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(54) Title: DRESSINGS

(57) Abstract

A dressing system suitable for use for example as a surgical incise drape comprises a solution of film-forming, skin-adhering first polymer and a second component comprising a non skin-adhering film of a second polymer but which will bond to a film of the first polymer.

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DRESSINGS

This invention relates to systems for forming dressings on the skin, to dressings formed therefrom and to methods of forming such dressings.

Filmic products employed in health care today include wound dressings, surgical incise drapes and I.V. dressings which are used, for example to cover and secure cannulae in place at intravenous access sites.

Known filmic products generally comprise a filmic backing layer in which there is a layer of pressure sensitive adhesive upon substantially the whole of one surface thereof. The adhesive layer may be a discontinuous coating or a continuous coating of, preferably a water-permeable adhesive. Water-absorbent adhesives are preferred because of their moisture vapour permeability.

Moisture vapour permable incise drapes have been disclosed in British Patent No. 1280631 and in United

States Patent No. 3645834, European Patent Applications Nos. 51935, 178740, 196459 and United States Patents Nos. 4372303 and 4374520. The known incise drapes of this type in commercial use have proved useful because they held prevent ingress of bacteria into the wound and some reduce bacterial contamination of the surrounding skin.

Certain known incise drapes have the added advantage that they do not cause maceration of healthy skin to which they may be applied because both the film and ahdesive layer are moisture vapour permeable and generally provide the drape with a moisture vapour transmission rate (MVTR) of about between 300 and 800 $g/m^2/24hr$ at 37°C and 100% to 10% relative humidity difference when the adheisve is in contact with moisture vapour.

A disadvantage which may arise with known incise drapes is that if the patient sweats profusely the adhesive may be affected and the drape may lift away from the skin and thereby may compromise the sterility of the operation site.

It has been suggested that high moisture vapour permeabilities may be obtained by employing a discontinuous layer of adhesive (see for example

European Patent No. 91800). However this is not appropriate for incise drapes where gaps in the adhesive are no acceptable.

It would be advatageous therefore if a drape could be found possessing a sufficiently high moisture vapour transmission rate and water absorption capacity so that it could be adhered to the skin as a substantially continuous unitary layer whereby the disadvantages of both continuous and discontinuous adhesive layers could be avoided. It would be a further advantage if there was little or no propensity for irritation to be caused ever after prolonged contact of the drape with the skin.

A further problem common to adhesive dressings used for incise drape as well as other applications is that of selfadhesion. This problem can be particularly severe when handling large size dressings.

If parts of the adhesive surface area allowed to touch each other those parts will adhere to each other (block) causing rucks or folds in the dressing. The presence of such folds, besides being unsightly, may introduce pathways by which bacteria can enter the wound area or by which exudate can uncontrollably escape. Pulling the self-adhered parts apart is likely

to destroy the adhesive layer at that point promoting the disadvantage associated with discontinuous adhesive layers.

Additional problems may also occur with elastomeric films in that pulling of adhered parts may cause the film to permanently stretch. The distorted film may no longer be capable of being laid down flat, again allowing tracts for bacterial infection.

We have no found that the disadvantage of the prior art can be significantly reduced or eliminated by providing a system for forming a dressing on the skin and comprises a film compound which are not adhesive per se but which can be applied to the skin as a continuous layer.

Therefore according to the present invention there is provided a two component system for forming a dressing on the skin which comprises a liquid component adapted to be applied to the skin to form a skin-adherent film of a first polymer thereon and comprising a solution of the first polymer and a second component comprising a non skin-adherent film of a second polymer which will autohesively bond to formed film of first polymer. The solvents employed for the solution of first polymer should be pharmacologically

acceptable for topical application.

In the system of the invention the films of the second component will autohesively bond to the film of skin adhering polymer formed from the first component that is the two films adhere by autoahesion. Autohesion as used herein means the ability of two contiguous polymer surfaces which have substantially no adhesive properties, to bond together. Such a bond is believed to be achieved by diffusion of polymer molecules between the contiguous surfaces of the two polymer films. Normally, the two polymers will, generally, be similar although they need not be chemically identical.

The film components used or formed in the system are substantially non-adhesive per se and thus are non-skin adhering or tacky.

The formed filmic compositions are suitable for use in situ as dressings such as those employed for surgical incise drapes, I.V. dressings and wound dressing or the like. Because such films comprising the second component are not adhesive per se they can be employed as large sheets and can be readily handled.

Although such films are readily handled and can be laid down and smoothed to remove wrinkles, they are

not adherence per se to the skin. They can be rendered adherent by contact with the film formed from the polymer present in the first component.

Therefore in another aspect the present invention provides a method of forming a dressing which comprises applying to an area of skin a first component comprising a solution of film forming first polymer, in a solvent which is pharmacologically acceptable for topical application, allowing the solvent to evaporate to form a skin adhering film layer and applying over the thus formed film a second component comprising a film of a second polymer. Preferably the second polymer is insoluble in the first component. The film of the will autohesively bond with the skin adherent film layer of first polymer thereby to form on the skin a dressing which is preferably both bacteria proof and moisture vapour permeable.

In application, using the two-component system, a liquid component comprising the first polymer in solution is first applied to the skin around or over the area to be covered and thereafter, eg. when solvent has dried a sheet or strip of the filmic backing component is applied to the skin over the area to which the liquid has been previously applied. The second polymer thus adheres to the polymer constituting the

backing layer.

Thus a dressing can be formed in situ on to the skin which is suitable for use for example as a surgical incise drape.

Such a dressing will comprise a skin-adhering filmic first polymer autohesively bonded to second component which comprises a non skin adherent film of a second polymer. Such a dressing is preferably both moisture vapour permeable and bacteria proof.

The liquid first component of the dressings of the invention may be liquid per se for direct topical application by, for example, swab or brush or may be absorbed onto a fabric for use as a wipe. In another embodiment the liquid may be applied as spray either from a pump action dispenser or as an aerosol together with a suitable propellant. Upon drying the polymer will adhere to the skin. However, when dry the formed film has no pressure sensitive adhesive properties.

The dressing materials of the present invention as would be formed in situ on the skin may exhibit different moisture vapour transmission rates depending upon the materials employed and whether the skin contacting layer of the dressing is in contact with

moisture vapour or with water.

The moisture vapour transmission rates of the dressing of the present invention may be determined by first forming applying the first component to a releasable substrate such as siliconised paper and, when dry overlaying the second component. The 'laminate' is then released from the substrate.

The moisture vapour transmission rate may be measured by a procedure known as the Payne Cup method. The method uses a cup 1.5cm deep with a flanged top. The inner diameter of the flange is such to provide an area for moisture vapour transmission of $10cm^2$. In this method 10ml of distilled water is added to the cup and a sample of the laminate under test, large enough to completely cover the flange, is clamped over the cup. The complete assembly is then weighed and placed in a cabinet where the temperature and relative humidity are maintained at 37°C and 10% respectively. After 17 hours the cup is removed from the cabinet and allowed to cool at room temperature. After re-weighing, the mass of water lost by vapour transmission is calculated and the result expressed as in $g/m^2/24hrs$ at 37°C at 100% to 10% relative humdity difference. Hereinafter the units for moisture vapour transmission will be abbreviated to $g\ m^{-2}$.

The cup is maintained in upright position during measurement of the MVTR of a sample in contact with moisture vapour and in an inverted position during measurement of the MVTR of sample in contact with water.

The moisture vapour transmission rate when in contact with moisture vapour but not water is referred to herein after as the upright moisture vapour transmission rate (upright MVTR). Suitably the dressing materials of the present invention may have an upright MVTR of at least 300g m^{-2}, suitably at least 500g m^{-2}, greater than 800g m^{-2}. More suitably the upright MVTR will be greter than 1000g m^{-2}, most suitably more than 1200g m^{-2} and preferably will have an upright MVTR of greater than 1400g m^{-2} under the conditions specified above.

The moisture vapour transmission rate when is in contact with water is referred to herein after as the inverted moisture vapour transmission rate (inverted MVTR) and may be measured by the method described hereinafter. Suitably the dressing materials of the present invention will have an inverted MVTR of greater than 2400g m^{-2} humidity difference. More suitably, depending upon the particular application the inverted

MVTR may be greater than 4000g m^{-2}, most suitably it is greater than 6000g m^{-2} and preferably greater than 10,000g m^{-2}.

Preferably the polymers constituting the formed filmic composition will be such as to permit visual observation of the skin, or in the case of an I.V. dressing, of the cannula site through the dressing when it is in place. The composition should preferably be translucent and more preferably transparent.

When the dressings of the invention are employed as surgical incise drapes they are applied to an operation site prior to incision through the skin. Usually the drape remains in postion during the operation and is removed afterward. In some cases at the the end of the operation the drape may be left in position and a second drape or dressing applied over the first drape. In this instance it is particularly desirable that the first drape should have a large upright and inverted moisture vapour transmission rate to avoid causing maceration to the underlying healthy skin.

An incise drape is adhered to intact skin and it is found that in certain patients sweat may collect

beneath known incise drapes and effect their adherency. To avoid moisture gathering beneath the drape, it is now thought that the drape should have a moisture vapour transmission rate of greater than 500g m^{-2} $24h^{-1}$ at 37°C an 100% to 10% relative humidity difference when in contact with moisture vapour and greater than 2500g m^{-2} $24h^{-1}$ when in contact with water.

The polymeric material forming the second component may be one used to form any moisture vapour permeable material suitable for use in incise drapes, I.V. dressings and wound dressings. Suitable materials include polyurethanes such as polyester polyurethanes or polyether polyurethanes, polether polyester, polyether polyamides, polymer blends of incompatible polymers, celluslosics, polyvinyl acetate derivatives or the like. Other materials which may be employed as the insoluble polymer include rubbers marketed under the trade mark Cariflex, polyisobutadiene, ethyl vinyl acetate polymers and copolymers or blends thereof, eg. with high impact polystyrene, and polyacrylates and methacrylates.

Preferred polyurethanes for use as the second component are thermoplastic polyether polyurethanes. Other hydrophilic polyurethanes which are polyester polyurethanes or which have potentially reactive

substituents such as hydroxyl or carboxyl groups are less preferred. Examples of suitable thermoplastic polyurethanes are the linear polyester and polyether urethanes known as Estanes (trade mark).

Apt polyether polyurethanes for use in this invention will be random polymers containing units derive a form dihydroxy compound and di-isocyanates.

Aptly the ether units in the hydrophilic polyurethane for use in this invention will be notionally derivable from ethylene diol and propylene or butylene diol; that is they will contain CH_2CH_2O- units and $-CH_2CH_2CH_2O-$ and $-CH_2CH(CH_3)O-$ or $-(CH_2)_4O-$ mixtures thereof of which poly $-CH_2CH(CH_3)O-$ blocks are preferred. Desirably the mole ratio of poly(ethylene glycol) to poly[(prop or but)ylene glycol] derivable blocks present in the hydrophilic polyurethanes vary between 1:1 to 1:30, more suitably from 1:2 to 1:10 and preferably from 1:2.5 to 1:4. The molecular weights of these blocks is aptly from 600 to 60000 and favourably from 900 to 4000, for example 1000 to 2000.

Less preferred are hydrophilic polyurethanes which contain poly(ethylene-glycol) derived blocks alone together with a higher proportion of chain extender and di-isocyanate.

Normally and preferably the hydrophilic polyurethane used in the devices of this invention is essentially a single type of polymer (a product of the polymerisation of the same materials) although the blends may be employed to form the hydrophilic polyurethane if desired.

Preferably, the hydrophilic polyurethane for use in this invention will contain residues of aliphatic diols of up to 10 carbon atoms and more suitably up to 4 carbon atoms as chain extenders. The mole ratio of diol to polyglycol used in the preparation of the polymer may be within the general range of 3:1 to 1:4, more aptly 5:2 to 1:3 and preferably from 2:1 to 1:2. A preferred diol is ethane diol in a molar ratio from 1:1 to 2:1. Mole ratios of less than 1 mole ethane diol per mole of polyglycol increases the tendency for a permanent residual tack to be inputed to the first component even when it has dried, whereas ratios of greater than 2 to 1 increases the hard sector content of the polymer which may cause adhesive/cohesive failure between the first and second components, when applied.

Equivalent quantities of aliphatic diamine or aliphatic amine chain extenders, eg. ethylene diamine

may also be used. Similarly somewhat less aptly than using aliphatic diol chain extenders, the hydrophilic polyurethane may employ an aromatic diamine such as phenylenediamine, benzidine or diaminodiphenylmethane.

The hydrophilic polyurethane will contain sufficient di-isocyanate residues to produce the water contents set forth hereinbefore when the polymer is hydrated.

Most aptly the hydrophilic polyurethane for use in this invention will contain di-isocyanate residues which may be residues of aromatic or aliphatic di-isocyanates such as 4,4'-diphenylmethane di-isocyanate, toluene di-isocyanate, 1,6-hexamethylene di-isocyanate, 4,4'-dicyclohexylmethane di-isocyanate or the like. Favoured di-isocyanates for use in the hydrophilic polyurethane of this invention are 4,4'-dicyclohexylmethane di-isocyanate (which is preferred) and 4,4'-diphenylmethyl di-isocyanate.

The material which forms the second component or backing layer should itself have a moisture vapour transmission rate of above 300g m^{-2} $24h^{-1}$ at 37°C and 100% to 10% relative humidity difference, more suitably more than 800g m^{-2} $24h^{-1}$ typically from 1200 to 2000g m^{-2} $24h^{-1}$ when the in contact with moisture vapour.

The material which forms the backing layer should preferably provide an in situ dressing or drape with an inverted moisture vapour transmission rate of greater than 2500g m^{-2} $24h^{-1}$ at 37°C, more suitably, for wound dressings in the range of from 3000 to 18000g m^{-2} $24h^{-1}$ and preferably from 5000 to 12000g m^{-2} $24h^{-1}$.

Suitably the backing layer will have a thickness of from 10 to 80μm, more suitably 20 to 50μm and preferably from 25 to 40μm.

The soluble polymer present in the first component may be a similar material to that employed for the first polymer and can be a polyacrylate, a polyester, a polyamide or a polyurethane or blends. A particularly preferred polymer is one which is capable of containing from 5 to 95% by weight of water when hydrated.

A preferred polymer, is a hydrophilic polyurethane. Suitable hydrophilic polyurethanes include those having the composition and prepared by the process described in British Patent No. 2093190B. The most suitable hydrophilic polyurethanes are those which will contain upto 95%, preferably from 5 to 50% by weight of water when hydrated and especially those which contain from 10 to 40% by weight of water.

It has been observed that the adhesion between a primer layer of the first component and the filmic second component will be effected by the thickness of the primer layer. Thus in order to maintain integrity of the two components such that a primer layer of a thickness of from 10μ to 80μm.

Thickness of the primer layer also effects the adhesion between the primer layer (first component) and its substrate ie. skin. It is therefore more preferred that the thickness of the primer layer be about 15μm.

It is further preferred that the soluble and insoluble polymers forming, respectively the first and second components are both of the same class of polymers. A preferred pair comprises two polyurethanes formulated such that one is soluble in a solvent, for example an organic solvent such as isopropanol whilst the other is not. Polyurethanes containing long chain aliphatic isocyanates tend to be soluble in isopropanol whereas those formulated using short chain aliphatic, eg but more than for carbon atoms or aromatic isocyanates tend not to be soluble in isopropanol.

The liquid component containing the first polymer should be one which is soluble for topical application

to the skin and should include a solvent for the first polymer components of the film eg. that employed for a skin contacting layer. Physiologically acceptable solvents include aqueous solvents such as water itself, and organic solvents such as isopropanol, industrial methylated spirits, ethyl acetate, acetone, methyl ethyl ketone, dimethyl sulphoxide or mixtures thereof.

A preferred solvent, particularly for use with polyurethanes is isopropanol or an aqueous solution therof.

The liquid component may be formulated to provide a skin preparation liquid of the type normally used prior to surgical operation.

Suitably the filmic composition containing the second polymer, the liquid containing the first polymer or both may also contain a medicament such as an antibacterial agent.

Suitable antibacterial agents include chlorhexidine and salts thereof such as the acetate, gluconate or hydrochloride, iodophors such as polyvinyl pyrrolidone-iodine, silver salts such as silver sulphadiazine and polymeric biguanides for example those antibacterial agents known as Vantocil (Trade

mark).

In those cases where the antibacterial agent is included in the liquid component of the invention it may be present in amounts ranging from 0.5 to 5% by weight. Preferably the liquid contains from 2.5 to 4.0% by weight of antibacterial agent. Alternatively if an antibacterial agent is to be included in the filmic component it may be present in amounts ranging from 1 to 10% by weight of the film. Preferably, about 5% by weight antibacterial agent is included in the film.

The dressings and filmic compositions of the present invention have applications for surgical incise drapes, I.V. dressings and wound dressings or the like. For use as a drape or I.V. dressing it may be convenient to apply the liquid component, for example by painting, or spraying the liquid in the general area or area where adherency is required, followed by application of the filmic component. The first polymer contained in the liquid composition will adhere readily to the filmic composition containing the second polymer even when the solvent for the first polymer has evaporated prior to bonding.

For wound care applications the liquid component may be applied around the edges of the wound site and

thereafter eg. when the solvent has evaporated a sheet of filmic material applied over both the wound site and the area to which the liquid has been applied will the second polymer-containing filmic composition adhere; the dressing in the region over the wound site will remain unaffected. Thus the dressing in accordance with the invention can form effective window dressings.

Because the dressings of the invention are two component systems, and the final size of the dressing will depend only on the size of the area to which the liquid component is applied, it is not necessary to provide the filmic component in specific sizes. The filmic component can be provided in fewer sizes and cut down if necessary to the actual size and/or shape required. Furthermore since the film is not selfadherent it can be managed and handled easily.

Where it is necessary or desirable to ensure that all of the filmic component is adhered, the liquid component can be applied over a larger area than that required for the dressing.

When the solvent has dried off. The film of skin adhering first polymer formed from the liquid component, although it may be slightly tacky, will have a substantially non-adhesive surface. Such a film

therefore will not have a pressure sensitive adhesive surface which could be contaminated or lifted off by adherency to an operator's clothing for example gloves or a film carrier when applying a backing film of the second polymer to the skin adhering film. The adhesion of first polymer film to the skin and the second polymer film should be sufficient to hold the dressing in place on the skin during healing or the time it is expected to operate. However, it is preferred that the adhesion of first polymer film to the skin is less than that of the adhesion of this film to second polymer film (backing film) to ensure that the formed dressing can be removed intact from the skin when required.

When the solvent has dried off, the laid-down skin adhering polymer film will have substantially non-adhesive surface for example a pressure sensitive and will only adhere and block to like polymers.

It may be preferred to coat the filmic composition with an antiblocking agent such as Gaisil, especially if the film is employed as a roll. The effect of the antiblocking agent is neutralised when the film contacts the liquid component.

The invention will now be illustrated by the following example.

Example 1

A series of hydrophilic polyurethanes, P1 to P6, was prepared from 3 moles of polyethylene glycol (PEG600), 3 moles of polypropylene glycol (PPG600), from 3 to 13 moles of ethane diol (ED) and 4,4^{1}-dicyclohexyl methane di-isocyanate (Desmodur W) in an amount sufficient to maintain the overall NCO/OH ratio at 1:1. The polymers where prepared by adding the polyethylene glycol to polypropylene glycol ethane diol and a dibutyltin dilaurate catalyst (T12) in an amount of 0.2% by weight of the total weight of the reactants to a reaction vessel. The vessel was placed into a fan assisted oven set at 60°C to melt the polyethylene glycol. When the polyethylene glycol had melted the mixture was well stirred and the 4,4'-dicyclohexylmethane di-isocyanate added with continued stirring. Stirring was further continued until the polymerisation mixture has changed from an opaque liquid to a clear one. At this point the temperature of the reaction mass was raised to 90°C and left for an hour to cure. The elastomer was cured for a further 24 hours at ambient temperature before being broken up and dissolved in 95:5 IPA/Water Mixture to provide a 25% solids solution.

The composition of the polymers was as shown in Table 1:

Table 1

Polymer	ED Moles	PEG Moles	PPG Moles
P1	3	3	3
P2	5	3	3
P3	6	3	3
P4	8	3	3
P5	10	3	3
P6	13	3	3

A subjective assessment of the residual tackiness was made when samples of each of the polymers was cast using a 0.07mm spreading block onto a 0.15mm microporous embossed plasticised PVC film (Porvic). After the bulk of the solvent has evaporated the polymer coating was lightly touched with the finger. The results are shown in Table 2:

Table 2

Polymer	ED(moles)	Assessment
P1	3	tacky surface
P2	5	tacky surface
P3	7	slightly tacky surface
P4	9	virtually no tack on surface
P5	11	no tack on surface
P6	13	no tack on surface.

It will be apparent from the above results that diol/glycol ratios of greater than about 1:1 are preferred to avoid pick-up of dirt on surplus uncontacted primer.

The 25% wt solution of polymers P1 to P6 were spread onto Porvic film supported on a card base and Estane film (0.035mm thick) was applied to test surfaces of the polymer 1, 5 and 30 minutes after the polymer had been spread, herein referred to as "contact time".

After contact with the Estane film, a 2kg roller was run over the contacted film and the samples left

for 18 hours. At the end of this 2.54cm wide samples were cut out and subjected to a T-Peel Adhesion Test using an Instron Tensile Testing Machine. The cross-head speed was 300mm min^{-1}. The peel force was recorded on a chart also running at 300mm min^{-1}. Full scale deflection was set to 1 or 2 kg f as required. The results are shown in Table 3.

Table 3

Polymer	Adhesive Failure(mjm^{-2}) at Contact Time		
	1 min	5 min	30 min
P1	125	120	115
P2	162	80	105
P3	60	45	55
P4	75	70	45
P5	65	30	0
P6	55	0	-

The decrease in peel energy with increase in ethane diol content for contact times of 1 and 5 minutes is believed to be attributable to the residual solvent present in the polymer film. At higher ethane diol contents adhesive failure at corresponding lower

peel energies for increasing ethane diol content is because of the increasing incompatibility between the hydrophilic polyurethane coating and Estane film.

Example 2

A polymer P7 was produced by reacting PEG600 (3 moles), PPG600 (3 moles), ethane diol (8 moles) and Desdomur W, sufficient to maintain the NCO/OH ratio at 1:1, according to the method described in Example 1.

Five samples of a solution of polymer P7 in a mixture (95:5) of isopropanol and water were spread each at a different thickness on a supported Porvic film. After the lapse of 30 minutes to allow solvent to evaporate from the coating, Estane film was applied to the coating using the 2kg roller. The peel energy at which adhesive failure occured was determined using the Instron tester and the results are shown in Table 4:

Table 4

Polymer	Solids Content of Solution %wt	Coating Thickness(mm)	Peel Energyjm^{-2}
P7/1	25	0.006	0
P7/2	25	0.019	50
P7/3	25	0.031	90
P7/4	25	0.038	87
P7/5	8	0.06	100

Adjustments of the thickness affects the adhesion between the primer (first component) layer and the backing (second component) layer.

Example 3

A 12.5% solution of polymer P5 in a 95:5 mixture of isopropanol and ethanol, was sprayed into the palm of the hand using a 1.4ml chamber pump action spray bottle. After 45 seconds, allowed for evaporation of isopropanol, a piece of estane film was placed on top and smoothed over. The film adhered well and had gentle peel for removal, comparible to the removal of a conventional adhesive coated Estane film (OpSite).

Adhesion failure occured at the primer/skin interface since peel of the film left little polymer P5 residue on the skin.

Claims

1. A two component system for forming a dressing on the skin which comprises a first component comprising a solution of a film forming skin adhering first polymer and a second component comprising a non-skin adhering film of a second polymer which will autohesively bond to a film of the first polymer.

2. A system as claimed in claim 1 wherein the second polymer is insoluble in the solution of the first polymer or the solvent therefor.

3. A system as claimed in claim 1 in which the solvent is an organic solvent.

4. A system as claimed in claim 3 in which the solvent is isopropanol.

5. A system as claimed in any of the preceeding claims both polymers are polyurethanes.

6. A system as claimed in claim 5 in which the polyurethane is a polyether polyurethane.

7. A system as claimed in any one of the preceeding claims in which the film of second polymer has a thickness of 10 to 80μm.

8. A system as claimed in any one of claims 1 to 7 in which the first component polymer comprises a hydrophilic polyurethane which contains 5 to 50% of water when hydrated.

9. A system as claimed in claim 8 in which the polyurethane comprises residues of a chain extending aliphatic diol of up to 4 carbon atoms.

10. A system as claimed in claim 8 or 9 in which the hydrophilic polyurethane is a polyether polyurethane and the ether blocks of the polyurethane are derived from polyethylene glycol and polypropylene glycol.

11. A system as claimed in claim 9 and claim 10 wherein the mole ratio of diol to polyglycol residues in the polyurethane is from 5:2 to 1:3.

12. A system as claimed in claim 11 in which the aliphatic diol is ethane diol and the molar ratio of diol to polyglycol residues in the polyurethane is from 1:1 to 2:1.

13. A dressing system as claimed in any of claims 1 to 12 in which either or both of the first and second components contain a medicament.

14. A dressing system as claimed in claim 13 in which the medicament is a topical antibacterial agent.

15. A system as claimed in any of claims 1 to 14 in which the dressing is an incise drape.

16. A system as claimed in any of claims 1 to 15 in which the second component film is in the form of a sheet or a continuous roll.

17. A system as claimed in any of claims 1 to 16 in the first liquid component is adapted to be applied to the skin directly, in the form of a spray or from a wipe.

18. A dressing comprising a skin-adhering filmic first polymer autohesively bonded to a non-skin adhering film of a second polymer.

19. A dressing as claimed in claim 16 which is an incise drape.

20. A dressing as claimed in either of claims 18 or 19 which is moisture vapour transmitting and bacteria proof.

21. A method of forming a dressing as claimed in any of claims 18 to 20 which comprises applying to an area of skin a first component comprising a solution of film forming first polymer thereby to form a skin adhering film layer and applying over the thus formed film layer a second component comprising a non-skin adherent film of a second polymer which will autohesively bond to said skin adhering film of said first polymer.

INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 89/00725

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC[5]: A 61 L 25/00, 15/06, 31/00

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC[5]	A 61 L

Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
Y	WO, A 88/01878 (SMITH & NEPHEW ASS. COMPANIES PLC) 24 March 1988, see page 4, lines 13-18; page 12, lines 9-23; page 13, lines 4-15; page 14; page 15 --	1-21
Y	EP, A, 0091800 (SMITH & NEPHEW ASSOCIATED COMPANIES PLC) 19 October 1983, see page 4, lines 17-24; page 7, lines 17-24; claims 1-6 (cited in the application) --	1-21
P,Y	WO, A, 89/01346 (SMITH & NEPHEW ASSOCIATED COMPANIES PLC) 23 February 1989, see page 2, lines 15-24; page 3, lines 20-24; page 4, lines 1-6; page 5, lines 5-11; page 6, lines 1-4; page 7, lines 1-3; claims 1-5 --	1-21

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* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
27th September 1989	26. 10. 89
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	T.K. WILLIS

Form PCT/ISA/210 (second sheet) (January 1985)

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
A	GB, A, 2093190 (SMITH & NEPHEW ASSOCIATED COMPANIES LTD) 25 August 1982 (cited in the application) --	
A	FR, A, 2542201 (LABORATOIRES d'HYGIENE ET DE DIETETIQUE) 14 September 1984 --	
A	EP, A, 0114581 (SOGIMI Srl) 1 August 1984	

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. GB 8900725

SA 29847

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 24/10/89
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO-A- 8801878	24-03-88	AU-A- 7916787	07-04-88
		AU-A- 8028887	07-04-88
		EP-A- 0282533	21-09-88
		EP-A- 0282554	21-09-88
		WO-A- 8801877	24-03-88
		GB-A- 2198971	29-06-88
		GB-A- 2198949	29-06-88
		JP-T- 1501287	11-05-89
		JP-T- 1500801	23-03-89
		AU-A- 8215687	09-06-88
		EP-A- 0271292	15-06-88
		GB-A- 2199040	29-06-88
EP-A- 0091800	19-10-83	AU-B- 560088	26-03-87
		AU-A- 1379383	04-11-83
		WO-A- 8303549	27-10-83
		US-A- 4595001	17-06-86
WO-A- 8901346	23-02-89	AU-A- 2256888	09-03-89
		GB-A- 2207867	15-02-89
GB-A- 2093190	25-08-82	AU-A- 7648781	11-05-82
		CA-A- 1170719	10-07-84
		EP-A,B 0050035	21-04-82
		WO-A- 8201306	29-04-82
		US-A- 4534355	13-08-85
FR-A- 2542201	14-09-84	DE-A- 3408051	13-09-84
EP-A- 0114581	01-08-84	AU-A- 2248383	21-06-84
		CA-A- 1244590	08-11-88
		JP-A- 59172422	29-09-84
		US-A- 4560555	24-12-85