

United States Patent

McCormick

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- [54] **PROTECTIVE SEAL FOR CATHETER**
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[22] Filed: **Aug. 13, 1970**
[21] Appl. No.: **63,438**

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- [52] **U.S. Cl.**.....**128/214 R**, 128/348, 128/DIG. 26,
248/205 A
[51] **Int. Cl.**.....**A61m 25/02**
[58] **Field of Search**.....128/348-351, 133,
128/214 R, 214.2, 215, DIG. 26; 248/205 A;
24/DIG. 11

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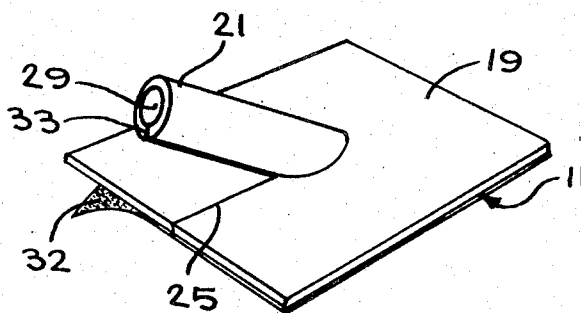
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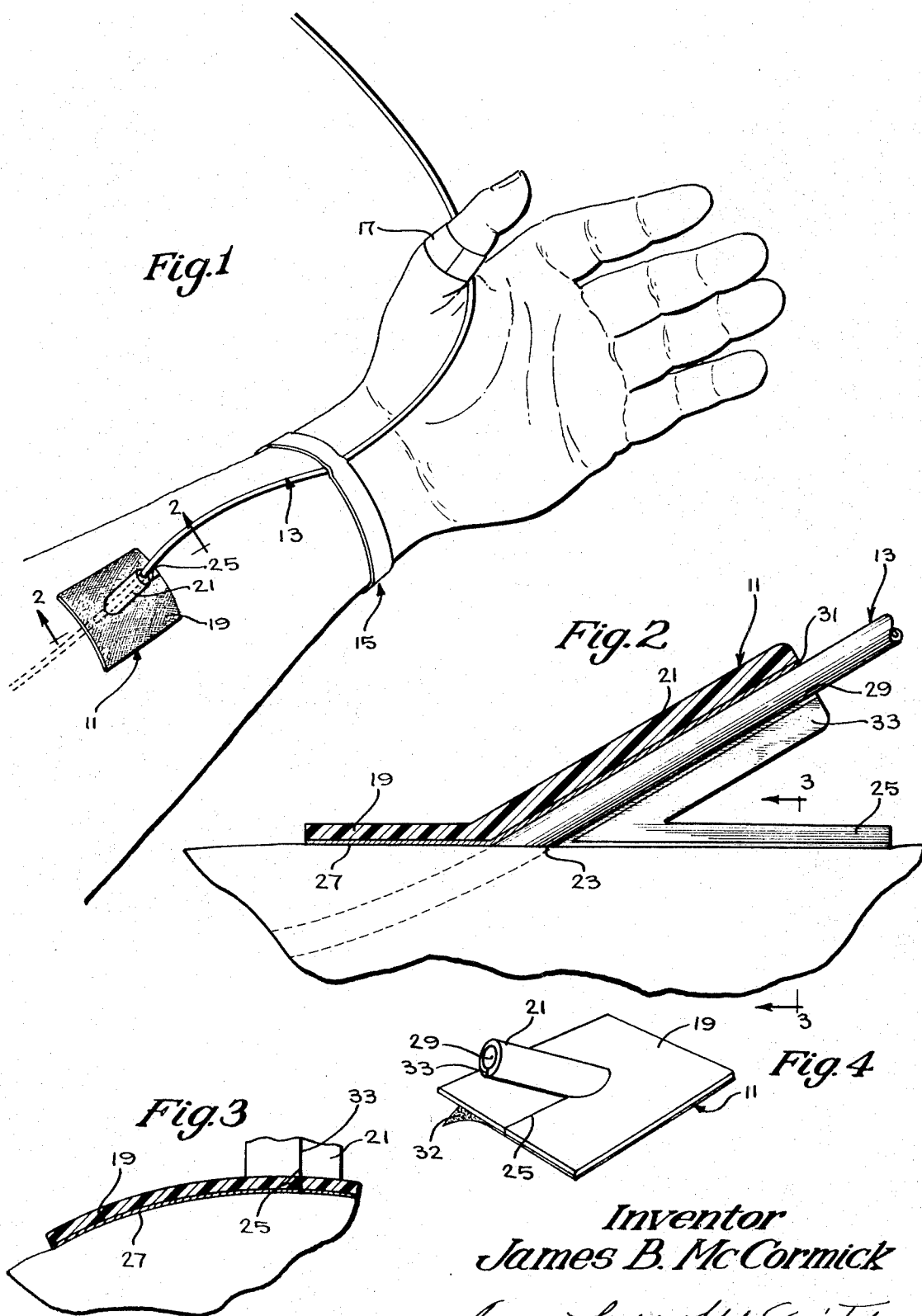
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[57] **ABSTRACT**

A device for providing a protective seal at an incision provided incident to the insertion of a catheter beneath the skin includes a shield having an adhesive coating on one surface so that the shield adheres to the skin in the area of the incision to prevent bacteria from passing beneath the shield. A tubular sleeve extends outwardly from and is sealed to the shield to define a passageway for the catheter, the sleeve having an inner adhesive coating to provide a seal between the sleeve and catheter so as to prevent bacteria from gaining access to the incision.

7 Claims, 4 Drawing Figures





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PROTECTIVE SEAL FOR CATHETER

The present invention relates to a protective seal for inhibiting bacteria from gaining access to an incision provided incident to the insertion of a catheter beneath the skin.

The insertion of a catheter beneath the skin of an individual to administer parenteral fluids or to facilitate the drainage of fluids from a body cavity or organ is not uncommon. In the majority of instances, the catheter enters the body through an incision in the skin, by a needle or other device, and it is not unusual for it to remain in this position for several days or even longer. The exposure of an incision or puncture site for such an extended period of time renders it particularly vulnerable to infection.

It is the principal object of the present invention to provide an improved, economical and easily applied device for providing a protective seal at the locus of an incision provided incident to the insertion of a catheter beneath the skin.

A related object of the invention is to provide such a device which is effective to essentially preclude access to the incision by infectious bacteria.

Other objects and advantages of the invention will become apparent with reference to the following description and the accompanying drawing.

In the drawing:

FIG. 1 is a perspective view showing a device embodying various of the features of the invention as the device might appear on the arm of an individual receiving an intravenous injection;

FIG. 2 is an enlarged fragmentary sectional view taken along line 2—2 of FIG. 1;

FIG. 3 is an enlarged fragmentary sectional view taken along line 3—3 of FIG. 2; and

FIG. 4 is a perspective view of the device of FIG. 1 as it might appear before being applied at the locus of an incision.

There is illustrated in the drawing a device 11 which constitutes a preferred embodiment of the present invention. The device is intended to be positioned at the locus of an incision or puncture (not shown) provided incident to the insertion of a catheter 13 beneath the skin of the arm of an individual receiving an intravenous injection and, in this instance, an elastic band 15 holds the catheter adjacent the wrist of the individual and a tape 17 secures it to the thumb. However, it should be clear that the device 11 is not limited to use with catheters inserted into the arm and that it can be used in connection with catheters inserted through the skin at various areas of the body, not only for supplying fluids but also for the drainage of body cavities and organs.

Basically, the device 11 includes a shield 19 having an outwardly projecting sleeve 21 sealed thereto. The shield is adhesively secured to the skin of the individual which encircles the incision, and the sleeve is adhesively secured to the catheter. The adhesive material contains a bacteriostatic or bacteriocidal chemical to arrest the growth of or destroy any organisms present in deep pores or sweat glands or hair follicles of the skin surface and structure. Thus, bacteria are precluded from reaching the incision through or under the shield or along the catheter, and those which may be present are destroyed. The incision is thereby insulated from a major source of infection.

The shield 19 is preferably formed of a flat sheet of a suitable plastic such as polyethylene which is essentially air-impervious and is thus capable of preventing bacteria-laden air from having access to the incision.

The shield is provided with an internal opening 23 (FIG. 2) located within its periphery to accommodate the catheter. The opening may be merely an internal hole, in which case the shield is placed in encircling relation to the catheter by passing one end of the catheter through the hole either before it is inserted or, at least, before it is connected at its outer end to a fluid supply or drainage receptacle. However, in order to enable the shield to be placed in position relative to a catheter previously inserted beneath the skin and connected to a fluid supply or receptacle as, for example, to enable replacement of a device 11 previously applied without the necessity of disconnecting or removing the catheter, the preferred device 11 includes a cut 25 which extends from the periphery of the opening 23 to the periphery of the shield itself. Thus, in positioning the device, the opposed edges defining the cut 25 may be spread to facilitate placement of the shield around the catheter and then returned to an abutting relationship to provide the desired seal. Of course, in positioning the shield provided with the cut 25 around the catheter 13 and securing it to the skin, it is possible that a slight slit will be left along the cut 25; however, it will be appreciated that ideally there will be no slit and even if one should be present, the shield still covers essentially the entirety of an area of skin encircling the incision.

One surface of the shield, the lower surface as the device 11 is viewed in the drawing, is provided with an adhesive coating 27 to enable it to be secured or attached to that area of the skin of the individual which encircles the incision. This coating is preferably antibacterial in that it possesses bacteriostatic or bacteriocidal properties which enable it to arrest the growth of or destroy any bacteria on that portion of the skin with which it is placed in contact. Thus, the coating may include a quaternary ammonium complex, or any one of many antibiotics such as, for example, that sold under the name Bacitracin by the American Pharmaceutical Company. The thickness of this coating is exaggerated in the drawing for clarity of illustration.

Preferably, all of the lower surface of the shield is covered so that no passageway or route is left open through which bacteria can gain access to the incision. However, if the shield is provided with merely an internal opening 23 and no cut 25, it may be sufficient to merely provide the coating 27 adjacent the outer periphery of the shield, specifically omitting any coating adjacent the periphery of the opening 23 to avoid placing the adhesive in contact with the incision. If a cut 25 is provided, an additional coating should be provided adjacent the edges of the cut. In any event, the adhesive coating should be sufficient to maintain the shield in contact with the skin so that bacteria will not be able to gain access to the incision by passing beneath the shield.

The sleeve 21 extends outwardly from the periphery of the internal opening 23. It may constitute a separate element from the shield 19 and be adapted to be adhesively secured thereto so that the shield and sleeve may be secured in place separately around the catheter. In the illustrated embodiment, however, the sleeve is in-

tegral with the shield and both are formed together as one unit. This is considered the preferred embodiment since it eliminates the possibility of bacteria passing between the shield and sleeve through openings which may occur through incomplete joining of the two during the positioning of the sleeve.

The sleeve 21 is tubular in shape and defines an internal passageway 29 to receive the catheter 13. The entire internal surface of the passageway in the illustrated embodiment is provided with the bacteriostatic or bacteriocidal adhesive coating 31 so that the sleeve can be secured to the outer surface of the catheter in such a manner as to prevent bacteria from gaining access to the incision through the passageway 29. However, in some instances, it may not be necessary to provide an adhesive coating in the area of the passageway immediately adjacent the incision, and it may be desired to terminate the coating 31 short of that end of the sleeve which is immediately adjacent the incision. A removable backing sheet 32 of plastic or the like is preferably maintained in contact with the coating 31 of the sleeve and with the coating 27 of the shield to prevent these coatings from becoming attached to material other than the catheter or skin prior to the actual placement of the device around the catheter.

The internal diameter of the passageway 29 preferably corresponds closely to the outer diameter of the catheter to insure an intimate engagement between the two. To facilitate placement of the sleeve around the catheter, the sleeve is provided with a cut 33 which enables a wall of the sleeve to be opened to receive the catheter and eliminates the difficulty of inserting the catheter longitudinally through the sleeve when the inner surface of the sleeve is provided with an adhesive coating. When the shield is also cut, both cuts 25 and 33 are preferably in alignment (FIG. 3).

It would be possible to merely coat the upper portion of the inner surface of the passageway 29 with adhesive and to then fold this coated portion back upon itself, placing the adhesive on the outside of the sleeve. The catheter could then be easily inserted longitudinally through the passageway 29 and, subsequently, the upper portion of the sleeve unfolded to place the adhesive in contact with the catheter.

In the use of the device 11 of the illustrated embodiment, the catheter 13 is preferably inserted beneath or through the skin in the usual manner and suitably connected to a supply of parenteral fluid or to a drainage receptacle as the situation dictates. Prior to forming the incision or puncture for insertion of the catheter, the skin is normally sterilized by means of a suitable reagent, but it may also be desirable if conditions permit to shave the skin surrounding the area where the incision or puncture is to be made to insure complete adherence to the skin by the shield 19. The device 11, which ideally is distributed in a sealed envelope, is then unwrapped and the protective sheet 32 is removed from the adhesive coatings 27 and 31 on the outer surface of the shield 19 and the inner surface of the sleeve 21. The wall of the sleeve, and the shield, are spread along the cuts 33 and 25, respectively, and the device is placed around the catheter 13 immediately adjacent the incision where the catheter penetrates the skin. The shield is then secured to the skin by means of the bacteriostatic or bacteriocidal adhesive coating 27, with

the edges defining the cut 25 in abutting or overlapping relation, and the sleeve is secured to the catheter 13 with the edges defining the cut 33 also in abutting or overlapping relation.

When the device 11 is properly positioned, the shield 19 is sealed to the skin and precludes access to the incision by bacteria except through the internal opening 23. The sleeve, on the other hand, in addition to supporting the catheter, is sealed to the catheter and prevents access to the incision through the opening 23 as well as along the outer surface of the catheter 13. The device 11 not only serves to protect the incision, but is secured in place in such a manner as to prevent the displacement of the device incident to the normal movements of the individual. Assuming that the device is applied in a relatively sterile field and includes an antibacterial adhesive, infection of the incision is greatly minimized.

While one of the specific embodiments of the device 11 has been shown and described, it should be apparent that various modifications may be made therein without departing from the scope of the invention. Such modifications include the forming of the shield and sleeve as separate parts, the provision of an adhesive coating on less than an entire surface of the shield and/or sleeve, and the elimination of the cuts in the shield and sleeve if it is desired to place them on the catheter before the catheter is both inserted in the body and connected at its opposite end, as to a supply of fluid or to a drainage receptacle.

Various of the features of the invention are set forth in the following claims.

What is claimed is:

1. A device for providing a protective seal at the locus of an incision provided incident to the insertion of a catheter beneath the skin, said device comprising

A. a shield adapted to overlie essentially the entirety of an area of skin encircling the incision,

1. the body of said shield being formed so as to be impervious to the passage of bacteria therethrough and being provided with an opening located within its periphery alignable with the incision to accommodate a catheter,

2. at least a portion of one surface of said shield being provided with an adhesive coating effective to maintain said shield in contact with the skin so as to prevent bacteria from passing beneath said shield and gaining access to the incision,

B. a tubular sleeve extending outwardly from the non-adhesive surface of said shield and sealed thereto so as to prevent bacteria from gaining access to said opening in said shield at the juncture of said sleeve and shield,

1. the walls of said sleeve being formed so as to be impervious to the passage of bacteria therethrough,

2. said sleeve defining a passageway in alignment with said opening in said shield and adapted to accommodate the catheter intimately therein,

3. at least a portion of the inner surface of said sleeve being provided with an adhesive coating effective to create a seal between said sleeve and the catheter so as to prevent bacteria from passing between said sleeve and the catheter and gaining access to the incision.

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2. A device in accordance with claim 1, wherein lateral access means includes a cut extending from the periphery of the catheter-accommodating opening to the outer periphery to facilitate the placement of the shield in a position encircling a catheter.

3. A device in accordance with claim 1, wherein said lateral access means includes a cut extending the length of said sleeve to facilitate the placement of the sleeve in a position surrounding a catheter.

4. A device in accordance with claim 1, wherein said shield and sleeve are integral, and wherein said lateral access means is a cut which extends from the outer end of said sleeve along said sleeve and shield to the periphery of said shield so as to facilitate the placement of the device relative to a catheter.

5. A device in accordance with claim 1, wherein essentially the entire inner surface of said shield and essentially the entire inner surface of said sleeve are provided with an adhesive coating, and wherein a removable backing sheet overlies each coating to protect it prior to use.

6. A device in accordance with claim 1, wherein said adhesive coating contains an antibacterial chemical.

7. A device for providing a protective seal at the locus of an incision provided incident to the insertion of a catheter beneath the skin, the device comprising:

A. a flat shield having top and bottom surfaces adapted to overlie essentially the entirety of an area of skin encircling the incision,

1. the body of said shield being formed so as to be

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impervious to the passage of bacteria therethrough and being provided with an opening located within its periphery alignable with the incision to accommodate a catheter,

2. at least a portion of one surface of said shield being provided with an adhesive coating effective to maintain said shield in contact with the skin so as to prevent bacteria from passing beneath said shield and gaining access to the incision,

B. and a tubular sleeve extending outwardly from the non-adhesive surface of said shield and sealed thereto so as to prevent bacteria from gaining access to said opening in said shield at the juncture of said sleeve and shield,

1. the walls of said sleeve being formed so as to be impervious to the passage of bacteria therethrough,

2. said sleeve defining a passageway in alignment with said opening in said shield and adapted to accommodate the catheter intimately therein,

3. at least a portion of the inner surface of said sleeve being provided with an adhesive coating effective to create a seal between said sleeve and the catheter so as to prevent bacteria from passing between said sleeve and the catheter and gaining access to the incision, said adhesive coating containing an antibacterial chemical.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,683,911

Dated August 15, 1972

Inventor(s) James B. McCormick

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Claim 1, line 67, change period to a comma and add
subparagraph C.

--C. and means on said shield and said sleeve walls
for providing lateral access of a catheter into said
sleeve passageway.--

Signed and sealed this 9th day of January 1973.

(SEAL)
Attest:

EDWARD M. FLETCHER, JR.
Attesting Officer

ROBERT GOTTSCHALK
Commissioner of Patents