

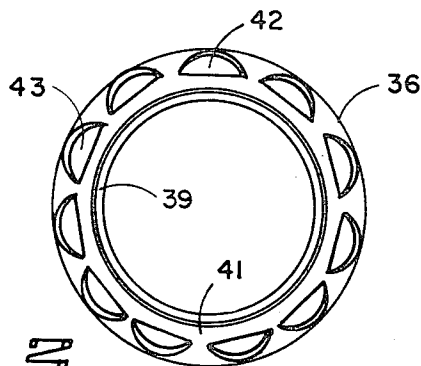
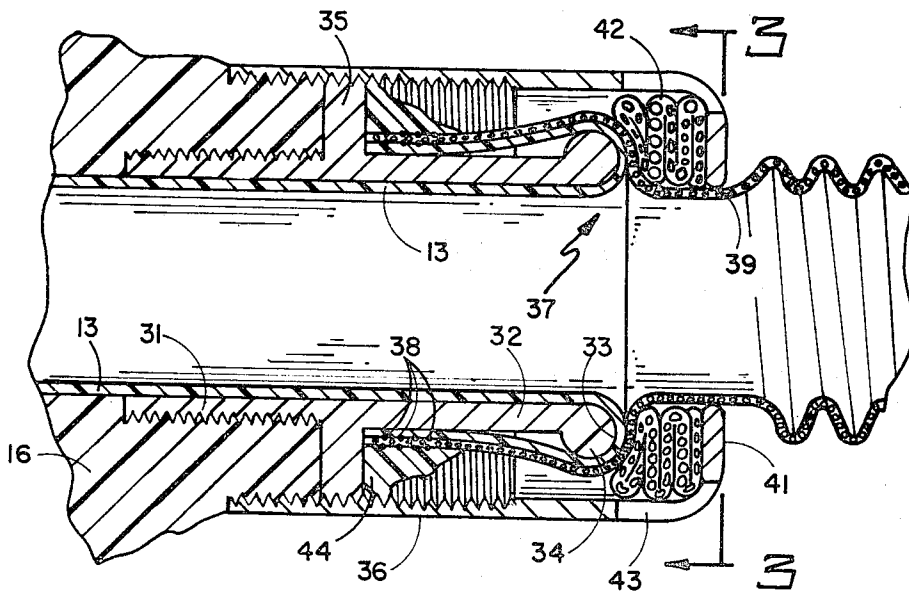
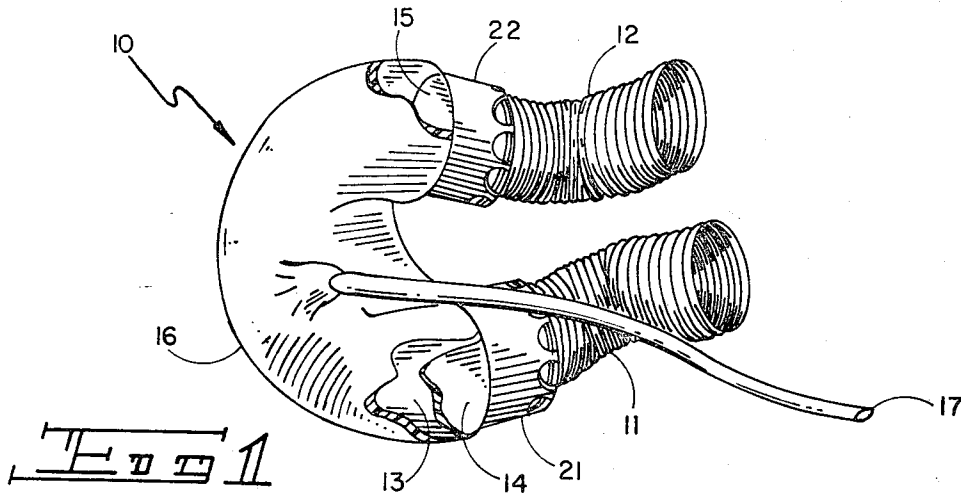
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CONNECTOR FOR IMPLANTABLE PROSTHETIC DEVICES

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1

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CONNECTOR FOR IMPLANTABLE PROSTHETIC DEVICES

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This invention relates to implantable prosthetic devices and more particularly to means for connecting artificial graft sections and the like to implantable prosthetic devices such as blood pumps.

The advent of open heart surgery has presented to the medical profession the opportunity of repairing damaged or diseased hearts of individuals and where appropriate using circulatory assist systems in individuals who without such correction and/or systems face premature death. Many devices are involved in this type of surgery. For example, one circulatory assist system may comprise an auxiliary ventricle or valveless blood pump connected across the arch of the aorta and driven by fluid pressure in response to electronic signals (QRS wave) provided by the heart itself. By operating the auxiliary ventricle in proper phase, the systolic pressure in the left heart can be reduced and the systemic circulation can be maintained with a substantially reduced work load on the heart muscle. In addition, the operation of the auxiliary ventricle has the effect of shifting the phase of the normal systolic pressure so that this pressure appears in the aorta at a time when the left ventricle is relaxed. Assuming competence of the normal aortic valve, one then has an increased perfusion pressure available to the coronary arteries. It is believed that such an increase in coronary perfusion, together with a reduction in the effort required from the heart, should be effective in a number of cases of cardiac insufficiency.

As may be seen from the above, one important component of circulatory assist systems is a pump that either assumes the heart's role of pumping blood or which reduces the work load of the heart muscle. By using heart pump equipment for extended periods of time, it is contemplated that the equipment may be utilized for regional perfusions in therapeutic treatment of the heart. Still other use of the equipment will be to provide circulation of blood through an artificial organ such as an artificial kidney. In connection with this function of the apparatus, it should be noted that many research institutions at this time are concentrating their research activities on providing artificial counterparts of other organs and whenever such application requires circulation, the present invention may be utilized.

Implantable prior art pulsatile pumps usually consist of a flexible bulb or ventricle squeezed by pressurized fluids and coupled to one or more blood vessels such as arteries or veins. Generally, arterial graft sections connect the bulb to the circulatory system. These arterial graft sections are generally of the woven Teflon-type or Dacron-type employed in the insertion of arterial grafts and the replacement of damaged sections of an artery.

Heretofore in such prior art pumps, the manner in which the pump was fabricated resulted in one or more of the following disadvantages: Minimum contact surface between the tissue which grows on the graft material and the bulb on which tissue will not grow, failure of the bulb and/or unsatisfactory growth of tissue at the junction of the graft material and the bulb. Unsatisfactory growth of tissue is believed to include insufficient blood flow in the tissue after it has formed, growth in such a manner as to result in injury to the blood (he-

2

molysis) and/or free forming clots or clots which break off and are carried away by the blood stream. Accordingly, a feature of the present invention is the provision of a connector in an implantable prosthetic device connected to the circulatory system which has improved clotting characteristics.

Another feature of the invention is the provision of a connector which provides maximum area of contact between tissue growth in an arterial graft section and a material acceptable to the blood but on which tissue will not grow.

Another feature of the invention is the provision of a connector which not only provides maximum area of contact between tissue growth in an arterial graft section and a material acceptable to the blood but on which tissue will not grow, but which also permits normal blood flow in and through such tissue growth after it has formed.

A further feature of the invention is the provision of a connector which increases the life and dependability of a connection between a graft section and an elastomer material.

The novel features that are considered characteristic of the present invention are set forth in the appended claims; the invention itself, however, both as to its organization and method of operation together with additional objects and advantages thereof, will best be understood from the description of a specific embodiment when read in conjunction with the accompanying drawings, in which:

FIGURE 1 is a perspective view with parts broken away of an implantable prosthetic device comprising an auxiliary ventricle incorporating the present invention;

FIGURE 2 is a side view with parts broken away of a connector in accordance with the present invention; and

FIGURE 3 is an end view taken on line 3—3 of FIGURE 2.

Directing attention now to FIGURE 1, there is shown by way of example a valveless auxiliary ventricle generally designated by the numeral 10, incorporating the present invention. While the present invention will, for convenience, be described in connection with an auxiliary ventricle, it is to be understood that it may be used in conjunction with prosthetic devices, plastic tubes and the like adapted for connection to the circulatory system.

The auxiliary ventricle as shown in FIGURE 1 is adapted for implantation within a living body. Arterial graft sections 11 and 12 are attached to the open ends of the auxiliary ventricle by connector means more fully described hereinafter. For the type of auxiliary ventricle shown, the arterial graft sections 11 and 12 generally are surgically attached to the aorta (not shown) in conventional manner. The arterial graft sections may be of the well known woven Teflon-type employed in the insertion of arterial grafts and the replacement of damaged sections of an artery. Edwards Seamless Arterial Graft manufactured by the United States Catheter and Instrument Company have been found to be satisfactory.

The auxiliary ventricle is comprised of an elongated and compliant bulb 13 having two openings 14 and 15 to permit blood to freely flow therethrough. The aforementioned arterial graft sections are attached to the auxiliary ventricle at these openings. The bulb may be comprised of a flexible material acceptable to the blood, such as for example Medical Silastic 372 supplied by Dow Corning Corporation, Midland, Mich. The bulb may have a generally ellipsoidal configuration or alternately, have a generally U-shaped configuration as shown in FIGURE 1. The bulb has a capacity sufficient to receive an appreciable fraction of the outflow from the left ventricle

of the heart and is shaped to provide optimum flow conditions and minimum stresses during use.

Surrounding and sealably connected to the bulb 13 at its open ends is a rigid and air tight case 16 including a pressure conduit 17 coupled thereto for transmitting pulses of a fluid or a gas, such as for example oxygen, to the region between the bulb 13 and the case 16. Connector means generally designated by the numerals 21 and 22 attach the arterial graft sections to the auxiliary ventricle. Connector means in accordance with the present invention now to be described in detail attaches the arterial graft sections to the auxiliary ventricle in a new and novel manner and in its preferred embodiment provides an air tight seal between the bulb and the case.

Directing attention now to FIGURES 2 and 3, there is shown a connector in accordance with a preferred embodiment of the present invention comprising a rigid hollow cylindrical inner member 31 sealably attached as by bonding or potting it to the portion of the case 16 surrounding an opening in the bulb 13. The extreme end 32 of the inner member 31 remote from the case 16 is provided with a continuous smooth curved end surface 33 preferably in the form of an outwardly extending lip 34 and intermediate its end portions, the inner member 31 is also provided with an outwardly projecting annular ring 35 threaded to receive a rigid cylindrical outer member 36 more fully described hereinafter. The portion of the bulb defining an open end extends through the inner member 31 and over, around and past the aforementioned curved end surface 33 to form a cuff 37. The cuff 37 is preferably sealably attached to the outer surface of the inner member by both a suitable adhesive and by wrapping and tying it with thread 38 such as Dacron thread or the like adjacent threaded ring 35.

The provision of the cuff 37 formed by the end portion of the bulb disposed over continuously curved end surface 33 is particularly advantageous in that it essentially eliminates the possible of failure of the bulb as by fatigue at or adjacent its junction with the case and/or inner member 31.

Disposed over the cuff 37 formed by the end portion of the bulb is an arterial graft section 39 which is preferably also tied and bonded to the cuff adjacent threaded ring 35. Directing attention now to the cylindrical outer member 36, it will be noted that it surrounds inner member 31 and is adapted for threaded engagement with threaded ring 35 to facilitate assembly of the connector. Integral with that portion of the outer member 36 remote from the case 16 is an inwardly extending ring-like member 41 the radial dimension of which is sufficient to at least substantially cover lip 34 and permit a cloth-like filler material 42 having a large number of interstices, such as for example a short piece of arterial graft section having a diameter slightly greater than that of graft section 39 and comprising several layers, to be gripped between ring 41 and cuff 37. A plurality of openings 43 are provided in the outer member 36 adjacent ring 41 to permit blood to pass from the interior of the arterial graft section to and through the filler material 42 at the junction of the arterial graft section 39 and cuff 37.

The inner and outer members 31 and 36 may be composed of surgically implantable stainless steel, such as for example 303 or 316 stainless steel, dipped in silicone resin prior to assembly to provide a coating of about 1/2 to 1 mil in thickness.

After the arterial graft section 39 has been attached to inner member 31, the filler material 42 preferably comprising several layers is disposed within the outer member at ring 41. The outer member 36 is then slipped over the arterial graft section and threaded onto the inner member 31 to compress the filler material 42 to a point where substantially maximum contact is provided between the filler material 42, ring 41 and that portion of the arterial graft section 39 covering the extreme end of cuff 37. A suitable adhesive 44 such as Silastic may be provided at threaded

ring 35 to provide a seal at this point and to hold ring 36 in place. A high compression connection is neither necessary nor desirable as it will result in excessive restriction of blood flow in and through the filler material and any tissue which subsequently forms in this region. While the number and type of openings 43 provided in outer member 36 is not critical, it is recommended that at least a substantial portion of the outer periphery of the filler material 42 be exposed to permit maximum perfusion of blood through the tissue which subsequently forms in and around the filler material 42.

Having described a preferred embodiment of the invention, what is claimed is:

1. In apparatus for receiving blood from a blood vessel such as an artery or vein in a living body and having a medically inert inner liner exposed to said blood and open at at least one end and a substantially inflexible case surrounding said liner, the combination comprising:

- (a) an arterial graft section;
- (b) connector means attached to said case and surrounding at least part of the portion of said liner defining said open end for attaching said graft section to said case, said connector means surrounding a portion of said graft section and having a plurality of openings adjacent its junction with said graft section; and
- (c) perforate means disposed within said connector means at its junction with said graft section for providing a large number of interstices of a size to promote clotting.

2. In apparatus for receiving blood from a blood vessel such as an artery or vein in a living body and having a medically inert inner liner exposed to said blood and open at at least one end a substantially inflexible case surrounding said liner, the combination comprising:

- (a) perforate cylindrical cloth-like material comprising an arterial graft section;
- (b) cylindrical connector means attached to said case and surrounding the portion of said liner defining said open end for attaching said graft section to said case, said connector means surrounding a portion of said graft section and having a plurality of openings adjacent its junction with said graft section; and
- (c) perforate means disposed within said connector means at its junction with said graft section for providing a large number of interstices of a size to promote clotting, said perforate means comprising a cloth-like material in communication with said openings and said graft section.

3. The combination as defined in claim 2 wherein said connector means includes a rigid cylindrical outer member having a first portion remote from said graft section and a second portion surrounding a portion of said graft section, the end of said second portion remote from said first portion extending inwardly to define a circular surface in contact with said graft section and having a diameter less than that of said first portion, and said openings are disposed adjacent said circular surface.

4. The combination as defined in claim 3 wherein the portion of said liner defining said opening extends through said connector means and between said connector means and said perforate means.

5. In apparatus for receiving blood from a blood vessel such as an artery or vein in a living body including a flexible bulb exposed to said blood and open at at least one end and a substantially inflexible case surrounding said bulb, the combination comprising:

- (a) an arterial graft section; and
- (b) connector means sealably attached to said case and surrounding the portion of said bulb defining said open end for attaching said bulb and said graft section to said case, said connector means being in sealing contact with said bulb and providing a large number of interstices of a size to promote clotting within said connector means adjacent the junction

5

of said connector means and said graft section, said connector means having a plurality of openings adjacent said junction with said graft section whereby blood can pass through said connector means adjacent said junction.

6. In apparatus for receiving blood from a blood vessel such as an artery or vein in a living body and having a medically inert flexible bulb exposed to said blood and open at at least one end and a substantially inflexible case surrounding said bulb, the combination comprising:

- (a) a generally cylindrical arterial graft section;
- (b) cylindrical connector means sealably attached to said case and surrounding the portion of said bulb defining said open end for attaching said bulb and said graft section to said case, said connector means including a cylindrical outer member surrounding an inner member, said inner member being in contact with and surrounding the portion of said bulb defining said opening, said portion of said bulb extending over and around the end of said inner member remote from said case, the end of said outer member remote from said case extending inwardly to define a circular surface and having a plurality of openings adjacent said surface; and
- (c) perforate means carried by said outer member and in communication with said openings and said graft section, said perforate means having a large number of interstices of a size to promote clotting.

7. In apparatus for receiving blood from a blood vessel such as an artery or vein in a living body and having a substantially inflexible case and a medically inert flexible bulb disposed within said case and exposed to said blood, said bulb having at least one portion defining an opening and extending through said case, the combination comprising:

- (a) perforate cloth-like material comprising a generally cylindrical arterial graft section;
- (b) cylindrical connector means attached to said case and surrounding said portion of said bulb defining said opening for attaching said graft section to said case and sealably attaching said bulb to said case, said connector means including a cylindrical outer member surrounding an inner member integral with said case, said inner member being in contact with and surrounding said portion of said bulb defining said opening, said portion of said bulb extending over and around the end of said inner member remote from said case, the end of said outer member remote from said case extending inwardly to define a circular surface spaced from said inner member and having a plurality of openings adjacent said surface; and
- (c) perforate means carried by said outer member and in communication with said openings and said graft section, said perforate means having a large number of interstices of a size to promote clotting.

8. The combination as defined in claim 7 wherein the said end of said inner member defines a smooth curved surface and said bulb is maintained in sealing contact with the outer surface of said inner member.

9. The combination as defined in claim 8 wherein said smooth curved surface defines an outwardly extending lip.

10. The combination as defined in claim 7 wherein said perforate means comprises a cloth-like material disposed between the said portion of said bulb extending

6

around the end of said inner member and said circular surface space from said inner member.

11. The combination as defined in claim 10 wherein said graft section extends between the said perforate means and the said portion of said bulb extending around the end of said inner member.

12. In apparatus for augmenting blood flow from a heart in a living body including a flexible bulb open at both ends and a substantially inflexible case surrounding said bulb intermediate its open ends, the combination comprising:

- (a) a rigid, hollow, cylindrical inner end member sealably attached to respectively each end of said case;
- (b) an outwardly extending lip integral with the extreme end of each said inner member remote from said case, each said lip defining a smooth generally cylindrical surface connecting said inner and outer surfaces of said inner member, the end portions of said bulb extending through said inner members and being disposed over said lips to form a cuff;
- (c) means for sealably attaching the end portions of said bulb to the outer surface of each said inner member rearwardly of said lips;
- (d) an arterial graft section having one end disposed over and surrounding respectively each said cuff;
- (e) a rigid cylindrical outer end member carried by and surrounding each said inner member, the end of said outer member remote from said case extending past said inner member and inwardly to define a smooth circular surface spaced from said inner member and having a plurality of openings adjacent said surface; and
- (f) a plurality of thicknesses of a cloth-like material disposed between said graft sections surrounding said cuffs and said circular surfaces, said cloth-like material having a large number of interstices of a size to promote clotting and being in communication with said openings in said outer members.

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