

United States Patent

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[54] **MECHANICAL VENTRICULAR ASSISTANCE CUP**
 11 Claims, 10 Drawing Figs.

[52] U.S. Cl. 128/24.5,
 128/64
 [51] Int. Cl. A61h 29/00
 [50] Field of Search 128/24,
 24.2, 24.5, 44, 64

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ABSTRACT: An improved mechanical ventricular assistance cup for assisting a heart in the performance of its pumping operations or for aiding the heart in achieving normal pumping rhythm, which cup assembly is provided with a semiflexible or inflatable powder shell to reduce the size of the incision required for implanting the mechanical pump and further being comprised of constituent materials which render the cup effectively indestructible, make the cup compatible with blood and body tissue and further act to provide a sturdier cup structure.

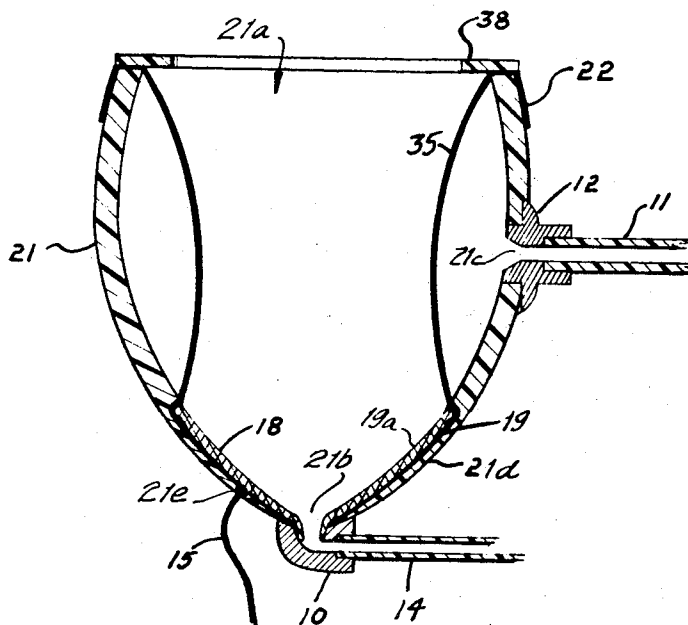


FIG. 1

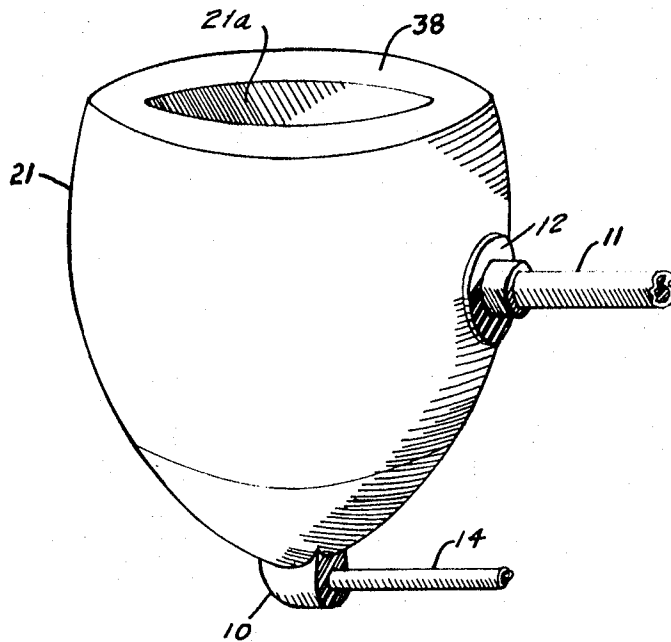
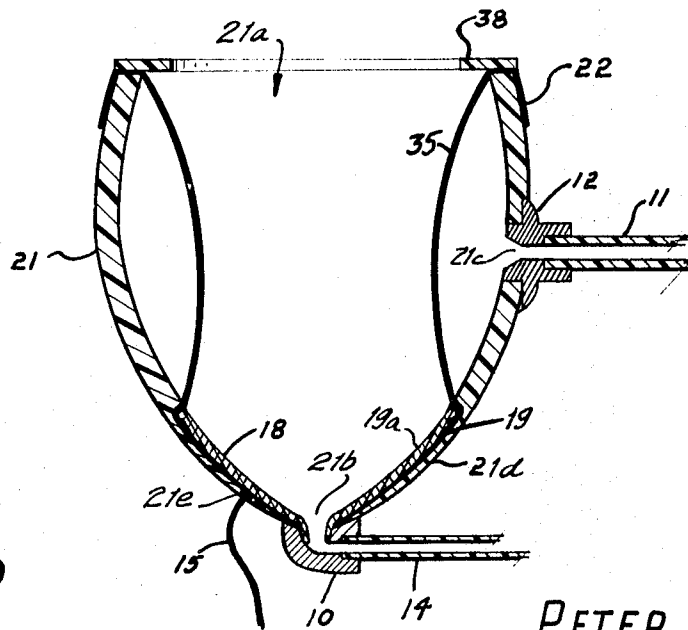


FIG. 2



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FIG. 3

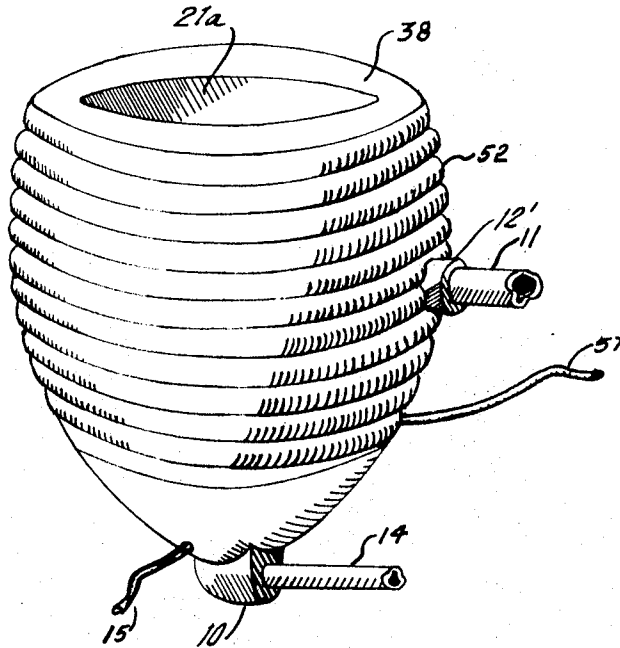
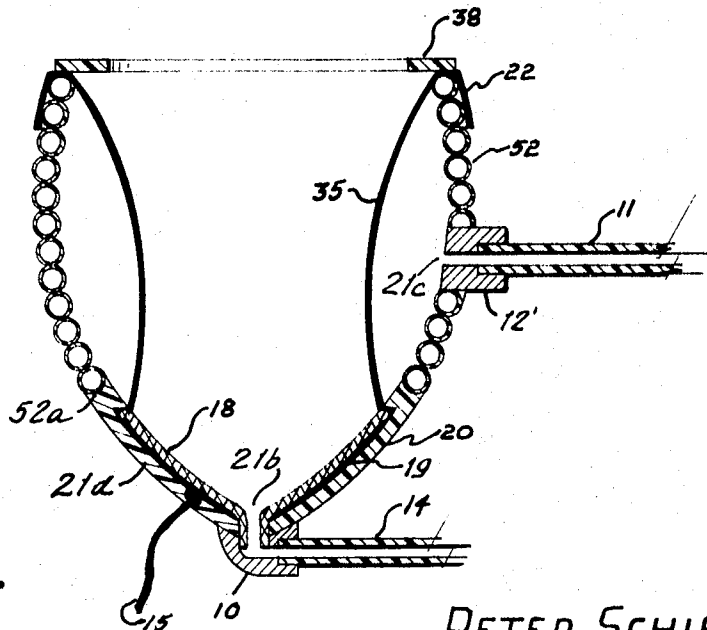


FIG. 4



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FIG. 5.

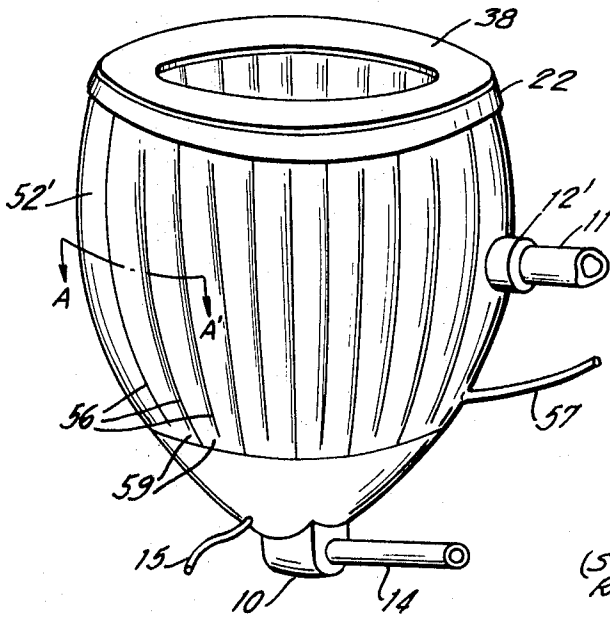


FIG. 6.

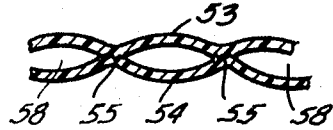


FIG. 7.

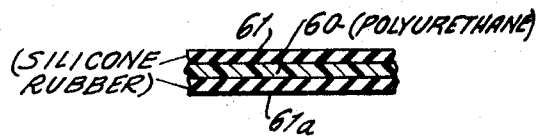


FIG. 8.

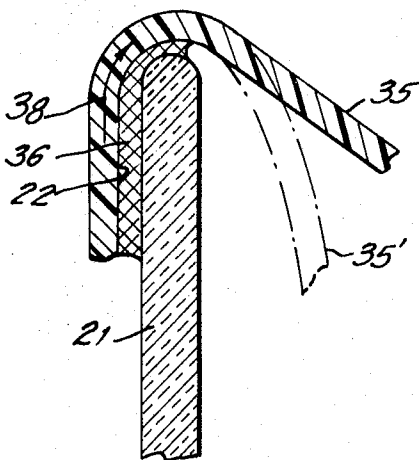


FIG. 8a.

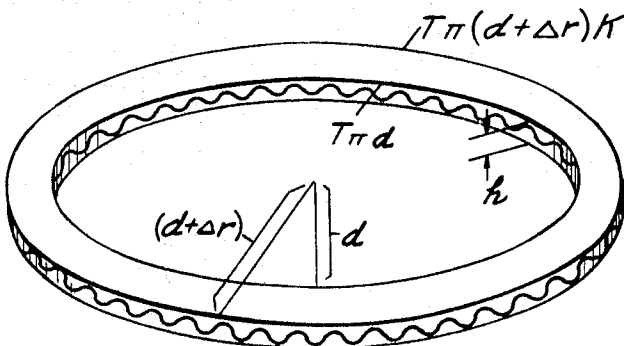
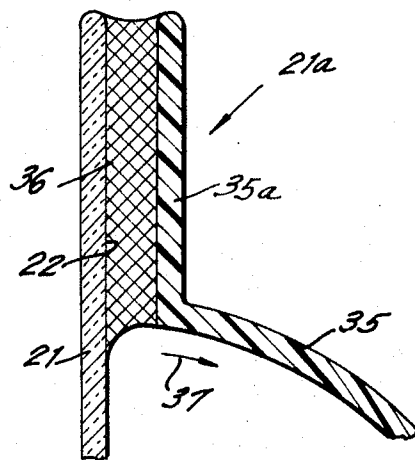


FIG. 7.

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MECHANICAL VENTRICULAR ASSISTANCE CUP

Conventional mechanical ventricular assistance cups, for example, of the type described in copending application Ser. No. 785,652, filed Dec. 20, 1968 are normally comprised of a rigid shell or cup member having a large opening for receiving and positioning the heart therein and at least first and second ports for applying negative pressure and pulsatile pressure, respectively, to retain the heart within the cup and to provide assistive pumping action. When mechanical ventricular assistance cups of this general type are employed, the rigid shell structure requires a relatively large surgical incision to be made in the patient in order to insert and position the cup assembly around the ventricles of the heart. In addition thereto, it is frequently desirable to implant such a circulator assistance cup for long periods of time and have the cup remain in a dormant state around the heart during its implantation period until it becomes necessary to mechanically activate the cup so as to support any temporary or long term inadequacy of the natural heart pumping function. In such instances, the rigid assistance cup severely impairs the natural heart function when the assistance cup is not mechanically activated.

The invention is characterized by providing a mechanical ventricular assistance cup assembly which is made more readily insertable through a relatively small surgical incision by the provision of a semiflexible outer shell. In addition, the use of an inflatable outer shell as one alternative embodiment advantageously adapts the cup for long term implantations wherein the cup may remain dormant and in an unimpairing state until it is inflated for mechanical assistance.

BACKGROUND

This invention relates to improvements in mechanical ventricular assistance so as to yield a more flexible, versatile and effectively indestructible cup assembly. Mechanical ventricular assistance may generally be utilized to provide either constant short term circulatory support or partial periodic long-term circulatory support.

When mechanical ventricular assistance devices are used in either of the above-mentioned modes, it is desirable to be able to implant the device with a surgical incision of minimal size. In order to reduce the size of the surgical incision, a semiflexible cup shell is utilized, which shell is of sufficient rigidity to aid in mechanical assistance during the diastole cycle and yet be manually compressible for insertion of the cup through a small surgical opening. In addition, the cup has a construction which permits recording of an electrocardiogram in spite of the electrical insulating properties of the cup as well as providing long-term reliability as a result of its unique mechanical design.

If such as cup assembly is utilized in a partial circulatory support or in a periodic long-term circulatory support mode, a rigid shell would severely interfere with the natural pumping of the heart such as, for example, in cases where the heart, when enlarged, would attempt to increase its size beyond the size of the rigid cup and thereby be restrained by the cup. As a result thereof, the cup shell is formed of a flexible material and is of such a nature, when dormant, as to be similar to the sack or pericardium which normally surrounds the heart. Upon demand, the sacklike assistance device must be capable of being made rigid so that it will support not only the systole action, but also the diastole or filling action of the ventricles.

The present invention is comprised of a mechanical ventricular assistance device having a flexible cup shell with the first large opening provided for receiving the ventricles of the heart. A second opening provided at or near the apex of the cup is adapted to receive a negative pressure of an amplitude sufficient to retain the heart within the cup at least during those periods in which the mechanical ventricular assistance device is being activated.

A flexible shell or membrane is positioned within the interior of the cup and is sealed about the margin of the cup large opening and in the region of the opening located near the apex

of the cup so as to form a hollow enclosure which communicates with a third cup opening for receiving alternating positive and negative (pulsatile) pressure to alternately expand and contract the flexible membrane and thereby impart a pumping action to the heart ventricles.

A conductive member positioned within the interior of the cup and adapted to engage the heart ventricles is electrically connected through a suitable lead to enable electrocardiograms of the heart action to be taken when the cup is either in its dormant or active state.

The flexibility of the cup shell permits it to be manually squeezed or contracted together so as to reduce its overall size during insertion and thereby reduce the size of the incision required for insertion.

The flexible membrane is preferably formed of a material having a high tensile strength so as to be capable of being easily collapsed while being substantially incapable of being stretched. The flexible membrane is preferably secured within the interior of the cup in the region of the apex by suitable adhesive means and is sandwiched between the metallic electrode and the semiflexible cup shell. The remaining seal between the flexible diaphragm and the cup is obtained through the use of an adhesive material which adheres a marginal portion of the flexible membrane along the marginal exterior surface of the cup shell in the region of the cup shell large opening so as to eliminate tearing stresses at the seals between shell and membrane and causing the flexible membrane to experience only tensile or pulling stresses. The use of a flexible membrane having a high tensile strength renders the shell structure substantially indestructible due to the nature of the seals employed.

The cup shell may alternatively be formed of a ribbed inflatable structure having a plurality of internally inflatable chambers preferably communicating with one another for the receipt of air pressure therein so as to form a substantially rigid shell structure when inflated and a highly flexible shell structure when deflated and in the dormant state. This structure also serves to minimize the size of the surgical incision required during implantation of the device.

It is therefore one object of the present invention to provide a mechanical ventricular assistance cup for assisting a heart in the performance of its pumping operations for aiding the heart in achieving normal pumping rhythm.

Another object of the present invention is to provide a novel mechanical ventricular assistance assembly having a cup shell which is flexible and inflatable to facilitate implantation within the body of a patient and necessitating only a minimal size incision for insertion thereof.

Still another object of the present invention is to provide a novel mechanical ventricular assistance assembly having a cup shell which is flexible and inflatable to facilitate implantation within the body of a patient and necessitating only a minimal size incision for insertion thereof and whereby the flexible membrane of the assembly which assists in the pumping action is formed of materials and is of a design such as to render the cup totally compatible with body tissue and substantially indestructible.

These as well as other objects of the present invention will become apparent when reading the accompanying description and drawings in which:

FIG. 1 is a perspective view showing one mechanical ventricular assistance cup assembly designed in accordance with the principles of the present invention.

FIG. 2 is a sectional view of the assembly shown in FIG. 1.

FIG. 3 is a perspective view of a cup assembly showing another preferred embodiment of the invention.

FIG. 4 is a sectional view of the cup assembly of FIG. 3.

FIG. 5 is a perspective view showing another preferred embodiment of the cup assembly of the present invention.

FIG. 6 is a sectional view of a portion of the cup assembly of FIG. 5 looking in the direction of arrows A-A'.

FIG. 7 is a perspective view of a single tubular, inflated ring portion of the assembly of FIG. 3 useful in describing the effectiveness of the cup assembly shown therein.

FIG. 8 shows a portion of the cup assembly of FIG. 2, for example, in detail for purposes of explaining the structural advantages of the invention.

FIG. 8a shows a detailed sectional view of a portion of a conventional cup assembly for purposes of further explaining the advantages of the cup structure of the present invention.

FIG. 9 shows a sectional view of a portion of the flexible membrane which may be employed in the present invention.

FIG. 1 illustrates a perspective view of a mechanical ventricular assistance cup. The assembly is comprised of a semiflexible cup shell 21 which may, for example, be formed of a rubber or plastic material having a fibrous matrix so as to prevent the cup material from being stretched while being yieldable and capable of being bent or contracted. A large opening 21a is provided at the top end of the cup shell 21 as designated by numeral 21a, and is adapted to receive the ventricles of the heart. The apex of the cup is provided with an opening, as shown best in FIG. 2, communicating with a fitting 10 which acts to secure a hollow tubular member 14 to the apex opening of the cup. A sustained vacuum or negative holding pressure is applied through tube 14 to fitting 10 to retain the ventricles of the heart within the cup interior. Pulsatile (i.e. alternating positive and negative) pumping pressures are applied through a hollow tubular member 11 and a fitting 12 to an opening provided intermediate the openings 21a and 21b. This opening 21c, which is provided along one surface of the cup, communicates with an enclosed interior volume to be more fully described. A lip member 38 maintains a seal between the cup assembly and the AV groove, not shown, of the heart.

FIG. 2 shows the internal structure of the cup assembly in greater detail and includes an electrode member adapted to permit electrocardiogram recording, fibrillation and defibrillation in the manner set forth in detail, for example, in copending application Ser. No. 785,652, filed Dec. 20, 1968. For example, FIG. 2 of this copending application shows the particular pressure sources employed for sustaining the heart within the cup and for providing the assistive mechanical pumping action.

The cup assembly further incorporates a flexible shell or membrane 35 having a construction which insures against the possible bursting of the membrane due to weaknesses in the design or material of the liner. The lip 38 surrounding the large opening 21a of the cup is secured to liner 35 such as, for example, by a heating-sealing or by a suitable adhesive. Liner 35 extends at its upper end about the margin of the cup defining opening 21a and the marginal portion of the liner extends downwardly along the outer surface of the cup and is secured to the marginal exterior portion of the cup 21 immediately adjacent opening 21a. Liner 35 is preferably cemented by a suitable cement or adhesive applied at 22.

Liner, or membrane, 35 is further cemented in the region of the apex of the cup wherein one surface of liner 35 is cemented at 19 to the portion 21d of reduced cup thickness and is further cemented in the region 19a to the convex surface of stainless steel electrode 18 so that the liner 35 is "sandwiched" between electrode 18 and the reduced thickness portion 21d of cup 21. A wire 15 is electrically connected to the stainless steel electrode 18 and extends through a suitable opening 21e provided in the reduced thickness portion 21d of cup 21 for connection to peripheral circuitry. For example, this electrode may be employed to couple the signals detected from the heart ventricle to an electrocardiogram. As was previously mentioned, the material of cup shell 21 is preferably of flexible nonstretchable material which may be, for example, a plastic material or a combination of a plastic or rubber material in conjunction with a fiberlike matrix embedded therein.

In operation, the negative pressure applied through tubular member 14 retains the heart ventricles within the cup assembly. Alternating positive and negative pressure pulses applied through tubular member 11 cause the flexible membrane 35 to alternately expand in the manner shown in FIG. 2 and contract so as to move closer to the interior surface of cup 21,

thereby assisting the heart in the performance of its pumping action.

Another preferred embodiment of the present invention is shown in FIGS. 3 and 4 wherein the inflatable shell structure is comprised of a continuously helically wound tubular coil 52. The coil 52 forms the outer shell of the cup and is joined at its lower edge 52a to a solid, substantially rigid cup portion 21d. It should be noted that the bottom portion of the cup assembly is substantially identical to that shown in FIG. 2 wherein like elements have been designated by like numerals. A tubular member 57 of small diameter is connected to the coiled tubular structure 52 and serves to selectively either inflate or deflate coiled section 52 to form a rigid cup structure. In cases where the structure is deflated, the upper shell portion may lie dormant when implanted into the body of a patient in cases where the pumping action of the patient is satisfactory and requires no mechanical pumping assistance.

The sectional view of FIG. 3, shown in FIG. 4, depicts the cup lip member 38 as being bonded to the exterior surface of liner 35 which is stretched about the marginal exterior portion of the tubular coil 52 in a manner similar to that shown in FIG. 2. The liner is cemented in the region 22 which comprises the marginal exterior surface of the outer cup shell immediately surrounding opening 21a. Adjacent coils of elongated helically coiled tube 52 are preferably cemented to one another by a suitable adhesive or alternatively may be heat-sealed to one another.

The design principles employed in the attachment of liner 35 in FIGS. 1 through 4 provide extremely high tensile strength and substantially eliminate any tear stresses in the structure in a manner to be more fully described.

FIG. 8a shows a sectional view of an upper cup portion of a conventional cup assembly such as, for example, of the type described in the above-mentioned application Ser. No. 785,652. As shown in FIG. 8a, the liner or membrane 35 is joined to the upper marginal interior surface portion 22a of cup 22, which marginal portion is immediately adjacent the large cup opening 21a. The portion 35a of membrane 35 is bonded to marginal portion 22a of the rigid glass cup by a suitable adhesive 36. Assuming that a membrane 35 of high tensile strength is employed, the membrane itself, although bendable, will undergo almost no stretching. Thus, when the hollow interior region defined by membrane 35 and cup 21 is filled with a positive pressure pulse, the high-tensile strength of the membrane places a strong tear stress upon the bonding cement 36, causing the liner portion 35a to be pulled away from glass shell 22 in the direction substantially as shown by arrow 37. The application of repeated positive pressure pulses over prolonged periods of time will weaken the bonding agent and thereby tear the membrane away from marginal portion 22a of the cup shell.

FIG. 8 shows the upper marginal portion of the cup structures of FIGS. 2 or 4, for example, wherein the membrane 35 formed of a material having high-tensile strength extends upwardly over the lip of the cup shell and downwardly along its outer marginal portion where it is bonded in the region 22 by a suitable bonding cement 36. Dotted line portion 35' shows the membrane in the collapsed state. When a positive pressure pulse is applied through tubular member 11, the membrane moves to the expanded position shown by the solid line portion 35. Due to the high tensile strength of the membrane, substantially no tear stress is placed upon the bond between the membrane and the liner. Alternatively, the tensile stress as represented by arrow 38a is distributed substantially equally over the entire bond between membrane 35 and cup 21. Thus, even after repeated application of positive pressure pulses over prolonged periods of time, the bond between liner and shell will be unaffected, yielding a substantially indestructible structure.

In a similar manner, the "sandwiching" of the bottom portion of liner 35 between electrode 18 and reduced thickness shell portion 21d (by a suitable bonding cement) similarly distributes the pulling stress substantially equally along the length

of the membrane portion sandwiched between electrode 18 and shell portion 21d so as to provide a substantially indestructible structure in the apex region of the cup.

The flexible characteristics of either shell 21 of FIG. 2 or coiled shell 52 of FIG. 4 permits the cup to be squeezed (for example, by the hand) so as to be inserted through a relatively small surgical incision. If desired, the fitting 12 shown in FIGS. 1 through 4 may be replaced by a "right-angle" fitting of the type shown by fitting 10 of FIGS. 1 through 4 to further reduce the amount of clearance required for insertion and implantation into the body of a patient. Upon demand, the cup shown in FIGS. 3 and 4 may be made rigid by the injection of a high-pressure pulse applied through tube 57. Alternatively, the cup shown in FIGS. 3 and 4 may be caused to remain in a dormant state by removal of the pressure pulse, thereby deflating the coiled cup section. When in a dormant state, the cup assembly provides minimal interference to a heart unassisted by the mechanical pumping action.

FIG. 7 serves to explain the reason why the coiled cup assembly will remain rigid when in the inflated condition. FIG. 7 shows in schematic fashion one full turn of the coiled cup 52. When inflated, the air pressure within each coil will be substantially equally distributed throughout. Thus, the pressure along the interior surface of the coil shown in FIG. 7 will be equal to Khd , where d is equal to the diameter of the coil shown in FIG. 7; h is equal to the height of the interior surface of the coil (assuming the coil to be of a square cross-sectional configuration for purposes of simplifying the description set forth herein); and where K is equal to a constant. The pressure along the outer wall of the single loop of coil is equal to $Kh(d+\Delta r)$ wherein $(d+\Delta r)$ is equal to the diameter of the outer wall of the single loop coil. Since the surface area of the outer wall of the single loop of coil is greater than the surface area of the inner wall of the single loop of coil (due to the increased diameter $d+\Delta r$), the equally distributed air pressure will cause the coiled shell portion 52 to assume the shape as shown best in FIG. 3, which structure will remain substantially rigid when inflated.

FIGS. 5 and 6 show another alternative embodiment of the present invention wherein the helically coiled portion of FIG. 3 is replaced by a vertically ribbed inflatable portion 52' which is comprised of first and second plastic sheets 53 and 54 (shown best in FIG. 6) which are joined by a suitable adhesive 55 at regularly spaced intervals to form the vertical ribs 56. Inflating of the structure may occur in a manner similar to that shown in FIGS. 3 and 4 wherein a positive pressure pulse is applied through narrow diameter tube 57 to fill the inflatable structure with air. Each of the hollow interior portions 58 may be joined to adjacent hollow interior portions by providing narrow communicating passageways 59 arranged in alternating fashion near the bottom edge of the structure 52' and providing similar narrow communicating portions (not shown) near the top edge of structure 52' interspersed with portions 59 so that a positive pressure pulse applied through narrow diameter tube 57 will pass through each of the hollow interior sections 58 in a serpentine fashion, until the air pressure is equally distributed throughout interior hollow sections 58. Although the ribs 56 are shown as being vertically aligned in FIG. 5, it should be understood that these ribs may be arranged in horizontal fashion similar to the coiled tubular arrangement shown in FIG. 3. Whether vertically or horizontally aligned ribs are employed, the shell structure 52' will form a substantially rigid structure when inflated for the reasons as set forth in connection with the description of FIG. 7. Thus, the structure of FIG. 5 is equally as versatile as that shown in FIGS. 1 and 3 insofar as being capable of being retained in either a dormant or active state while implanted within a patient.

The flexible membrane 35 shown in the present invention has a further advantage of the membrane structure 35 employed in conventional cup assemblies (for example, of the type described in copending application 785,652) in that the liner, by being bonded to the outside of the cup, increases the

effective pumping area of the diaphragm as compared with conventional design, which has the liner bonded to the inside of the shell just below the cup lip 38. For this reason, higher pumping volumes and pressures are obtainable with the structure described herein.

FIG. 9 shows one preferred embodiment for the cup liner 35 wherein the liner may be comprised of a sheet of material 60 having high-tensile strength. Some materials which have been found advantageous for use in this application are polyurethane which has a tensile strength of approximately 7,000 p.s.i. or Mylar which has a tensile strength of about 40,000 p.s.i. Such materials are substantially nonstretchable when employed as a membrane in the present invention and are, therefore, practically indestructible. However, these materials, if sharply bent or creased, will deform along the crease and possibly develop a weakness along the crease which may be caused to tear after prolonged use essentially due to the repeated application of positive and negative pressure pulses to the cup assembly.

In addition thereto, it is most advantageous to provide a cup assembly whose materials are most favorably compatible with body tissue and blood cells. It has been found that silicone rubber exhibits excellent compatibility with body tissue and blood. However, the tensile strength of silicone rubber is of the order of 400 p.s.i., making it highly stretchable as compared with polyurethane or Mylar. Thus, in order to make most advantageous use of these materials, the sheet 60 of high-tensile strength material shown in FIG. 9 is coated along both surfaces thereof by silicone rubber layers 61 and 61a, which coating process may be performed, for example, by dipping the high-tensile strength sheet 60 into a bath of silicon rubber in liquid form contained in an enclosure having a moisture-free atmosphere. The dipping operation may be so timed and so performed so as to preferably form a coating of approximately 3 mils thickness on a sheet of high-tensile strength material having a thickness of the order of 0.5 to 1 mil. Likewise, the cup assembly 22 or 52 may be dipped in the liquid silicone rubber to provide a similar coating thereon. Alternative approaches which may be taken consist either of coating the membrane 35 on both sides thereof, as shown in FIG. 9, and then bonding the membrane to the cup shell, or, alternatively, initially bonding the cup membrane to the cup shell and then dipping the entire structure within a liquid bath of silicone rubber. The latter method can be seen to provide a silicone rubber coating on only the exposed surface of the membrane which has been found to be satisfactory, since only this surface will be exposed to body tissue. Coating the entire exposed surface of the cup shell 22 or 52 renders it compatible with body tissue. The lip 38 of the shell structure may also be formed of silicone rubber of a thickness of the order of 40 mils. Alternatively, the membrane 35 may be formed exclusively of silicone rubber of a thickness of the order to 30 mils.

It can be seen from the foregoing description that the present invention provides a novel mechanical ventricular assistance cup assembly which is capable of being contracted when implanted within the body of a patient to permit incisions of minimal size for insertion thereof wherein the cup assembly may lie dormant for prolonged periods of time when implanted so as to have no impairing effect upon normal heart pumping action, and may further be inflated to form a substantially rigid cup structure upon demand when assistive mechanical pumping action is desired.

Although this invention has been described with respect to its preferred embodiments, it should be understood that many variations and modifications will now be obvious to those skilled in the art, and it is preferred, therefore, that the invention be limited not by the specific disclosure herein but only by the appended claims.

The embodiments of the invention in which an exclusive privilege or property is claimed are defined as follows:

1. A cup assembly for use in applying mechanical assistive pumping action to the heart comprising:

a substantially flexible nonstretchable cup-shaped member having a configuration generally conforming to the configuration of at least a portion of the heart;

said cup having a first substantially large diameter opening for receiving a portion of the heart and positioning said portion within the interior of the cup, and having second and third small diameter openings;

at least one of said second and third openings being located at the apex of said cup which is furthest removed from said first opening and the remaining one of said second and third openings being located along the surface of said cup at a position intermediate said first opening and the opening at the apex of said cup;

a flexible liner being positioned within said cup and having a configuration substantially conforming to the interior of said cup when the liner is in an unstressed condition;

a first continuous marginal edge of said liner being positioned against the marginal exterior surface portion of said cup which surrounds said first opening;

a second continuous marginal portion of said liner being positioned against the interior surface of said cup and adjacent to and surrounding the opening in said cup provided in the cup apex;

bonding means for securing the continuous marginal edges of said liner to the exterior and interior cup surfaces, respectively, located in the region of said first opening and the opening located in the cup apex;

said liner cooperating with said cup to form a hollow interior region communicating with said remaining one of said second and third openings, which hollow region is adapted to receive pulsatile pressure to cause the liner to expand and contract and thereby assist the heart in the performance of its pumping activity; said flexible cup being contractable to reduce the cup size when implanted in the body of a patient to minimize the size of the required incision.

2. A device of the type described in claim 1 further comprising a metallic electrode positioned within the interior of the cup in the region of the cup apex;

means for bonding said electrode to the marginal portion of said liner surrounding the cup apex.

3. The device of claim 1 further comprising a tube con-

nected to the opening provided in the apex of the cup for communicating a sustained negative pressure thereto for retaining said heart portion within the cup.

4. The device of claim 1 wherein a major portion of said cup extending between said electrode and said first opening is comprised of an inflatable structure comprising inner and outer flexible inelastic members defining a hollow interior;

a narrow diameter tubular member being connected to said inflatable structure to fill said inflatable structure with air and thereby form a substantially rigid cup configuration when mechanical assistive pumping action is required.

5. The device of claim 4 wherein said inflatable structure is comprised of an elongated tubular member being coiled to form the configuration of the cup portion extending between said electrode and said first opening;

bonding means for joining adjacent exterior surface portions of said coiled tubular member.

6. The device of claim 4 wherein said inflatable structure is comprised of first and second substantially flexible, nonstretchable sheets of material extending between said electrode and said first opening;

bonding means for joining said first and second sheets at spaced intervals to form spaced, substantially parallel ribs defining elongated hollow interior portions communicating with one another to receive air under pressure from said narrow diameter tubular member and thereby form an inflated substantially rigid cuplike configuration generally conforming to the shape of the portion of the heart positioned therein.

7. The device of claim 6 wherein said ribs extend in a direction transverse to the edge of the cup surrounding said first opening.

8. The device of claim 6 wherein said ribs extend in a direction substantially parallel to the edge of the cup surrounding said first opening to form a singular helically shaped elongated hollow interior portion.

9. The device of claim 1 wherein said liner material is a sheet of flexible material having high-tensile strength.

10. The device of claim 9 wherein the surface of said sheet making contact with the heart is coated with silicone rubber.

11. The device of claim 1 wherein all of the exposed surface of said device is coated with silicon rubber.

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