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(71) Applicant(s):
David William Richardson
Lantor (UK) Ltd, St Helens Road, BOLTON, BL3 3PR, United Kingdom

(72) Inventor(s):
David William Richardson

(74) Agent and/or Address for Service:
David William Richardson
Lantor (UK) Ltd, St Helens Road, BOLTON, BL3 3PR, United Kingdom

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WO 2002/000269 A **WO 2001/067888 A**
US 5980875 A **US 5456745 A**
US 20040127826 A **US 20040121027 A**
US 20040043062 A

(58) Field of Search:
UK CL (Edition X) **A5R**
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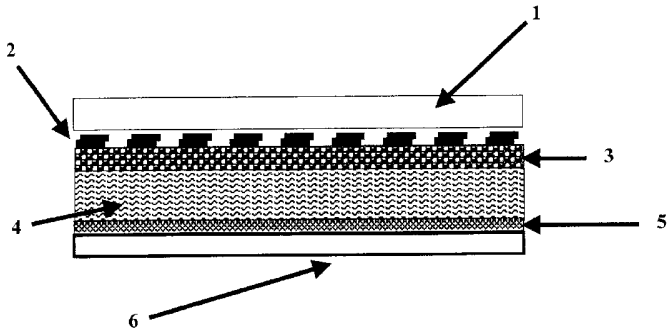
Other:

(54) Abstract Title: **Wound healing system and dressing containing a dried form of a liquid**

(57) A wound healing system and dressing comprise a layer of a dried liquid 3. The dried liquid may be dried honey, dried essential oils or dried herbal extracts. The dried liquid may be combined with an alginate, chitosan, carboxy-methyl cellulose or pectin. The dried liquid may be coated onto a non-woven base material 4. The dressing may incorporate a low adherent contact surface 2 and/or a water repellent film 6 on a side opposing a wound 1.

Figure 1



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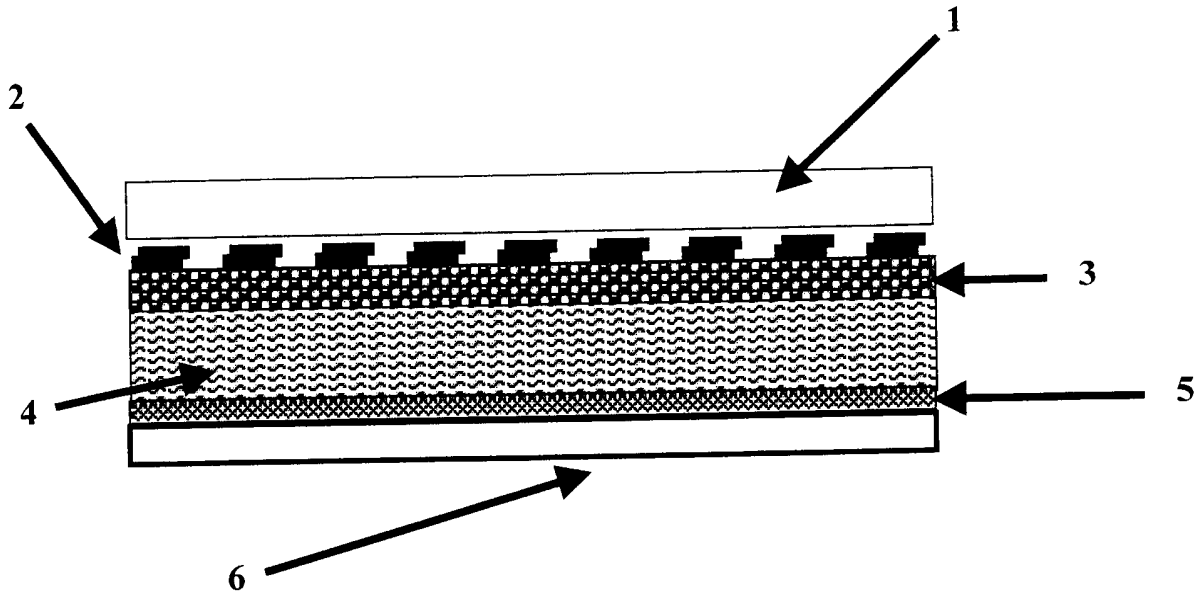
Drawings

Figure 1



Medical Wound Healing Treatment

Field of the Invention

The present invention relates to Systems and Products to provide a Medical Wound Healing Treatment, particularly, though not exclusively, to dressings and to nonwoven materials for use in such products.

Background to the Invention

Wounds are dressed for many reasons including:

- To stop blood flow and prevent exudate soiling
- To protect the wound from further damage
- To prevent contamination and infection
- To provide conditions for healing

Wound healing is a natural process that occurs after any injury, either traumatic or elective and there are four recognised phases of the healing process:

1. Inflammation - Clotting
2. Migration - Epithelial Cells replace lost tissue
3. Proliferation - Granulation and closure
4. Maturation - Strengthening of new skin

These phases take place sequentially and timing is dependent on a number of variables.

The healing process may vary due to internal or external conditions at the healing site, for example moisture content, oxygen levels, bacterial presence, blood flow and so on.

It is now firmly established that optimal wound healing takes place under moist conditions so provision and retention of moist conditions at the wound healing site is beneficial.

Every wound is different, but it is accepted that improvements in the speed and/or quality of the wound healing process are beneficial.
These benefits may be, for example cosmetic, earlier release from hospital (bed release and cost reduction), early return to work or patient quality of life for 'difficult to heal' wounds such venous ulcers.

In order to facilitate the wound healing process various treatments are available which can provide ways to accelerate the healing process by using a so called 'Active' ingredient, for example:

- Haemostats to provide additional or controlled clotting
- Biocides to reduce or eliminate potential infection
- Humectants or Gels to provide or maintain a moist healing site
- Enzymes to provide enzymatic activity at the healing site

Usually the 'Active' treatment application is applied directly to the wound as soon as possible after the wound has been made, for example a simple First Aid dressing or a Post Operative Surgical Dressing, and is replaced when needed.

Recently there has also been a revised interest in so called 'Natural' active materials for wound healing.
These 'Natural' materials include for example:

- Honey (especially Manuka honey)
- Herbs (e.g. Aloe Vera, Gotu kola, Chamomile, Calendula, Echinacea, Comfrey)
- So called 'Essential oils' occurring in plants and responsible for their properties (e.g. Tea Tree, Lavender, Eucalyptus, Witch hazel, Wintergreen)

Researchers are continuing to explore the complex dynamics of tissue repair and are finding that nutritional factors are involved in tissue regeneration, including Vitamins A, C and E, zinc, Glutamine and Glucosamine.
They are finding that botanical extracts from Aloe Vera, Centella asiatica and bromelain from pineapple, can improve healing time and wound outcome.

However one disadvantage of these 'Natural' materials and other potentially useful active ingredients, is that they are often only available in liquid form.
This means that they have to be applied to the wound site in liquid form (e.g. as an oil, lotion, cream etc.) and the covered with a protective wound dressing.
This is far less controllable, less convenient, more time consuming and normally more expensive than being able to apply a dry 'Active' wound dressing with a controlled amount of the active material already built in.
However an advantage of the liquid 'Active' materials is that they are compatible with the provision, retention and benefits of a moist healing environment.

Accordingly the present invention aims to retain the benefits whilst addressing at least one disadvantage associated with the prior art whether discussed herein or otherwise.

Summary of the Invention

To overcome this problem of the prior art, this invention proposes a system, which can provide a method of producing a wound dressing product using a liquid 'Active' material, by converting the liquid 'Active' material to a 'Dry' form.
This 'Dry' form of the 'Active liquid can then be handled by conventional machinery used for processing dry 'Active' materials to produce an 'Active' wound dressing material and a wound dressing product from this material.

The process for converting the liquid 'Active' material into a suitable dried form is used extensively in the Food Industry and is one of several methods mentioned below.

Four methods are typically used within the food industry to dry liquid materials, in order to make them usable in a 'Dry' form:

- **Freeze drying;**
- **Vacuum belt drying;**
- **Roller drying;**
- **Spray drying.**

In the Vacuum belt method the product is fed into the drying system in liquid or solid form. The water is evaporated under a vacuum to depress the boiling point. The advantage of this process is that thick or lumpy products can be dried.

These processes will be well known to those experienced in this area.

In addition to these basic drying processes special so-called 'drying agents' can be added to the liquid to be dried in order to speed up or remove more moisture during the drying process. These 'drying' agents are often in the form of a dry powder additive.

We have found that some powders, with properties that can help the wound healing process (so-called 'Active ingredient' powders), can also act as a 'drying agent'.

By combining an 'Active powder' as part or all of the 'drying agent' with an 'Active liquid' the healing properties can be further increased.

A variety of 'Active powders' can be used, for example alginates, chitosans, carboxy -methy cellulose, pectins etc.

For example, an 'Active' alginate powder can be used as part of the 'drying agent' with a 'sticky' liquid such as honey. In this way the moisture retaining and haemostatic properties of the 'Active' alginate powder can be combined with the anti-microbial properties of the dried liquid honey (particularly Manuka honey) in a dry form which can be applied as a coating layer to a suitable base, carrier material for use in a wound dressing..

A further benefit of combining an 'Active' liquid with an 'Active' powder is that current application of 'Active' dry materials can be dusty, leading to variations in weight application as well as contaminating process machinery and any other items in close proximity.

Thereby combination is mutually beneficial.

The dried 'Active' material is then used in a conventional coating process to apply an 'Active' layer to a suitable wound dressing base, carrier material.

This, for example, can be done by mixing the dried 'Active' material with a suitable thermo-sensitive fusible powder (e.g. Polyethylene, Polyamide), scatter coating the required weight onto the base, carrier material. Alternatively, the coating powder could be incorporated into the drying process together with the 'drying agent'.

The coated product is then passed through a laminator where it is carried between two non-stick belts (usually Teflon coated) through a heated zone in order to melt the fusible powder. By varying the belt gap and the pressure applied to the belt, the coating and base material are pressed together to form an adequately bonded 'Active' layer.

Alternatively the coated product is passed under Infra Red heaters to melt the fusible powder and then through water cooled rollers under pressure to press the coating and the base material together to form an adequately bonded 'Active' layer.

The methods described for the application of the coating layer and the production of base, carrier materials will be well know to those experienced in these areas.

This coated material can then be converted into a wound dressing product using conventional dressing conversion machinery since it is in a 'Dry' rather than a 'Wet' form.

The final product may be 'loose' for application under a bandage or a self-adhesive system, for example a so-called 'Island' dressing.

The final product may incorporate a low adherent wound contact layer and/or a liquid impervious, breathable outer membrane.

The product is constructed so that the required 'Active' ingredient is included in the layer closest to the wound surface,

The 'Active' ingredients are selected so that on contact with the exudate from the wound or by intervention (e.g. application of water or saline solution), they provide the required 'Active' effect

The construction of the structure is provided to allow for passage of liquids so that wound exudate or other liquid may more easily contact the 'Active' ingredient.
This passage of liquids can also be provided by what is normally called absorbency and is a well known feature of wound dressings.

The medical product may comprise the layered structure containing the 'Active' ingredients and a net, perforated film or gauze on one or both sides thereof.

The medical product may comprise a low adherent wound contact net or perforated film, known per se for use in wound dressings, bonded to at least one side of the layered structure said side to be a wound contact side. The net or perforated film thus provides a wound contact layer having apertures to allow wound fluids to pass into the 'Active' layered structure of the dressing.

The net may comprise a low adherent bi-extruded net where one of the bi-extruded layers acts as a fusible adhesive and can be heat bonded to the 'Active' layered structure.

The medical product may comprise the 'Active' layered structure having a film or water repellent layer, known per se for use in wound dressings, on one side thereof.
The said film or water repellent layer is provided on a side of the product opposed to the wound contacting side and may assist in providing a moist wound environment and/or assist to reduce the rate of wound exudate strike through.
Suitably the medical product comprises a polyurethane film bonded to one side of the 'Active' layered structure.

The medical product is arranged to be used for wound care and/or padding bandage applications.

Brief description of the Drawings

Figure 1 shows a cross section through a multi-layer wound dressing incorporating the elements of the invention.
Not all the elements are needed in a wound dressing product and this drawing shows several elements for illustration only.
Figure 1 shows:

1. The Wound
2. A low adherent wound contact layer, which in use is in contact with the wound.
3. The 'Active' layer as described in the Summary of the Invention, Examples and Claims.
4. A base, carrier material, which allows passage of liquids, and exudates.
5. An adhesive layer if required to bond a Water-repellent cover.
6. A Water-repellent cover if required.

EXAMPLES

The invention is illustrated but not restricted by the following examples, which is not to be considered as limiting the scope of the protection as set out in the claims.

Example 1 : (Ref. No: 46.15.04)

A nonwoven base, carrier material (Ref. No: 47.05.44) was made with a weight of 220 g/m2, produced by a conventional carding, crossfolding, needling bonding route.
For this nonwoven base a 70/30, viscose / polyester fibre blend was used:

1. 70% 4.2 dtex, 60 mm Danufil V viscose (Acordis)
2. 30% 5.0 dtex, 60 mm Selenis T290 polyester

The fibres were weighed and blended via weigh hoppers and beaters and fed to a volumetric fed Card to produce a lightweight web of fibres.
This fibrous web was laid down, in multiple layers, by a Crossfolder and the fleece produced was fed to a Needleloom where it was needled to provide the necessary strength for processing. This nonwoven production route is well known to those experienced in nonwoven manufacture and provides a nonwoven construction which is absorbent and allows passage of liquid and wound exudate.

Dried 'Active' material was made from Manuka Honey by MOLDA AG, Gartentstasse 13, D-21368,Dahlenburg, Germany - using their commercial drying process. The Manuka Honey incorporated 5% Danisco alginate FD 120 as a drying agent.
The dried 'Active' material was mixed with a low melt co-polyester fusible powder adhesive (Dritex DT135 from Dritex Ltd, Essex, UK a product with Melting Point approx. 65 deg. Celsius and particle size range 150 to 350 micron), in mixture of 82 parts 'Active' material to 18 parts Fusible powder.

This mixture was the applied to the special nonwoven base, carrier material at a level of 150g/m2 using a scatter coating process via a wire covered roller. This scatter process is well known and applies controlled amounts of powder by doctoring the powder particles into a rotating wire covered roller, brushing the powder out and allowing it to fall as a powder curtain onto the substrate to be coated. By controlling the roller speed the g/min of powder delivered can be set and by varying the coating speed of the substrate under the coating head the g/m2 onto the base substrate can be set.

After application of the dried 'Active' material / Fusible mixture, the coated material was passed though a Belt laminator at 90 ^{0} C at 3.1 m/min with 1 bar pressure to partially melt the fusible powder adhesive and bond the 'Active' material.
In this process the material to be bonded or laminated is carried between two continuous top and bottom belts, through a heating zone where the temperature is sufficient to partially melt the adhesive components. The material then passes between pressure rollers (which can if needed be set to a specific gap) to facilitate the bonding or lamination. After cooling the bonded or laminated product can be wound up.

Because of the discrete nature of the dried 'Active' ingredient and the particle size of the fusible powder, the coating allows passage of liquid and wound exudate even after the bonding / laminating process.

During this bonding / laminating process, the coated nonwoven described above was also laminated with a low adherent, wound contact net (CB21, a bi-extruded net from Smith &

Nephew Extruded Films, East Yorkshire, UK, where one of the bi-extruded layers acts as a fusible adhesive) to produce the Wound Dressing product.
The net was introduced on top of the dried 'Active' ingredient coating as the material entered the two belts of the laminator.
The apertures in the net allow the passage of liquid and wound exudate.

In a further laminator pass a water repellent backing layer consisting of a 51 g/m2 hydroentangled polyester nonwoven with a fluorocarbon finish was laminated to the reverse side of the fleece using 9.5 g/m2 of the Dritex DT135 powder under the same laminating conditions.

This product was for use as a wound dressing where it can provide two properties, which are beneficial for wound healing:

1. Moist environment from alginate / honey when in contact with the wound exudates.
2. Natural anti-bacterial environment from the Manuka honey.

Example 2 : (Ref. No: 46.15.07)

A nonwoven base, carrier material (Ref. No: 81.01.05) was made with a weight of 180 g/m2, produced by a conventional carding, crossfolding, needling bonding route.
For this nonwoven base a 55/45, viscose / Anti-bacterial, Silver containing polyester fibre blend was used:

1. 55% 4.2 dtex, 60 mm Danufil V viscose (Acordis)
2. 45% 1.7 dtex, 38 mm Bacterbril polyester (Nurel, Spain)

The fibres were weighed and blended via weigh hoppers and beaters and fed to a volumetric fed Card to produce a lightweight web of fibres.
This fibrous web was laid down, in multiple layers, by a Crossfolder and the fleece produced was fed to a Needleloom where it was needled to provide the necessary strength for processing.
This nonwoven production route is well known to those experienced in nonwoven manufacture and provides a nonwoven construction which is absorbent and allows passage of liquid and wound exudate.

Dried 'Active' material was made from Manuka Honey by MOLDA AG, Gartentstasse 13, D-21368,Dahlenburg, Germany - using their commercial drying process. The Manuka Honey incorporated 5% Danisco alginate FD 120 as a drying agent.
The dried 'Active' material was mixed with a low melt co-polyester fusible powder adhesive (Dritex DT135 from Dritex Ltd, Essex, UK a product with Melting Point approx. 65 deg. Celsius and particle size range 150 to 350 micron), in mixture of 82 parts 'Active' material to 18 parts Fusible powder.

This mixture was the applied to the special nonwoven base, carrier material at a level of 300 g/m2 using a scatter coating process via a wire covered roller. This scatter process is well known and applies controlled amounts of powder by doctoring the powder particles into a rotating wire covered roller, brushing the powder out and allowing it to fall as a powder curtain onto the substrate to be coated. By controlling the roller speed the g/min of powder delivered can be set and by varying the coating speed of the substrate under the coating head the g/m2 onto the base substrate can be set.

After application of the dried 'Active' material / Fusible mixture, the coated material was passed though a Belt laminator at 90 ^{0} C at 2.5 m/min with 1 bar pressure to partially melt the fusible powder adhesive and bond the 'Active' material.

In this process the material to be bonded or laminated is carried between two continuous top and bottom belts, through a heating zone where the temperature is sufficient to partially melt the adhesive components. The material then passes between pressure rollers (which can if needed be set to a specific gap) to facilitate the bonding or lamination. After cooling the bonded or laminated product can be wound up.

Because of the discrete nature of the dried 'Active' ingredient and the particle size of the fusible powder, the coating allows passage of liquid and wound exudate even after the bonding / laminating process.

During this bonding / laminating process, the coated nonwoven described above was also laminated with a low adherent, wound contact net (CB21, a bi-extruded net from Smith & Nephew Extruded Films, East Yorkshire, UK, where one of the bi-extruded layers acts as a fusible adhesive) to produce the Wound Dressing product.
The net was introduced on top of the dried 'Active' ingredient coating as the material entered the two belts of the laminator.
The apertures in the net allow the passage of liquid and wound exudate.

In a further laminator pass a water repellent backing layer consisting of a 51 g/m2 hydroentangled polyester nonwoven with a fluorocarbon finish was laminated to the reverse side of the fleece using 9.5 g/m2 of the Dritex DT135 powder under the same laminating conditions.

This product was for use as a wound dressing where it can provide three properties, which are beneficial for wound healing:

1. Moist environment from alginate / honey when in contact with the wound exudates.
2. Natural anti-bacterial environment from the Manuka honey.
3. Anti-bacterial properties from the Silver in the anti-bacterial polyester.

Claims

1. A system to provide a layer of selected liquid 'Active' ingredients where the 'Active' ingredient is first converted to a dry form and which in a wound dressing can give improved wound healing.
2. A system to provide a layer of selected liquid 'Active' ingredients where the 'Active' ingredient is first converted to a dry form in combination with an 'Active' powder or powders and which in a wound dressing can give improved wound healing.
3. A wound dressing product produced by the system according to claim 1.
4. A wound dressing product produced by the system according to claim 1 which has a construction to allow the passage of liquids and wound exudate to contact the 'Active' ingredients.
5. A wound dressing product produced by the system according to claim 2.
6. A wound dressing product produced by the system according to claim 2 which has a construction to allow the passage of liquids and wound exudate to contact the 'Active' ingredients.
7. A wound dressing product produced by the system according to claim 4 where the layer is obtained by use of dried liquid anti-bacterial Honey as the 'Active' ingredient.
8. A wound dressing product produced by the system according to claim 4 where the layer is obtained by use of dried liquid herbal extracts as the 'Active' ingredient.
9. A wound dressing product produced by the system according to claim 4 where the layer is obtained by use of dried liquid Essential oils as the 'Active' ingredient.
10. A wound dressing product produced by the system according to claim 4 where the layer incorporating dried liquid 'Active' ingredients is coated onto nonwoven base materials.
11. A wound dressing product produced according to claim 4 where the dried liquid 'Active' ingredients are held in place on the base, carrier material using a fusible adhesive.
12. A wound dressing product produced by the system according to claim 6 where the layer is obtained by use of dried liquid anti-bacterial Honey as the 'Active' liquid ingredient in combination with an alginate as the 'Active' dry ingredient.
13. A wound dressing product produced by the system according to claim 6 where the layer is obtained by use of dried liquid anti-bacterial Honey as the 'Active' liquid ingredient in combination with chitosan as the 'Active' dry ingredient.
14. A wound dressing product produced by the system according to claim 6 where the layer is obtained by use of dried liquid anti-bacterial Honey as the 'Active' liquid ingredient in combination with carboxy-methyl cellulose as the 'Active' dry ingredient.
15. A wound dressing product produced by the system according to claim 6 where the layer is obtained by use of dried liquid anti-bacterial Honey as the 'Active' liquid ingredient in combination with pectin as the 'Active' dry ingredient.
16. A wound dressing product produced by the system according to claim 6 where the layer is obtained by use of dried liquid herbal extracts as the 'Active' liquid ingredient in combination with alginate as the 'Active' dry ingredient.
17. A wound dressing product produced by the system according to claim 6 where the layer is obtained by use of dried liquid herbal extracts as the 'Active' liquid ingredient in combination with chitosan as the 'Active' dry ingredient.
18. A wound dressing product produced by the system according to claim 6 where the layer is obtained by use of dried liquid herbal extracts as the 'Active' liquid ingredient in combination with carboxy-methyl cellulose as the 'Active' dry ingredient.
19. A wound dressing product produced by the system according to claim 6 where the layer is obtained by use of dried liquid herbal extracts as the 'Active' liquid ingredient in combination with pectin as the 'Active' dry ingredient.

20. A wound dressing product produced by the system according to claim 6 where the layer is obtained by use of dried liquid essential oils as the 'Active' liquid ingredient in combination with alginate as the 'Active' dry ingredient.
21. A wound dressing product produced by the system according to claim 6 where the layer is obtained by use of dried liquid essential oils as the 'Active' liquid ingredient in combination with chitosan as the 'Active' dry ingredient.
22. A wound dressing product produced by the system according to claim 6 where the layer is obtained by use of dried liquid essential oils as the 'Active' liquid ingredient in combination with carboxy-methyl cellulose as the 'Active' dry ingredient.
23. A wound dressing product produced by the system according to claim 6 where the layer is obtained by use of dried liquid essential oils as the 'Active' liquid ingredient in combination with pectin as the 'Active' dry ingredient.
24. A wound dressing product produced by the system according to claim 6 where the layer incorporating dried liquid 'Active' ingredients is coated onto nonwoven base materials.
25. A wound dressing product produced by the system according to claim 6 where the layer incorporating dried liquid 'Active' ingredients is coated onto nonwoven base materials incorporating other 'Active' ingredients.
26. A wound dressing product produced according to claim 6 where the dried liquid 'Active' ingredients and dry 'Active' ingredients are held in place on the base, carrier material using a fusible adhesive.
27. A wound dressing product according to claims 3 to 26 which incorporates a low adherent wound contact layer between the 'Active' ingredient layer(s) and the wound.
28. A wound dressing product according to claim 27 where the low adherent wound contact layer is a bi-extruded net where one of the bi-extruded layers acts as a fusible adhesive.
29. A wound dressing product according to claim 27 where the low adherent wound contact layer is a perforated film.
30. A wound dressing product according to claim 27 where the low adherent wound contact layer is a lightweight, polyester, thermally bonded nonwoven.
31. A wound dressing product according to claims 3 to 30 which incorporates a film or water repellent layer on the side opposing the wound contact side.
32. A wound dressing product according to claim 31 where the film is a polyurethane film.
33. A wound dressing product according to claim 31 where the water repellent layer comprises a hydroentangled polyester nonwoven with a fluorocarbon finish.
34. A medical device as described in claims 3 to 33 where the wound care device is presented as a wound dressing, wound covering or bandage format.

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Application No:	GB0603630.5	**Examiner:**	Hayley Yates
Claims searched:	1, 3, 4, 7-34	**Date of search:**	20 June 2006

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
X	1, 3, 6, 7, 10, 24, 25, 27-34	US 2004/0127826 A Caskey; see paragraphs [0058 and 0059]
X	1, 3, 6, 7, 10, 24, 25 27-34	WO 02/00269 A Caskey; see page 7 lines 17-24
X	1, 3, 7, 15 and 34	WO 01/67888 A Caskey; see claims 1, 5, 15 and 37
X	1, 4 and 34	US 5980875 A Mousa; see column 2 lines 13-33
A	-	US 5456745 A Roreger et al; see examples 19 and 20
A	-	US 2004/0043062 A Sun; see abstract
A	-	US 2004/0121027 A Pushpangadan et al; see paragraph [0045]

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^{X} :

A5R

Worldwide search of patent documents classified in the following areas of the IPC

A61F; A61L

The following online and other databases have been used in the preparation of this search report

11

WPI & EPODOC