DISINFECTANT DISPENSING PERCUTANEOUS CONNECTOR

A percutaneous connector having fluid and/or electrical conduit means, the connector being provided with a disinfectant filling site exterior of the skin and connected with a wall passage terminating in openings for dispensing a disinfectant into the subcutaneous region surrounding the connector.

This invention relates to percutaneous connectors and more particularly to percutaneous connectors which allow the application of a disinfectant subcutaneously adjacent the connector.

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 in whom such correction and/or assistance face premature death. Many devices are involved in this type of surgery. For example, one circulatory assist system may comprise an auxiliary ventricle 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, then there will be 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 percutaneous connector for permitting the application of fluid pressure to the auxiliary ventricle and electrical connection of the electronic signals provided by the heart itself to suitable electronic apparatus exterior of the body.

Infection has been a problem when prosthetic devices such as percutaneous connectors permit air to come into contact with regions below the body wall. Any chronically indwelling device provides an open channel (due to incomplete healing around the foreign body) through which bacteria may enter and cause infection. Percutaneous connectors are generally formed of a material that is not only acceptable to body tissue but a material to which tissue will not grow. Accordingly, there invariably exists the aforementioned open channel which, so far as infection is concerned, is a chronically open wound.

Herefore, prior art percutaneous connectors could only be carefully surgically dressed daily with topically applied disinfectants. Accordingly, with such prior art connectors infections deeper than that which can be reached by topically applied disinfectants were not eliminated and often resulted in serious complication that can require removal of the connector or that can end in death, i.e., septicemia, peritonitis, pericarditis, and the like.

In accordance with the present invention, a filling site is provided in the connector exterior of the skin and a passage or passages within the connector allow diffusion of a disinfectant into the subcutaneous region surrounding the connector.

Although the present invention was designed for use with circulatory assist systems as described above, it is to be understood that it is applicable to any application which requires the provision of pulsatile pressure and/or electrical connections within a living body.

It is therefore an object of the present invention to provide an improved percutaneous connector.

Another object of the present invention is to provide a disinfectant dispensing percutaneous connector.

A further object of the present invention is to provide a percutaneous connector adapted to permit a disinfectant to be simply and easily introduced into the subcutaneous region surrounding the connector to reach deep seated infections.

The novel features that are considered characteristic of the 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 following description of a specific embodiment, which read in conjunction with the accompanying drawings, in which:

FIGURE 1 is a vertical view partly in section of a connector incorporating the present invention;

FIGURE 2 is an end view of the metallic coupler shown in FIGURE 1;

FIGURE 3 is a perspective view partly in cross section of the coupler and an end member adapted to be connected thereto; and

FIGURE 4 is a fragmentary sectional view on a greatly enlarged scale showing details of the invention.

Referring now to FIGURE 1, a percutaneous connector generally designated by the numeral 10 and incorporating the present invention is shown comprising a flexible electrically nonconductive tube 11 having a dog-leg like configuration, a plurality of electrical conductors 12, 13 and 14 helically embedded in the wall of the tube, and a metallic coupler 15 more fully described hereinafter sealably attached to the lefthand end of the tube 11 as shown in FIGURE 1 for sealably coupling the tube 11 to a source of pressure (not shown) and coupling the electrical conductors 12-14 to electrical apparatus (also not shown).

Directing attention now to the tube 11, as shown in FIGURE 1, it is comprised of a first end portion 16 adapted to be disposed interior of a living body, a second end portion 17 adapted to be disposed exterior of the body and a middle portion 18 typically normal to the first end portion 16 and interconnecting both end portions 16-17. While the angle between the middle portion 18 and the skin in the final instance will be determined by anatomy and/or medical requirements, this angle should not be a small one. The tube 11 should have a smooth outer surface and be formed of a flexible material which is acceptable to the body, such as Medical Silastic 372 supplied by Dow Corning Corporation, Midland, Mich. A skirt 23 in the form of mesh consisting of a material also acceptable to the body, such as RM-54, Mersilene mesh supplied by Ethicone Incorporated, Somerville, N.J., is bonded to the middle portion 18 of the tube adjacent the first end portion 16 to permit the percutaneous connector to be internally attached to the inner surface of the skin by suturing and subsequent tissue growth through and around the skirt.

Extending upwardly from and at the inner periphery of skirt 23 are several turns of a mesh material 19 identical
to that of skirt 23. The material 19 preferably comprises several turns sewn to skirt 23 and extending upwardly a distance such that the distal periphery of the turns will be disposed below the outer surface of the skin. There should be a sufficient number of turns (three are shown only by way of example in FIGURE 4 but as many as five have been used) that the tissue can grow into and through the turns to help hold the skin as close as possible to portion 18. However, as tissue will not grow or adhere to suitable material for tube 11, such as for example silicon rubber, it will be appreciated that infection can enter the body along portion 18. Tube 11 is also provided with a bulb 20 the interior of which is fully disclosed hereinafter, in communication through a flow passage 22 in the walls of portion 18, with a plurality of small holes 21 opening onto the material 19. The holes 21 are disposed all around that portion of tube 11 covered by material 19 to permit an antisepsic liquid, introduced into the bulb 20 as by a hypodermic syringe, to flow down passage 22 and escape, thereby flushing out and/or destroying pathogenic organisms which might otherwise invade the crevice between portion 18 and the body wall.

A suitable tube may be fabricated in the following manner: A melt-out core holding a stainless steel transition piece mounted on one end is bent in the form of a transition. Thereafter, a sheet of uncured Silastic approximately 0.040 inch thick is wrapped around the core and the enlargement end of the transition piece, all air bubbles are removed and the silicon rubber or Silastic then cured as by heating it in boiling water for approximately one-half hour. Thereafter, the electrical conductors are communally wound in spaced relationship one with another on the cured Silastic beginning at the inner portion 16 of the tube and terminating adjacent the transition piece 24. Suitable electrical conductors may comprise Hc1licable Research Electrodes supplied by General Electric Company, X-ray Department, Milwaukee, Wis. The portion of each electrical conductor disposed within the walls of the tube prior to being embedded, preferably is a straight bare wire as the wall of the tube in addition to functioning as a pressure conduit also provides the necessary electrical insulation for these conductors.

As another way of example, in FIGURE 1 two electrodes 12-13 and one ground wire 14, all of which may have a diameter of approximately 0.015 inch, are provided. In addition to the conductors, an additional smooth wire of a soft material such as copper is also wound on the cured Silastic to form, when it is removed from completed tube 11, fasten the cable 22 in the manner previously described at the junction of portions 17 and 18 and ending at about the point where skirt 23 is to be attached. After the electrical conductors and the aforementioned wire have been wound on and attached at their ends in any suitable manner to the Silastic, a second layer of Silastic is pressed over and between the wires, all air bubbles removed and the Silastic cured in the manner noted hereinabove. Thereafter, a third layer of Silastic is similarly provided to complete fabrication of the tube. After fabrication of the tube or alternately at the time the third layer of Silastic is cured, the mesh skirt 23 may be bonded to the tube in conventional manner. At this point, the melt-out core is no longer required and may be removed in conventional manner as by heating the tube to the required temperature. However, it is preferable that the soft wire be removed first to reduce the possibility of damage to tube 11 during removal.

As an example of how to form the flow passage 22, bulb 20 is formed to provide an integral covering over the upper opening of the flow passage 22 and the lower opening of the flow passage is sealed. Openings 21 may be formed in any conventional manner either before or after the wire used to form passage 22 is removed. Openings 21 need not be made small ones as a high rate of flow there-through is not essential.

Inasmuch as presently available Silastic does not bond well to metal, it is recommended that the tube be tied on the transition piece at as 25 with Dacron thread to provide increased mechanical strength and to insure the maintenance of a good seal at this point. Upon completion of the tube for the connector shown and described herein, by way of example, the electrical conductors comprising the electrode and the like are connected as by soldering and/or swaging to respectively hollow electrical connectors 26 and 27 carried by the metallic couple 15 and the ground wire soldered to the coupler itself as at 28. At this time, the transition piece 24 is disposed in and bonded to the passage 33 of the metallic couple 15. Additionally, for purposes of providing strength and bend relief, the extreme outer portion of the tube adjacent the metallic couple may have embedded therein mesh material 34 comprised of Dacron or the like. The enlarged end of the transition piece and the reinforcement at this point cooperate to provide bend relief and also prevent the tube 11 from being pinched and thereby prevent the free flow of a suitable gas or fluid in the tube. By way of example, the tube may have an internal diameter of approximately 9/16 inch, a wall thickness of approximately 3/32 inch, the outer portion may be approximately 3 1/2 inches long, the middle portion approximately 2 1/4 inches long, and the inner portion approximately 3 3/4 inch long, its exact length depending on the medical application. For example, if the percutaneous connector is to permit the application of pulsatile pressure to pumps, such as an auxiliary ventricle or the like, the inner portion 16 may be of sufficient length to permit direct connection to the pump.

The provisions of the transition piece 24 is particularly advantageous as it greatly facilitates and simplifies the attachment of the tube and its electrical conductors to the coupler. Further, in the event of wear or damage to coupler 15, it may be easily removed by breaking the bond between it and the transition piece (and if they too are bonded in place) and attaching a new coupler to tube 11.

Attention is now directed to the metallic couple 15. The metallic couple is preferably fabricated from stainless steel such as 303 or 316 stainless steel. The metallic couple attached to tube 11 as shown in FIGURE 1 is provided with a cylindrical outer surface 41 and axial passage 33 open at both ends to provide communication through the coupler with the interior of tube 11. It is significant to note that passage 33 is eccentrically located with respect to the longitudinal axis of the coupler whereby by the radial dimensions of the connector 30 (as shown in FIGURE 2) is greater at one portion 42 than any other portion. Where the percutaneous connector is intended to permit connection to only two electrodes disposed interior of the body, two electrical connectors 26-27 comprising hollow metal tubes of the type used in low-noise type banana plug electrical connectors are disposed in the aforementioned thickest portion 42 of the coupler and electrically insulated therefrom as by sleeves 43-44 of electrically nonconductive material bonded to respectively both the tube connector and the coupler. The electrical connectors 26-27 are preferably located on opposite sides of the coupling defining the passage 33 (as shown in FIGURE 2) is greater at one portion 42 than any other portion. Where the percutaneous connector is intended to permit connection to only two electrodes disposed interior of the body, two electrical connectors 26-27 comprising hollow metal tubes of the type used in low-noise type banana plug electrical connectors are disposed in the aforementioned thickest portion 42 of the coupler and electrically insulated therefrom as by sleeves 43-44 of electrically nonconductive material bonded to respectively both the tube connector and the coupler. The electrical connectors 26-27 are preferably located on opposite sides of the coupling defining the passage 33 (as shown in FIGURE 2) is greater at one portion 42 than any other portion. Otherwise disposed axially aligning grooves 45-46 and radial locating grooves 47 are provided and arranged in conventional manner in the outer surface 41 of the coupler. One aligning groove is located nearer to the electrical connectors than the other groove of the location of the locating grooves which of course extend circumferentially in the same direction.

The transition piece 24 which is sealably carried in passage 33 will now be described. To facilitate attachment of the coupler 15 to the tube 11, the transition piece 24 is provided with a shoulder 51, to provide space between the transition piece and the coupled to apply an epoxy bonding material or the like 52 for bonding the transition piece to the coupler.
Attention is particularly directed to the extreme end of the transition piece disposed within the coupler which is provided with a frusto-conical surface 53 which tapers inwardly and away from the transition piece and joins with a flat end surface 54 normal to the inner surface of the transition piece 24. An annular gasket 55 having a generally triangular shaped cross section and composed of a suitable compressible material is disposed in the groove defined by the frusto-conical surface 53 and the portion of the wall of passage 33 adjacent thereto. The exposed end of the gasket 55 extends slightly past and at an angle of approximately 45° to the flat end surface 54. It is important that not only gasket 55 provide a pressure seal but that the extreme ends and transition piece 24 and the hollow sliding member 56 (see FIGURE 3) mate one with another to prevent turbulence, whistling and/or extrusion of the gasket past the inner edge of end surface 54.

To facilitate coupling of the percutaneous connector to a source for pressure, a knurled grip ring 57 may be fixedly attached as by screws to the portion of the coupler adjacent the tube. The coupler preferably is sealably connectible to a pressure conduit and further electrical conductors via a cable that can be easily and quickly attached to the coupler in such a manner that the connection cannot be made incorrectly or result in damage to any component. For this purpose and referring now to FIGURE 3, the cable may be provided with a stainless steel end member generally designated by the numeral 61 having a passage 62 and two banana type electrical connectors 64 arranged and adapted to register with respectively passage 33 and the electrical connectors 26-27 in the coupler 15. Thus, as shown in FIGURE 3, the end member 61 is provided with an eccentrically located passage 62 coaxial with passage 33 in coupler 15. The end member 61 is counterbored to provide a sleeve portion 65 which slidably fits over coupler 15 and which will bottom on coupler 15 when the coupler and the member 61 are in operative engagement. Electrical connectors 64 preferably extend past shoulder 66 but terminate within sleeve portion 65. As is the case with the female connectors 26-27, the male electrical connectors 64 are bonded to but electrically insulated from the end member 61 by electrically nonconductive epoxy resin and the like. Sleeve portion 65 is provided with oppositely disposed and inwardly extending lugs 68 and adapted to register with and fit into aligning grooves 45-46. A locking screw 69 surrounds sleeve 65 and is also provided with oppositely disposed lugs 72 which respectively extend inwardly and through slots 74 in sleeve 65. Slots 74 and lugs 71-72 maintain locking sleeve 69 in position and permit limited rotation thereof.

Sliding member 56 is provided with substantially the same radial dimensions as transition piece 24 and is slidably carried in passage 62 of the end member 61. An nular lip 75 and spring 76 function to permit the sliding member 56 to move rearwardly when the coupler and end member are brought into operative engagement. Sliding member 56 is preferably of sufficient length to extend past the end of sleeve 65 to further facilitate alignment of the end member 61 with coupler 15. As will be shown from inspection of FIGURE 3, the extension of sliding member 56 past the end of the end member 61 not only facilitates alignment of coupler 15 and end member 61, but prevents damage to the exposed portions of electrical connectors 64. Spring 76 is conveniently held in position by a split ring 77 and bend relief member 78 attached as by screws to the rear surface of end member 61. In addition to holding the split ring 77 in place, the bend relief member 78 protects the electrical conductors 81-82 disposed therein and holds them in a position which provides clearance for attachment of a pressure conduit (not shown) to the extreme rear end portion of a sliding member 56.

Coupler 15 and end member 61 are simply and quickly brought into operative engagement without danger of damage by first aligning lugs 68 and 72, inserting the slidable member 56 into passage 33, forcing the coupler 15 and end member 61 together until the locking lugs 72 are aligned with locking grooves 47 and rotating the locking sleeve 69 to lock the coupler 15 and end member 61 together in conventional manner. It will now be seen that the provision of an eccentrically located passage in coupler 15 which receives member 56 is particularly advantageous as it results in the requirement that the coupler and an end member be properly orientated before they can be joined, thereby making it virtually impossible to damage the coupler and, incidentally, end member 61.

Directing attention now to FIGURE 4, details of the invention are shown on an enlarged scale. For convenience, the electrical conductors shown in FIGURE 1 have been omitted.

As more clearly shown in FIGURE 4, bulb 20 defines a cavity 29 which, while sealed off from the air by bulb 20, is in communication with flow passage 22 which is helically disposed in the walls of portion 18 and which terminates at skirt 23. Openings 21 spaced one from another are in communication with and extend along passage 22 from about the upper periphery of member 19 to skirt 23. As will now be apparent, when an antiseptic in liquid form, such as for example nemoxylin or polyvinyl, is introduced under pressure into cavity 29, it will flow along passage 22 and exit therefrom at the various openings 21. Accordingly, any infection existing in the crevice between the tube 11 and material 19 which would otherwise be extremely difficult if not impossible to reach may be quickly and effectively eliminated. The crevice may be flushed by continuously injecting liquid into cavity 29 and thereafter extended protection against infection is provided by the seepage of liquid into the crevice.

While there is shown and described herein certain specific structure embodying the invention, it will be manifest to those skilled in the art that various modifications and rearrangements of the parts may be made without departing from the spirit and scope of the underlying inventive concept and that the same is not limited to the particular forms herein shown and described except insofar as indicated by the scope of the appended claims:

I claim:

1. In a percutaneous connector for permitting the application of pressure, fluids and/or electrical connections through the skin of a living body, said connector comprising an elongated member having a second end portion adapted to be disposed exterior of a living body, a middle portion adapted to be disposed in the body wall and a first end portion adapted to be disposed interior of said body, the combination comprising:

(a) at least one substantially flat layer of cloth-like, tissue permeable material carried by and surrounding said middle portions, said material being adapted for attachment to a living body; and

(b) means including bulb means carried by said second end portion and a flow passage disposed in the wall of said member for receiving a fluid at said second end portion, conducting said fluid within the wall of said member, and dispensing said fluid through the outer surface of said member defining said middle portion whereby fluid introduced at said second end portion will come in contact with substantially all of the outer surface defining said middle portion.

2. The combination as defined in claim 1 wherein said flow passage is in communication with and extends from said bulb means to about the end of said middle portion distal from said second end, and a plurality of ports in said middle portion communicating with said flow passage and said flat layer of cloth.
like material is wound around and coaxial with said middle portion, and additionally including further cloth-like, tissue permeable material attached to said middle portion and extending radially out therefrom.

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