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Provisional Application for Patent Cover Sheet

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c)

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Title of Invention	MOISTURE ABSORBING SEAL
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Attorney Docket Number (if applicable)	VAC.1071PRO
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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

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Entity Status

Applicant claims small entity status under 37 CFR 1.27

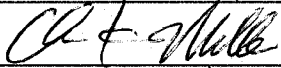
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MOISTURE ABSORBING SEAL

TECHNICAL FIELD

[0001] The following subject matter relates generally to tissue treatment systems and, more particularly, but not by way of limitation, to medical sealing drapes and systems including medical sealing drapes.

BACKGROUND

[0002] Known tissue treatment systems typically use a sealing drape to provide a fluid seal about a tissue site requiring treatment. Sealing around particular anatomical areas of the tissue site can be complicated and a leak-free seal is often difficult to achieve and maintain. Typical sealing drape materials often lack a sufficiently conformable adhesive capable of flowing into creases and cracks around the tissue site to achieve a good seal. Current materials also suffer from being unable to transfer moisture away from the tissue site. Thus, if the sealing drape remains in place for an extended period of time, moisture present near the tissue site can cause maceration of the tissue and the formation of leaks between the tissue site and the sealing drape. Accordingly, improvements to sealing and moisture transfer capabilities for sealing drapes are desirable.

SUMMARY

[0003] Shortcomings with certain aspects of known tissue treatment systems and methods utilizing sealing drapes are addressed as shown and described in a variety of illustrative, non-limiting embodiments herein. Other features and advantages of the illustrative embodiments will become apparent with reference to the drawings and detailed description that follow.

[0004] In one embodiment, provided is a reduced-pressure system for treating a tissue site including a manifold, a sealing drape, and a reduced-pressure interface. The manifold is adapted to be positioned adjacent the tissue site and to distribute reduced pressure to the tissue site. The sealing drape has an interior surface and an external surface. The interior surface of the sealing drape is adapted to cover the manifold and the tissue site to provide a sealed space between the interior surface of the sealing drape and the tissue site. Additionally, the sealing drape includes a sealing material and an absorbent material. The sealing material is hydrophobic and substantially free of hydrophilic components. The absorbent material is associated with the sealing material such that the sealing material is positioned between the interior surface of the sealing drape and the absorbent material. The reduced-pressure interface is adapted to deliver reduced-pressure. The reduced-pressure interface is in fluid communication with the sealed space and the manifold.

[0005] In another embodiment, provided is a sealing drape for treating a tissue site. The sealing drape includes an interior surface, an external surface, a sealing material, and an absorbent material. The interior surface is adapted to be positioned adjacent a peripheral surface surrounding the tissue site and to overlap the peripheral surface to provide a sealed space between the sealing drape and the tissue site. The sealing material includes a fluid permeable, hydrophobic material substantially free of hydrophilic components. The absorbent material is disposed in the sealing material such that the sealing material is positioned between the interior surface of the sealing drape and the absorbent material. The absorbent material is adapted to absorb fluid communicated through the sealing material.

[0006] In yet another embodiment, provided is a method of manufacturing a sealing drape for treating a tissue site. The method includes the steps of: providing a sealing material being hydrophobic and substantially free of hydrophilic components; providing an absorbent material; and disposing the absorbent material in the sealing material.

[0007] In yet another embodiment, provided is a reduced-pressure system for treating a tissue site including a manifold, a sealing drape, and a reduced-pressure interface. The manifold is adapted to be positioned adjacent the tissue site and to distribute reduced pressure to the tissue site. The sealing drape has an interior surface and an external surface. The interior surface of the sealing drape is adapted to be positioned adjacent a peripheral surface surrounding the tissue site and to cover the manifold and the tissue site to provide a sealed space between the interior surface and the tissue site. Further, the sealing drape is adapted to extend beyond the tissue site and to overlap the peripheral surface. Additionally, the sealing drape includes a sealing material and an absorbent material. The sealing material is hydrophobic and substantially free of hydrophilic components. The absorbent material is associated with the sealing material such that the sealing material is positioned between the interior surface of the sealing drape and the absorbent material. The reduced-pressure interface is adapted to deliver reduced-pressure. The reduced-pressure interface is in fluid communication with the sealed space and the manifold.

[0008] In yet another embodiment, provided is a method for treating a tissue site, including the steps of positioning a sealing drape adjacent a peripheral surface surrounding the tissue site, the sealing drape extending beyond the tissue site and overlapping the peripheral surface; and transferring moisture away from the peripheral surface through the sealing drape.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] A more complete understanding of this specification may be obtained by reference to the following detailed description when taken in conjunction with the accompanying drawings wherein:

[0010] FIGURE 1 is a side view, with a portion shown in cross section, of an embodiment of a reduced-pressure treatment system employing an embodiment of a sealing drape;

[0011] FIGURE 2 is a perspective view of another embodiment of a sealing drape suitable for use with the reduced-pressure treatment system;

[0012] FIGURE 3 is a perspective view of another embodiment of a sealing drape suitable for use with the reduced-pressure treatment system;

[0013] FIGURE 4 is a perspective, exploded view of another embodiment of a sealing drape suitable for use with the reduced-pressure treatment system;

[0014] FIGURE 5 is a perspective, exploded view of another embodiment of a sealing drape suitable for use with the reduced-pressure treatment system; and

[0015] FIGURE 6 is a perspective, exploded view of another embodiment of a sealing drape suitable for use with the reduced-pressure treatment system.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

[0016] In the following detailed description of the illustrative, non-limiting embodiments, reference is made to the accompanying drawings that form a part hereof. These embodiments are described in sufficient detail to enable those skilled in the art to practice the following subject matter. It is understood that other embodiments may be utilized, and that logical structural, mechanical, electrical, and chemical changes may be made without departing from the scope of this specification. To avoid detail not necessary to enable those skilled in the art to practice the embodiments described herein, the detailed description may omit certain information known to those skilled in the art. The following detailed description is not to be taken in a limiting sense, the scope of the illustrative embodiments being defined by the appended claims.

[0017] Referring generally to the drawings, this specification provides a reduced-pressure treatment system 100 utilizing a sealing drape 101 for treating a tissue site 102. The reduced-pressure treatment system 100 is presented in the context of a tissue site 102 that may include, without limitation, a wound 104 extending through the epidermis 106, the dermis 108, and reaching into a hypodermis, or subcutaneous tissue 110. The reduced-pressure treatment system 100 includes a reduced-pressure dressing 112, a reduced-pressure source 114, and a reduced-pressure delivery conduit 116. The reduced-pressure delivery conduit 116 provides reduced pressure from the reduced-pressure source 114 to the reduced-pressure dressing 112. As will be described in an embodiment below, the sealing drape 101 may be a component of the reduced-pressure dressing 112 that will provide a fluid seal with the tissue site 102 while preventing the surface of the tissue site 102 from becoming saturated with moisture.

[0018] The term “tissue site” in this context, for example, may broadly refer to a wound or defect located on or within any tissue, including but not limited to, bone tissue, adipose tissue, muscle tissue, neural tissue, dermal tissue, vascular tissue, connective tissue, cartilage, tendons, or ligaments. A wound may include, without limitation, any irregularity with a tissue, such as an open wound, surgical incision, or diseased tissue. For example, the wound may include chronic, acute, traumatic, subacute, and dehiscent wounds, partial-thickness burns, ulcers (such as diabetic, pressure, or venous insufficiency ulcers), flaps, and grafts. The term “tissue site” may also refer to areas of any tissue that are not necessarily wounded or defective, but are instead

areas in which it is desired to add or promote the growth of additional tissue. For example, reduced pressure may be used in certain tissue areas to grow additional tissue that may be harvested and transplanted to another tissue location.

[0019] In general, components of the reduced-pressure treatment system 100 may be coupled directly or indirectly. For example, the reduced-pressure source 114 may be directly coupled to the reduced-pressure dressing 112 or indirectly coupled to the reduced-pressure dressing 112 through the reduced-pressure delivery conduit 116. Components may be fluidly coupled to each other to provide a path for transferring fluids (*e.g.*, liquid and/or gas) between the components. In some embodiments, components may be fluidly coupled with a tube. A “tube,” as used herein, broadly refers to any tube, pipe, hose, conduit, or other structure with one or more lumina adapted to convey fluids between two ends. In some embodiments, components may be coupled by virtue of physical proximity, being integral to a single structure, or being formed from the same piece of material. Coupling may also include mechanical, thermal, electrical, or chemical coupling (*e.g.*, a chemical bond).

[0020] “Reduced pressure” generally refers to a pressure less than the ambient pressure at the tissue site being subjected to treatment. Typically, this reduced pressure will be less than the atmospheric pressure. The reduced pressure may also be less than a hydrostatic pressure at a tissue site. Unless otherwise indicated, values of pressure stated herein are gauge pressures. Consistent with the use herein, an increase in reduced pressure or vacuum pressure typically refers to a relative reduction in absolute pressure.

[0021] The reduced-pressure source 114 provides reduced pressure as a part of the reduced-pressure treatment system 100. The reduced-pressure source 114 may be any device for supplying a reduced pressure, such as a vacuum pump, wall suction, micro-pump, or other source. While the amount and nature of reduced pressure applied to a tissue site may vary according to the treatment application, the reduced pressure typically ranges between -5 mm Hg (-667 Pa) and -500 mm Hg (-66.7 kPa) and more typically between -75 mm Hg (-9.9 kPa) and -300 mm Hg (-39.9 kPa).

[0022] As shown in FIGURE 1, in one embodiment, the reduced-pressure dressing 112 includes a manifold 118, the sealing drape 101, and a reduced-pressure interface 122. The manifold 118 has a first side 119 and a second side 121. The first side 119 of the manifold 118 may be placed within, over, proximate, or adjacent the tissue site 102.

[0023] The manifold 118 maybe a substance or structure capable of applying reduced pressure to, delivering fluids to, or removing fluids from the tissue site 102. The manifold 118 is positionable between the sealing drape 101 and the tissue site 102. The manifold 118 may be partially or fully in contact with the tissue site 102. If the tissue site 102 is a wound, *e.g.* wound 104 in FIGURE 1, the manifold 118 may partially or completely fill the wound, or the manifold 118 may be placed over the wound. The manifold 118 may take many forms, and may be any size, shape, or thickness depending on a variety of factors, such as the type of treatment being implemented or the nature and size of a particular tissue site. For example, the size and shape of the manifold 118 may be adapted to the contours of deep and irregular shaped tissue sites.

[0024] The manifold 118 may include a plurality of flow channels or pathways that distribute fluids to and remove fluids from the tissue site 102. In one embodiment, the flow channels or pathways are interconnected to improve distribution of fluids provided to or removed from the tissue site 102. The manifold 118 may be a biocompatible material that is capable of being placed in contact with the tissue site 102 and distributing reduced pressure to the tissue site 102. For example, the manifold 118 may include without limitation, devices that have structural elements arranged to form flow channels, such as, cellular foam, open-cell foam, porous tissue collections, liquids, gels, and foams that include, or cure to include, flow channels. Additionally, the manifold 118 may be a gauze, felted mat, or any other material suited to a particular biological application.

[0025] In one embodiment, the manifold 118 may be a porous foam having interconnected cells or pores that act as flow channels. The porous foam may be, for example, a hydrophobic material such as a polyurethane, open-cell reticulated foam manufactured under the trade name GranuFoam® by Kinetic Concepts, Inc. of San Antonio, Texas. In some situations, the manifold 118 may also be used to distribute fluids such as medications, antibacterials, growth factors, and various solutions to the tissue site 102. Other layers may be included in or on the manifold 118, such as absorptive materials, wicking materials, hydrophobic materials, and hydrophilic materials.

[0026] In another embodiment, the manifold 118 is made from a hydrophilic material capable of wicking fluid away from the tissue site 102 while continuing to distribute reduced pressure to the tissue site 102. The wicking properties of the manifold 118 may draw fluid away from the tissue site 102 by capillary flow or other wicking mechanisms. An example of a

hydrophilic foam is a polyvinyl alcohol, open-cell foam such as V.A.C. WhiteFoam® dressing available from Kinetic Concepts, Inc. of San Antonio, Texas. Other hydrophilic foams may include those made from polyether. Other foams that may exhibit hydrophilic characteristics include hydrophobic foams that have been treated or coated to provide hydrophilicity.

[0027] The manifold 118 may promote granulation at a tissue site when reduced-pressure is present within the reduced-pressure dressing 112. For example, any or all of the surfaces of the manifold 118 may have an uneven, coarse, or jagged profile that induce microstrains and stresses at the tissue site 102 when reduced pressure is applied through the manifold 118.

[0028] In one embodiment, the manifold 118 may be constructed from a bioresorbable material that may remain in a patient's body following use of the reduced-pressure dressing 112. Suitable bioresorbable materials may include, without limitation, a polymeric blend of polylactic acid (PLA) and polyglycolic acid (PGA). The polymeric blend may also include, without limitation, polycarbonates, polyfumarates, and caprolactones. The manifold 118 may further serve as a scaffold for new cell-growth, or a scaffold material may be used in conjunction with the manifold 118 to promote cell-growth. A scaffold is a substance or structure used to enhance or promote the growth of cells or formation of tissue, such as a three-dimensional porous structure that provides a template for cell growth. Illustrative examples of scaffold materials include calcium phosphate, collagen, PLA/PGA, coral hydroxy apatites, carbonates, or processed allograft materials.

[0029] The sealing drape 101 may be adapted to cover the second side 121 of the manifold 118 and to seal to a peripheral surface 128 proximate the tissue site 102. Thus, the sealing drape 101 provides a fluid seal between the reduced-pressure dressing 112 and the tissue site 102. "Fluid seal," or "seal," means a seal adequate to hold reduced pressure at a desired tissue site given the particular reduced-pressure source involved.

[0030] The peripheral surface 128 may be undamaged epidermis 106 peripheral to the tissue site 102. Thus, the sealing drape 101 provides a sealed space 123 proximate to the tissue site 102 that is substantially isolated from the external environment, and capable of maintaining a reduced pressure provided by the reduced-pressure source 114. Reduced pressure applied uniformly through the manifold 118 in the sealed space 123 can promote healing by inducing macrostrain and microstrain in the tissue site 102, as well as by removing exudates and other

fluids from the tissue site 102 that can be collected by a fluid canister (not shown) associated with the reduced-pressure source 114 and disposed of properly.

[0031] The sealing drape 101 may comprise an elastomeric material. “Elastomeric” means having the properties of an elastomer, generally referring to a polymeric material that has rubber-like properties. More specifically, most elastomers have elongation rates greater than 100% and a significant amount of resilience. The resilience of a material refers to the material’s ability to recover from an elastic deformation.

[0032] In other embodiments, the reduced-pressure dressing 112 may also include additional layers (not shown) positioned between the tissue site 102 and the sealing drape 101. For example, the reduced-pressure dressing 112 may further include an absorption layer, tissue-interface layer, or additional manifold layers. The reduced-pressure dressing 112 may also include an attachment device (not shown) capable of adhering or otherwise sealing the sealing drape 101 to the peripheral surface 128. Materials used as attachment devices for adhering sealing drapes to a tissue site, may include, for example, silicones and hot-melt adhesives. Other attachment devices may include, for example, hydrogels and hydrocolloids.

[0033] Reduced pressure may be applied to the reduced-pressure dressing 112 via the reduced-pressure interface 122. The reduced-pressure interface 122 may be fluidly coupled to the sealing drape 101 through an aperture 124 in the sealing drape 101. In the illustrative example of FIGURE 1, the aperture 124 is shown centrally located on the sealing drape 101. However, the aperture 124 may be located anywhere on the sealing drape 101, including a peripheral portion of the sealing drape 101 that is adjacent to an edge of the sealing drape 101. Although the aperture 124 is shown to be circular, the aperture 124 may have any shape. The shape of the aperture 124 may also be adapted to contour, or substantially coordinate with the shape of the reduced-pressure delivery conduit 116. The reduced-pressure interface 122 provides fluid communication between the sealed space 123 and the reduced-pressure delivery conduit 116 through the aperture 124.

[0034] The reduced pressure provided by the reduced-pressure source 114 may be delivered through the reduced-pressure delivery conduit 116 to the reduced-pressure interface 122. Thus, the reduced-pressure source 114 is fluidly coupled to the reduced-pressure interface 122 by the reduced-pressure delivery conduit 116. In one embodiment, the reduced-pressure interface 122 is a T.R.A.C.[®] Pad or Sensa T.R.A.C.[®] Pad available from Kinetic Concepts, Inc.

of San Antonio, Texas. The reduced-pressure interface 122 allows the reduced pressure to be delivered to the sealing drape 101 and realized within the sealed space 123 formed between the sealing drape 101 and the tissue site 102. In this illustrative, non-limiting embodiment, the reduced-pressure interface 122 extends through the sealing drape 101 to the manifold 118, but numerous arrangements are possible. The reduced-pressure interface 122 delivers the reduced pressure through the aperture 124 of the sealing drape 101 to the manifold 118 and the tissue site 102.

[0035] Upon application of the reduced pressure to the reduced-pressure dressing 112, fluids such as exudates from the tissue site 102 may be drawn into the manifold 118. Some amount of fluid as a consequence may also be brought into contact with the sealing drape 101, including portions of the sealing drape 101 that may be adjacent the peripheral surface 128 surrounding the tissue site 102. Moisture from the tissue site 102 present at the interface between the peripheral surface 128 and the sealing drape 101 may adversely affect the seal between the sealing drape 101 and the peripheral surface 128. Further, if the dressing remains in place for an extended period of time the risk of maceration of the tissue site 102 increases. “Maceration” or “macerating” in this context broadly refers to the softening or breaking down of tissue as a result of prolonged exposure to moisture.

[0036] The sealing drape 101 of the reduced-pressure treatment system 100 can overcome these shortcomings and others by maintaining a fluid seal with the tissue site 102, while also preventing the peripheral surface 128 from becoming saturated with moisture. The sealing drape 101 may adhere to a tissue site 102 when wet or dry, may transmit and manage low levels of skin moisture to avoid maceration, and may be left in place for extended time periods.

[0037] Continuing with the embodiment of FIGURE 1, the sealing drape 101 has an external surface 130 and an interior surface 132 adapted to face the tissue site 102 when positioned at the tissue site 102. As previously described, the sealing drape 101 is adapted to sealingly engage the peripheral surface 128 to provide a sealed space 123 with the tissue site 102. The interior surface 132 of the sealing drape 101 may contact the peripheral surface 128 surrounding the tissue site 102 to provide the sealed space 123. The sealing drape 101 may also be stretchable, or elastic, in nature. The stretchable properties of the sealing drape 101 may facilitate placement of the sealing drape 101 proximate to tissue sites having a variety of shapes,

topologies, or flexibility requirements. The sealing drape 101 may be sized to extend beyond the tissue site 102 to overlap the peripheral surface 128 surrounding the tissue site 102.

[0038] The sealing drape 101 may include a sealing material 134 and an absorbent material 136. The sealing material 134 may be fluid permeable, may provide a substantially sheet-like structure for the sealing drape 101, and may form a part of the interior surface 132 of the sealing drape 101. The absorbent material 136 may, for example, be contained within the sealing material 134, dispersed throughout the sealing material 134, or embedded as a sheet-like layer within the sealing material 134. The absorbent material 136 may be adapted to absorb moisture, such as exudate, from the tissue site 102 by drawing or wicking the fluid from the peripheral surface 128 of the tissue site 102.

[0039] The sealing material 134 may be comprised of any substantially pure hydrophobic material, and may have a variety of structures, including materials and structures that allow fluid, *e.g.*, liquid or gas, to pass through the sealing material 134 without being absorbed by the sealing material 134. As defined herein, a hydrophobic material that is substantially pure will be substantially free of hydrophilic components due to the tendency for hydrophilic materials to retain fluid. For example, the substantially pure hydrophobic sealing material 134 will not be a copolymer incorporating a hydrophilic component, such as a hydrophilic monomer. The sealing material 134, for example, may comprise a hydrophobic elastomer, such as a hydrophobic silicone elastomer. The hydrophobic characteristics of the sealing material 134 may prevent the sealing material 134 from directly absorbing fluid, such as exudate, from the tissue site 102, but may allow the fluid to pass through. Thus, the sealing material 134 may permit the passage of fluid away from the peripheral surface 128 and the tissue site 102 to substantially preclude any adverse affect the fluid may have on the seal being maintained with the tissue site 102. In this manner, the sealing material 134 enhances the management of fluid in the reduced-pressure dressing 112 to allow for a continued fluid seal with the tissue site 102, while also protecting the tissue site 102 from maceration.

[0040] The absorbent material 136 may be a hydrophilic material capable of absorbing fluid. The absorbent material 136 is a separate and distinct component that is coupled with the sealing material 134 as described herein to provide the sealing drape 101. In one embodiment, the absorbent material 136 may comprise a super-absorbent material. For example, the absorbent material 136 may comprise one or more super-absorbent materials, such as, for

example, carboxymethyl cellulose (CMC), or a carboxymethylcellulose salt, a cross-linked hydrophilic acrylic, or a cross-linked hydrophilic acrylic salt, or an acrylamide.

[0041] When coupled with the sealing material 134, the absorbent material 136 may provide an absorption gradient to draw or otherwise wick fluid away from the tissue site 102. Fluid from the tissue site 102 may be drawn by the absorption gradient through the sealing material 134 and then absorbed by the absorbent material 136. The absorbent material 136 may retain or bond to the fluid in conjunction with a physical or chemical change to the absorbent material 136. The absorbent material 136 may, for example, gel, increase in viscosity, or otherwise thicken upon contact with fluid from the tissue site 102, thereby trapping the fluid. The wicking properties of the absorbent material 136 may help to quickly draw fluid, *e.g.* exudate, away from the tissue site 102, and thus may prevent the accumulation of fluid at or near the tissue site 102. In a similar manner, the sealing material 134 may facilitate the evaporation of fluid absorbed by the absorbent material 136 or otherwise transferred through the sealing material 134 towards the external surface 130 of the sealing drape 101. Since fluid from the tissue site 102 passes through the sealing material 134 to reach the absorbent material 136 as described above, the sealing material 134 may provide a separation between the tissue site 102 and the absorbent material 136, *i.e.*, the sealing material 134 may be positioned between the interior surface 132 of the sealing drape 101 and the absorbent material 136. Thus, the sealing material 134 substantially precludes fluid that has been absorbed by the absorbent material 136 from contacting the tissue site 102 and the peripheral surface 128.

[0042] The sealing material 134 may have any size, shape, or thickness depending on a variety of factors, such as the type of treatment being implemented or the nature of the tissue site 102 or the peripheral surface 128. The thickness of the sealing material 134 may be increased or decreased to optimize the effectiveness of the sealing material 134 as a separator between the tissue site 102 and the absorbent material 136. For example, in applications in which the tissue site 102 releases a large amount of fluid, a thicker sealing material 134 may be desirable to restrain or prevent the fluid from contacting the tissue site 102 or the peripheral surface 128. Conversely, a thinner sealing material 134 may be desirable in applications in which a lower amount of fluid is present. For example, the sealing material 134 may be between about 100 to 200 micrometers in thickness. The thickness of the sealing material 134 may also be adjusted according to a desired ratio of hydrophobic sealing material to absorbent material comprising the

sealing drape 101 depending on the application. In one embodiment, the overall thickness of the sealing drape 101 including the sealing material 134 and absorbent material 136 may be about 250 micrometers.

[0043] The absorbent material 136 may be dispersed throughout and/or embedded as a sheet-like layer within the sealing material 134. FIGURE 2 illustrates one embodiment of a sealing drape 201 including the sealing material 134 having absorbent particles 236 dispersed throughout the sealing drape 201. The absorbent particles 236 provide the previously described absorbent material 136. The absorbent particles 236 may have any size or shape, depending on a variety of factors, such as the nature of the tissue site 102 or the amount of fluid anticipated to be released by the tissue site 102. In applications in which the tissue site 102 releases a large amount of fluid, larger absorbent particles 236 may be desirable to provide adequate absorptive capacity for the fluid.

[0044] FIGURE 3 illustrates another embodiment of a sealing drape 301 in which absorbent fibers 336, such as elongate tubes, are dispersed throughout the sealing material 134. The absorbent fibers 336 provide the previously described absorbent material 136. The absorbent fibers 336 may have any size or shape, depending on a variety of factors including the amount of fluid anticipated to be released by the tissue site 102. This specification contemplates embodiments including a mixture of absorbent particles 236 and absorbent fibers 336 dispersed within the sealing material 134 as described herein.

[0045] FIGURE 4 illustrates another embodiment of a sealing drape 401 in which the absorbent material 136 is an absorbent layer 436 positioned within the sealing material 134. In this embodiment, the sealing drape 401 may include a first layer 134a of the absorbent material 134 and a second layer 134b of the absorbent material 134. The absorbent layer 436 may be positioned between the first layer 134a and the second layer 134b. The first and second layers 134a, 134b may have thicknesses that are the same as or different from each other or the absorbent layer 436. Thus, the absorbent layer 436 may be disposed at varying distances from an external surface 130 of the sealing drape 401 and the interior surface 132 of the sealing drape 401 depending on the thicknesses of each of the first and second layers 134a, 134b.

[0046] The absorbent layer 436 may be provided as a nonwoven or woven structure. For example, the absorbent layer 436 may comprise a nonwoven or a woven sheet of CMC fibers.

Spaces or voids in the absorbent layer 436 may allow a reduced pressure that is applied to the reduced-pressure dressing 112 to be transferred within and through the absorbent layer 436.

[0047] Further, the absorbent layer 436 may have any size, shape, or thickness, depending on a variety of factors, such as the type of treatment being implemented or the nature of the tissue site 102. The size and shape of the absorbent layer 436 may be customized by a user to extend through a particular portion of the sealing drape 401. Thus, the absorbent layer 436 may be designed to cover a particular portion of the tissue site 102 or nearby tissue. The absorbent layer 436 may also have a thickness that is the same or different from the first layer 134a or the second layer 134b. For example, the width or thickness of the absorbent layer 436 may be increased to cause a corresponding increase in the fluid storage capacity of the absorbent layer 436.

[0048] Referring to the embodiments of FIGURES 2-3, in one embodiment, the absorbent particles 236 and/or the absorbent fibers 336 may be dispersed or otherwise disposed throughout the sealing material 134 in a substantially uniform manner. A substantially uniform dispersion of the absorbent particles 236 and/or the absorbent fibers 336 may reduce the distance fluid must travel from the interior surface 132 before being absorbed when compared to embodiments utilizing the absorbent layer 436. In another embodiment, described below, utilizing a configuration for the sealing drape 101 that employs the absorbent particles 236 and/or the absorbent fibers 336 and/or the absorbent layer 436 may allow a user to customize the absorption gradient through the cross section of the sealing drape 101 for a desired application. In yet another embodiment, the absorbent particles 236 and/or the absorbent fibers 336 may be dispersed or otherwise disposed within the sealing material 134 at a desired concentration and location within the sealing drape 101 to suit a particular application.

[0049] FIGURE 5 illustrates another embodiment of a sealing drape 501 having a plurality of the previously described absorbent materials 136, 236, 336, 436 disposed within the sealing drape 501. The absorbent materials 136, 236, 336, 436 may be layered upon one another and may have the same or different dimensions and include the same or different absorbent properties. In one embodiment, the plurality of absorbent materials 136, 236, 336, 436 may increase in concentration with increasing distance from the interior surface 132 of the sealing drape 501 through the cross section of the sealing drape 501, *i.e.*, from the interior surface 132 toward the external surface 130. Similarly, the sealing drape 501 may have a higher ratio of the

absorbent material 136, 236, 336, 436 to the sealing material 134 with increasing distance from the interior surface 132. In another embodiment, the absorbent materials 136, 236, 336, 436 may exhibit increasing hydrophilicity with increasing distance from the interior surface 132. In another embodiment, the plurality of absorbent materials 136, 236, 336, 436 may be disposed within the sealing drape 501 such that the absorbent materials 136, 236, 336, 436 positioned farthest from the interior surface 132 absorb more fluid than those closer to the interior surface 132. For example, the absorbent layer 436 positioned furthest away from the interior surface 132 may have a higher fluid storage capacity than the absorbent materials 336, 236 positioned successively closer to the interior surface 132. In this manner, the plurality of absorbent materials 136, 236, 336, 436 provide a 3-dimensional network of absorbent material 136 to enhance the transfer of moisture away from the tissue site 102 for retention at a maximum distance away from the tissue site 102. This configuration may be customized as described to provide a desired absorptive gradient, or Moisture Vapor Transmission Rate (MVTR), and fluid storage capacity to suit a particular application.

[0050] FIGURE 6 illustrates yet another embodiment of a sealing drape 601 including the absorbent material 136 carried by a carrier 635 rather than the sealing material 134. The carrier 635 including the absorbent material 136 is positioned within the sealing material 134, for example, between a first layer 134a and a second layer 134b of the sealing material 134. Thus, the carrier 635 acts as a support structure that carries the absorbent material 136. The carrier 635 may comprise any of a variety of shapes and sizes and may comprise any suitable nonwoven or woven materials. In one embodiment, the carrier 635 may comprise a nonwoven hydrophobic polypropylene material that is formed into a sheet-like structure. The carrier 635 provides support and strength to the absorbent material 136, the absorbent material 136, in one embodiment, being dispersed within the carrier 635 as absorbent particles 236 and/or absorbent fibers 336.

[0051] The sealing drape 101, 201, 301, 401, 501, and 601 may be self-sealing to the tissue site 102, or may require an additional sealing device. As discussed above, in one embodiment, the sealing material 134 of the sealing drape 101, 201, 301, 401, 501, and 601 comprises a hydrophobic silicone elastomer, which may function as a silicone adhesive and form a direct bond with the peripheral surface 128 of the tissue site 102, the epidermis 106, or the manifold 118.

[0052] In other embodiments, the reduced-pressure dressing 112 may include an additional attachment device to fluidly seal the sealing drape 101, 201, 301, 401, 501, and 601 around the tissue site 102. The attachment device may be affixed to the interior surface 132 of the sealing drape 101, 201, 301, 401, 501, and 601 and may fluidly seal the sealing drape 101, 201, 301, 401, 501, and 601 to the epidermis 106 to provide the sealed space 123 surrounding the tissue site 102. The attachment device may cover at least a portion of the interior surface 132 of the sealing drape 101, 201, 301, 401, 501, and 601. Attachment devices may include, without limitation, a medically acceptable, pressure-sensitive adhesive that extends about a periphery, a portion of, or the entire sealing drape 101, 201, 301, 401, 501, and 601, a double-sided drape tape, paste, hydrocolloid, hydrogel, or other sealing devices or elements. In this manner the sealing drape 101, 201, 301, 401, 501, and 601 may be adapted to adhere to the peripheral surface 128 to secure the reduced-pressure dressing 112 to the tissue site 102.

[0053] In operation, the reduced-pressure treatment system 100 may be applied to a patient in the operating room after a surgical procedure or elsewhere. According to one illustrative embodiment, the manifold 118 may be placed proximate to the tissue site 102, *e.g.*, the wound 104. The manifold 118 may be placed within the wound 104, or may overlay a portion of the wound 104. The sealing drape 101, 201, 301, 401, 501, and 601 may be placed over the manifold 118 such that a portion of the sealing drape 101, 201, 301, 401, 501, and 601 overlays the peripheral surface 128 around the tissue site 102. The sealing drape 101, 201, 301, 401, 501, and 601 may be secured to the peripheral surface 128 in order to form a fluid seal between the tissue site 102 and the sealing drape 101, 201, 301, 401, 501, and 601. The fluid seal need only be adequate to allow the reduced-pressure treatment system 100 to maintain a reduced pressure on the tissue site 102 for a desired treatment time. The individual components of the reduced-pressure dressing 112 may be sized according to the particular application or the procedure being performed by a healthcare provider. For example, the components of the reduced-pressure dressing 112 may be sized, shaped, and configured to work in different anatomical applications such as the abdomen, chest, thighs, hip, etc.

[0054] The reduced-pressure interface 122 may be fluidly coupled to the sealing drape 101, 201, 301, 401, 501, and 601 before or after the installation of the sealing drape 101, 201, 301, 401, 501, and 601. Subsequently, the reduced-pressure conduit 116 may be fluidly coupled to the reduced-pressure interface 122. The reduced-pressure interface 122 may also be omitted

and the reduced-pressure conduit 116 may be directly inserted into the sealing drape 101, 201, 301, 401, 501, and 601 in fluid communication with the sealed space 123. The reduced-pressure conduit 116 is fluidly coupled to the reduced-pressure source 114. The reduced-pressure source 114 may then be activated to deliver reduced pressure to the sealed space 123 provided by the sealing drape 101, 201, 301, 401, 501, and 601 surrounding the tissue site 102. In another embodiment, the reduced-pressure source 114 may be a micro-pump in or on the reduced-pressure dressing 112.

[0055] Upon application of the reduced pressure to the reduced-pressure dressing 112, exudates or other fluids from the tissue site 102 may be drawn into the manifold 118, the sealing drape 101, 201, 301, 401, 501, and 601, and through the reduced-pressure interface 122. As fluids are drawn from the tissue site 102, the peripheral surface 128 as well the components of the reduced-pressure dressing 112 may become moist, including the interior surface 132 of the sealing drape 101, 201, 301, 401, 501, and 601 where the sealing drape 101, 201, 301, 401, 501, and 601 contacts the peripheral surface 128 around the tissue site 102. Because of the ability of the sealing drape 101, 201, 301, 401, 501, and 601 to transfer moisture away from the peripheral surface 128 of the tissue site 102, the sealing drape 101, 201, 301, 401, 501, and 601 will maintain a fluid seal with the tissue site 102. The sealing drape 101, 201, 301, 401, 501, and 601 will allow fluid to pass through the interior surface 132 of the sealing drape 101, 201, 301, 401, 501, and 601 to reach the absorbent material 136 contained within the sealing material 134 of the sealing drape 101, 201, 301, 401, 501, and 601, thus helping to prevent saturation of the tissue site 102 and possible maceration.

[0056] This specification also provides methods of manufacturing the sealing drape 101, 201, 301, 401, 501, and 601 for use with the reduced-pressure treatment system 100. In one embodiment, the method includes the steps of providing the sealing material 134, and disposing the absorbent material 136 within the sealing material 134. The absorbent material 136 may be the previously described absorbent particles 236, the absorbent fibers 336, the absorbent layer 436, or any combination thereof.

[0057] In embodiments utilizing the absorbent particles 236 and the absorbent fibers 336, such as the sealing drape 201, 301, the method may include the step of mixing the absorbent particles 236 and/or the absorbent fibers 336 within the sealing material 134 prior to curing or otherwise solidifying the sealing material 134. The method further includes the steps of forming

the mixture of the absorbent particles 236 and/or the absorbent fibers 336 into a desired shape, such as a sheet, and curing or otherwise solidifying the mixture. In one embodiment, the absorbent particles 236 and/or the absorbent fibers 336 may be mixed within the sealing material 134 to provide a substantially uniform dispersion of the absorbent particles 236 and/or the absorbent fibers 336 within the sealing material 134. In another embodiment, the absorbent particles 236 and/or the absorbent fibers 336 may be mixed within the sealing material 134 to provide a desired concentration of the absorbent particles 236 and/or the absorbent fibers 336 within the sealing material 134 at desired location therein.

[0058] In embodiments utilizing the absorbent layer 436, such as the sealing drape 401, 501, the method may include the steps of providing the first layer 134a of the absorbent material 134 and providing the second layer 134b of the absorbent material 134. The method additionally includes the steps of providing the absorbent layer 436, positioning the absorbent layer 436 between the first and second layers 134a, 134b, and enclosing the first and second layers 134a, 134b about the absorbent layer 436. In other embodiments, multiple layers of absorbent material 134 and absorbent layers 436 may be utilized to suit a particular application.

[0059] In embodiments utilizing the carrier 635, such as the sealing drape 601, the method includes the step of carrying the absorbent material 136, such as the absorbent particles 236 and/or the absorbent fibers 336, with the carrier 635. For example, the absorbent particles 236 and/or the absorbent fibers 336 may be applied to the carrier 635 for support and retention by the previously described non-woven or woven structure of the carrier 635. The method may additionally include the steps of providing the first layer 134a of the absorbent material 134, and providing the second layer 134b of the absorbent material 134. Further, the method may include the steps of positioning the carrier 635 including the absorbent material 136 between the first and second layers 134a, 134b, and enclosing the first and second layers 134a, 134b about the carrier 635. In other embodiments, multiple layers of absorbent material 134 and carriers 635 including the absorbent material 136 may be utilized to suit a particular application.

[0060] Although the treatment system 100 has been disclosed in the context of certain illustrative, non-limiting embodiments, it should be understood that various changes, substitutions, permutations, and alterations can be made without departing from the scope of this specification as defined by the appended claims. It will be appreciated that any feature described in connection to any one embodiment may also be applicable to any other embodiment.

CLAIMS

We claim:

1. A reduced-pressure system for treating a tissue site, the system comprising:
 - a manifold adapted to be positioned adjacent the tissue site and to distribute reduced pressure to the tissue site;
 - a sealing drape having an interior surface and an external surface, the interior surface adapted to cover the manifold and the tissue site to provide a sealed space between the interior surface of the sealing drape and the tissue site, the sealing drape further comprising:
 - a sealing material, the sealing material being hydrophobic and substantially free of hydrophilic components; and
 - an absorbent material associated with the sealing material, the sealing material being positioned between the interior surface of the sealing drape and the absorbent material; and
 - a reduced-pressure interface adapted to deliver reduced-pressure, the reduced-pressure interface in fluid communication with the sealed space and the manifold.
2. The system of claim 1, the manifold having a first side and a second side, the first side adapted to be positioned adjacent the tissue site and the second side adapted to be positioned adjacent the interior surface of the sealing drape.
3. The system of claim 1, further comprising a reduced-pressure source in fluid communication with the reduced-pressure interface.
4. The system of claim 1, wherein the sealing drape is adapted to extend beyond the tissue site and to overlap a peripheral surface surrounding the tissue site, and wherein the interior surface of the sealing drape is adapted to be positioned adjacent the peripheral surface.
5. The system of claim 1, the absorbent material disposed in the sealing material.
6. The system of claim 1, the absorbent material disposed substantially uniformly within the sealing material.

7. The system of claim 5, the absorbent material comprising a plurality of absorbent particles.
8. The system of claim 5, the absorbent material comprising a plurality of absorbent fibers.
9. The system of claim 1, the absorbent material comprising a sheet-like absorbent layer disposed between a first layer and a second layer of the sealing material.
10. The system of claim 1, the absorbent material configured to provide an absorptive gradient through the sealing drape.
11. The system of claim 1, further comprising a carrier that carries the absorbent material, the carrier and the absorbent material being disposed between a first layer and a second layer of the sealing material.
12. The system of claim 11, the carrier comprising a hydrophobic polypropylene sheet.
13. The system of claim 1, further comprising a plurality of absorbent materials associated with the sealing material of the sealing drape, the plurality of absorbent materials having an absorptive capacity that increases with increasing distance through a cross section of the sealing drape from the interior surface of the sealing drape.
14. The system of claim 1, wherein the absorbent material comprises a three-dimensional structure of interconnected absorbent fibers, absorbent particles, and sheet-like absorbent layers.
15. The system of claim 1, wherein the sealing material is fluid permeable.
16. The system of claim 1, wherein the sealing material comprises an elastomeric material.
17. The system of claim 1, wherein the sealing material comprises a hydrophobic silicone elastomer.
18. The system of claim 1, wherein the sealing material of the sealing drape is adapted to provide evaporation of fluid retained in the absorbent material through the external surface of the sealing drape.

19. A sealing drape for treating a tissue site, the sealing drape comprising:
- an interior surface and an external surface, the interior surface adapted to be positioned adjacent a peripheral surface surrounding the tissue site and to overlap the peripheral surface to provide a sealed space between the sealing drape and the tissue site;
 - a sealing material, the sealing material comprising a fluid permeable hydrophobic material substantially free of hydrophilic components; and
 - an absorbent material disposed in the sealing material, the sealing material being positioned between the interior surface of the sealing drape and the absorbent material, the absorbent material adapted to absorb fluid communicated through the sealing material.
20. The sealing drape of claim 19, the absorbent material disposed substantially uniformly within the sealing material.
21. The sealing drape of claim 19, the absorbent material comprising a plurality of absorbent particles.
22. The sealing drape of claim 19, the absorbent material comprising a plurality of absorbent fibers.
23. The sealing drape of claim 19, the absorbent material comprising a sheet-like absorbent layer disposed between a first layer and a second layer of the sealing material.
24. The sealing drape of claim 19, the absorbent material configured to provide an absorptive gradient through the sealing drape.
25. The sealing drape of claim 19, further comprising a carrier that carries the absorbent material, the carrier and the absorbent material being disposed between a first layer and a second layer of the sealing material.
26. The sealing drape of claim 25, the carrier comprising a hydrophobic polypropylene sheet.
27. The sealing drape of claim 19, further comprising a plurality of absorbent materials disposed

in the sealing material of the sealing drape, the absorbent materials having an absorptive capacity that increases with increasing distance through a cross section of the sealing drape from the interior surface of the sealing drape.

28. The sealing drape of claim 19, wherein the absorbent material comprises a three-dimensional structure of interconnected absorbent fibers, absorbent particles, and sheet-like absorbent layers.
29. The sealing drape of claim 19, wherein the sealing material comprises an elastomeric material.
30. The sealing drape of claim 19, wherein the sealing material comprises a hydrophobic silicone elastomer.
31. The sealing drape of claim 19, wherein the sealing material of the sealing drape is adapted to provide evaporation of fluid retained in the absorbent material through the external surface of the sealing drape.

32. A method of manufacturing a sealing drape for treating a tissue site, the method comprising:
- providing a sealing material being hydrophobic and substantially free of hydrophilic components;
 - providing an absorbent material; and
 - disposing the absorbent material in the sealing material.
33. The method of claim 32, the step of disposing the absorbent material in the sealing material comprising:
- mixing the absorbent material and the sealing material together to provide a substantially uniform dispersion of absorbent material within the sealing material; and
 - curing the mixture.
34. The method of claim 33, further comprising the step of forming a sheet-like layer from the mixture.
35. The method of claim 33, the absorbent material comprising a plurality of absorbent fibers.
36. The method of claim 33, the absorbent material comprising a plurality of absorbent particles.
37. The method of claim 32, further comprising providing a first layer of the sealing material and providing a second layer of the sealing material, wherein the step of disposing the absorbent material in the sealing material comprises positioning the absorbent material between the first layer of the sealing material and the second layer of the sealing material.
38. The method of claim 37, the absorbent material comprising a sheet-like absorbent layer.
39. The method of claim 32, further comprising providing a first layer of the sealing material and providing a second layer of the sealing material, wherein the step of disposing the absorbent material within the sealing material comprises:
- providing a carrier;
 - carrying the absorbent material with the carrier; and

positioning the carrier and the absorbent material between the first layer of the sealing material and the second layer of the sealing material.

40. The method of claim 39, wherein the carrier comprises a hydrophobic polypropylene sheet.

41. A reduced-pressure system for treating a tissue site, the system comprising:

- a manifold adapted to be positioned adjacent the tissue site and to distribute reduced pressure to the tissue site;

- a sealing drape having an interior surface and an external surface, the interior surface adapted to be positioned adjacent a peripheral surface surrounding the tissue site and to cover the manifold and the tissue site to provide a sealed space between the interior surface and the tissue site, wherein the sealing drape is adapted to extend beyond the tissue site and to overlap the peripheral surface, the sealing drape further comprising:

- a sealing material, the sealing material being hydrophobic and substantially free of hydrophilic components; and

- an absorbent material associated with the sealing material, the sealing material being positioned between the interior surface of the sealing drape and the absorbent material; and

- a reduced-pressure interface adapted to deliver reduced-pressure, the reduced-pressure interface in fluid communication with the sealed space and the manifold.

42. A method for treating a tissue site, comprising:

- positioning a sealing drape adjacent a peripheral surface surrounding the tissue site, the sealing drape extending beyond the tissue site and overlapping the peripheral surface; and

- transferring moisture away from the peripheral surface through the sealing drape.

ABSTRACT

Disclosed is a sealing drape suitable for use with a reduced-pressure treatment system for treating a tissue site. The sealing drape has an interior surface and an external surface, the interior surface being adapted for positioning adjacent to a peripheral surface of the tissue site. The sealing drape includes a sealing material and an absorbent material. The sealing material is hydrophobic and substantially free of hydrophilic components. The positioning of the sealing material is between the interior surface of the sealing drape and the absorbent material. The absorbent material is adapted to absorb fluid communicated through the sealing material. As a part of the reduced-pressure treatment system, the sealing drape may be utilized with a manifold adapted to be positioned at the tissue site, a reduced-pressure interface, and a reduced-pressure source. Further disclosed are methods of manufacturing the sealing drape and methods of treatment utilizing the sealing drape.

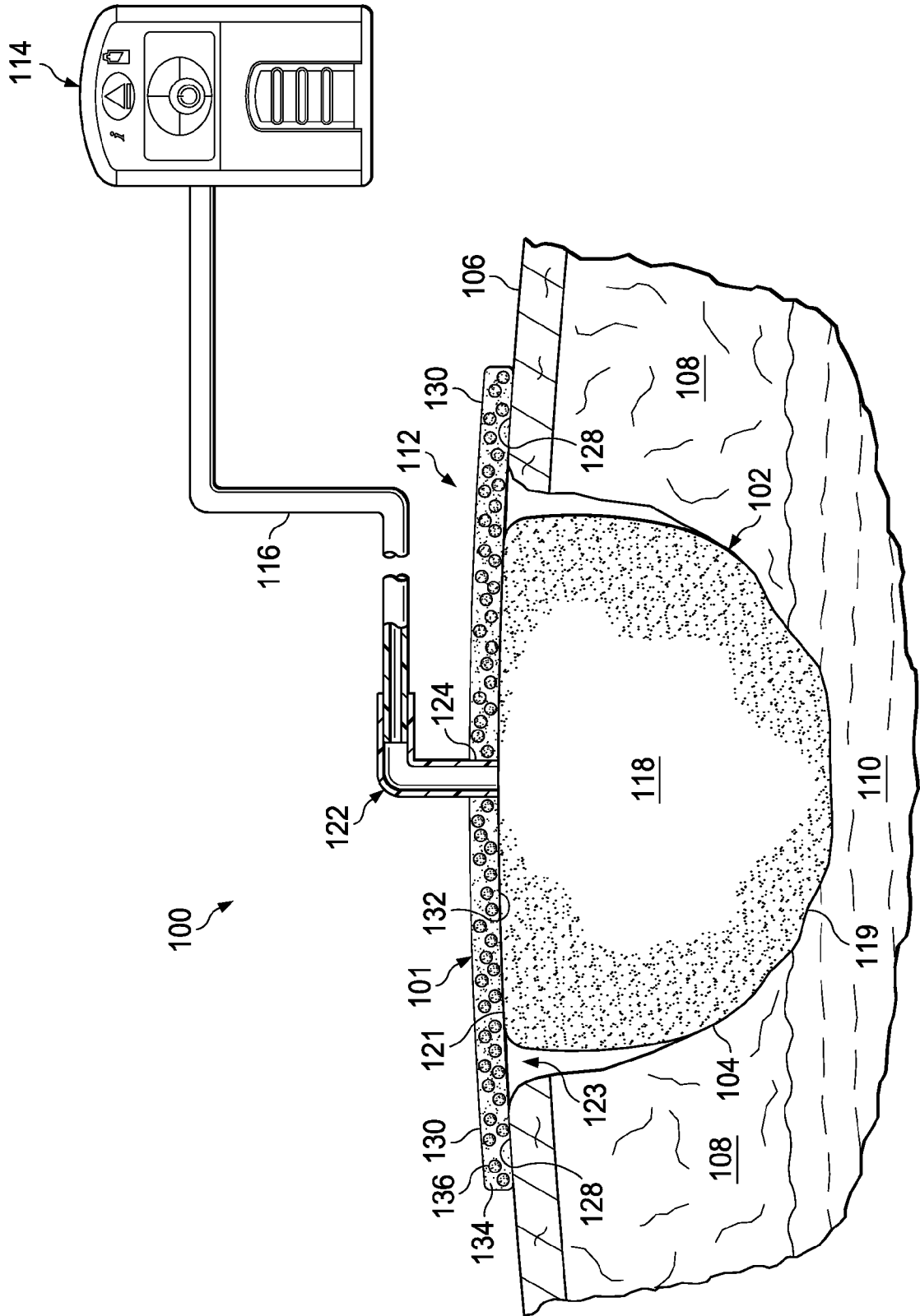
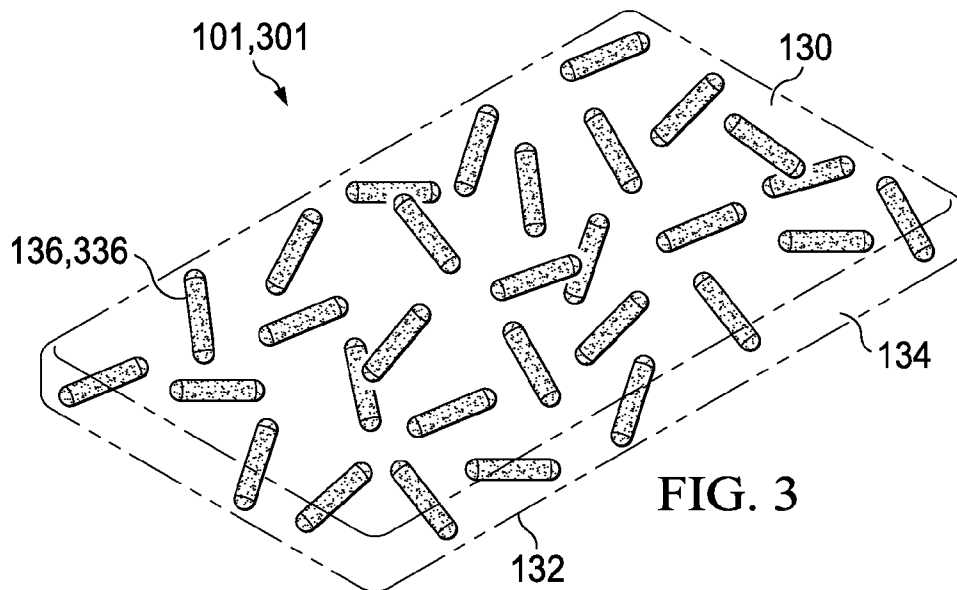
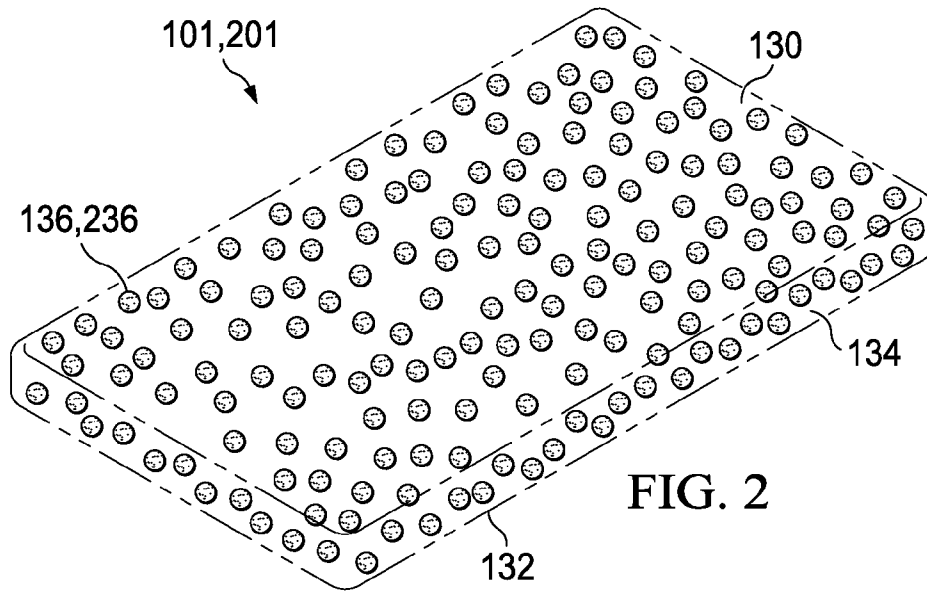


FIG. 1



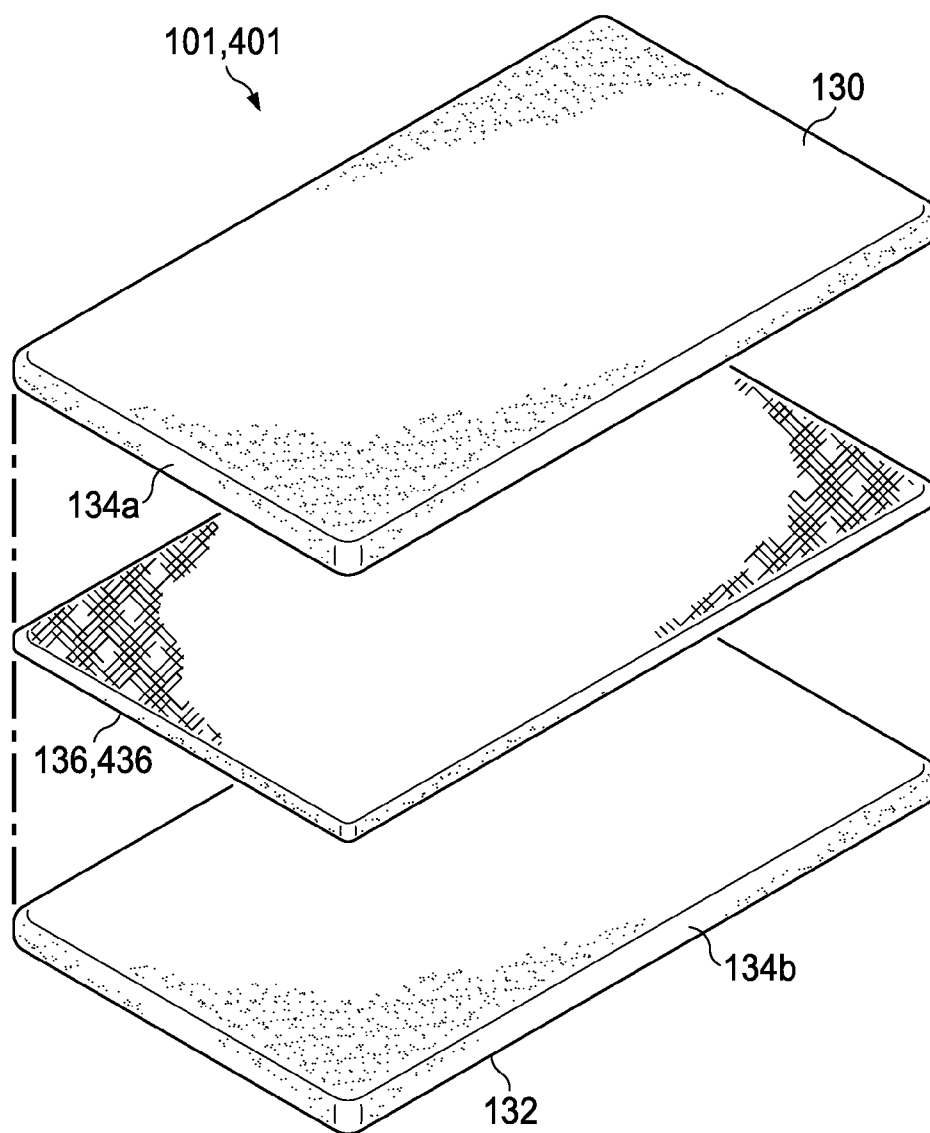


FIG. 4

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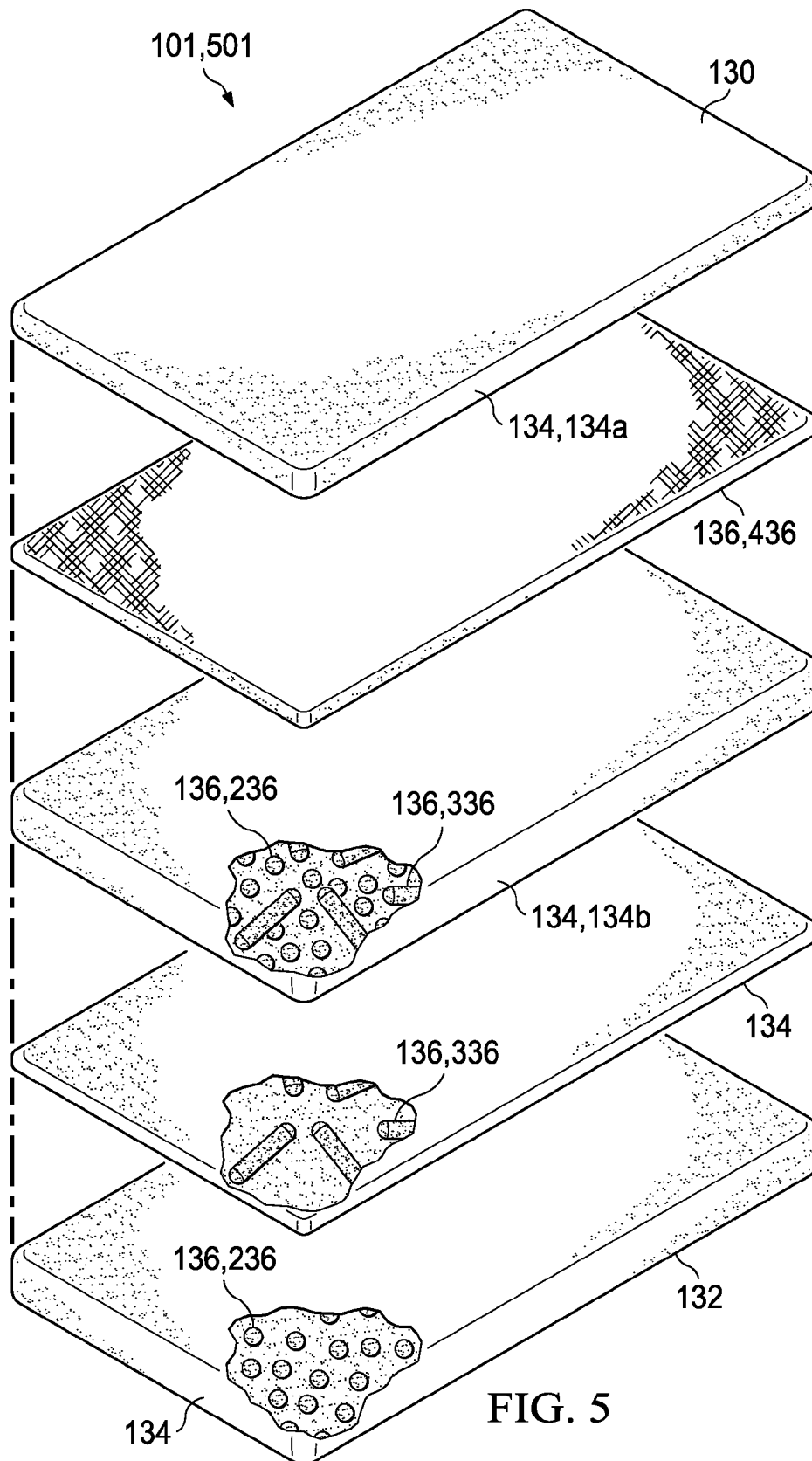


FIG. 5

