

# PATENT SPECIFICATION

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## (54) IMPROVEMENTS RELATING TO WOUND DRESSING MATERIALS

5 (71) We, PETER MAURICE LOCK, a British Subject of Petrosa, 327 Lordswood Lane, Walderslade, Chatham, Kent and DAVID ROGER WEBB, a British Subject of 9 Lambourn Way, Lordswood, Chatham, Kent, do hereby declare the invention for which we pray that a patent may be granted to us and the method by which it is to be performed to be particularly described in and by the following statement:—

10 This invention relates to wound dressing materials, and more specifically to a material which can be applied to many types of injury or wound but is particularly useful as a temporary wound cover in the therapeutic treatment of burns, varicose ulcers, pressure areas and other related injuries. The term "burns" covers thermal, chemical, electrical and similarly inflicted wounds involving skin damage or destruction.

15 Burns require a unique combination of therapy and dressing when the function of the skin is absent or impaired, because nutritious body fluids and their essential components are continuously lost through the wound, which in the case of a large area burn can cause dehydration of the patient and in turn involve more serious complications such as lung and kidney malfunctions, while the normal protection provided by the skin from invading harmful bacteria and other toxic and noxious agents is no longer available.

20 Many types of dressing material have been used heretofore. Absorbent fibrous materials such as cotton gauze can cause excessive dehydration and drying of the wound and thus become firmly adhered to the affected area, so that dressing changes are painful and can cause further damage to the wound. The natural healing process in which skin cells multiply and migrate across the moist wound surface is delayed, because the cells have to burrow deep under the dried area. Individual fibres can also become detached from the dressing and

embedded in the wound and thereby impede healing.

To prevent adherence and maintain a moist wound environment, dressing materials impregnated with greasy substances such as petroleum jelly have been employed. These dressings require frequent changing to avoid drying out, with consequent frequent exposure of the wound to airborne bacteria, and the greasy substances provide a good environment for the proliferation of bacteria so that wound infection is difficult to avoid, while the greasy substances can also be absorbed into the wound and retard healing by acting as foreign bodies.

25 Dressings made of polyethylene, polypropylene and polyamide films eliminate adherence of the dressing to the wound and prevents particles being embedded therein, but being non-porous they cannot absorb the excess of liquid exudate which exudes from a burn and they can therefore become painful to the patient unless changed frequently, with consequent exposure of the wound to air-borne bacteria. The micro-climate under such film dressings, while favourable for healing, is also ideal for such bacteria so that wound infection again becomes a problem, while the fact that the condition of the wound is visible through the film dressing is depressing to the patient. Other film dressing materials made of gelatins, alginates and celluloses have been designed to create the same favourable micro-climate in the wound by dissolving or melting in the exudate and reforming as part of the eschar (scab). This increases wound dehydration and the films, when mixed with the exudate in the eschar, become supportive of bacteria but cannot be removed from the wound because they have become an integral part of it. Even if infection is avoided, the dehydration effect delays healing. Plastic spray-on dressings involve similar problems, particularly encapsulation of dressing material deep in the wound.

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5 Absorbant dressings of polyvinyl alcohol  
 sponge and of polyurethane foam with an  
 open cell structure have been found to  
 cause wound dehydration and adherence of  
 the dressing to the wound, while small  
 particles of the cells of the dressing material  
 can become detached and embedded in the  
 wound, causing undesirable reactions. Also,  
 10 passage of the exudate right through the  
 dressing can provide a nutrient path for  
 airborne bacteria back through the dressing  
 into the wound. A polyurethane foam  
 dressing with an impermeable backing of  
 15 polytetrafluoroethylene avoids the latter  
 problem but still suffers from the problem of  
 detached particles.

Biological wound covers, mainly of  
 porcine and cadaver skin, perform well in  
 many respects but suffer from the problem  
 20 that it is extremely difficult to avoid leaving  
 small fragments of dermis in the wound  
 when removing the dressing, producing  
 subsequent foreign body reactions which  
 can cause rejection of autografts and later  
 breakdown of healed wounds, and causing  
 25 production of antibodies which might  
 involve serious consequences at a later date.

An object of the present invention is to  
 provide a wound dressing material which is  
 30 free from the disadvantages of the known  
 materials described above.

According to the present invention, a  
 wound dressing material comprises a sheet  
 of a synthetic plastics material which is  
 35 permeable to water vapour and to air,  
 having on one side a smooth glazed surface  
 for application to a wound, a cellular region  
 behind the smooth surface, the cells in the  
 cellular region being closed cells, and a  
 40 more dense region behind the other surface,  
 so that on contact with liquid exudate from  
 a wound the dressing material will absorb a  
 limited amount of exudate but prevent it  
 from passing right through the dressing  
 45 material.

The fact that the dressing material is  
 water vapour- and air-permeable, but will  
 not permit the liquid exudate to pass  
 through it, assists in maintaining a moist  
 50 micro-climate favourable for healing in the  
 wound. The smooth glazed surface avoids  
 the danger of detachment of cell particles  
 and assists in preventing adherence of the  
 dressing to the wound. The cellular region  
 55 enables the dressing to absorb excess of  
 liquid exudate without drawing out so much  
 exudate that the wound would become  
 dried and the patient dehydrated. Dressings  
 need not be changed too frequently.

60 Preferably the synthetic plastics material  
 is a polyurethane, in particular the product  
 of polymerisation of an isocyanate capped  
 polyoxyethylene polyol employing a cross-  
 linking agent or catalyst which is reactive  
 65 with the isocyanate groups, without any

substantial amount of water present. The  
 synthetic plastics material preferably also  
 incorporates an alkylene oxide surfactant to  
 increase the hydrophilic nature of the  
 dressing material.

The cross-linking agent or catalyst  
 preferably contains in its molecule two or  
 more amine and/or hydroxyl groups which  
 are reactive with the isocyanate groups.

In the preferred embodiment, the polyol  
 is a polyoxyethylene diol having a weight  
 average molecular weight of approximately  
 1500, containing a proportion of polyols  
 having three or more hydroxyl groups, the  
 diol and polyols having been capped with di-  
 isocyanates. The preferred cross-linking  
 agent or catalyst is dimethylethanolamine.  
 Other cross-linking agents or catalysts may  
 be selected from diethylenetriamine, tri-  
 ethylenetetramine, tetraethylenepentamine,  
 polyethylenimine, glycerol, trimethylol-  
 propane, pentaerythritol, tolylene-2,4,6-  
 triamine, ethylene diamine, trimethylene-  
 diamine, tetramethylenediamine, penta-  
 methylenediamine, hexamethylenediamine,  
 ethanolamine, diethanolamine, hydrazine,  
 triethanolamine, benzene-1,2,4-  
 tricarboxylic acid, nitrilotriacetic acid,  
 citric acid, and 4,4'-methylenebis(o-  
 chloroaniline). The alkylene oxide  
 surfactant may contain ethylene oxide and  
 propylene oxide units, and the proportions  
 of these may lie in the range from 75:25% to  
 40:60% by weight.

The invention also comprehends a  
 method of making a wound dressing  
 material which is permeable to water  
 vapour and of air, the method comprising  
 the steps of mixing an isocyanate capped  
 polyoxyethylene polyol with an alkylene  
 oxide surfactant with agitation to form an  
 aerated creamy mix, incorporating a cross-  
 linking agent or catalyst in the mix,  
 spreading the mix on to a smooth glazed  
 release paper to form a sheet of a  
 predetermined uniform thickness, and  
 heating the sheet to assist polymerization  
 of the mix, with the exclusion of any  
 substantial amount of water from the mix  
 during the said steps and with application of  
 heat in the last mentioned step in such  
 manner that polymerisation is initiated first  
 in the upper surface of the sheet to form a  
 dense outer region which is impervious to  
 liquids while trapping sufficient gases in the  
 region behind the lower surface to render  
 the latter region cellular. Preferably, the  
 release paper is supported on a flat surface,  
 such as a sheet of glass, during the spreading  
 and heating steps. The spreading may be  
 effected by means of at least one spreader  
 bar with a corrugated surface which is  
 drawn over the surface of the paper at a  
 fixed distance above it. The heating is  
 preferably effected in an oven using a fan to

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ensure even application of heated air to the upper surface of the sheet.

A preferred embodiment of the invention will now be described by way of example and with reference to the accompanying drawings, in which:—

Figure 1 is an enlarged cross-section through an example of a dressing material according to the invention.

Figure 2 is a perspective diagrammatic view of apparatus used in the spreading step in the manufacture of the dressing material, and

Figure 3 is a diagrammatic cross-section of a curing cabinet or oven used to effect heating and polymerization of the material.

In this preferred embodiment, the dressing material is formed by polymerisation of a polyol supplied by W. R. Grace & Co., of New York, U.S.A., under the Trade Name Hypol, which is described in British Patent Specification No. 1429711. The polyol is a polyoxyethylene diol having a weight average molecular weight of approximately 1500, containing a proportion of polyols having three or more hydroxyl groups, the diol and polyols having been capped with diisocyanates. British Patent Specification No. 1429711 describes the reaction of the isocyanate capped polyol with water to form a polyurethane foam, and states that, particularly where the isocyanate functionality is only about 2, a cross-linking agent or catalyst should be employed to promote cross-linking of the foamed polymer. The cross-linking agent or catalyst should be polyfunctional and reactive with isocyanate groups and include but are not limited to materials such as diethylenetriamine, triethylenetetramine, tetraethylenepentamine, polyethylene imine, glycerol, trimethylolpropane, pentaerythritol, tolylene-2,4,6-triamine, ethylene diamine, amino-ethanol, trimethylenediamine, tetramethylenediamine, pentamethylenediamine, hexamethylenediamine, diethanolamine, hydrazine, triethanolamine, benzene-1,2,4-tricarboxylic acid, nitrilotriacetic acid, citric acid and 4,4'-methylenebis(o-chloroaniline).

In the formation of the dressing material according to the present invention, polymerization is effected in the substantial total absence of water and the product, although evidently a polyurethane, is only cellular to a limited extent in one region and is not blown to form a polyurethane foam by water reaction as in the product of British Patent Specification No. 1429711.

In the production of the preferred embodiment of the dressing material according to the present invention, the Hypol polyol is polymerized with dimethylethanolamine and incorporates an

ethylene oxide/propylene oxide surfactant to increase the hydrophilic nature of the dressing material.

The nature of the dressing material is illustrated in an enlarged cross section in Figure 1. The dressing material generally indicated at 10 has a smooth, highly glazed surface 11 on the side which is to be applied to a wound, a cellular region 12 behind the smooth surface 11, and a more dense region 14 behind the other surface 15. The cells 16 of the cellular region 12 are substantially smaller than those of a normal plastics foam and are normally closed. The material between the cells 16 in the region 12 is itself porous and hydrophilic, containing very small pores which are much smaller again than the cells 16, so that on contact with an aqueous fluid it swells and absorbs at least some of the fluid.

In the production of a preferred dressing material, 100 parts by weight of the Hypol polyol are mixed with from 0.1 to 5 parts by weight, preferably 1.8 parts by weight, of a surfactant/stabiliser containing 75% ethylene oxide units and 25% propylene oxide units, by weight, using whisk type paddles to form an aerated creamy mix, in an atmosphere of low relative humidity at a temperature between 15°C and 55°C, preferably 25°C. The mixture is allowed to stand for approximately 3 to 4 minutes to permit escape of large air bubbles trapped during mixing, but should not be left for longer periods to avoid reaction with atmospheric moisture. From 0.1 to 1.5 parts by weight, preferably 0.7 parts by weight, of dimethylethanolamine are then added and mixing is resumed for a further 30 to 60 seconds. The creamed mixture is then poured on to a smooth glazed release paper having a release coating of polyethylene and silicone, which is tightly stretched over a long table having a flat surface, such as a sheet of smooth plate glass  $\frac{1}{4}$  inch thick, to ensure absence of wrinkles, folds or ridges. The creamy mix is then spread over the paper to form a layer of uniform thickness.

A device which has been devised for this purpose is illustrated in Figure 2 and comprises three parallel stainless steel tubes 17 of 2 inch external diameter which are spaced about 1 inch apart, and each of which is wound externally with 1 mm round stainless steel wire 18 from end to end, the wire being held in position by soldering, to provide a corrugated surface. Alternatively, the tubes 17 may be formed with a screw thread on their external surfaces. The tubes 17 can be rotated in end plates 19, 20 which are mounted on a sled running in tracks on each side of the table. The end plates 19, 20 are of stainless steel and support each end of the tubes 17 so that, the corrugated surfaces of the tubes 17 are

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5 maintained at a uniform spacing from the  
 10 glass sheet 21. The spacing of the tubes 17  
 from the sheet 21 may be adjusted  
 according to the thickness of the dressing  
 material to be produced, from e.g. 0.25 mm  
 to 3 mm. The normal spacing is 0.75 mm to  
 produce a dressing material 1 mm thick. By  
 15 traversing the tubes 17 over the creamy mix  
 on the paper 22, the mix is spread into an  
 even layer over the paper while large air  
 bubbles are burst or encouraged to emerge  
 from the mixture. The tubes 17 may be  
 rotated through 120° between traverses  
 over the mix, so that three traverses can be  
 made before the tubes must be removed and  
 cleaned.

20 A spray head may be employed for  
 pouring the creamed mixture on to the  
 paper 22, with a V-shaped plough to effect  
 preliminary spreading before the tubes 17.  
 This arrangement is not illustrated.

25 When the spreading has been completed  
 the paper 22 is drawn lengthwise off the  
 glass plate 21 and cut transversely into  
 sections which are received on trays 23  
 which are then transferred rapidly through  
 30 louvre doors 31 to a curing cabinet 32 or  
 oven illustrated in Figure 3, which has a set  
 of glass shelves 24 mounted one above the  
 other to support the trays 23. The cabinet 32  
 is heated by means of three electrical  
 elements 25 and a fan 26 which circulates  
 the heating air in the directions illustrated  
 35 by the arrows. Thermostats 27, 28 are  
 connected to the heating elements to ensure  
 an even temperature throughout the  
 cabinet. Silica gel is contained in a mesh  
 screen 29 and placed on a sloping ramp 30 in  
 the path of the heated air after it leaves the  
 40 heating elements 25 before it reaches the  
 glass shelves 24, so as to maintain the  
 relative humidity in the cabinet at a low  
 level, preferably below 10% or at most 20%.  
 The temperature in the curing cabinet is  
 45 preferably maintained at 150°F, though  
 temperatures between 90°F and 160°F can  
 be used in certain circumstances. A relative  
 humidity as high as 45% can also be used in  
 some cases, though this is normally  
 50 undesirable. The circulation of the heated  
 air through the cabinet 32 ensures an even  
 temperature throughout the cabinet and  
 even application of the heated air to the  
 upper surface of the mix on the trays 23.

55 The heating maintains the creamy mix in  
 a viscous liquid state which allows a large  
 part of the entrapped gases to escape during  
 the polymerisation process and  
 consequently prevents the formation of a  
 60 conventional foam, while accelerating the  
 polymerisation of the material. Due to the  
 fact that the heat is supplied to the mix  
 principally by the heated air passing over its  
 exposed upper surface 15, polymerisation is  
 65 initiated first in the upper part of the sheet,

so that after escape of the aforesaid part of  
 the entrapped gases, a sufficient amount of  
 gas remains trapped by the formation of  
 the dense upper region 14 to produce the  
 cellular region 12. The cells 16 appear to  
 70 contain principally air entrapped in the  
 mixing step of the process.

Curing of material is completed in  
 approximately 30 minutes, and on removal  
 from the curing cabinet the material is  
 75 found to have the form illustrated in Figure  
 1. The dressing material, still with its release  
 paper backing, is cut into the required  
 shapes and sizes for a medical/surgical  
 wound cover by means of a band knife or  
 80 roller press and is wrapped in a siliconised  
 tissue and packaged in foil pouches which  
 are sealed and gamma-irradiated to ensure  
 sterile conditions.

85 Tests have shown that the polymerised  
 dressing material is free from toxic cyanate  
 or amine residues and is highly effective as a  
 wound cover in the treatment of burns. On  
 application to a burn, it conforms to the  
 contour of the wound and absorbs a limited  
 90 amount of the liquid exudate, while swelling  
 slightly. It is believed that this swelling on  
 contact with liquid causes the cells 16 to  
 open to receive liquid.

95 In addition to the advantages mentioned  
 above, the dressing material has the specific  
 advantages of resembling skin in texture, of  
 conforming easily and readily to any  
 anatomical contour, and of causing no pain  
 in application. It also has thermal insulation  
 100 qualities which enable it to maintain an  
 optimum temperature in the wound to  
 promote healing. It is permeable to water  
 vapour and air, so as to permit the passage  
 of gases through it, but being impermeable  
 105 to liquids it prevents drying and dehydration  
 in or around the wound area. It is non-  
 adherent to wounds, making for painless  
 dressing changes. It does not distort or  
 impede X-ray examination. It is unaffected  
 110 by contact with antiseptics, and under slight  
 pressure it can act as a haemostat. It will not  
 support bacterial life or growth and it  
 produces no loose fibres or particles which  
 could become embedded or encapsulated in  
 115 a wound. It requires no soaking before use  
 as with biological wound covers, thus saving  
 valuable nursing time, and it can be applied  
 by any trained nurse without specialised  
 training. The risk of infection is reduced  
 120 because of the relatively infrequent dressing  
 changes required, and the similarity to skin  
 in texture has a good psychological effect on  
 the patient. The production of a correct  
 micro-climate in the wound increases the  
 125 speed of healing.

#### WHAT WE CLAIM IS:—

1. A wound dressing material, comprising  
 a sheet of a synthetic plastics material which

- is permeable to water vapour and to air, having on one side a smooth glazed surface for application to a wound, a cellular region behind the smooth surface, the cells in said cellular region being closed cells, and a more dense region behind the other surface, so that on contact with liquid exudate from a wound the dressing material will absorb a limited amount of exudate but prevent it from passing right through the dressing material.
2. A dressing material according to Claim 1 wherein the synthetic plastics material is a polyurethane.
3. A dressing material according to Claim 2, wherein the synthetic plastics material is the product of polymerisation of an isocyanate capped polyoxyethylene polyol employing a cross-linking agent or catalyst which is reactive with the isocyanate groups, without any substantial amount of water present.
4. A dressing material according to Claim 3, wherein the synthetic plastics material also incorporates an alkylene oxide surfactant to increase the hydrophilic nature of the dressing material.
5. A dressing material according to Claim 3 or 4, wherein the cross-linking agent or catalyst contains in its molecule two or more amine and/or hydroxyl groups which are reactive with the isocyanate groups.
6. A dressing material according to any one of Claims 3 to 5, wherein the polyol is a polyoxyethylene diol having a weight average molecular weight of approximately 1500, containing a proportion of polyols having three or more hydroxyl groups, the diol and polyols having been capped with diisocyanates.
7. A dressing material according to Claim 5, wherein the cross-linking agent or catalyst is dimethylethanolamine.
8. A dressing material according to Claim 6, wherein the cross-linking agent or catalyst is selected from diethylenetriamine, triethylenetetramine, tetraethylenepentamine, polyethyleneimine, glycerol, trimethylolpropane, pentaerythritol, tolylene-2,4,6-triamine, ethylene diamine, trimethylenediamine, tetramethylenediamine, pentamethylenediamine, hexamethylenediamine, ethanolamine, diethanolamine, hydrazine, triethanolamine, benzene-1,2,4-tricarboxylic acid, nitrilotriacetic acid, citric acid and 4,4'-methylenebis(o-chloroaniline).
9. A dressing material according to Claim 4 or any one of Claims 5 to 8 as appendent to Claim 4, wherein the alkylene oxide surfactant contains ethylene oxide units and propylene oxide units.
10. A dressing material according to Claim 9, wherein the proportions of ethylene oxide units to propylene oxide units lie in the range from 75:25% to 40:60% by weight.
11. A method of making a wound dressing material which is permeable to water vapour and to air, comprising the steps of mixing an isocyanate capped polyoxyethylene polyol with an alkylene oxide surfactant with agitation to form an aerated creamy mix, incorporating a cross-linking agent or catalyst in the mix, spreading the mix on to a smooth glazed release paper to form a sheet of a predetermined uniform thickness, and heating the sheet to assist polymerisation of the mix, with the exclusion of any substantial amount of water from the mix during the said steps and with application of heat in the last-mentioned step in such manner that polymerisation is initiated first in the upper surface of the sheet to form a dense outer region which is impervious to liquids while trapping sufficient gases in the region behind the lower surface to render the latter region cellular.
12. A method according to Claim 11, wherein the release paper is supported on a flat surface during the spreading and heating steps.
13. A method according to Claim 12, wherein the flat surface is provided by a sheet of glass.
14. A method according to any one of Claims 11 to 13, wherein the spreading is effected by means of at least one spreader bar with a corrugated surface which is drawn over the surface of the paper at a fixed distance above it.
15. A method according to any one of Claims 11 to 14, wherein the heating is effected in an oven using a fan to ensure even application of heated air to the upper surface of the sheet.
16. A wound dressing material according to Claim 1 substantially as hereinbefore described with reference to Figure 1 of the accompanying drawings.
17. A method of making a wound dressing material according to Claim 11 substantially as hereinbefore described with reference to Figures 2 and 3 of the accompanying drawings.

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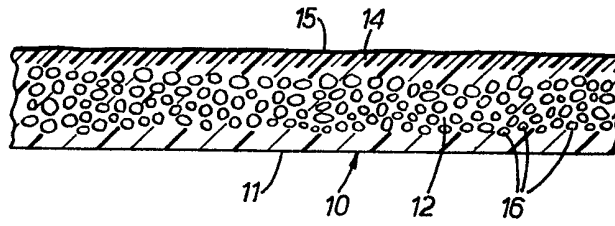


FIG. 1.

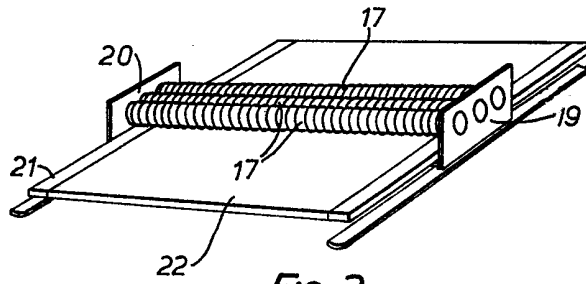


FIG. 2.

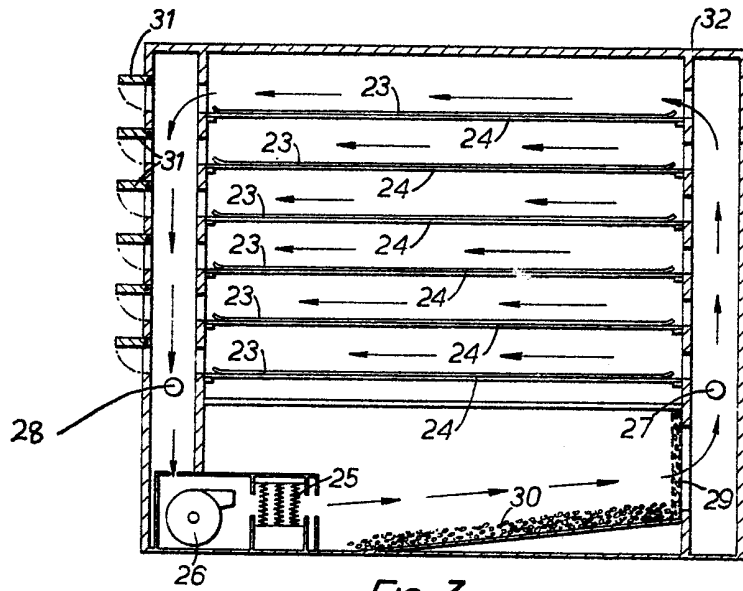


FIG. 3.