the use of the present device. Appropriate input leads, whether internal or external to the heart, are selected depending upon the parameter(s) of cardiac activity selected to be observed or monitored. To some extent, the overall placement and configuration of the chamber array may be modified in view of the physiologic factor or factors chosen to be monitored.

[**0034**] It is possible that the sensor/input means **115** can have sensors separate from the electrodes **500** that measure cardiac output i.e., blood flow or blood volume, directly. Various sensors e.g., cardiac sensing/pacing leads, which measure cardiac output directly or indirectly, are available from Medtronic, Inc., in Fridley, Minn., U.S.A. Cardiac output also can be measured using a sensor inserted into an artery at the wrist.

[**0035**] It also is within the contemplation of this invention that the input **115** to control means **114** could be the output from a cardiac pacemaker. Integration of the present device with a cardiac pacemaker would provide the advantage of e.g., fewer organ-electrode interfaces. It follows, of course, that a sophisticated pacemaker may control the pump and pressure regulator without the need for a second implanted control means (i.e., in the absence of control means **114**).

[**0036**] It is understood that the device shown in FIG. **1** presumes the chambers are either attached to the outside of the heart (e.g., by suturing) or placed within a semi-rigid cup such as is that shown and as also is depicted in U.S. Pat. No. 5,169,381, the teaching of which is incorporated by reference herein. Alternatively, a mesh or net arrangement (not shown) may be used in this latter embodiment. The individual chambers **108** would be attached or retained on the inside surface of the cup so as to maintain the relative separation d, d' between the chambers themselves while maintaining the chambers in contact with the heart's surface. The cup or mesh arrangement also causes all expansion of helices **108** to be inwardly directed to create the advantageous bottom-to-top cardiac massage contemplated by this invention.

[**0037**] Referring to FIG. **1** arrows **120** show the general direction of incompressible fluid flow within the system. As is shown, fluid leaves pump **112** passes toward the apex of the heart and then passes through the system toward the heart's base or basal region. It is this direction and the pulse effect given to the fluid via the use of pressure regulator **110** which creates the advantageous cardiac compression wave form which provides the unique cardiac assist of the present invention.

[**0038**] Referencing FIGS. **2** and **3** there is shown an embodiment to the present invention in which a heart-shaped cup member **202** is employed exteriorly of the chamber array **101** discussed above. In this version of cardiac assist device **201** the exterior cup is used to anchor the individual chambers **108** and to maintain their separation distance d, d'. In this version of the invention cup member **202** is merely inserted over the heart **100** and sutured into place. As is shown in FIG. **3** cup member **202** substantially envelopes heart **100** so as to maintain the chamber members **108** in exterior contact with the heart. Partial or complete coverage of heart **100** are both contemplated. Thus, when fluid is pulsed into the helices of the present invention the heart is massaged or compressed in the advantageous fashion described herein thereby generating additional cardiac output.

[**0039**] FIG. **4** shows a fully implanted version of the present assist device **201**. In addition to the components of the invention shown in FIG. **1** (and which similar designations have been used) there is shown an additional implanted source of electrical energy, e.g., a battery **203** and an implanted fluid reservoir **205**. As is shown battery **203** is electrically coupled to pump **112** and, preferably the chamber controller **114** and the phased electrode array controller **502** while optional fluid reservoir **205** is fluidically coupled to pump **112** to replenish fluid to be pumped through the device **201**. Equivalents to optional fluid reservoir **205**, e.g., a larger diameter chamber array which would contain sufficient fluid, are within the contemplation of the present invention and will be readily apparent to one skilled in this art.

[**0040**] FIG. **5** shows schematically, a further embodiment of the present invention in which the chamber array **300** comprises a series of fingers or elongated patches **302** directed around the heart in a palm-open upward fashion. The fingers or patches **302**, as shown, are sutured to the exterior of heart **100**. Chamber array **300** envelopes heart **100** such that when compressed radially inwardly e.g., by generation of a pulsatile wave or wave form, heart **100** is massaged or compressed in accordance with the invention. Surrounding and enveloping fingers **302** is cup-shaped member **304**. Member **304** is substantially radially rigid such that expansion of fingers **302** by pulsatile input of fluid from pump **112** (via input tubes or input connectors **308**) causes fingers **302** (or at least the inside surface thereof **303**) to be displaced inwardly arrow **305** thereby compress heart **100**. Fluid flows from the apex of heart **100** toward its base, pulsatile fluid emerging from fingers **302** into return connector or output connectors **310** to be returned to pressure regulator **110** for reuse. The outside surface **305** of finger **302** is in substantial contact with the inside surface **307** of member **304**. FIG. **5** also shows the phased electrode array where the electrodes **500** are located on the patches **302** of the chamber array **300**, the electrodes **500** being adjacent to the heart. The electrodes **500** are connected by wires **506** to the phased electrode array controller **502**, which is in turn connected to the sensor/input means **115**.

[**0041**] FIG. **6** shows the embodiment of the invention of FIG. **5**, discussed above, fully implanted within the human chest cavity **42**. It should be noted that the devices shown in FIG. **4** and FIG. **6** are not necessarily drawn to the same scale.

[0042] FIG. **7** shows schematically, a further embodiment of the present invention in which the chamber array **400** comprises a series of "Bourdon type" fingers or elongated patches **402** directed around the heart in a palm-open upward fashion. Bourdon fingers are made from an elastic material to allow them to expand and contract. The Bourdon type fingers **402**, as shown, are sutured to the elastic cup **403** which is sutured to the exterior of heart **100**. The Bourdon chamber array envelops heart **100** such that it compresses the heart radially inward by straightening the fingers due to the pulsation of pressure inside the Bourdon tubes, massages the heart in accordance with the invention. The cup-shaped elastic members **403** are substantially radially rigid and hence help the fingers **402** to compress the heart **100** effectively when pulsatile input of fluid from pump **112** (via pressure regulator valve **110** and input tube or input connector **408**) cause the elastic fingers **402** to be displaced inwardly thereby massaging heart **100**. The pressure generated due to the fluid flow from the pump **112** helps the heart to be massaged from the apex to its base in accordance with the invention. When pressure regulator **110** changes the direction of fluid flow upon the signal received from the microprocessor **114**, the backward fluid flow will contract the Bourdon tube fingers outwardly to release the pressure from the heart **100**. The outflow of the fluid from the fingers **402** will return through the output connector **409** and pressure regulator valve **110**) back into the pump **112** and reservoir **205** for reuse. Bourdon tubes are described in greater detail at pages 444 and 445 of Van Nostrand's Scientific Encyclopedia, 8th edition (1995), the entire description of which is incorporated by reference herein.

[0043] The Bourdon tube **402** arrangement is constructed to apply pressure in a coordinated and physiologic pattern about the heart in order to apply pressure to the needed location and timing sequence to aid the failing heart. A Bourdon tube **402** is a curved and partially flattened tube that tends to straighten out in proportion to thermal pressure. The unique feature of this is that the material properties of the Bourdon tube **402** in the non-pressurized state return to the "relaxed" or "non-compressive" state. Therefore when the Bourdon **402** tube is in a pressurized state from the input of fluid from pump **112**, the tubes **402** contract the heart, and when they are not in a pressurized state, the tubes **402** recoil away from heart, facilitating the refilling of heart passively.

[0044] These Bourdon tubes **402** have a lining with the electrodes **500** positioned in a phased array to be able to electrically stimulate/pace the heart in a specific time and location if indicated to get the heart to "actively" contract on its own as needed

[0045] The present invention has the advantage of providing cardiac assistance or enhancement without creating the kind of blood/device interfaces characteristic of artificial hearts, implanted blood pumps, and other such mechanical, fluid-circulating assist therapies. Thus, blood/interface artifacts, e.g., damage to blood constituents, thrombus creation, and coagulation do not result because the present invention uses only the normal cardiac endothelium to interface with blood.

[0046] The present invention is also broadly applicable to cardiac muscle infirmities which are evidenced by weakened cardiac muscle wall and muscle aneurysms or bulges. Such muscular infirmities are evidenced by dyskinetic cardiac muscle segments (i.e., wall segments which do not reliably contract, and hypokinetic segments i.e., wall segments which contract too slowly. Utilization of the present invention with its cardiac cupping or enveloping structure tends to mitigate or eliminate these phenomena. Thus, in one aspect, the present invention is a method of mitigation of cardiac muscle infirmities including dyskinesia and hypokinesia, which method involves the steps of providing a heart-shaped, cup apparatus; deploying the cup apparatus so that it substantially envelopes a patient's heart evidencing muscle infirmities, the apparatus being located so as to provide exterior support thereto; and anchoring the cup apparatus to the patient's heart.

[0047] All patents, publications and references cited herein are hereby fully incorporated by reference. In the case of conflict between the present disclosure and the incorporated patents, publications and references, the present disclosure should control.

[0048] While the present invention has now been described and exemplified with some specificity, those skilled in the art will appreciate the various modifications, including variations, additions, and omissions that may be made in what has been described. Accordingly, it is intended that these modifications also be encompassed by the present invention and that the scope of the present invention be limited solely by the broadest interpretation that lawfully can be accorded the appended claims.

What is claimed is:

**1**. An implantable cardiac massage apparatus for providing assistance to a heart having an apex and a base, the apparatus comprising:

a chamber array, the array comprising a series of spaced-apart, fluidically coupled chambers, the array having fluid input and output ports, wherein the input ports are located near the apex of the heart and the output ports are located near the base of the heart, and the chambers defining an inside surface which closely conforms to the external surface of a heart and;

pressure regulator means, the pressure regulator means being fluidly coupled to the array input port and output port, the pressure regulator means also being fluidically coupled to;

pump means, the pump means and the pressure regulator means being electronically coupled to;

controller means, the controller means being adapted to actuate the pump means and the pressure regulator means so that fluid is pumped substantially continuously by the pump means to the input port and the pressure regulator means intermittently inflates and deflates the chambers starting at the apex of the heart to create a rhythmic message of the heart from its apex to its base thereby substantially imitating the natural contraction of the heart, the controller means being further adapted to receive sensor information input from a cardiac activity/sensor means;

a phased electrode array comprising a series of electrodes, the electrodes in contact with the heart and capable of providing electronic stimulation to the heart;

a phased electrode array controller means, the phased electrode array controller means being adapted to control the discharge of electrical stimulation of the phased electrode array; and

wherein the cardiac activity/sensor means, the cardiac activity/sensor means being adapted to sense cardiac activity and input sensor information to the controller means and to input sensor information to the phased electrode array controller.

**2**. The apparatus of claim 1 which further includes an implantable reservoir means fluidly coupled to the chamber array.

**3**. The apparatus of claim 1 which further includes an implantable source of electrical energy electronically coupled to the pump means.

**4**. The apparatus of claim 1 electronically coupled to the controller means.

**5**. An apparatus of claim 1 wherein the pressure regulator means comprises a relief valve.

**6**. An apparatus of claim 1 wherein the pump means comprises a kinetic pump or axial turbine.

**7**. A method of mechanically assisting a heart comprising the steps of:

deploying an apparatus of claim 1 about the external surface of the heart;

activating the apparatus by energizing the controller means and in turn the pump means so as to cause fluid to flow through the apparatus;

pulsing fluid flow through the apparatus by operating the pressure regulator means the fluid flow starting at the apex of the heart and passing to the base of the heart thereby rhythmically massaging the heart from the apex toward its base to enhance the heart's fluid output in a manner similar to unassisted cardiac discharge.

**8**. An implantable cardiac massage apparatus for providing assistance to a heart having an apex and a base, the apparatus comprising:

a chamber array, wherein the chamber array comprises elastic Bourdon tubes, the array comprising a series of spaced-apart, fluidically coupled chambers the array having fluid input and output ports, and the chambers defining an inside surface which closely conforms to the external surface of a heart and;

pressure regulator means, the pressure regulator means being fluidly coupled to the array input port and output port, the pressure regulator means also being fluidically coupled to;

pump means, the pump means and the pressure regulator means being electronically coupled to;

controller means, the controller means being adapted to actuate the pump means and the pressure regulator means so that fluid is pumped by the pump means to the input port and the pressure regulator means intermittently inflates and deflates the chambers starting at the apex of the heart to create a rhythmic message of the heart from its apex to its base thereby substantially imitating the natural contraction of the heart, the controller means being further adapted to receive sensor information input from a cardiac activity/sensor means;

a phased electrode array comprising a series of electrodes, the electrodes in contact with the heart and capable of providing electronic stimulation to the heart;

a phased electrode array controller means, the phased electrode array controller means being adapted to control the discharge of electrical stimulation of the phased electrode array; and

wherein the cardiac activity/sensor means, the cardiac activity/sensor means being adapted to sense cardiac activity and input sensor information to the controller means and to input sensor information to the phased electrode array controller means.

**9**. An implantable cardiac massage apparatus for providing assistance to a heart having an apex and a base, the apparatus comprising:

a helically wound tubing formed into an array, the array having a fluid input port located near the apex of the heart and a fluid output port located near the base of the heart, and the array defining an inside surface which closely conforms to the external surface of a heart and;

pressure regulator means, the pressure regulator means being fluidly coupled to the array input port and output port, the pressure regulator means also being fluidically coupled to;

pump means, the pump means and the pressure regulator means being electronically coupled to;

controller means, the controller means being adapted to actuate the pump means and the pressure regulator means so that fluid is pumped substantially continuously by the pump means to the input port and the pressure regulator means intermittently inflates and deflates the helically wound tubing starting at the apex of the heart to create a rhythmic message of the heart from its apex to its base thereby substantially imitating the natural contraction of the heart, the controller means being further adapted to receive sensor information input from a cardiac activity/sensor means;

a phased electrode array comprising a series of electrodes, the electrodes in contact with the heart and capable of providing electronic stimulation to the heart;

a phased electrode array controller means, the phased electrode array controller means being adapted to control the discharge of electrical stimulation of the phased electrode array; and

wherein the cardiac activity/sensor means, the cardiac activity/sensor means being adapted to sense cardiac activity and input sensor information to the controller means and to input sensor information to the phased electrode array controller means.

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