

[54] **PROSTHETIC PUMP**

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[22] Filed: **July 16, 1971**

[21] Appl. No.: **163,372**

[52] U.S. Cl. **128/1 D, 3/1, 3/DIG. 2, 417/413**

[51] Int. Cl. **A61b 19/00, A61f 1/24**

[58] Field of Search **128/1 R, 1 D; 3/1, DIG. 2; 417/413**

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[57] **ABSTRACT**

A pump particularly suited for use as a prosthetic device in a biological system to replace a pumping component of said system; a novel electro-mechanical transducer; a method for providing a prosthetic pump in a biological system; and method for forming an electrically actuated contractile element for use on a pump. The pump is formed of a resilient sidewalled chamber with exterior and interior surfaces contoured in the shape of the component to be replaced. The walls of the chamber are provided with one or more contractile elements arranged so that upon contraction of said elements the chamber will be contracted. A preferred contractile element is formed of a titanium-nickel alloy such as Nitinol selected from the class of binary equiatomic compounds of transition elements from group IV and group VIII. By arranging the Nitinol secured in a stressed orientation with respect to the chamber wall, subsequent application of current pulses to the wire will produce a heating of the Nitinol wire returning the wire to its original unstressed shape, thereby contracting the the chamber wall to produce pumping. The pump has particular application as an artificial heart.

11 Claims, 8 Drawing Figures

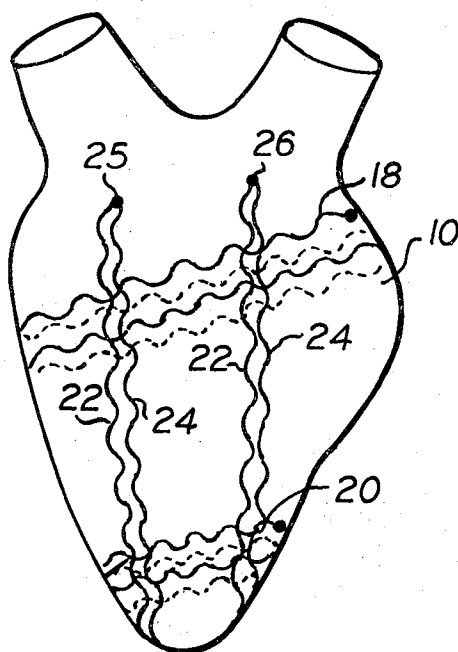


FIG. 1.

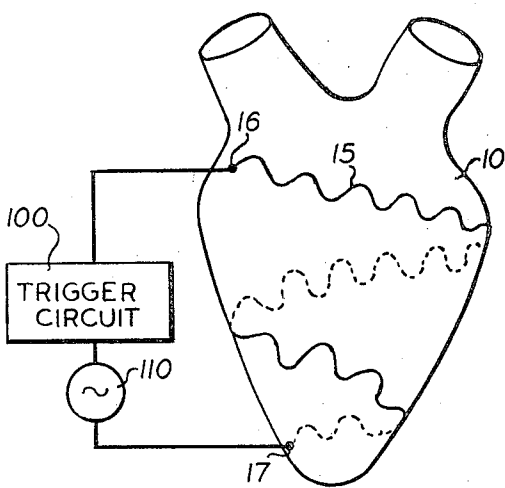


FIG. 2.

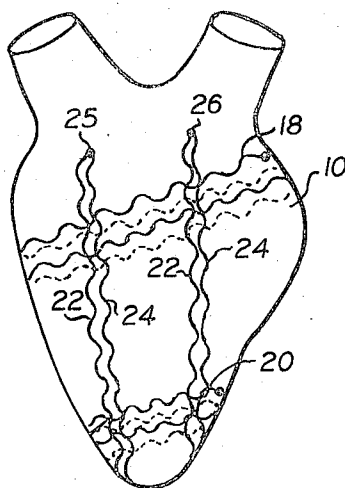


FIG. 3.

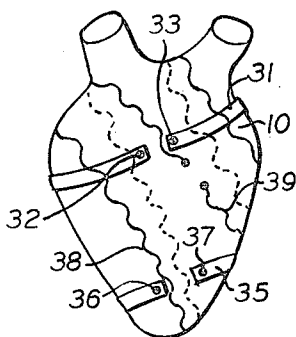


FIG. 4.

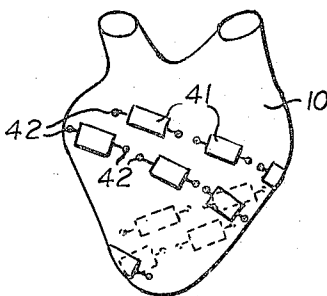


FIG. 5.

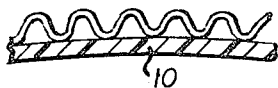


FIG. 6.

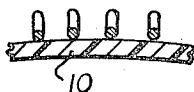


FIG. 7.

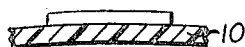
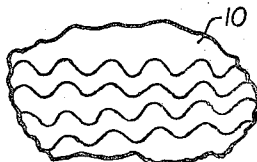


FIG. 8.



PROSTHETIC PUMP

BACKGROUND OF INVENTION

This invention relates to the art of prosthetic devices, and more particularly to a pump and means for actuating the pump so that the pump becomes particularly suited for use in replacing a natural pumping component of a biological system, such as a mammalian heart.

A variety of attempts have been made to evolve an artificial pumping member suitable for implantation in a living body to replace a diseased or otherwise deteriorated pumping component of the body. Thus a variety of artificial hearts have been evolved intended for use in replacing a mammalian heart.

Such previously developed artificial hearts have in the past employed diaphragm actuated or reciprocating mechanical pumps or have utilized hydraulic or pneumatically powered balloons to eject the contents of substantially cylindrical rigid walled chambers in which the balloon was positioned. These pumping members are often employed to produce desired pumping action in a flexible walled member inserted to replace the natural heart, with the flexible walled member acting as a reservoir. However, the natural heart is itself a pump with the sidewalls of the heart chambers contracting and expanding to effect desired blood pumping through the circulatory system. Thus the previously evolved artificial heart systems employing a pump in addition to the replaced prosthetic heart chambers are difficult of emplacement since they require an additional pumping member difficult of insertion into the available thoracic cavity space in which the natural heart being replaced was positioned.

The mammalian heart has a number of characteristics which are unique and have in the past been difficult of replication by an artificial device. Some of these characteristics are:

1. Relatively low pressure contractile atrial collecting and pressure sensitive reservoirs;
2. Surfaces which are not smooth, but contain contracting trabeculae, to prevent dead space stasis of blood at the blood-heart interface and thus prevent mural thrombus formation;
3. Chamber contents ejection capability built into the muscle walls of the chambers themselves;
4. A contractile neurological timing system including the SA and AV node and Purkinje fiber system to insure satisfactory rhythmicity of the multi-chambered heart with timed interdigitated contractions of the multiple chambers of the heart;
5. Built in volume pressure, and flow sensors in the heart and, inflow and outflow veins and arteries which prevent overdilatation of the myofibrillae and abnormal chamber pressures;
6. Valving at least partially active with good hydraulic configuration to insure (a) minimal leakage; (b) minimal resistance to flow; (c) minimal turbulence; and (d) long term function.

In attempting to attain the above recited characteristics in a prosthetic pump, it is desirable to provide some means for contracting the chamber simulating the natural pumping member, which can be incorporated in the chamber walls.

SUMMARY OF INVENTION

It is with the above desiderata in mind that the present pump, means for actuating same, and method for employing the pump as a prosthetic pump such as an artificial heart in a biological system such as a mammalian body has been evolved. The pump provides the two fold function of storing and pumping the fluid such as blood in the same fashion as performed by the natural heart or other natural pumping component to be replaced, and may be formed to the identical configuration of the replaced natural organ to perform the identical functions.

It is accordingly among the primary objects of the invention to provide an improved prosthetic pump capable of simulating and replacing a natural pump such as a heart in a mammalian body.

Another object of the invention is to provide a prosthetic pump subject to being formed with identical interior and exterior surface contours of a natural pumping organ such as a mammalian heart.

A further object of the invention is to provide a prosthetic pump having a flexible walled fluid receiving chamber, in which the chamber confines may be contracted to effect pumping in the same fashion as occurs in a natural pump such as a heart.

It is also an object of the invention to provide an artificial heart which does not require any auxiliary pumping apparatus other than that provided by the artificial heart.

A further object is to provide a method of replacing a natural heart with a prosthetic pump.

It is also an object of the invention to provide an improved electro-mechanical transducer.

These and other objects of the invention which will become hereafter apparent are achieved by forming a pump of a resilient biologically inert material shaped to form a chamber with the exterior and interior surfaces of the chamber preferably contoured to duplicate the exterior and interior surfaces of the natural pumping component such as a mammalian heart to be replaced in the biological system. Contractile elements are arranged with respect to the chamber walls so that upon contraction of the contractile elements the chamber will be contracted to provide desired pumping. The contractile elements according to the hereinafter described preferred embodiment of the invention are formed of a titanium-nickel alloy such as 55 Nitinol bent to form one or more return bends, a sinusoidally shaped configuration being preferred. The undulations of the sinusoidally shaped Nitinol wire are displaced from their normal configuration, preferably by stretching to spread the legs between the return bends of the sinusoidally shaped wire from their normal shape and the wire is secured with respect to the chamber walls. Thereafter upon passage of a current through the Nitinol wire, the increase in temperature of the wire causes the stretched sinusoidally shaped wire to return to its initial condition of shaping, contracting the chamber sidewalls and the chamber volume to produce a pumping action.

A feature of the invention resides in the arrangement of the contractile elements with respect to the chamber walls so as to provide a replica of typical twisting, wringing heart contracting action.

Another feature of the invention resides in the dimensioning of the heat actuated contractile elements of

a cross-sectional size such that heat energy is converted to mechanical energy of restoration of the sinusoidal wire, without excessively raising the temperature of any surrounding tissue in which the prosthetic pump is implanted, to a level which is detrimental to the function of the tissue.

BRIEF DESCRIPTION OF DRAWINGS

The specific details of a preferred embodiment of the invention and their mode of functioning will be particularly pointed out in full, clear, concise and exact terms in conjunction with the accompanying drawings wherein:

FIG. 1 is a perspective diagrammatic view of a prosthetic pump simulating a heart chamber made in accordance with the teachings of the invention showing the contractile elements formed by a plurality of sinusoidally shaped Nitinol wires arranged to helically encircle a heart ventricle simulating pump;

FIG. 2 is a perspective view of another embodiment of a prosthetic pump simulating a heart ventricle showing an arrangement of contractile elements providing multiple helical bands surrounding the pump chamber at two levels along with multiple hemi-ellipsoid strands extending longitudinally about the chamber;

FIG. 3 is a perspective view of another embodiment of another prosthetic pump simulating a heart ventricle showing an arrangement of bands of Nitinol helically surrounding two spaced transverse levels of the ventricle, with longitudinally extending contractile elements to provide for both the exertion of lateral and longitudinal forces on the pump chamber;

FIG. 4 is a perspective view of a ventricle simulating pump illustrating an arrangement utilizing a plurality of spaced Nitinol bands arranged to helically surround the pump chamber;

FIG. 5 is a schematic cross sectional elevational view through a chamber wall showing a sinusoidally arranged Nitinol wire positioned to lie in a plane perpendicular to the chamber wall;

FIG. 6 is an end view of the proposed arrangement shown in FIG. 5;

FIG. 7 is a cross sectional view through a chamber wall showing the sinusoidally shaped Nitinol wire positioned to lie in a plane tangent to the chamber; and

FIG. 8 is a top plan view of the arrangement shown in FIG. 7.

DESCRIPTION OF PREFERRED EMBODIMENTS OF THE INVENTION

Referring now more particularly to the drawings, like numerals in the various Figures will be employed to designate like parts.

As illustratively shown in FIG. 1, the inventive concept is shown as embodied in the formation of a prosthetic pump suitable for use in forming an artificial heart. As seen in FIG. 1, a pump chamber 10 is formed to simulate the interior and exterior contours of a mammalian heart ventricle. In forming the pump chamber 10 so as to permit its use in replacing a heart ventricle, a mold is first made of a natural mammalian heart ventricle simulating the contours of the natural heart ventricle. The chamber 10 is then formed in this mold utilizing a molding apparatus of the type shown by Page U.S. Pat. No. 3,881,476, charging the mold with a non-thrombogenic material. Ethylenevinyl-acetate (EVA) is found to provide desired antithrombogenic proper-

ties. The addition of additives such as Dextran "40" to the ethylenevinylacetate (EVA) is found to further improve the anti-thrombogenic properties. The chamber has additionally been formed of silicone rubber. As will be understood by those skilled in the art, a variety of flexible antithrombogenic materials may be molded to form the resilient walled chamber 10. Polymers such as Silastic, polyurethane, block polyurethane or the like may be employed.

As schematically illustrated in FIG. 1, a contractile element 15 is shown as helically wound to extend from a top terminal point 16 adjacent the upper left end of the illustrated pump chamber 10 around the walls of the chamber down to a lower terminal point 17.

The contractile element 15 in the illustrated embodiment is formed of a Nitinol wire bent into a sinusoidal shape. Nitinol is an alloy of titanium and nickel. A 55 Nitinol, that is an alloy containing 55 percent nickel by weight, with the balance titanium with or without the addition of cobalt is found satisfactory. However, a variety of other percentages of nickel in the Nitinol alloy may be employed. It is further contemplated within the scope of this invention that a number of alloys formed of binary equiatomic compounds of transition elements from group IV (Ti, Zr or Hf) and group VIII (Ni, Co, Fe or Ru and Rh, Pd; or Os, Ir, Pt) which have a martensitic transition in a temperature range of between 50° to 80° F. may be suitable. If such compounds are formed into a given shape and annealed at a given temperature (of between 700° and 1,400° F.), subsequent plastic deformation occurring at temperatures below the annealing temperature will be removed upon heating of the material through its Temperature Transition Range (TTR) which dependent on the alloy composition may be formed to range between -150° to 225° F. returning the material to its original annealed shape. Messrs. F. E. Wang and W. J. Buehler of the U.S. Naval Ordinance Laboratory have described this phenomena in the Journal of Applied Physics 39:2166 1968.

In the embodiment of the invention illustrated in FIG. 2, the pump chamber 10 is formed as described in connection with the FIG. 1 embodiment to simulate the contours of a mammalian heart ventricle, with the chamber 10 being formed preferably of an antithrombogenic material such as EVA, or the like. In this FIG. 2 embodiment of the invention, the contractile elements are arranged so as to provide a plurality of sinusoidally bent Nitinol wire helically wound about an upper transverse level 18 of the chamber 10; and a second plurality of sinusoidally bent Nitinol wire helically wound about a second level 20 of the chamber 10. The sinusoidally bent Nitinol wire shown in the illustrated embodiment is a 55 Nitinol wire which has been bent into a sinusoidal configuration and annealed at a temperature of approximately 700° C. In positioning the sinusoidally bent wire on the chamber wall 10 the undulations of the annealed sinusoidally shaped wire are spread so as to elastically deform same. In addition to the contractile elements arranged at levels 18 and 20 a plurality of annealed sinusoidally bent wire strands 22 and 24 are arranged to extend between terminal points 25 and 26 (at the top of the chamber 10) down around the lower tip of the chamber to provide a double hemi-ellipsoid girdling of the chamber in a direction extending along the longitudinal axis of the chamber 10.

In the embodiment of the invention illustrated in FIG. 3, a suggested arrangement of contractile ele-

ments shown is provided by an illustratively shown circumferentially extending upper contractile band 31 formed of a strip of Nitinol annealed at between 950° and 1,100° F. and elastically stretched at room temperature of between 50° and 100° F. to extend about the upper end of the illustratively shown chamber 10 between terminals 32 and 33. A second lower band 35 is shown stretched between terminals 36 and 37 and circumferentially surrounding a lower end of the chamber 10. In order to provide contraction of the chamber 10 in a longitudinal direction, as illustrated a sinusoidally shaped annealed Nitinol wire is helically wound as shown to extend from top to bottom of the chamber 10 in a substantially helical wrap around arrangement. The wire is preferably separated into two or more segments 38 and 39, each providing a separate circuit for a reason to be hereinafter described.

In the FIG. 4 embodiment of the invention, the chamber 10 is shown as provided with a plurality of spaced straps 41 of Nitinol annealed at a temperature between 950° and 1,400° F. which are arranged to helically surround the chamber 10. Electrical terminals 42 are provided between each of the straps 41 for electrical connection to the straps. The straps 41 are elastically stretched at room temperature between 50° and 90° F. before securing them to the chamber wall.

Some suggested arrangements for positioning of the sinusoidally shaped contractile elements are illustrated in FIGS. 5-8. The sinusoidal contouring of the Nitinol may be accomplished in a variety of fashions. Thus Nitinol wire may be bent on a jig to provide desired sinusoidal contour; or a plate of Nitinol may be punched or etched into the desired sinusoidal shape. The Nitinol which has been either bent etched, machined or otherwise formed into desired shape at normal room temperatures of between 50° and 100° F. is then annealed at a temperature of between 700° and 1,500° F.

In the FIG. 5 illustration, a section of a pump chamber 10 is shown in cross section, with the sinusoidally contoured annealed Nitinol secured to the surface of the chamber 10 with the sinusoidally contoured Nitinol stretched to separate the undulations and arranged in a plane perpendicular to the chamber surface, as shown in FIG. 6.

Alternatively, as shown in FIGS. 7 and 8, a plurality of annealed sinusoidally contoured Nitinol elements may be stretched and secured to the chamber surface in a plane tangent thereto.

It will be understood by those skilled in the art that though the contractile elements have been shown as applied to the chamber wall on the surface thereof, these contractile elements may readily be incorporated into the chamber wall.

OPERATION

Four suggested arrangements of contractile elements on a prosthetic pump chamber contoured to simulate a mammalian heart ventricle have been illustrated and described. It will of course be understood by those skilled in the art that the illustrated and described arrangements may readily be varied within the scope of this invention.

In use, the contractile elements are energized to produce a contractile force on the pump chamber 10 to provide desired pumping action.

The thermo-mechanical transducer properties of Nitinol have been recognized. Though the exact mech-

anism permitting this thermo-mechanical transduction has not been fully explained, Buehler and Wang have suggested a model having a crystalline structure with two states closely related in terms of energy and inter-atomic distances. In this model, all atoms in the same plane of dislocation move cooperatively when the crystal is deformed by shear stress. Thus, some atoms in adjacent layers approach each other. With increasing temperature the relatively lighter titanium atoms will tend to vibrate at a larger amplitude around their equilibrium position and exert a repulsive diagonal force which contributes to the recovery of the crystal to its initial crystalline structure which has been formed by annealing. The necessary heat to produce the crystalline transformation required to restore a deformed Nitinol element to its original annealed shape may be obtained due to the electrical resistivity of the Nitinol element, as a result of which the passage of an electrical current through the Nitinol appears to produce sufficient heat in the Temperature Transition Range to provide desired crystalline transformation. As a result, electro-mechanical transducing may be obtained.

By connecting the Nitinol contractile elements shown in the various illustrated and described embodiments, and energizing these elements selectively, desired pumping to simulate the pumping action of a natural element to be replaced by the prosthetic pump is obtained. Thus, in order to simulate a heart, the contractile modules are arranged to simulate the muscle fibers in the heart. These contractile elements are arrayed with respect to the walls of the chamber by either molding in place, or post-molding emplacement. They are arrayed in a multiple helical pattern and are activated and timed sequentially to contract and thereby helically wring the pump chamber 10 from apex to base as in the mammalian heart, as takes place in the normal ventricular contractile process during the systolic phase of the heart beat. Upon termination of flow of the electrical current through the contractile element, the contractile element which is anchored at spaced points to the elastic walled chamber will be stretched by the return of the chamber wall to its initial diastolic orientation.

In forming the prosthetic pump as illustrated schematically in FIG. 1, a length of 50 Nitinol wire having a Temperature Transition Range (TTR) of between 90° and 120° F. is wound into a sinusoidal configuration with a wave length between undulations of approximately three-fourths of an inch, and an amplitude of approximately three-eighths of an inch. This sinusoidally oriented 50 Nitinol wire is then baked in an oven to anneal same at a temperature of between 700° and 1,400° F. The annealed sinusoidally oriented wire is then permitted to cool gradually to room temperature. The annealed wire is then stretched and secured to the chamber 10, in the orientation illustrated in FIG. 1 to extend helically around the chamber between terminals 16 and 17. In positioning the contractile element 15 on the chamber 10, the undulations of the wire are separated to provide a wave length of approximately ¾ inches between undulations. Subsequent heating of the stretched sinusoidally shaped wire to the TTR (which is selected to lie between 105° and 130° F.) will result in return of the Nitinol wire to its original annealed orientation. The application of the desired temperature may be obtained by connecting terminals 16 and 17 in an electrical circuit preferably including a trigger cir-

cuit 100 which may take the form of a Schmidt trigger or any one of a wide variety of conventionally available pulse forming circuits to an electrical current source 110. Upon discontinuance of current flow, in order to effect the desired crystalline transformation according to the Buehler model of titanium, it is required that a given quantity of heat be added to the wire.

In selecting the gauge of Nitinol, and current to be applied so as to produce the necessary crystalline change, the wire is preferably selected of a dimension such that the electrical resistance will produce the required heat which is substantially dissipated in crystalline transformation so that there is no excessive temperature increase in the surrounding ambience of the wire, as a result of which implantation of the prosthetic pump in living tissue will not interfere with desired tissue function. A 55 Nitinol wire gauge of 0.020 inch, with a length of 2 inches between terminals connected across a 45 volt source is found to produce eminently satisfactory results. Nitinol wires containing between 45 and 60 percent weight having a gauge between 0.015 inch and 0.090 inch with a TTR of between 100° F. and 130° F. have been employed.

The operation of the various illustrated embodiments will of course be apparent to those skilled in the art, it being understood that the different contractile modules are selected of a length and thickness permitting their positioning as illustrated with respect to the pump chamber wall. Electrical connections are made to the terminals of each wire or strap array and the circuit energized to provide desired pulses to provide desired frequency of pumping, it being understood that an electrical pulse will be provided in desired sequence and of desired duration to heat the array to a temperature in its TTR causing the array to contract to its original annealed position.

What is claimed is:

1. A pump chamber comprising a flexible wall contoured to enclose and define a fluid containing space, said space forming a confined volume chamber having inlet and outlet openings therein through which fluid may flow to and from said confined volume; an elongate contractile element secured at two spaced points to the wall defining said confined volume externally of said confined volume, said contractile element comprising an elongate member formed of an alloy of binary equiatomic compounds of transition elements selected from group IV of the periodic table of elements and group VIII; and means periodically actuating said contractile element to bring the points of said chamber wall between which said contractile element is secured towards each other whereby the volume confined by

said wall is reduced to discharge fluid contained in said chamber.

2. A pump chamber as in claim 1 in which said flexible walled chamber is a molded plastic material.

3. A pump chamber as in claim 2 in which said chamber is formed of ethylenevinylacetate.

4. A pump chamber as in claim 1 in which said contractile element comprises Nitinol.

5. A pump chamber as in claim 4 in which said element is sinusoidally shaped and annealed at a temperature of between 700° and 1,400° F., with the sinusoidally shaped element stretched at a temperature below the annealing temperature and secured in this stretched condition to said flexible walled chamber in distended condition.

6. A pump chamber as in claim 5 in which said element is formed of Nitinol having a Temperature Transition Range between 90° and 120° F.

7. A pump chamber as in claim 5 in which said chamber is of a shape simulating a human organ and is formed of a non-thrombogenic material.

8. A pump chamber as in claim 7 in which said contractile element comprises a Nitinol wire having a Temperature Transition Range between 90° and 120° F. having a sinusoidal shape and annealed at a temperature of over 700° F. and secured with respect to the chamber wall in a stretched orientation at a temperature below 700° F. to separate the undulations of the annealed sinusoidally shaped Nitinol wire.

9. A pump chamber as in claim 7 in which said contractile element comprises in addition to said annealed sinusoidally shaped Nitinol wire, a strip of Nitinol annealed at a temperature above 700° F. and secured with respect to the chamber wall in a stretched orientation at a temperature below 700° F.

10. A method for utilizing the pump chamber as formed in claim 7 comprising the steps of surgically removing the pumping organ from the mammalian body which is to have the pumping organ replaced; connecting the chamber to the fluid conducting ducts to which the removed organ had been connected positioning the pump chamber in place of the removed organ; and connecting the ends of the Nitinol material secured to the chamber to a source of electrical energy providing pulses of electrical energy timed to simulate the pumping pulses of the replaced organ.

11. A method as in claim 10 in which the Nitinol material is provided in a plurality of spaced arrays on the pump chamber; and said arrays are electrically energized in a timed sequence to contract different portions of the pump chamber sequentially.

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