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

(57) Abstract: Wounds and temporary appliances can be protected against liquid contamination using a prophylactic dressing. The dressing includes 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. Adsorbent's and liquid indicators can be employed within the gap to add further functionality to the dressing. Also disclosed herein is a support useful for stabilizing leads to transcutaneous or percutaneous devices.

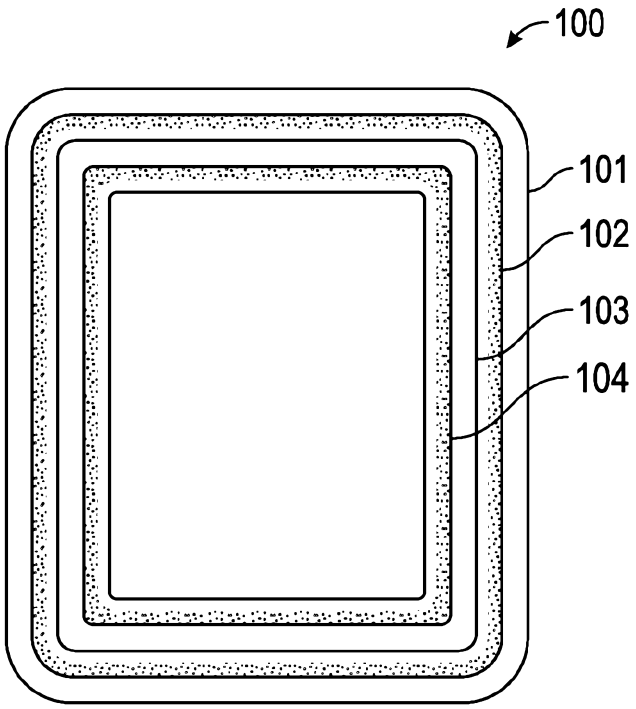

FIG. 1

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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. It is an object of the present invention to at least substantially satisfy the above desire, at least to an extent.

SUMMARY

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

[0004] In another aspect, the invention is a method of protecting open wounds and transcutaneous or percutaneous devices from contamination comprising placing a dressing over the wound or a point of insertion of the transcutaneous or percutaneous device, the dressing comprising a liquid resistant sheet and disposed thereon first and second adhesive strips, wherein the first and second adhesive strips are concentric; located at or near the periphery of the resistant sheet; are separated from one another by a gap; and are impermeable to liquids, wherein the gap is filled with a liquid indicator.

[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 first and second adhesive strips, wherein the first and second adhesive strips are concentric; located at or near the periphery of the liquid resistant sheet; and are separated from one another by a gap; disposed within the gap is a liquid indicator configured to indicate the infiltration of liquids from the outside of the dressing; 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

[0006a] Preferred embodiments of the present invention will now be described, by way of examples only, with reference to the accompanying drawings, wherein:

[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.

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

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

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

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

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

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

CLAIMS

1. A dressing comprising: a liquid resistant sheet and disposed thereon first and second adhesive strips, wherein the first and second adhesive strips are concentric; are located at or near the periphery of the liquid resistant sheet; are separated from one another by a gap; and are impermeable to liquids, wherein the gap is filled with a liquid indicator.

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 according to any one of the preceding claims wherein the liquid resistant sheet is of one or more layers.

5. The dressing according to any one of the preceding claims wherein the liquid resistant sheet is prepared using a polymer.

6. The dressing of Claim 1 wherein the first and the second adhesive strips comprise the same adhesive.

7. The dressing of Claim 1 wherein the gap is filled with an adsorbent material.

8. The dressing according to any one of the preceding claims wherein the gap is filled with an absorbent.

9. The dressing of any one of the preceding claims, wherein the first adhesive strip is located concentrically outwardly of the second adhesive strip.

10. The dressing of any one of the preceding claims, wherein the liquid indicator is indicative of liquid penetrating past the first adhesive strip into the gap.

11. The dressing of any one of the preceding claims, wherein the liquid indicator is a chromatic liquid indicator.

12. The dressing of any one of the preceding claims 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.

13. The dressing of any one of the preceding claims further comprising a bottom piece.

14. The dressing of Claim 13 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.

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

16. The dressing of any one of the preceding claims 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 would from sticking to the dressing.

17. A method of protecting open wounds and transcutaneous or percutaneous devices from contamination comprising placing a dressing over the wound or a point of insertion of the transcutaneous or percutaneous device, the dressing comprising a liquid resistant sheet and disposed thereon first and second adhesive strips, wherein the first and second adhesive strips are concentric; located at or near the periphery of the resistant sheet; are separated from one another by a gap; and are impermeable to liquids, wherein the gap is filled with a liquid indicator.

18. 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 first and second adhesive strips, wherein the first and second adhesive strips are concentric; located at or near the periphery of the liquid resistant sheet; and are separated from one another by a gap; disposed within the gap is a liquid indicator configured to indicate the infiltration of liquids from the outside of the dressing; 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.

19. The method of Claim 18 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.

20. A dressing prepared by applying to one side of a liquid resistant sheet an adhesive layer and creating a gap in the adhesive layer by applying thereto a liquid indicator, wherein resulting first adhesive strip and second adhesive strip are concentric; and located at or near a periphery of the liquid resistant sheet; and the dressing is configured to indicate the infiltration of liquids from outside of the dressing.

21. The dressing of Claim 20 wherein the liquid indicator is flush against skin when applied to a patient.

22. The dressing of Claim 21 wherein the gap is located near the periphery of the dressing.

23. The method of Claim 18 wherein the dressing is exposed to liquid infiltration during bathing, showering, or other forms of ablution.

24. The dressing of Claim 1 wherein the gap is filled with the liquid indicator.

25. The dressing of Claim 1 wherein the liquid indicator is flush against skin when applied to a patient.

26. The dressing of Claim 1 wherein the gap is located near the periphery of the dressing.

27. The dressing of Claim 1 wherein an adhesive is applied to an entire surface of the dressing.

28. The dressing of Claim 27 wherein an adhesive is not applied across an area away from the periphery of the liquid resistant sheet.

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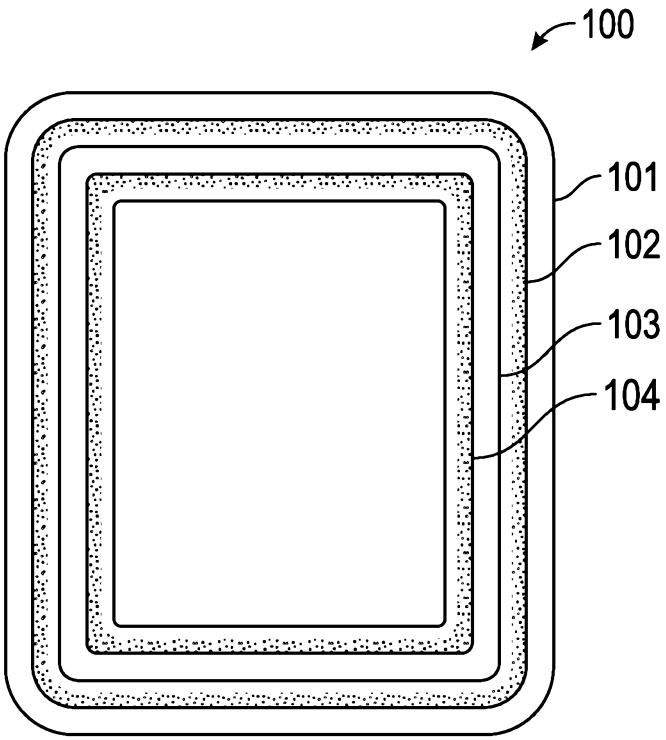

FIG. 1

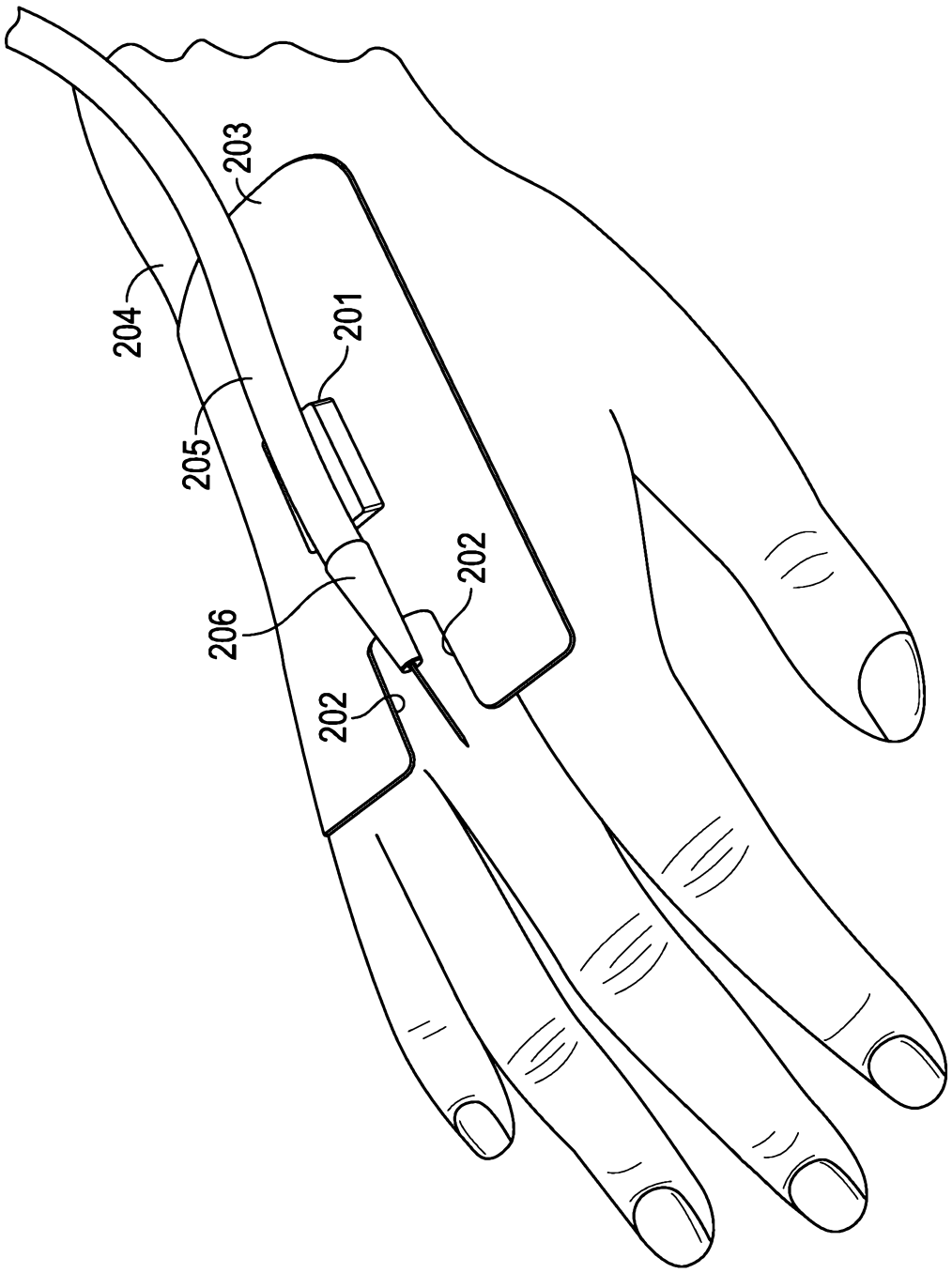

FIG. 2A

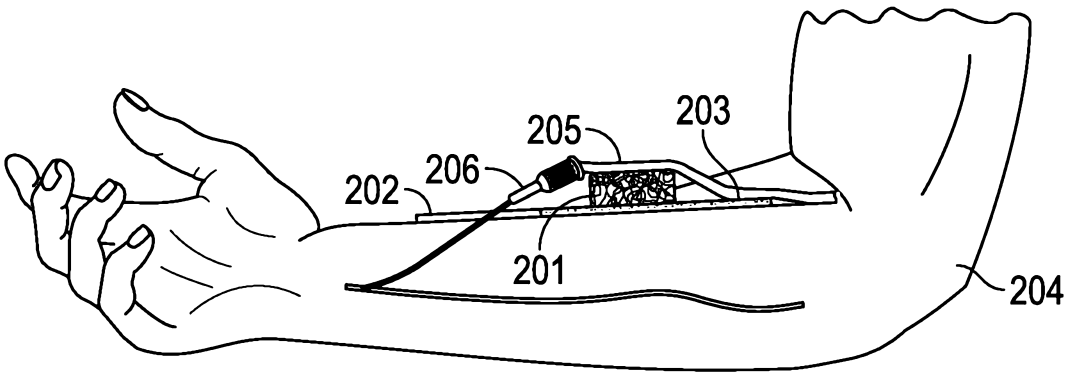

FIG. 2B

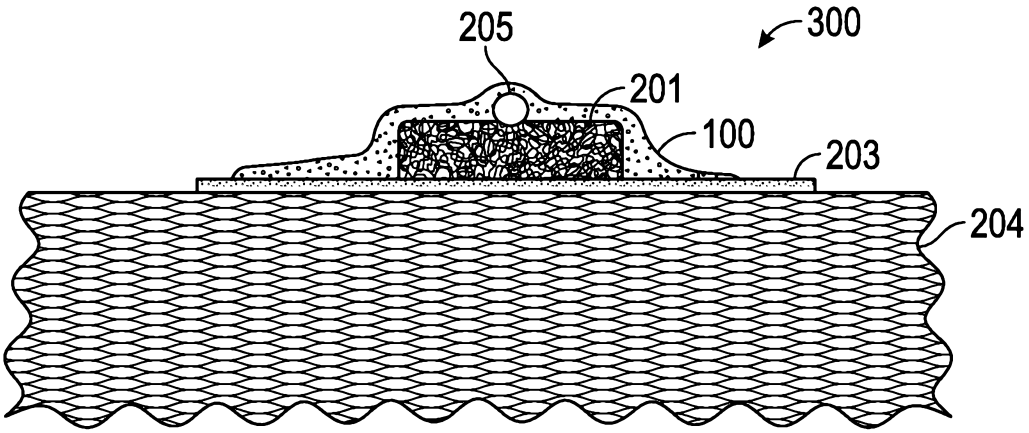

FIG. 3

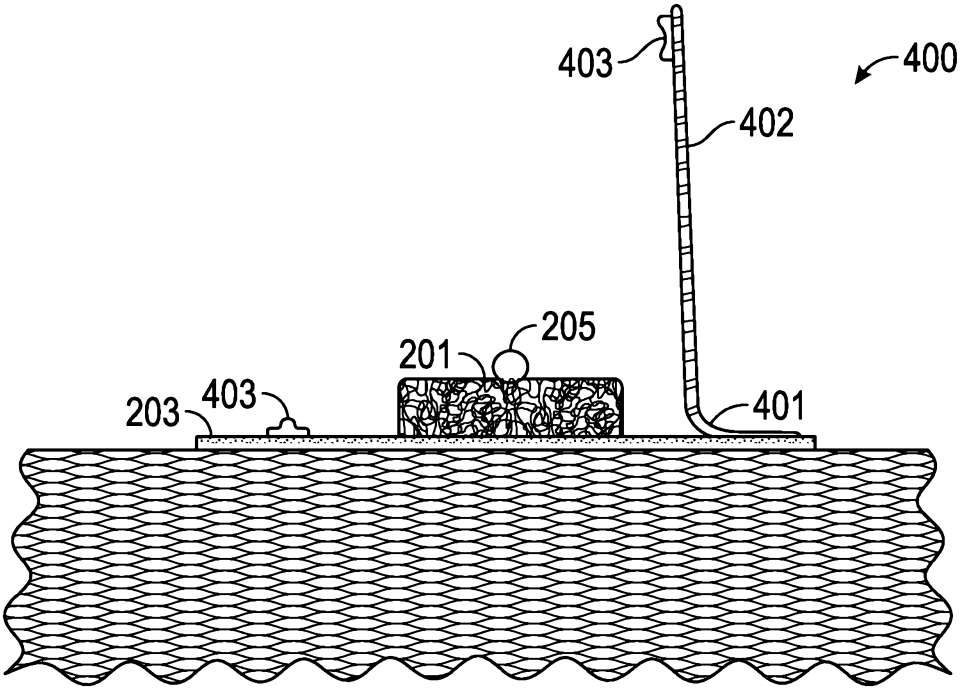

FIG. 4

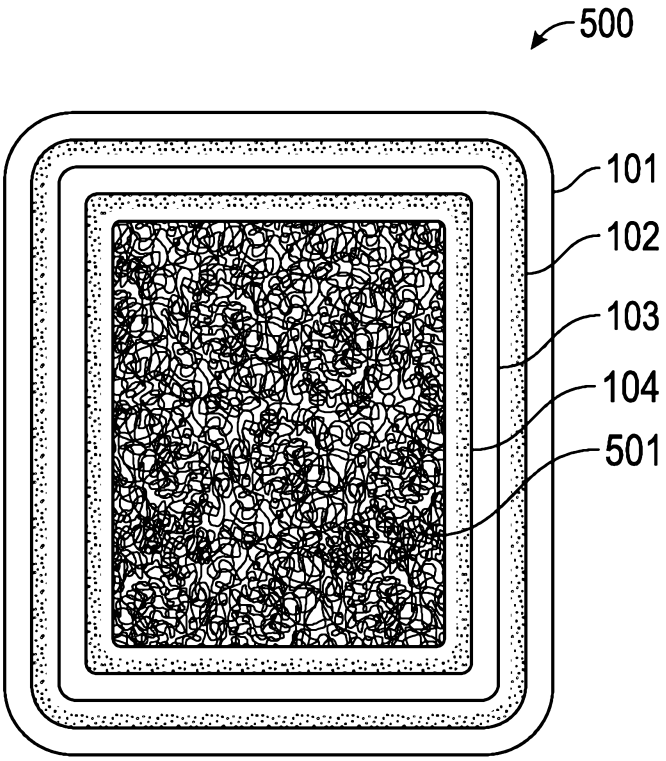

FIG. 5