

Feb. 6, 1968

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3,367,332

PRODUCT AND PROCESS FOR ESTABLISHING A STERILE AREA OF SKIN

Filed Aug. 27, 1965

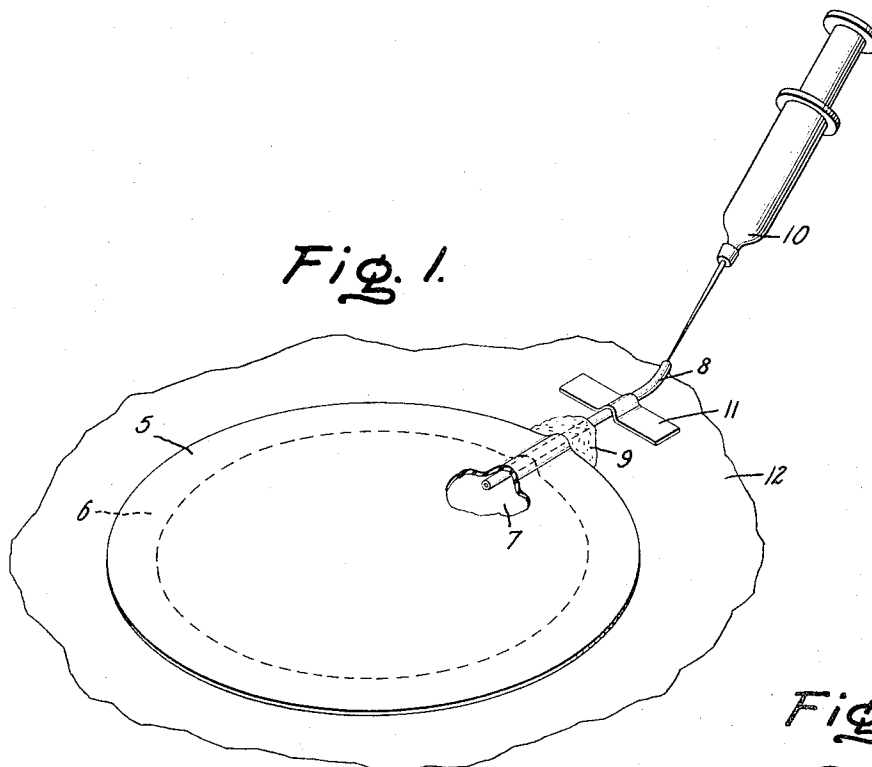


Fig. 1.

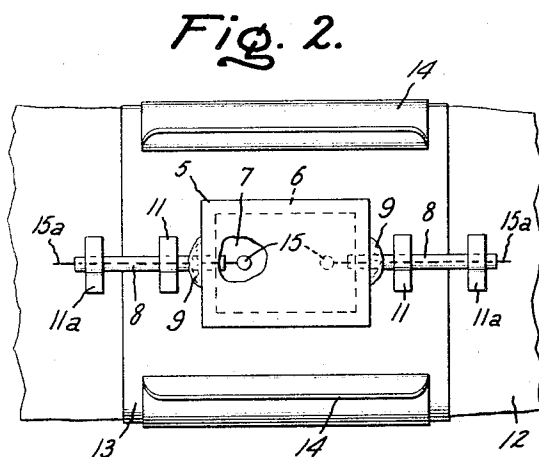


Fig. 2.

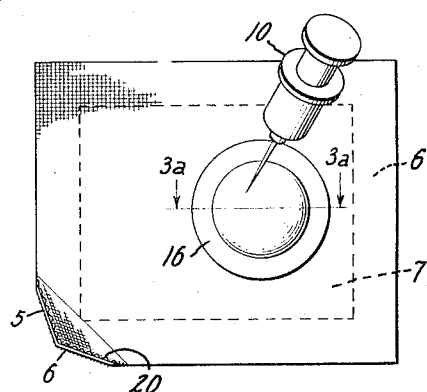


Fig. 3.



Fig. 3a.

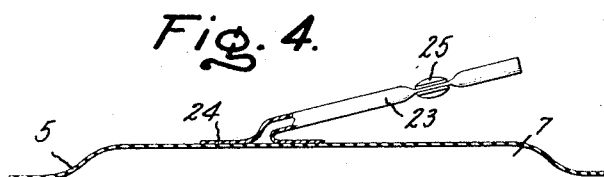


Fig. 4.

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PRODUCT AND PROCESS FOR ESTABLISHING A STERILE AREA OF SKIN

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Filed Aug. 27, 1965, Ser. No. 483,073

9 Claims. (Cl. 128—268)

ABSTRACT OF THE DISCLOSURE

The construction of, and several uses for, a new non-porous skin cover, or surgical bandage, are described, this cover being capable of retaining liquids and of selectively passing gases and vapors, while maintaining a sterile treatment zone between the cover and the body surface to which it is applied.

My invention relates to a new type of surgical bandage, and in particular, to a bandage having a selectively permeable membrane which is impermeable to a selected fluid introduced to the wound area for treatment thereof.

Known surgical bandages, wherein such bandages range in size from the small type covering shallow minor surface wounds, burns, and the like, commonly known as the Band-Aid, a Johnson and Johnson trademark, to the large surgical dressing type, are fabricated from a gauze material which permits some passage therethrough of gas, vapor and fluid, the degree of passage being determined by the type of gauze material and layers thereof employed. These known bandages are not completely exclusive of infectious organisms and occasionally employ germicides to reduce chance of infection. A concurrently filed U.S. patent application, Ser. No. 483,072 entitled, "Surgical Bandage and Method of Fabrication," inventor Norman R. Dibelius, and assigned to the assignee of the present invention, describes a surgical bandage of impermeate construction which is selectively permeable to specific fluids and substantially nonpermeable to undesirable solid matter or infectious organisms such as bacteria, virus and germs. The surgical bandage described in the above-identified patent application is not directed to, and makes no provision for, introducing a selected fluid in contact with the wound area for treatment thereof.

Therefore, one of the principal objects of my invention is to provide a new surgical bandage adapted for fluid treatment of wounds, burns and the like.

Another object of my invention is to fabricate such bandage from a thin membrane selectively permeable to specific fluids.

A still further object of my invention is to provide a bandage which obtains and maintains an antiseptically sterile condition of a body area being treated.

In accordance with my invention and the objects enumerated above, I provide a surgical bandage which includes a membrane selectively permeable to specific fluids and substantially impermeable to a selected fluid to be introduced to a body area being treated. An adhesive disposed along the edges of one side of the membrane seals the edges thereof to healthy skin around the body area to be treated and forms a pocket between the body and sealed membrane. The selected fluid is introduced to the pocket by means of a flexible tubing, cannula or hypodermic needle. In the case of the tubing, the communication to the pocket is by passage between the membrane and skin at a point along the edge of the membrane, or a direct attachment to the pocket portion of the membrane. The cannula or hypodermic needle passes through the tubing into the pocket, or a self-sealing patch may be attached to the outside of the pocket portion of the membrane

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and the cannula or hypodermic needle inserted into the pocket through the patch to maintain sterility within the pocket. The membrane may be provided with two tubing connections to obtain circulation of fluid through the pocket. My membrane bandage obtains and can maintain antiseptic sterilization of the entire inner pocket region of the bandage including the skin surface and also is adapted for fluid treatment of a wound, a burn or the like located under the pocket region of the bandage.

The features of my invention which I desire to protect herein are pointed out with particularity in the appended claims. The invention, itself, however, both as to its organization and method of operation, together with further objects and advantages thereof, may best be understood by reference to the following description taken in connection with the accompanying drawings, wherein:

FIGURE 1 is a perspective view of a first embodiment of a surgical bandage fabricated in accordance with my invention;

FIGURE 2 is a top view of a second embodiment of my invention wherein fluid may be circulated within a wound area or electrodes implanted;

FIGURE 3 is a top view of a third embodiment of my invention employing a self-sealing patch;

FIGURE 3a is a sectional view taken on the line 3a—3a of FIG. 3; and

FIGURE 4 is a sectional view of a fourth and preferred embodiment of my invention.

In FIGURE 1, there is shown a first embodiment of my invention wherein a surgical bandage is fabricated from a suitable membrane illustrated as a whole by numeral 5, which is selectively permeable to specific fluids. Membrane 5 is adhesively sealed along the edges thereof to healthy skin 12 surrounding a body area to be treated. The space between the body surface and membrane within the area of the adhesive outline thus forms what is hereinafter described as a pocket 7. Membrane 5 is constructed of a material, such as the silicone rubber membranes described in U.S. Patent Applications, S.N. 241,346 filed Nov. 30, 1962; 247,904 filed Dec. 28, 1962; 269,430 filed April 1, 1963; 397,687 filed Sept. 21, 1964; and 466,698 filed June 24, 1965 all by the inventor Walter L. Robb and assigned to the assignee of the present invention. The selectively (or semi-) permeable membrane 5 is defect-free, at least initially is impermeate, and has a uniform thickness in the range of 1 to 10 mils. Membrane 5 is selectively permeable to specific fluids such as the gases, oxygen, nitrogen and water vapor, but is substantially impermeable to other fluids and prevents passage of solid matter or infectious organisms such as bacteria, virus, germs and the like to the wound area which interfere with the healing processes or cause infection. Thus, air and body water pass through the membrane in opposite directions at controlled rates but body salts are retained. The concentration of retained body salts can be optimized to hasten wound healing. The transfer of fluid through the (permselective) membrane 5 is based on a partial pressure differential across the membrane wherein fluid that is to be transferred is at a greater partial pressure on one side of the permselective membrane than on the other side. The transfer process itself is one of permeation through the membrane due to the partial pressure differential and is not related to the conventional filtering process which is based on certain size molecules passing through related size holes in a membrane. The permeation proceeds from the area of higher partial pressure to the area of lower partial pressure as described in the above-cited patent applications to Robb. It is to be understood that the permeation of a fluid (gas or liquid) through the membrane is in the gaseous or vapor state. The above-mentioned permeability characteristic of mem-

brane 5 is necessary for the proper operation of the concurrently filed patent application to Norman R. Dibelius, and is also very useful in my invention. However, it is the membrane's relative impermeability to specific fluids that is necessary for the proper operation of my invention. Thus, my surgical bandage is adapted to retain or circulate an antiseptic (sterilization) fluid and, or, suitable fluid medications such as silicone oil in the case of body burns. A further advantage of the silicone rubber membrane is that it is nontoxic with respect to the body and wounds, as compared to plastic materials and the like.

Adhesive 6 is disposed along the edges of one side of the membrane 5 for sealing the edges thereof to healthy skin and to form pocket 7 as hereinabove described. Adhesive 6 may be any of several suitable types, as for example RTV-102 silicone adhesive produced by the General Electric Company.

The communication by which a selected fluid(s) is introduced to the body area to be treated (pocket 7) is a small flexible tubing 8 which passes between membrane 5 and the surface of skin 12 at a point along the edge of the membrane. Tubing 8 is attached to the membrane edge and skin 12 by an adhesive 9, which may also be the RTV-102 silicone adhesive to assure that a seal of the membrane to the skin is maintained at the point of passage of tubing 8 therethrough. Flexible tubing 8 may be a silicone or polyethylene medical tubing and a first end thereof terminates in the pocket area 7. A particular fluid such as an antiseptic for sterilization of the entire area within pocket 7 or a suitable medicine or drug for the particular wound, burn or skin disorder is readily introduced into the pocket by means of tubing 8. Additionally, a hypodermic needle 10 can be inserted through the second end of tubing 8 to insert and withdraw the fluid from the pocket area. The hypodermic needle can also be inserted through the tubing 8 into the pocket for shallow injections of the needle directly into the body, as dictated by a particular medical treatment. A cannula (not shown) may also be inserted through the second end of tubing 8 to provide passage for fluid to pocket 7. An adhesive patch (strip) 11 is preferably employed to retain tubing 8 in fixed and tension-free relationship with respect to membrane 5.

FIGURE 2 illustrates a second embodiment of my surgical bandage which is especially adapted for circulation of a suitable fluid within pocket 7. Two flexible tubings 8 are in communication with the interior of pocket 7, passing between the edge of the membrane and body surface and sealed thereto as described with relation to FIGURE 1. Adhesive patches 11 are employed to retain tubings 8 in fixed relationship with respect to membrane 5. In the case wherein the portion of the body to be treated is an extremity such as a leg or arm, conventional bandage 13, such as of gauze material, and clamp 14 are conveniently employed to provide greater mechanical support for the membrane 5-tubing 8 system.

The FIGURE 2 arrangement is also employed when inserting electrodes for electrocardiograph application, for other instrumentation sensors which extract signals from the surface or interior of the body, and for blood transfusion catheters. Heart-lung machine cannulae, and kidney machine cannulae may also be inserted into the body by employing the two-passage bandage of FIGURE 2. The electrodes, cannulae, and the like are passed through the tubings 8 to maintain sterile conditions. As an example, two electrodes 15 are shown within pocket 7. They may be on the body surface or implanted, as dictated by the medical event. The electrical conductors 15a attached to the electrodes pass through tubings 8 and are further mechanically supported on the body surface 12 by adhesive patches (strips) 11a. It is to be understood that the line designation for conductors 15a may also represent cannulae, hypodermic needles and the like.

In the most general application of the FIGURE 2 bandage when employing a circulating flow of medication

or treatments employing instrumentation sensors and the like, an antiseptic fluid is first introduced into pocket 7 through one tubing 8 and extracted therefrom through the other tubing. Upon sterilization of the area within pocket 7, the medicating fluid is circulated through pocket 7 by means of tubing 8 or additional tubings (not shown), or suitable electrodes or cannulae within tubings 8 are utilized for a subsequent medical treatment.

FIGURE 3 illustrates a third embodiment of my invention wherein a self-sealing patch 16 is attached to the bandage during manufacture or after the bandage is applied. Patch 16 is comprised of a high viscosity silicone elastomer as one example, and is adhesive coated on the flat side to be attached to the membrane. A sectional view of patch 16, taken on line 3a is illustrated in FIGURE 3a. The patch is of sufficient thickness in the central portion thereof to provide the self-sealing feature upon repeated penetration by a hypodermic needle or cannula. A peelable tab (not shown) is attached to the adhesive coated side of patch 16 and is removed upon attachment to the bandage. The membrane 5 may be suitably attached, as by bonding, to a backing material 20 to prevent rupture or other damage to the membrane, and also to increase the mechanical strength thereof since it adds reinforcement to the relatively weak membrane without impairing its operation. The backing 20 may also be attached to the membranes illustrated in FIGURES 1, 2 and 4, if desired, and is normally secured to the side of the membrane removed from the body area being treated. The backing material is porous and nontoxic, that is should not be of a material or contain dyes which are harmful to the wound or the body skin, and is made of a suitable fabric such as nylon or Dacron. The backing material need not have a thickness of any particular dimensions, the only requirements being that the thickness be sufficiently great to provide the desired mechanical strength for the bandage and yet not completely impede any fluids which desirably permeate the membrane. The embodiment of FIGURE 3 is thus especially well adapted for shallow or deep penetration into the body by a hypodermic needle 10 since the self-sealing patch may be used for repeated insertion of such needle, and the membrane being relatively transparent, insertion of the needle into the body can be made after the bandage is in place. This feature is a considerable advantage since antiseptic sterilization of the entire inside pocket region of the bandage including the skin surface can be obtained before penetration of the body by the needle. In like manner, a cannula may be inserted into pocket 7 through patch 16 for introducing a suitable fluid into the pocket region. Two or more patches 16 may be employed, if desired, to circulate fluid within pocket 7, for other purposes.

FIGURE 4 illustrates a sectional tubing attachment which, similar to the self-sealing patch of FIGURE 3 may be attached to membrane 5 during manufacture or after the bandage is applied. The tubing arrangement of FIGURE 4 is distinguished from that of FIGURES 1 and 2 in that the tubing does not pass under the edge of membrane 5 but has a direct attachment to the pocket portion of the membrane. The tubing attachment comprises a flexible tubing 23 which may be made of polyethylene or silicone and has a flanged end portion 24 that is sealed to membrane 5 by means of a suitable adhesive. A clamp 25 or other suitable valve is used to control the flow of fluid to the pocket region 7 enclosed on one side by membrane 5 and on the other side by the body surface. Tubing attachment 23 is sealed in place on membrane 5 and a hypodermic needle or cannula is then passed through tubing 23 to puncture membrane 5 at the flanged end of tubing 23. Fluid may then be injected and withdrawn from pocket 7. In like manner, a hypodermic needle may be passed through tubing 23 and inserted into the body. The use of two tubings 23 permits continuous circulation of fluid through pocket 7 or treatments utilizing a pair of electrodes, instrumentation sensors, cannulae for various

body organ machines, blood transfusion catheters and the like.

The fluid retaining bandages hereinabove described can be as large or small, as desired. The large bandages preferably include a backing material 20 for added strength. There are many applications for my bandages. In the case of burn treatment, my fluid retaining bandage provides for circulation of silicone oil (or other fluids) over the burn surface and thus avoids the necessity for total body immersion as has been done in the prior art. The fluid can be circulated either continuously or periodically through the tubing connected to the bandage pocket area and contains appropriate cell metabolites, gases such as oxygen, medicines and an infection combating agent such as an antibiotic. Decomposed tissue and by-products are removed in the circulated fluid. Thus, a new approach for optimizing the conditions for maintenance and repair of injured cellular material is provided. Treatment of wounds where exposed tissue is involved including surgical wounds uses the same approach and has the advantage that prior infections can be combated and any subsequent infection prevented. The ability to sterilize and maintain sterility of a point of insertion of instrumentation sensors, heart-lung machine cannulae, kidney machine cannulae and blood transfusion catheters are other important applications. At the present time there is a natural reluctance in the medical field to penetrate the body except when absolutely necessary because of risk of infection. Much of this is overcome with my invention since sterility can be virtually guaranteed. My invention also should promote the study of improved electrodes for electrocardiograph application. Thus, the present reluctance to penetrate the body surface is overcome and the use of inserted electrodes to extract more meaningful signals is now possible. Use of a fluid electrolyte in pocket 7 provides an opportunity to design new surface electrodes.

From the foregoing description, it is apparent that my invention attains the objectives set forth and provides a new surgical bandage which is capable of retaining selective fluids in the body area being treated and also provides a means for assuring that a body surface is antiseptically sterile prior to further medical treatment such as the insertion of a hypodermic needle into the body. Since the surgical bandage is selectively permeable to specific fluids it has the further advantages that: it permits control of loss of body fluids which are discharged by a wound, burn or the like; prevents body tissue in the wounded area from being deprived of oxygen and air which passes through the bandage to the wound area to further hasten or promote the healing process; and excludes undesirable solid matter or infectious organisms such as bacteria, virus or germs which might cause infection in the wound area and subsequent complications.

Having described a new surgical bandage, it is believed obvious that modification and variation of my invention is possible in the light of the above teachings. Thus, the bandages may be provided with a variety of means for introducing and, or withdrawing fluid from the area of a body being treated. Also, two or more self-sealing patches in the FIGURE 3 embodiment, and two or more tubing attachments in the preferred FIGURE 4 embodiment may be employed for circulating fluid in the pocket. It is, therefore, to be understood that changes may be made in the particular embodiments of my invention described which are within the full intended scope of the invention as defined by the following claims.

What I claim as new and desire to secure by Letters Patent of the United States is:

1. In the determination and maintenance of a sterile treatment zone extending over a selected portion of skin area wherein an area of skin larger than, and including, said portion of skin area is overlaid by a non-porous cover fitting against the skin bordering said portion of skin area in a closed circuit defining a centrally-located unadhered

area of said cover, said cover having in combination therewith means for controlled access to the space beneath the centrally-located unadhered area of said cover enabling the admission of fluids and/or instrumentations, the improvement comprising:

- (a) the non-porous cover being a thin membrane impermeable to liquids and infectious organisms and selectively permeable to gases and vapors and
- (b) a sealing material impermeable to liquids and infectious organisms directly adhering the periphery of said membrane to the skin bordering said portion of skin for complete sealing of said membrane along said periphery.

2. The improvement substantially as recited in claim 1 wherein the membrane exhibits a relatively high permeability to oxygen, nitrogen and water vapor and is non-toxic to the organisms, to the skin of which the membrane is applied.

3. The improvement set forth in claim 1 and further comprising

- a nontoxic porous backing material bonded to a major surface of the membrane for increasing the mechanical strength thereof.

4. The improvement set forth in claim 1 wherein the membrane has a uniform thickness in the range of 1 to 10 mils.

5. The improvement set forth in claim 1 wherein the membrane is a silicone rubber material.

6. In the determination and maintenance of a sterile treatment zone extending over a selected portion of skin area wherein an area of skin larger than, and including, said portion of skin area is overlaid by a non-porous cover fitting against the skin bordering said portion of skin area in a closed circuit defining a centrally-located unadhered area of said cover, the improvement comprising a patch of elastomeric material capable of self-sealing against the passage therethrough of liquids or infectious organisms after penetration therethrough and removal therefrom of a sharp instrument, said patch being sealed to the outer surface of the non-porous cover in the unadhered area thereof.

7. A method for determining and maintaining a sterile treatment zone over a selected portion of skin area comprising steps of:

- (a) covering an area of skin larger than, and including, said portion of skin area with a non-porous membrane impermeable to liquids and infectious organisms and selectively permeable to gases and vapors,
- (b) sealing said membrane directly to the skin bordering said portion of said skin area with adherent sealing material impermeable to liquids and infectious organisms and,
- (c) introducing liquid to, and containing a quantity of said liquid in, the space beneath the unadhered centrally-located area of said membrane.

8. The improvement substantially as recited in claim 7 wherein liquid is continuously introduced to and removed from the space defined.

9. In the determination and maintenance of a sterile treatment zone extending over a selected portion of skin area wherein an area of skin larger than, and including, said portion of skin area is overlaid by a non-porous cover fitting against the skin bordering said portion of skin area, the improvement comprising:

- (a) employing a thin membrane impermeable to liquids and infectious organisms and selectively permeable to gases and vapors as the non-porous cover,
- (b) sealing said membrane directly to the skin bordering said portion of skin area with adherent sealing material impermeable to liquids and infectious organisms and
- (c) sealing to the outer surface of said membrane a patch of elastomeric material capable of self-healing against the passage therethrough of liquids or

infectious organisms after repeated penetration of a sharp instrument therethrough and withdrawal therefrom.

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