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(54) Title: PROPHYLACTIC DRESSING AND USE OF SAME IN THE PREVENTION OF INFECTION

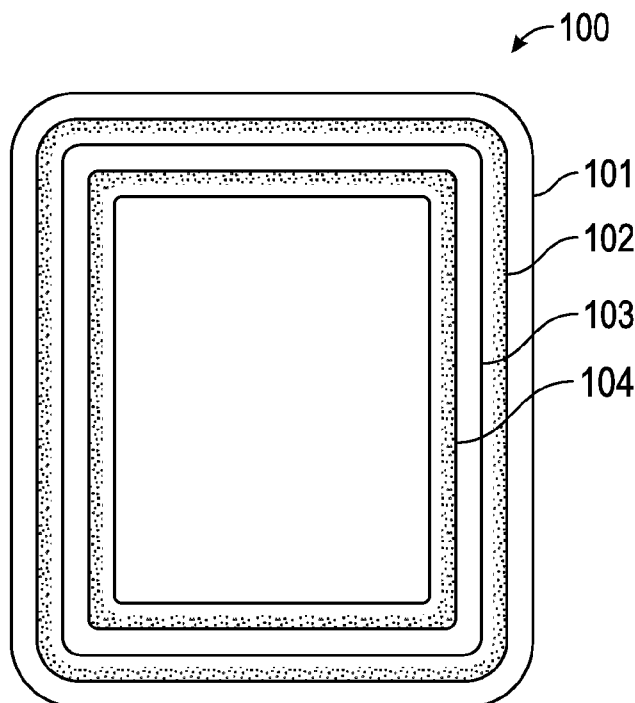


FIG. 1

(57) Abstract: Wounds and temporary appliances can
be protected against liquid contamination using a pro-
phylactic dressing. The dressing includes a liquid resist-
ant sheet and disposed thereon a first liquid barrier/ad-
hesive strip and a second liquid barrier/adhesive strip
wherein the first and second liquid barrier/adhesive
strips are concentric; located at or near the periphery of
the liquid resistant sheet; and are separated from one
another by a gap. Adsorbent's and liquid indicators can
be employed within the gap to add further functionality
to the dressing. Also disclosed herein is a support use-
ful for stabilizing leads to transcutaneous or percu-
taneous devices.



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- 1 -

TITLE: PROPHYLACTIC DRESSING AND USE OF SAME IN
 THE PREVENTION OF INFECTION

TECHNICAL FIELD

[0001] The present invention relates to a dressing. The present invention particularly relates to a dressing having prophylactic properties.

BACKGROUND

[0002] According to the Center for Disease Control, central line associated bloodstream infections result in thousands of deaths each year and billions of dollars in added costs to the U. S. healthcare system. Any transcutaneous or percutaneous medical device can lead to such infections. It would be desirable in the art treating wounds and caring for patients having transcutaneous or percutaneous devices to have a prophylactic dressing capable of preventing infection caused by contamination of the wound or the point where the medical device passes through the skin.

SUMMARY

[0003] In one aspect, the invention is a dressing comprising a liquid resistant sheet and disposed thereon a first liquid barrier/adhesive strip and a second liquid barrier/adhesive strip wherein the first and second liquid barrier/adhesive strips are concentric; located at or near the periphery of the liquid resistant sheet; and are separated from one another by a gap.

[0004] In another aspect, the invention is a method of protecting open wounds and transcutaneous or percutaneous devices from contamination comprising placing a dressing comprising a liquid resistant sheet and disposed thereon a first liquid barrier/adhesive strip and a second liquid barrier/adhesive strip wherein the first and second liquid barrier/adhesive strips are concentric; located at or near the periphery of the resistant sheet;

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and are separated from one another by a gap; over the wound or point of insertion of the transcutaneous or percutaneous device.

[0005] In still another aspect, the invention is a method of protecting open wounds and transcutaneous or percutaneous devices from contamination comprising placing a dressing comprising a liquid resistant sheet and disposed thereon a first liquid barrier/adhesive strip and a second liquid barrier/adhesive strip wherein the first and second liquid barrier/adhesive strips are concentric; located at or near the periphery of the liquid resistant sheet; and are separated from one another by a gap; and disposed within the gap is a liquid indicator; over the wound or point of insertion of the transcutaneous or percutaneous device and then periodically observing the liquid indicator to determine whether the first liquid barrier has been breached.

[0006] Another aspect of the invention is an adhesive sheet and affixed upon the side opposite the adhesive, a foam pad wherein the foam pad is configured to support the leads from a transcutaneous or percutaneous device.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] FIG. 1 is an illustration of a first embodiment of a dressing of the disclosure.

[0008] FIG 2A illustrates a first part of an embodiment of a dressing configured to be used with a catheter or other temporary appliance.

[0009] FIG 2B illustrates the use of 2A with an IV.

[0010] FIG 3 is a side view of a lead foam support using a 2 part dressing.

[0011] FIG 4 is a side view of a lead foam support including a strap to hold the lead or leads in place.

[0012] FIG. 5 is an illustration of an embodiment similar to that in FIG. 1 additionally comprising a surface treated to be resistant to sticking to a wound.

[0013] It will be appreciated that the various Figures are not necessarily to scale and that certain features have been exaggerated for clarity and do not necessarily limit the features of the invention.

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DETAILED DESCRIPTION

[0014] For the purposes of this application, the term “transcutaneous” means existing across the depth of the skin but also may mean passing through and into deeper tissues. The term “percutaneous” means made, done, or effected through the skin, such as using a needle. While not generally used interchangeably in the medical arts, for the purposes of this application, these terms are effectively synonyms because the dressings of this application may be used with any type of wound to the skin (except as noted below) as well as any opening into the body no matter how the wound or opening may have occurred. Similarly, the use of the term transcutaneous modifying a device or appliance also means including a percutaneous device or appliance.

[0015] Central line associated bloodstream infections result in thousands of deaths each year and billions of dollars in added costs to the U. S. healthcare system. Any transcutaneous or percutaneous medical device can lead to such infections. In addition to central line catheters, these infections may be caused by abdominal drains such as those used in liver transplants and hernia repair. Temporary devices used to assist other patients such as the so called left ventricular assistant devices (LVAD)s are of particular concern because they also very expensive and can be damaged by infections.

[0016] To improve the quality of life of patients with transcutaneous or percutaneous devices or even “slow to heal wounds,” it is important to protect against infection caused by liquid infiltration. Such infiltration often occurs in mundane situation such as bathing, showering or other forms of ablution. For example an aseptic or antiseptic field around a wound can be compromised when water from a bath or shower passes into a dressing carrying with it harmful bacteria.

[0017] Employing a dressing of the disclosure can mitigate or prevent infiltration of environmental fluids into the wounds or insertion point of a transcutaneous or percutaneous device. Turning to **Figure 1**, a first

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embodiment of a dressing (**100**) of the disclosure is illustrated wherein (**101**) is a liquid resistant sheet. The liquid resistant sheet may be completely impermeable but in some embodiments may pass vapor while precluding the passage of liquids (sometime referred in the art as being able to breathe). Such sheets may be of one or more layers. In some embodiments, the liquid resistant sheet may be prepared from a polymeric material. Any material known to be useful in preparing such liquid resistant sheets to those of ordinary skill in the art may be used with the method of the disclosure.

[0018] Disposed upon the liquid resistant sheet is a first liquid barrier/adhesive strip (**102**). The first liquid barrier/adhesive strip is located closest to the edge of the liquid resistant sheet. The liquid barrier functions to prevent infiltration of liquid under the dressing. Exemplary adhesives useful with the dressings of the disclosure include but are not limited to Allevyn™ from Smith & Nephew, Largo, Fla., and Elasto-Gel™ from Southwest Technologies, Inc., North Kansas City, Mo. Any adhesive known to those of ordinary skill in the art which are impermeable to liquids but also suitable for adhering a dressing to human skin may be employed in preparing the dressings of the disclosure.

[0019] Also shown in **Figure 1** is a second liquid barrier/adhesive strip (**104**). The second liquid barrier/adhesive strip is concentric with the first and they are separated from one another by a gap (**103**). The first and second liquid barrier/adhesive strip may be the same or different.

[0020] The gap between the first and second liquid barrier/adhesive strips is important. In one embodiment, the gap is filled with an adsorbent material. In another embodiment, the gap is filled with a liquid indicator. And in still another embodiment, the gap is filled with an absorbent also including a liquid indicator.

[0021] The use of an absorbent and/or a liquid indicator may permit for an extended period of prophylactic protection. When the gap is filled with an absorbent material, liquids that managed to infiltrate past the first liquid barrier/adhesive strip can be stopped by the absorbent materials for a period

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of time sufficient for the patient or the caregiver to perceive that the dressing has been compromised and should be replaced.

[0022] The use of a liquid indicator functions to make it easier to detect the infiltration of a liquid. The use of chromatic liquid indicators is especially useful as it allows for a very quick examination of the dressing. When the liquid indicator indicates that liquid has penetrated past the first liquid barrier/adhesive strip, the patient or a caregiver can make a ready determination that the dressing has been compromised and should be replaced.

[0023] The absorbent materials used with the method of the disclosure can be any known to be useful for preparing dressings. For example, in one embodiment a cellulose pad may be used. In another embodiment, a polymeric foam may be used for this purpose.

[0024] The liquid indicator may be any known to be useful to those of ordinary skill in the art of preparing dressings. It should be biologically benign and in some embodiments it may be hypoallergenic. While the indicator does not have to be a classical dye, if it is a dye and it is not proscribed for use on human skin, it may be used as long as it has a visible (chromatic) change in the presence of liquid water. In practicing the invention of the application, in some embodiments, the liquid indicator dye is a triarylmethane dye, a monoazo dye, a diazo dye, a xanthene dye, an anthraquinone dye, an indigoid dye, a quinoline dye, an FD&C dye, or a D&C dye. Such dyes useful with the present application include, but are not limited to: gentian violet, methylene blue, crystal violet, FD&C Yellow No. 5, FD&C Yellow No. 6, D&C Red NO. 17, FD&C Red No. 3, D&C Green No. 6, ethyl violet, brilliant green, FD&C Blue No. 2, D&C Yellow No. 1, FD&C Blue No. 1, or FD&C Green No. 3. IN some embodiments, it is desirable that the indicator turn blue on contact with water.

[0025] The dressings of the disclosure, especially when used with catheters and other transcutaneous or percutaneous devices may be composed of 2 parts. A first part that is applied either before the devices

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installed are also slipped underneath the lines leading from the device which functions to provide support to prevent rocking of the needle or catheter.

[0026] Turning to **Figures 2A & B**, the bottom piece of a two-part dressing is shown at **(200A)**. In **Figure 2B**, the bottom part of the dressing is in place on a patient, held in place by an adhesive covering most or all of the bottom of the bottom dressing. A foam block **(201)** which functions to stabilize movement of the line **(205)** leading from the appliance (in this case an IV **(206)**) and also functions to create a seal with the top part of the dressing such as is illustrated in **Figure 1**. Note that there is a **(202)** that is sized to fit around the part of the appliance sitting on the surface of the patient **(204)**. Beside stabilizing the needle are other part of the appliance, which reduces the amount of pain caused with movement of the line; the foam block allows the line to at least partially be submerged within the foam minimizing the amount of stretching required by the top of the dressing in order to make a liquid proof seal.

[0027] Turning to **Figure 3**, a two-part dressing of the disclosure is shown in place on a patient **(204)**. The bottom part of the dressing **(200A)** including a foam pad **(201)** is illustrated wherein the foam pad both stabilizes the lead **(205)**. The upper part of the dressing **(100)** is shown in place over the bottom part. It may be “baggy” or taut.

[0028] In an alternative embodiment, the bottom part of the two part dressing can be used even without the top portion. Turning to **Figure 4**, the bottom portion of the dressing illustrated in Figure 3 is shown with additional elements. This new element is a strap **(402)** affixed adjacent to or on the base of the foam pad with reference number **(401)** illustrating an attachment of the strap to the dressing surface. Reference number **(403)** shows a two part hook and eye attachment that functions to hold the strap in a folded over configuration when the two components are brought together. A tacky or other form of adhesive may be used in place of the hook and eye. When folded over a lead or leads, the strap secures the leads in place on the foam pad and also prevents the leads from being lifted up causing the device

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attached to the leads to press down on a needle or the transcutaneous or percutaneous device.

[0029] Turning now to **Figure 5**, therein is illustrated an embodiment similar to that of Figure 1 (**500**), but additionally comprising treating at least part of the dressing that would be in contact with a wound (**501**) with a composition that would prevent or at least reduce sticking. For example the part of the dressing in contact with the wound could be coated with or have integrated within it silica gel, or some other component to provide those properties. Any component that is safe for contact with a wound and which mitigate or prevent sticking to a wound may be used with the embodiments of the application. The area of non stick may encompass the entire inside surface of the dressing or it may be a narrow strip merely wide enough to cover at least part of the wound on which it is being used.

[0030] For the purpose of this application, the term lead or leads means an electrical wire or tubing for conveying a fluid, such as the line leading from an IV.

[0031] In alternative embodiments, the dressings of the disclosure can have separate apertures allowing for the exit of leads. Employment of antimicrobial elements is also within the scope of the disclosure. In one embodiment, the antimicrobial elements are delivered using a nano particle delivery system.

[0032] The dressings of the application are directed to the prevention of external liquid contamination of wounds or insertion points for transcutaneous or percutaneous devices. They are not suitable for use with wounds requiring maintaining a moist environment for the wounds. Exemplary of same would be ulcers and burns.

The dressings of the application are meant for temporary use. For example in some embodiments, they may be discarded after 5 days use. In other embodiments, they may be discarded after 2 days use. In still other embodiments, they may be used only to protect a patient for a single ablution and then discarded. They are also meant to be sized suitable for their

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intended applications with the dressing having dimensions suitable for its intended use.

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WHAT IS CLAIMED:

1. A dressing comprising a liquid resistant sheet and disposed thereon a first liquid barrier/adhesive strip and a second liquid barrier/adhesive strip wherein the first and second liquid barrier/adhesive strips are concentric; located at or near the periphery of the liquid resistant sheet; and are separated from one another by a gap.
2. The dressing of Claim 1 wherein the liquid resistant sheet is completely impermeable.
3. The dressing of Claim 1 wherein the liquid resistant sheet is able to pass vapor while precluding the passage of liquids.
4. The dressing of Claim 1 wherein the liquid resistant sheet is of one or more layers.
5. The dressing of Claim 1 wherein the liquid resistant sheet is prepared using a polymer.
6. The dressing of Claim 1 wherein the first liquid barrier/adhesive strip is selected from the group consisting of Allevyn™, and Elasto-Gel™.
7. The dressing of Claim 1 wherein the first liquid barrier/adhesive strip and the second liquid barrier/adhesive strip are prepared using the same adhesive.
8. The dressing of Claim 1 wherein the gap is filled with an adsorbent material.
9. The dressing of Claim 1 wherein the gap is filled with a liquid indicator.

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10. The dressing of Claim 1 wherein the gap is filled with an absorbent also including a liquid indicator.

11. The dressing of Claim 1 wherein the liquid indicator is a dye selected from the group consisting of: triarylmethane dye, a monoazo dye, a diazo dye, a xanthene dye, an anthraquinone dye, an indigoid dye, a quinoline dye, an FD&C dye, and a D&C dye.

12. The dressing of Claim 1 further comprising a bottom piece.

13. The dressing of Claim 12 wherein the bottom piece comprises an adhesive sheet and affixed upon the side opposite the adhesive, a foam pad wherein the foam pad is configured to support the leads from a transcutaneous or percutaneous device.

14. The dressing of Claim 13 wherein the dressing further comprises a strap which, when folded over a lead or leads secures the leads in place on the foam pad.

15. The dressing of Claim 1 wherein at least a part of the dressing that will be in contact with a wound is treated with a composition to mitigate or stop the wound from sticking to the dressing.

16. A method of protecting open wounds and transcutaneous or percutaneous devices from contamination comprising placing a dressing comprising a liquid resistant sheet and disposed thereon a first liquid barrier/adhesive strip and a second liquid barrier/adhesive strip wherein the first and second liquid barrier/adhesive strips are concentric; located at or near the periphery of the liquid resistant sheet; and are separated from one another by a gap; over the wound or point of insertion of the transcutaneous or percutaneous device.

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17. A method of protecting open wounds and transcutaneous or percutaneous devices from contamination comprising:

placing a dressing comprising a liquid resistant sheet and disposed thereon a first liquid barrier/adhesive strip and a second liquid barrier/adhesive strip wherein the first and second liquid barrier/adhesive strips are concentric; located at or near the periphery of the liquid resistant sheet; and are separated from one another by a gap; and disposed within the gap is a liquid indicator; over the wound or point of insertion of the transcutaneous or percutaneous device; and

then periodically observing the liquid indicator to determine whether the first liquid barrier has been breached.

18. The method of Claim 17 wherein the liquid indicator is a dye selected from the group consisting of: triarylmethane dye, a monoazo dye, a diazo dye, a xanthene dye, an anthraquinone dye, an indigoid dye, a quinoline dye, an FD&C dye, and a D&C dye.

19. A device comprising an adhesive sheet and affixed upon the side opposite the adhesive, a foam pad wherein the foam pad is configured to support the leads from a transcutaneous or percutaneous appliance.

20. A method of reducing the pain from the use of a transcutaneous or percutaneous appliance comprising employing the device of Claim 19 on a patient to stabilize the lead of the appliance.

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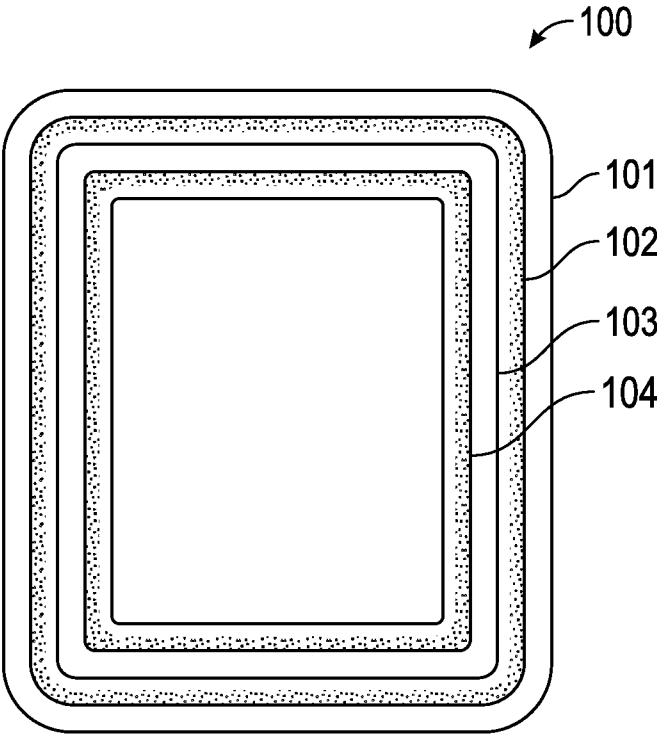


FIG. 1

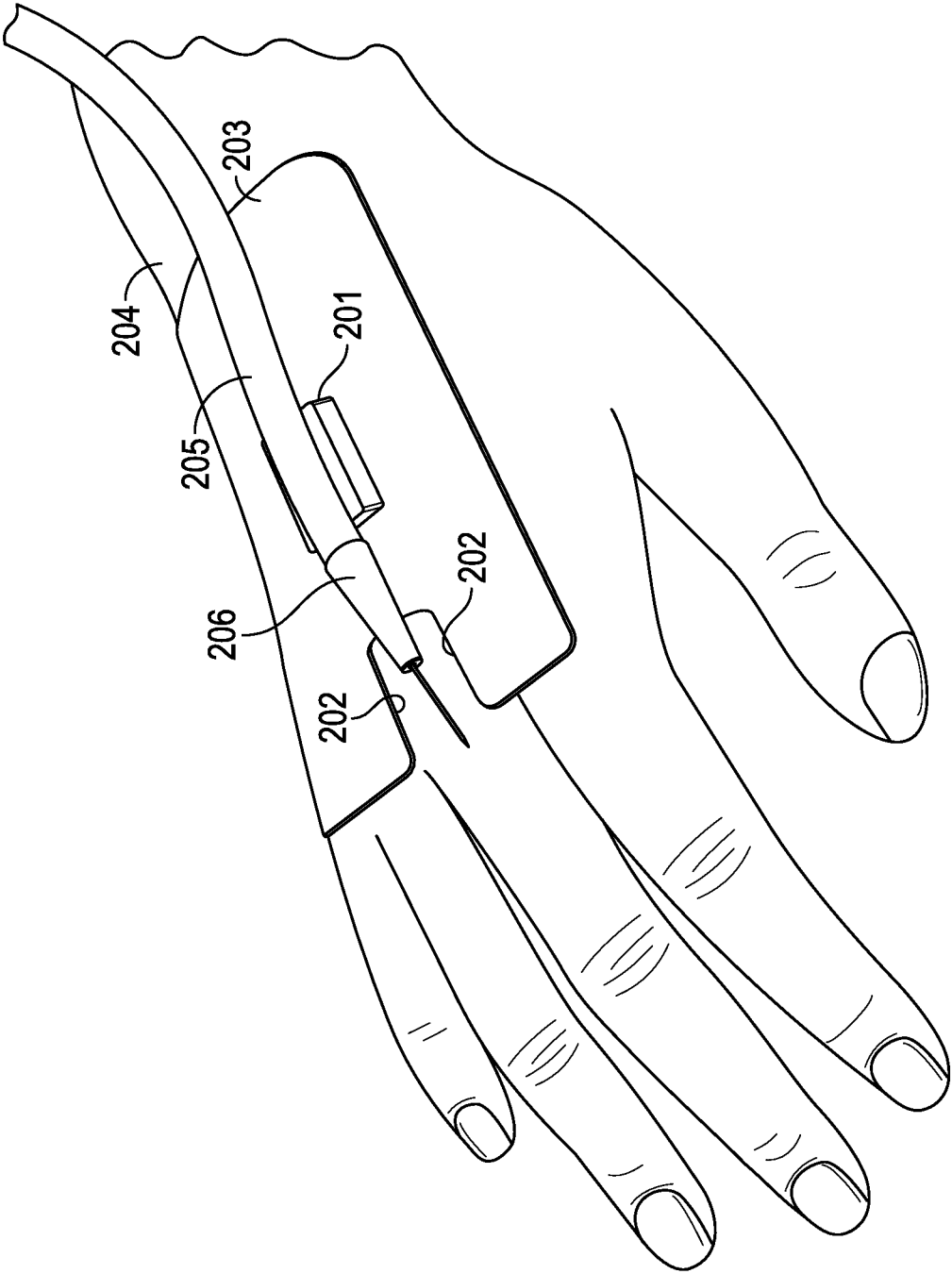


FIG. 2A

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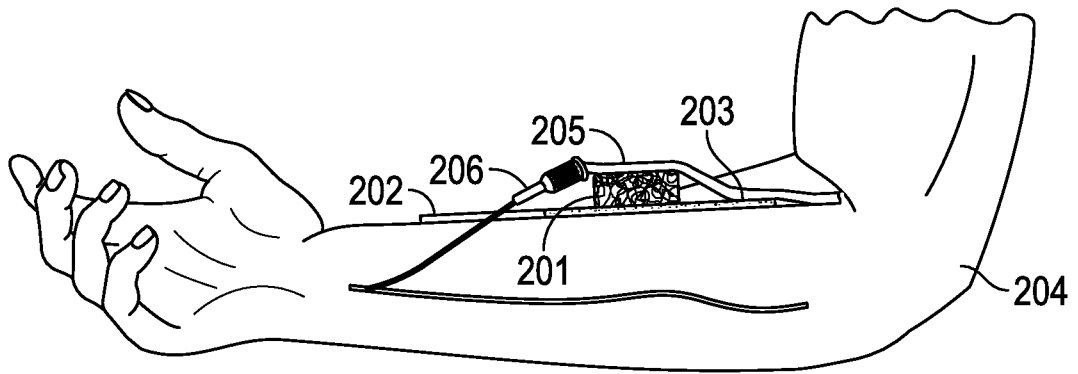


FIG. 2B

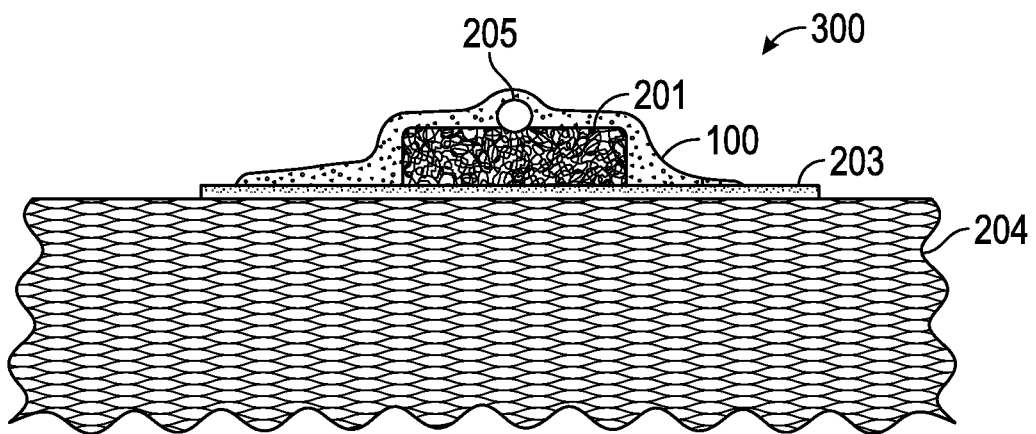


FIG. 3

4/4

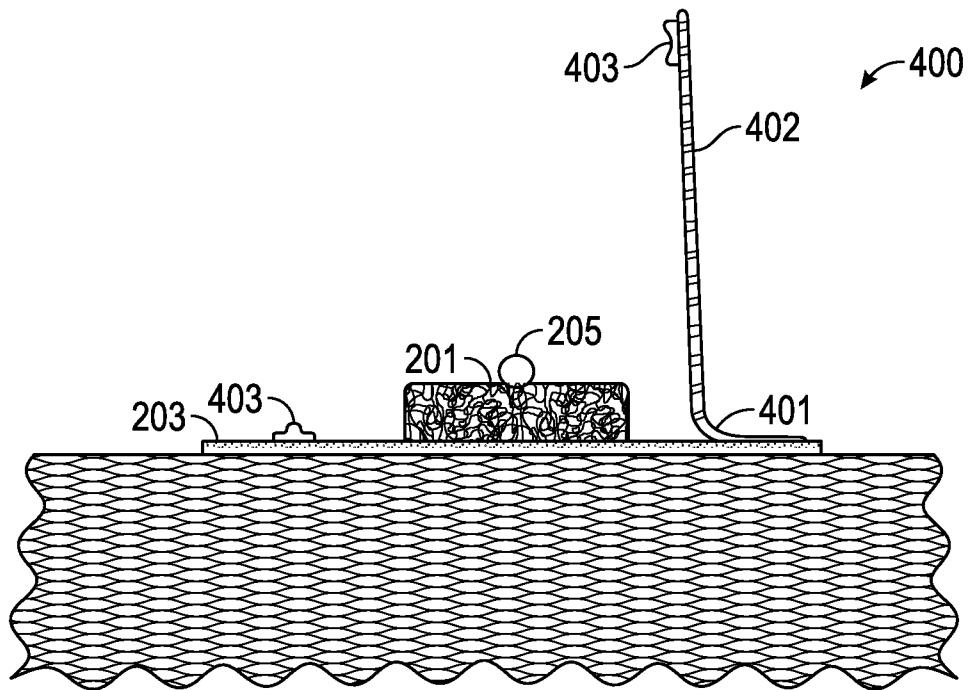


FIG. 4

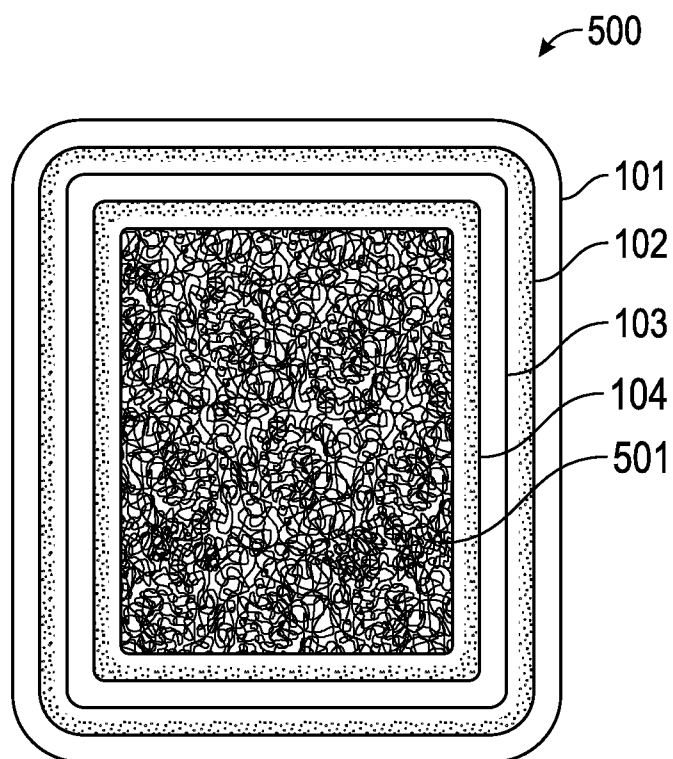


FIG. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/040878**A. CLASSIFICATION OF SUBJECT MATTER****A61F 13/02(2006.01)i, A61L 15/22(2006.01)i, A61M 39/16(2006.01)i, A61M 5/32(2006.01)i**

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)

A61F 13/02; A61L 15/42; A61M 25/02; A61M 5/00; A61F 13/00; A61F 13/15; B32B 27/08; A61L 15/22; A61M 39/16; A61M 5/32

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

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

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

eKOMPASS(KIPO internal) & keywords: wound, dressing, liquid resistant, waterproof, gap, separated, liquid indicator, pad

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3918446 A (BUTTARAVOLI, P. M.) 11 November 1975 See abstract; column 3, lines 34-35; column 5, lines 4-5; claims 1, 3; and figures 1-9, 12.	19
A		1-15
X	US 4966590 A (KALT, G. G.) 30 October 1990 See abstract; claims 1-3; and figures 1-2.	19
A		1-15
A	WO 02-100639 A1 (THE PROCTER & GAMBLE COMPANY) 19 December 2002 See abstract; page 8, lines 20-24; and claim 1.	1-15, 19
A	US 5607388 A (EWALL, R.) 4 March 1997 See abstract; column 2, lines 42-59; claim 1; and figures 1-2.	1-15, 19
A	EP 0236104 A2 (COURTAULDS PLC) 9 September 1987 See abstract; claim 1; and figure 2-3.	1-15, 19
A	US 7759537 B2 (BISHOP, S. M. et al.) 20 July 2010 See abstract; claim 1; and figures 1-2, 6-7.	1-15, 19



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

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

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

26 September 2014 (26.09.2014)

Date of mailing of the international search report

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Name and mailing address of the ISA/KR

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/040878

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 16-18,20
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 16-18, and 20 pertain to methods for treatment of the human and thus relate to a subject-matter which this International Searching Authority is not required to search under PCT Article 17(2)(a)(i) and PCT Rule 39.1(iv).
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of any additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2014/040878

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