

[54] **ARTIFICIAL HEART CONSISTING OF A BIVENTRICULAR PUMP WITH CONTROL MECHANISMS FOR TOTAL REPLACEMENT OF HUMAN HEART**

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[63] Continuation of Ser. No. 37,181, May 14, 1970, abandoned.

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 [51] Int. Cl. A61f 1/24
 [58] Field of Search 3/1, DIG. 2;
 128/1 R, DIG. 3

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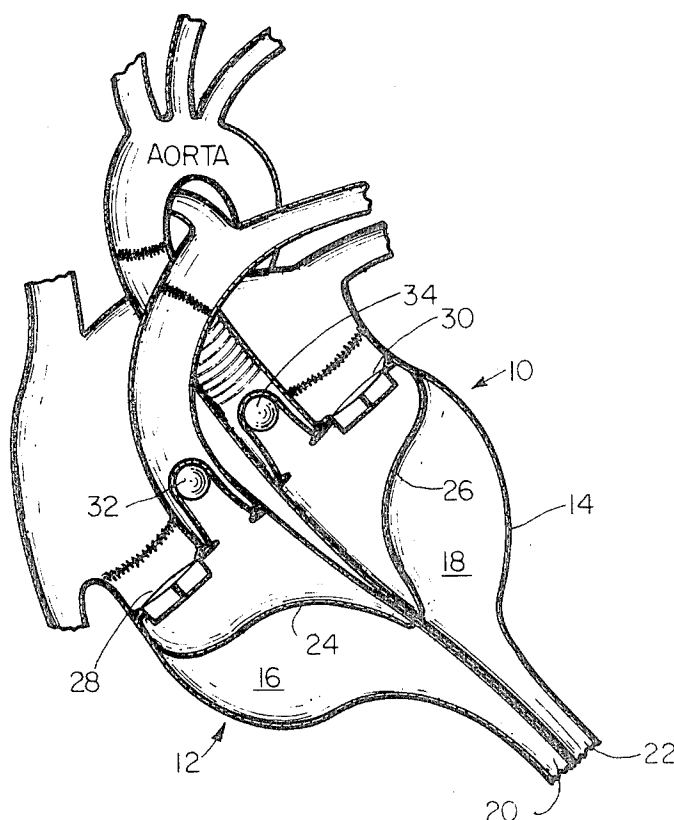
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[57]

ABSTRACT

A pneumatically controlled biventricular artificial heart lined with Dacron reticular fabric and including a left and right ventricular pump unit with controls for operating the left and right ventricular pumps at different and controlled pressures.

3 Claims, 6 Drawing Figures



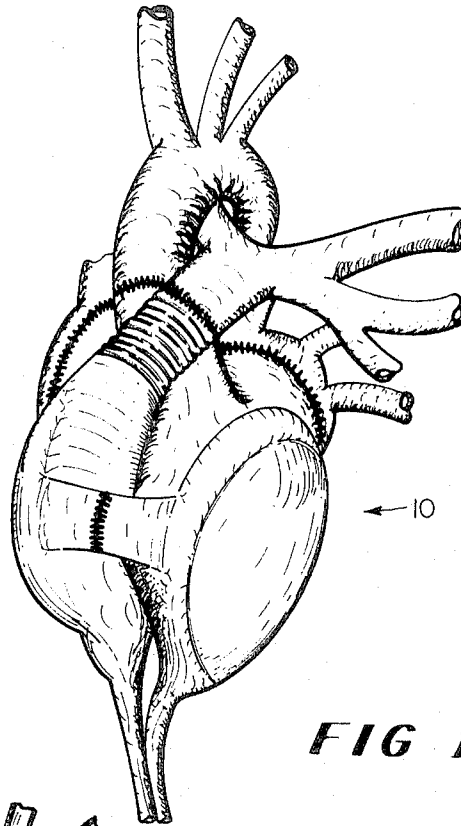


FIG 1

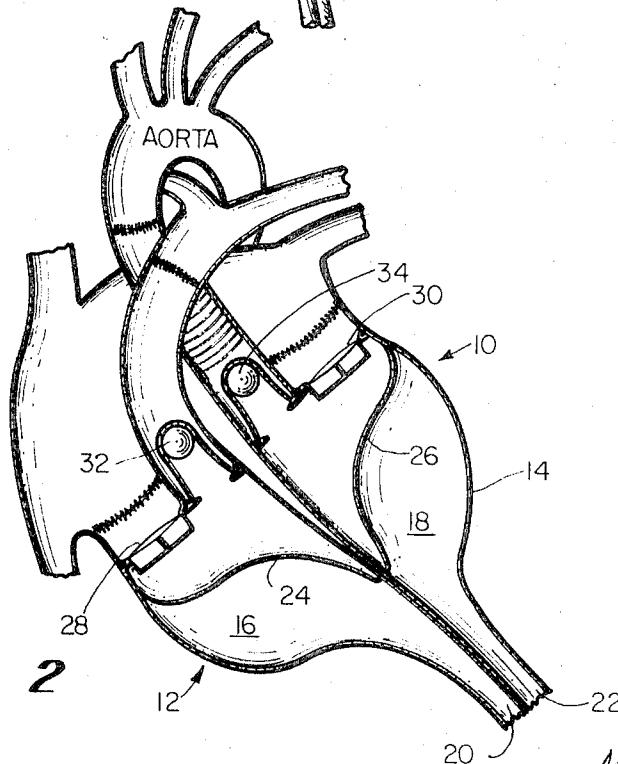
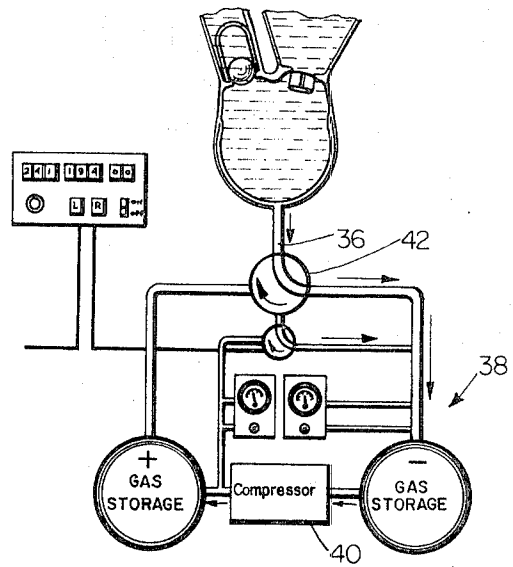
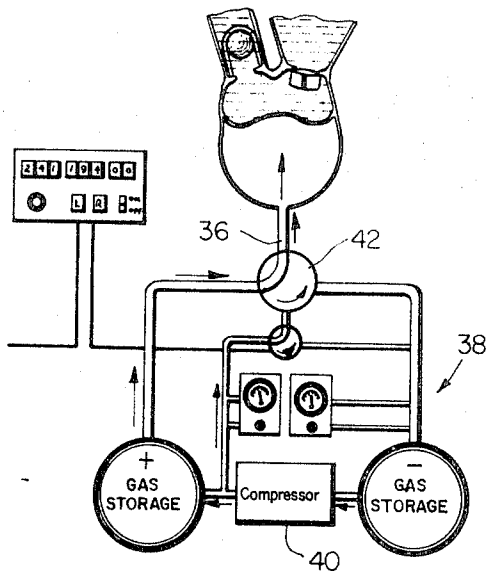
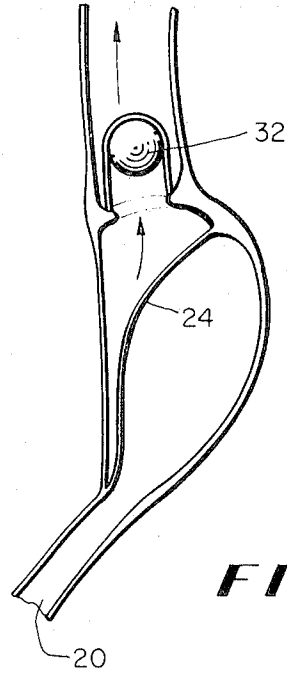
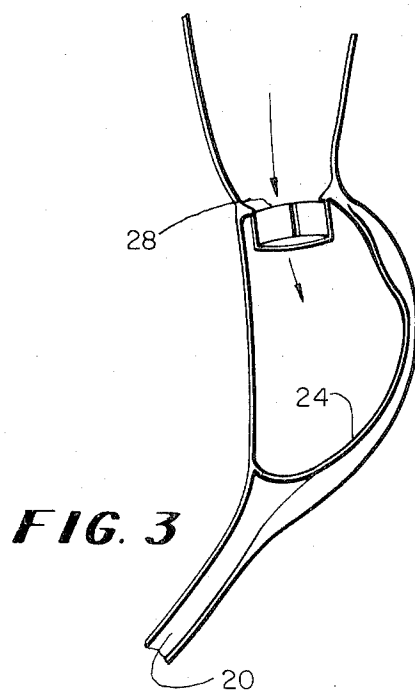


FIG 2

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ARTIFICIAL HEART CONSISTING OF A BIVENTRICULAR PUMP WITH CONTROL MECHANISMS FOR TOTAL REPLACEMENT OF HUMAN HEART

This application is a continuation of application Ser. No. 37,181, filed May 14, 1970, now abandoned.

The present invention relates to an artificial heart and, more particularly, to an artificial heart including a biventricular pump with the necessary control mechanisms.

In the normal mammal circulatory system, circulation is primarily effected by the left ventricle which, by its contraction or systole, forces blood into the aorta, any back flow of blood into the left ventricle being prevented by the closing of the aortic valve. The blood leaving the contracting ventricle during systole and forced into the aorta increases the pressure in the aorta and effects some stretching or inflation thereof. At the completion of the contraction and upon the closing of the aortic valve, the flow of blood through the circulatory system continues, due to the exertion of pressure on the blood as the aorta shrinks to its normal diameter. As is well known, many cases of heart insufficiency occur because the heart muscle (myocardium) does not contract effectively, thus requiring excessive work from the heart to maintain normal circulation.

Artificial auxiliary ventricles have been previously devised and certain of these have met with success, particularly the pump which was developed for support of the failing left ventricle. This left ventricular bypass pump proved safe and effective in test animals (*Hall, C. W., Liotta, D., and DeBakey, M. E.: Bioengineering Efforts in Developing Artificial Hearts and Assistors. The American Journal of Surgery, 114:24, 1967.) and a series of patients critically ill with heart failure; the success with this device resulted in the development of the present biventricular device for human orthotopic implantation.

It is, therefore, an object of the present invention to provide an improved artificial heart, and to overcome certain defects in the prior art.

It is an object of the present invention to provide a pneumatically controlled biventricular cardiac prosthesis.

A further object of the present invention is to provide the control mechanisms required for maintaining proper balance of both pulmonary and systemic circulation and adequate cardiac output and perfusion during total mechanical replacement of the heart.

These and other objects of the nature and advantages of the present invention will be more apparent from the following detailed exemplary description, taken in conjunction with the accompanying drawings wherein:

FIG. 1 is a perspective view showing the artificial heart after implantation;

FIG. 2 is a schematic drawing thereof showing the biventricular pump;

FIGS. 3 and 4 are frontal cross-sections showing the design of a ventricle and inflow and outflow connectors respectively; and

FIGS. 5 and 6 are schematic illustrations of the control mechanism connected to a ventricle during systole and diastole, respectively.

Briefly, an artificial heart system 10 is provided which includes, in general, a left ventricle 12 and a right ventricle 14. The left and right ventricles 12 and 14 are preferably fabricated of impervious Dacron

(polyethylene terephthalate) embedded in Silastic (a heat vulcanizable silicone rubber having an elongation of about 300 percent and tensile strength of about 1,000 psi; Dow Corning Corporation). Each of the two separate units contains a ventricle chamber 16, 18 with connections 20, 22 to an external power source. A movable diaphragm 24, 26 is provided in each ventricle with an inflow pressure monitor 28, 30. Each of the units contains an outflow valve 32, 34 between the atrioventricular chamber and the outflow chamber. Tubing 36 made of Silastic is connected to each ventricle and is brought through an intercostal space to provide a pathway for pulsing the diaphragm by attachment of two external pneumatic power units 38.

A separate pressure line attached to the left atrial chamber permits continuous monitoring of the atrial pressure. A whirling motion of the blood during diastole, produced by the position of the inflow and outflow connectors, assures a constant flux in the region of the apex. Tests of paracorporeal bypass systems in animals and in vitro flow studies have shown that potential stagnation of blood is reduced by the large radius of the apex of the pump, which is determined by the diameter of the round diaphragm.

An important feature of the invention is the use of Dacron reticular or net-like fabric to line the pump chamber as well as the inflow and outflow tracts to enhance formation of an autologous blood interface. The thin, flexible, cuff-shaped inflow tracts are made of impervious Dacron felt and Silastic adhesive. Woven DeBakey arterial grafts (25 mm) are attached to the infundibular-shaped outflow tracts for suturing to the pulmonary artery and ascending aorta.

The individual components of the pump unit, i.e., body, dome, and diaphragm, are constructed separately, and the two ventricles of the pump are then bound together with Dacron embedded in Silastic, whereas the diaphragm is made of 0.030 Silastic No. 372 pressed into reticular Dacron to give a total thickness of about 0.045 inch. Molding of this diaphragm in a systolic position (reverse type), rather than the usual diastolic position, reduces stretching of the Silastic at the flexion area when the pneumatic chamber is under pressure.

For maximal durability, the diaphragm must be as thin as possible, to reduce compression and tension of the material. This requirement is complicated by the necessity for material of sufficient strength to withstand the tension exerted on it during normal use.

The durability of the diaphragm depends on other criteria as well, such as a large radius of curvature in the region of flexion, which can be achieved by use of fairly large radius shoulders to capture the diaphragm and limit its excursion. In addition, a fairly uniform thickness of the diaphragm will help eliminate concentration of stress.

The diaphragm is attached to the pump unit by a modified "O" ring, which is molded into the rim of the diaphragm and which not only anchors the diaphragm but also seals the halves of the pump.

The external energizing unit is connected to the intrapericardial pumps by Silastic tubing (5 mm internal diameter) covered with special Dacron. In our previous laboratory and clinical use of the left ventricular bypass pumps, we observed that attachment of surrounding tissue takes place in percutaneous leads covered with

Dacron and that later fibrocytes become embedded in this lining to eliminate sinus tract formation.

The dual ventricle power unit (FIGS. 5 and 6), a major feature of the present invention, has two major subsystems: the pneumatic pressure sources and the monitor and control unit. The two pneumatic power units, each with a motor-driven pump, generate the pressure and vacuum necessary for pulsing the prosthesis. Each of the pneumatic pressure sources consists of a compressor 40, a pressure (ejection pressure) regulator, a vacuum (filling vacuum) regulator, a pressure gauge, a vacuum gauge, a three-way solenoid pilot valve, and a pneumatic transfer valve 42. In operation, the ejection pressure and the filling vacuum are connected alternately to the output line by the pneumatic transfer valve. The transfer valve 42 is controlled in the monitor and control unit. The magnitudes of the pressure and vacuum are set manually with the two regulators and are monitored on the precision gauges. Pressure (0-250 mm Hg) and vacuum (0-50 mm Hg) can be adjusted instantaneously by the regulators. A $\frac{1}{2}$ hp motor powers the pump in each unit, which requires about 345 va at 115 v 60 hz. The transmitting gas is carbon dioxide. Pulse rate and systolic duration are controlled in the pulse unit, which also provides for synchronization of the two pneumatic sources.

The monitor and control unit consists of a display oscilloscope, four pressure preamplifiers, and the pulse unit. The pulse timer unit, consisting of electronic rate and duration circuits, controls the solenoid valve which applies pressure and vacuum, alternately, to the prosthesis. The pulse unit incorporates a relaxation oscillator (rate), adjustable over a range of 20 to 120 pulses per minute, and two monostable multivibrators (right and left systolic duration), adjustable over a range of 100 to 900 milliseconds. The two timers are identical, and one power unit can be triggered or synchronized from the other, an essential feature for a biventricular artificial heart, since the rate and time sequence on both sides must be the same. Direct reading thumb-wheel switches are used to set rate and duration. The pulse unit also contains the main power controls for the system.

The operative technic of orthotopic cardiac replacement with the biventricular pump is similar to that used for allotransplantation of the human heart. The heart is excised, a posterior cuff of the left and right atria, atrial septum, ascending aorta, and main pulmonary artery of the biologic heart being left in the recipient. The prosthetic heart is attached to the recipient by a continuous suture, beginning with the atria and proceeding around the septum. The aorta and pulmonary artery are joined to the outflow connector from the left and right ventricles, respectively. Air is evacuated from the chambers, and the pumps are energized.

This apparatus permits varying the control variables including flow, rate, ventricular ejection, atrial pressure, and ventricular pressure.

It was found during experimentation with animals that difficulty was encountered during implantation in suture anastomosis of the atrial flange. The fabrication of the present biventricular pump as two units permits attachment of the atrial flanges of the two ventricles to the interatrial septum and the left and right residual atrial walls. After completion of the suture anastomosis of the pulmonary artery and aorta, the two halves of the

pump are firmly bonded together by a Dacron attachment.

Utilizing the present invention, the pressure in both the left and right ventricular pumps may be varied. In experiments conducted with calves the pressure in the left ventricular pump was maintained at about 150 to 160 mm Hg systolic, and little or no vacuum was required. The systolic duration was 250 milliseconds. The right ventricular pump was energized with a systolic pressure of about 50 mm Hg, and a diastolic pressure of -2 to 4 mm Hg, and the systolic duration was 350 milliseconds. The systolic arterial pressure ranged from 120 to 150 mm Hg, and the diastolic values from 50 to 70 mm Hg. The right atrial pressure was maintained within the range of 4 to 15 cm H₂O, and the left atrial pressure from 3 to 10 mm Hg.

Results of preliminary experiments show that a biventricular pump of the present design can be made to duplicate the function of the two ventricles of the heart.

Satisfactory valvular function is obtained with a number of valves, including those in clinical practice at this time. Wada-Cutter valves were used in the experiments conducted with calves.

It will be obvious to those skilled in the art that various changes may be made without departing from the scope of the invention and the invention is not to be considered limited to what is shown in the drawings and described in the specification.

What is claimed is:

1. A pneumatically controlled biventricular artificial heart for orthotopic implantation comprising:

a left ventricular pump unit and a separate right ventricular pump unit, each said unit being adapted for attachment to the interatrial septum and, respectively, the left and right residual atrial walls of the heart, and for subsequent attachment together;

each said pump unit comprising a ventricle chamber having a connection to an external source of fluid pressure, a movable diaphragm molded in the systolic position extending across said ventricle chamber and thereby defining said ventricle chamber into a variable size blood chamber and a variable size fluid pressure chamber, a blood inlet into each said blood chamber and inflow blood pressure monitor at each said inlet, and a blood outlet from each said blood chamber and an outflow blood valve at each said blood outlet;

control means to operate said left ventricular pump at about 150 - 160 mm. Hg systolic pressure, and separate control means to operate said right ventricular pump at about 50 mm. Hg. systolic pressure and -2 to 4 mm. Hg. diastolic pressure, to pulse said diaphragms from said external power source;

and wherein said blood chambers are lined with a Dacron reticular fabric embedded in silicone rubber to provide a non-porous, impervious layer.

2. A pneumatically controlled biventricular artificial heart for orthotopic implantation comprising:

a left ventricular pump unit and a separate right ventricular pump unit, each said unit being adapted for attachment to the interatrial septum and, respectively, the left and right residual atrial walls of the heart, and for subsequent attachment together;

each said pump unit comprising a ventricle chamber having a connection to an external source of fluid

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pressure, a movable diaphragm molded in systolic position extending across said ventricle chamber and thereby defining said ventricle chamber into a variable size blood chamber and a variable size fluid pressure chamber, a blood inlet into each said blood chamber and inflow blood pressure monitor at each said inlet, and a blood outlet from each said blood chamber and an outflow blood valve at each said blood outlet;
control means adapted to operate said left and right ventricular pumps at different and controlled pressures, said controls acting to control fluid pressure

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to said diaphragm to thereby pulse said diaphragm from said external power source;
and wherein said blood chambers are lined with a Dacron reticular fabric embedded in silicone rubber to provide a non-porous, impervious layer.
3. A device in accordance with claim 2 wherein said control means constitute a first control to operate said left ventricular pump at about 150–160 mm. Hg. systolic pressure and a second control to operate said right ventricular pump at about 50 mm. Hg. systolic pressure.

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