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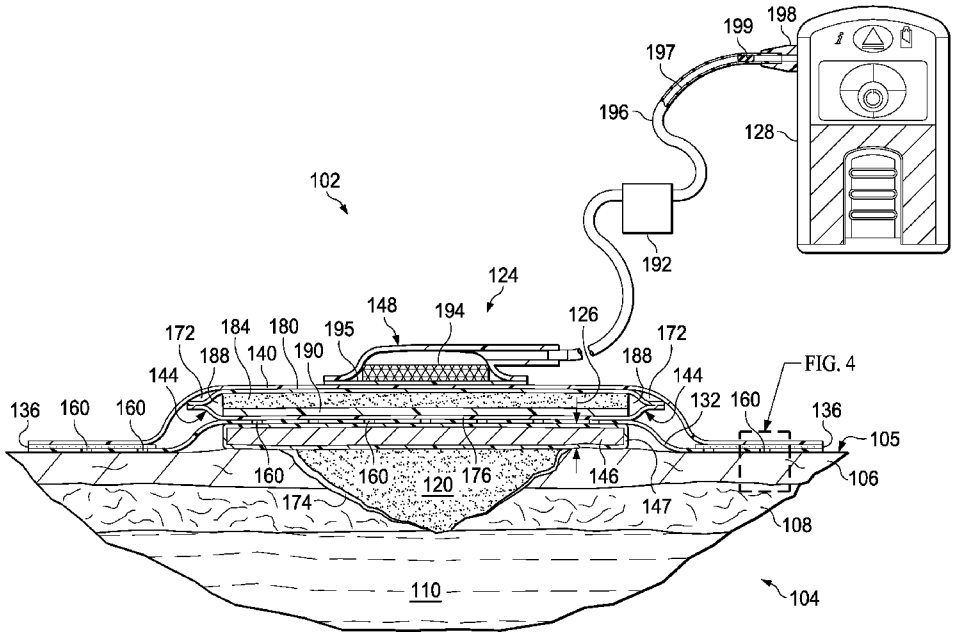

FIG. 4

FIG. 1

(57) Abstract: An apparatus, system, and method for closing an opening through a surface of a tissue site is described. The apparatus includes an apposition layer adapted to be positioned over the opening. The apposition layer is formed from a material having a firmness factor, and has a plurality of holes extending through the apposition layer. The holes form a void space and have a perforation shape factor and a strut angle configured to collapse the apposition layer in a first direction relative to a second direction. A sheet having a plurality of perforations is configured to surround the apposition layer, the sheet having a plurality of perforations. The apposition layer generates a closing force in the first direction that is substantially parallel to the surface of the tissue site to close the opening in response to application of a negative pressure.

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TISSUE CONTACT INTERFACE

RELATED APPLICATION

[0001] This application claims the benefit, under 35 U.S.C. § 119(e), of the filing of U.S. Provisional Patent Application serial number 62/516,540, entitled "TISSUE CONTACT INTERFACE," filed June 7, 2017; U.S. Provisional Patent Application serial number 62/516,550, entitled "COMPOSITE DRESSINGS FOR IMPROVED GRANULATION AND REDUCED MACERATION WITH NEGATIVE-PRESSURE TREATMENT" filed June 7, 2017; and U.S. Provisional Patent Application serial number 62/516,566, entitled "COMPOSITE DRESSINGS FOR IMPROVED GRANULATION AND REDUCED MACERATION WITH NEGATIVE-PRESSURE TREATMENT" filed June 7, 2017, each of which is incorporated herein by reference for all purposes.

TECHNICAL FIELD

[0002] The invention set forth in the appended claims relates generally to tissue treatment systems and more particularly, but without limitation, to a dressing having a contracting layer for assisting in closure of linear tissue sites.

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 it has proven particularly advantageous for treating wounds. Regardless of the etiology of a wound, whether trauma, surgery, or another cause, proper care of the wound is important to the outcome. Treatment of wounds or other tissue with negative 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," "vacuum-assisted closure," and "topical negative-pressure," 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, improvements to therapy systems, components, and processes may further benefit healthcare providers and patients.

BRIEF SUMMARY

[0005] New and useful systems, apparatuses, and methods for closing an opening through a surface of a tissue site are set forth in the appended claims. Illustrative embodiments are also provided to enable a person skilled in the art to make and use the claimed subject matter. For example, a system for closing an opening through a surface of a tissue site is described. The system can include an apposition layer adapted to be positioned over the opening. The apposition layer may be formed from a material having a firmness factor, and have a plurality of holes extending through the apposition layer. The holes can form a void space and have a perforation shape factor and a strut angle configured to collapse the apposition layer in a first direction relative to a second direction. A first layer can be adapted to be positioned below the apposition layer, the first layer having at least one perforation. A second layer can be adapted to be positioned above the apposition layer, the second layer having at least one perforation. The system can also include a dressing adapted to cover the apposition layer to form a sealed space, and a negative-pressure source adapted to be fluidly coupled to the sealed space to provide negative pressure to the sealed space. The apposition layer can generate a closing force in the first direction that is substantially parallel to the surface of the tissue site to close the opening in response to application of a negative pressure.

[0006] Alternatively, other example embodiments include an apparatus for closing an opening through a surface of a tissue site. The apparatus can include a contracting layer adapted to be positioned over the opening. The contracting layer is formed from a material having a firmness factor, and has a plurality of holes extending through the contracting layer. The holes form a void space and have a perforation shape factor and a strut angle configured to collapse the apposition layer in a first direction relative to a second direction. The apparatus may further include a lower layer adapted to be positioned below the contracting layer, the lower layer having at least one perforation, and an upper layer adapted to be positioned above the contracting layer, the upper layer having at least one perforation. The contracting layer generates a closing force in the first direction that is substantially parallel to the surface of the tissue site to close the opening in response to application of a negative pressure.

[0007] A method for closing an opening through a surface of a tissue site is also described. An apposition layer can be encapsulated in a sheet having an upper layer above the apposition layer and a lower layer below the apposition layer, the sheet having at least

one perforation in the upper layer and at least one perforation in the lower layer. The apposition layer can be positioned over the opening. The apposition layer may be adapted to be positioned adjacent the opening and formed from a material having a firmness factor and a plurality of holes extending through the apposition layer to form a void space. The holes have a perforation shape factor and a strut angle causing the apposition layer to collapse in a direction substantially perpendicular to the opening. The apposition layer can be collapsed parallel to the surface of the tissue site to generate a closing force.

[0008] Objectives, advantages, and a preferred mode of making and using the claimed subject matter may be understood best by reference to the accompanying drawings in conjunction with the following detailed description of illustrative embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] Figure 1 is a sectional view with a portion shown in elevation of an illustrative example of a system for treating a tissue site having a dressing deployed at the tissue site;

[0010] Figure 2 is a plan view of a base layer of the dressing of Figure 1, illustrating additional details that may be associated with some embodiments;

[0011] Figure 3 is an exploded view of the dressing of Figure 1, illustrating additional details that may be associated with some embodiments;

[0012] Figure 4 is detail view of a portion of the dressing of Figure 1, illustrating additional details that may be associated with some embodiments;

[0013] Figure 5 is a plan view of an apposition layer of the system of Figure 1, illustrating additional details that may be associated with some embodiments;

[0014] Figure 6A is a plan view of the apposition layer of Figure 5 in a first position, illustrating additional details that may be associated with some embodiments;

[0015] Figure 6B is a detail view of a portion of the holes of the apposition layer of Figure 6A, illustrating additional details that may be associated with some embodiments;

[0016] Figure 6C is a plan view of the apposition layer of Figure 6A in a second position, illustrating additional details that may be associated with some embodiments;

[0017] Figure 7 is a schematic view of a hole of the apposition layer of Figure 6A having a perforation shape factor, illustrating additional details that may be associated with some embodiments;

[0018] Figure 8 is a schematic view of a hole of the apposition layer of Figure 6A having another perforation shape factor, illustrating additional details that may be associated with some embodiments;

[0019] Figure 9 is a schematic view of a hole of the apposition layer of Figure 6A having another perforation shape factor, illustrating additional details that may be associated with some embodiments;

[0020] Figure 10 is an exploded view of the apposition layer and the dressing of Figure 1 disposed over the tissue site, illustrating additional details that may be associated with some embodiments;

[0021] Figure 11 is a perspective view of the apposition layer and the dressing disposed over the tissue site in a first position, illustrating additional details that may be associated with some embodiments;

[0022] Figure 12 is a perspective view of the apposition layer and the dressing disposed over the tissue site in a second position, illustrating additional details that may be associated with some embodiments;

[0023] Figure 13A is a perspective section view of another apposition layer that may be used with the negative-pressure therapy system of Figure 1, illustrating additional details that may be associated with some embodiments;

[0024] Figure 13B is a sectional view the apposition layer of Figure 13A in a first position taken along line 13B—13B, illustrating additional details that may be associated with some embodiments;

[0025] Figure 13C is a sectional view of the apposition layer of Figure 13A in a second position, illustrating additional details that may be associated with some embodiments;

[0026] Figure 14 is a perspective view of a another apposition layer that may be used with the negative-pressure therapy system of Figure 1, illustrating additional details that may be associated with some embodiments; and

[0027] Figure 15 is a perspective view of another apposition layer that may be used with the negative-pressure therapy system of Figure 1, illustrating additional details that may be associated with some embodiments.

DESCRIPTION OF EXAMPLE EMBODIMENTS

[0028] The following description of example embodiments provides information that enables a person skilled in the art to make and use the subject matter set forth in the appended claims, but may omit certain details already well-known in the art. The following detailed description is, therefore, to be taken as illustrative and not limiting.

[0029] The example embodiments may also be described herein with reference to spatial relationships between various elements or to the spatial orientation of various elements depicted in the attached drawings. In general, such relationships or orientation assume a frame of reference consistent with or relative to a patient in a position to receive treatment. However, as should be recognized by those skilled in the art, this frame of reference is merely a descriptive expedient rather than a strict prescription.

[0030] Referring to the drawings, Figure 1 depicts an illustrative 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 Figure 1 that may extend below a tissue surface 105 of the epidermis 106. Further, the tissue site 104 may predominantly reside on the tissue surface 105 of the epidermis 106, such as, for example, an incision. Regardless of the positioning of the system 102 or the type of tissue site 104, the system 102 may provide therapy to, for example, the epidermis 106, the dermis 108, and the subcutaneous tissue 110. The system 102 may also be used without limitation at other tissue sites.

[0031] The tissue site 104 may be the bodily tissue of any human, animal, or other organism. Treatment of the tissue site 104 may include the removal of fluids, such as exudate or ascites. The term "tissue site" in this context may also broadly refer to a wound or a defect located on or within tissue, including but not limited to, bone tissue, adipose tissue, muscle tissue, neural tissue, dermal tissue, vascular tissue, connective tissue, cartilage, tendons, ligaments, or any other tissue. A wound may include chronic, acute, traumatic, subacute, and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure, or venous insufficiency ulcers), flaps, and grafts, for example. The term "tissue site" may also refer to areas of any tissue that are not necessarily wounded or defective, but are instead areas in which it may be desirable to add or promote the growth of additional tissue. For example,

negative pressure may be used at a tissue site to grow additional tissue that may be harvested and transplanted to a tissue site at another location.

[0032] A tissue site may also refer to a linear tissue site. A linear tissue site may generally refer to a tissue site having an elongated shape, such as an incision having a length substantially greater than its width. An incision may have edges that may be substantially parallel, particularly if the incision is caused by a scalpel, knife, razor, or other sharp blade. Other examples of a linear tissue site may include a laceration, a puncture, or other separation of tissue, which may have been caused by trauma, surgery, or degeneration. In some embodiments, a linear tissue site may also be an incision in an organ adjacent a fistula. In some embodiments, a linear tissue site may be an incision or puncture in otherwise healthy tissue that extends up to 40 cm or more in length. In some embodiments, a linear tissue site may also vary in depth. For example, an incision may have a depth that extends up to 15 cm or more or may be subcutaneous depending on the type of tissue and the cause of the incision.

[0033] The system 102 may include a tissue interface, such as an interface manifold 120, a contracting layer, such as an apposition layer 146, a dressing 124, and a negative-pressure source 128. 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 to fit the tissue site 104. In other embodiments, the interface manifold 120 may be omitted. The apposition layer 146 may have a thickness 126 and be enclosed by a sheet 147 and positioned over the interface manifold 120 and the tissue site 104. And the dressing 124 may be positioned over the apposition layer 146 and the interface manifold 120. The negative-pressure source 128 can be coupled to the dressing through a conduit interface 148.

[0034] The dressing 124 may include a base layer 132, an adhesive layer 136, a fluid management assembly 144, and a cover, such as a sealing member 140. The base layer 132 may be positioned over the apposition layer 146, the interface manifold 120, and the tissue surface 105 of the epidermis 106. The base layer 132 may include a plurality of apertures 160 extending through the base layer 132. The fluid management assembly 144 may be positioned over the base layer 132. The sealing member 140 can be positioned over the fluid management assembly 144. In some embodiments, a periphery of the sealing member 140 may be sealed to a periphery of the base layer 132 by the adhesive layer 136 to form an enclosure 172 containing the fluid management assembly 144. Components of the dressing 124 may be added or removed to suit particular applications.

[0035] The conduit interface 148 may be coupled to the dressing 124. The conduit interface may be coupled to the sealing member 140 so that the conduit interface 148 fluidly communicates with the enclosure 172. The conduit interface 148 may include an odor filter 194 and a first hydrophobic filter 195. The conduit interface 148 can be fluidly coupled to the negative-pressure source 128 through a conduit 196 having an internal lumen 197. In some embodiments, the conduit 196 may be coupled to the negative-pressure source through a coupling 198 of the negative-pressure source 128. A secondary hydrophobic filter 199 may be disposed in the fluid path through the coupling 198. A liquid trap 192 may be disposed in the fluid path between the conduit interface 148 and the negative-pressure source 128. For example, the conduit 196 may comprise two or more conduits. A first conduit fluidly coupled between the conduit interface 148 and the liquid trap 192, and a second conduit fluidly coupled between the liquid trap 192 and the negative-pressure source 128.

[0036] In general, components of the system 102 may be coupled directly or indirectly. For example, the negative-pressure source 128 may be directly coupled to the liquid trap 192 and indirectly coupled to the dressing 124 through the liquid trap 192. Components may be fluidly coupled to each other to provide a path for transferring fluids (i.e., liquid and/or gas) between the components.

[0037] In some embodiments, components may be fluidly coupled through a tube, such as the conduit 196. A "conduit" or "tube," as used herein, broadly refers to a tube, pipe, hose, conduit, or other structure with one or more lumina adapted to convey a fluid between two ends. Typically, a tube is an elongated, cylindrical structure with some flexibility, but the geometry and rigidity may vary. In some embodiments, components may additionally or alternatively be coupled by virtue of physical proximity, being integral to a single structure, or being formed from the same piece of material. Coupling may also include mechanical, thermal, electrical, or chemical coupling (such as a chemical bond) in some contexts.

[0038] In operation, a tissue interface, such as an interface manifold 120, may be placed within, over, on, or otherwise proximate to a tissue site. A cover, such as the sealing member 140, may be placed over a tissue interface and sealed to tissue near a tissue site. For example, the interface manifold 120 may be placed over the tissue site 104, and the sealing member 140 may be sealed to undamaged epidermis peripheral to the tissue site 104, for example, to the tissue surface 105. Thus, a cover can provide a sealed therapeutic environment or a sealed space 174 proximate to the tissue site 104 that is substantially

isolated from the external environment, and the negative-pressure source 128 may reduce the pressure in the sealed space 174.

[0039] The fluid mechanics of using a negative-pressure source to reduce pressure in another component or location, such as within a sealed therapeutic environment, can be mathematically complex. However, the basic principles of fluid mechanics applicable to negative-pressure therapy are generally well-known to those skilled in the art, and the process of reducing pressure may be described illustratively herein as "delivering," "distributing," or "generating" negative pressure, for example.

[0040] In general, exudates and other fluids flow toward lower pressure along a fluid path. Thus, the term "downstream" typically refers to a position in a fluid path relatively closer to a negative-pressure source. Conversely, the term "upstream" refers to a position relatively further away from a negative-pressure source. Similarly, it may be convenient to describe certain features in terms of fluid "inlet" or "outlet" in such a frame of reference. This orientation is generally presumed for purposes of describing various features and components of negative-pressure therapy systems herein. However, the fluid path may also be reversed in some applications (such as by substituting a positive-pressure source for a negative-pressure source) and this descriptive convention should not be construed as a limiting convention.

[0041] "Negative pressure" generally refers to a pressure less than a local ambient pressure, such as the ambient pressure in a local environment external to a sealed therapeutic environment provided by the dressing 124. In many cases, the local ambient pressure may also be the atmospheric pressure at which a tissue site is located. Alternatively, the pressure may be less than a hydrostatic pressure associated with tissue at the tissue site. Unless otherwise indicated, values of pressure stated herein are gauge pressures. Similarly, references to increases in negative pressure typically refer to a decrease in absolute pressure, while decreases in negative pressure typically refer to an increase in absolute pressure. While the amount and nature of negative pressure applied to a tissue site may vary according to therapeutic requirements, the pressure is generally a low vacuum, also commonly referred to as a rough vacuum, between -5 mm Hg (-667 Pa) and -500 mm Hg (-66.7 kPa). Common therapeutic ranges are between -75 mm Hg (-9.9 kPa) and -300 mm Hg (-39.9 kPa).

[0042] A negative-pressure supply, such as the negative-pressure source 128, may be a reservoir of air at a negative pressure, or may be a manual or electrically-powered device

that can reduce the pressure in a sealed volume, such as a vacuum pump, a suction pump, a wall suction port available at many healthcare facilities, or a micro-pump, for example. A negative-pressure supply may be housed within or used in conjunction with other components, such as sensors, processing units, alarm indicators, memory, databases, software, display devices, or user interfaces that further facilitate therapy. For example, in some embodiments, the negative-pressure source 128 may be combined with controllers and other components into a therapy unit. A negative-pressure supply may also have one or more supply ports configured to facilitate coupling and de-coupling the negative-pressure supply to one or more distribution components.

[0043] The interface manifold 120 can be generally adapted to contact a tissue site. The interface manifold 120 may be partially or fully in contact with the tissue site. If the tissue site is a wound, for example, the interface manifold 120 may partially or completely fill the wound, or may be placed over the wound. The interface manifold 120 may take many forms, and may have many sizes, shapes, or thicknesses depending on a variety of factors, such as the type of treatment being implemented or the nature and size of a tissue site. For example, the size and shape of the interface manifold 120 may be adapted to the contours of deep and irregular shaped tissue sites. Moreover, any or all of the surfaces of the interface manifold 120 may have projections or an uneven, course, or jagged profile that can induce strains and stresses on a tissue site, which can promote granulation at the tissue site.

[0044] In some illustrative embodiments, the pathways of a manifold may be interconnected to improve distribution or collection of fluids across a tissue site. In some illustrative embodiments, a manifold may be a porous foam material having interconnected cells or pores. For example, cellular foam, open-cell foam, reticulated foam, porous tissue collections, and other porous material such as gauze or felted mat generally include pores, edges, and/or walls adapted to form interconnected fluid channels. Liquids, gels, and other foams may also include or be cured to include apertures and fluid pathways. In some embodiments, a manifold may additionally or alternatively comprise projections that form interconnected fluid pathways. For example, a manifold may be molded to provide surface projections that define interconnected fluid pathways.

[0045] The average pore size of a foam may vary according to needs of a prescribed therapy. For example, in some embodiments, the interface manifold 120 may be a foam having pore sizes in a range of 400-600 microns. The tensile strength of the interface manifold 120 may also vary according to needs of a prescribed therapy. For example, the

tensile strength of a foam may be increased for instillation of topical treatment solutions. In one non-limiting example, the interface manifold 120 may be an open-cell, reticulated polyurethane foam such as GranuFoam® dressing or VeraFlo® foam, both available from Kinetic Concepts, Inc. of San Antonio, Texas.

[0046] The interface manifold 120 may be either hydrophobic or hydrophilic. In an example in which the interface manifold 120 may be hydrophilic, the interface manifold 120 may also wick fluid away from a tissue site, while continuing to distribute negative pressure to the tissue site. The wicking properties of the interface manifold 120 may draw fluid away from a tissue site by capillary flow or other wicking mechanisms. An example of a hydrophilic foam is a polyvinyl alcohol, open-cell foam such as V.A.C. WhiteFoam® dressing available from Kinetic Concepts, Inc. of San Antonio, Texas. Other hydrophilic foams may include those made from polyether. Other foams that may exhibit hydrophilic characteristics include hydrophobic foams that have been treated or coated to provide hydrophilicity.

[0047] The interface manifold 120 may further promote granulation at a tissue site when pressure within the sealed therapeutic environment is reduced. For example, any or all of the surfaces of the interface manifold 120 may have an uneven, coarse, or jagged profile that can induce microstrains and stresses at a tissue site if negative pressure is applied through the interface manifold 120.

[0048] In some embodiments, the interface manifold 120 may be constructed from bioresorbable materials. Suitable bioresorbable materials may include, without limitation, a polymeric blend of polylactic acid (PLA) and polyglycolic acid (PGA). The polymeric blend may also include without limitation polycarbonates, polyfumarates, and capralactones. The interface manifold 120 may further serve as a scaffold for new cell-growth, or a scaffold material may be used in conjunction with the interface manifold 120 to promote cell-growth. A scaffold is generally a substance or structure used to enhance or promote the growth of cells or formation of tissue, such as a three-dimensional porous structure that provides a template for cell growth. Illustrative examples of scaffold materials include calcium phosphate, collagen, PLA/PGA, coral hydroxy apatites, carbonates, or processed allograft materials.

[0049] The sealing member 140 may be formed from a material that allows for a fluid seal. A fluid seal may be a seal adequate to maintain negative pressure at a desired site given

the particular negative 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.

[0050] The sealing member 140 may be vapor permeable and 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 may be used. The sealing member 140 may comprise a range of medically suitable films having a thickness between about 25 microns (μm) to about 50 microns (μm).

[0051] An attachment device, such as the adhesive layer 136, may be used to attach the sealing member 140 to an attachment surface, such as undamaged epidermis, a gasket, another cover, or the base layer 132. The attachment device may take many forms. For example, an attachment device may be a medically-acceptable, pressure-sensitive adhesive that extends about a periphery, a portion, or an entire sealing member. In some embodiments, for example, some or all of the sealing member 140 may be coated with an acrylic adhesive having a coating weight between 25-65 grams per square meter (g.s.m.). Thicker adhesives, or combinations of adhesives, may be applied in some embodiments to improve the seal and reduce leaks. Other example embodiments of an attachment device may include a double-sided tape, paste, hydrocolloid, hydrogel, silicone gel, or organogel.

[0052] In some embodiments, the adhesive layer 136 may be deformable or flowable. For example, the adhesive layer 136 may comprise an acrylic adhesive, rubber adhesive, high-tack silicone adhesive, polyurethane, or other adhesive substance. In some

embodiments, the adhesive layer 136 may be a pressure-sensitive adhesive comprising an acrylic adhesive. The adhesive layer 136 may be continuous or discontinuous. Discontinuities in the adhesive layer 136 may be provided by the apertures (not shown) in the adhesive layer 136. The apertures in the adhesive layer 136 may be formed after application of the adhesive layer 136 or by coating the adhesive layer 136 in patterns on a carrier layer, such as, for example, a side of the sealing member 140 adapted to face the tissue surface 105 of the epidermis 106. The apertures in the adhesive layer 136 may also be sized to enhance the Moisture Vapor Transfer Rate (MVTR) of the dressing 124, described further herein.

[0053] A fluid storage device, such as the fluid management assembly 144, may be an example of a device to configured to store liquids in the dressing 124. The fluid management assembly 144 may include a first dressing wicking layer 176, a second dressing wicking layer 180, and an absorbent layer 184. The first dressing wicking layer 176 is positioned adjacent to the base layer 132, and the absorbent layer 184 is positioned adjacent the first dressing wicking layer 176. The second dressing wicking layer 180 may be positioned over the absorbent layer 184 and peripheries of the first dressing wicking layer 176 and the second dressing wicking layer 180 may be coupled to each other to form a wicking layer enclosure 188 containing the absorbent layer 184. In some embodiments, an anti-microbial layer 190 may be disposed in the wicking layer enclosure 188 between the first dressing wicking layer 176 and the absorbent layer 184. In some embodiments, the wicking layer enclosure 188 may surround or otherwise encapsulate the absorbent layer 184 between the first dressing wicking layer 176 and the second dressing wicking layer 180.

[0054] In some embodiments, the absorbent layer 184 may be in fluid communication with the first dressing wicking layer 176 and the second dressing wicking layer 180. The first dressing wicking layer 176 may have a grain structure adapted to wick fluid along a surface of the first dressing wicking layer 176. Similarly, the second dressing wicking layer 180 may have a grain structure adapted to wick fluid along a surface of the second dressing wicking layer 180. For example, the first dressing wicking layer 176 and the second dressing wicking layer 180 may wick or otherwise transport fluid in a lateral direction along the surfaces of the first dressing wicking layer 176 and the second dressing wicking layer 180, respectively. The surface of the first dressing wicking layer 176 may be normal relative to the thickness of the first dressing wicking layer 176, and the surface of the second dressing wicking layer 180 may be normal relative to the thickness of the second dressing wicking layer 180. The wicking of fluid along the first dressing wicking layer 176 and the second dressing wicking

layer 180 may enhance the distribution of the fluid over a surface area of the absorbent layer 184, which 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 dressing wicking layer 176, the second dressing wicking layer 180, and the absorbent layer 184 may be adapted as described above to maintain an open structure, resistant to blockage, capable of maintaining fluid communication with, for example, the tissue site 104.

[0055] 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, the absorbent layer 184 may be a plurality of absorbent layers 184 positioned in fluid communication between the first dressing wicking layer 176 and the second dressing wicking layer 180. Further, in some embodiments, at least one intermediate wicking layer may be disposed in fluid communication between the plurality of absorbent layers 184. Similar to the absorbent layer 184, the plurality of absorbent layers 184 and the at least one intermediate wicking layer may be positioned within the wicking layer enclosure 188. In some embodiments, the absorbent layer 184 may be disposed between the sealing member 140 and the interface manifold 120, and the first dressing wicking layer 176 and the second dressing wicking layer 180 may be omitted.

[0056] 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, without limitation, super absorbent polymers and similar absorbent materials; Luquafleece® material; TEXSUS FP2326; BASF 402C; Technical Absorbents 2317, available from Technical Absorbents, Ltd. of Lincolnshire, United Kingdom; sodium polyacrylate super absorbers; cellulosics (carboxy methyl cellulose and salts such as sodium CMC); or alginates. Materials suitable for the first dressing wicking layer 176 and the second dressing wicking layer 180 may include, without limitation, any material having a grain structure capable of wicking fluid as described herein, such as, for example, LIBELTEX TDL2, 80gsm, or similar materials, which may be non-woven.

[0057] The fluid management assembly 144 may be manufactured as a pre-laminated structure, or supplied as individual layers of material that can be 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 of the base layer 132 in any suitable manner, such as, for example, by a weld or an adhesive. The border, being free of the apertures 160 as described herein, may provide a flexible barrier between the fluid management assembly 144 and the tissue site 104 for enhancing comfort.

[0058] 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, 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 a similar compound, for example. In some embodiments, the anti-microbial agent may be formulated in any suitable manner and associated with other components of the dressing 124.

[0059] The dressing 124 may be modified in various embodiments to suit a particular application. In some embodiments, the absorbent layer 184 may be omitted from the fluid management assembly 144, which may be beneficial, but not required, for communicating fluid exterior to or away from the dressing 124 and the tissue site 104 for offsite or remote storage. In such an embodiment, the first dressing wicking layer 176 and the second dressing wicking layer 180 may wick or draw fluid away from the tissue site 104 for transport to a location exterior to the dressing 124. Further, the configuration of the first dressing wicking layer 176 and the second dressing wicking layer 180 described herein may preference fluid away from the tissue site 104 and prevent the fluid from returning to the tissue site 104 prior to removal of the fluid from the dressing 124, for example, by the application of negative pressure. The wicking layer enclosure 188 may enhance this ability to preference fluid away from the tissue site 104 and to prevent the fluid from returning to the tissue site 104.

[0060] The dressing 124 may be further modified in various embodiments that may be suitable for some applications that communicate fluid from the tissue site 104 exterior to the dressing 124. For example, in some embodiments, the first dressing wicking layer 176 or the second dressing wicking layer 180 may be omitted along with the absorbent layer 184 and the base layer 132. In such an embodiment, the dressing 124 may comprise the sealing member 140 and one of the first dressing wicking layer 176 or the second dressing wicking layer 180 for disposing in the sealed space 174 between the sealing member 140 and the tissue site 104. Further, in some embodiments, the fluid management assembly 144 may be

omitted from the dressing 124, and a dressing manifold (not shown) may be positioned in the enclosure 172 in place of the fluid management assembly 144. The dressing manifold may be configured as a layer and may be comprised of any material suitable for removing fluids from a tissue site through a plurality of pores, pathways, or flow channels as described herein, such as, without limitation, a foam, a woven material, a cast silicone, a polyurethane material, or any of the materials recited for the interface manifold 120. Further, in some embodiments, the dressing 124 may be modified by omitting the base layer 132 and replacing the fluid management assembly 144 with the above-described dressing manifold. In such an embodiment, the dressing 124 may comprise the sealing member 140 and the dressing manifold for disposing in the sealed space 174 between the sealing member 140 and the tissue site 104. Further, in some embodiments, the absorbent layer 184 may be omitted and replaced with the dressing manifold such that the dressing manifold is positioned between the first dressing wicking layer 176 and the second dressing wicking layer 180.

[0061] A dressing interface, such as the conduit interface 148 may be positioned proximate to a cover and in fluid communication with the sealed space 174 provided by the dressing 124. For example, the conduit interface 148 may be in fluid communication with the dressing 124 through an aperture in the sealing member 140. The conduit interface 148 may provide negative pressure from the negative-pressure source 128 to the dressing 124. The conduit interface 148 may also be adapted to be positioned in fluid communication with the interface manifold 120.

[0062] 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. In some illustrative, non-limiting embodiments, the 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.

[0063] 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.

[0064] 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.

[0065] The conduit interface 148 may carry the 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 the first hydrophobic filter 195 adapted to substantially preclude the passage of liquids through the first hydrophobic filter 195. The odor filter 194 and the first hydrophobic filter 195 may be disposed in the conduit interface 148 or other suitable location such that fluid communication between the negative-pressure source 128 and the dressing 124 is provided through the odor filter 194 and the first hydrophobic filter 195. In some embodiments, the odor filter 194 and the first hydrophobic filter 195 may be secured within the conduit interface 148 in a suitable manner, such as by adhesive or welding. In other embodiments, the odor filter 194 or the first hydrophobic filter 195 may be omitted, or positioned proximate to an exit location in the system 102 or the dressing 124 that is in fluid communication with the atmosphere, the negative-pressure source 128, or the optional therapy unit.

[0066] 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. The first hydrophobic filter 195 may be comprised of a material that is liquid

impermeable and vapor permeable. For example, the first 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 first hydrophobic filter 195 may be provided in the form of a membrane or layer.

[0067] The liquid trap 192 is representative of a container, canister, pouch, or other storage component, which can be used to manage exudates and other fluids withdrawn from a tissue site. In many environments, a rigid container may be preferred or required for collecting, storing, and disposing of fluids. In other environments, fluids may be properly disposed of without rigid container storage, and a re-usable container could reduce waste and costs associated with negative-pressure therapy.

[0068] Similar to the conduit interface 148, the liquid trap 192, and other components of the system 102, 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.

[0069] 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.

[0070] The conduit 196 may have the internal lumen 197 and may be fluidly coupled between the negative-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. In some embodiments, the internal diameter of the internal lumen 197 may be between 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 negative-pressure source 128. The conduit interface 148 may be fluidly coupled to the conduit 196 in a suitable manner, such as, for example, by an adhesive, solvent or non-solvent bonding, welding, or interference fit. An aperture in the sealing member 140 may provide fluid communication between the dressing 124 and the conduit interface 148. For example, the conduit interface 148 may be in fluid communication with the enclosure 172 or the sealed space 174 through the aperture in the sealing member 140. In some embodiments, the conduit 196 may be inserted into the dressing 124 through the aperture in the sealing member 140 to provide fluid communication with the negative-pressure source 128 without use of the conduit interface 148. The negative-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. In some embodiments, 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 negative-pressure source 128.

[0071] The conduit 196 may have the secondary hydrophobic filter 199 disposed in the internal lumen 197 such that fluid communication between the negative-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 negative-pressure source 128, rather than the dressing 124, may allow a user to detect the presence of liquid in the internal lumen 197.

[0072] 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.

[0073] Figure 2 is a plan view of the base layer 132 of the dressing 124 of Figure 1, illustrating additional details that may be associated with some embodiments. The base layer 132 may have a periphery 152 surrounding a central portion 156, and the plurality of apertures 160 are 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. In some embodiments, the border 161 may be free of the apertures 160. In some embodiments, the base layer 132 may be adapted to cover the interface manifold 120 or the apposition layer 146 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 or the apposition layer 146, and the periphery 152 of the base layer 132 is positioned adjacent to or proximate to the tissue surface 105 surrounding the tissue site 104. In such embodiments, the periphery 152 of the base layer 132 may surround the interface manifold 120 or the apposition layer 146. Further, the apertures 160 in the base layer 132 may be in fluid communication with the interface manifold 120 and the tissue surface 105 surrounding the tissue site 104.

[0074] The apertures 160 in the base layer 132 may have a variety of shapes, such as, circles, squares, stars, ovals, polygons, slits, complex curves, rectilinear shapes, triangles, or other shapes. The apertures 160 may be formed by cutting (such as laser cutting), by application of local RF energy, punching, or other suitable techniques for forming an

opening. Each of the apertures 160 of the plurality of apertures 160 may be substantially circular in shape, having a diameter and an area. 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.

[0075] 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 between about 1 millimeter to about 50 millimeters. In some embodiments, the diameter of each of the apertures 160 may be between 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.

[0076] In some embodiments, the apertures 160 positioned in the periphery 152 may be apertures 160a, the apertures 160 positioned at the corners 158 of the periphery 152 may be apertures 160b, and the apertures 160 positioned in the central portion 156 may be apertures 160c. In some embodiments, the apertures 160a may have an area greater than the apertures 160b. Further, the apertures 160b may have an area greater than the apertures 160c. The dimensions of the base layer 132 may be increased or decreased, for example, substantially in proportion to one another to suit a particular application.

[0077] The apertures 160a may have a diameter between about 9.8 millimeters to about 10.2 millimeters. The apertures 160b may have a diameter between about 7.75 millimeters to about 8.75 millimeters. The apertures 160c may have a diameter between about 1.8 millimeters to about 2.2 millimeters. The diameter of each of the apertures 160a may be separated from one another by a distance A between about 2.8 millimeters to about 3.2 millimeters. Further, the diameter of at least one of the apertures 160a may be separated from the diameter of at least one of the apertures 160b by the distance A. The diameter of

each of the apertures 160b may also be separated from one another by the distance A. A center of one of the apertures 160c may be separated from a center of another of the apertures 160c in a first direction by a distance B between about 2.8 millimeters to about 3.2 millimeters. In a second direction transverse to the first direction, the center of one of the apertures 160c may be separated from the center of another of the apertures 160c by a distance C between about 2.8 millimeters to about 3.2 millimeters. The distance B and the distance C may be increased for the apertures 160c in the central portion 156 being positioned proximate to or at the border 161 compared to the apertures 160c positioned away from the border 161.

[0078] The central portion 156 of the base layer 132 may be substantially square with each side of the central portion 156 having a length D between about 100 millimeters to about 108 millimeters. In some embodiments, the length D may be between about 106 millimeters to about 108 millimeters. The border 161 of the base layer 132 may have a width E between about 4 millimeters to about 11 millimeters and may substantially surround the central portion 156 and the apertures 160c in the central portion 156. In some embodiments, the width E may be between about 9 millimeters to about 10 millimeters. The periphery 152 of the base layer 132 may have a width F between about 25 millimeters to about 35 millimeters and may substantially surround the border 161 and the central portion 156. In some embodiments, the width F may be between about 26 millimeters to about 28 millimeters. Further, the periphery 152 may have a substantially square exterior with each side of the exterior having a length G between about 154 millimeters to about 200 millimeters. In some embodiments, the length G may be between about 176 millimeters to about 184 millimeters. Although the central portion 156, the border 161, and the periphery 152 of the base layer 132 are depicted as having a substantially square shape, these and other components of the base layer 132 may have any shape to suit a particular application. Further, the dimensions of the base layer 132 as described herein may be increased or decreased, for example, substantially in proportion to one another to suit a particular application. The use of the dimensions in the proportions described above may enhance the cosmetic appearance of a tissue site. For example, these proportions may provide a surface area for the base layer 132, regardless of shape, that is sufficiently smooth to enhance the movement and proliferation of epithelial cells at the tissue site 104, and reduce the likelihood of granulation tissue in-growth into the dressing 124.

[0079] 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 gel, a foamed gel, a soft closed cell foam such as polyurethanes and polyolefins coated with an adhesive as 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 may have a stiffness between about 5 Shore OO and about 80 Shore OO. Further, in some embodiments, the base layer 132 may be comprised of hydrophobic or hydrophilic materials.

[0080] 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 layer 136 may extend through openings in the spaced material analogous to the apertures 160.

[0081] Figure 3 is an exploded view of the dressing 124 of Figure 1, illustrating additional details that may be associated with some embodiments. A release liner 162 may be attached to or positioned adjacent to the base layer 132 to protect the adhesive layer 136 prior to application of the dressing 124 to the tissue site 104. The fluid management assembly 144 may be disposed over the base layer 132. In some embodiments, the fluid management assembly 144 may be disposed over the central portion 156 so that the apertures 160c are in fluid communication with the fluid management assembly 144. Preferably, the fluid management assembly 144 may be bounded by the border 161 inboard of the periphery 152 of the base layer 132. The adhesive layer 136 may be disposed over the periphery 152. In some embodiments, the adhesive layer 136 may be a ring surrounding the fluid management assembly 144. The adhesive layer 136 may be bounded by the edges 159 of the base layer 132 and the border 161. The sealing member 140 may be disposed over the adhesive layer 136 and the fluid management assembly 144. The sealing member 140 can be coupled to the adhesive layer 136. The sealing member 140 may include an aperture 170 formed near a center of the sealing member 140.

[0082] 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 layer 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 fluorosilicone. In other embodiments, the release liner 162 may be uncoated or otherwise used without a release agent.

[0083] A periphery of the sealing member 140 may be positioned proximate to the periphery 152 of the base layer 132 such that a central portion of the sealing member 140 and the central portion 156 of the base layer 132 define the enclosure 172. The adhesive layer 136 may be positioned at least between the periphery of the sealing member 140 and the periphery 152 of the base layer 132. In some embodiments, a portion of the periphery of the sealing member 140 may extend beyond the periphery 152 of the base layer 132. In other embodiments, the periphery of the sealing member 140 may be positioned in contact with the tissue surface 105 surrounding the tissue site 104 to provide the sealed space 174 without the base layer 132. Thus, the adhesive layer 136 may also be positioned at least between the periphery of the sealing member 140 and the tissue surface 105 surrounding the tissue site 104. The adhesive layer 136 may be disposed on a surface of the sealing member 140 adapted to face the tissue site 104 and the base layer 132.

[0084] In some embodiments, the adhesive layer 136 may be a layer having substantially the same shape as the periphery 152 of the base layer 132. The adhesive layer 136 may be exposed to at least the apertures 160b in at least the periphery 152 of the base layer 132. The adhesive layer 136 may be positioned adjacent to, or positioned in fluid

communication with, at least the apertures 160b in at least the periphery 152 of the base layer 132.

[0085] Figure 4 is a detail view of a portion of the dressing 124 of Figure 1, illustrating additional details that may be associated with some embodiments. The adhesive layer 136 may be exposed to or in fluid communication with the tissue surface 105 surrounding the tissue site 104 through at least the apertures 160b in the base layer 132. The adhesive layer 136 may extend, deform, or be pressed through at least the plurality of apertures 160b to contact the tissue surface 105 of the epidermis 106 for securing the dressing 124 to, for example, the tissue surface 105 surrounding the tissue site 104. At least the apertures 160b may provide sufficient contact of the adhesive layer 136 to the tissue surface 105 of the epidermis 106 to secure the dressing 124 about the tissue site 104. However, the configuration of at least the apertures 160b and the adhesive layer 136 may permit release and repositioning of the dressing 124 about the tissue site 104.

[0086] In some embodiments, the apertures 160b at the corners 158 of the periphery 152 may be smaller than the apertures 160a in other portions of the periphery 152. For a given geometry of the corners 158, the smaller size of the apertures 160b compared to the apertures 160a may enhance or increase the surface area of the adhesive layer 136 exposed to the apertures 160b and to tissue through the apertures 160b at the corners 158. The size and number of the apertures 160b in the corners 158 may be adjusted as necessary, depending on the chosen geometry of the corners 158, to enhance or increase the exposed surface area of the adhesive layer 136 as described herein.

[0087] Similar to the apertures 160b in the corners 158, any of the apertures 160 may be adjusted in size and number to increase the surface area of the adhesive layer 136 exposed to or in fluid communication with the apertures 160 for a particular application or geometry of the base layer 132. For example, in some embodiments (not shown) the apertures 160b, or apertures of another size, may be positioned in the periphery 152 and at the border 161. Similarly, the apertures 160b, or apertures of another size, may be positioned as described herein in other locations of the base layer 132 that may have a complex geometry or shape.

[0088] Factors that may be utilized to control the adhesion strength of the dressing 124 may include the diameter, area, 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 layer 136, and the tackiness of the adhesive layer 136. An increase in the amount of the adhesive layer 136

extending through the apertures 160 may correspond to an increase in the adhesion strength of the dressing 124. A decrease in the thickness of the base layer 132 may correspond to an increase in the amount of adhesive layer 136 extending through the apertures 160. Thus, the diameter, area, 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.

[0089] In some embodiments, the tackiness of the adhesive layer 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 layer 136 may have a lower tackiness than other locations of the base layer 132 where the apertures 160 are smaller, such as the apertures 160b and 160c. In this manner, locations of the base layer 132 having larger apertures 160 and a lower tackiness of the adhesive layer 136 may have an adhesion strength comparable to locations having smaller apertures 160 and a higher tackiness of the adhesive layer 136.

[0090] For low-acuity tissue sites, i.e., tissue sites that do not produce large amounts of fluids, a storage container, such as the liquid trap 192 may provide more capacity than is needed. In some cases, a patient with a low acuity tissue site may be mobile. To increase a patient's mobility, some dressings include an absorbent component, such as the fluid management assembly 144, to store liquid produced by the tissue site during therapy. By including an absorbent component in the dressing, the dressing is able to provide a sealed space for therapy without requiring a patient to carry a secondary storage device. Such dressings are a useful tool for the provision of negative-pressure therapy.

[0091] Dressings for low-acuity tissue sites may often be what is considered a peel-and-place dressing. A peel-and-place dressing can be a dressing that is manufactured to include a plurality of components, permitting a user to simply expose an adhesive portion of the dressing and apply the dressing over the tissue site. Such peel-and-place dressings are often sized to provide coverage of a variety of tissue sites.

[0092] For some ambulatory patients, the tissue site, while low-acuity, may nonetheless benefit from the application of a closing force or an apposition force to encourage closure of the tissue site. A closing force may be a force that is substantially parallel to the tissue surface 105 and urges opposing sides of a tissue site toward each other to close an opening of the tissue site. Closure of an opening may help maintain a healing

environment for internal structures of a tissue site, as well as inhibit entry of bacteria or other harmful substances into the tissue site. For example, a linear tissue site, such as a surgical incision, may be a low-acuity tissue site; however, a surgical incision may be prone to opening during movement. As a result, an ambulatory patient may benefit from additional closing forces, forces generally parallel to the tissue surface 105 that urge an opening to close, encouraging the surgical incision to remain closed. However, many devices used to provide a closing force are not suitable for use with a peel and place dressing. For example, the device used to provide a closing force may be bulky, causing the peel-and-place dressing to be unable to seal around the device. Other devices may need additional components to prevent further trauma to a tissue site. The additional components may prevent the peel-and-place dressing from forming a seal around the tissue site, or may inhibit the transmission of negative pressure to the tissue site. Some peel-and-place devices overcome these issues by providing a peel-and-place dressing that includes a closing device. Such devices provide both dressing liquid storage and a closing force; however, they may not be customizable for different wounds, preventing dynamic placement of the device.

[0093] The system 102 having the dressing 124 can provide a peel-and-place dressing having a customizable closing device for dynamic application of a closing force to a tissue site. For example, the system 102 may include the apposition layer 146. The apposition layer 146 may be customized to selectively apply a closing or apposition force to a tissue site. The dressing 124 may also supply negative pressure and store liquid produced by the tissue site in the dressing. The apposition layer 146 may also be sizeable to provide apposition forces to an irregularly shaped tissue site, or to a discontinuous tissue site. The apposition layer 146 may also be customizable to provide apposition forces to a non-linear tissue site, such as a curved incision.

[0094] Figure 5 is a plan view, illustrating additional details that may be associated with some embodiments of the apposition layer 146. A sheet 147 may be disposed on a surface of the apposition layer 146. The sheet 147 may be positioned on a surface of the apposition layer 146 intended to contact the interface manifold 120 or the tissue surface 105 surrounding the tissue site 104. The sheet 147 can also encapsulate the apposition layer 146. For example, the sheet 147 may surround all surfaces of the apposition layer 146. For example, the sheet 147 may comprise a continuous sheet of material, the sheet 147 can be wrapped around the apposition layer 146 and coupled to itself, for example, by adhering, welding, bonding, or otherwise securing, to encapsulate the apposition layer 146. In other

embodiments, the sheet 147 may comprise an first layer or upper layer and a second layer or lower layer. The first layer can be disposed over the apposition layer 146 and the second layer can be disposed under the apposition layer 146. The first layer and the second layer can be coupled to each other. In some embodiments, the sheet 147 may be wrapped around the apposition layer 146 without otherwise securing it to itself, allowing friction following the application of negative pressure to hold the sheet 147 in position. In other embodiments, the sheet 147 may be cut to an approximate size of a surface of the apposition layer 146. The sheet 147 may be coupled to the surface of the apposition layer 146 to secure the sheet 147 to the apposition layer 146. For example, the sheet 147 may be welded or bonded to the surface of the apposition layer 146, such as with an acrylic adhesive.

[0095] The sheet 147 may have at least one perforation and, preferably, a plurality of perforations 149. For example, the first layer may have at least one perforation and the second layer may have at least one perforation. Each of the perforations 149 can have an effective diameter of about 2 mm or less. An effective diameter of a non-circular area may be defined as a diameter of a circular area having the same surface area as the non-circular area. The perforations 149 may have a pitch of about 3 mm. Pitch describes a spacing between objects having translational symmetry. The perforations 149 may have a pitch between adjacent perforations 149 in orthogonal directions. The pitch of the perforations 149 may be parallel to edges of the sheet 147. In some embodiments, adjacent rows of perforations 149 may be offset. For example, a first row of perforations 151 may have a pitch of 3 mm parallel to an edge of the sheet 147. A second row of perforations 153 adjacent to the first row of perforations 149 may be offset so that a center of each perforation 149 is equidistant from the centers of adjacent perforations 149 in the adjacent rows. In this manner, the perforations 149 may be regularly spaced across the sheet 147. In other embodiments, the pitch between adjacent perforations 149 may not be regularly repeating, may not be parallel to edges of the sheet 147, and may not be continuous across the sheet 147.

[0096] The sheet 147 may be formed from silicone having a coat weight between about 100 gsm and about 200 gsm. In other embodiments, the sheet 147 may be formed from a hydrogel that has been cross-linked sufficient to prevent absorption, dissociation, mobility, and breakdown or a polyurethane having a thickness of about 50 microns to about 200 microns. In some embodiments, the sheet 147 may be coated onto a non-woven scrim layer. The non-woven scrim layer may have a coating weight of about 25 gsm to about 100 gsm,

corresponding to a thickness of about 25 microns to 100 microns. The scrim layer may be formed from polyurethane, polyamide, polyester, or cellulosic material. The hydrogel of the sheet 147 may be coated on one or both sides of the scrim layer. In other embodiments, the sheet 147 may be coated onto a mesh scrim layer or formed without the use of a scrim. The sheet 147 may be provided in sheets having a length of about 200 mm. The sheet 147 may be adherent, permitting the sheet 147 to adhere to the apposition layer 146 and the interface manifold 120. If the sheet 147 is adherent, the sheet 147 may have a peel force between about 0.5N/25mm and about 6N/25mm. The peel forces is the measure of the average force required to part two materials bonded by an adhesive.

[0097] The sheet 147 may mimic the base layer 132 in operation and benefits to the healing of a tissue site. For example, the sheet 147 may aid in scar reduction of an incisional tissue site. The sheet 147 may prevent ingrowth into layers or bodies disposed over the sheet 147, such as the apposition layer 146. The sheet 147 may also act as a comfort layer, aiding in pain free application of therapy.

[0098] The apposition layer 146 may include a plurality of holes 602 or perforations extending through the apposition layer 146 to form walls 608 extending through the apposition layer 146. In some embodiments, the walls 608 may be generally parallel to a thickness of the apposition layer 146. In other embodiments, the walls 608 may be generally perpendicular to a surface of the apposition layer 146. In some embodiments, the holes 602 may have an ellipsoid shape as shown.

[0099] Figure 6A is a plan view, illustrating additional details that may be associated with some embodiments of the apposition layer 146 disposed over the tissue site 104 so that the apposition layer 146 may be proximate to the tissue surface 105. The sheet 147 is not shown to aid in illustration of features of the apposition layer 146. The apposition layer 146 may be formed from a foam. For example, cellular foam, open-cell foam, reticulated foam, or porous tissue collections, may be used to form the apposition layer 146. In some embodiments, the apposition layer 146 may be formed of GranuFoam®, grey foam, or Zotefoam. Grey foam may be a polyester polyurethane foam having about 60 pores per inch (ppi). Zotefoam may be a closed-cell crosslinked polyolefin foam. The apposition layer 146 can also be formed from a polyvinyl alcohol (PVA) foam or a 3D foam. In one non-limiting example, the apposition layer 146 may be an open-cell, reticulated polyurethane foam such as GranuFoam® dressing available from Kinetic Concepts, Inc. of San Antonio, Texas; in other

embodiments, the apposition layer 146 may be an open-cell, reticulated polyurethane foam such as a VeraFlo® foam, also available from Kinetic Concepts, Inc., of San Antonio, Texas.

[00100] In some embodiments, the apposition layer 146 may be formed from a foam that is mechanically or chemically compressed to increase the density of the foam at ambient pressure. A foam that is mechanically or chemically compressed may be referred to as a compressed foam or a felted foam. A compressed foam may be characterized by a firmness factor (FF) that can be defined as a ratio of the density of a foam in a compressed state to the density of the same foam in an uncompressed state. For example, a firmness factor (FF) of 5 may refer to a compressed foam having a density that is five times greater than a density of the same foam in an uncompressed state. Mechanically or chemically compressing a foam may reduce a thickness of the foam at ambient pressure when compared to the same foam that has not been compressed. Reducing a thickness of a foam by mechanical or chemical compression may increase a density of the foam, which may increase the firmness factor (FF) of the foam. Increasing the firmness factor (FF) of a foam may increase a stiffness of the foam in a direction that is parallel to a thickness of the foam. For example, increasing a firmness factor (FF) of the apposition layer 146 may increase a stiffness of the apposition layer 146 in a direction that is parallel to the thickness 126 of the apposition layer 146. In some embodiments, the apposition layer 146 may have a thickness of about 6 mm. In other embodiments, the thickness 126 may be between about 5 mm and about 10 mm. In some embodiments, a compressed foam may be a compressed GranuFoam®. GranuFoam® may have a density of about 0.03 grams per centimeter^3 (g/cm^3) in its uncompressed state. If the GranuFoam® is compressed to have a firmness factor (FF) of 5, the GranuFoam® may be compressed until the density of the GranuFoam® is about 0.15g/cm^3. VeraFlo® foam may also be compressed to form a compressed foam having a firmness factor (FF) up to 5.

[00101] The firmness factor (FF) may also be used to compare compressed foam materials with non-foam materials. For example, a Supracor® material may have a firmness factor (FF) that allows Supracor® to be compared to compressed foams. In some embodiments, the firmness factor (FF) for a non-foam material may represent that the non-foam material has a stiffness that is equivalent to a stiffness of a compressed foam having the same firmness factor. For example, if the apposition layer 146 is formed from Supracor®, the apposition layer 146 may have a stiffness that is about the same as the stiffness of a compressed GranuFoam® material having a firmness factor (FF) of 3. Generally, a material

having a firmness factor (FF) of about 1 may have a stiffness of about 5 kPa. A stiffness of 5 kPa requires the application of about 5 kPa to compress the material to 50% of its original thickness. A material having a firmness factor (FF) of about 3 corresponds to the application of about 15 kPa to compress the material to 50% of its original thickness, that is, a stiffness of about 15 kPa. The apposition layer 146 may have a stiffness between about 10 kPa to about 20 kPa.

[00102] Generally, if a compressed foam is subjected to negative pressure, the compressed foam exhibits less deformation than a similar uncompressed foam. If the apposition layer 146 is formed of a compressed foam, the thickness 126 of the apposition layer 146 may deform less than if the apposition layer 146 is formed of a comparable uncompressed foam. The decrease in deformation may be caused by the increased stiffness as reflected by the firmness factor (FF). If subjected to the stress of negative pressure, the apposition layer 146 formed of compressed foam may flatten less than the apposition layer 146 that is formed from uncompressed foam. Consequently, when negative pressure is applied to the apposition layer 146, the stiffness of the apposition layer 146 in the direction parallel to the thickness 126 of the apposition layer 146 allows the apposition layer 146 to be more compliant or compressible in other directions, e.g., a direction parallel to the tissue surface 105 or in a direction perpendicular to a lesion, incision, or opening of the tissue site 104. The foam material used to form a compressed foam may be either hydrophobic or hydrophilic. The pore size of a foam material may vary according to needs of the apposition layer 146 and the amount of compression of the foam. For example, in some embodiments, an uncompressed foam may have pore sizes in a range of about 400 microns to about 600 microns. If the same foam is compressed, the pore sizes may be smaller than when the foam is in its uncompressed state. In some embodiments, the apposition layer 146 may have a width 610. The width 610 may be between about 15 mm and about 40 mm.

[00103] The apposition layer 146 may cover a lesion, incision, or opening in the tissue surface 105 of the tissue site 104. In some embodiments, the apposition layer 146 may have a first orientation line 627 and a second orientation line 629 that is perpendicular to the first orientation line 627. The first orientation line 627 may be parallel to an edge 632 of the apposition layer 146 and the second orientation line 629 may be parallel to an edge 634 of the apposition layer 146. In some embodiments, the first orientation line 627 and the second orientation line 629 may be used to refer to the desired directions of contraction for the apposition layer 146. For example, if the first orientation line 627 is oriented parallel to the

lesion, incision, or opening, the desired direction of contraction may be parallel to the second orientation line 629 and perpendicular to the first orientation line 627. Generally, the apposition layer 146 may be placed at the tissue site 104 so that the first orientation line 627 is parallel to the lesion, incision, or opening and may cover portions of the tissue surface 105 on one or more sides of the lesion, incision, or opening. In some embodiments, the first orientation line 627 may be coincident with the lesion, incision, or opening. The apposition layer 146 may include the plurality of holes 602 or perforations extending through the apposition layer 146. In some embodiments, the walls 608 of the holes 602 may extend through the apposition layer 146 parallel to the thickness 126 of the apposition layer 146. In some embodiments, the holes 602 may have an ovoid shape as shown.

[00104] Referring more specifically to Figure 7, a single hole 602 having an ovoid shape is shown. The hole 602 may include a center 636, a perimeter 638, and a perforation shape factor (PSF). For reference, the hole 602 may have an X-axis 642 extending through the center 636 parallel to the first orientation line 627, and a Y-axis 640 extending through the center 636 parallel to the second orientation line 629. In some embodiments, the perforation shape factor (PSF) of the hole 602 may be defined as a ratio of a line segment 644 on the Y-axis 640 extending from the center 636 to the perimeter 638 of the hole 602, to a line segment 646 on the X-axis 642 extending from the center 636 to the perimeter 638 of the hole 602. If a length of the line segment 644 is 2.5 mm and the length of the line segment 646 is 2.5 mm, the perforation shape factor (PSF) would be 2.5/2.5 or about 1.

[00105] Referring to Figure 8, if the hole 602 is rotated relative to the first orientation line 627 and the second orientation line 629 so that a major axis of the hole 628 is parallel to the second orientation line 629 and a minor axis of the hole 602 is parallel to the first orientation line 627, the perforation shape factor (PSF) may change. For example, the perforation shape factor (PSF) is now the ratio of a line segment 660 on the Y-axis 640 extending from the center 636 to the perimeter 638 of the hole 628, to a line segment 662 on the X-axis 642 extending from the center 636 to the perimeter 638 of the hole 628. If a length of the line segment 660 is 5 mm and the length of the line segment 662 is 2.5 mm, the perforation shape factor (PSF) would be 5/2.5 or about 2.

[00106] Referring to Figure 9, if the hole 602 is rotated relative to the first orientation line 627 and the second orientation line 629 so that a major axis of the hole 602 is parallel to the first orientation line 627 and a minor axis of the hole 602 is parallel to the second orientation line 629, the perforation shape factor (PSF) may change. For example, the

perforation shape factor (PSF) is now the ratio of a line segment 664 on the Y-axis 640 extending from the center 636 to the perimeter 638 of the hole 628, to a line segment 666 on the X-axis 642 extending from the center 636 to the perimeter 638 of the hole 602. If a length of the line segment 664 is 2.5 mm and the length of the line segment 666 is 5 mm, the perforation shape factor (PSF) would be 2.5/5 or about 1/2.

[00107] Referring to Figure 6B, a portion of the apposition layer 146 of Figure 6A is shown. The apposition layer 146 may include the plurality of holes 602 aligned in a pattern of parallel rows. The pattern of parallel rows may include a first row 648 of the holes 602, a second row 650 of the holes 602, and a third row 652 of the holes 602. The X-axis 642 of Figures 8, 9, and 10 of each hole 602 may be parallel to the first orientation line 627 of Figure 7B. The centers 636 of the holes 602 in adjacent rows, for example, the first row 648 and the second row 650, may be characterized by being offset from the second orientation line 629 along the first orientation line 627. In some embodiments, a line connecting the centers of adjacent rows may form a strut angle (SA) with the first orientation line 627. For example, a first hole 602A in the first row 648 may have a center 637A, and a second hole 602B in the second row 650 may have a center 637B. A strut line 654 may connect the center 637A with the center 637B. The strut line 654 may form an angle 656 with the first orientation line 627. The angle 656 may be the strut angle (SA) of the apposition layer 146. In some embodiments, the strut angle (SA) may be less than about 60°. In other embodiments, the strut angle (SA) may be between about 30° and about 70° relative to the first orientation line 627. As described above, if negative pressure is applied to the apposition layer 146, the apposition layer 146 may be more compliant or compressible in a direction perpendicular to the first orientation line 627. By increasing the compressibility of the apposition layer 146 in a direction perpendicular to the first orientation line 627, the apposition layer 146 may collapse to apply the closing force 631 to the lesion, incision, or opening of the tissue site 104, as described in more detail herein.

[00108] In some embodiments, the centers 636 of the holes 602 in alternating rows, for example, the center 637A of the first hole 602A in the first row 648 and a center 636C of a hole 602C in the third row 652, may be spaced from each other parallel to the second orientation line 629 by a length 658. In some embodiments, the length 658 may be greater than an effective diameter of the hole 602. If the centers 636 of holes 602 in alternating rows are separated by the length 658, the walls 608 parallel to the first orientation line 627 may be

considered continuous. Generally, the walls 608 may be continuous if the walls 608 do not have any discontinuities or breaks between holes 602.

[00109] Regardless of the shape of the holes 602, the holes 602 in the apposition layer 146 may leave void spaces in the apposition layer 146 and on the surface of the apposition layer 146 so that only the walls 608 of the apposition layer 146 remain with a surface available to contact the surface of the tissue site 104. It may be desirable to minimize the walls 608 so that the holes 602 may collapse, causing the apposition layer 146 to collapse the closing force 631 in a direction perpendicular to the first orientation line 627. However, it may also be desirable not to minimize the walls 608 so much that the apposition layer 146 becomes too fragile for sustaining the application of a negative pressure. The void space percentage (VS) of the holes 602 may be equal to the percentage of the volume or surface area of the void spaces created by the holes 602 to the total volume or surface area of the apposition layer 146. In some embodiments, the void space percentage (VS) may be between about 40% and about 60%. In other embodiments, the void space percentage (VS) may be about 56%.

[00110] In some embodiments, an effective diameter of the holes 602 may be selected to permit flow of particulates through the holes 602. In some embodiments, each hole 602 may have an effective diameter of about 7 mm. In other embodiments, each hole 602 may have an effective diameter between about 2.5 mm and about 20 mm.

[00111] Figure 6C is a plan view of the apposition layer 146 in a second position, illustrating additional details that may be associated with some embodiments. The holes 602 may form a pattern depending on the geometry of the holes 602 and the alignment of the holes 602 between adjacent and alternating rows in the apposition layer 146 with respect to the first orientation line 627. If the apposition layer 146 is subjected to negative pressure, the holes 602 of the apposition layer 146 may collapse, causing the apposition layer 146 to collapse along the second orientation line 629 perpendicular to the first orientation line 627. If the apposition layer 146 is positioned on a tissue surface of the tissue site 104 so that the first orientation line 627 coincides with the lesion, incision, or opening, the apposition layer 146 may generate a closing force 631 along the second orientation line 629 such that the tissue surface is contracted in the same direction to facilitate closure of the lesion, incision, or opening. The closing force 631 may be optimized by adjusting the factors described above as set forth in Table 1 below. In some embodiments, the holes 602 may be ovular, have a strut angle (SA) of approximately 47°, a void space percentage (VS) of about 56%, a firmness

factor (FF) of 5, a perforation shape factor (PSF) of 1, and an effective diameter of about 7 mm (where the major axis is about 8 mm and the minor axis is about 5 mm). If the apposition layer 146 is subjected to a negative pressure of about -125 mm Hg, the apposition layer 146 may assert the closing force 631 of approximately 13.5 N.

[00112] In some embodiments, the apposition layer 146 and the sheet 147 may be disposed within a subcutaneous tissue site. If disposed in a subcutaneous tissue site, the apposition layer 146 and the sheet 147 may approximate the subcutaneous tissue.

[00113] A closing force, such as the closing force 631, generated by a apposition layer, such as the apposition layer 146, may be related to a compressive force generated by applying negative pressure at a therapy pressure to a sealed therapeutic environment. For example, the closing force 631 may be proportional to a product of a therapy pressure (TP) in the sealed therapeutic environment or a sealed space 174, the compressibility factor (CF) of the apposition layer 146, and a surface area (A) of the apposition layer 146. The relationship is expressed as follows:

$$\text{Closing force } \alpha \text{ (TP * CF * A)}$$

[00114] In some embodiments, the therapy pressure TP is measured in N/m^2, the compressibility factor (CF) is dimensionless, the area (A) is measured in m^2, and the closing force is measured in Newtons (N). The compressibility factor (CF) resulting from the application of negative pressure to a contracting layer may be, for example, a dimensionless number that is proportional to the product of the void space percentage (VS) of a contracting layer, the firmness factor (FF) of the contracting layer, the strut angle (SA) of the holes in the contracting layer, and the perforation shape factor (PSF) of the holes in the contracting layer. The relationship is expressed as follows:

$$\text{Compressibility Factor (CF) } \alpha \text{ (VS * FF * sin(SA) * PSF)}$$

[00115] Based on the above formulas, contracting layers formed from different materials with holes of different shapes were manufactured and tested to determine the closing force of the contracting layers. For each contracting layer, the therapy pressure TP was about -125 mmHg and the dimensions of the contracting layer were about 200 mm by about 53 mm so that the surface area (A) of the contracting layer was about 106 cm^2 or 0.0106 m^2. Based on the two equations described above, the closing force for a Supracor® contracting layer 114 having a firmness factor (FF) of 3 was about 13.3 where the Supracor® contracting layer 114 had hexagonal holes 702 with a distance between opposite vertices of 5

mm, a perforation shape factor (PSF) of 1.07, a strut angle (SA) of approximately 66°, and a void space percentage (VS) of about 55%. A similarly dimensioned GranuFoam® contracting layer 114 generated the closing force 631 of about 9.1 Newtons (N).

TABLE 1

Material	VS	FF	SA	Hole Shape	PSF	Major diam. (mm)	Closing force
GranuFoam®	56	5	47	Ovular	1	10	13.5
Supracor®	55	3	66	Hexagon	1.1	5	13.3
GranuFoam®	40	5	63	Triangle	1.1	10	12.2
GranuFoam®	54	5	37	Circular	1	5	11.9
GranuFoam®	52	5	37	Circular	1	20	10.3
Grey Foam	N/A	5	N/A	Horizontal stripes	N/A	N/A	9.2
GranuFoam®	55	5	66	Hexagon	1.1	5	9.1
GranuFoam®	N/A	5	N/A	Horizontal stripes	N/A	N/A	8.8
Zotefoam	52	3	37	Circular	1	10	8.4
GranuFoam®	52	5	37	Circular	1	10	8.0
GranuFoam®	52	5	64	Circular	1	10	7.7
GranuFoam®	56	5	66	Hexagon	1.1	10	7.5
Grey Foam	N/A	3	N/A	Horizontal stripes	N/A	N/A	7.2
Zotefoam	52	3	52	Circular	1	20	6.8
GranuFoam®	N/A	3	N/A	Horizontal Striping	N/A	N/A	6.6
GranuFoam®	52	5	52	Circular	1	20	6.5
GranuFoam®	N/A	5	N/A	Vertical Stripes	N/A	N/A	6.1
GranuFoam®	N/A	1	N/A	None	N/A	N/A	5.9
GranuFoam®	N/A	3	N/A	Vertical stripes	N/A	N/A	5.6
GranuFoam®	52	1	37	None	1	10	5.5

[00116] Figure 10 is a perspective view of the apposition layer 146 and the dressing 124, illustrating additional details associated with some embodiments. In operation, the apposition layer 146 covered by the sheet 147 may be positioned over the tissue site 104. The sheet 147 contacts the tissue surface 105 and adheres the apposition layer 146 to the

tissue surface 105, holding the apposition layer 146 on the tissue surface 105. Preferably, the apposition layer 146 is aligned with the tissue site 104 so that a length of the apposition layer 146 is generally parallel an opening of the tissue site 104. The apposition layer 146 may be bisected by the opening of the tissue site 104 so that the apposition layer 146 contacts a portion of the tissue surface 105 on opposite sides of the opening of the tissue site 104.

[00117] The dressing 124 can be positioned over the apposition layer and the sheet 147. Preferably, the dressing 124 is aligned with the apposition layer 146 so that the central portion 156 of the base layer 132 is over the apposition layer 146.

[00118] Figure 11 is a perspective view of the apposition layer 146 and the dressing 124 adhered to the tissue surface 105, illustrating additional details that may be associated with some embodiments. Some components of the dressing 124 are not shown in Figure 11 to aid in illustration of the described features. While components may not be shown, the components can be included. As shown in Figure 11, the apposition layer 146 is bordered by the border 161 of the base layer 132. In other embodiments, the apposition layer 146 may extend into the border 161 or further.

[00119] Figure 12 is a perspective view of the apposition layer 146 and the dressing 124 during negative-pressure therapy, illustrating additional details that may be associated with some embodiments. As shown, the apposition layer 146 generates the closing force 631 urging the opening of the tissue site 104 closed. The apposition layer 146 can generate the closing force 631 while also distributing fluids from the tissue site 104 into the fluid management assembly 144.

[00120] Figure 13A is a perspective section view of another apposition layer 1646, illustrating additional details that may be associated with some embodiments. The apposition layer 1646 may be similar to and operate as described above with respect to the apposition layer 146. For example, the apposition layer 1646 includes a plurality of holes 1602. The plurality of holes 1602 may be similar to and operate as described above with respect to the plurality of holes 602 of the apposition layer 146. The apposition layer 1646 may also have a thickness 1626. The thickness 1626 may be similar to and operate as described above with respect to the thickness 126 of the apposition layer 146. The apposition layer 1646 may also include a plurality of walls 1608. The plurality of walls 1608 may be similar to and operate as described above with respect to the plurality of walls 608 of the apposition layer 146. In some embodiments, the apposition layer 1646 may include a film (not shown) encapsulating

the apposition layer 1646. The film may be similar to and operate as described above with respect to the sheet 147 of the apposition layer 146.

[00121] The apposition layer 1646 may have a first end 1648 and a second end 1650 opposite the first end 1648. In some embodiments, the first end 1648 and the second end 1650 may be a width of the apposition layer 1646. The apposition layer 1646 may include a first side 1652 extending between the first end 1648 and the second end 1650. The apposition layer 1646 also includes a second side 1654 opposite the first side 1652. The apposition layer may also include a top surface 1656 and a bottom surface 1658 opposite the top surface 1656. Edges are formed at the intersection of the top surface 1656 with the first side 1652 and the second side 1654. Similarly, edges are formed at the intersection of the bottom surface 1658 and the first side 1652 and the second side 1654. The edge between the top surface 1656 and the first side 1652 may be removed to form a first angled surface 1620. The first angled surface 1620 may be a beveled or chamfered surface, forming an angle 1660 with the top surface 1656. In some embodiments the angle 1660 may be about 45 degrees. In other embodiments, the angle 1660 may be between about 20 degrees and about 75 degrees. Similarly, the edge between the top surface 1656 and the second side 1654 may be removed to form a second angled surface 1622; the edge between the bottom surface 1658 and the first side 1652 may be removed to form a third angled surface 1624; and the edge between the bottom surface 1658 and the second side 1654 may be removed to form a fourth angled surface 1628. Each of the second angled surface 1622, the third angled surface 1624, and the fourth angled surface 1628 may form an angle with the respective top surface 1656 and the bottom surface 1658 that is similar to the angle 1660. In some embodiments, the first angled surface 1620, the second angled surface 1622, the third angled surface 1624, and the fourth angled surface 1628 may include the holes 1602.

[00122] Figure 13B is a cross-sectional view of the apposition layer 1646 of Figure 13A taken along line 13B—13B, illustrating additional details that may be associated with some embodiments. In at least some embodiments, a sealing member 1640 may be positioned over the apposition layer 1646, creating a sealed space that includes the apposition layer 1646. The sealing member 1640 may be similar to and operate as described above with respect to the sealing member 140 of Figure 1. If placed over the apposition layer 1646, the sealing member 1640 may be in contact with the top surface 1656 and contoured to contact the first angled surface 1620 and the second angled surface 1622 of the apposition layer 1646. Gaps may be formed between the third angled surface 1624 and tissue adjacent the tissue site

and the fourth angled surface 1628 and tissue adjacent the adjacent tissue. As illustrated in Figure 10B, the apposition layer 1646 is in a first position. In the first position, the bottom surface 1658 may contact a surface of a tissue site, for example, undamaged tissue adjacent the tissue site. In the first position, a sealed space formed by the sealing member 1640 that includes the apposition layer 1646 may be at an ambient pressure.

[00123] Figure 13C is a cross-sectional view of the apposition layer 1646 of Figure 13A in a second position, illustrating additional details that may be associated with some embodiments. If fluid is drawn from the sealed spaced formed by the sealing member 1640, generating a negative pressure, the apposition layer 1646 may be drawn down into the second position or compressed position. In the second position, any gaps formed between the third angled surface 1624 and the tissue adjacent the tissue site or between the fourth angled surface 1628 and the tissue adjacent the tissue site may close. The third angled surface 1624 and the fourth angled surface 1628 may contact the tissue adjacent the tissue site. Closing of the gap between third angled surface 1624 and the fourth angled surface 1628 may draw the first angled surface 1620 and the second angled surface 1622 downward and inward. The angle 1660 of the first angled surface 1620 and the second angled surface 1622 may transition the sealing member 1640 in a smooth manner, minimizing any local disturbance of the tissue adhered to the sealing member 1640. In some embodiments, the gap between the first angled surface 1620 and the second angled surface 1622 may collapse under partial application of negative pressure, for example, under a negative pressure less than about 120 mm Hg. Collapse under partial application of negative pressure may decrease the angle of adherence, mitigating the application of load and reducing the amount of skin reddening or blister formation that may occur from the apposition layer 1646. Furthermore, the first angled surface 1620, the second angled surface 1622 may decrease the total volume of the sealing space formed by the sealing member 1640, requiring removal of less fluid to generate a therapeutic negative pressure than a similar apposition layer having sides formed by right angles.

[00124] The apposition layer 1646 transitioning from the first position to the second position may generate an apposition force at the tissue site. For example, the apposition layer 1646 may generate an apposition force 1662 from the first side 1652 toward the second side 1654 and from the second side 1654 toward the first side 1652. The apposition layer 1646 can be positioned over a tissue site, such as an incision where the first side 1652 is on a first side of the incision and the second side 1654 is on a second side of the incision, so that the

apposition layer 1646 straddles the incision. The apposition force 1662 can draw the opposing sides of the incision toward each other, encouraging the incision to close.

[00125] Figure 14 is a perspective view of another embodiment of an apposition layer 1746, illustrating additional details that may be associated with some embodiments. The apposition layers described herein can be sized. For example, the apposition layer 1746 can be provided in strips and cut to size to a desired size to cover a tissue site. The apposition layer 1746 may be similar to and operate as described above with respect to the apposition layer 146. Some tissue sites may be irregularly shaped. For example, a tissue site 1704 may be formed from two incisions, a horizontal incision 1705 and a vertical incision 1703. In some embodiments, the vertical incision 1703 may intersect the horizontal incision 1705 near a center of the horizontal incision 1705. The intersection of the horizontal incision 1705 and the vertical incision 1703 may cause the tissue site 1704 to be shaped like a "T." The apposition layer 1746 can be formed to have a shape matching the shape of the tissue site. For example, the apposition layer 1746 may comprise strips of the apposition layer 1746 that can be formed to match the tissue site, for example by cutting. In the illustrated embodiment, the apposition layer 1746 may include a first apposition layer 1745 and a second apposition layer 1747. The first apposition layer 1745 may be cut to a length of the vertical incision 1703, and the second apposition layer 1747 may be cut to a length of the horizontal incision 1705. The first apposition layer 1745 can be placed over the vertical incision 1703 and the second apposition layer 1747 can be positioned over the horizontal incision 1705. The first apposition layer 1745 and the second apposition layer 1747 may include a sheet (not shown) similar to the sheet 147 of the apposition layer 146. After placement over the tissue site 104, the first apposition layer 1745 and the second apposition layer 1747 may be covered by an appropriately sized dressing, such as the dressing 124. The dressing 124 may be sized so that the border 161 of the base layer 132 surrounds the apposition layer 1746. During operation, a negative-pressure source may be coupled to the dressing 124 and operated to draw down the dressing 124 and the apposition layer 1746. The first apposition layer 1745 may develop an apposition force perpendicular to the vertical incision 1703, and the second apposition layer 1747 may develop an apposition force perpendicular to the horizontal incision 1705, urging the tissue site 1704 closed as described above with respect to the apposition layer 146.

[00126] In other embodiments, the tissue site 1704 may be discontinuous. For example, the vertical incision 1703 may not intersect the horizontal incision 1705. The first apposition layer 1745 may be placed over the vertical incision 1703 and the second

apposition layer 1747 can be placed over the horizontal incision 1705. The first apposition layer 1745 may not abut the second apposition layer 1747, providing an area uncovered by the apposition layer 1746. In this manner, the apposition layer 1746 may provide apposition forces where needed, and provide no apposition forces where not needed.

[00127] Figure 15 is a perspective view of another embodiment of an apposition layer 1846, illustrating additional details that may be associated with some embodiments. The apposition layers described herein can be customized. For example, the apposition layer 1846 can be provided in strips and cut to provide a curvature or an angled portion to cover a similarly shaped tissue site. The apposition layer 1846 may be similar to and operate as described above with respect to the apposition layer 146. Some tissue sites may be irregularly shaped. For example, a tissue site 1804 may be curved. The apposition layer 1846 can be formed to have a shape matching the shape of the tissue site. For example, the apposition layer 1846 may comprise strips of the apposition layer 1846 that can be formed to match the tissue site, for example by cutting. In the illustrated embodiment, the apposition layer 1846 may be curved to match the radius of curvature of the tissue site 1804. For example, the apposition layer 1846 may have a plurality cuts 1870 formed along a first side of the apposition layer 1846. The cuts 1870 may segment the apposition layer 1846, permitting the apposition layer 1846 to expand along the side having the cuts 1870. The expansion of the side of the apposition layer 1846 having the cuts 1870 causes the opposite side to contract, curing the apposition layer 1846. In some embodiments, the cuts 1870 permit the apposition layer 1846 to match the curvature of the tissue site 1804. The apposition layer 1847 may also be cut to a length of the tissue site 1804. The apposition layer 1846 may include a sheet (not shown) similar to the sheet 147 of the apposition layer 146. After placement over the tissue site 104, the apposition layer 1846 may be covered by an appropriately sized dressing, such as the dressing 124. The dressing 124 may be sized so that the border 161 of the base layer 132 surrounds the apposition layer 1846. During operation, a negative-pressure source may be coupled to the dressing 124 and operated to draw down the dressing 124 and the apposition layer 1846. The first apposition layer 1845 may develop an apposition force perpendicular to the tissue site 1804, urging the tissue site 1804 closed as described above with respect to the apposition layer 146.

[00128] The systems, apparatuses, and methods described herein may provide significant advantages. For example, the apposition layers described herein can permit apposition forces to be applied with a peel-and-place negative-pressure dressing. The

addition of apposition forces by the apposition layer does not require modifications to peel-and-place dressings, allowing additional therapies to be performed without increasing the complexity of application of the therapy device. The apposition layers described herein further permit customization that can allow an apposition layer to be customized to a particular tissue site, such as a contoured tissue site, or even a discontinuous tissue site. Furthermore, the apposition layers described herein permit a clinician to selectively place apposition force within a negative pressure dressing. Selective placement may allow areas that may be damaged by apposition forces to still receive negative pressure therapy. The apposition layers can also manifold pressure and fluid into the absorbent structure of a dressing. The apposition layers described herein can also maintain a position while a dressing is being placed over the apposition layer through the use of the sheet to envelop the apposition layer. The sheet, often formed of silicone, may also help reduce scar formation and can be particularly advantageous in a surgical dressing used for aesthetic reasons.

[00129] While shown in a few 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. 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. Components may be also be combined or eliminated in various configurations for purposes of sale, manufacture, assembly, or use.

[00130] The appended claims set forth novel and inventive aspects of the subject matter described above, but the claims may also encompass additional subject matter not specifically recited in detail. For example, certain features, elements, or aspects may be omitted from the claims 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 or illustrated in the context of some example embodiments may also be omitted or combined with features, elements, and aspects of other example embodiments. 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.

CLAIMS

What is claimed is:

1. A system for closing an opening through a surface of a tissue site, the system comprising:
an apposition layer adapted to be positioned over the opening, the apposition layer comprising:
a material having a firmness factor, and
a plurality of holes extending through the apposition layer, the holes forming a void space and having a perforation shape factor and a strut angle configured to collapse the apposition layer in a first direction relative to a second direction;
a first layer adapted to be positioned below the apposition layer, the first layer having at least one perforation;
a second layer adapted to be positioned above the apposition layer, the second layer having at least one perforation;
a dressing adapted to cover the apposition layer to form a sealed space; and
a negative-pressure source adapted to be fluidly coupled to the sealed space to provide negative pressure to the sealed space;
wherein the apposition layer generates a closing force in the first direction that is substantially parallel to the surface of the tissue site to close the opening in response to application of the negative pressure.

2. The system of claim 1, wherein the first layer and the second layer each comprise a silicone adhesive.

3. The system of claim 1, wherein the first layer and the second layer each comprise a silicone adhesive having a coating weight between about 100 gsm and about 200 gsm.

4. The system of claim 1, wherein the first layer and the second layer each comprise a polyurethane material.

5. The system of claim 1, wherein the first layer and the second layer each comprise a hydrogel.

6. The system of claim 1, 2, 3, 4, or 5, wherein the first layer and the second layer comprise a single, continuous sheet of material.

7. The system of claim 1, 2, 3, 4, 5, or 6, wherein the at least one perforation of the first layer comprises a plurality of perforations.

8. The system of claim 7, wherein the at least one perforation of the second layer comprises a plurality of perforations.

9. The system of claim 1, 2, 3, 4, 5, or 6, wherein the at least one perforation of the second layer comprises a plurality of perforations.

10. The system of claim 1, 2, 3, 4, 5, 6, 7, 8, or 9, wherein the plurality of holes have an average effective diameter of about 5 mm.

11. The system of claim 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10, wherein the plurality of holes are formed in two or more parallel rows.

12. The system of claim 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, or 11, wherein the strut angle is about 90 degrees.

13. The system of claim 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, or 11, wherein the strut angle is less than about 90 degrees.

14. The system of claim 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, or 13, wherein the perforation shape factor of each hole is less than about 1.

15. The system of claim 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, or 14, wherein a thickness of the apposition layer is about 15 mm.

16. The system of claim 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, or 15, wherein the firmness factor is about 5.

17. The system of claim 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, or 15, wherein the firmness factor is about 3.

18. The system of claim 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, or 17, wherein a shape of each hole of the plurality of holes is elliptical.

19. The system of claim 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, or 18, wherein the apposition layer comprises a felted foam.

20. The system of claim 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 12, 14, 15, 16, 17, 18, or 19, wherein the dressing comprises:

a base layer having a plurality of apertures extending through the base layer, at least a portion of the plurality of apertures configured to transmit fluid across the base layer;

a fluid management assembly positioned over the base layer, the fluid management assembly comprising:

a first wicking layer;

an absorbent disposed over the first wicking layer, and

a second wicking layer disposed over the absorbent and having a periphery coupled to a periphery of the first wicking layer to enclose the absorbent;

a sealing member disposed over the fluid management assembly; and

an adhesive layer positioned between a periphery of the base layer and the sealing member, the adhesive layer coupling the base layer to the sealing member to enclose the fluid management assembly.

21. The system of claim 20, wherein the plurality of apertures in the base layer comprise:

a first group of apertures disposed in a center portion of the base layer and having a first diameter;

a second group of apertures disposed in a perimeter portion of the base layer and having a second diameter, the first group of apertures and the second group of apertures separated by a border; and

the second group of apertures having an average diameter that is larger than the average diameter of the first group of apertures.

22. An apparatus for closing an opening through a surface of a tissue site, the apparatus comprising:

an contracting layer adapted to be positioned over the opening, the contracting layer comprising:

a material having a firmness factor, and

a plurality of holes extending through the contracting layer, the holes forming a void space and having a perforation shape factor and a strut angle configured to collapse the contracting layer in a first direction relative to a second direction;

a lower layer adapted to be positioned below the contracting layer, the lower layer having at least one perforation; and

an upper layer adapted to be positioned above the contracting layer, the upper layer having at least one perforation;

wherein the contracting layer generates a closing force substantially parallel to the surface of the tissue site to close the opening in response to application of a negative pressure.

23. The apparatus of claim 22, wherein the lower layer and the upper layer each comprise a silicone adhesive.

24. The apparatus of claim 22, wherein the lower layer and the upper layer each comprise a silicone adhesive having a coating weight between about 100 gsm and about 200 gsm.

25. The apparatus of claim 22, wherein the lower layer and the upper layer each comprise a polyurethane material.

26. The apparatus of claim 22, wherein the lower layer and the upper layer each comprise a hydrogel.

27. The apparatus of claim 22, 23, 24, 25, or 26, wherein the lower layer and the upper layer comprise a single, continuous sheet of material.

28. The apparatus of claim 22, 23, 24, 25, 26, or 27, wherein the at least one perforation of the lower layer comprises a plurality of perforations.

29. The apparatus of claim 28, wherein the at least one perforation of the upper layer comprises a plurality of perforations.

30. The apparatus of claim 22, 23, 24, 25, 26, or 27, wherein the at least one perforation of the upper layer comprises a plurality of perforations.

31. The apparatus of claim 22, 23, 24, 25, 26, 27, 28, 29, or 30, wherein the plurality of holes have an average effective diameter of about 5 mm.

32. The apparatus of claim 22, 23, 24, 25, 26, 27, 28, 29, 30, or 31, wherein the plurality of holes are formed in two or more parallel rows.

33. The apparatus of claim 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, or 32, wherein the strut angle is about 90 degrees.

34. The apparatus of claim 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, or 32, wherein the strut angle is less than about 90 degrees.

35. The apparatus of claim 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, or 34, wherein the perforation shape factor of each hole is less than about 1.

36. The apparatus of claim 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, or 35, wherein a thickness of the contracting layer is about 15 mm.

37. The apparatus of claim 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, or 36, wherein the firmness factor is about 5.

38. The apparatus of claim 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, or 36, wherein the firmness factor is about 3.

39. The apparatus of claim 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, or 38, wherein a shape of each hole of the plurality of holes is elliptical.

40. The apparatus of claim 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, or 39, wherein the contracting layer comprises a compressed foam.

41. The apparatus of claim 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, or 40, further comprising a dressing configured to form a sealed space over the contracting layer, the dressing comprising:

a base layer having a plurality of apertures extending through the base layer, at least a portion of the plurality of apertures configured to transmit fluid across the base layer;

a fluid management assembly positioned over the base layer, the fluid management assembly comprising:

a first wicking layer;

an absorbent disposed over the first wicking layer, and

a second wicking layer disposed over the absorbent and having a periphery coupled to a periphery of the first wicking layer to enclose the absorbent;

a sealing member disposed over the fluid management assembly; and

an adhesive layer positioned between a periphery of the base layer and the sealing member, the adhesive layer coupling the base layer to the sealing member to enclose the fluid management assembly.

42. The apparatus of claim 41, wherein the plurality of apertures in the base layer comprise:

a first group of apertures disposed in a center portion of the base layer and having a first diameter;

a second group of apertures disposed in a perimeter portion of the base layer and having a second diameter, the first group of apertures and the second group of apertures separated by a border; and

the second group of apertures having an average diameter that is larger than the average diameter of the first group of apertures.

43. A method for closing an opening through a surface of a tissue site, the method comprising:

encapsulating an apposition layer in a sheet having an upper layer above the apposition layer and a lower layer below the apposition layer, the sheet having at least one perforation in the upper layer and at least one perforation in the lower layer;

positioning the apposition layer over the opening, the apposition layer adapted to be positioned adjacent the opening and formed from a material having a firmness factor and a plurality of holes extending through the apposition layer to form a void space, the holes having a perforation shape factor and a strut angle causing the apposition layer to collapse in a direction substantially perpendicular to the opening; and

collapsing the apposition layer parallel to the surface of the tissue site to generate a closing force.

44. The method of claim 43, further comprising:

positioning a sealing member over the apposition layer;

sealing the sealing member to tissue surrounding the tissue site to form a sealed space; and

fluidly coupling a negative-pressure source to the sealed space.

45. The method of claim 44, wherein collapsing the apposition layer comprises: supplying negative pressure to the sealed space with the negative-pressure source.

46. The method of claim 45, wherein collapsing the apposition layer comprises: supplying negative pressure to the apposition layer.

47. The method of claim 45, wherein collapsing the apposition layer comprises:

collapsing the apposition layer in response to a supply of negative pressure; and

drawing edges of the apposition layer toward a center of the apposition layer in response to the collapse of the holes of the apposition layer.

48. The systems, apparatuses, and methods substantially as described herein.

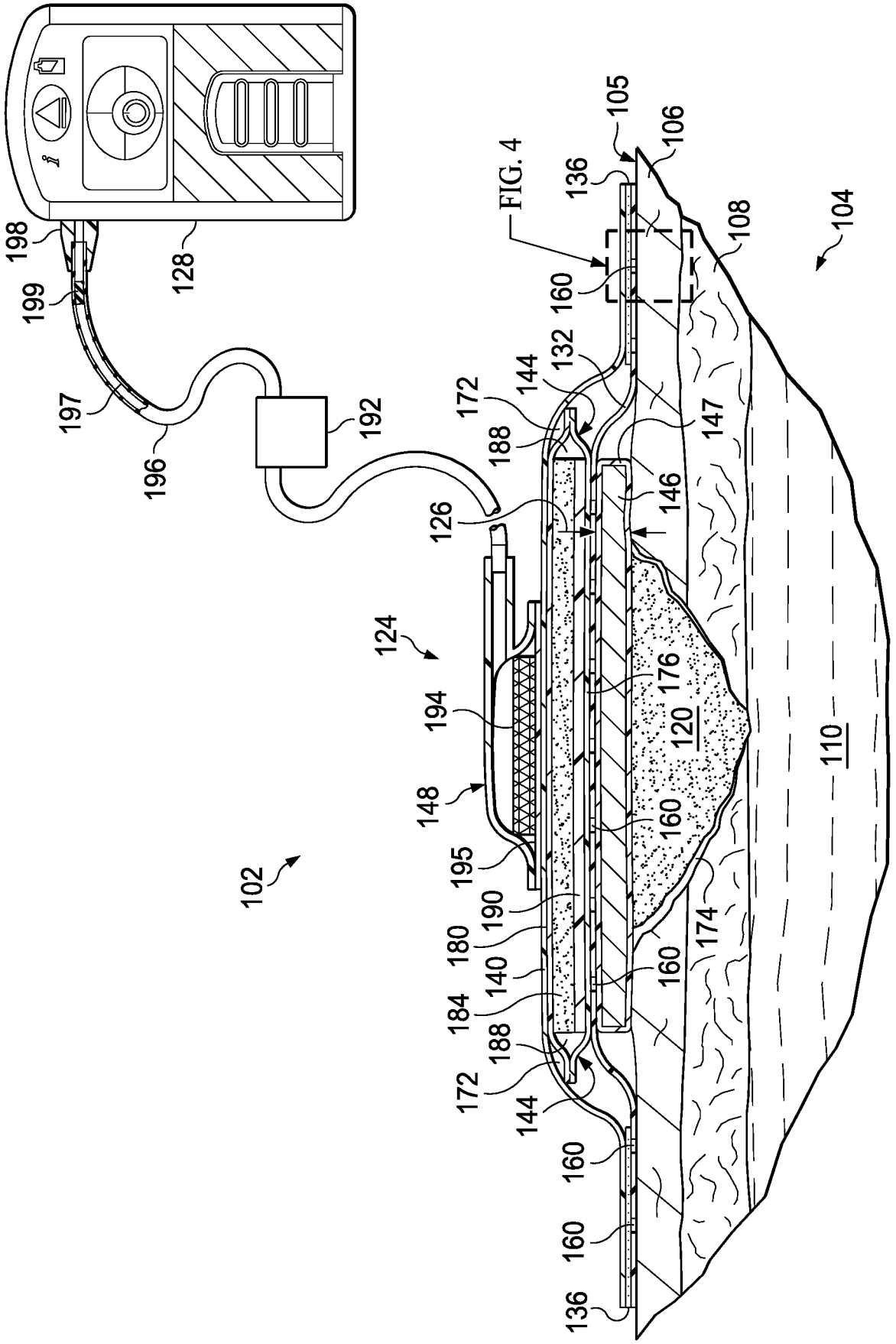
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FIG. 1

FIG. 4

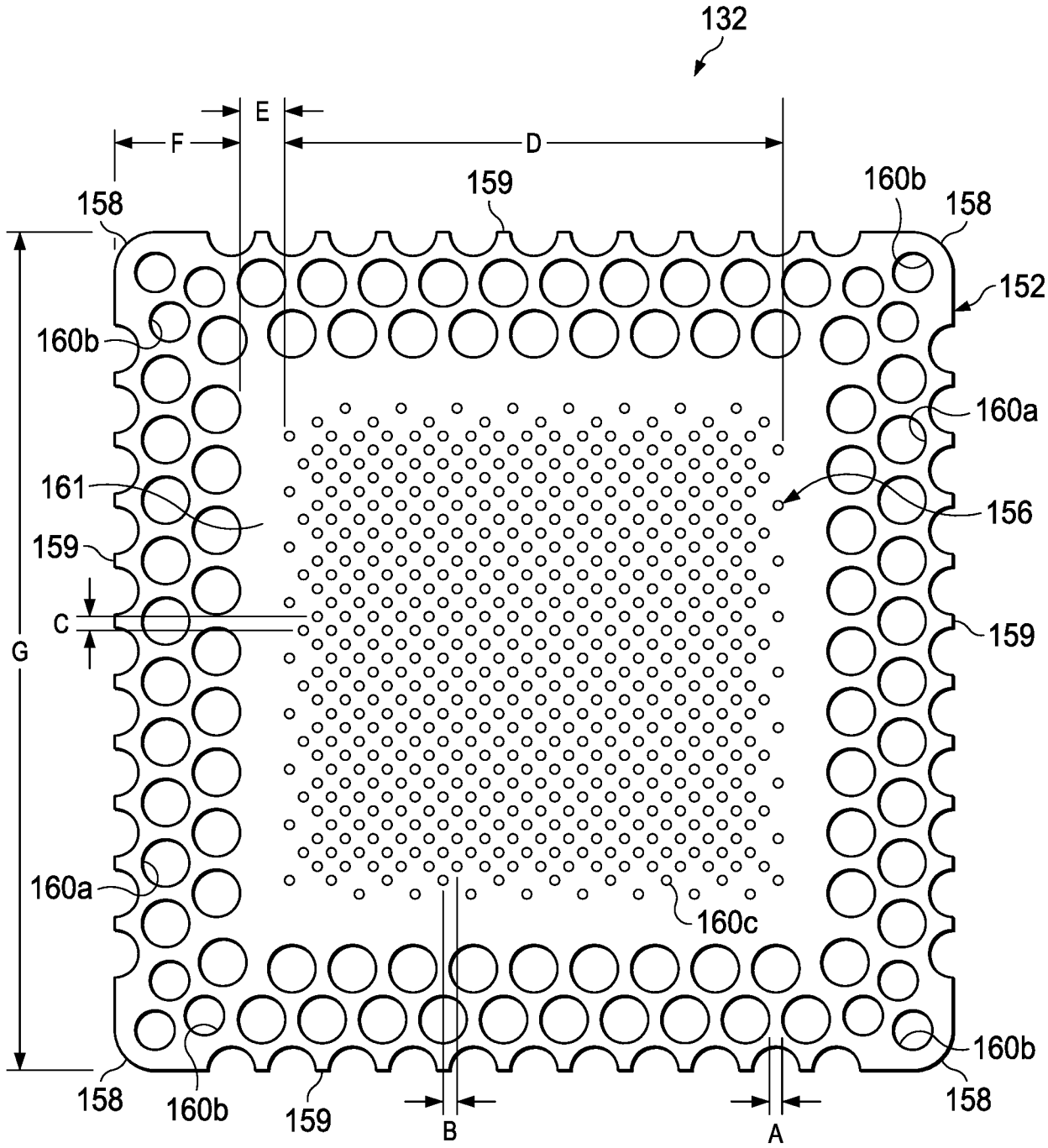
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FIG. 2

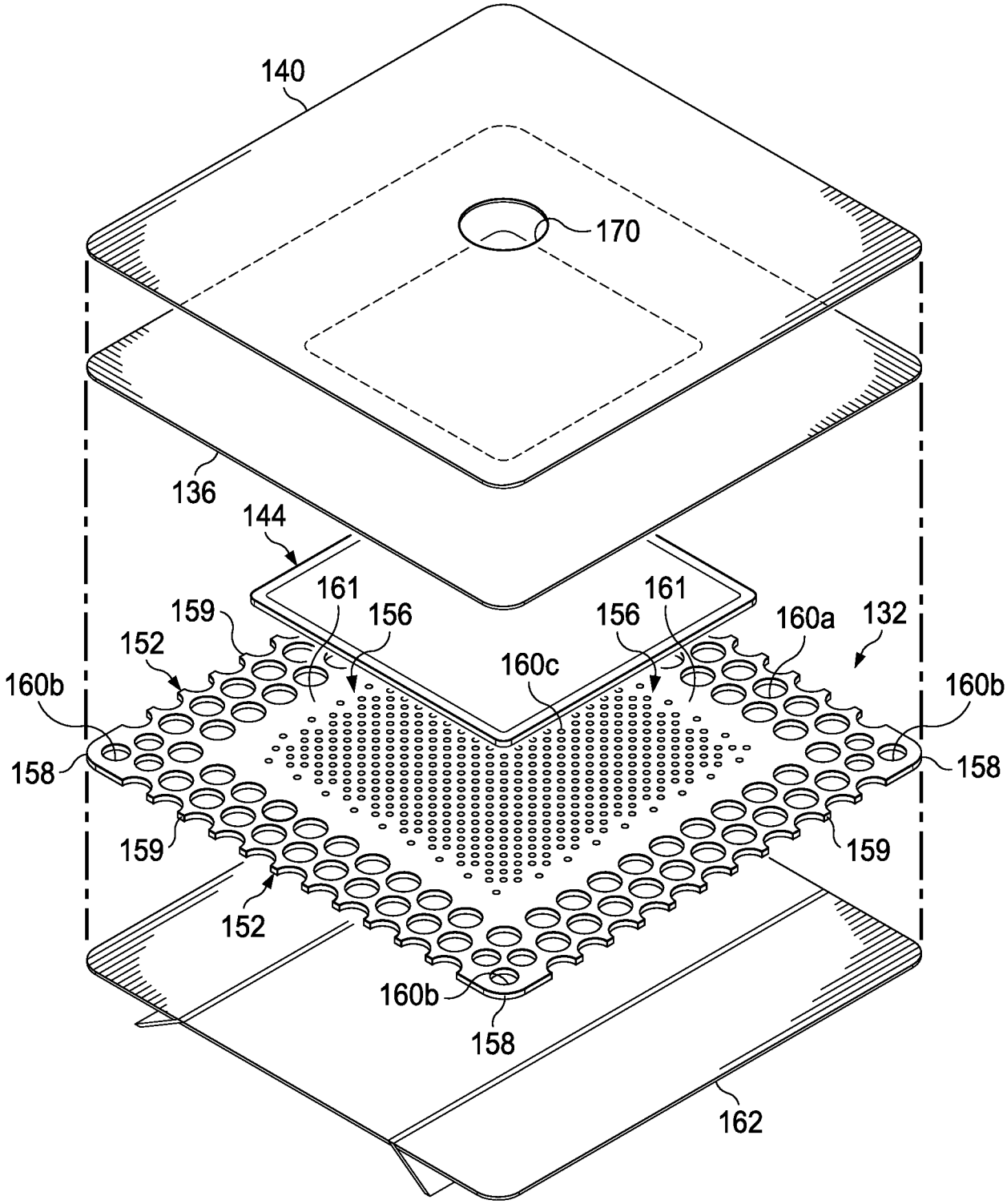
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FIG. 3

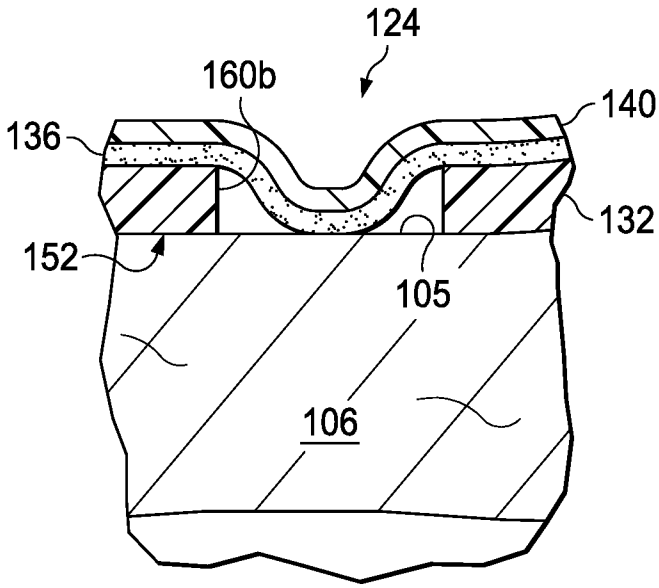
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FIG. 4

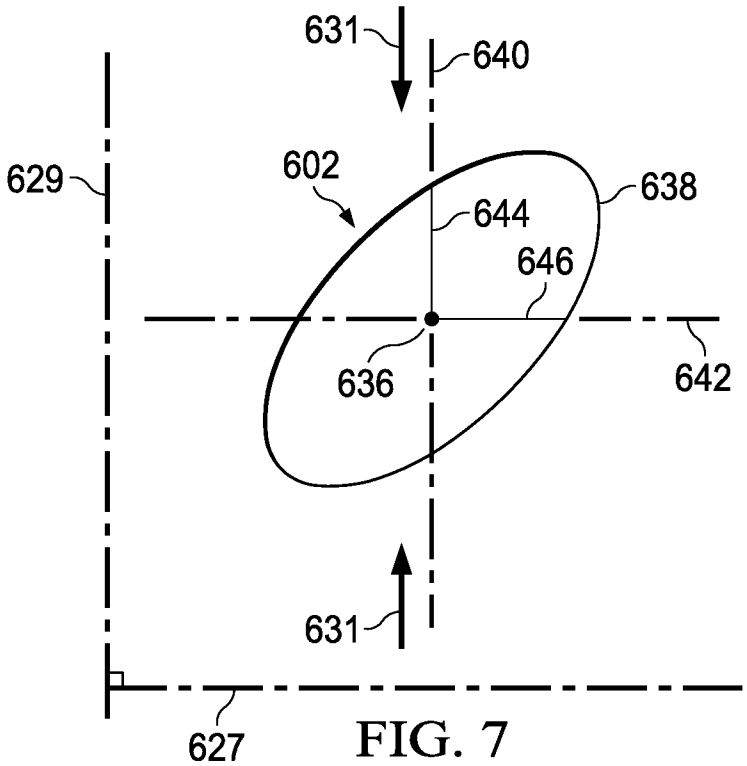
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FIG. 7

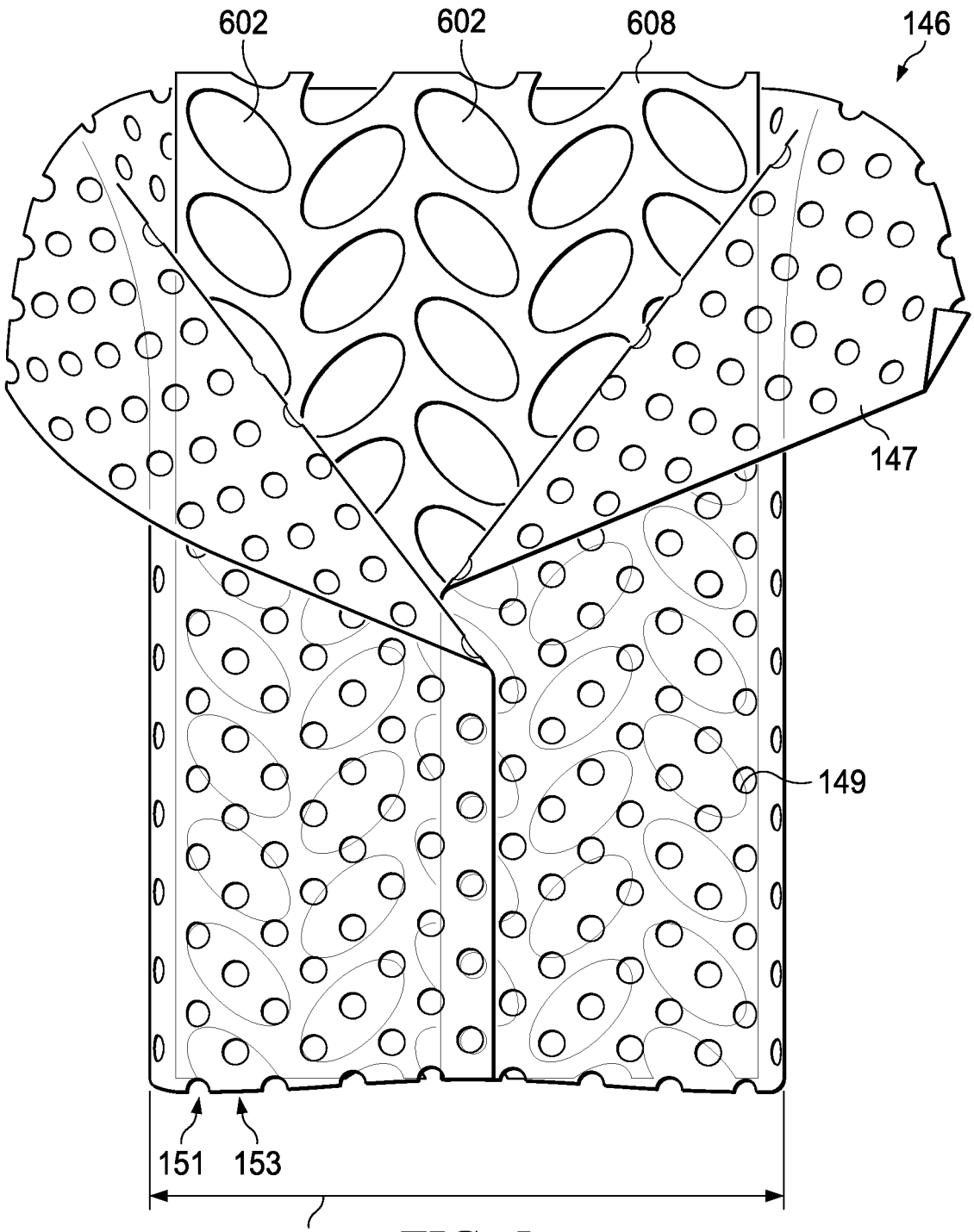


FIG. 5

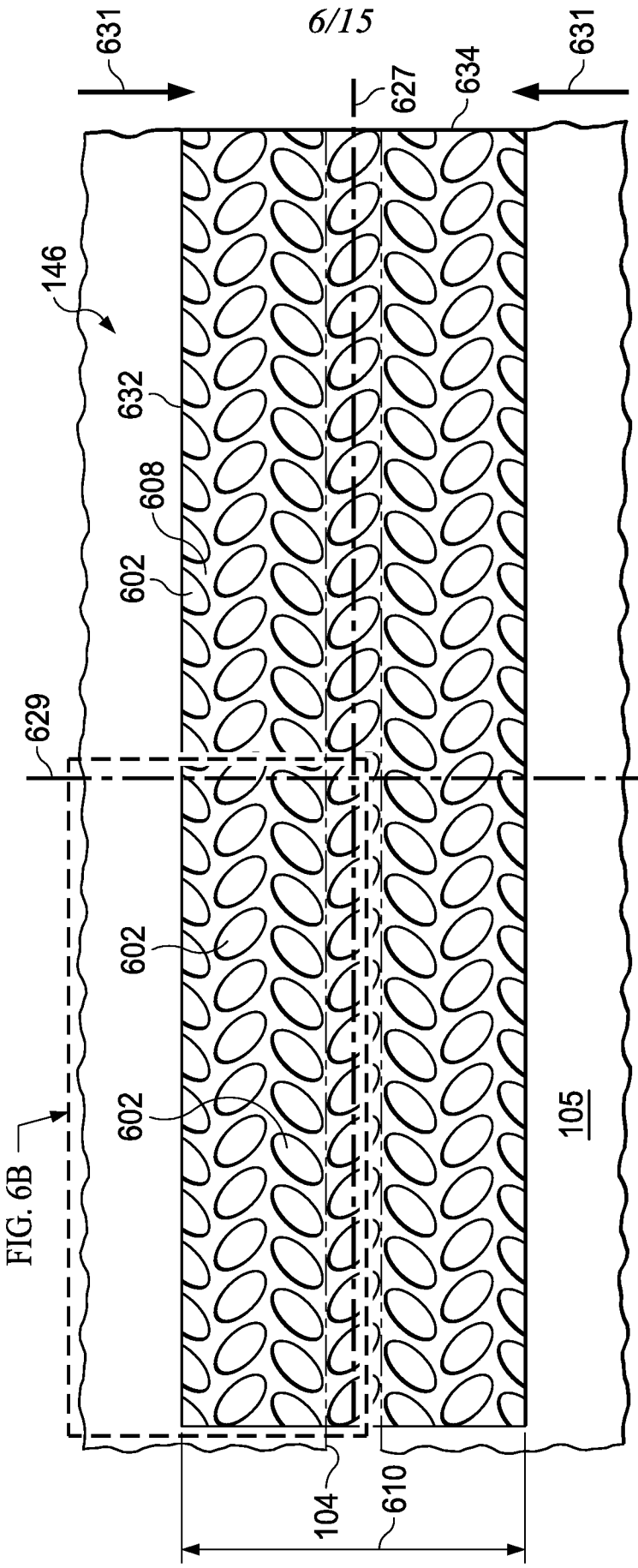
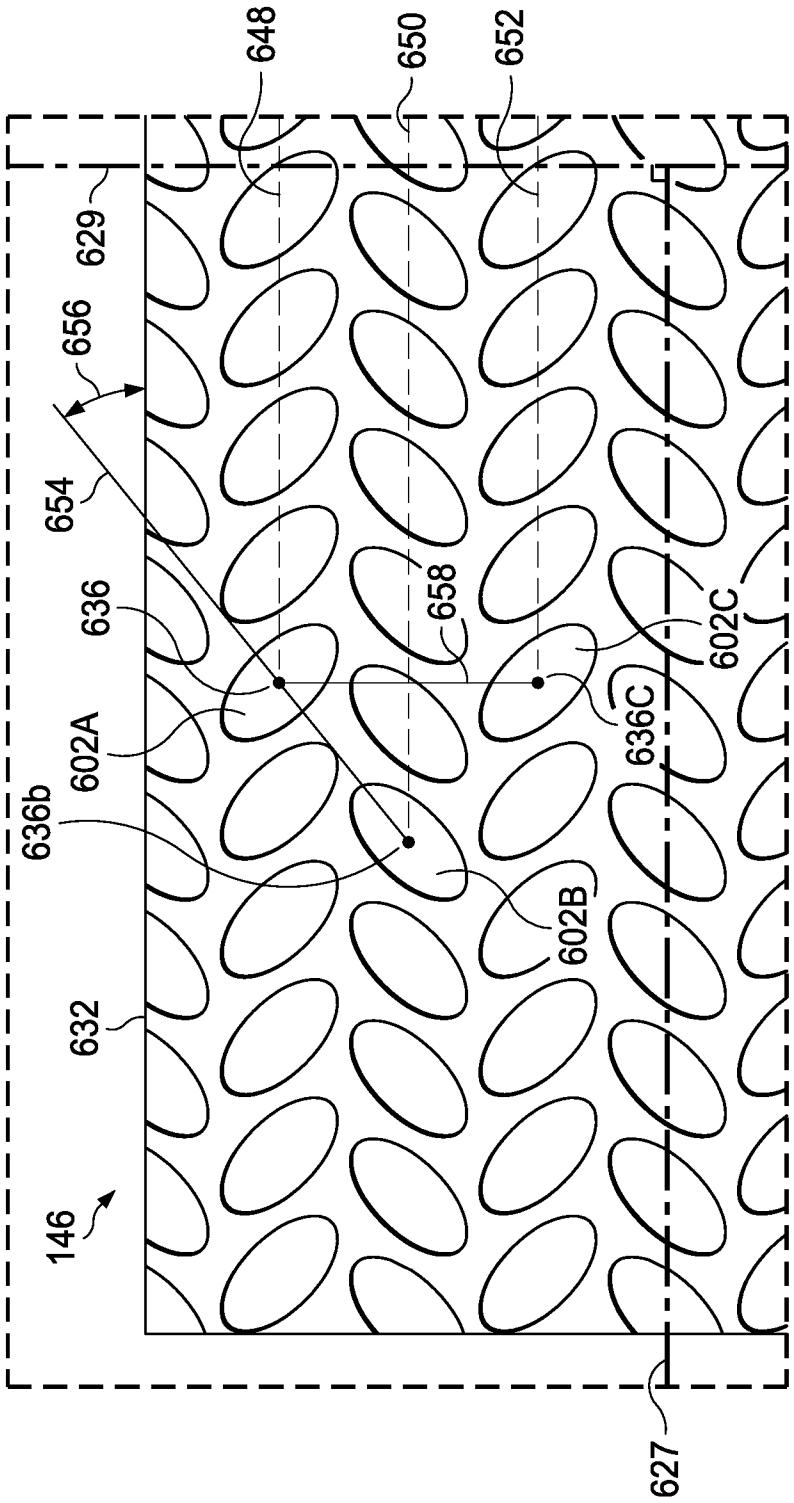


FIG. 6A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602C
636C
602A
636b
602B
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146
627

FIG. 6B

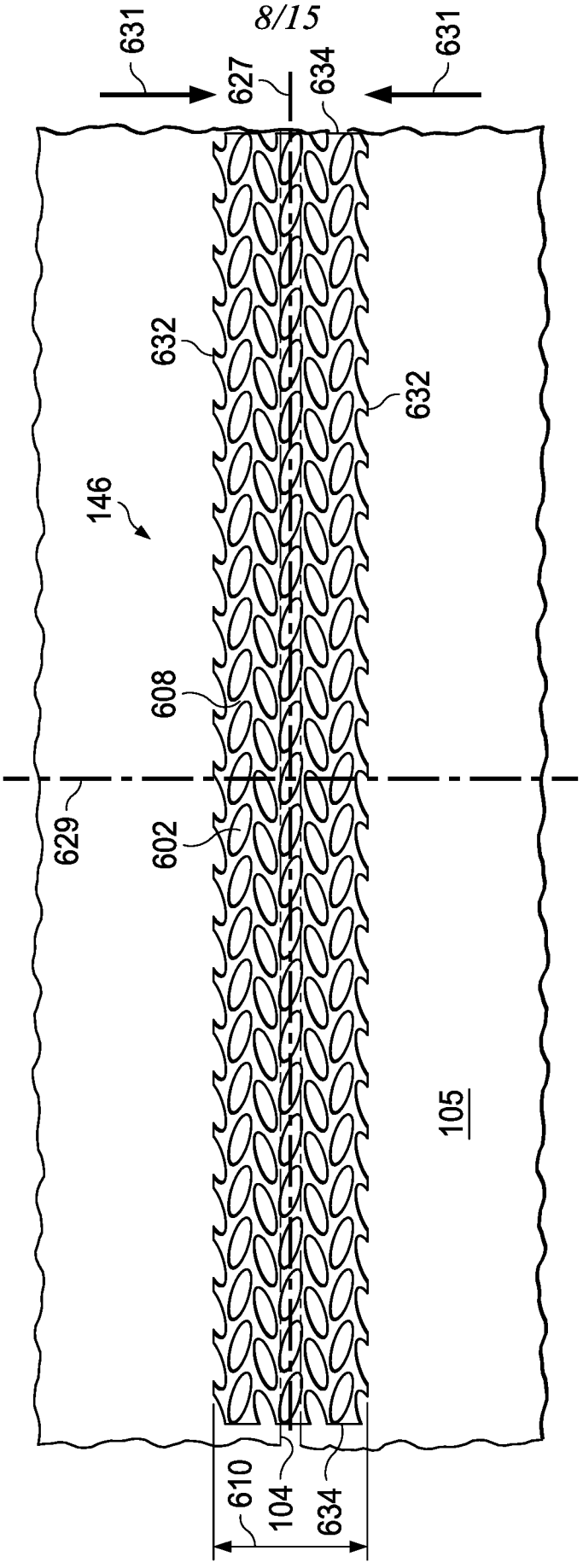

FIG. 6C

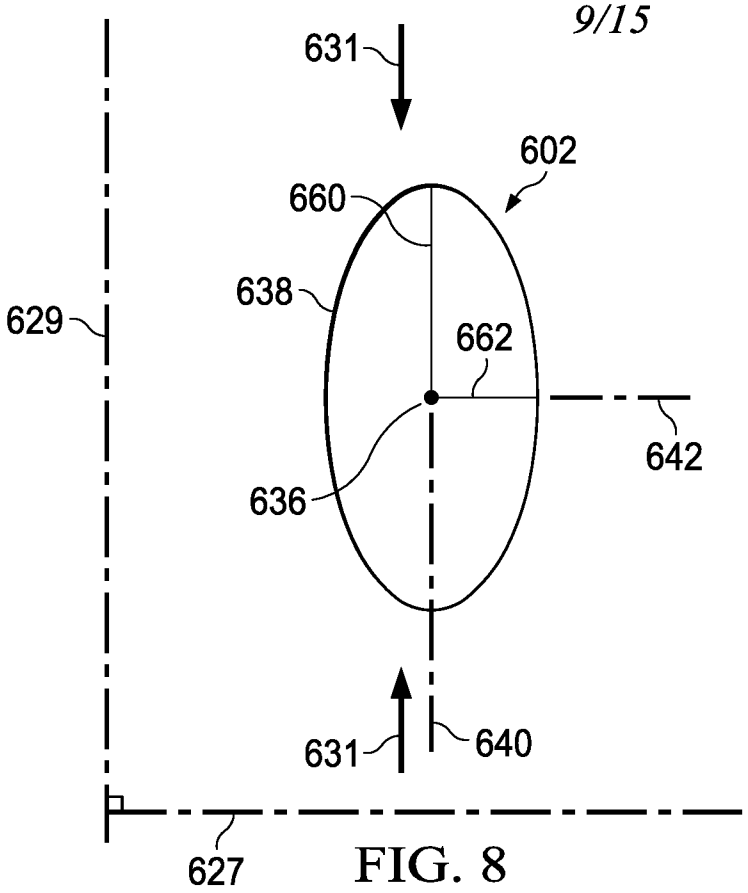
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FIG. 8

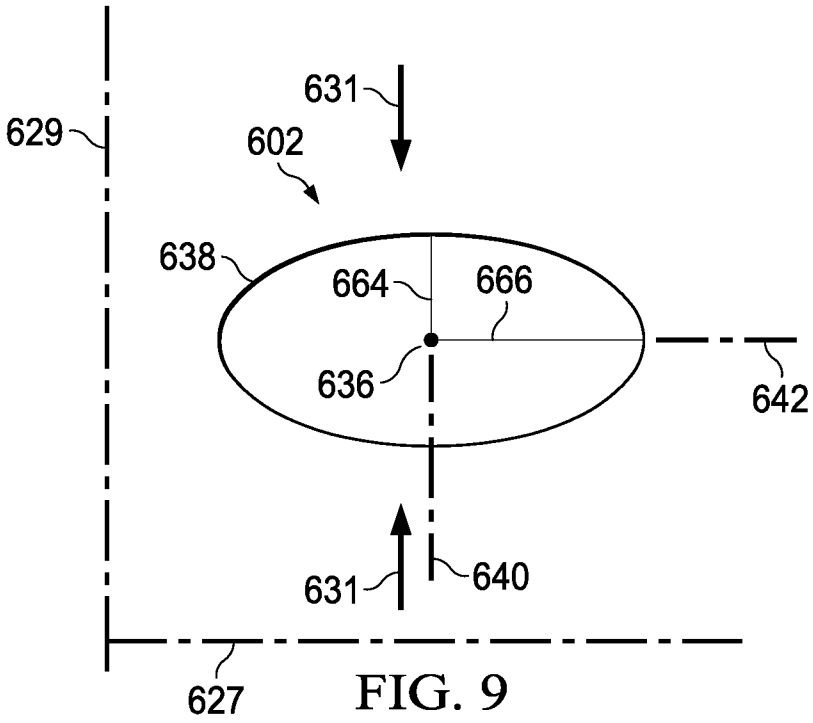
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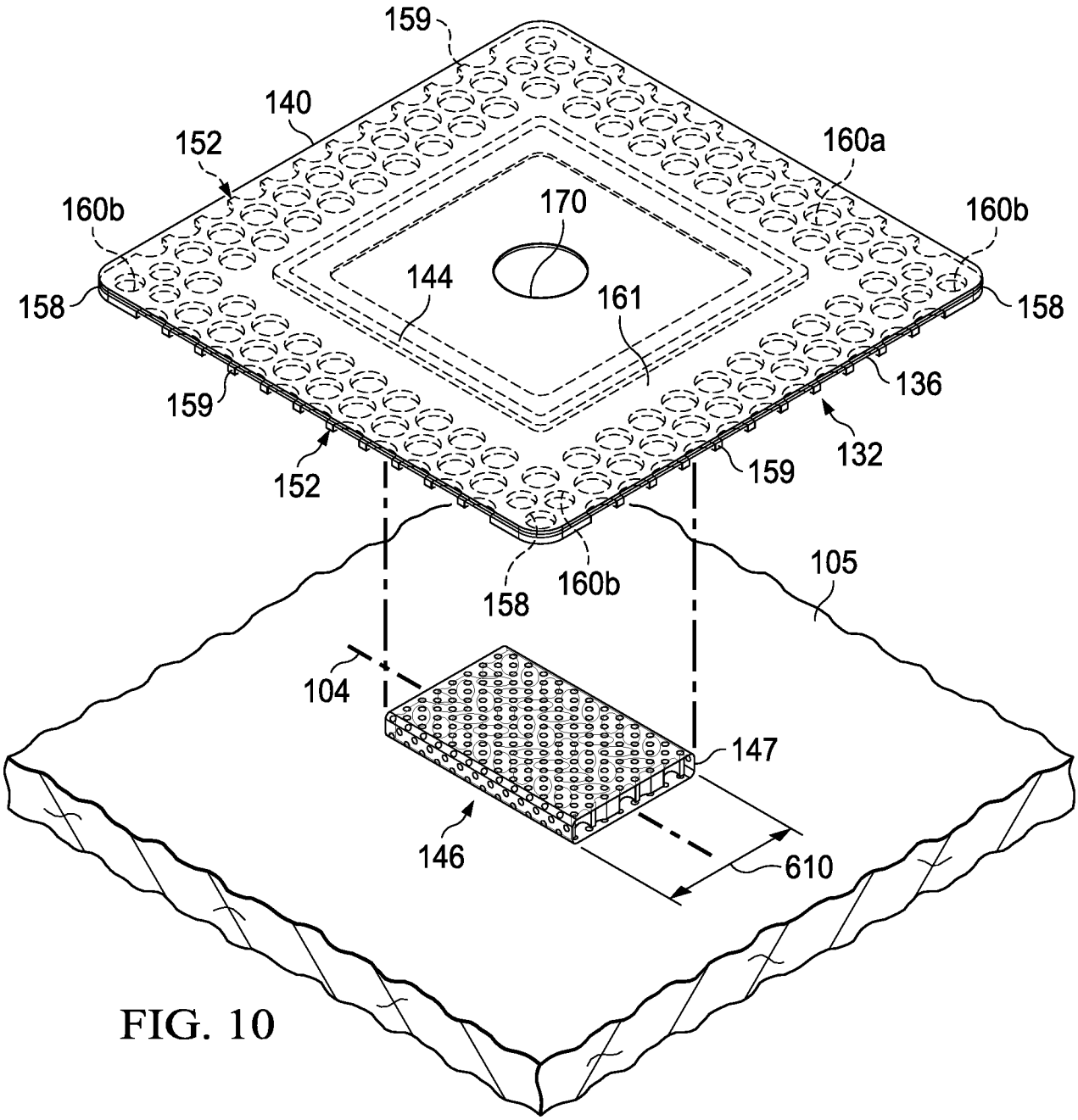
FIG. 9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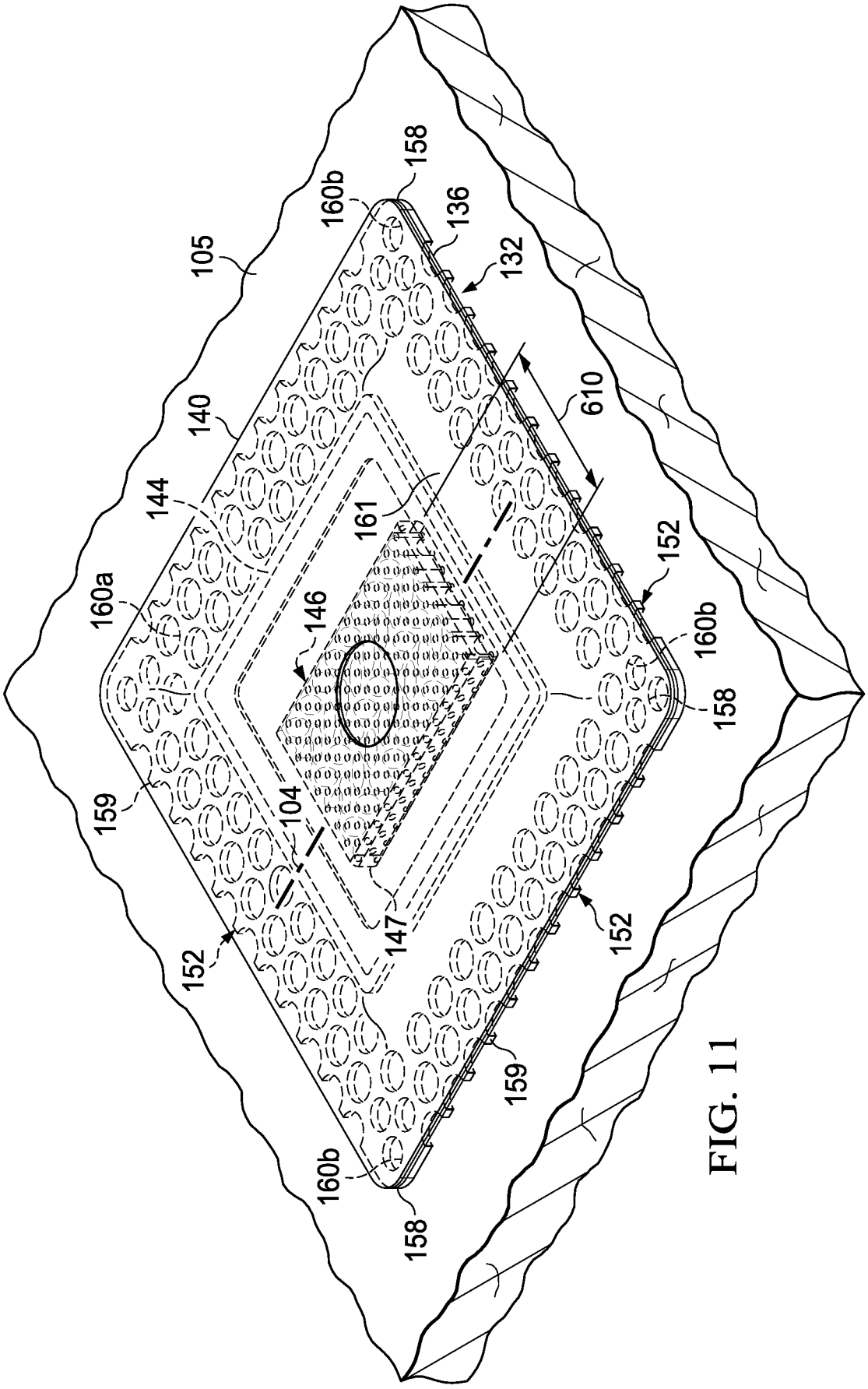
146
610

FIG. 10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160b
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FIG. 11

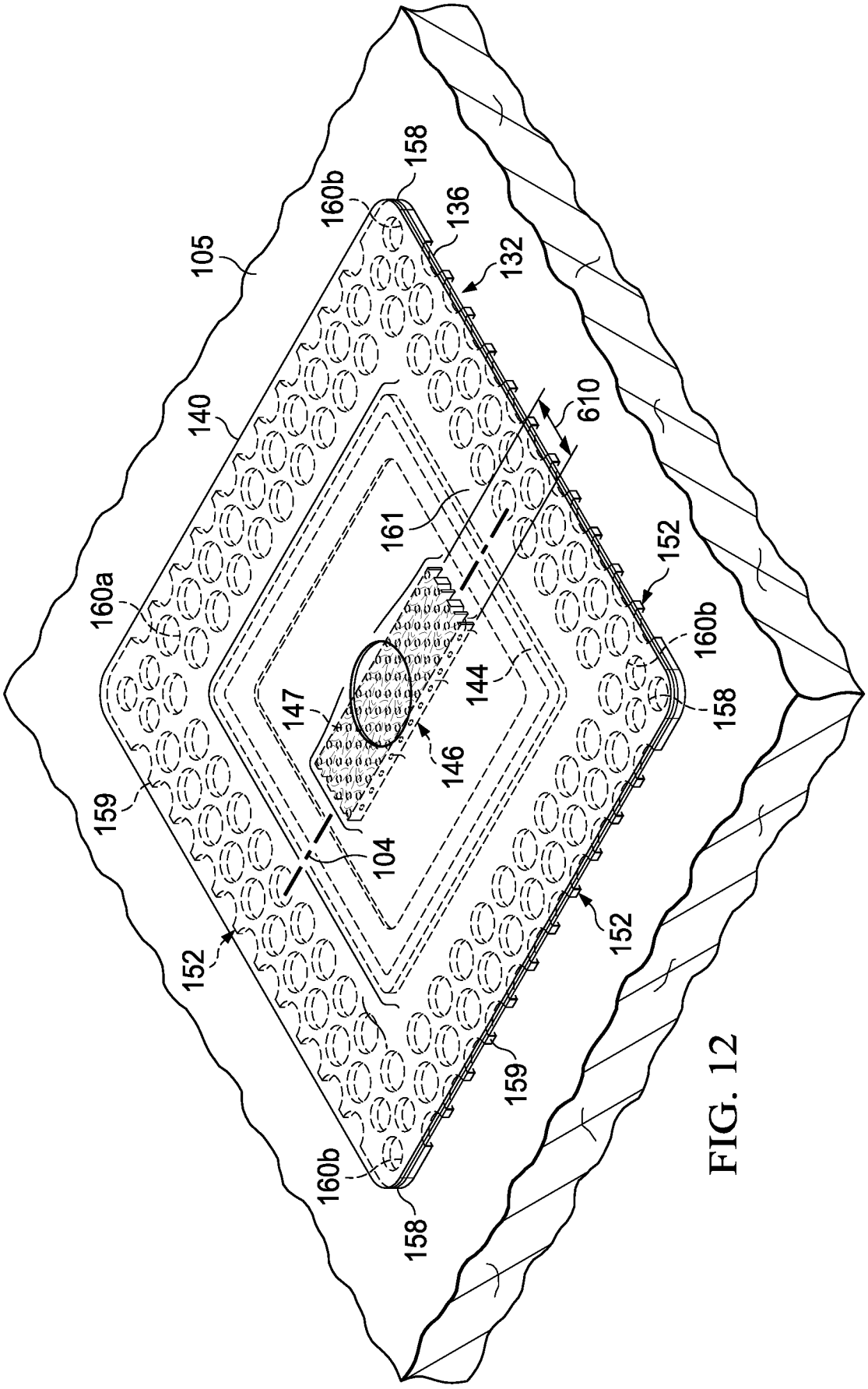
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FIG. 12

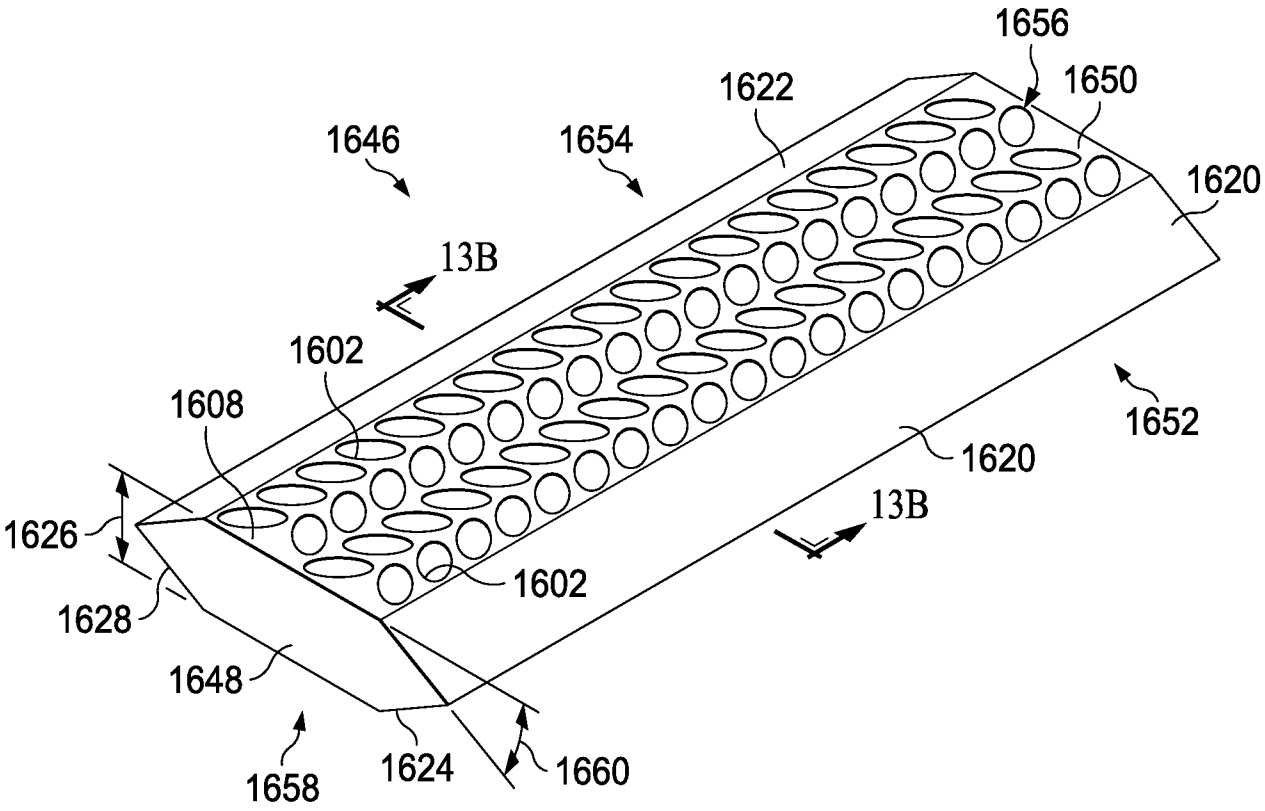

FIG. 13A

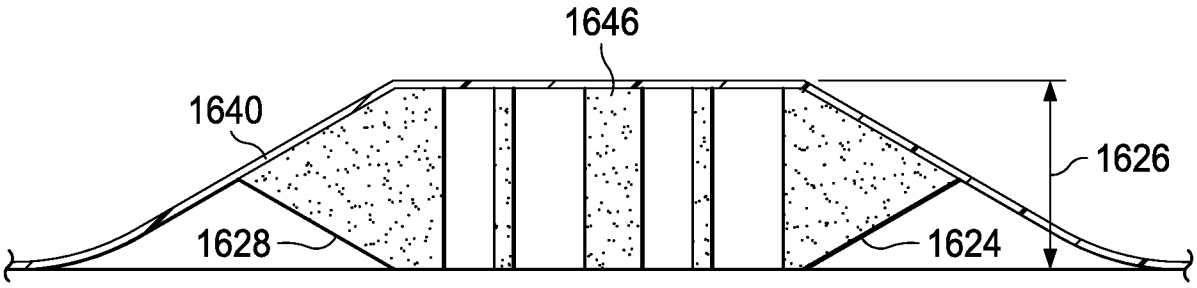

FIG. 13B

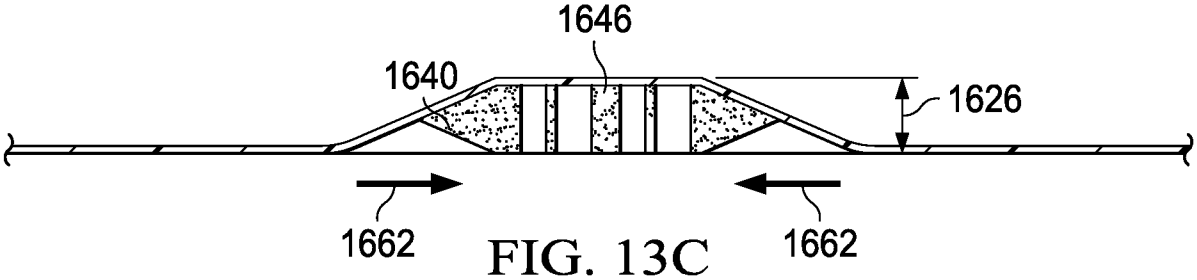

FIG. 13C

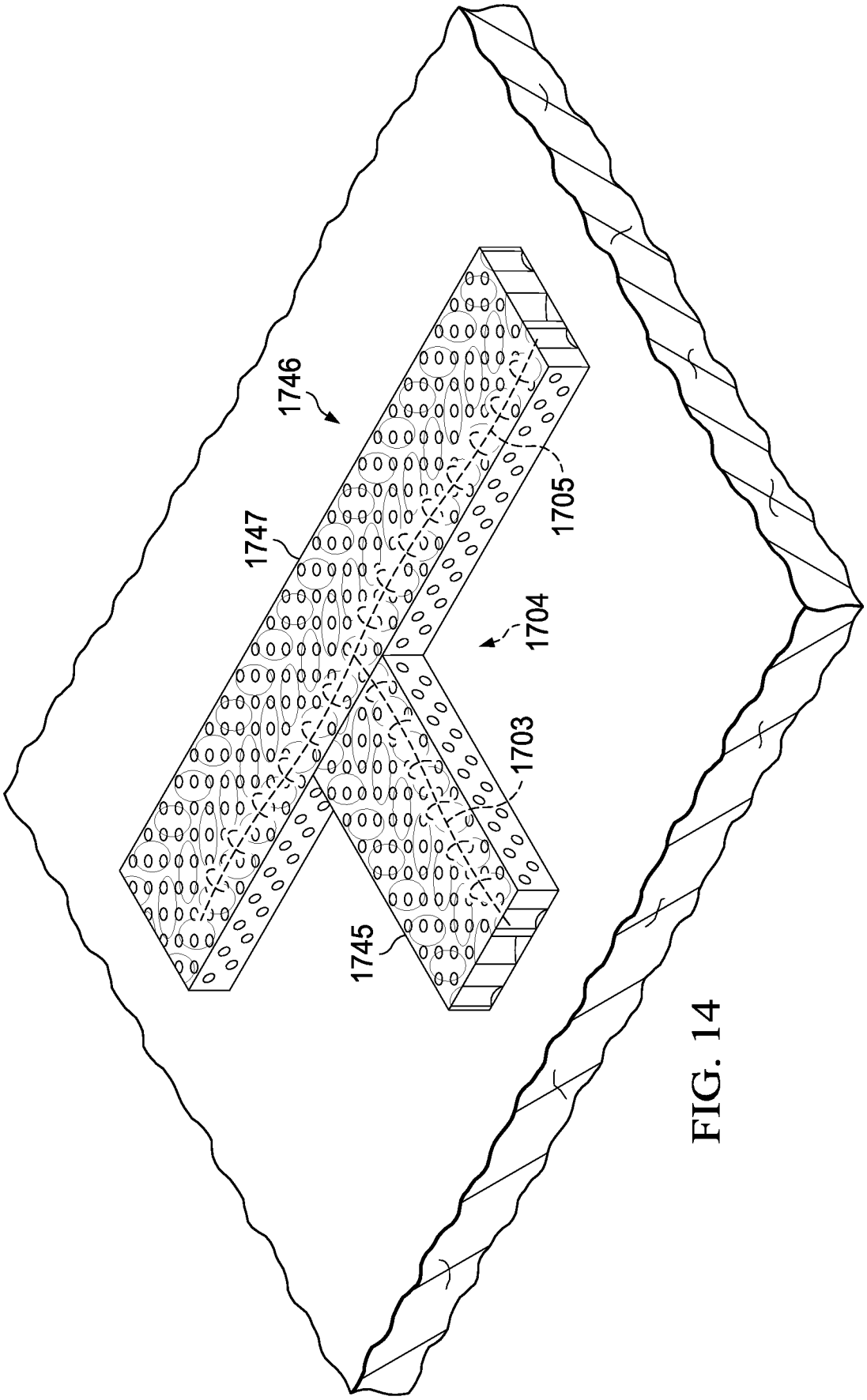

FIG. 14

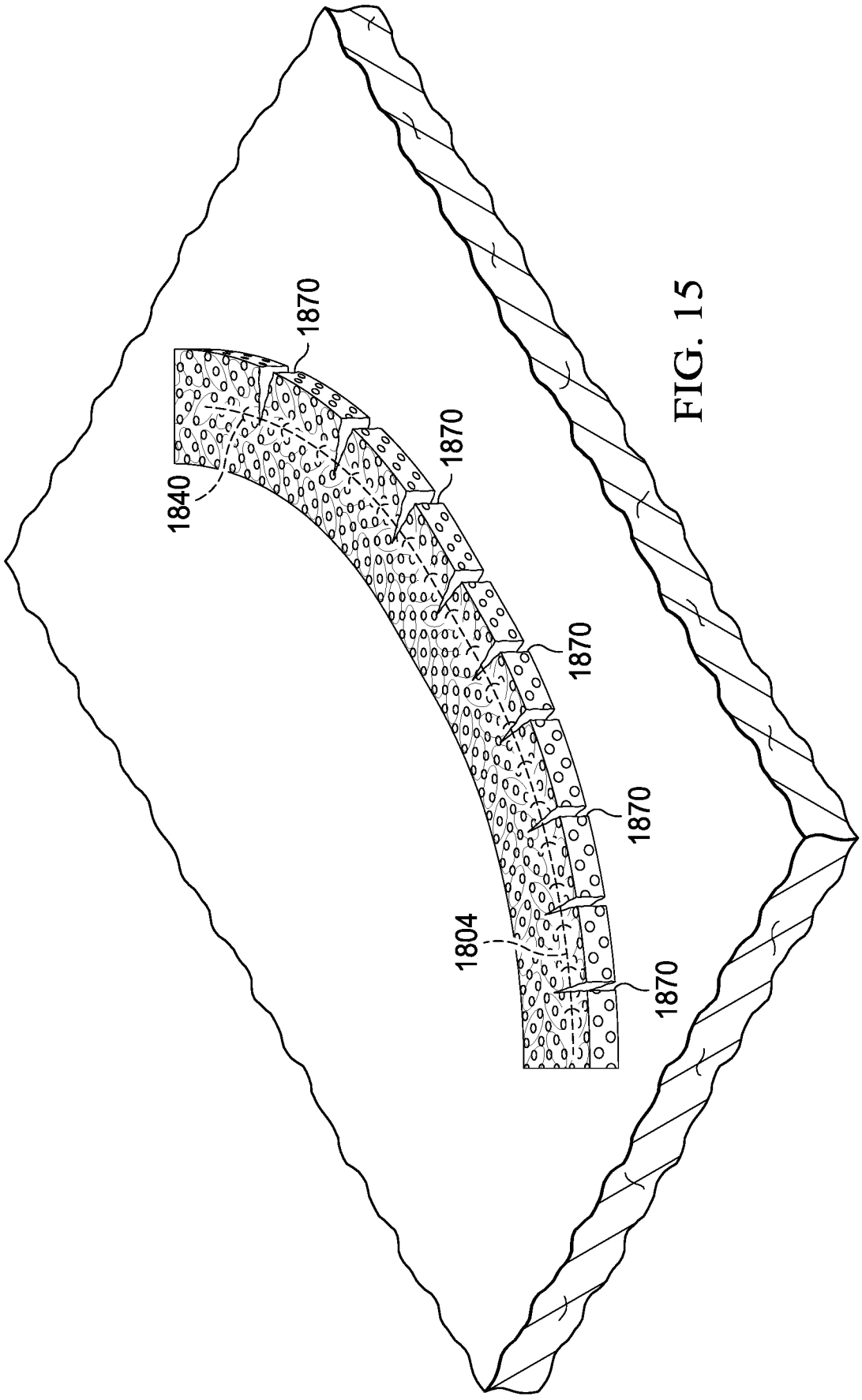

FIG. 15

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/036013

A. CLASSIFICATION OF SUBJECT MATTER
INV. 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)
A61M A61F

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

Electronic data base consulted during the international search (name of data base and, where 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	US 2015/320602 A1 (LOCKE CHRISTOPHER BRIAN [GB] ET AL) 12 November 2015 (2015-11-12) paragraphs 0005, 0029, 0046, 0047, 0055, 0058, 0062, 0063; figures 1-4	1-42
A	WO 2015/193257 A1 (SMITH & NEPHEW [GB]) 23 December 2015 (2015-12-23) paragraphs 0047, 0064; figures 3A-C	1-42
A	US 2014/031771 A1 (LOCKE CHRISTOPHER BRIAN [GB] ET AL) 30 January 2014 (2014-01-30) paragraphs 0067, 0070; figure 3	1-42
A	US 2015/119830 A1 (LUCKEMEYER JAMES A [US] ET AL) 30 April 2015 (2015-04-30) figures 4A, 5	1-42

☐ 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
16 July 2018	07/08/2018

Name and mailing address of the ISA/	Authorized officer
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/036013

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

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

1. [X] Claims Nos.: 43-47
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [X] Claims Nos.: 48
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

see FURTHER INFORMATION sheet PCT/ISA/210

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2018/036013

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2015320602 A1	12-11-2015	AU 2015255723 A1	03-11-2016
		CA 2947302 A1	12-11-2015
		CN 106255480 A	21-12-2016
		EP 3139878 A1	15-03-2017
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		EP 2879633 A1	10-06-2015
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US 2015119830 A1	30-04-2015	EP 3062833 A1	07-09-2016
		US 2015119830 A1	30-04-2015
		US 2018161213 A1	14-06-2018
		WO 2015065615 A1	07-05-2015

Continuation of Box II.1

Claims Nos.: 43-47

Claims 43-47 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 39.1(iv) PCT. The method disclosed therein has the purpose of closing an opening through a surface of a tissue site. According to paragraph 0092 of the application, closure of an opening helps maintain a healing environment for internal structures of a tissue site, as well as inhibit entry of bacteria or other harmful substances into the tissue site. Furthermore, it comprises in scope (e.g. dependent claim 44) fluidly coupling a negative pressure source to the tissue site. Hence it is considered a method for treatment of the human or animal body by therapy/surgery.

Continuation of Box II.2

Claims Nos.: 48

Claim 48 contains references to the description. According to Rule 6.2(a) PCT, claims should not contain such references except where absolutely necessary, which is not the case here.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) declaration be overcome.