

[54] BACTERIAL SEALS

[75] Inventor: Louis Bucalo, Holbrook, N.Y.

[73] Assignee: Investors In Ventures, Inc., New York, N.Y.

[22] Filed: July 10, 1972

[21] Appl. No.: 270,458

[52] U.S. Cl. 128/1 R, 3/1

[51] Int. Cl. A61b 19/00

[58] Field of Search..... 128/1 R, 334 R, 283, 348; 3/1

[56] References Cited

UNITED STATES PATENTS

3,216,420	11/1965	Smith et al.	128/283
3,402,710	9/1968	Paleschuck	128/1 R
3,447,161	6/1969	Weikel	128/1 R
3,687,129	8/1972	Nuwayser	128/1 R
3,704,704	12/1972	Gonzales	128/1 R

FOREIGN PATENTS OR APPLICATIONS

1,961,531	7/1970	Germany	3/1
-----------	--------	---------	-----

Primary Examiner—Dalton L. Truluck
Attorney, Agent, or Firm—Steinberg & Blake

[57] ABSTRACT

Bacterial seals for humans, animals, and the like. An outer sleeve extends through a body opening from the exterior of the body to an interior space therein, this outer sleeve having a tight, intimate engagement with body tissue so that it is securely connected with the tissue. An elongated member is situated within and surrounded by the sleeve and has an extremely close precise fit with the sleeve at the interface between the exterior surface of the elongated member and the interior surface of the sleeve. Through this elongated member it is possible to have any desired type of communication between the exterior of the body and the internal space. A barrier is located at the interface between the elongated member and the sleeve for preventing any bacteriological contamination of the interior body space from the exterior.

12 Claims, 7 Drawing Figures

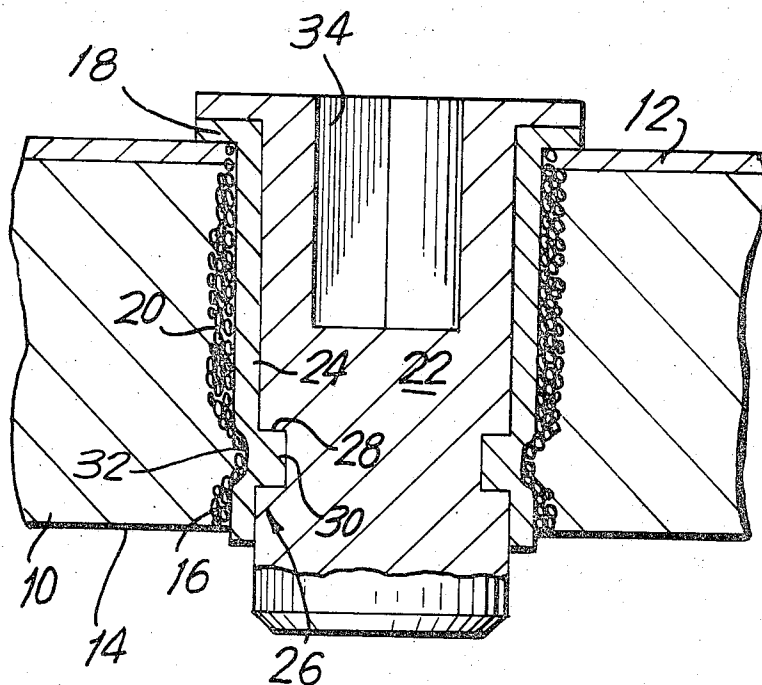


FIG. 1

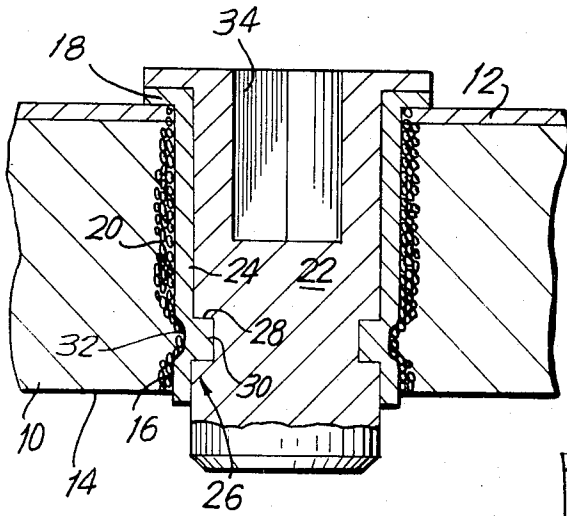


FIG. 2

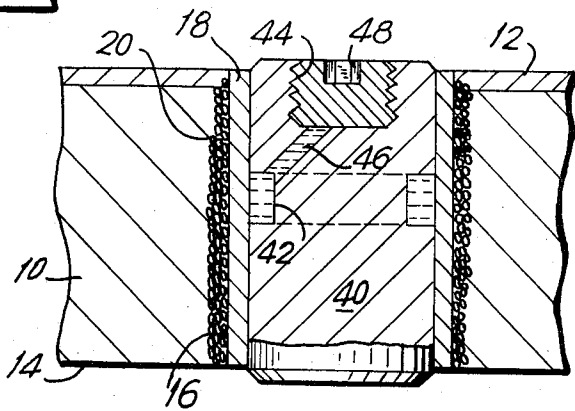


FIG. 3

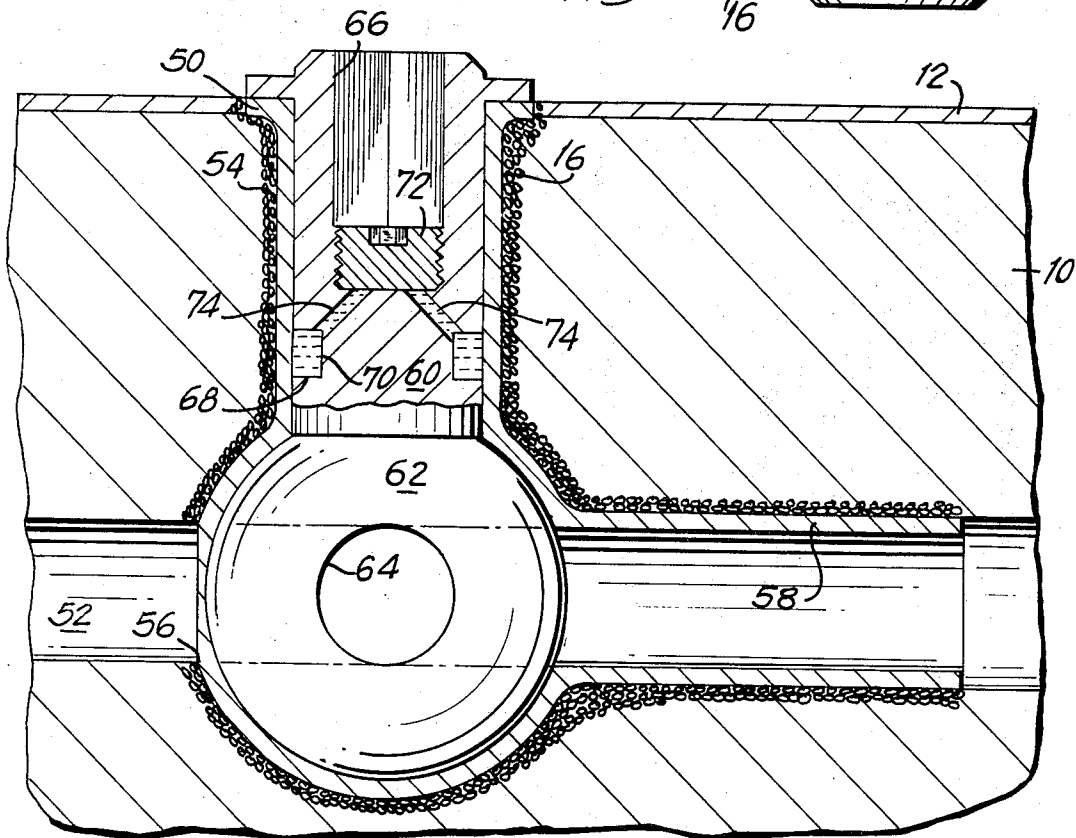


FIG. 4

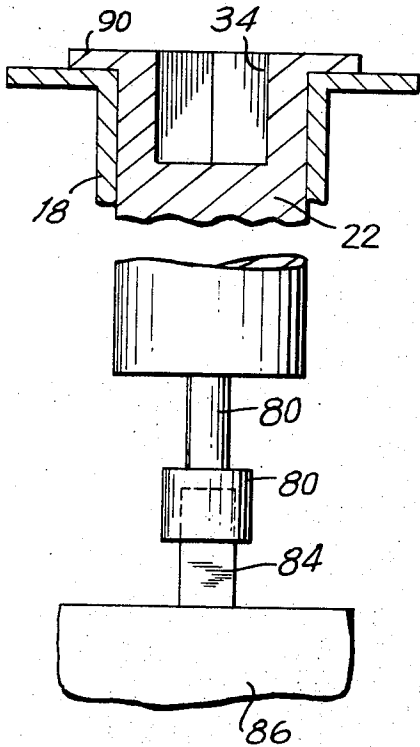


FIG. 5

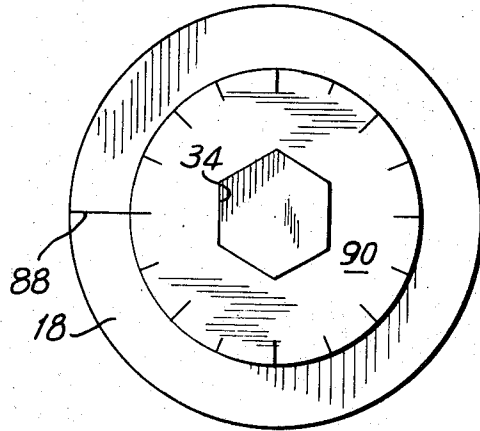


FIG. 6

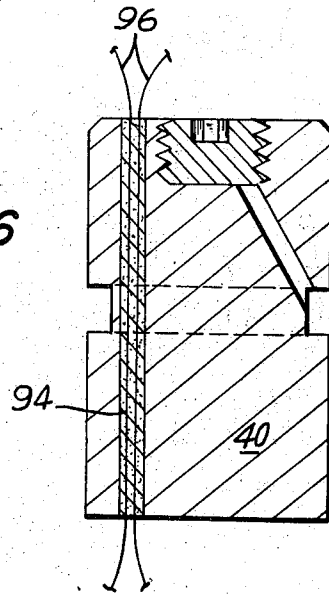
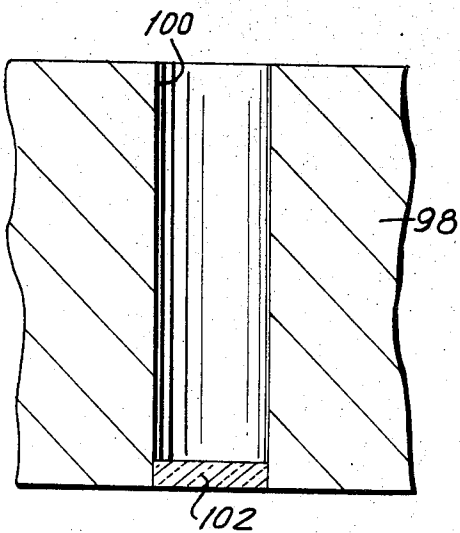


FIG. 7



BACTERIAL SEALS**BACKGROUND OF THE INVENTION**

The present invention relates to bacterial seals.

Thus, the present invention relates to structures which will enable many different types of communication to be achieved between the exterior of a body and an interior space thereof while at the same time preventing bacterial contamination of the internal body space.

Thus, at the present time there are various types of known devices which enable desired types of communication between the exterior and interior of a body such as a human body to be achieved. However, all of these known structures are relatively complex. The most serious defect encountered with such structures, however, resides in the fact that there is a great likelihood of bacterial contamination of the body because of the possibility of communication between the exterior of the body and the interior through the structure which is mounted on the body to provide a particular type of communication between the exterior and interior of the body.

SUMMARY OF THE INVENTION

Accordingly it is a primary object of the present invention to provide a structure which will give practically any desired type of communication between the exterior and interior of a body such as a human body while at the same time reliably preventing bacterial contamination.

Furthermore it is an object of the present invention to provide a structure of this type which is far simpler and far more effective than known structures designed for the same purpose.

Yet another object of the present invention is to provide a construction of this type which is easily mounted in the human body while assuring a tight intimate and secure connection between the structure of the invention and the body of the living being.

Furthermore, it is an object of the invention to provide a structure of this type which enables a bacterial barrier to be achieved in an exceedingly effective and at the same time simple manner.

According to the invention an outer sleeve means is mounted within an opening in the body which extends from the exterior of the body to an internal space therein, this sleeve means carrying at its exterior a means for providing a tight secure connection between the sleeve means and the tissue of the body. An elongated member is situated within and surrounded by the sleeve means and at the interface between the elongated member and the sleeve means there is an extremely close, precise fit obtained, for example, by initially depositing the sleeve means directly on the exterior surface of the elongated member. At the interface between the elongated member and the sleeve means there is a barrier means for preventing bacterial travel between the exterior of the body and the interior space thereof so that in this way a reliable prevention of bacterial contamination is achieved. The elongated member may be used for any number of purposes. For example it may form part of a valve for achieving incontinence control when the valve is situated in the male urethra, or it may be used to adjust a device implanted in the body. It may also be used for providing electrical

communication between the exterior and interior of the body, or it may simply have a window to provide for visual observation of the interior body space.

BRIEF DESCRIPTION OF DRAWINGS

The invention is illustrated by way of example in the accompanying drawings which form part of this application and in which:

FIG. 1 is a schematic partly sectional elevation of one embodiment of the invention;

FIG. 2 is a schematic partly sectional elevation of a second embodiment of the invention;

FIG. 3 is a schematic partly sectional elevation illustrating the manner in which the invention may be used for incontinence control;

FIG. 4 is a schematic representation of one purpose which may be served by the structure of the invention;

FIG. 5 is a schematic top plan view of the structure of FIG. 4;

FIG. 6 is a partly sectional elevation of the structure of the invention illustrating a further manner in which it may be used; and

FIG. 7 is a schematic representation of yet another use to which the structure of the invention may be put.

DESCRIPTION OF PREFERRED EMBODIMENTS

Referring now to the drawings and to FIG. 1 in particular, there is schematically represented in FIG. 1 a wall of tissue 10 forming part of a human body, for example, and having an exterior surface 12 where the exterior skin of the human being is located. The opposed surface 14 of the wall 10 forms part of any internal space of the human body, or the body of an animal, if desired. Thus, the surface 14 may form part of an elongated body passage through which a fluid flows or it may form part of the interior of an organ of the human body.

The wall 10 of the human body is formed with an opening 16 which is lined with a sleeve means 18 which carries at its exterior surface a means 20 for providing a tight, intimate, and secure connection between the wall 10 and the sleeve means 18. The sleeve 18 may be made of a material which is compatible with the body, such as gold, and the means 20 in the illustrated example takes the form of a fine gold wire which is wound around and engages the exterior of the sleeve means 18. Instead of a single strand of wire which is wound several times around the exterior of the sleeve 18 it is possible to use a fine gold wire mesh, for example. In any event, the means 20 provides a large number of interstices into which the tissue 10 grows to provide the tight, intimate and secure connection between the sleeve means 18 and the wall 10 in the opening 16 thereof.

An elongated member 22 extends through the sleeve means 18 and is turnable therein. This elongated member 22 has an extremely close, precise fit at the interface 24 between the elongated member 22 and the sleeve means 18. The assembly of the elongated member 22 and the sleeve means 18 may be carried out in accordance with the teachings of U.S. Pat. No. 3,616,520. Thus, the elongated member 22 is made of a material to which the sleeve means 18 will not adhere. The material of the sleeve means 18 is deposited in any number of different ways, such as electrolyti-

cally, directly on the exterior surface of the elongated member 22, and the deposition is continued until the desired thickness of the sleeve means 18 is achieved. In this way it is possible to provide the desired extremely close precise fit between the sleeve means 18 and the elongated member 22 while at the same time the latter is turnable within the sleeve means 18 and with respect thereto at the interface 24.

According to the invention a barrier means 26 is provided to prevent bacterial communication between the exterior of the body at the skin 12 and the interior space which is defined in part by the inner surface 14 of the wall 10. In the example of FIG. 1 the barrier means 26 takes the form of an annular groove 28 formed in the elongated member 22 and a projection 30 forming part of the sleeve means 18. This projection 30 is formed during deposition of the sleeve means 18 on the member 22 so that a corresponding annular groove 32 forms at the exterior of the sleeve 18 which has a uniform thickness due to the deposition of the sleeve means 18 on the member 22. This groove 32 provides further security in the connection between the sleeve means and the wall 10 because the tissue of the latter will grow into the groove 32.

Because of the extremely close and precise fit between the sleeve means 18 and the elongated member 22, the projection 30 in the groove 28 will form a barrier through which bacteria cannot travel, so that in this way a bacterial seal is achieved with the structure of FIG. 1.

At its exterior the member 22 may be formed with a non-circular bore 34 extending partly into the member 22 along the axis thereof and capable of receiving a wrench, such as an Allen wrench, so that through this structure it is possible to turn the member 22 within the sleeve means 18 for any desired purpose.

The embodiment of the invention which is illustrated in FIG. 2 is similar to that of FIG. 1 except for the structure of the barrier means. Thus it will be seen that FIG. 2 also illustrates the wall 10 having the exterior skin 12 and the interior surface 14 which forms part of an interior space of the body, and the opening 16 is also lined with a sleeve means 18 made of gold and having at its exterior surface a means 20 in the form of wound gold wire or a gold wire mesh to achieve the tight, intimate, secure connection between the sleeve means 18 and the wall 10. In the case of FIG. 2 the sleeve means does not have an exterior flange, but of course this feature is immaterial. The sleeve means 18 of FIG. 2 surrounds and engages with an extremely close precise fit an elongated member 40 which is also made, for example, of a material to which the gold will not adhere and on which the gold of the sleeve means 18 is directly deposited in a manner described above in connection with FIG. 1.

In the embodiment of FIG. 2 the elongated member 40 is formed with an annular groove 42 which is filled with wax, for example, before the gold of the sleeve means 18 is deposited on the elongated member 40. In addition the member 40 is formed with a bore 44 which is internally threaded so that it can be closed by a closure means such as a suitable set screw. The bore 44 in turn communicates through an inclined bore 46 with the groove 42. At its exterior end the elongated member 40 may be formed with notches 48 so that the member 40 can be turned by a screwdriver, for example, for any desired purpose, as referred to below.

After the sleeve means 18 has been deposited on the member 40, the wax is removed from the groove 42 by heating the member 40 so that the wax will melt and will flow out through the bore 46 and the internally threaded bore 44. Then, after the structure is mounted in the opening 16 in the manner shown in FIG. 2, or even before it is mounted therein, a suitable antibiotic material is situated within the annular groove 42 by introducing this antibiotic through the bore 44 and the inclined bore 46. The antibiotic can fill the groove 42 and can extend up the bore 46 to the bore 44, and then the latter can be closed with a suitable set screw.

Thus, the antibiotic in the groove 44 will form a barrier means preventing the travel of living bacteria past the groove 42.

With this particular embodiment it is possible from time to time to remove the set screw situated within the internally threaded bore 44 and replenish the supply of antibiotic by introducing additional antibiotic, if required, through the bore 46.

FIG. 3 illustrates how the invention is used in connection with control of incontinence. Thus, in this case the outer sleeve means 50 is extended to form a valve housing. The sleeve means 50 is again situated in an opening 16 in a wall 10 of the human body, this wall 10 in this case being part of a penis and being situated at the urethra 52. Thus in the example of FIG. 3 the inner surface 14 forms part of the urethra. The sleeve means 50 is again covered at its exterior surface by the means 54 in the form of fine gold wire, or a wire mesh, providing the small interstices into which the tissue grows so as to provide the secure tight connection between the valve housing and the wall 10 as well as the part of the urethra 52 opposite from the wall 10, as illustrated. The valve housing formed by the sleeve means 50 has an inlet opening 56 and an outlet opening 58 in the form of an elongated tube.

The elongated member of this embodiment takes the form of a rotary valve member 60, and the gold which forms the valve housing is deposited directly on the member 60 so as to provide the close precise fit referred to above. The elongated member 60 in this case terminates at its inner end in a rotary substantially spherical valve body 62 formed with the valve opening 64 extending diametrically therethrough and having an axis situated at the elevation of the axis of the tubular outlet 58. The elongated member or valve member 60 is shown in FIG. 3 in its closed position where the axis of the opening 64 extends perpendicularly with respect to the axis of the urethra passage 52. At its outer end the elongated member 60 is formed with a non-circular bore 66 capable of receiving a wrench, such as an Allen wrench, as referred to above, so that it is possible to turn the valve member between the closed position shown in FIG. 3 and an open position where the bore 64 will assume the dot-dash line position illustrated providing a clear passage continuously through the urethra. Therefore, in order to control incontinence it is possible to close the valve so as to prevent urine from flowing through the urethra, while at the same time it is possible whenever desired to place the valve in its open position permitting free flow of urine.

In the embodiment of FIG. 3 the elongated member 60 is formed at its portion which forms the valve stem with an annular groove 68 which is filled with an antibiotic material 70. The interior portion of the non-

circular bore 66 is circular and internally threaded so as to receive a closure means in the form of a set screw 72. The lower or interior end of the bore 66 communicates through the inclined bores 74 with the annular groove 68. Thus, by removing the set screw 72 it is possible at any time to replenish the supply of antibiotic material in the annular groove 70. In this respect the embodiment of FIG. 3 is similar to that of FIG. 2, and of course when the structure of FIG. 3 is formed the groove 68 is initially filled with wax so that during disposition of the gold which forms the valve housing or sleeve means 50 the groove 68 will not become filled with the gold. Thereafter this wax is melted out in the manner referred to above and the antibiotic is supplied with the closure means 72 reliably retaining the antibiotic in the groove 68. Thus this embodiment has the bacterial barrier means which prevents bacterial contamination of the interior of the body by travel of bacteria at the interface between the outer sleeve means 50 and the elongated member 60.

In addition, it is to be noted that when the valve is in its closed position shown in FIG. 3, the exterior surface portions of the spherical valve body 62 which extend across and close the openings 56 and 58 are exposed to bodily fluids and will receive deposits such as calcium deposits. Because of the close precise fit, achieving the seal between the sleeve means and elongated member in accordance with the invention, any turning of the member 60 will result in wiping of the surfaces previously exposed through the openings 56 and 58 to the interior space of the body, so that in this way any deposits such as calcium are reliably cleaned away from the exterior surface of the rotary member, maintaining the latter in a clean condition simply as a result of rotary movement of the member 60.

The above-described embodiments of the invention, illustrated in FIGS. 1 and 2, may be used in a number of different ways. As examples of possible uses thereof, FIGS. 4-7 illustrate some applications. Thus, FIG. 4 illustrates an embodiment similar to that of FIG. 1 where the inner end of member 22 is provided with an integral extension 80 terminating in a socket wrench type of cup 82. The non-circular interior of the wrench or cup 82 receives a non-circular rotary adjusting member 84 of an implanted device 86 which may, for example, be a pacemaker.

At the exterior of the body, the flange of the sleeve means 18 is extended beyond the outer periphery of the outer flanged end of the member 22. In this way it is possible to provide on the extended flange of member 18 an index 88, as illustrated in FIG. 5. The outer flange end 90 of the member 22 is provided with graduations. Thus, when the wrench is introduced into the bore 34 in order to make an adjustment, one of the graduations can be aligned with the index 88, and in this way it is possible to know the extent of adjustment of an implanted device such as the device 86 shown in FIG. 4. Thus, with the particular use of the invention shown in FIGS. 4 and 5 it is possible while maintaining a bacterial seal to provide from the exterior of the body suitable adjustments at the interior thereof.

It is to be noted that the illustrated direct connection between the movable device accessible at the exterior of the body and the device implanted in the interior of the body is not absolutely essential. For example it is possible to utilize a pair of permanent magnets respectively carried by the rotary member 22 and the im-

planted device and aligned with each other in such a way that turning of the exterior element will result in a corresponding turning of the interior element.

FIG. 6 illustrates a rotary member 40 corresponding in all respects to the member 40 of FIG. 2 and mounted in precisely the same way as described above in connection with FIG. 2 and as shown in FIG. 2. In this particular application of the invention the member 40 is formed with an elongated bore 94 passing therethrough and receiving elongated electrical conductors 96. The interior of the bore 94 is sealed with any suitable sealing material which tightly closes the bore 94 while the sealing material closely surrounds the conductors 96 with the latter being embedded in the sealing material in the bore 94 so that there is not the possibility of bacterial contamination through the bore 94. With such a construction the outer portions of the conductors 96 can be connected to any suitable electrical device such as a meter, a potentiometer, a battery, etc., and the interior portions of the conductors 96 can be connected to any unit implanted within the body so that while preventing bacterial communication it is possible in this way to achieve an electrical connection between the interior and exterior of the body.

Referring to FIG. 7, the member 98 which is fragmentarily illustrated therein may take the form either of the member 40 of FIG. 2 or of the member 22 of FIG. 1, with this member being mounted either as illustrated in FIG. 2 or as illustrated in FIG. 1. According to this embodiment the member 98 is formed with a bore 100 extending completely therethrough at a location where this bore will not interfere with an opening for a wrench, for example, or with an opening such as the recess 44 of FIG. 2 through which the supply of antibiotic may be replenished. At its inner end the bore 100 is tightly closed by a transparent plate 102 made of a material such as clear glass, a suitable plastic, or the like, with the outer periphery of the plate 102 being tightly fixed along its entire periphery to the inner surface of the bore 100 as by using a suitable glue or the like. Thus, with this embodiment it is possible to visually observe the interior of the body cavity through the window 102.

Thus, FIGS. 4-7, as well as FIG. 3, illustrate some of the possible applications of the present invention.

In all of these applications the structure by which the elongated member is mounted in the opening of the body is exceedingly simple and at the same time provides a secure tight connection with the body tissue. An exceedingly great safety with respect to prevention of bacterial contamination is achieved by way of the very close seal between the inner member and the sleeve means which surrounds the same, this seal being achieved by way of the deposited fit according to which the sleeve means is directly deposited on the elongated member so as to have the closest possible fit therewith. As was pointed out above, by choosing for deposition a material which will not adhere to the element on which the material is deposited it is possible to achieve the close fit of the invention.

However, in addition to the safety achieved with this deposited seal fit, the barrier means of the invention, whether it takes the form of the tongue-and-groove type of barrier shown in FIG. 1 or the encapsulated antibiotic as shown in FIG. 2, will provide with the utmost reliability prevention of bacterial contamination.

What is claimed is:

1. For use in the body of a human being, animal, or the like, outer sleeve means for lining a body opening extending from the exterior thereof to an internal body space, said sleeve means having opposed open ends respectively adapted to be situated at the exterior of the body and the internal body space and having an uninterrupted hollow interior extending between said opposed open ends, and said sleeve means carrying on its exterior surface a means for providing a tight, sealed engagement between tissue of the body and the exterior surface of said sleeve means, an elongated member situated in and surrounded by said sleeve means, said elongated member having at an exterior surface thereof a close, precise fit in said sleeve means at an inner surface of said sleeve means which defines an interface with said exterior surface of said elongated member, and barrier means situated at said interface between said elongated member and sleeve means for preventing bacteriological communication between the exterior of the body and the internal space thereof to achieve a bacteriological seal.

2. The combination of claim 1 and wherein one of said surfaces is formed with a groove and the other of said surfaces is formed with an annular projection extending into and filling said groove with a fit sufficiently tight and precise for providing said barrier means while permitting said elongated member to turn in said sleeve means.

3. The combination of claim 2 and wherein said sleeve means has a deposited fit on said elongated member at said interface.

4. The combination of claim 3 and wherein said groove is formed in said member and said projection is formed on said sleeve means.

5. The combination of claim 4 and wherein said sleeve means is in the form of deposited gold.

6. The combination of claim 5 and wherein said means for achieving said tight engagement between the exterior of said sleeve means and the body tissue is in the form of fine gold filamentary material surrounding said sleeve means at its exterior and situated between the latter and the body tissue for promoting growth of the latter into intimate contact with the exterior surface of said sleeve means.

7. The combination of claim 1 and wherein said barrier means is in the form of an annular groove formed at the exterior of said elongated member at said interface between the latter and said sleeve means, and an antibiotic material encapsulated in said groove to prevent travel of bacteria past said groove.

8. The combination of claim 7 and wherein said elongated member is formed at an outer end thereof which is accessible at the exterior of the body with a recess and with a bore extending from said recess to said groove so that the antibiotic material may be replenished through said bore, and closure means situated at said recess for releasably closing the latter.

9. The combination of claim 1 and wherein said sleeve means forms a valve housing having openings situated in the body space, and said elongated member forming part of a valve member rotatable in said housing, the close fit between the latter and said valve member being sufficient to remove during turning of said valve member deposits which form on the exterior surface of said valve member through said housing openings.

10. The combination of claim 1 and wherein said elongated member is adapted to be operatively connected within the body to an instrument implanted therein and requiring adjustment from time to time, said combination further including scale means situated at said sleeve means and valve member and visible at the exterior of the body for indicating the adjustment made by turning said elongated member in said sleeve means.

11. The combination of claim 1 and wherein an elongated electrical conductor means extends through said elongated member and is fluid-tightly carried thereby for providing an electrical connection between the interior and exterior of the body.

12. The combination of claim 1 and wherein said elongated member is formed with an elongated bore extending therethrough, and said member carrying at an inner end region a window through which the inner space of the body would be visible when said combination is implanted.

* * * * *

45

50

55

60

65