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(71) Applicant: **KCI LICENSING, INC.** [US/US]; Legal Department-Intellectual Property, P.O. Box 659508, San Antonio, TX 78265 (US).

(72) Inventors: **LOCKE, Christopher Brian**; 6 Bosworth Mews, Bournemouth BH9 3SD (GB). **PRATT, Benjamin Andrew**; 1 Winifred Road, Poole BH15 3PU (GB).

(74) Agent: **MILLER, Christopher K.** et al.; Harness, Dickey & Pierce, P.L.C., 5445 Corporate Drive, Suite 200, Troy, MI 48098 (US).

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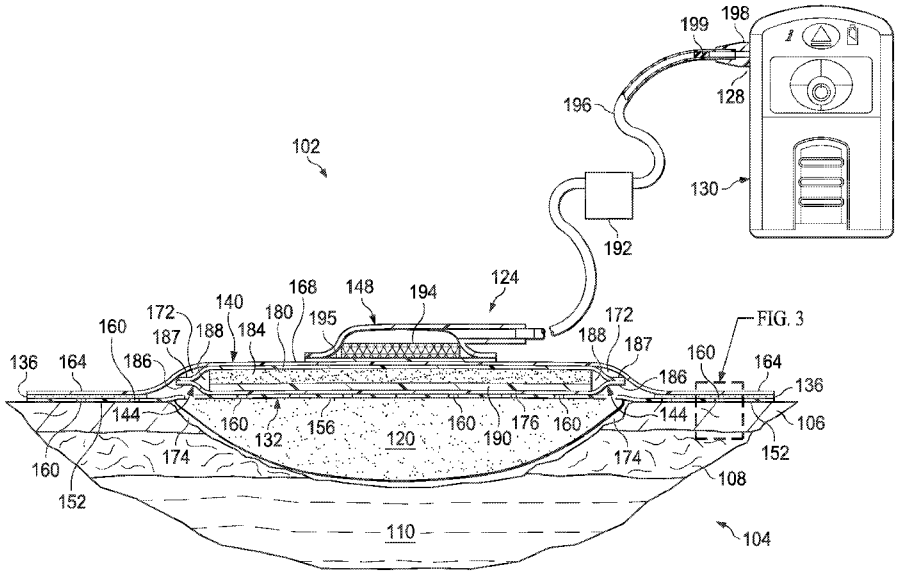


FIG. 1

(57) Abstract: In some examples, a dressing suitable for treating a tissue site may include a sealing member having a periphery and a central portion. The central portion of the sealing member may include a breathable zone having a higher vapor permeability than the periphery of the sealing member. Other features may be associated with the dressing including, by way of example and without limitation, a base layer, an adhesive, one or more wicking layers, and an absorbent layer. Other dressings, apparatus, systems, and methods are disclosed.

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DRESSING AND SYSTEM WITH IMPROVED TOTAL FLUID HANDLING

RELATED APPLICATIONS

[0001] The present application claims the benefit, under 35 USC § 119(e), of the filing of U.S. Provisional Patent Application serial number 62/720,595, entitled "Dressing and System with Improved Total Fluid Handling," filed August 21, 2018, which is incorporated herein by reference for all purposes.

TECHNICAL FIELD

[0002] This disclosure relates generally to medical treatment systems and, more particularly, but not by way of limitation, to absorbent dressings, systems, and methods for treating a tissue site with reduced pressure.

BACKGROUND

[0003] Clinical studies and practice have shown that reducing pressure in proximity to a tissue site can augment and accelerate growth of new tissue at the tissue site. The applications of this phenomenon are numerous, but have proven particularly advantageous for treating wounds. Regardless of the etiology of a wound, whether trauma, surgery, or another cause, proper care of a wound is important to the outcome. Treatment of wounds or other tissue with reduced pressure may be commonly referred to as "negative-pressure therapy," but is also known by other names, including "negative-pressure wound therapy," "reduced-pressure therapy," "vacuum therapy," and "vacuum-assisted closure," for example. Negative-pressure therapy may provide a number of benefits, including migration of epithelial and subcutaneous tissues, improved blood flow, and micro-deformation of tissue at a wound site. Together, these benefits can increase development of granulation tissue and reduce healing times.

[0004] While the clinical benefits of negative-pressure therapy are widely known, the cost and complexity of negative-pressure therapy can be a limiting factor in its application, and the development and operation of negative-pressure systems, components, and processes continues to present significant challenges to manufacturers, healthcare providers, and patients.

SUMMARY

[0005] Shortcomings with certain aspects of tissue treatment dressings, systems, and methods are addressed as shown and described in a variety of illustrative, non-limiting example embodiments herein.

[0006] In some example embodiments, a system for treating a tissue site may include a dressing and a reduced-pressure source. The dressing may include a base layer, an adhesive, a sealing member, at least one wicking layer, and an absorbent layer. The base layer may include a periphery surrounding a central portion and a plurality of apertures disposed through the periphery and the central portion. The adhesive may be configured to extend through the apertures at least in the periphery of the base layer to contact tissue surrounding the tissue site. The sealing member may include a periphery and a central portion. The periphery of the sealing member may be positioned proximate to the periphery of the base layer. The central portion of the sealing member and the central portion of the base layer may define an enclosure. The central portion of the sealing member may include a breathable zone having a higher vapor permeability than the periphery of the sealing member. The at least one wicking layer and the absorbent layer may be disposed in the enclosure. The reduced-pressure source may be configured to be coupled in fluid communication with the dressing.

[0007] Further, in some example embodiments, a dressing for treating a tissue site may include a base layer, an adhesive, a sealing member, a first wicking layer, a second wicking layer, and an absorbent layer. The base layer may have a periphery surrounding a central portion and a plurality of apertures disposed through the periphery and the central portion. The adhesive may be configured to extend through the apertures at least in the periphery of the base layer to contact tissue surrounding the tissue site. The sealing member may have a periphery and a central portion, and the periphery of the sealing member may be positioned proximate to the periphery of the base layer. The central portion of the sealing member and the central portion of the base layer may define an enclosure. The central portion of the sealing member may include a breathable zone having a higher vapor permeability than the periphery of the sealing member. The first wicking layer and the second wicking layer may be disposed in the enclosure. The absorbent layer may be positioned in fluid communication between the first wicking layer and the second wicking layer.

[0008] Further, in some example embodiments, a system for treating a tissue site may include a dressing, a conduit interface, and a reduced-pressure source. The dressing may be adapted to distribute reduced pressure to the tissue site and to store fluid extracted from the tissue site. The dressing may include a base layer, an adhesive, a sealing member, a first wicking layer, a second wicking layer, and an absorbent layer. The base layer may include a periphery surrounding a central portion and a plurality of apertures disposed through the periphery and the central portion. The apertures in the periphery of the base layer may be larger than the apertures in the central portion of the base layer. The periphery of the base layer may be configured to surround the tissue site, and the apertures in the base layer may be configured to be in fluid communication with the tissue site and the tissue surrounding the tissue site. The adhesive may be configured to extend through the apertures at least in the periphery of the base layer to contact tissue surrounding the tissue site. The sealing member may have a periphery and a central portion, and the periphery of the sealing member may be positioned proximate to the periphery of the base layer. The central portion of the sealing member and the central portion of the base layer may define an enclosure. The central portion of the sealing member may include a breathable zone having a higher vapor permeability than the periphery of the sealing member. The first wicking layer and the second wicking layer may be disposed in the enclosure. The absorbent layer may be positioned in fluid communication between the first wicking layer and the second wicking layer. The conduit interface may be configured to be positioned proximate to the sealing member and in fluid communication with the enclosure. The reduced-pressure source may be adapted to be coupled in fluid communication with the conduit interface to provide reduced pressure to the dressing.

[0009] Further, in some example embodiments, a dressing for treating a tissue site may include a sealing member. The sealing member may include a periphery and a central portion. The central portion of the sealing member may include a breathable zone having a higher vapor permeability than the periphery of the sealing member.

[0010] Other aspects, features, and advantages of the illustrative example embodiments will become apparent with reference to the drawings and detailed description that follow.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] FIG. 1 is a front, cut-away view of an illustrative example embodiment of a system for treating a tissue site, depicting an example embodiment of a dressing deployed at a tissue site;

[0012] FIG. 2 is a front, cut-away view of the example dressing of FIG. 1;

[0013] FIG. 3 is detail view taken at reference FIG. 3, depicted in FIG. 1, illustrating the example dressing of FIG. 1 positioned proximate to tissue surrounding the tissue site;

[0014] FIG. 4A is a perspective, exploded view of the example dressing of FIG. 1, depicted without a conduit interface and with an example embodiment of a release liner for protecting the dressing prior to application at a tissue site;

[0015] FIG. 4B is a perspective, exploded view of another example embodiment of a dressing suitable for use with the example system of FIG. 1, depicted without a conduit interface and with an example embodiment of a release liner for protecting the dressing prior to application at a tissue site;

[0016] FIG. 5 is a plan view of an illustrative example embodiment of a base layer depicted with the example dressings of FIG. 4A and FIG. 4B;

[0017] FIG. 6A is a perspective view of an example embodiment of a breathable zone suitable for use with the example systems and dressings according to this disclosure;

[0018] FIG. 6B is a side view of the example breathable zone of FIG. 6A;

[0019] FIG. 6C is bottom or plan view of an interior facing surface of another example embodiment of a breathable zone suitable for use with the example systems and dressings according to this disclosure;

[0020] FIG. 7A is a cut-away view of an illustrative example embodiment of a fluid management assembly suitable for use with the example systems and dressings according to this disclosure;

[0021] FIG. 7B is a perspective, exploded view of the example fluid management assembly of FIG. 7A;

[0022] FIG. 8 is a cut-away view of an illustrative example embodiment of a conduit interface depicted with the example dressing of FIG. 1;

[0023] FIG. 9A is a cross-section of an illustrative example embodiment of a multi-lumen conduit suitable for use with the example systems and dressings according to this disclosure; and

[0024] FIG. 9B is a cross-section of another illustrative example embodiment of a multi-lumen conduit suitable for use with the example systems and dressings according to this disclosure.

DETAILED DESCRIPTION OF EXAMPLE EMBODIMENTS

[0025] The following description of example embodiments enables a person skilled in the art to make and use the subject matter set forth in the appended claims. Certain details already known in the art may be omitted. Therefore, the following detailed description is illustrative and non-limiting.

[0026] Referring to the drawings, FIG. 1 depicts an embodiment of a system 102 for treating a tissue site 104 of a patient. The tissue site 104 may extend through or otherwise involve an epidermis 106, a dermis 108, and a subcutaneous tissue 110. The tissue site 104 may be a sub-surface tissue site as depicted in FIG. 1 that extends below the surface of the epidermis 106. Further, the tissue site 104 may be a surface tissue site (not shown) that predominantly resides on the surface of the epidermis 106, such as, for example, an incision. The system 102 may provide therapy to, for example, the epidermis 106, the dermis 108, and the subcutaneous tissue 110, regardless of the positioning of the system 102 or the type of tissue site. The system 102 may also be utilized without limitation at other tissue sites.

[0027] Further, the tissue site 104 may be the bodily tissue of any human, animal, or other organism, including bone tissue, adipose tissue, muscle tissue, dermal tissue, vascular tissue, connective tissue, cartilage, tendons, ligaments, or any other tissue. Treatment of tissue site 104 may include removal of fluids, *e.g.*, exudate or ascites.

[0028] Continuing with FIG. 1, the system 102 may include an optional tissue interface, such as an interface manifold 120. Further, the system 102 may include a dressing 124, and a reduced-pressure source 128. The reduced-pressure source 128 may be a component of an optional therapy unit 130 as shown in FIG. 1. In some embodiments, the reduced-pressure source 128 and the therapy unit 130 may be separate components. As indicated above, the interface manifold 120 is an optional component that may be omitted for different types of tissue sites or different types of therapy using reduced pressure, such as, for example, epithelialization. If equipped, the interface manifold 120 may be adapted to be positioned proximate to or adjacent to the tissue site 104, such as, for example, by cutting or otherwise shaping the interface manifold 120 in any suitable manner to fit the tissue site 104. As described below, the interface manifold 120 may be adapted to be positioned in fluid communication with the tissue site 104 to distribute reduced pressure to the tissue site 104. In some embodiments, the interface manifold 120 may be positioned in direct contact with the tissue site 104. The tissue interface or the interface manifold 120 may be formed from

any manifold material or flexible bolster material that provides a vacuum space, or treatment space, such as, for example, a porous and permeable foam or foam-like material, a member formed with pathways, a graft, or a gauze. As a more specific, non-limiting example, the interface manifold 120 may be a reticulated, open-cell polyurethane or polyether foam that allows good permeability of fluids while under a reduced pressure. One such foam material is the VAC® GranuFoam® material available from Kinetic Concepts, Inc. (KCI) of San Antonio, Texas. Any material or combination of materials may be used as a manifold material for the interface manifold 120 provided that the manifold material is operable to distribute or collect fluid. For example, herein the term manifold may refer to a substance or structure that is provided to assist in delivering fluids to or removing fluids from a tissue site through a plurality of pores, pathways, or flow channels. The plurality of pores, pathways, or flow channels may be interconnected to improve distribution of fluids provided to and removed from an area around the manifold. Examples of manifolds may include, without limitation, devices that have structural elements arranged to form flow channels, cellular foam, such as open-cell foam, porous tissue collections, and liquids, gels, and foams that include or cure to include flow channels.

[0029] A material with a higher or lower density than GranuFoam® material may be desirable for the interface manifold 120 depending on the application. Among the many possible materials, the following may be used: GranuFoam® material, Foamex® technical foam (www.foamex.com), a molded bed of nails structures, a patterned grid material such as those manufactured by Sercol Industrial Fabrics, 3D textiles such as those manufactured by Baltex of Derby, U.K., a gauze, a flexible channel-containing member, a graft, etc. In some instances, ionic silver may be added to the interface manifold 120 by, for example, a micro bonding process. Other substances, such as anti-microbial agents, may be added to the interface manifold 120 as well.

[0030] In some embodiments, the interface manifold 120 may comprise a porous, hydrophobic material. The hydrophobic characteristics of the interface manifold 120 may prevent the interface manifold 120 from directly absorbing fluid, such as exudate, from the tissue site 104, but allow the fluid to pass through.

[0031] Continuing with FIG. 1, the dressing 124 may be adapted to provide reduced pressure from the reduced-pressure source 128 to the interface manifold 120, and to store fluid extracted from the tissue site 104 through the interface manifold 120. The dressing 124 may include a base layer 132, an adhesive 136, a sealing member 140, a fluid management

assembly 144, and a conduit interface 148. Components of the dressing 124 may be added or removed to suit a particular application.

[0032] Referring to FIGS. 1-5, the base layer 132 may have a periphery 152 surrounding a central portion 156, and a plurality of apertures 160 disposed through the periphery 152 and the central portion 156. The base layer 132 may also have corners 158 and edges 159. The corners 158 and the edges 159 may be part of the periphery 152. One of the edges 159 may meet another of the edges 159 to define one of the corners 158. Further, the base layer 132 may have a border 161 substantially surrounding the central portion 156 and positioned between the central portion 156 and the periphery 152. The border 161 may be free of the apertures 160.

[0033] The central portion 156 of the base layer 132 may be configured to be positioned proximate to the tissue site 104, and the periphery 152 of the base layer 132 may be configured to be positioned proximate to tissue surrounding the tissue site 104. In some embodiments, the base layer 132 may cover the interface manifold 120 and tissue surrounding the tissue site 104 such that the central portion 156 of the base layer 132 is positioned adjacent to or proximate to the interface manifold 120, and the periphery 152 of the base layer 132 is positioned adjacent to or proximate to tissue surrounding the tissue site 104. In this manner, the periphery 152 of the base layer 132 may surround the interface manifold 120. Further, the apertures 160 in the base layer 132 may be in fluid communication with the interface manifold 120 and tissue surrounding the tissue site 104.

[0034] The apertures 160 in the base layer 132 may have any shape, such as, for example, circles, squares, stars, ovals, polygons, slits, complex curves, rectilinear shapes, triangles, or other shapes. The apertures 160 may be formed by cutting, by application of local RF energy, or other suitable techniques for forming an opening. As shown in FIGS. 4A-5, each of the apertures 160 of the plurality of apertures 160 may be substantially circular in shape, having a diameter and an area. The area of each of the apertures 160 may refer to an open space or open area defining each of the apertures 160. The diameter of each of the apertures 160 may define the area of each of the apertures 160. For example, the area of one of the apertures 160 may be defined by multiplying the square of half the diameter of the aperture 160 by the value 3.14. Thus, the following equation may define the area of one of the apertures 160: Area = 3.14*(diameter/2)^2. The area of the apertures 160 described in the illustrative embodiments herein may be substantially similar to the area in other embodiments (not shown) for the apertures 160 that may have non-circular shapes. The diameter of each of

the apertures 160 may be substantially the same, or each of the diameters may vary depending, for example, on the position of the aperture 160 in the base layer 132. For example, the diameter of the apertures 160 in the periphery 152 of the base layer 132 may be larger than the diameter of the apertures 160 in the central portion 156 of the base layer 132. Further, the diameter of each of the apertures 160 may be about 1 millimeter to about 50 millimeters. In some embodiments, the diameter of each of the apertures 160 may be about 1 millimeter to about 20 millimeters. The apertures 160 may have a uniform pattern or may be randomly distributed on the base layer 132. The size and configuration of the apertures 160 may be designed to control the adherence of the dressing 124 to the epidermis 106 as described below.

[0035] Referring to FIGS. 4A-5, in some embodiments, the apertures 160 positioned in the periphery 152 may be apertures 160a and the apertures 160 positioned in the central portion 156 may be apertures 160c. The apertures 160a may have a diameter between about 9.8 millimeters to about 10.2 millimeters. The apertures 160c may have a diameter between about 1.8 millimeters to about 2.2 millimeters.

[0036] As shown in FIGS. 4A-5, in some embodiments, the central portion 156 of the base layer 132 may be substantially oval in shape. The border 161 of the base layer 132 may substantially surround the central portion 156 and the apertures 160c in the central portion 156. The periphery 152 of the base layer 132 may substantially surround the border 161 and the central portion 156. Further, the periphery 152 may have a substantially oval exterior shape. Although FIGS. 4A-5 depict the central portion 156, the border 161, and the periphery 152 of the base layer 132 as having a substantially oval shape, these and other components of the base layer 132 may have any shape to suit a particular application.

[0037] The base layer 132 may be a soft, pliable material suitable for providing a fluid seal with the tissue site 104 as described herein. For example, the base layer 132 may comprise a silicone gel, a soft silicone, hydrocolloid, hydrogel, polyurethane gel, polyolefin gel, hydrogenated styrenic copolymer gels, a foamed gel, a soft closed cell foam such as polyurethanes and polyolefins coated with an adhesive described below, polyurethane, polyolefin, or hydrogenated styrenic copolymers. The base layer 132 may have a thickness between about 500 microns (μm) and about 1000 microns (μm). In some embodiments, the base layer 132 has a stiffness between about 5 Shore OO and about 80 Shore OO. The base layer 132 may be comprised of hydrophobic or hydrophilic materials.

[0038] In some embodiments (not shown), the base layer 132 may be a hydrophobic-coated material. For example, the base layer 132 may be formed by coating a spaced material, such as, for example, woven, nonwoven, molded, or extruded mesh with a hydrophobic material. The hydrophobic material for the coating may be a soft silicone, for example. In this manner, the adhesive 136 may extend through openings in the spaced material analogous to the apertures 160 described below.

[0039] The adhesive 136 may be in fluid communication with the apertures 160 in at least the periphery 152 of the base layer 132. In this manner, the adhesive 136 may be in fluid communication with the tissue surrounding the tissue site 104 through the apertures 160 in the base layer 132. As described below and shown in FIG. 3, the adhesive 136 may extend through or be pressed through the plurality of apertures 160 to contact the epidermis 106 for securing the dressing 124 to, for example, the tissue surrounding the tissue site 104. The apertures 160 may provide sufficient contact of the adhesive 136 to the epidermis 106 to secure the dressing 124 about the tissue site 104. However, the configuration of the apertures 160 and the adhesive 136, described below, may permit release and repositioning of the dressing 124 about the tissue site 104.

[0040] At least one of the apertures 160a in the periphery 152 of the base layer 132 may be positioned at the edges 159 of the periphery 152 and may have an interior cut open or exposed at the edges 159 that is in fluid communication in a lateral direction with the edges 159. The lateral direction may refer to a direction toward the edges 159 and in the same plane as the base layer 132. As shown in FIGS. 4A-5, a plurality of the apertures 160a in the periphery 152 may be positioned proximate to or at the edges 159 and in fluid communication in a lateral direction with the edges 159. The apertures 160a positioned proximate to or at the edges 159 may be spaced substantially equidistant around the periphery 152 as shown in FIGS. 4A-5. However, in some embodiments, the spacing of the apertures 160a proximate to or at the edges 159 may be irregular. The adhesive 136 may be in fluid communication with the edges 159 through the apertures 160a being exposed at the edges 159. In this manner, the apertures 160a at the edges 159 may permit the adhesive 136 to flow around the edges 159 for enhancing the adhesion of the edges 159 around the tissue site 104, for example.

[0041] Continuing with FIGS. 4A-5, any of the apertures 160 may be adjusted in size and number to maximize the surface area of the adhesive 136 in fluid communication through the apertures 160 for a particular application or geometry of the base layer 132. For example,

in some embodiments, apertures analogous to the apertures 160, having varying size, may be positioned in the periphery 152 and at the border 161. Similarly, apertures analogous to the apertures 160, having varying size, may be positioned as in other locations of the base layer 132 that may have a complex geometry or shape.

[0042] The adhesive 136 may be a medically-acceptable adhesive. The adhesive 136 may also be flowable. For example, the adhesive 136 may comprise an acrylic adhesive, rubber adhesive, high-tack silicone adhesive, polyurethane, or other adhesive substance. In some embodiments, the adhesive 136 may be a pressure-sensitive adhesive comprising an acrylic adhesive with coating weight of 15 grams/m^2 (gsm) to 70 grams/m^2 (gsm). The adhesive 136 may be a layer having substantially the same shape as the periphery 152 of the base layer 132 as shown in FIGS. 4A and 4B. In some embodiments, the layer of the adhesive 136 may be continuous or discontinuous. Discontinuities in the adhesive 136 may be provided by apertures (not shown) in the adhesive 136. The apertures in the adhesive 136 may be formed after application of the adhesive 136 or by coating the adhesive 136 in patterns on a carrier layer, such as, for example, a side of the sealing member 140 adapted to face the epidermis 106. Further, the apertures in the adhesive 136 may be sized to control the amount of the adhesive 136 extending through the apertures 160 in the base layer 132 to reach the epidermis 106. The apertures in the adhesive 136 may also be sized to enhance the Moisture Vapor Transfer Rate (MVTR) of the dressing 124, described further below.

[0043] Factors that may be utilized to control the adhesion strength of the dressing 124 may include the diameter and number of the apertures 160 in the base layer 132, the thickness of the base layer 132, the thickness and amount of the adhesive 136, and the tackiness of the adhesive 136. An increase in the amount of the adhesive 136 extending through the apertures 160 generally corresponds to an increase in the adhesion strength of the dressing 124. A decrease in the thickness of the base layer 132 generally corresponds to an increase in the amount of adhesive 136 extending through the apertures 160. Thus, the diameter and configuration of the apertures 160, the thickness of the base layer 132, and the amount and tackiness of the adhesive utilized may be varied to provide a desired adhesion strength for the dressing 124. For example, the thickness of the base layer 132 may be about 200 microns, the adhesive layer 136 may have a thickness of about 30 microns and a tackiness of 2000 grams per 25 centimeter wide strip, and the diameter of the apertures 160a in the base layer 132 may be about 10 millimeters.

[0044] In some embodiments, the tackiness of the adhesive 136 may vary in different locations of the base layer 132. For example, in locations of the base layer 132 where the apertures 160 are comparatively large, such as the apertures 160a, the adhesive 136 may have a lower tackiness than other locations of the base layer 132 where the apertures 160 are smaller, such as the apertures 160c. In this manner, locations of the base layer 132 having larger apertures 160 and lower tackiness adhesive 136 may have an adhesion strength comparable to locations having smaller apertures 160 and higher tackiness adhesive 136.

[0045] Clinical studies have shown that the configuration described herein for the base layer 132 and the adhesive 136 may reduce the occurrence of blistering, erythema, and leakage when in use. Such a configuration may provide, for example, increased patient comfort and increased durability of the dressing 124.

[0046] Referring to the embodiments of FIGS. 4A and 4B, a release liner 162 may be attached to or positioned adjacent to the base layer 132 to protect the adhesive 136 prior to application of the dressing 124 to the tissue site 104. Prior to application of the dressing 124 to the tissue site 104, the base layer 132 may be positioned between the sealing member 140 and the release liner 162. Removal of the release liner 162 may expose the base layer 132 and the adhesive 136 for application of the dressing 124 to the tissue site 104. The release liner 162 may also provide stiffness to assist with, for example, deployment of the dressing 124. The release liner 162 may be, for example, a casting paper, a film, or polyethylene. Further, the release liner 162 may be a polyester material such as polyethylene terephthalate (PET), or similar polar semi-crystalline polymer. The use of a polar semi-crystalline polymer for the release liner 162 may substantially preclude wrinkling or other deformation of the dressing 124. For example, the polar semi-crystalline polymer may be highly orientated and resistant to softening, swelling, or other deformation that may occur when brought into contact with components of the dressing 124, or when subjected to temperature or environmental variations, or sterilization. Further, a release agent may be disposed on a side of the release liner 162 that is configured to contact the base layer 132. For example, the release agent may be a silicone coating and may have a release factor suitable to facilitate removal of the release liner 162 by hand and without damaging or deforming the dressing 124. In some embodiments, the release agent may be flourosilicone. In other embodiments, the release liner 162 may be uncoated or otherwise used without a release agent.

[0047] Continuing with FIGS. 1-5, the sealing member 140 has a periphery 164 and a central portion 168. The sealing member 140 may additionally include a sealing member

aperture 170, as described below. The periphery 164 of the sealing member 140 may be positioned proximate to the periphery 152 of the base layer 132 such that the central portion 168 of the sealing member 140 and the central portion 156 of the base layer 132 define an enclosure 172. The adhesive 136 may be positioned at least between the periphery 164 of the sealing member 140 and the periphery 152 of the base layer 132. The sealing member 140 may cover the tissue site 104 and the interface manifold 120 to provide a fluid seal and a sealed space 174 between the tissue site 104 and the sealing member 140 of the dressing 124. Further, the sealing member 140 may cover other tissue, such as a portion of the epidermis 106, surrounding the tissue site 104 to provide the fluid seal between the sealing member 140 and the tissue site 104. In some embodiments, a portion of the periphery 164 of the sealing member 140 may extend beyond the periphery 152 of the base layer 132 and into direct contact with tissue surrounding the tissue site 104. In other embodiments, the periphery 164 of the sealing member 140, for example, may be positioned in contact with tissue surrounding the tissue site 104 to provide the sealed space 174 without the base layer 132. Thus, the adhesive 136 may also be positioned at least between the periphery 164 of the sealing member 140 and tissue, such as the epidermis 106, surrounding the tissue site 104. The adhesive 136 may be disposed on a surface of the sealing member 140 adapted to face the tissue site 104 and the base layer 132.

[0048] The sealing member 140 may be formed from any material that allows for a fluid seal. A fluid seal is a seal adequate to maintain reduced pressure at a desired site given the particular reduced-pressure source or system involved. The sealing member 140 may comprise, for example, one or more of the following materials: hydrophilic polyurethane; cellulosics; hydrophilic polyamides; polyvinyl alcohol; polyvinyl pyrrolidone; hydrophilic acrylics; hydrophilic silicone elastomers; an INSPIRE 2301 material from Expopack Advanced Coatings of Wrexham, United Kingdom having, for example, an MVTR (inverted cup technique) of 14400 g/m^2/24 hours and a thickness of about 30 microns; a thin, uncoated polymer drape; natural rubbers; polyisoprene; styrene butadiene rubber; chloroprene rubber; polybutadiene; nitrile rubber; butyl rubber; ethylene propylene rubber; ethylene propylene diene monomer; chlorosulfonated polyethylene; polysulfide rubber; polyurethane (PU); EVA film; co-polyester; silicones; a silicone drape; a 3M Tegaderm® drape; a polyurethane (PU) drape such as one available from Avery Dennison Corporation of Pasadena, California; polyether block polyamide copolymer (PEBAX), for example, from Arkema, France; Expopack 2327; or other appropriate material.

[0049] The sealing member 140 may be vapor permeable and/or liquid impermeable, thereby allowing vapor and inhibiting liquids from exiting the sealed space 174 provided by the dressing 124. In some embodiments, the sealing member 140 may be a flexible, breathable film, membrane, or sheet having a high MVTR of, for example, at least about 300g/m^2 per 24 hours. In other embodiments, a low or no vapor transfer drape might be used. The sealing member 140 may comprise a range of medically suitable films having a thickness up to about 50 microns (μm).

[0050] Referring to FIGS. 4A-4B and 6A-6C, in some embodiments, at least a portion of the sealing member 140, such as the central portion 168 of the sealing member 140, may include a breathable zone 202. The breathable zone 202 may be, by way of example and without limitation, a breathable zone 202a as shown in FIGS. 4A-4B, a breathable zone 202b as shown in FIGS. 6A-6B, or a breathable zone 202c as shown in FIG. 6C. The breathable zone 202 may have or include a higher vapor permeability than other portions of the sealing member 140, such as the periphery 164 of the sealing member 140. The higher vapor permeability of the breathable zone 202 may allow more moisture vapor to permeate, evaporate, or pass through the breathable zone 202 than other portions of the sealing member 140. In some embodiments, the breathable zone 202 may comprise, form, or occupy about 50% to about 70% of a surface area of the sealing member 140 that is exposed to an ambient environment external to the sealing member 140 and the dressing 124. The breathable zone 202 may be integrally formed as part of the sealing member 140 in some embodiments, or attached as a separate component in other embodiments. Further, in some embodiments, the breathable zone 202 may have a color or identifier that is different or distinguishable from the sealing member 140.

[0051] In some embodiments, the breathable zone 202 may include or be formed of an evaporative or breathable layer, cover, or film, such as a vapor permeable and liquid impermeable film, which may have a thickness of 10 microns (μm) to 30 microns (μm). In some embodiments, the breathable zone 202 may include or be formed of a polyurethane film that is non-adhesive or free of any adhesive that may reduce or inhibit breathability. For example, in some embodiments, the adhesive 136 may be disposed on a surface of at least the periphery 164 of the sealing member 140 that is configured to face the base layer 132, and the breathable zone 202 may be free of the adhesive 136. The breathable zone 202 may be formed of or include similar materials as described herein for the sealing member 140. However, compared to other portions of the sealing member 140, the breathable zone 202

may, for example, have a higher Moisture Vapor Transfer Rate (MVTR), a reduced thickness, surface features for enhanced evaporation and breathability, or be entirely or substantially free of adhesive as described herein.

[0052] The sealing member 140 may include the sealing member aperture 170 and a zone opening 206 disposed through the sealing member 140. The reduced-pressure source 128 may be configured to be coupled in fluid communication with the enclosure 172 through the sealing member aperture 170. The breathable zone 202 may be positioned at or within the zone opening 206 and exposed to an ambient environment external to the sealing member 140 and the dressing 124 through or at the zone opening 206. In some embodiments, the sealing member aperture 170 and the zone opening 206 may be positioned at opposing ends of the sealing member 140.

[0053] In some embodiments, a border or a perimeter 207 of the breathable zone 202 may be coupled to or at a border or a perimeter 208 of the zone opening 206. A portion of the perimeter 207 may overlap a portion of the perimeter 208 to provide a connecting or coupling surface or interface between the breathable zone 202 and the zone opening 206 of the sealing member 140. For example, the breathable zone 202 may be coupled to or at the perimeter 208 of the zone opening 206 on an exterior facing surface 210 of the sealing member 140 by an adhesive gasket 212 as shown in FIG. 4A. In other examples, the perimeter 207 of the breathable zone 202 may be coupled to or at the perimeter 208 of the zone opening 206 on an interior facing surface 214 of the sealing member 140 by the adhesive 136 as shown in FIG. 4B. In some embodiments, the zone opening 206 may comprise, form, or occupy between about 50% to about 70% of a surface area of the sealing member 140 that is exposed to an ambient environment external to the dressing 124.

[0054] In some embodiments, the breathable zone 202 may have an interior facing surface 216 configured to be in direct contact with or directly exposed to the interior of the dressing 124, such as the enclosure 172, and moisture that may be present in the enclosure 172. Further, the breathable zone 202 may have an exterior facing surface 218 configured to be in direct contact with or directly exposed to an ambient environment external to the dressing 124 and the sealing member 140. In some embodiments, the breathable zone 202 may be positioned between the interior facing surface 214 of the sealing member 140 and an absorbent layer 184, shown as part of the fluid management assembly 144 in FIGS. 7A-7B, and exposed to an ambient environment external to the dressing 124 through an opening, such as the zone opening 206 in the sealing member 140. Further, in some embodiments, the

breathable zone 202 may be positioned between an interior facing surface 214 of the sealing member 140 and a wicking layer, such as a second wicking layer 180, also shown as part of the fluid management assembly 144 in FIGS. 7A-7B, and exposed to an ambient environment external to the dressing 124 through the zone opening 206 in the sealing member 140. The positioning of the breathable zone 202 described herein may be in direct contact with the absorbent layer 184, a wicking layer, or other component of the fluid management assembly 144 without intervening layers or components that could inhibit the breathability of the breathable zone 202 or the transfer of moisture to and through the breathable zone 202.

[0055] In some embodiments, the breathable zone 202 may be coupled to components of the fluid management assembly 144, such as one or more wicking layers or the absorbent layer 184 shown in FIGS. 7A-7B, by a fuse-able fiber non-woven material (not shown). In other embodiments, the breathable zone 202 may be moveable relative to the one or more wicking layers, the absorbent layer 184, or other components of the fluid management assembly 144 or the dressing 124. In some embodiments, the breathable zone 202 may have substantially the same plan-view shape as the fluid management assembly 144 or components of the fluid management assembly 144. For example, the breathable zone 202 may be coupled to a surface of a wicking layer configured to face the sealing member 140, such as a fluid distribution side 220 of the second wicking layer 180 shown in FIGS. 7A-7B and described further below, which may simplify assembly. In such an embodiment, the breathable zone 202 may have the same or substantially the same plan-view shape as the wicking layer or the second wicking layer 180 such that the breathable zone 202 covers substantially or entirely a surface of the wicking layer, such as the fluid distribution side 220 of the second wicking layer 180.

[0056] Referring more specifically to FIGS. 6A-6B, in some embodiments, the breathable zone 202 may be a breathable zone 202b, which may include a surface feature such as an embossed portion 224. The embossed portion 224 may have a compressed or decreased thickness 226 relative to another portion of the breathable zone 202b having a standard or increased thickness 228. The embossed portion 224 may be configured to increase the vapor permeability and an evaporative surface area of the breathable zone 202b. For example, the embossed portion 224 of the breathable zone 202b may be vacuum formed to have ribs or other surface features configured to increase a surface area of the breathable zone 202b. Such a configuration may create localized thinning of a portion of the breathable

zone 202b as described herein and may allow for swelling or expansion of the breathable zone 202b as fluid enters the dressing 124.

[0057] Referring more specifically to FIG. 6C, in some embodiments, the breathable zone 202 may be a breathable zone 202c. The interior facing surface 216 of the breathable zone 202c may include a patterned coating of an adhesive, such as the adhesive 136. The coating pattern of the adhesive 136 may be in the form of dots or circles spaced apart from each other as shown in FIG. 6C. In other examples, the adhesive 136 may be applied in any shape or pattern configured to have sufficient open area or space, free of the adhesive 136, to prevent the adhesive 136 from reducing the breathability of the breathable zone 202c. Further, in some embodiments, the breathable zone 202c may include a moisture indicator 230 configured to indicate a color change when in contact with moisture or liquid. The moisture indicator 230 may include or be formed of an ink or wax coating on a surface of the breathable zone 202c, and may be used with or without the patterned coating of the adhesive 136.

[0058] The configuration of the breathable zone 202 described in the example embodiments herein may increase or improve the total fluid handling capability or fluid storage capacity of the dressing 124 while maintaining the structural integrity of the dressing 124. For example, the breathable zone 202 may be configured as described in the example embodiments to be highly breathable, thereby promoting the evaporation of fluid from within the dressing 124 through the breathable zone 202 to the environment exterior to the dressing 124.

[0059] Referring to FIGS. 1-2, 4A-4B, and 7A-7B, the fluid management assembly 144 may be disposed in the enclosure 172 and may include one or more wicking layers. In some embodiments, the fluid management assembly 144 may include a first wicking layer 176 and a second wicking layer 180. Further, in some embodiments, the fluid management assembly 144 may include an absorbent layer 184. The absorbent layer 184 may be positioned in fluid communication between the first wicking layer 176 and the second wicking layer 180. The first wicking layer 176 may have a grain structure adapted to wick fluid along a surface of the first wicking layer 176. Similarly, the second wicking layer 180 may have a grain structure adapted to wick fluid along a surface of the second wicking layer 180. For example, the first wicking layer 176 and the second wicking layer 180 may wick or otherwise transport fluid in a lateral direction along the surfaces of the first wicking layer 176 and the second wicking layer 180, respectively. The surfaces of the first wicking layer 176

and the second wicking layer 180 may be normal relative to the thickness of each of the first wicking layer 176 and the second wicking layer 180. The wicking of fluid along the first wicking layer 176 and the second wicking layer 180 may enhance the distribution of the fluid over a surface area of the absorbent layer 184 that may increase absorbent efficiency and resist fluid blockages. Fluid blockages may be caused by, for example, fluid pooling in a particular location in the absorbent layer 184 rather than being distributed more uniformly across the absorbent layer 184. The laminate combination of the first wicking layer 176, the second wicking layer 180, and the absorbent layer 184 may be adapted as described herein to maintain an open structure, resistant to blockage, capable of maintaining fluid communication with, for example, the tissue site 104.

[0060] In some embodiments, a peripheral portion 186 of the first wicking layer 176 may be coupled to a peripheral portion 187 of the second wicking layer 180 to define a wicking layer enclosure 188 between the first wicking layer 176 and the second wicking layer 180. In some exemplary embodiments, the wicking layer enclosure 188 may surround or otherwise encapsulate the absorbent layer 184 between the first wicking layer 176 and the second wicking layer 180.

[0061] Referring more specifically to FIGS. 7A and 7B, the fluid management assembly 144 may include, without limitation, any number of wicking layers and absorbent layers as desired for treating a particular tissue site. For example, in some embodiments, at least one intermediate wicking layer 189 may be disposed in fluid communication between the absorbent layer 184 and the second wicking layer 180. In such an embodiment, the second wicking layer 180 may be positioned between the intermediate wicking layer 189 and the breathable zone 202. Further, including additional absorbent layers 184 may increase the absorbent mass of the fluid management assembly 144 and generally provide greater fluid capacity. However, for a given absorbent mass, multiple light coat-weight absorbent layers 184 may be utilized rather than a single heavy coat-weight absorbent layer 184 to provide a greater absorbent surface area for further enhancing the absorbent efficiency.

[0062] Each of the wicking layers 176, 180, and 189 may include a fluid distribution side 220 and a fluid acquisition side 234. The fluid distribution side 220 may be positioned facing an opposite direction from the fluid acquisition side 234. The fluid distribution side 220 may include longitudinal fibers 238 that define a grain structure. The longitudinal fibers 234 may be oriented substantially in a longitudinal direction along a length of the wicking layers 176, 180, and 189. The fluid acquisition side 234 may include vertical fibers 240,

which are shown enlarged in FIG. 7A for illustrative purposes only. The vertical fibers 240 may be oriented substantially vertical or normal relative to the longitudinal fibers 238 and the length of wicking layers 176, 180, and 189. In some embodiments, the fluid acquisition side 234 of both the second wicking layer 180 and the intermediate wicking layer 189 may be positioned facing the absorbent layer 184, and the fluid acquisition side 234 of the first wicking layer 176 may be positioned facing away from the absorbent layer 184. In such an embodiment, the fluid acquisition side 234 of the second wicking layer 180 may be positioned facing the fluid distribution side 220 of the intermediate wicking layer 189, and the fluid distribution side 220 of the first wicking layer 176 may be positioned facing the absorbent layer 184.

[0063] In some embodiments, the absorbent layer 184 may be a hydrophilic material adapted to absorb fluid from, for example, the tissue site 104. Materials suitable for the absorbent layer 184 may include Luquafleece® material, Texsus FP2326, BASF 402C, Technical Absorbents 2317 available from Technical Absorbents (www.techabsorbents.com), sodium polyacrylate super absorbers, cellulosics (carboxy methyl cellulose and salts such as sodium CMC), or alginates. Materials suitable for the first wicking layer 176 and the second wicking layer 180 may include any material having a grain structure capable of wicking fluid as described herein, such as, for example, Libeltex TDL2 80gsm.

[0064] The fluid management assembly 144 may be a pre-laminated structure manufactured at a single location or individual layers of material stacked upon one another as described above. Individual layers of the fluid management assembly 144 may be bonded or otherwise secured to one another without adversely affecting fluid management by, for example, utilizing a solvent or non-solvent adhesive, or by thermal welding. Further, the fluid management assembly 144 may be coupled to the border 161 of the base layer 132 in any suitable manner, such as, for example, by a weld or an adhesive. The border 161 being free of the apertures 160 as described above may provide a flexible barrier between the fluid management assembly 144 and the tissue site 104 for enhancing comfort.

[0065] In some embodiments, the enclosure 172 defined by the base layer 132 and the sealing member 140 may include an anti-microbial layer 190. The addition of the anti-microbial layer 190 may reduce the probability of excessive bacterial growth within the dressing 124 to permit the dressing 124 to remain in place for an extended period. The anti-microbial layer 190 may be, for example, an additional layer included as a part of the fluid management assembly 144 as depicted in FIGS. 1 and 2, or a coating of an anti-microbial

agent disposed in any suitable location within the dressing 124. The anti-microbial layer 190 may be comprised of elemental silver or similar compound, for example. In some embodiments, the anti-microbial agent may be formulated in any suitable manner into other components of the dressing 124.

[0066] Referring to FIGS. 1, 2, and 8, the conduit interface 148 may be positioned proximate to the sealing member 140 and in fluid communication with the dressing 124 through the sealing member aperture 170 in the sealing member 140 to provide reduced pressure from the reduced-pressure source 128 to the dressing 124. Specifically, the conduit interface 148 may be positioned in fluid communication with the enclosure 172 of the dressing 124. The conduit interface 148 may also be positioned in fluid communication with the optional interface manifold 120. As shown, an optional liquid trap 192 may be positioned in fluid communication between the dressing 124 and the reduced-pressure source 128. The liquid trap 192 may be any suitable containment device having a sealed internal volume capable of retaining liquid, such as condensate or other liquids, as described below.

[0067] The conduit interface 148 may comprise a medical-grade, soft polymer or other pliable material. As non-limiting examples, the conduit interface 148 may be formed from polyurethane, polyethylene, polyvinyl chloride (PVC), fluorosilicone, or ethylene-propylene, etc. In some illustrative, non-limiting embodiments, conduit interface 148 may be molded from DEHP-free PVC. The conduit interface 148 may be formed in any suitable manner such as by molding, casting, machining, or extruding. Further, the conduit interface 148 may be formed as an integral unit or as individual components and may be coupled to the dressing 124 by, for example, adhesive or welding.

[0068] In some embodiments, the conduit interface 148 may be formed of an absorbent material having absorbent and evaporative properties. The absorbent material may be vapor permeable and liquid impermeable, thereby being configured to permit vapor to be absorbed into and evaporated from the material through permeation while inhibiting permeation of liquids. The absorbent material may be, for example, a hydrophilic polymer such as a hydrophilic polyurethane. Although the term hydrophilic polymer may be used in the illustrative embodiments that follow, any absorbent material having the properties described herein may be suitable for use in the system 102. Further, the absorbent material or hydrophilic polymer may be suitable for use in various components of the system 102 as described herein.

[0069] The use of such a hydrophilic polymer for the conduit interface 148 may permit liquids in the conduit interface 148 to evaporate, or otherwise dissipate, during operation. For example, the hydrophilic polymer may allow the liquid to permeate or pass through the conduit interface 148 as vapor, in a gaseous phase, and evaporate into the atmosphere external to the conduit interface 148. Such liquids may be, for example, condensate or other liquids. Condensate may form, for example, as a result of a decrease in temperature within the conduit interface 148, or other components of the system 102, relative to the temperature at the tissue site 104. Removal or dissipation of liquids from the conduit interface 148 may increase visual appeal and prevent odor. Further, such removal of liquids may also increase efficiency and reliability by reducing blockages and other interference with the components of the system 102.

[0070] Similar to the conduit interface 148, the liquid trap 192, and other components of the system 102 described herein, may also be formed of an absorbent material or a hydrophilic polymer. The absorptive and evaporative properties of the hydrophilic polymer may also facilitate removal and dissipation of liquids residing in the liquid trap 192, and other components of the system 102, by evaporation. Such evaporation may leave behind a substantially solid or gel-like waste. The substantially solid or gel-like waste may be cheaper to dispose than liquids, providing a cost savings for operation of the system 102. The hydrophilic polymer may be used for other components in the system 102 where the management of liquids is beneficial.

[0071] In some embodiments, the absorbent material or hydrophilic polymer may have an absorbent capacity in a saturated state that is substantially equivalent to the mass of the hydrophilic polymer in an unsaturated state. The hydrophilic polymer may be fully saturated with vapor in the saturated state and substantially free of vapor in the unsaturated state. In both the saturated state and the unsaturated state, the hydrophilic polymer may retain substantially the same physical, mechanical, and structural properties. For example, the hydrophilic polymer may have a hardness in the unsaturated state that is substantially the same as a hardness of the hydrophilic polymer in the saturated state. The hydrophilic polymer and the components of the system 102 incorporating the hydrophilic polymer may also have a size that is substantially the same in both the unsaturated state and the saturated state. Further, the hydrophilic polymer may remain dry, cool to the touch, and pneumatically sealed in the saturated state and the unsaturated state. The hydrophilic polymer may also remain substantially the same color in the saturated state and the unsaturated state. In this

manner, this hydrophilic polymer may retain sufficient strength and other physical properties to remain suitable for use in the system 102. An example of such a hydrophilic polymer is offered under the trade name Techophilic HP-93A-100, available from The Lubrizol Corporation of Wickliffe, Ohio, United States. Techophilic HP-93A-100 is an absorbent hydrophilic thermoplastic polyurethane capable of absorbing 100% of the unsaturated mass of the polyurethane in water and having a durometer or Shore Hardness of about 83 Shore A.

[0072] The conduit interface 148 may carry an odor filter 194 adapted to substantially preclude the passage of odors from the tissue site 104 out of the sealed space 174. Further, the conduit interface 148 may carry a primary hydrophobic filter 195 adapted to substantially preclude the passage of liquids out of the sealed space 174. The odor filter 194 and the primary hydrophobic filter 195 may be disposed in the conduit interface 148 or other suitable location such that fluid communication between the reduced-pressure source 128, or optional therapy unit 130, and the dressing 124 is provided through the odor filter 194 and the primary hydrophobic filter 195. In some embodiments, the odor filter 194 and the primary hydrophobic filter 195 may be secured within the conduit interface 148 in any suitable manner, such as by adhesive or welding. In other embodiments, the odor filter 194 and the primary hydrophobic filter 195 may be positioned in any exit location in the dressing 124 that is in fluid communication with the atmosphere, the reduced-pressure source 128, or the optional therapy unit 130. The odor filter 194 may also be positioned in any suitable location in the system 102 that is in fluid communication with the tissue site 104.

[0073] The odor filter 194 may be comprised of a carbon material in the form of a layer or particulate. For example, the odor filter 194 may comprise a woven carbon cloth filter such as those manufactured by Chemviron Carbon, Ltd. of Lancashire, United Kingdom (www.chemvironcarbon.com). The primary hydrophobic filter 195 may be comprised of a material that is liquid impermeable and vapor permeable. For example, the primary hydrophobic filter 195 may comprise a material manufactured under the designation MMT-314 by W.L. Gore & Associates, Inc. of Newark, Delaware, United States, or similar materials. The primary hydrophobic filter 195 may be provided in the form of a membrane or layer.

[0074] Continuing with FIGS. 1, 2, and 8, the reduced-pressure source 128 provides reduced pressure to the dressing 124 and the sealed space 174. The reduced-pressure source 128 may be any suitable device for providing reduced pressure, such as, for example, a vacuum pump, wall suction, hand pump, manual pump, or other source. As shown in FIG. 1,

the reduced-pressure source 128 may be a component of the therapy unit 130. The therapy unit 130 may include control circuitry and sensors, such as a pressure sensor, that may be configured to monitor reduced pressure at the tissue site 104. The therapy unit 130 may also be configured to control the amount of reduced pressure from the reduced-pressure source 128 being applied to the tissue site 104 according to a user input and a reduced-pressure feedback signal received from the tissue site 104.

[0075] As used herein, "reduced pressure" generally refers to a pressure less than the ambient pressure at a 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. While the amount and nature of reduced pressure applied to a tissue site will typically vary according to the application, the reduced pressure will typically be between -5 mm Hg and -500 mm Hg, and more typically in a therapeutic range between -100 mm Hg and -200 mm Hg.

[0076] The reduced pressure delivered may be constant or varied (patterned or random), and may be delivered continuously or intermittently. Although the terms "vacuum" and "negative pressure" may be used to describe the pressure applied to the tissue site, the actual pressure applied to the tissue site may be more than the pressure normally associated with a complete vacuum. Consistent with the use herein, an increase in reduced pressure or vacuum pressure typically refers to a relative reduction in absolute pressure. An increase in reduced pressure corresponds to a reduction in pressure (more negative relative to ambient pressure) and a decrease in reduced pressure corresponds to an increase in pressure (less negative relative to ambient pressure).

[0077] As shown in FIG. 8, a conduit 196 having an internal lumen 197 may be coupled in fluid communication between the reduced-pressure source 128 and the dressing 124. The internal lumen 197 may have an internal diameter between about 0.5 millimeters to about 3.0 millimeters. More specifically, the internal diameter of the internal lumen 197 may be about 1 millimeter to about 2 millimeters. The conduit interface 148 may be coupled in fluid communication with the dressing 124 and adapted to connect between the conduit 196 and the dressing 124 for providing fluid communication with the reduced-pressure source 128. The conduit interface 148 may be fluidly coupled to the conduit 196 in any suitable manner, such as, for example, by an adhesive, solvent or non-solvent bonding, welding, or interference fit. The sealing member aperture 170 in the sealing member 140 may provide

fluid communication between the dressing 124 and the conduit interface 148. Specifically, the conduit interface 148 may be in fluid communication with the enclosure 172 or the sealed space 174 through the sealing member aperture 170 in the sealing member 140. In some embodiments, the conduit 196 may be inserted into the dressing 124 through the sealing member aperture 170 in the sealing member 140 to provide fluid communication with the reduced-pressure source 128 without use of the conduit interface 148. The reduced-pressure source 128 may also be directly coupled in fluid communication with the dressing 124 or the sealing member 140 without use of the conduit 196. The conduit 196 may be, for example, a flexible polymer tube. A distal end of the conduit 196 may include a coupling 198 for attachment to the reduced-pressure source 128.

[0078] The conduit 196 may have a secondary hydrophobic filter 199 disposed in the internal lumen 197 such that fluid communication between the reduced-pressure source 128 and the dressing 124 is provided through the secondary hydrophobic filter 199. The secondary hydrophobic filter 199 may be, for example, a porous, sintered polymer cylinder sized to fit the dimensions of the internal lumen 197 to substantially preclude liquid from bypassing the cylinder. The secondary hydrophobic filter 199 may also be treated with an absorbent material adapted to swell when brought into contact with liquid to block the flow of the liquid. The secondary hydrophobic filter 199 may be positioned at any location within the internal lumen 197. However, positioning the secondary hydrophobic filter 199 within the internal lumen 197 closer toward the reduced-pressure source 128, rather than the dressing 124, may allow a user to detect the presence of liquid in the internal lumen 197.

[0079] In some embodiments, the conduit 196 and the coupling 198 may be formed of an absorbent material or a hydrophilic polymer as described above for the conduit interface 148. In this manner, the conduit 196 and the coupling 198 may permit liquids in the conduit 196 and the coupling 198 to evaporate, or otherwise dissipate, as described above for the conduit interface 148. The conduit 196 and the coupling 198 may be, for example, molded from the hydrophilic polymer separately, as individual components, or together as an integral component. Further, a wall of the conduit 196 defining the internal lumen 197 may be extruded from the hydrophilic polymer. The conduit 196 may be less than about 1 meter in length, but may have any length to suit a particular application. More specifically, a length of about 1 foot or 304.8 millimeters may provide enough absorbent and evaporative surface area to suit many applications, and may provide a cost savings compared to longer lengths. If an application requires additional length for the conduit 196, the absorbent hydrophilic polymer

may be coupled in fluid communication with a length of conduit formed of a non-absorbent hydrophobic polymer to provide additional cost savings.

[0080] In operation of the system 102 according to some illustrative embodiments, the interface manifold 120 may be disposed against or proximate to the tissue site 104. The dressing 124 may then be applied over the interface manifold 120 and the tissue site 104 to form the sealed space 174. Specifically, the base layer 132 may be applied covering the interface manifold 120 and the tissue surrounding the tissue site 104. The materials described above for the base layer 132 have a tackiness that may hold the dressing 124 initially in position. The tackiness may be such that if an adjustment is desired, the dressing 124 may be removed and reapplied. Once the dressing 124 is in the desired position, a force may be applied, such as by hand pressing, on a side of the sealing member 140 opposite the tissue site 104. The force applied to the sealing member 140 may cause at least some portion of the adhesive 136 to penetrate or extend through the plurality of apertures 160 and into contact with tissue surrounding the tissue site 104, such as the epidermis 106, to releaseably adhere the dressing 124 about the tissue site 104. In this manner, the configuration of the dressing 124 described above may provide an effective and reliable seal against challenging anatomical surfaces, such as an elbow or heal, at and around the tissue site 104. Further, the dressing 124 permits re-application or re-positioning to, for example, correct air leaks caused by creases and other discontinuities in the dressing 124 and the tissue site 104. The ability to rectify leaks may increase the reliability of the therapy and reduce power consumption.

[0081] As the dressing 124 comes into contact with fluid from the tissue site 104, the fluid moves through the apertures 160 toward the fluid management assembly 144. The fluid management assembly 144 wicks or otherwise moves the fluid through the interface manifold 120 and away from the tissue site 104. As described above, the interface manifold 120 may be adapted to communicate fluid from the tissue site 104 rather than store the fluid. Thus, the fluid management assembly 144 may be more absorbent than the interface manifold 120. The fluid management assembly 144 being more absorbent than the interface manifold 120 provides an absorbent gradient through the dressing 124 that attracts fluid from the tissue site 104 or the interface manifold 120 to the fluid management assembly 144. Thus, in some embodiments, the fluid management assembly 144 may be adapted to wick, pull, draw, or otherwise attract fluid from the tissue site 104 through the interface manifold 120. In the fluid management assembly 144, the fluid initially comes into contact with the first wicking layer 176. The first wicking layer 176 may distribute the fluid laterally along the surface of

the first wicking layer 176 as described above for absorption and storage within the absorbent layer 184. Similarly, fluid coming into contact with the second wicking layer 180 may be distributed laterally along the surface of the second wicking layer 180 for absorption within the absorbent layer 184. As fluid enters the fluid management assembly 144 and the enclosure 172, moisture carried by or associated with the fluid is evaporated through the breathable zone 202, thereby extending the useable life and fluid handling capacity of the dressing 124 without compromising structural integrity.

[0082] Referring to FIGS. 9A-9B, in other embodiments, the conduit 196 may be a multi-lumen conduit 302. For example, FIG. 9A depicts an illustrative embodiment of a multi-lumen conduit 302a. The multi-lumen conduit 302a may have an external surface 306, a primary lumen 310, a wall 314, and at least one secondary lumen 318. The wall 314 may carry the primary lumen 310 and the at least one secondary lumen 318. The primary lumen 310 may be substantially isolated from fluid communication with the at least one secondary lumen 318 along the length of the multi-lumen conduit 302a. Although shown in FIG. 9A as having a substantially circular cross-section, the external surface 306 of the multi-lumen conduit 302a may have any shape to suit a particular application. The wall 314 of the multi-lumen conduit 302a may have a thickness between the primary lumen 310 and the external surface 306. As depicted in FIG. 9A, the at least one secondary lumen 318 may be four secondary lumens 318 carried by the wall 314 substantially parallel to the primary lumen 310 and about a perimeter of the primary lumen 310. The secondary lumens 318 may be separate from one another and substantially isolated from fluid communication with one another along the length of the multi-lumen conduit 302a. Further, the secondary lumens 318 may be separate from the primary lumen 310 and substantially isolated from fluid communication with the primary lumen 310. The secondary lumens 318 may also be positioned concentric relative to the primary lumen 310 and substantially equidistant about the perimeter of the primary lumen 310. Although FIG. 9A depicts four secondary lumens 318, any number of secondary lumens 318 may be provided and positioned in any suitable manner for a particular application.

[0083] Similar to the internal lumen 197 of the conduit 196, the primary lumen 310 may be coupled in fluid communication between the reduced-pressure source 128 and the dressing 124 as described above. In some embodiments, the primary lumen 310 may be coupled in fluid communication between the conduit interface 148 and the reduced-pressure source 128. Further, analogous to the internal lumen 197, reduced pressure may be provided

through the primary lumen 310 from the reduced-pressure source 128 to the dressing 124. In some embodiments, the primary lumen 310 may be configured to extract fluid such as exudate from the tissue site 104. The secondary lumens 318 may be coupled in fluid communication between the therapy unit 130 and the dressing 124. In some embodiments, the at least one secondary lumen 318 may be coupled in fluid communication between the conduit interface 148 and the therapy unit 130. Further, the secondary lumens 318 may be in fluid communication with the primary lumen 310 at the dressing 124 and configured to provide a reduced-pressure feedback signal from the dressing 124 to the therapy unit 130. For example, the secondary lumens 318 may be in fluid communication with the primary lumen 310 at the conduit interface 148 or other component of the dressing 124.

[0084] The multi-lumen conduit 302a may be comprised of an absorbent material or hydrophilic polymer, such as, for example, the absorbent material or the hydrophilic polymer described above in connection with the conduit interface 148, the conduit 196, and the coupling 198. The absorbent material or the hydrophilic polymer may be vapor permeable and liquid impermeable. In some embodiments, at least a portion of the wall 314 and the external surface 306 of the multi-lumen conduit 302a may be comprised of the absorbent material or the hydrophilic polymer. In this manner, the multi-lumen conduit 302a may permit liquids, such as condensate, in the multi-lumen conduit 302a to evaporate, or otherwise dissipate, as described above. For example, the absorbent material or the hydrophilic polymer may allow the liquid to pass through the multi-lumen conduit 302a as vapor, in a gaseous phase, and evaporate into the atmosphere external to the multi-lumen conduit 302a. Liquids such as exudate from the tissue site 104 may also be evaporated or dissipated through the multi-lumen conduit 302a in the same manner. This feature may be advantageous when the optional therapy unit 130 is used for monitoring and controlling reduced pressure at the tissue site 104. For example, liquid present in the secondary lumens 318 may interfere with a reduced-pressure feedback signal being transmitted to the therapy unit 130 through the secondary lumens 318. The use of the hydrophilic polymer for the multi-lumen conduit 302a may permit removal of such liquid for enhancing the visual appeal, reliability, and efficiency of the system 102. After evaporation of liquid in the multi-lumen conduit 302a, other blockages from, for example, desiccated exudate, solids, or gel-like substances that were carried by the evaporated liquid may be visible for further remediation. Further, the use of the hydrophilic polymer as described herein may reduce the occurrence of

skin damage caused by moisture buildup between components of the system 102, such as the multi-lumen conduit 302a, and the skin of a patient.

[0085] Referring to FIG. 9B, depicted is an illustrative embodiment of a multi-lumen conduit 302e having an oblong cross section. Similar to the multi-lumen conduit 302a, the multi-lumen conduit 302e may have the external surface 306, the primary lumen 310, the wall 314, and the at least one secondary lumen 318. However, FIG. 9B depicts the at least one secondary lumen 318 of the multi-lumen conduit 302e as a single secondary lumen 318 that may be carried by the wall 314 beside the primary lumen 310. Such a configuration may provide a substantially flat, low profile shape that may enhance user comfort and may increase the flexibility of the multi-lumen conduit 302e. For example, in this configuration, the multi-lumen conduit 302e may be routed through tight spaces with reduced risk of kinking or blockages of fluid communication. Although not depicted, additional lumens may be added in this substantially flat configuration, laterally disposed from the primary lumen 310 and the secondary lumen 318, as necessary to suit a particular application. The above features described in connection with the multi-lumen conduits 302a and 302e may be used in combination with one another to suit a particular application.

[0086] The appended claims set forth novel and inventive aspects of the subject matter in this disclosure. While shown in several illustrative embodiments, a person having ordinary skill in the art will recognize that the systems, apparatuses, and methods described herein are susceptible to various changes and modifications. Features may be emphasized in some example embodiments while being omitted in others, but a person of skill in the art will appreciate that features described in the context of one example embodiment may be readily applicable to other example embodiments. Further, certain features, elements, or aspects may be omitted from this disclosure if not necessary to distinguish the novel and inventive features from what is already known to a person having ordinary skill in the art. Features, elements, and aspects described herein may also be combined or replaced by alternative features serving the same, equivalent, or similar purpose without departing from the scope of the invention defined by the appended claims. Moreover, descriptions of various alternatives using terms such as “or” do not require mutual exclusivity unless clearly required by the context, and the indefinite articles "a" or "an" do not limit the subject to a single instance unless clearly required by the context.

We claim:

1. A system for treating a tissue site, comprising:
a dressing, comprising:
a base layer including a periphery surrounding a central portion and a plurality of apertures disposed through the periphery and the central portion,
an adhesive configured to extend through the apertures at least in the periphery of the base layer to contact tissue surrounding the tissue site,
a sealing member including a periphery and a central portion, the periphery of the sealing member positioned proximate to the periphery of the base layer, wherein the central portion of the sealing member and the central portion of the base layer define an enclosure, and wherein the central portion of the sealing member includes a breathable zone having a higher vapor permeability than the periphery of the sealing member,
at least one wicking layer disposed in the enclosure, and
an absorbent layer disposed in the enclosure; and
a reduced-pressure source configured to be coupled in fluid communication with the dressing.

2. The system of claim 1, wherein the breathable zone comprises a vapor permeable and liquid impermeable film having a thickness between 10 to 30 microns.

3. The system of claim 1, wherein the breathable zone comprises a non-adhesive polyurethane film.

4. The system of claim 1, wherein the adhesive is disposed on a surface of at least the periphery of the sealing member that is configured to face the base layer, and wherein the breathable zone is free of the adhesive.

5. The system of claim 1, wherein the periphery of the sealing member comprises a liquid impermeable film.

6. The system of claim 1, wherein the sealing member comprises a sealing member aperture and a zone opening disposed through the sealing member, wherein the reduced-pressure source is configured to be coupled in fluid communication with the enclosure through the sealing member aperture, and wherein the breathable zone is positioned at the zone opening and exposed to an ambient environment external to the dressing through the zone opening.

7. The system of claim 6, wherein the sealing member aperture and the zone opening are positioned at opposing ends of the sealing member.

8. The system of claim 1, wherein the sealing member comprises a zone opening disposed through the sealing member, and wherein the breathable zone is positioned at the zone opening and exposed to an ambient environment external to the dressing through the zone opening.

9. The system of claim 8, wherein the breathable zone is coupled to a perimeter of the zone opening.

10. The system of claim 9, wherein the breathable zone is coupled to the perimeter of the zone opening on an interior facing surface of the sealing member.

11. The system of claim 9, wherein the breathable zone is coupled to the perimeter of the zone opening on an exterior facing surface of the sealing member by an adhesive gasket.

12. The system of claim 1, wherein an interior facing surface of the breathable zone is configured to be in direct contact with moisture in the enclosure, and wherein an exterior facing surface of the breathable zone is configured to be in direct contact with an ambient environment external to the dressing.

13. The system of claim 1, wherein the breathable zone comprises an embossed portion having a decreased thickness relative to another portion of the breathable zone, and

wherein the embossed portion is configured to increase the vapor permeability and an evaporative surface area of the breathable zone.

14. The system of claim 1, wherein an interior facing surface of the breathable zone comprises a pattern coating of an adhesive.

15. The system of claim 1, wherein the breathable zone is positioned between an interior facing surface of the sealing member and the absorbent layer and exposed to an ambient environment external to the dressing through an opening in the sealing member.

16. The system of claim 1, wherein the breathable zone is coupled to the at least one wicking layer by a fuse-able fiber non-woven material.

17. The system of claim 1, wherein the breathable zone comprises a moisture indicator configured to indicate a color change when in contact with moisture, and wherein the moisture indicator includes an ink or wax coating on a surface of the breathable zone.

18. The system of claim 1, wherein the at least one wicking layer has a grain structure adapted to wick fluid along a surface of the at least one wicking layer.

19. The system of claim 1, wherein the at least one wicking layer is a first wicking layer and a second wicking layer, wherein the absorbent layer is positioned in fluid communication between the first wicking layer and the second wicking layer, and wherein a peripheral portion of the first wicking layer is coupled to a peripheral portion of the second wicking layer providing a wicking layer enclosure surrounding the absorbent layer between the first and the second wicking layer.

20. The system of claim 19, wherein the breathable zone is positioned between an interior facing surface of the sealing member and the second wicking layer and exposed to an ambient environment external to the dressing through an opening in the sealing member.

21. The system of claim 19, further comprising at least one intermediate wicking layer disposed in fluid communication between the absorbent layer and the second wicking layer, wherein the second wicking layer is positioned between the intermediate wicking layer and the breathable zone.

22. The system of claim 1, wherein the apertures in the periphery are larger than the apertures in the central portion, at least one of the apertures in the periphery being positioned at an edge of the periphery and having an interior exposed at the edge, and wherein the base layer is adapted to cover a tissue interface and tissue surrounding the tissue site.

23. The system of claim 1, wherein a plurality of the apertures in the periphery are positioned along an edge of the periphery and have an interior exposed at the edge.

24. The system of claim 1, further comprising a conduit interface configured to be positioned proximate to the sealing member and in fluid communication with the enclosure, wherein the reduced-pressure source is adapted to be in fluid communication with the conduit interface to provide reduced pressure to the dressing, and wherein the dressing is adapted to provide a sealed space relative to the tissue site for receiving reduced pressure at the tissue site.

25. The system of claim 1, wherein the central portion of the base layer is adapted to be positioned proximate to the tissue site and the periphery of the base layer is adapted to be positioned proximate to the tissue surrounding the tissue site.

26. The system of claim 1, wherein the base layer is comprised of silicone.

27. The system of claim 1, wherein the adhesive is positioned at least between the periphery of the sealing member and the periphery of the base layer.

28. The system of claim 1, wherein the adhesive is an acrylic adhesive.

29. A dressing for treating a tissue site, comprising:

a base layer having a periphery surrounding a central portion and a plurality of apertures disposed through the periphery and the central portion;

an adhesive configured to extend through the apertures at least in the periphery of the base layer to contact tissue surrounding the tissue site;

a sealing member having a periphery and a central portion, the periphery of the sealing member positioned proximate to the periphery of the base layer, wherein the central portion of the sealing member and the central portion of the base layer define an enclosure, and wherein the central portion of the sealing member includes a breathable zone having a higher vapor permeability than the periphery of the sealing member;

a first wicking layer disposed in the enclosure;

a second wicking layer disposed in the enclosure; and

an absorbent layer positioned in fluid communication between the first wicking layer and the second wicking layer.

30. The dressing of claim 29, wherein a peripheral portion of the first wicking layer is coupled to a peripheral portion of the second wicking layer providing a wicking layer enclosure surrounding the absorbent layer between the first wicking layer and the second wicking layer.

31. The dressing of claim 29, wherein the breathable zone comprises a vapor permeable and liquid impermeable film having a thickness between 10 to 30 microns.

32. The dressing of claim 29, wherein the breathable zone comprises a non-adhesive polyurethane film.

33. The dressing of claim 29, wherein the adhesive is disposed on a surface of at least the periphery of the sealing member that is configured to face the base layer, and wherein the breathable zone is free of the adhesive.

34. The dressing of claim 29, wherein the sealing member comprises a zone opening disposed through the sealing member, and wherein the breathable zone is positioned

at the zone opening and exposed to an ambient environment external to the dressing through the zone opening.

35. The dressing of claim 34, wherein the breathable zone is coupled to a perimeter of the zone opening.

36. The dressing of claim 34, wherein the breathable zone is coupled to the perimeter of the zone opening on an interior facing surface of the sealing member by the adhesive.

37. The dressing of claim 29, wherein an interior facing surface of the breathable zone is configured to be in direct contact with moisture in the enclosure, and wherein an exterior facing surface of the breathable zone is configured to be in direct contact with an ambient environment external to the dressing.

38. The system of claim 29, wherein the breathable zone comprises an embossed portion having a decreased thickness relative to another portion of the breathable zone, and wherein the embossed portion is configured to increase the vapor permeability and an evaporative surface area of the breathable zone.

39. A system for treating a tissue site, comprising:

a dressing adapted to distribute reduced pressure to the tissue site and to store fluid extracted from the tissue site, comprising:

a base layer comprising a periphery surrounding a central portion and a plurality of apertures disposed through the periphery and the central portion, the apertures in the periphery being larger than the apertures in the central portion, wherein the periphery of the base layer is configured to surround the tissue site, and wherein the apertures in the base layer are configured to be in fluid communication with the tissue site and the tissue surrounding the tissue site,

an adhesive configured to extend through the apertures at least in the periphery of the base layer to contact tissue surrounding the tissue site,

a sealing member having a periphery and a central portion, the periphery of the sealing member positioned proximate the periphery of the base layer, wherein the central portion of the sealing member and the central portion of the base layer define an enclosure, and wherein the central portion of the sealing member includes a breathable zone having a higher vapor permeability than the periphery of the sealing member,

a first wicking layer disposed in the enclosure,

a second wicking layer disposed in the enclosure, and

an absorbent layer positioned in fluid communication between the first wicking layer and the second wicking layer;

a conduit interface configured to be positioned proximate to the sealing member and in fluid communication with the enclosure; and

a reduced-pressure source adapted to be coupled in fluid communication with the conduit interface to provide reduced pressure to the dressing.

40. The system of claim 39, wherein the sealing member comprises a zone opening disposed through the sealing member, and wherein the breathable zone is positioned at the zone opening and exposed to an ambient environment external to the dressing through the zone opening.

41. The system of claim 39, wherein the breathable zone comprises a vapor permeable and liquid impermeable film having a thickness between 10 to 30 microns.

42. The system of claim 39, wherein the breathable zone comprises a non-adhesive polyurethane film.

43. A dressing for treating a tissue site, comprising:

a sealing member including a periphery and a central portion, wherein the central portion of the sealing member includes a breathable zone having a higher vapor permeability than the periphery of the sealing member.

44. The systems, dressings, apparatuses, and methods substantially as shown and described herein.

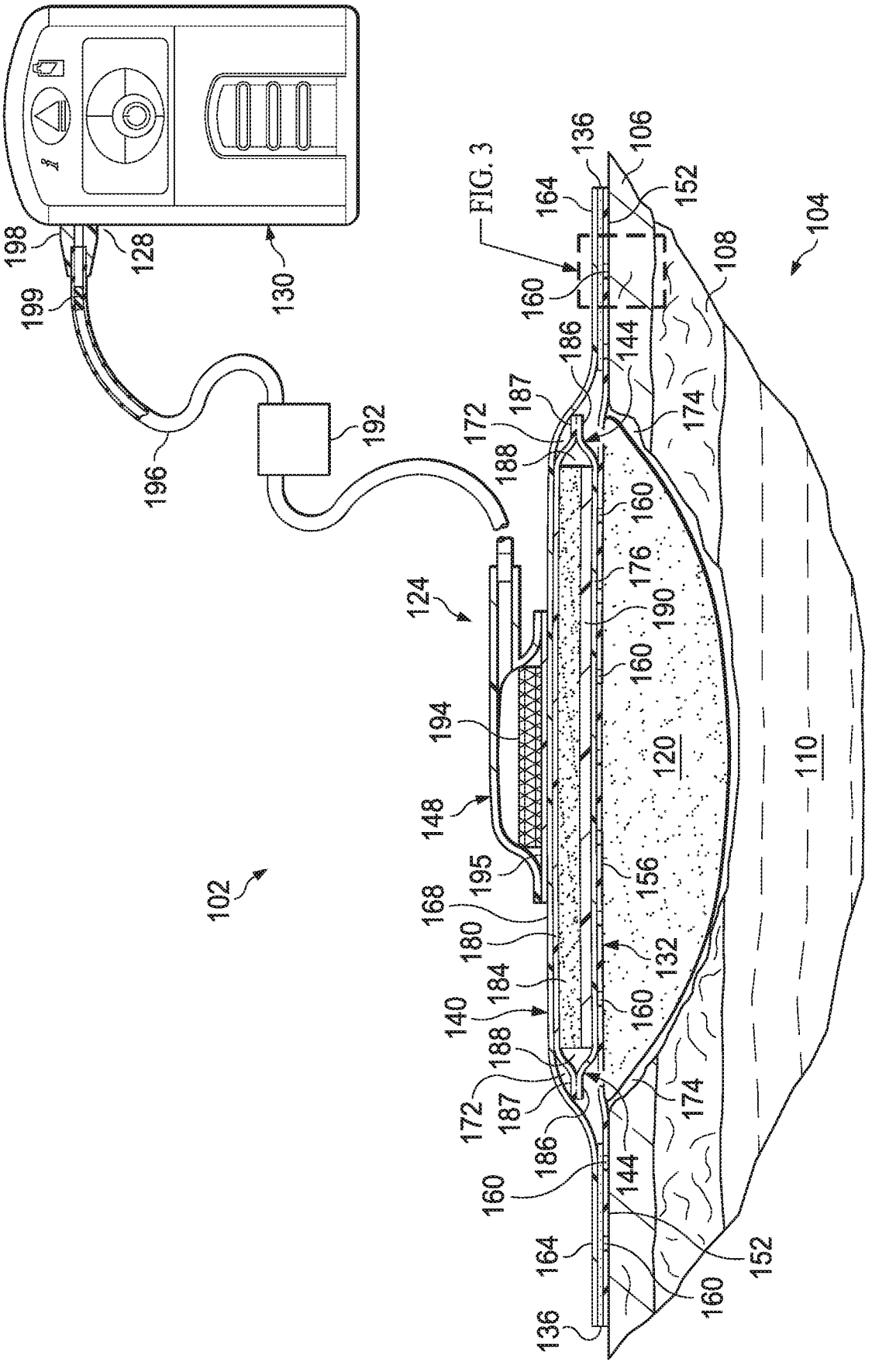

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FIG. 3

FIG. 1

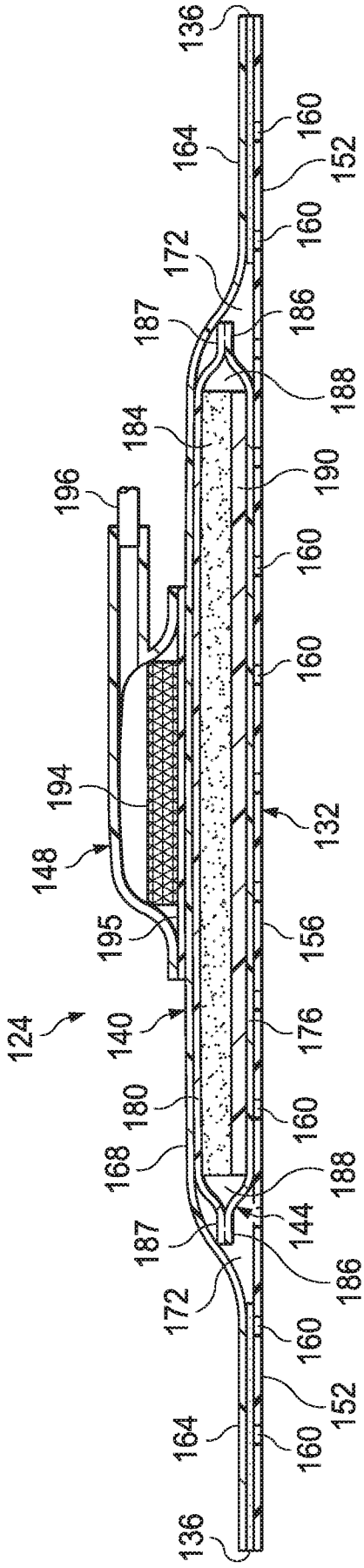

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FIG. 2

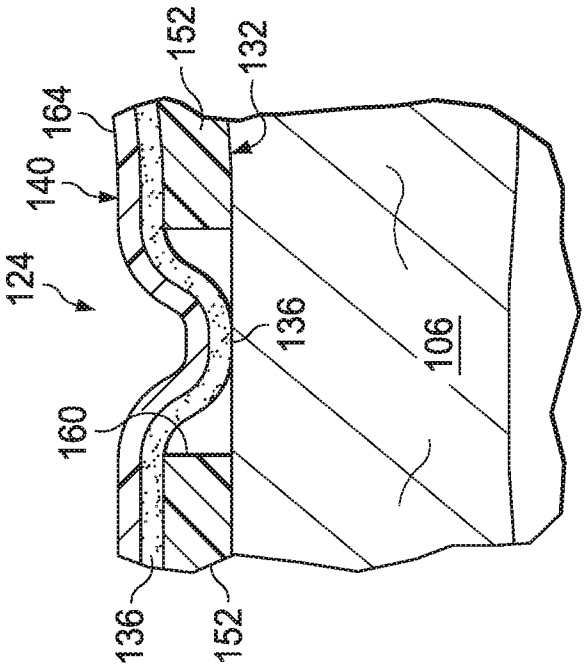

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FIG. 3

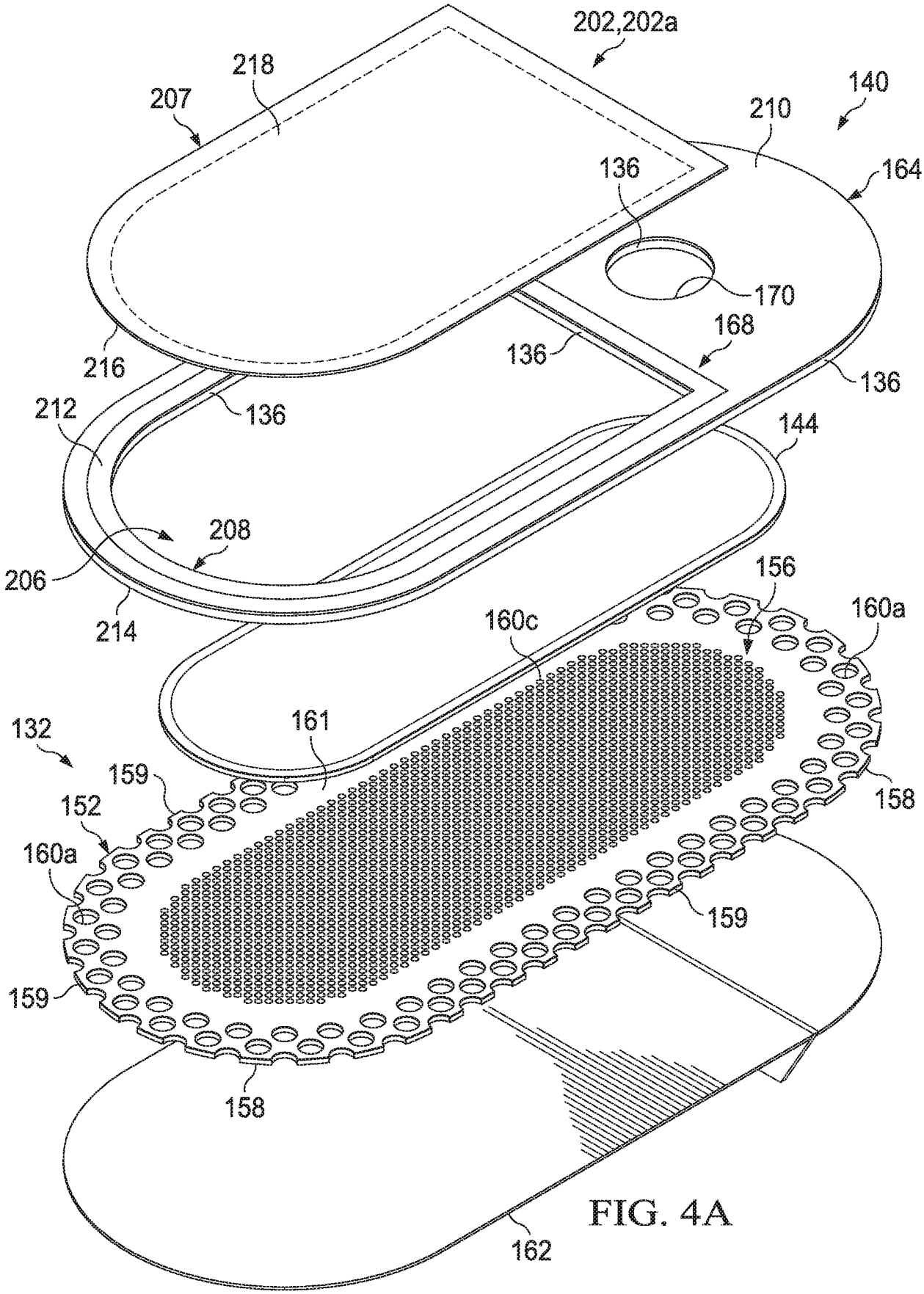

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FIG. 4A

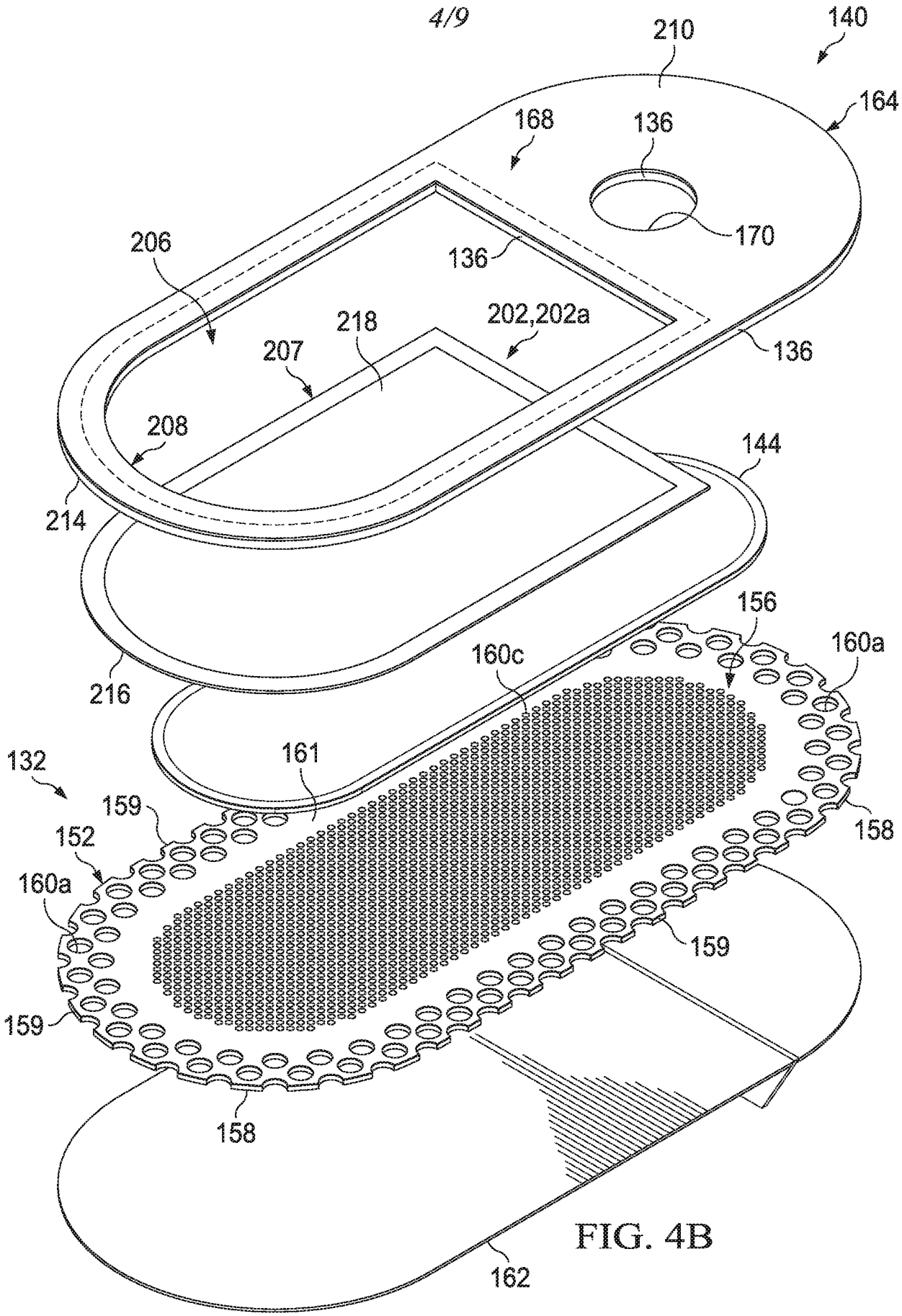

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FIG. 4B

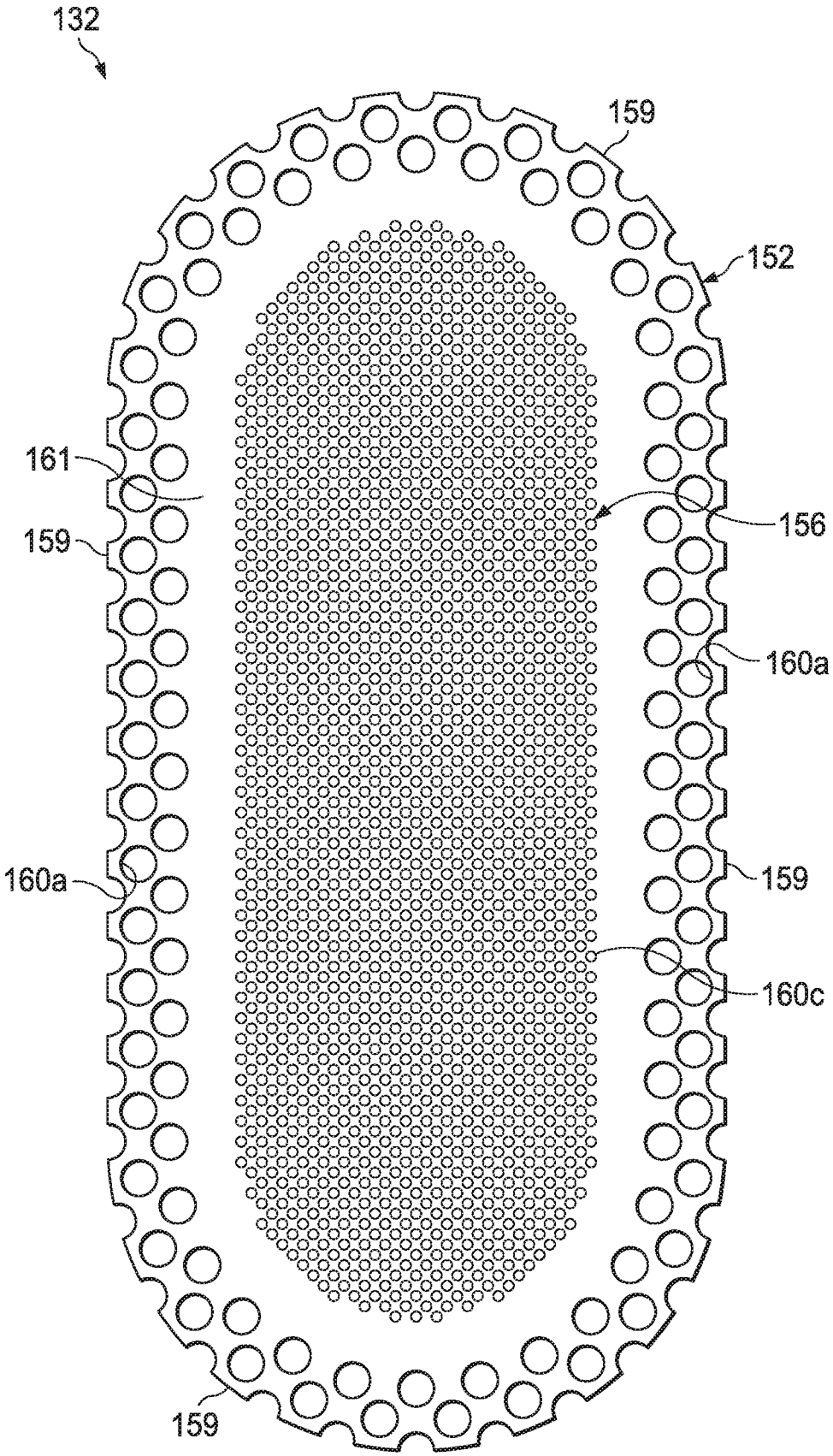


FIG. 5

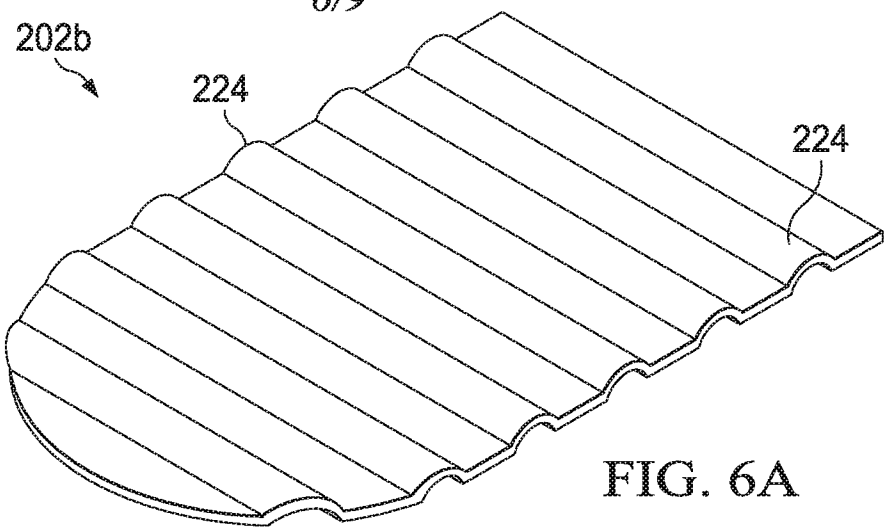


FIG. 6A

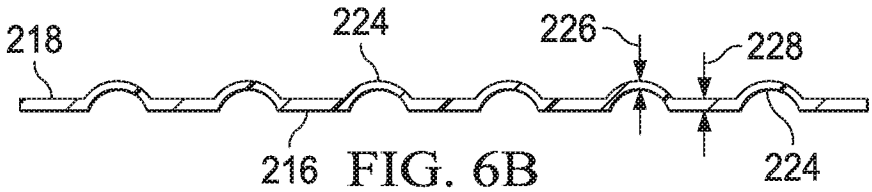


FIG. 6B

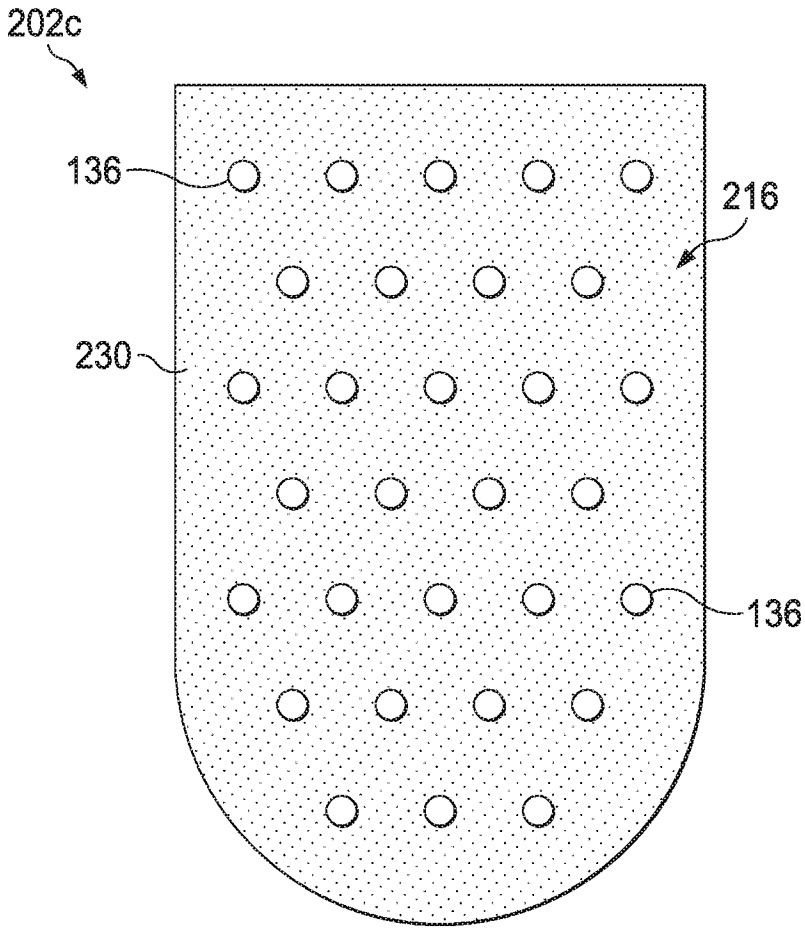


FIG. 6C

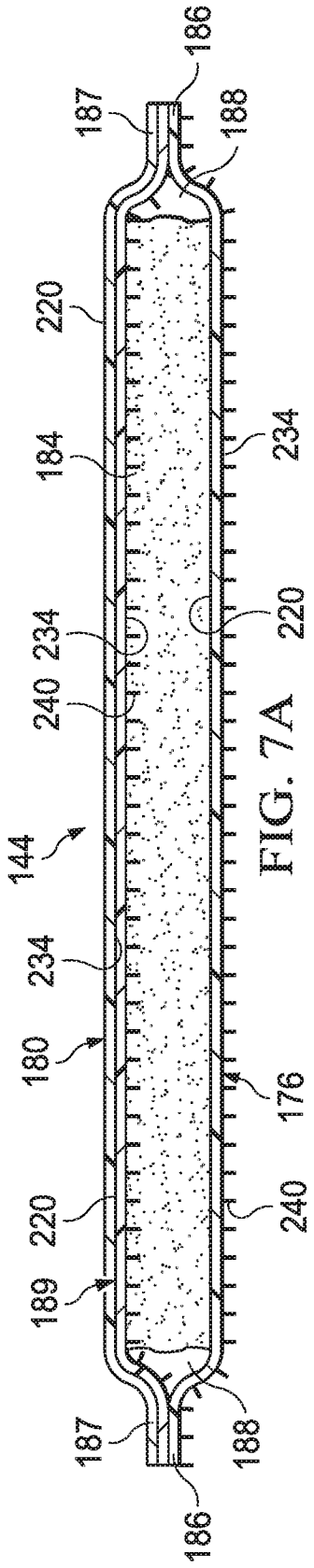

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FIG. 7A

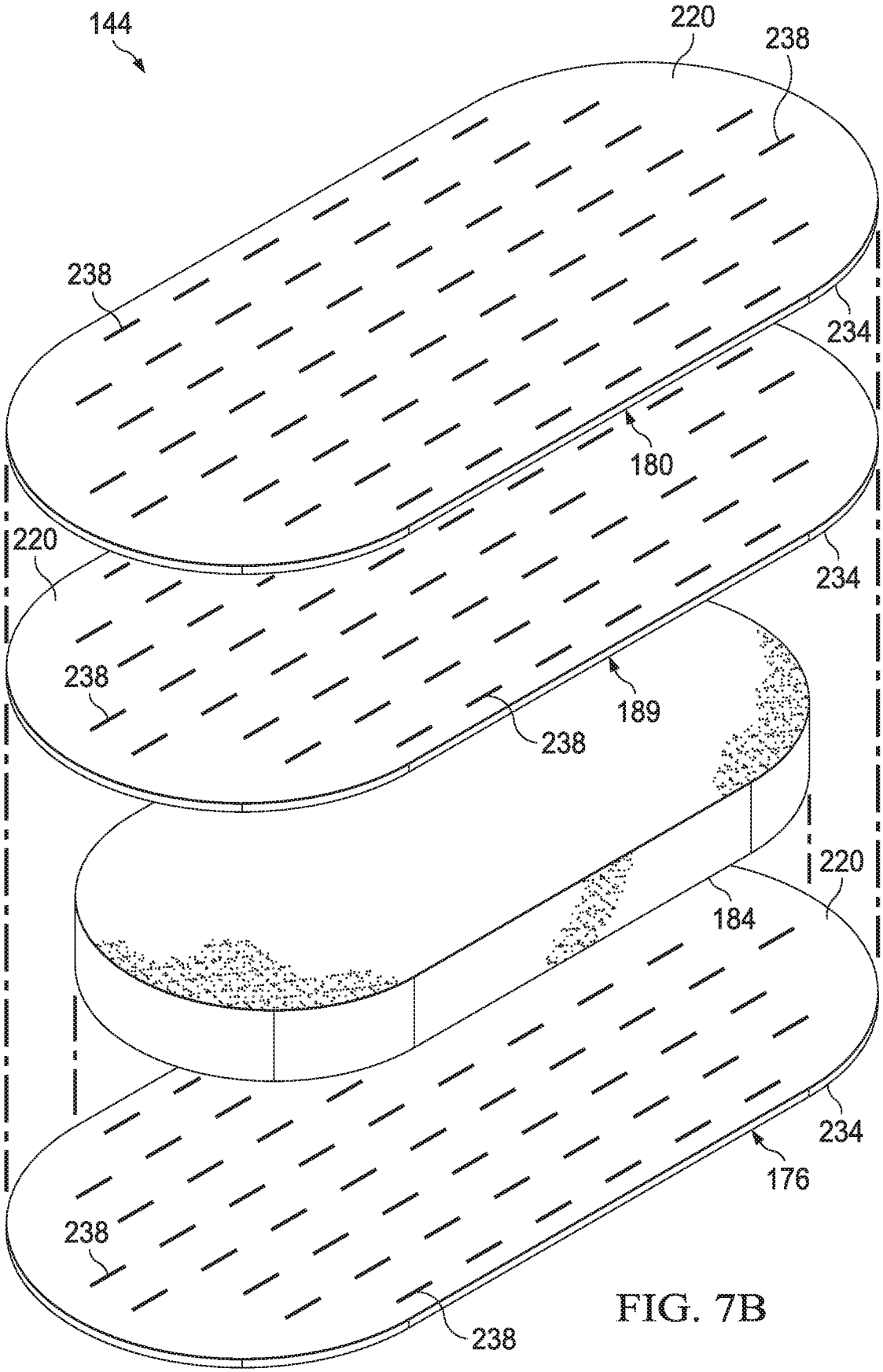

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FIG. 7B

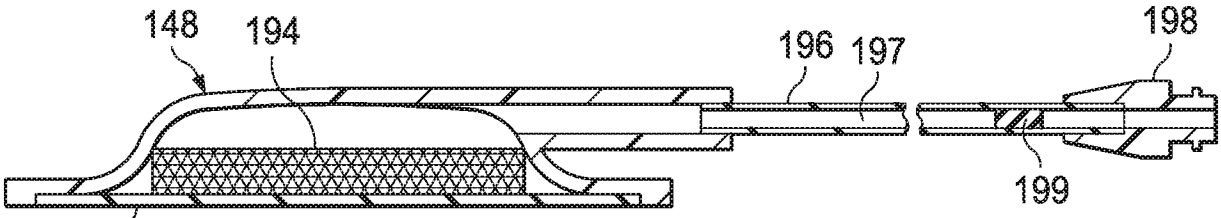


FIG. 8

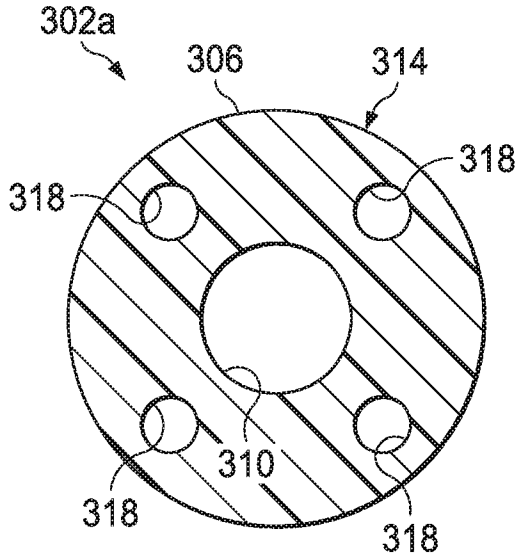


FIG. 9A

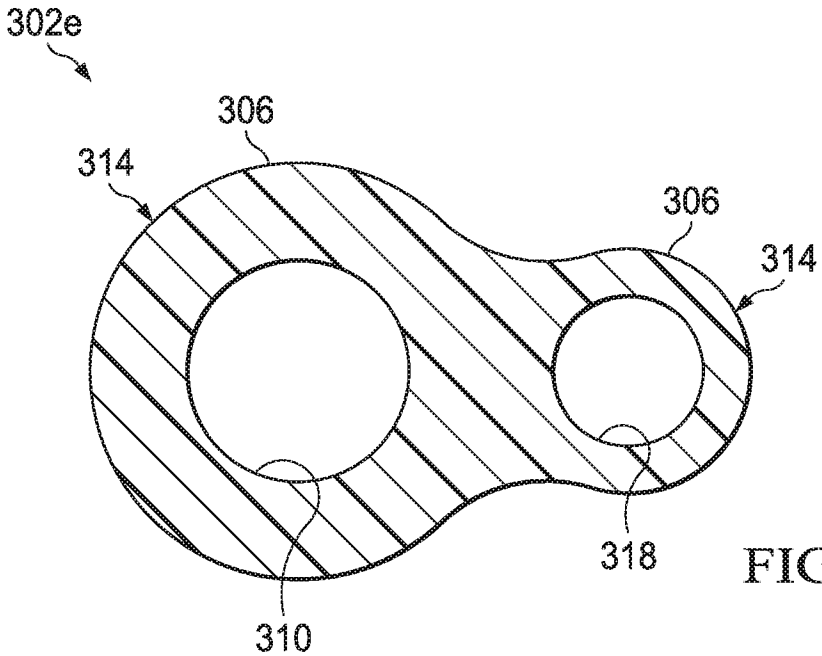


FIG. 9B

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2019/042844

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F13/00 A61F13/02 A61M1/00
ADD.

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 A61M

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 3 257 486 A1 (KCI LICENSING INC [US]) 20 December 2017 (2017-12-20) paragraph [0003] paragraph [0011] - paragraph [0013] paragraph [0016] - paragraph [0019] paragraph [0021] - paragraph [0023] paragraph [0027] paragraph [0032] - paragraph [0037] paragraph [0041] - paragraph [0042]; figures 1-8 -----	1-44
A	WO 2017/040045 A1 (KCI LICENSING INC [US]) 9 March 2017 (2017-03-09) paragraph [0052] - paragraph [0069]; figures 1-4 -----	1-44

☐ 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	Date of mailing of the international search report
23 October 2019	29/10/2019

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Demay, Stéphane

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2019/042844

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		EP 3513773 A1	24-07-2019
		US 2015119831 A1	30-04-2015
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		WO 2015065612 A1	07-05-2015
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		US 2018214313 A1	02-08-2018
		WO 2017040045 A1	09-03-2017