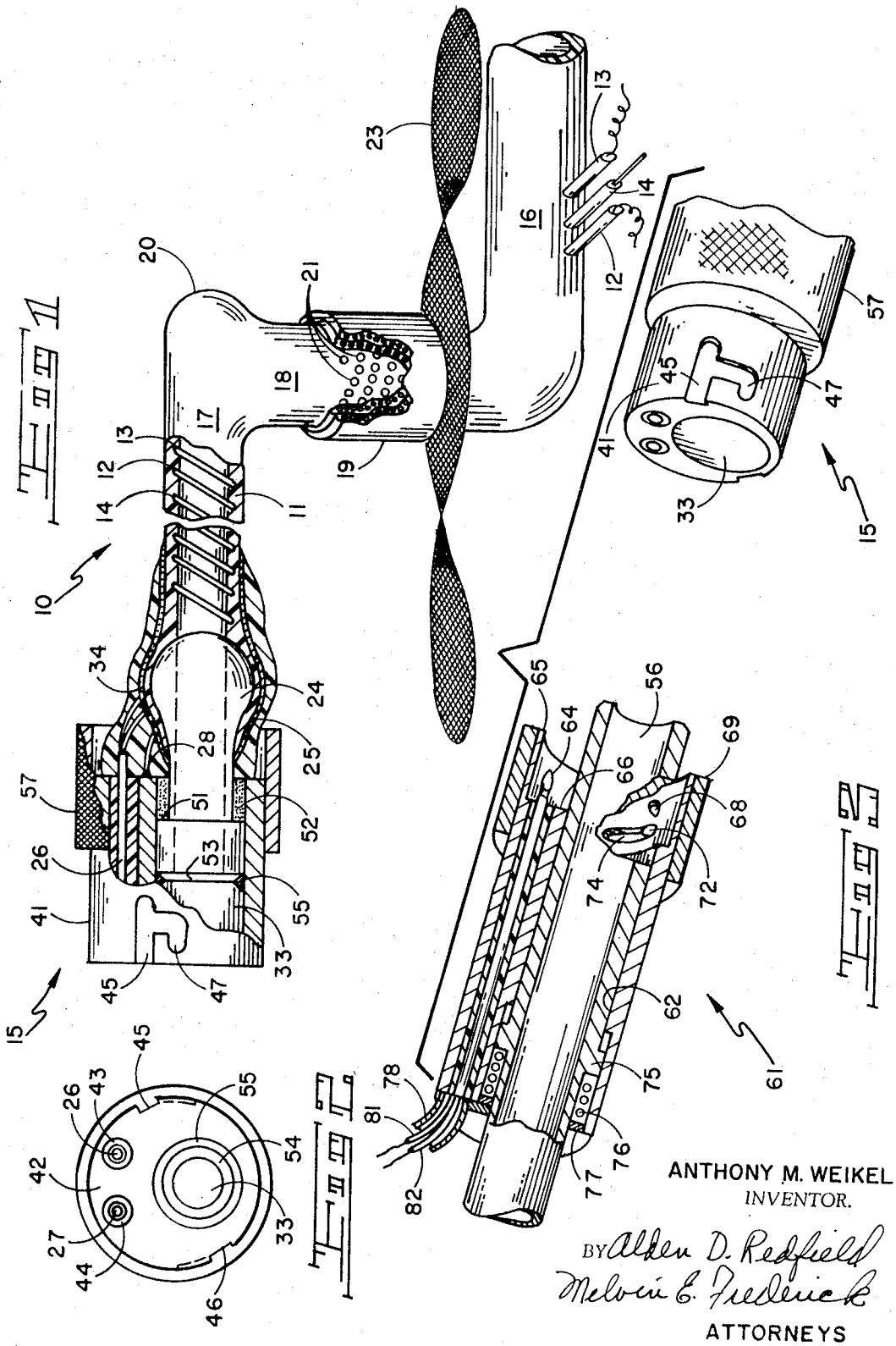
June 3, 1969 A. M. WEIKEL 3,447,161

DISINFECTANT DISPENSING PERCUTANEOUS CONNECTOR

Filed Aug. 1, 1966 Sheet 1 of 2



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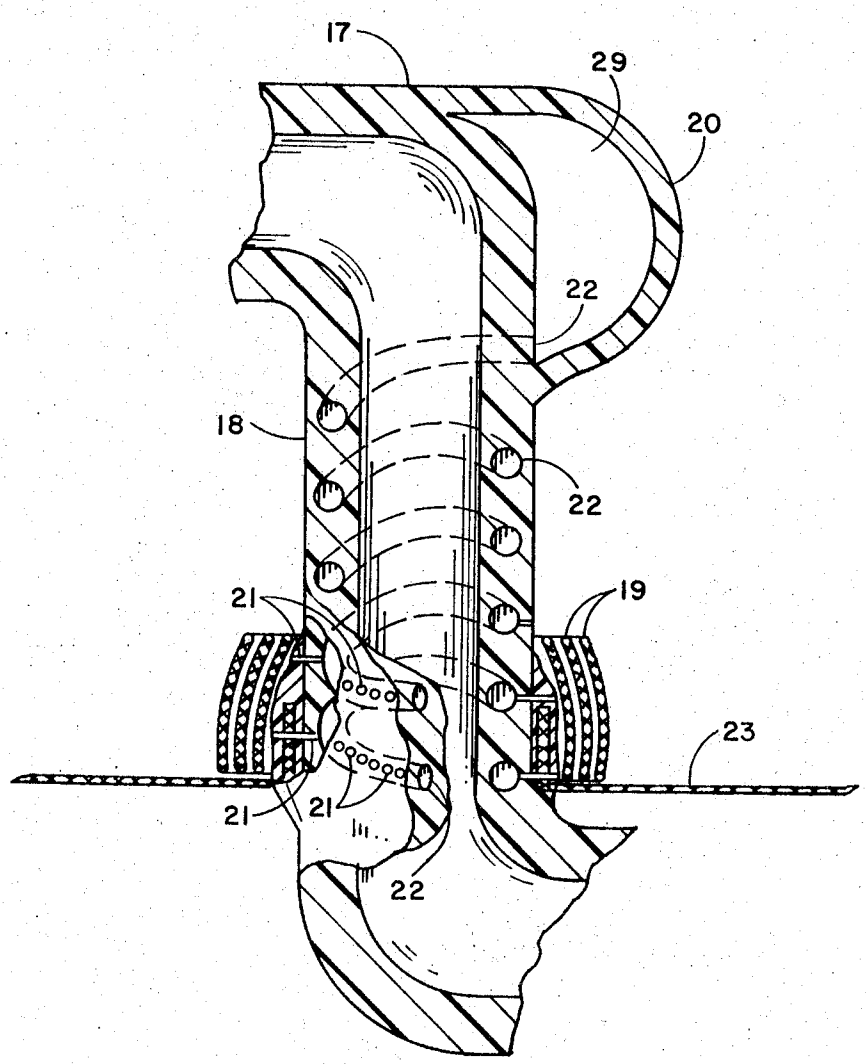

FIG 4

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DISINFECTANT DISPENSING PERCUTANEOUS CONNECTOR

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3 Claims

ABSTRACT OF THE DISCLOSURE

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 who without 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 compentence 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 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 the skin by which bacteria may enter and cause infection. Percutaneous connectors are generally formed of a material that is not only accptable 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.

Heretofore, 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, when read in conjunction with the accompaning 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 metalic couper **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 Incorported, Somerville, N.J., is bonded to the middle portion **18** of the tube adjacent the first end portion to permit the percutaneous connector to be internally attached to the inner surface of the skin as 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 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, as more fully disclosed hereinafter, is 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 antiseptic 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 having a stainless steel transition piece mounted on one end is bent to the desired configuration. Thereafter, a sheet of uncured Silastic approximately .040 inch thick is wrapped around the core and the enlarge end of the transition piece, all air bubbles are removed and the silicone rubber or Silastic then cured as by heating it in boiling water for approximately one-half hour. Thereafter, the electrical conductors are continuously helically 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 Helicable Research Electrodes supplied by General Electric Company, X-ray Department, Milwaukee, Wis. The portion of each electrical conductor disposed within the wall 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 shown by way of example, in FIGURE 1 two electrodes **12–13** and one ground wire **14**, all of which may have a diameter of approximately .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**, flow passage **22** in the wall of portion **18** beginning conveniently at about 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.

After the wire is removed 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 be only small ones as a high rate of flow therethrough 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 as at **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 electrodes or the like are connected as by soldering and/or swaging to respectively hollow electrical connectors **26** and **27** carried by the metallic coupler **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 coupler **15**. Additionally, for purposes of providing strength and bend relief, the extreme outer portion of the tube adjacent the metallic coupler 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 $\frac{3}{16}$ inch, a wall thickness of approximately $\frac{1}{10}$ inch, the outer portion may be approximately 3½ inches long, the middle portion approximately 2¼ inches long and the inner portion at least approximately ¾ 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 provision 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 the connectors if they too are bonded in place) and attaching a new coupler to tube **11**.

Attention is now directed to the metallic coupler **15**. The metallic coupler is preferably fabricated from stainless steel such as **303** or **316** stainless steel. The metallic coupler 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 the radial dimensions of the coupler defining the passage **33** (as best 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 a plane passing through the longitudinal axis of both the coupler **15** and passage **33**. Oppositely disposed axial aligning grooves **45–46** and radial locking 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 to permit the provision of the locking 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 frustro-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 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 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** arranged and adapted to register with and fit into aligning grooves **45–46**. A locking sleeve **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**. Annular 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 material **19** to skirt **23**. As will now be apparent, when an antiseptic in liquid form, such as for example neomycin or polymyxin, 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 adapated to be disposed exterior of a living body, a middle portion adapated 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 material.

3. The combination as defined in claim **2** wherein said elongated member is a hollow tube, 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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