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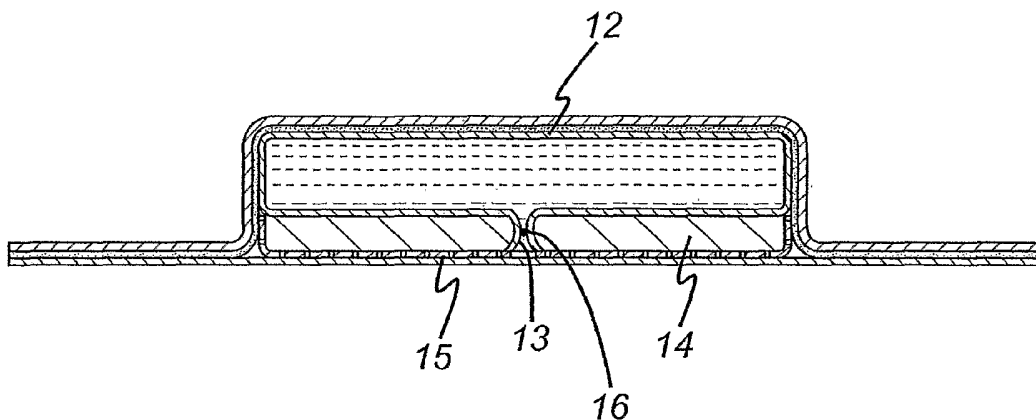
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(54) Title: SELF-IRRIGATING WOUND DRESSING



(57) Abstract: A wound dressing comprising: a liquid-impermeable backing sheet, a layer of adhesive on the backing sheet, an absorbent pad applied to the adhesive-coated side of the backing sheet such that an adhesive-coated margin of the backing sheet extends around the absorbent pad, and a reservoir of wound irrigation liquid situated between the absorbent pad and the backing sheet, wherein the reservoir comprises a zone of weakness whereby the irrigation liquid can be released from the reservoir while the wound dressing is attached to a patient.

SELF-IRRIGATING WOUND DRESSING

The present invention relates to self-irrigating wound dressings.

- 5 Wound irrigation is an important aspect of wound treatment. Irrigation with sterile saline solutions is used to clean, humidify, and soothe wounds, and in particular to assist with the removal of adherent fragments of wound dressings or the like. The saline solution may also include therapeutic agents, such as a local anaesthetic or an antiseptic.
- 10 Classical wound irrigation is relatively messy and takes place under non-sterile conditions. A need exists for more economical, efficient and sterile methods of wound irrigation.

So-called island dressings are widely used in wound treatment. Such dressings comprise : a liquid-impermeable backing sheet, a layer of adhesive on the backing sheet, and an
15 absorbent pad (or island) applied to the adhesive-coated side of the backing sheet such that an adhesive-coated margin of the backing sheet extends around the absorbent pad for attaching the dressing to the skin of a patient around the wound to be treated.

WO01/12116 describes island-type wound dressings having a perforated conduit for
20 liquids extending under the adhesive margin. Liquid can be introduced into the conduit to assist removal of the dressing by dissolving or otherwise releasing the adhesive. There is no teaching or suggestion to use such a conduit for wound irrigation.

US-A-2489675 describes island-type wound dressings having a reservoir of a medicament
25 located between the absorbent pad and the backing sheet. A frangible portion of the reservoir is broken off to release the medicament immediately before the dressing is applied to a patient.

US-A-3580254 describes island-type dressings having a capsule of medicament located
30 between the absorbent island and the backing sheet. The capsule can be ruptured to release the medicament after the dressing has been applied to a patient. There is no teaching or suggestion of using such a capsule for wound irrigation.

The present invention provides a wound dressing comprising: a liquid-impermeable backing sheet, a layer of adhesive on the backing sheet, an absorbent pad applied to the adhesive-coated side of the backing sheet such that an adhesive-coated margin of the backing sheet extends around the absorbent pad, and a reservoir of wound irrigation liquid
5 situated between the absorbent pad and the backing sheet, wherein the reservoir comprises a zone of weakness whereby the irrigation liquid can be released from the reservoir while the wound dressing is attached to a patient.

The backing sheet is usually substantially liquid-impermeable. That is to say, it is
10 substantially continuous and substantially free from macroscopic apertures or slits that could allow the passage of liquid water or wound fluid. However, an aperture may be present for passage of the optional reservoir pull-tab described in more detail below. The backing sheet is preferably formed from a semipermeable sheet material. That is to say, the backing sheet material is preferably permeable to water vapour, but not permeable to
15 liquid water or wound exudate. Preferably, the backing sheet material is also substantially microorganism-impermeable. Suitable continuous conformable backing sheets will preferably have a moisture vapor transmission rate (MVTR) of the backing sheet alone of 300 to 5000 g/m²/24hrs, preferably 500 to 2000 g/m²/24hrs at 37.5 °C at 100% to 10% relative humidity difference. The backing sheet thickness is preferably in the range of 10 to
20 1000 micrometers, more preferably 100 to 500 micrometers.

Suitable polymers for forming the backing sheet include polyurethanes and polyalkoxyalkyl acrylates and methacrylates such as those disclosed in GB-A-1280631. Preferably, the backing sheet comprises a continuous layer of a high density blocked
25 polyurethane foam that is predominantly closed-cell. A suitable backing sheet material is the polyurethane film available under the Registered Trade Mark ESTANE 5714F. Preferably, the backing sheet is substantially inelastic. Preferably, the sheet exhibits an elastic recovery at 50% strain of less than 90%, preferably less than 75%, more preferably less than 50%.

30

The backing sheet may have any shape, such as circular, oval or rectangular. Preferably, the backing sheet is shaped with at least one line of symmetry, and in certain embodiments the absorbent pad may be offset along a line of symmetry of the backing sheet. Suitably,

the backing sheet is substantially rectangular (including square). For example, the backing sheet may be substantially rectangular and has dimensions of from 5 to 25 cm by from 5 to 25 cm, more preferably from 10 to 20 cm by from 10 to 20 cm.

- 5 The adhesive layer should be moisture vapor transmitting and/or patterned to allow passage of water vapor therethrough. The adhesive layer is preferably a continuous moisture vapor transmitting, pressure-sensitive adhesive layer of the type conventionally used for island-type wound dressings, for example, a pressure sensitive adhesive based on acrylate ester copolymers, polyvinyl ethyl ether and polyurethane as described for example
10 in GB-A-1280631. The basis weight of the adhesive layer is preferably 20 to 250 g/m², and more preferably 50 to 150 g/m². Polyurethane-based pressure sensitive adhesives are preferred.

The adhesive layer extends outwardly from the absorbent pad to form an adhesive-coated
15 margin on the backing sheet around the adhesive island as in a conventional island dressing. Preferably, the wound facing surface of the absorbent island itself is substantially free of the adhesive present on the backing sheet, and more preferably it is substantially free of any adhesive.

- 20 The absorbent pad or island may comprise any of the layers conventionally used for absorbing wound fluids, serum or blood in the wound healing art, including gauzes, nonwoven fabrics, superabsorbents, hydrogels and mixtures thereof. Preferably, the absorbent pad comprises a layer of absorbent foam, such as an open celled hydrophilic polyurethane foam prepared in accordance with EP-A-0541391, the entire content of which
25 is expressly incorporated herein by reference. In other embodiments, the absorbent pad may comprise a nonwoven fibrous web, for example a carded web of viscose staple fibers. The basis weight of the absorbent pad may be in the range of 50-500g/m², such as 100-400g/m². The absorbent pad may comprise more than one layer. For example, it may comprise an absorbent layer laminated to a non-adherent, liquid-permeable wound
30 contacting top sheet. The uncompressed thickness of the absorbent pad may be in the range of from 0.5mm to 10mm, such as 1mm to 4mm. In some embodiments, the uncompressed thickness of the pad may be less than 3mm. The free (uncompressed) liquid

absorbency of the pad measured for physiological saline may for example be in the range of 5 to 30 g/g at 25°.

Suitably, the absorbent island has at least one dimension greater than 4cm, preferably 5 to 10cm. The shape of the pad likewise may be any shape, such as circular, oval or rectangular, and may be the same or different from the shape of the backing sheet. The area of the absorbent pad is typically in the range of from 1cm² to 200cm², more preferably from 4cm² to 100cm². In certain embodiments, such as sacral dressings, the area of the absorbent pad is preferably greater than 16cm², more preferably greater than 20cm².

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Suitably, the wound irrigation liquid comprises a sterile saline solution, and preferably it consists essentially of such a solution. The saline solution may comprise a therapeutic agent, for example selected from the group consisting of an antimicrobial agent, a pain relieving agent, a growth factor and mixtures thereof.

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The antimicrobial agent may be selected from the group consisting of antiseptics and antibiotics and mixtures thereof. Suitable antibiotics include peptide antimicrobials (e.g. defensins, Magainin, synthetic derivatives of them); antibiotics such as gentamycin, tetracycline, penicillins, terramycins, erythromycin, bacitracin, neomycin, polymycin B, mupirocin, clindamycin and mixtures thereof. Suitable antiseptics include silver sulfadiazine, chlorhexidine, povidone iodine, triclosan, other silver salts and colloidal silver, sucralfate, antimicrobial quaternary ammonium salts and mixtures thereof.

Suitably, the antimicrobial agent may be incorporated into the the wound irrigation liquid at concentrations of between about 0.1-30% by weight based on the final weight of the sponge, more suitable from about 0.5-15% by weight, and preferably from about 1 to about 5% by weight.

The pain relieving agent may be selected from the group consisting of an anaesthetic, an analgesic, an antiinflammatory or mixtures thereof. Suitable anaesthetics include lidocaine or novocaine. Suitable analgesics include non-steroidal anti-inflammatory drugs (NSAIDs). Suitable antiinflammatory agents include steroids such as prostaglandins.

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Suitably, the pain relieving agent may be incorporated into the the wound irrigation liquid at concentrations of between about 0.1-30% by weight based on the final weight of the sponge, more suitably from about 0.5-15% by weight, and preferably between about 1-5% by weight.

5

The growth factor may be selected from the group consisting of platelet derived growth factor (PDGF), fibroblast growth factor (FGF), transforming growth factor beta (TGF- β), epidermal growth factor (EGF), vascular endothelial growth factor (VEGF) and insulin-like growth factor (IGF), and mixtures thereof.

10

Suitably, the growth factor may be incorporated into the wound irrigation liquid at concentrations of between about 1ppm to about 1% by weight based on the final weight of the sponge, more suitably from about 10ppm to about 1000ppm by weight.

15 Suitably, the reservoir contains from about 1ml to about 40ml of the wound irrigation liquid, for example from about 4ml to about 25ml. In any case, there is preferably sufficient wound irrigation liquid to substantially saturate the absorbent pad and thereby ensure easy, pain-free removal of the dressing from the wound after use.

20 The reservoir is suitably made out of polymer sheet material, which may be shaped and filled by any of the methods conventional in the art. Suitable methods include injection molding or form-fill-seal packaging, for example vertical form-fill-seal packaging with through-liquid impulse sealing. Preferably, the polymer used for the reservoir sheet is conformable but not substantially elastomeric. Suitable polymers include, but are not
25 limited to: polyolefins such as polyethylene, polypropylene, or ethylene methyl acrylate (EMA); polyesters; polyamides such as nylons; fluoropolymers such as polyvinylidene fluoride (PVDF) or polytetrafluoroethylene (PTFE); and mixtures thereof. The reservoir sheet material is preferably a polyolefin film. Preferably, the film has a thickness by weight (ASTM E252-84) of from 10 to 200 micrometers, more preferably from 25 to 100
30 micrometers.

The term "zone of weakness" refers to a region of the reservoir that releases the liquid from the reservoir when an external force is applied to the reservoir. The zone of

weakness may, for example, comprise a score line in the sheet material making up the reservoir. In other embodiments, the zone of weakness may comprise a region of thinned sheet material making up the reservoir. In yet other embodiments, the zone of weakness may comprise a region of relatively weak sealing between two layers of sheet material making up the reservoir. In yet other embodiments, the zone of weakness may comprise a plug in an outlet of the reservoir that can be expelled or released by the application of a force from outside the dressing.

The dressing may further comprise a pull tab attached to the zone of weakness for applying a force to the zone while the dressing is attached to a patient. In other embodiments, the reservoir may be opened by applying a force through the backing sheet to increase the pressure in the reservoir to rupture the zone of weakness. In these embodiments, the wound dressing may further comprise indicia on the backing sheet showing where to apply a force to open the reservoir.

In certain embodiments it may be desirable for the irrigation liquid to contact the wound before it is absorbed by the absorbent pad. Accordingly, the wound dressing according to the invention may further comprise a channel or conduit for liquid leading from the reservoir to a wound facing surface of the dressing. The channel or conduit is preferably in liquid communication with the zone of weakness in the reservoir and with the wound facing surface of the dressing. In certain embodiments, the channel or conduit may extend around the edges of the absorbent pad so that the irrigation liquid bypasses the absorbent pad on its way to the wound surface. This may be achieved, for example, by leaving suitable adhesive-free regions extending down the sides of the absorbent pad. In other embodiments, the absorbent pad may be enclosed in an envelope having liquid-impermeable back and sides and a liquid-permeable front (wound facing) surface, so that the saline from the reservoir flows around the pad onto the wound surface before being reabsorbed into the pad. In yet other embodiments, the channel or conduit may comprise a tube extending from the reservoir, and suitably the channel or conduit may then be formed integrally with the reservoir. In these embodiments, the zone of weakness may comprise a plug or pinch or score line in the channel that can be ruptured by applying pressure to the reservoir through the backing sheet. For example, the channel or conduit could be in the form shown in US-A-2489675 (the entire content of which is incorporated herein by reference).

In use, the irrigation liquid passes down the channel or conduit onto the surface of the wound, and is then reabsorbed back into the absorbent pad thereby irrigating and cleaning the wound.

5

The wound dressing according to the present invention optionally further comprises a liquid-permeable wound facing top sheet over the absorbent pad. The top sheet may be any medically acceptable wound facing sheet, including woven and nonwoven textile materials. In certain embodiments, the wound facing top sheet comprises a layer of
10 absorbent foam, such as an open celled hydrophilic polyurethane foam prepared in accordance with EP-A-0541391, the entire content of which is expressly incorporated herein by reference.

In other embodiments, the wound facing top sheet comprises an apertured thermoplastic
15 film. The top sheet film may be formed from a thermoplastic film-forming polymer. Preferably, the polymer is conformable but not substantially elastomeric. Suitable polymers include, but are not limited to: polyolefins such as polyethylene, polypropylene, or ethylene methyl acrylate (EMA); polyesters; polyamides such as nylons; fluoropolymers such as polyvinylidene fluoride (PVDF) or polytetrafluoroethylene (PTFE); and mixtures
20 thereof. The top sheet is preferably a polyolefin film. Preferably, the film has a thickness by weight (ASTM E252-84) of from 10 to 200 micrometers, more preferably from 25 to 100 micrometers.

25 In certain embodiments, the top sheet of the wound dressing according to the invention is liquid permeable, but acts to block or restrict the flow of liquid from the back surface to the wound site. That is to say, the top sheet allows fluid to pass through the top sheet from the wound site, but blocks or restricts flow of the fluid back through the top sheet onto the wound (also known as wet-back). Such non-wetting or top sheets may for example be
30 made from porous non-woven fabrics comprising a layer of hydrophobic fibers, or having a hydrophobic finish applied to at least the outer surface thereof. In other embodiments, the top sheet is formed from a substantially liquid-impermeable sheet material provided with tapered capillaries, each capillary having a base substantially in the plane of the

wound facing surface of the top sheet and an apical opening remote from the wound facing surface of the top sheet and preferably in contact with an absorbent layer. The conical capillaries provide rapid one-way wicking of fluid from the front of the top sheet, with minimal wet-back. Top sheets of this type are described in GB-A-1526778.

5

In yet other suitable embodiments the wound facing top sheet comprises an apertured film of water-insoluble hydrogel material. For example, the apertured sheet may be a self-supporting sheet of such a hydrogel material as described in WO03/011352, the entire content of which are incorporated herein by reference.

10

For the embodiments wherein the wound facing top sheet comprises an apertured film, the apertures typically make up from about 0.1% to about 50% of the area of the film, more typically from about 1% to about 30% of the area of the apertured film, and preferably from about 10% to about 25% of the area of the apertured film. Typically, the apertured
15 film has from about 1 to about 30 apertures per square cm, for example from about 4 to about 15 apertures per square cm or from about 5 to about 10 apertures per square cm. In certain embodiments the apertures are uniformly distributed over the surface of the film, preferably in a regular pattern. The mean area of each aperture may for example be from about 0.01 to about 10 mm², preferably from about 0.1 to about 4 mm², and more
20 preferably from about 1mm² to about 2mm². In certain embodiments, the apertures have a ratio of maximum length to maximum width of from about 1 to about 10, preferably from about 1 to about 3, and more preferably from about 1 to about 1.5. Suitable aperture shapes include round, oval or regular polygonal

25 The wound facing top sheet may also consist of, or comprise, or be occlusively coated by, a composition that is soluble in a component of wound exudate, whereby the permeability of the wound facing sheet is dependent on the amount and/or the composition of wound exudate. For example, the composition may be soluble in water to provide increased absorption rates for highly exuding wounds, as described in GB-A-2379392. The
30 composition may be soluble in the presence of enzymes that are markers for wound chronicity, such as protease enzymes, as described in WO03/047643. The composition may be soluble in the presence of enzymes that are markers for wound infection, such as lysozyme, as described in WO2004/024196. The composition may be soluble in the

presence of enzymes that are markers for pain, or other wound conditions. The contents of all of the above applications are hereby incorporated by reference.

The wound facing top sheet may be bonded to the backing sheet around or behind the absorbent pad, and/or it may be bonded to the absorbent pad by any suitable means, including adhesive bonding, melt bonding, needling, or entanglement.

In these embodiments, a channel or conduit suitably leads from the reservoir to the wound facing surface of the top sheet. The top sheet prevents the liquid from being reabsorbed by the absorbent pad too quickly, before it has properly irrigated the wound.

The dressings according to the present invention can be used in similar fashion to conventional island dressings, but they have the added advantage that the reservoir can be used to irrigate the wound in situ, without removing the dressing. This provides for quick, easy and mess-free wound irrigation under sterile conditions. In addition, once the absorbent pad is soaked with the irrigation liquid, it is easier to remove the dressing because the absorbent pad is less adherent to the wound surface.

Preferably, the adhesive dressings according to the invention further comprise at least one release-coated cover sheet covering the absorbent pad and the adhesive-coated margin. More preferably, the dressings comprise two edge cover sheets covering opposed edges of the dressing and a central cover sheet extending between the edge cover sheets, preferably substantially as described in EP-A-0117632, the entire content of which is incorporated herein by reference.

25

The wound dressing according to the present invention usually is sterile, and may be packaged in a microorganism-impermeable container.

The wound dressings according to the present invention may be used in a method of treatment of a wound in a living animal or human comprising the steps of: applying a dressing according to the invention to the wound in need of treatment, followed by releasing the irrigation liquid from the reservoir to irrigate the wound. Suitably, the step of releasing is performed after the dressing has been applied to the wound for a suitable

treatment period, for example at least 1 hour or at least 6 hours. Suitably, the step of releasing is followed by a step of removing the dressing e.g. once a substantial part of the irrigation liquid has been reabsorbed by the absorbent pad.

- 5 Specific embodiments of the present invention will now be described further, by way of example, with reference to the accompanying drawings, in which:

Fig. 1 shows a sectional schematic view of a wound dressing according to a first embodiment of the present invention;

- Fig.2 shows shows a sectional schematic view of a wound dressing according to a second
10 embodiment of the present invention; and

Fig.3 shows shows a sectional schematic view of the wound dressing of Fig.2 during release of the irrigation liquid from the reservoir.

- Referring to Fig.1, the backing sheet 1 is formed from a microporous polyurethane sponge
15 film of the kind conventionally used to provide a breathable but microorganism-impermeable backing to island wound dressings. The backing sheet 1 is rectangular with rounded corners. The dimensions are approximately 150 mm by 150 mm, which makes the dressing suitable for protection of a human sacral region.

- 20 A lower surface of the backing sheet 1 is coated with a layer 2 of a medical grade pressure-sensitive adhesive. An absorbent pad 3 of hydrophilic nonwoven textile fabric is located centrally on the wound facing side of the backing sheet 1. A perforated thermoplastic top sheet 4 covers the absorbent pad 3. The edges 5 of the top sheet are folded back along the edges of the absorbent pad 3 and adhere to the adhesive layer 2, thereby retaining the top
25 sheet 4 and absorbent pad 2 in place centrally on the backing sheet 1. The adhesive-coated margin around the absorbent pad has an average width of about 20-50 mm.

- The dressing further comprises a reservoir 6 filled with a sterile saline solution 9. The reservoir 6 is in the form of an envelope of thermoplastic sheet material formed and filled
30 by injection molding, or by form-fill-seal equipment (for example vertical form-fill-seal with through-liquid impulse sealing). A tear strip 7 is formed in the wall of the reservoir 6, and a pull thread 8 extends along the tear strip and through the backing sheet 1 so that the end of the pull thread 8 can be grasped and pulled to open the reservoir while the dressing

is attached to a patient. The dressing may further comprise passages or adhesive-free channels (not shown) extending along the edges of the absorbent pad 3 and providing conduits for the passage of the sterile solution around the absorbent pad to the wound surface, from where it is then drawn back into the absorbent pad.

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The island and the adhesive-coated margin are covered by a release-coated cover sheet 10.

Referring to Figs. 2 and 3, the general construction of this embodiment is similar to that of the embodiment of Fig.1. However, the reservoir 12 in this embodiment comprises an
10 integrally formed conduit 13 extending through the absorbent pad 14 and the top sheet 15. The conduit comprises a collar of pressure-sensitive, waterproof adhesive 16 on an inner surface thereof, whereby the conduit is sealed by pinching this collar. In use, the saline can be released through the conduit by applying a gently force to the backing sheet to compress and pressurize the reservoir 12, thereby forcing open the conduit 13 as shown in
15 Fig.3.

The above embodiments have been described by way of example only. Many other embodiments falling within the scope of the accompanying claims will be apparent to the skilled reader.

20

CLAIMS

1. A wound dressing comprising: a liquid-impermeable backing sheet, a layer of adhesive on the backing sheet, an absorbent pad applied to the adhesive-coated side of the backing sheet such that an adhesive-coated margin of the backing sheet extends around the absorbent pad, and a reservoir of wound irrigation liquid situated between the absorbent pad and the backing sheet, wherein the reservoir comprises a zone of weakness whereby the irrigation liquid can be released from the reservoir while the wound dressing is attached to a patient.
2. A wound dressing according to claim 1, wherein the wound irrigation liquid comprises a sterile saline solution.
3. A wound dressing according to claim 1 or 2, wherein the wound irrigation liquid comprises a therapeutic agent selected from the group consisting of an antimicrobial agent, a pain relieving agent, a growth factor and mixtures thereof.
4. A wound dressing according to any preceding claim, wherein the reservoir contains from about 1ml to about 40ml of the wound irrigation liquid.
5. A wound dressing according to any preceding claim, wherein the reservoir is formed from sheet material, and the zone of weakness comprises a score line in the sheet material, or a thinned region of the sheet material, or a region of weak sealing between two layers of the sheet material.
6. A wound dressing according to any preceding claim, further comprising a pull tab attached to the reservoir for opening the reservoir at said zone of weakness.
7. A wound dressing according to any preceding claim, further comprising indicia on the backing sheet showing where to apply a force to open the reservoir.
8. A wound dressing according to any preceding claim, further comprising a channel or conduit for liquid leading from the reservoir to a wound facing surface of the dressing.

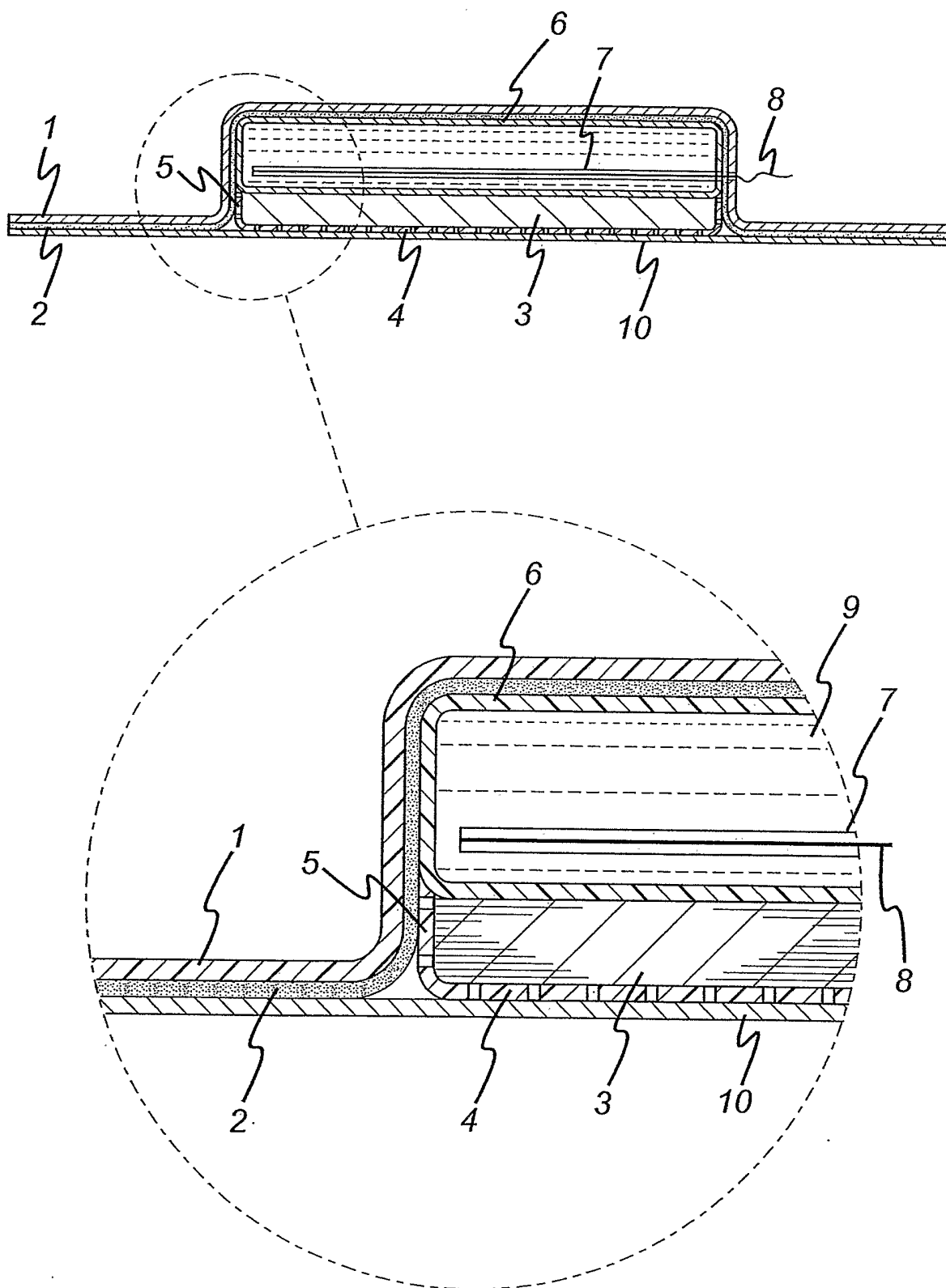
9. A wound dressing according to claim 8, wherein the dressing further comprises a liquid-permeable wound facing top sheet, and the channel or conduit leads from the reservoir to the wound facing surface of the top sheet.

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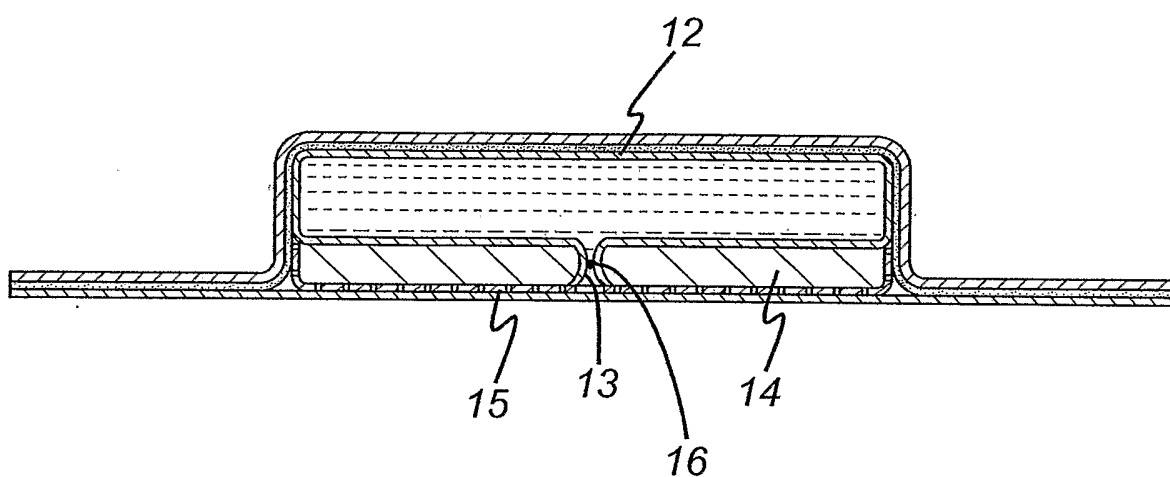
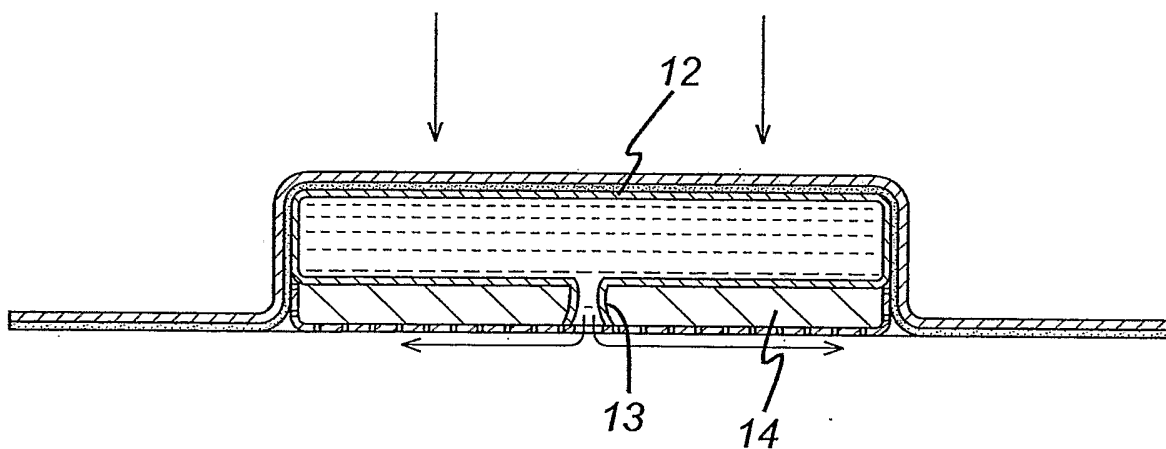
10. A wound dressing according to any preceding claim, wherein the absorbent pad is enclosed in an envelope having a substantially liquid-impermeable back surface and a liquid-permeable front (wound facing) surface.

10 11. A wound dressing according to any preceding claim, which is sterile and packaged in a microorganism-impermeable container.

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FIG. 1

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FIG. 2**FIG. 3**

INTERNATIONAL SEARCH REPORT

ational Application No

/GB2005/002044

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F13/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3 580 254 A (HENRY P. STUART) 25 May 1971 (1971-05-25) cited in the application the whole document	1-5, 8, 9, 11
X	EP 0 399 248 A (LTS LOHMANN THERAPIE-SYSTEME GMBH & CO.KG) 28 November 1990 (1990-11-28) the whole document	1-5, 7, 11
A	US 4 499 896 A (HEINECKE ET AL) 19 February 1985 (1985-02-19) claims; figures	1, 8
A	DE 34 24 837 C1 (HASSIA-VERPACKUNG KARL KLEIN GMBH, 1000 BERLIN, DE) 16 January 1986 (1986-01-16) claims; figures	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Patent document cited in search report		Publication date	Patent family member(s)	Publication date
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